UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 71-1170

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP MCGHEE, VERNON D. MEVIS, RALPH R. WARNER, RONALD D. KENNEDY, PAUL ROSS, HERMAN HEAD, GERALD G. NORMAN, PAUL MILLER, THOMAS U. MULLIGAN, LONNIE PAYNE, ROBERT MASON, GAYLORD L. ESPICH and KENNETH R. MARSHALL,

Plaintiffs-Appellants,

v.

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C.J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants-Appellees.

APPEAL FROM THE DISTRICT COURT OF THE UNITED STATES FOR THE EASTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

APPENDIX FOR PLAINTIFFS-APPELLANTS

LEITSON, DEAN, DEAN, SEGAR & HART, P.C.
BY ROBERT L. SEGAR
1616 Genesee Towers
Flint, Michigan 48502
Attorneys for Plaintiffs-Appellants

TABLE OF CONTENTS OF APPENDIX

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235-5631

RELEVANT DOCKET ENTRIES

1968		
Apr.	23	Complaint, filed.
May	8	Motion to add parties plaintiff pursuant to rule 21, filed.
May	8	Order to add parties plaintiff pursuant to rule 21, filed and entered. Roth, J.
May	16	Appearance of Upjohn Company, filed.
June	17	Appearance of Parke, Davis & Co., filed.
June	26	Answer of Parke, Davis & Company, filed.
July	2	Answer of The Upjohn Co., with proof of service, filed.
July	17	Motion and order to add party ptf., filed and entered.
Aug.	14	Interrogatories to Deft. Parke Davis & Co., filed.
Aug.	14	Interrogatories to Deft. UpJohn Company, filed.
Sept.	30	Motion and order to add party ptf. pursuant to Rule 21, F.R.C.P., filed and entered
Oct.	14	Answers of Parke Davis & Co. to interrogatories with exhibit, filed.
Oct.	14	Answers and objections to ptfs' interrogatories by Upjohn Co. with exhibit and proof of service, filed.
1969		
May	1	Notice of pre-trial for May 12/69, filed.
May	6	Notice of revised pre-trial for May 26/69, filed.
May	26	Pre-trial had and adj. to Sept. 29/69.
July	16	Additional interrogatories to defendant Parke Davis & Co., filed
July	16	Motion for Order of the court directing and requiring defendants to answer interrogatories under oath, interrogatories to defendant The Upjohn Co., with proof of service, filed. Hrg. on Aug. 11/69.
Sept.	29	Pre-trial had.
Oct.	30	Motion for order of the Court directing and requiring defts. to answer interrogatories under oath, with exhibits, filed.

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Oct.	30	Motion for trial by jury pursuant to Rule 39(b) with supporting affidavit filed.
Oct.	30	Motion to add parties deft. pursuant to Rules 20 and 21, F.R.C.P. with brief, filed.
Oct.	30	Ptfs' motion for summary judgment pursuant to Rule 56, F.R.C.P. with affidavit, exhibit and brief, filed.
Nov.	3	Motion to dismiss Count II of complaint with memorandum and certificate for service, filed. (of Upjohn Co.)
Nov.	3	Motion of Upjohn Co. for order that ptfs' action shall not be maintained as a class action with brief and certificate of service, filed.
Nov.	12	Motion of ptfs. to add parties ptf., with exhibit, filed.
Nov.	12	Motion of ptfs. to add party ptf., filed. (with exhibit)
Nov.	18	Order to add parties ptf., filed and entered. Freeman, J.
Nov.	18	Order to add parties ptf., filed and entered. Freeman, J.
Nov.	24	Notice of hearing on pending motions for Feb. 9/70, filed.
Dec.	16	Answers of Parke, Davis & Co. to additional interrogatories and affidavit, filed.
1970		
Jan.	21	Amended complaint filed. Summons issued.
Feb.	10	Answer (of individuals) with exhibit and proof of service, filed.
Feb.	12	Affidavit in support of ptfs' motion for summary judgment, filed.
Feb.	16	Affidavits in support of ptfs' motion for summary judgment, filed.
Mar.	5	Answers of Upjohn Co. to additional interrogatories, filed. (with affidavit)
June	5	Motion and order to add parties ptf. Pursuant to Rule 21, F.R.C.P., filed and entered.
July	24	Notice of hearing for Sept. 14/70, on pending motions, filed.
Aug.	17	Motion of Upjohn and Parke Davis & Co. for summary judgment with affidavits and supporting briefs, filed.

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Sept.	10	Motion of State of Michigan to dismiss with supporting brief, filed. (dated Mar. 26/70)
Sept.	11	Notice of hearing for Nov. 9/70, on pending motions, filed.
Nov.	9	Hearing had on pending motions - taken under advisement. Freeman, J.
Nov.	9	Affidavit of Gaylord Lee Espich in support of ptfs. motion for summary judgment and ptfs answer to defts motions for summary judgment filed.
Nov.	12	Parke Davis & Co's position with respect to motions pertaining to count II and to class action, filed.
Dec.	28	Affidavit of Warden George A. Kropp and exhibits, filed. (rec. Jan. 21/70)

1971

Jan.	5	Memorandum opinion, filed and entered. Freeman, J.
Feb.	2	Order granting defts' motions pertaining to class action, to dismiss and for summary judgment and denying ptfs' motion for summary judgment, filed and entered. Freeman, J.
Feb.	2	Ptfs' notice of appeal, filed.
Mar.	2	Stipulation pursuant to Rule 11(f) for District Court to retain parts of the record
Mar.	4	Notice of mailing file to CCA, filed.
Mar.	15	Acknowledgment filed.

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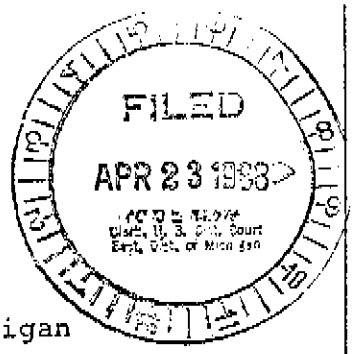
COMPLAINT
Filed 4-23-68



UNITED STATES DISTRICT COURT

For the Eastern District of Michigan
Southern Division

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK and BOYD KELTON,

Plaintiffs,

-vs-

PARKE DAVIS & CO., a Michigan Corporation and THE UPJOHN CO., a Delaware Corporation,

Defendants.

CASE NO. 7117

JUDGE

COMPLAINT

Plaintiffs complain of Defendants as follows:

COUNT I

1. Jurisdiction of this Court is grounded upon:

Title 29 United States Code Annotated: Sec. 216 (6) (Sec. 16 (b) of the Fair Labor Standards Act of 1938 as amended),

Title 28 United States Code Annotated: Sec. 1337 giving the District Court original jurisdiction of "Any civil action or proceedings arising under any Act of Congress regulating commerce" without regard to citizenship of the parties or amount in controversy.

Title 28 United States Code Annotated: Sec.1343

Title 42 United States Code Annotated: Sec.1983

Thirteenth Amendment to the United States Constitution.

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2. This action is brought in part (Count I) pursuant to Sec. 16 (b) of the Fair Labor Standards Act of 1938 (29 U.S.C.A., Sec. 201-219) to recover from Defendants unpaid minimum wages and overtime compensation, interest on said amounts since due, an equal additional amount as liquidated damages, Court costs and a reasonable attorney's fee.

3. Plaintiffs are or have been inmates of the State Prison of Southern Michigan at Jackson, Michigan, at all times relevant to this cause of action. Defendant Parke Davis & Co. is a Michigan Corporation for private profit engaged in the drug industry and Defendant The Upjohn Company is a Delaware Corporation for private profit similarly engaged. Both Defendants are doing business throughout the State of Michigan, and in interstate commerce.

4. There are numerous other people who either are or have been inmates in the State Prison of Southern Michigan at Jackson, Michigan, who have the same cause of action as hereinafter set forth on the part of the named Plaintiffs, and the named Plaintiffs adequately represent such unnamed people. This action is brought pursuant to Rule 23 A of the Federal Rules of Civil Procedure on behalf of all such people whose number make it impractical to have them join as Plaintiffs. The named Plaintiffs adequately represent said class.

5. In 1963 the named Defendants erected within the State Prison of Southern Michigan at Jackson, Michigan, research clinics for the private profit making purposes of said corporations and said clinics have been continuously and are currently in operation. The activities in said clinics among other things include the clinical testing of drugs not presently on the market as well as the testing of drugs currently being produced for, sold, transported, shipped and delivered in interstate commerce throughout the United States.

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Defendants are enterprises engaged in interstate commerce within the meaning of 29 U.S.C.A., Sec. 203.

6. Certain inmates of said prison including Plaintiffs were picked by Defendants in conjunction with representatives of the Michigan Corrections Commission to be employed by Defendants at the aforesaid research clinics. The work therein by said inmates is carried on under the sole direction and supervision of Defendants' representatives, and said employees work on a regular basis up to as much as one hundred twelve (112) hours per week.

7. The work carried on by the named Plaintiffs and other inmates is exactly the same work that would be required of nonprision personnel working in comparable capacities. The wages paid by the respective Defendants to each worker range from Thirty-Five Cents ($0.35) to One Dollar and 25/100 ($1.25) per day and all other costs of running the clinic are paid by Defendants, such as power, heat and water.

8. Among the job classifications of the inmates are the following: Chief Technician (in each classification); Trained Technician (in all classified areas); Technician Trainees (in all classified areas); Chief Clerk; Clerks; Nurse Supervisor; Nurse; Chief Cook; Kitchen Assistant; Kitchen Pot and Pan Man; Maintenance Man; Head Porter.

9. All of the activity by Plaintiffs inures to the benefit of the stockholders of Defendants Corporations and involve work which if not accomplished by said inmates would have to be accomplished by civilian help paid in accordance with applicable federal and state laws.

10. Plaintiffs were and are employees of Defendants within the meaning of the Fair Labor Standards Act of 1938 as

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amended, 29 U.S.C.A., Sec. 201 et seq. and were and are entitled to be paid the minimum wages provided for in said act.

11. Plaintiffs are entitled to recover from Defendants the difference between the amounts received by each Plaintiff and the minimum wage guaranteed by said law; all overtime compensation that may be due; an equal additional amount as liquidated damages; court costs and a reasonable attorney's fee as well as interest due on said back wages since they were due.

12. The number of hours and the amount of overtime worked by each Plaintiff as well as the amounts actually paid to each Plaintiff is within the knowledge of the Defendants through the records which they keep regarding Plaintiffs' employment.

WHEREFORE, Plaintiffs seek judgment in the amount of One Million ($1,000,000.00) Dollars plus interest, costs and attorney's fee.

COUNT II

1. Plaintiffs refer to and by such reference hereby incorporate as though expressly repeated herein the allegations of paragraphs one (1) through twelve (12) of Court I hereof.

2. The employment of Plaintiffs by Defendants as alleged aforesaid is in violation of Act Number 154 of the Public Acts of 1964 of the State of Michigan commonly known as the Minimum Wage Law of 1964 being Sec. 408.381 of the compiled laws of the State of Michigan.

3. Should this Court determine that the Fair Labor Standrads Act of 1938 as amended does not apply to Defendant employers herein then the Minimum Wage Law of the State of

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Michigan would apply as set out in Sec. 14 thereof, and this action is based in part upon Sec. 13 of said act and seeks recovery of the difference between the amounts paid to Plaintiffs and the minimum wage provided by said Minimum Wage Law and for an equal additional amount as liquidated damages together with interest, costs and a reasonable attorney's fee.

4. Defendants are employers and Plaintiffs employees within the meaning of said Mimimum Wage Law.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars plus interest, costs and attorney's fee.

COUNT III

1. Plaintiffs refer to and by such reference incorporate herein as though expressly repeated the allegations of paragraphs one (1) through twelve (12) of Court I hereof.

2. The appointment of said inmates by Defendants is expressly contrary to the law of the State of Michigan and particularly Sec. 800.305 of C.L.48 which provides in pertinent part. . .

> "Nor shall the labor of prisoners be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction, maintenance or operation of public works, ways, or property as directed by the Governor;"

and Sec. 800.310 C.L. 48 which provides in pertinent part:

> "It is hereby declared to be the intent of this act:
> (A) To provide adequate, regular, diversified and suitable employment for prisoners of the State consistent with proper penal purposes;

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(B) To utilize the labor of prisoners exclusively for self maintenance and for reimbursement of State for expenses incurred by reason of their crimes and imprisonment;

(C) To eliminate all competitive relationships between prisoner, labor or prison products and free labor or private industry;

(D) To affect the requisitioning and disbursement of prison labor and prison products directly through established state authorities with no possibility of private profits therefrom and with the minimum of intermediating financial considerations, appropriations or expenditures;..."

3. The utilization of the services and labor of Plaintiffs for Defendants own private profit and interest has resulted in and is resulting in the unjust enrichment of Defendants in the amount by which the reasonable value of Plaintiffs' services exceeds the amount paid by Defendants to Plaintiffs. The labor of Plaintiffs has been and is being utilized by Defendants with full knowledge that they are benefiting unjustly and illegally by the difference between the amount paid to Plaintiffs and the reasonable value of their services.

4. The reasonable value of Plaintiffs' services is at least the amount which would be due them under the Minimum Wage Laws of the State of Michigan and the United States of America.

5. Plaintiffs have therefore been unjustly deprived of their labor and the fruits thereof in violation of the laws of the State of Michigan as hereinbefore set forth.

6. The contracts existing between Plaintiffs and Defendants and between Defendants and any other party are void because of violation of the statutes of the State of Michigan regarding prison labor already set forth.

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7. Plaintiffs are, therefore, entitled to recover from Defendants the reasonable value of their services in excess of the amounts paid by Defendants to Plaintiffs for same.

8. Plaintiffs are entitled to interest on the amount due to them under this count from the dates said amounts were due.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars, plus interest, costs and attorney's fee.

COUNT IV

1. Plaintiffs refer to and by such reference incorporate herein the allegations of paragraphs one (1) through twelve (12) of Count I hereof.

2. The illegal employment of Plaintiffs by Defendants with the cooperation of the Michigan Department of Corrections and the payment by Defendants of nominal wages less than those required by law has resulted and is resulting in a deprivation of the liberty and property of Plaintiffs without due process of law and in violation of the Fourteenth Amendment.

3. Said conduct has also resulted and is resulting in the holding of Plaintiffs in involuntary servitude contrary to the Thirteenth Amendment to the Federal Constitution.

4. Said conduct is under color of the laws of the State of Michigan dealing with supervision of prisoners.

5. Also as a result of said conduct Plaintiffs have been denied equal protection of the laws guaranteed by the Fourteenth Amendment, in that Plaintiffs have been and are being arbitrarily discriminated against in the amount of wages paid to

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them for their labor since others doing the same work would be entitled to collect a reasonable wage therefor.

6. Jurisdiction under this count is grounded upon Sec. 1983 of Title 42 and Sec. 1343 of Title 28 of United States Code Annotated.

7. The actions complained of have proximately caused damages to Plaintiffs in the amount of One Million ($1,000,000.00) Dollars.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars, plus interest, costs and attorney's fee.

LEITSON,DEAN,DEAN,ABRAM,SEGAR & HART
Attorneys for Plaintiffs

BY: _____
ROBERT L. SEGAR

DATED: April 23, 1968.

LEITSON, DEAN, DEAN, ABRAM, SEGAR & HART
ATTORNEYS AT LAW
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FLINT, MICH. 48503
CEDAR 5-5531

TCrump JMIT 0016

CONSENT TO COMMENCEMENT OF SUIT
UNDER FAIR LABOR STANDARDS ACT

(Title 29 U.S.C.A. Sec. 216 (b))

Each of the undersigned hereby consents to be a party named in the attached complaint filed to recover back wages pursuant to the Fair Labor Standards Act and particularly as required by Section 216 (b) thereof.

Calvin R. Sims
Frederick H. Holroyd
Ray Speed
Howard K. Bell
Orcean Davis
Herbert Williams
Clarence Cleary
Jerry Mack
[illegible]
[illegible]
[illegible]
Ellison F. McDonald
Willie A. Lee
Odell L. Wilburn
Peter George Mellos
Boyd Segar
Kenneth Sommers

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CEDAR 5-5651

CONSENT TO COMMENCEMENT OF SUIT
UNDER FAIR LABOR STANDARDS ACT

(Title 29 U.S.C.A. Sec. 216 (b))

Each of the undersigned hereby consents to be a party named in the attached complaint filed to recover back wages pursuant to the Fair Labor Standards Act and particularly as required by Section 216 (b) thereof.

Mae Frank Rodgers

Billie Lee Williams

LEITSON, DEAN, DEAN, ABRAM, SEGAR & HART
ATTORNEYS AT LAW
604 DETROIT STREET
FLINT, MICH. 48503

CEDAR 5-5031

UNITED STATES OF AMERICA
THE DISTRICT COURT OF THE UNITED STATES
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK and BOYD KELTON,	:	
Plaintiffs,	:	
-vs-	:	Civil Action No. 31172
PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN CO., a Delaware corporation,	:	
Defendants.	:	

ANSWER

COUNT I

NOW COMES PARKE, DAVIS & COMPANY, a Michigan corporation, one of the defendants herein, by Miller, Canfield, Paddock and Stone, its attorneys, and in answer to plaintiffs' Complaint, says:

1. Answering paragraph 1, this defendant admits that this Honorable Court has jurisdiction over the subject matter in this cause. Further answering said paragraph, this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

2. Answering paragraph 2 of plaintiffs' Complaint, this defendant specifically denies any liability whatsoever on the part of Parke,

Davis & Company. Further answering said paragraph, this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

3. Answering paragraph 3 of plaintiffs' Complaint, this defendant admits the allegations contained therein which relate to Parke, Davis & Company. Further answering said paragraph, this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

4. Answering paragraph 4 of plaintiffs' Complaint, this defendant denies the propriety of bringing this cause as a purported class action. Further answering said paragraph, this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

5. Answering paragraph 5 of plaintiffs' Complaint, this defendant specifically denies the allegation that research clinics were erected in 1963. This defendant admits all other allegations contained in said paragraph which pertain to this defendant. Further answering said paragraph this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

6. This defendant denies the allegations contained in paragraph 6 of plaintiffs' Complaint.

7. Answering paragraph 7 of plaintiffs' Complaint, this defendant specifically denies that it paid any wages to any prison inmate. This defendant admits that it pays for power, heat and water. Further answering said paragraph, this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

8. Answering paragraph 8 of plaintiffs' Complaint, this defendant admits that there were various classifications for the prison inmates. Further answering said paragraph, this defendant neither admits nor denies the remaining allegations contained therein, but leaves the plaintiffs to their proofs.

9. This defendant neither admits nor denies the allegations contained in paragraph 9 of plaintiffs' Complaint, but leaves the plaintiffs to their proofs.

10. This defendant denies the allegations contained in paragraph 10 of plaintiffs' Complaint.

11. This defendant denies the allegations contained in paragraph 11 of plaintiffs' Complaint.

12. This defendant denies the allegations contained in paragraph 12 of plaintiffs' Complaint.

COUNT II

1. This defendant incorporates herein by reference its answers to paragraphs 1 through 12 of Count I as though the same were fully set forth herein.

2. This defendant denies the allegations contained in paragraph 2 of plaintiffs' Complaint.

3. Answering paragraph 3 of plaintiffs' Complaint, this defendant admits that it is subject to the minimum wage provisions of the Federal Fair Labor Standards Act of 1938, as amended. Further answering said paragraph, this defendant denies the remaining allegations contained therein.

4. This defendant denies the allegations contained in paragraph 4 of plaintiffs' Complaint.

COUNT III

1. This defendant incorporates herein by reference its answers to paragraphs 1 through 12 of Count I as though the same were fully set forth herein.

2. This defendant neither admits nor denies the allegations contained in paragraph 2 of plaintiffs' Complaint, but leaves the plaintiffs to their proofs.

3. This defendant denies the allegations contained in paragraph 3 of plaintiffs' Complaint.

4. This defendant denies the allegations contained in paragraph 4 of plaintiffs' Complaint.

5. This defendant denies the allegations contained in paragraph 5 of plaintiffs' Complaint.

6. This defendant denies the allegations contained in paragraph 6 of plaintiffs' Complaint.

7. This defendant denies the allegations contained in paragraph 7 of plaintiffs' Complaint.

8. This defendant denies the allegations contained in paragraph 8 of plaintiffs' Complaint.

COUNT IV

1. This defendant incorporates herein by reference its answers to paragraphs 1 through 12 of Count I as though the same were fully set forth herein.

2. Answering paragraph 2 of said plaintiffs' Complaint, this defendant admits that as prison inmates plaintiffs are deprived of their liberty. Further answering said paragraph, this defendant denies the remaining allegations contained therein.

3. This defendant denies the allegations contained in paragraph 3 of plaintiffs' Complaint.

4. This defendant denies the allegations contained in paragraph 4 of plaintiffs' Complaint.

5. This defendant denies the allegations contained in paragraph 5 of plaintiffs' Complaint.

6. This defendant neither admits nor denies the allegations contained in paragraph 6 of plaintiffs' Complaint, but leaves the plaintiffs to their proofs.

7. This defendant denies the allegations contained in paragraph 7 of plaintiffs' Complaint.

AFFIRMATIVE DEFENSE

In further answer and by way of affirmative defense, this defendant states that some or all of plaintiffs are barred in whole or in part, by reason of the applicable statute of limitations, from bringing this action.

WHEREFORE, defendant PARKE, DAVIS & COMPANY, a Michigan corporation, prays that plaintiffs' Complaint be dismissed with prejudice and that plaintiffs be ordered to pay all costs and reasonable attorney fees so wrongfully sustained.

Miller, Canfield, Paddock and Stone

By WOLFGANG HOPPE
Wolfgang Hoppe
Attorneys for Defendant Parke, Davis & Company
2500 Detroit Bank & Trust Building
Detroit, Michigan 48226 963-6420

Dated: June 26, 1968

ANSWER OF THE UPJOHN COMPANY Filed 7-2-68

UNITED STATES OF AMERICA
THE DISTRICT COURT OF THE UNITED STATES
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILES, LEO D. WALKER, CLEMONT DESSAUX, ORDELL WILBURN, WILLIAM CLEARY, HUBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH IMMAN, RAYMOND L. BAILEY, ORCENA DAVIS, JERRY MACK and BOYD KELTON,

Plaintiffs,

vs.

Civil Action No. 31172

PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN CO., a Delaware corporation,

Defendants.

ANSWER

COUNT I

NOW COMES THE UPJOHN COMPANY, a Delaware corporation, one of the Defendants herein, by Dykema, Wheat, Spencer, Goodnow & Trigg, its attorneys, and in answer to Plaintiffs' Complaint, says:

1. Answering paragraph 1, this Defendant admits that this Court has jurisdiction over the subject matter in this cause. Further answering said paragraph, this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

2. Answering paragraph 2 of Plaintiffs' Complaint, this Defendant specifically denies any liability whatsoever on the part of the Upjohn Company. Further answering said paragraph, this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

3. Answering paragraph 3 of Plaintiffs' Complaint, this Defendant admits the allegations contained therein which relate to The Upjohn Company. Further answering said paragraph, this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

4. Answering paragraph 4 of Plaintiffs' Complaint, this Defendant denies the propriety of bringing this cause as a purported class action. Further answering said paragraph, this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

5. Answering paragraph 5 of Plaintiffs' Complaint, this Defendant specifically denies the allegation that research clinics were erected in 1963. This Defendant admits all other allegations contained in said paragraph which pertain to this Defendant. Further answering said paragraph this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

6. This Defendant denies the allegations contained in paragraph 6 of Plaintiffs' Complaint.

7. Answering paragraph 7 of Plaintiffs' Complaint, this Defendant specifically denies that it paid any wages to any prison inmate. This Defendant admits that it pays for power, heat and water. Further answering said paragraph, this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

8. Answering paragraph 8 of Plaintiffs' Complaint, this Defendant admits that there were various classifications for the prison inmates. Further answering said paragraph, this Defendant neither admits nor denies the remaining allegations contained therein, but leaves the Plaintiffs to their proofs.

9. This Defendant neither admits nor denies the allegations contained in paragraph 9 of Plaintiffs' Complaint, but leaves the Plaintiffs to their proofs.

10. This Defendant denies the allegations contained in paragraph 10 of Plaintiffs' Complaint.

11. This Defendant denies the allegations contained in paragraph 11 of Plaintiffs' Complaint.

12. This Defendant denies the allegations contained in paragraph 12 of Plaintiffs' Complaint.

COUNT II

1. This Defendant incorporates herein by reference its answers to paragraphs 1 through 12 of Count I as though the same were fully set forth herein.

2. This Defendant denies the allegations contained in paragraph 2 of Plaintiffs' Complaint.

3. Answering paragraph 3 of Plaintiffs' Complaint, this Defendant admits that it is subject to the minimum wage provisions of the Federal Fair Labor Standards Act of 1938, as amended. Further answering said paragraph, this Defendant denies the remaining allegations contained therein.

4. This Defendant denies the allegations contained in paragraph 4 of Plaintiffs' Complaint.

COUNT III

1. This Defendant incorporates herein by reference its answers to paragraphs 1 through 12 of Count I as though the same were fully set forth herein.

2. This Defendant neither admits nor denies the allegations contained in paragraph 2 of Plaintiffs' Complaint, but leaves the Plaintiffs to their proofs.

3. This Defendant denies the allegations contained in paragraph 3 of Plaintiffs' Complaint.

4. This Defendant denies the allegations contained in paragraph 4 of Plaintiffs' Complaint.

5. This Defendant denies the allegations contained in paragraph 5 of Plaintiffs' Complaint.

6. This Defendant denies the allegations contained in paragraph 6 of Plaintiffs' Complaint.

7. This Defendant denies the allegations contained in paragraph 7 of Plaintiffs' Complaint.

8. This Defendant denies the allegations contained in paragraph 8 of Plaintiffs' Complaint.

COUNT XV

1. This Defendant incorporates herein by reference its answers to paragraphs 1 through 12 of Count I as though the same were fully set forth herein.

2. Answering paragraph 2 of said Plaintiffs' Complaint, this Defendant admits that as prison inmates Plaintiffs are deprived of their liberty. Further answering said paragraph, this Defendant denies the remaining allegations contained therein.

3. This Defendant denies the allegations contained in paragraph 3 of Plaintiffs' Complaint.

4. This Defendant denies the allegations contained in paragraph 4 of Plaintiffs' Complaint.

5. This Defendant denies the allegations contained in paragraph 5 of Plaintiffs' Complaint.

6. This Defendant neither admits nor denies the allegations contained in paragraph 6 of Plaintiffs' Complaint, but leaves the Plaintiffs to their proofs.

7. This Defendant denies the allegations contained in paragraph 7 of Plaintiffs' Complaint.

AFFIRMATIVE DEFENSE

In further answer and by way of affirmative defense, this Defendant states that some or all of Plaintiffs are barred in whole or in part, by reason of the applicable statute of limitations, from bringing this action.

WHEREFORE, Defendant THE UPJOHN COMPANY, a Delaware corporation, prays that Plaintiffs' Complaint be dismissed with prejudice and that Plaintiffs be ordered to pay all costs and reasonable attorney fees so wrongfully sustained.

DYKEMA, WHEAT, SPENCER, GOODNOW & TRIGG

By _____
Timothy K. Carroll
For the Firm and Individually
Attorneys for Defendant, The Upjohn Company
2700 Penobscot Building
Detroit, Michigan 48226
963-6040

Dated: July /, 1960

Filed: Oct. 14, 1968

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,

Plaintiffs,

vs. No. 31172

PARKE DAVIS & CO., a Michigan corporation and THE UPJOHN CO., a Delaware corporation,

Defendants

THE UPJOHN COMPANY
ANSWERS AND OBJECTIONS
TO PLAINTIFFS' INTERROGATORIES

The Upjohn Company asserts a general objection to the form of questions set forth in Plaintiffs' Interrogatories. The Upjohn Company does not admit that it "utilizes" inmate labor, "employs" inmates, or that inmates "work for" or "perform a job for" The Upjohn Company or "work in" the Upjohn program. All inmate Plaintiffs who were or are associated with the Upjohn clinic were assigned thereto by prison authorities.

Now comes Defendant, The Upjohn Company, and in response to Plaintiffs' Interrogatories states as follows:

1. State whether or not a written contract exists with regard to your utilization of prison labor in the State Prison of Southern Michigan.

A. State who the contract is with,
B. State the date thereof,
C. Who are the formal parties as designated therein,
D. Attach a copy of said contract to your answers to these interrogatories, or in the alternative, state word for word the content of such contract.

Answer: 1. No such contract exists.

2. State in complete detail the method of payment for labor utilized by you at said prison.

A. State the classification or type of each job performed by the prisoners,
B. State the rate of compensation for each such job,
C. State to whom such money is paid,
D. State in what form such money is paid,

E. Describe the work involved in each job classification or type you have named above.

Answer: 2. The Upjohn Company makes periodic payments to the State of Michigan which include amounts relating to inmates assigned by the prison authorities to the Upjohn clinic.

2. A. B. Upjohn clinic assignment classifications which have existed and most recent per diem charges by State of Michigan are as follows:

Chief Technician	$ .76 - 1.25
Technician	.50 - .75
Technician Trainee	.35 - .50
Chief Clerk	.75 - 1.25
Clerk	.40 - .75
Nurse Supervisor	.50 - 1.00
Nurse	.30 - .50
Chief Cook	.55 - .80
Kitchen	.40 - .55
Kitchen Pot & Pan	.25 - .40
Maintenance Man	.35 - .60
Head Porter	.40 - .60
Porter	.25 - .40

2. C. The State of Michigan

2. D. Company check

2. E. Chief Technician Technician Technician Trainee	Ordinarily performs specific tasks such as operation of EEG machine
Chief Clerk Clerk	Clerical tasks
Nurse Supervisor Nurse	Acts as nurse in connection with clinical tests
Chief Cook Cook	Cooks and serves food
Kitchen Kitchen Pot & Pan	Assists in kitchen
Maintenance Man	Maintenance and minor repairs
Head Porter Porter	Janitorial tasks

3. State the date on which you first began to utilize the labor of said prisoners.

Answer: 3. First inmate among Plaintiffs' was assigned by prison authorities to Upjohn Clinic on April 2, 1964.

4. State whether or not you have similar work programs at any other place of incarceration in the United States.

A. State whether or not you utilize the labor in a place of incarceration in any country or place other than the United States.

Answer: 4. None within or without the United States.

5. State the name of every prisoner whose labor has been utilized by you since the beginning of the program.

A. State the number of hours every such prisoner has worked,
B. State the amount of money each such prisoner has been paid or has been paid for such prisoner,
C. State the years during which such utilization of labor in the case of each prisoner has taken place,
D. State the total number of prisoners whose labor is being utilized at the present time.
E. State their names and job classifications.

Answer: 5. Information sought with respect to Plaintiffs is as follows:

Frank Rogers Trained Technician	$ 85.55	1965, 1966
Walter Lee Nurse Supervisor	456.20	1965, 1966
Lee D. Walker Chief Technician	637.60	1966, 1967, 1968
Clemont Dedeaux Chief Technician	644.25	1965, 1966, 1967
Ordell Vilburn Clerk	298.80	1966, 1967
Fred Holnagel Chief Technician	518.75	1965, 1966
Kenneth Inman Trained Technician	292.50	1965, 1966
Ralph Watson Cook	198.65	1964, 1965
Chester A. Sawicki Cook	335.75	1966, 1967
Vernon D. Mevis Nurse Supervisor	442.40	1966, 1967, 1968
Boyd Slager Chief Clerk	1,077.10	1964, 1965, 1966, 1967

Hours for above persons unknown.

Defendant objects to balance of question.

6. State in detail how inmates are selected to work in the program at the prison.

A. What part do you play in selecting the inmates?
B. Do the inmates have any freedom to refuse to work in the program.
C. Is the method of selection of inmates for work in your programs essentially similar to selection of inmates for work in other prison industries?
D. What differences exist with regard to the selection of inmates for work in your programs and the selection of inmates for work in other prison industries?
E. What sanctions are applied against a prisoner who refuses to work in your program?

Answer: 6. Inmates are assigned by prison authorities to work at Upjohn clinic.

6. A. The Upjohn clinic plays no part in the selection of inmates to be assigned to it, except that occasionally a request for a specific inmate has been made.

6. B. Unknown

6. C. Unknown. Upon information and belief the assignment of inmates by the prison authority to the Upjohn clinic is essentially the same as the assignment to other prison programs.

6. D. Unknown

6. E. Unknown

7. Do you know of any other drug company with similar programs in the United States:

A. If so, what method of payment is followed by that drug company, if you know, in its programs.
B. Name the drug company or companies and the place or places where such programs are carried on.

Answer: 7. A. Upon information and belief, Parke Davis and Company at the State Prison for Southern Michigan has an essentially identical program which operates in the same manner as the Upjohn clinic located at that prison.

8. What statutes of the State of Michigan will you rely on at the trial of this cause to authorize your use of prison labor?

Answer: 8. Defendant objects to question 8.

9. What members of the Department of Corrections for the State of Michigan own stock in your company?

A. Name them
B. Give the amount of stock for each person
C. Give the same information for any past member of the Department of Corrections since your program went into effect.

Answer: 9. Defendant objects to question 9.

10. Are you a profit making organization?

A. Do you market drugs in interstate commerce?
B. Do you market drugs which are tested at the State Prison of Southern Michigan in interstate commerce?
C. Do you sell such drugs for profit?
D. Are drugs used in testing at the prison shipped in interstate commerce?
E. State your profit for your last complete fiscal year.

Answer: 10. Defendant objects to question 10. Defendant's Answer, paragraph 3, adequately provides needed information.

11. For each job classification which inmates perform at the State Prison of Southern Michigan, give the rate of pay a civilian would receive for performing the job for you including overtime rates of pay.

Answer: 11. Unknown. Any answer to question 11 would result from pure conjecture.

12. How are the amounts paid to or for the benefit of the prisoners at the State Prison of Southern Michigan reflected in your federal income tax return?

A. Answer the same question for your state income tax return,
B. Answer the same question for your city income tax return if you, in fact, file one,
C. Are any amounts withheld for income tax purposes at any level,
D. Are any amounts withheld for social security benefits?

Answer: 12. Amounts paid by the Upjohn Company to the State of Michigan for charges with respect to inmate assignments are reflected on federal and state tax returns as Outside Clinical and Laboratory Research Expense.

12. C. No

12. D. No

13. Who determines the number of hours an inmate works for you?

A. Have you ever rejected an inmate considered by you for work in your clinic,
B. Have you ever sought replacement of an inmate because of unsatisfactory conduct,
C. Give the names and details as far as you are able for the prior two questions.

Answer: 13. Assignment hours are regulated by prison authority. There are no set hours for actual performance of tasks.

13. A. No

13. B. No

13. C. Inapplicable

14. On what facts do you rely in denying that this is a proper class action in your answer to Plaintiffs' complaint in this lawsuit?

Answer: 14. Defendant objects to question 14.

15. Who constructed the building in which your operations are carried on at the prison?

A. Who built the building
B. What was the cost
C. Who owns the building now
D. If the present owner is different from the original owner, how was title transferred
E. How was the transaction treated by you for federal income tax purposes
F. Attach copies of all documents involved in the title transfer or state them word for word as part of the answer to this interrogatory
G. Who is responsible for the maintenance of said building
H. Who does the maintenance work?

Answer: 15. A. Banta Brooks Company, Lansing, Michigan.

15. B. Approximately $317,390.00

15. C. The State of Michigan

15. D. Inapplicable

15. E. Depreciation of leasehold improvements over 30 year period.

15. F. Inapplicable

15. G. The State of Michigan and The Upjohn Company

15. H. Labor employed outside of the State Prison of Southern Michigan and inmates assigned by prison authority.

16. If you do not want a prisoner to continue working for you, is there any requirement that you keep them anyway?

Answer: 16. Yes.

17. Are there any custodial employees from the prison at your building?

Answer: 17. Yes.

18. Are the civilians employed by your company in the same job classifications as the prisoners members of any union?

A. State the union
B. Attach a copy of any applicable collective bargaining agreement
C. List all fringe benefits including but not limited to vacation pay, pension plan, etc.

Answer: 18. None of the civilian employees of the Upjohn Company working at the clinic are members of a union.

19. State in detail the history of the commencement of the clinics within the walls of Jackson Prison by your company.

A. State the names of your representatives and agents who carried on the negotiations
B. State the names of the persons representing the Department of Corrections who carried on negotiations for the State of Michigan
C. Attach copies of all correspondence and intercompany memoranda relating to the aforesaid negotiations and the contract signed between you and the prison if one was, in fact, signed.

Answer: 19. See attached Agreement, marked as Exhibit "A" and incorporated herein by reference. Defendant objects to balance of question 19.

20. State whether or not you sought legal advice as to the legality of the clinics under Michigan law.

A. Attach a copy of any legal opinion you have received in connection with said question
B. Attach all correspondence relating to any such legal opinion.

Answer: 20. Defendant objects to question 20.

21. Give the names of any inmates who have refused job assignments for your company.

Answer: 21. Unknown

rehab.

22. Have any inmates who worked for you in prison upon their release gone to work for you?

A. State the names of all such prisoners.

Answer: 22. None

23. Outline the chain of command or administration of your employees in the clinic within the prison walls.

A. State each administrative position
B. State the duties involved in carrying out each position.

Answer: 23. A. B. Dr. H. H. Schweem - Staff Physician, Jackson Research Clinic. Responsible for protocols and clinical studies, operation of clinic within rules and regulations of State Prison for Southern Michigan. Ralph F. Willy - Supervisor of Research Affairs. Responsible for execution of protocols at clinic, and for routine matters relating to the operation of the clinic. William G. Hossler - Supervisor of Operational Affairs. Responsible for maintenance of building and equipment, general supervision and routine matters relating to operation of the clinic.

24. Have you ever written a letter of recommendation for any inmate who worked for you in the prison clinic to aid him in obtaining another job upon his release?

Answer: 24. Yes

25. Give the complete name and court case number of all other suits involving any of the questions in this suit in which you are named a defendant.

A. Attach a copy of the complaint and answer in each such suit
B. Attach a copy of any motion to dismiss filed by you and any answer thereof

Answer: 25. Defendant objects to question 25.

26. Have there ever been discussions between your representatives or agents and agents or representatives of the Department of Corrections involving the payment of wages to inmates for work done in the clinics in accordance with the provisions of the federal minimum wage law or the state minimum wage law.

A. Give the details of any such discussions.

Answer: 26. Defendant objects to question 26.

27. In connection with your program, have you paid any money to any members of the Department of Corrections or any employees of the Department of Corrections for any reason?

A. If so, state the details of any such transaction.

Answer: 27. No

DYKEMA, WHEAT, SPENCER, GOODNOW & TRIGG

By _____

Timothy K. Carroll
2700 Penobscot Building
Detroit, Michigan 48226
963-6040
Attorneys for Defendant, The
Upjohn Company

Dated: October 14, 1968

AGREEMENT

The following agreement covers the method of construction, the operation and the ownership of a Clinical Research Building at the State Prison of Southern Michigan at Jackson:

1. The Upjohn Company will retain the services of an architect, and will contract for the construction of a Clinical Research Building at the State Prison of Southern Michigan.

2. The Upjohn Company will pay the entire expense of planning and constructing the building.

3. The plans and specifications for the Clinical Research Building must be approved by both the Department of Corrections and The Upjohn Company.

4. The Upjohn Company will purchase all necessary equipment for the building, and the portable research equipment will remain the property of the company.

5. Upon acceptance of the completed project by the Department of Corrections, the building and fixed equipment shall become the property of the State of Michigan. The proceeds of any insurance protection on the building or contents against damage shall be used to restore the facility, such insurance shall be provided by the Upjohn Company.

6. In the event of abandonment of a partially completed project, any materials and equipment at the construction site shall become the property of the Department of Corrections.

7. The Upjohn Company will heat, light, administer, maintain the building, and provide necessary supervision at its own expense. However, custody and security will be the responsibility of the Department of Corrections.

8. The Upjohn Company and only the Upjohn Company will have the right to use the building for clinical research so long as clinical research is conducted by any organization or corporation at the State Prison of Southern Michigan.

9. The Upjohn Company will be responsible for the conduct of the clinical research in the Clinical Research Building. They will abide by the policies of the Department of Corrections and the laws of Michigan and the United States.

EXHIBIT A

10. The Department of Corrections will take all reasonable steps to facilitate the conduct of clinical research by the Upjohn Company. The Department of Corrections will permit prisoners to volunteer to participate as subjects in the clinical research.

11. The Department of Corrections will appoint a Medical Advisory Committee composed of several qualified faculty members from Michigan Medical Schools which will review the operations on a yearly basis. The Committee will either approve or suggest changes in the procedures used in the clinical research.

12. The Upjohn Company agrees to indemnify the State of Michigan for any additional expenditures incurred by a volunteer inmate suffering from a drug incurred illness or disability.

13. The Upjohn Company agrees to continue to clear all of its research projects with the Department of Corrections before initiating them at the prison.

APPROVED AS TO LEGAL FORM
LEGAL DIVISION

THE UPJOHN COMPANY

Date November 15, 1963

By R. S. Schreiber
R. S. Schreiber
Vice President

MICHIGAN DEPARTMENT OF CORRECTIONS

Date 11/12/63

By
Director

Filed: Oct. 14, 1968

UNITED STATES OF AMERICA
THE DISTRICT COURT OF THE UNITED STATES
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,	:	Civil Action No. 31172
Plaintiffs,	:	
-vs-	:	
PARKE DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN CO., a Delaware corporation,	:	
Defendants.	:	

ANSWERS OF PARKE DAVIS & COMPANY
TO INTERROGATORIES

NOW COMES PARKE DAVIS & COMPANY, a Michigan corporation, and answering Plaintiff's Interrogatories says:

Introductory Note Made a Part of all Answers:

Unless otherwise noted all answers relate to the so-called "Parke Davis Clinic" located at the State Prison of Southern Michigan, Jackson, Michigan. Parke Davis & Company does not admit that it "utilizes" inmate labor, "employs" inmates or that inmates "work for" or "perform a job for" Parke Davis & Company or "work in" the Parke Davis Program. All inmates associated with the Parke Davis Clinic (hereafter "Clinic") are either volunteers for research studies or have been assigned to the Clinic

INTERROGATORY NO. 1:

State whether or not a written contract exists with regard to your utilisation of prison labor in the State Prison of Southern Michigan.

ANSWER TO NO. 1:

No.

INTERROGATORY NO. 2:

State in complete detail the method of payment for labor utilized by you at said prison.

A. State the classification or type of each job performed by the prisoners,

B. State the rate of compensation for each such job,

C. State to whom such money is paid,

D. State in what form such money is paid,

E. Describe the work involved in each job classification or type you have named above.

ANSWER TO NO. 2:

Parke Davis & Company makes monthly payments by check to the State of Michigan which include an amount relating to inmates assigned to the Clinic by the prison authorities.

A. Present Clinic assignment classifications and related daily charges by the State Department of Corrections:

Chief Clerk:	$1.25
Clerk:	.75
Chief Cook:	.80
Head Porter:	.60
Maintenance Man:	.60
Porter and Nurse Supervisor:	1.00

B. See answer to A above.

C. See answer to 2 above.

D. See answer to 2 above.

E. Chief Clerk: Preparation of prison details and call slips and volunteer payroll.

Clerk: Double checks labels.

Chief Cook: Cooking and other kitchen duties.

Head Porter: Janitor and messenger.

Maintenance Man: Maintenance and minor repairs.

Porter and Nurse Supervisor: Night janitor and attendant.

INTERROGATORY NO. 3:

State the date on which you first began to utilize the labor of said prisoners.

ANSWER TO NO. 3:

Michigan prison authorities first assigned inmates to Parke Davis & Company research projects sometime in 1934.

INTERROGATORY NO. 4:

State whether or not you have similar work programs at any other place of incarceration in the United States.

A. State whether or not you utilized the labor in a place of incarceration in any country or place other than the United States.

ANSWER TO NO. 4:

This question is objected to.

INTERROGATORY NO. 5:

State the name of every prisoner whose labor has been utilized by you since the beginning of the program.

A. State the number of hours every such prisoner has worked.

B. State the amount of money each such prisoner has been paid or has been paid for such prisoner.

C. State the years during which such utilization of labor in the case of each prisoner has taken place,

D. State the total number of prisoners whose labor is being utilized at the present time,

E. State their names and job classifications.

ANSWER TO NO. 5:

Parke Davis & Company does not have all the information requested with respect to the period 1934 - 1963. Information relating to the plaintiffs assigned to the Clinic for the period since 1964 is tabulated on Exhibit 1 attached. Remainder of question is objected to.

A. Parke Davis & Company does not know the number of hours spent by inmates in the performance of any tasks.

B. See Exhibit 1.

C. See Exhibit 1.

D. Presently nine inmates are assigned to the Clinic by prison authorities.

E. See Exhibit 1.

INTERROGATORY NO. 6:

State in detail how inmates are selected to work in the program at the prison,

A. What part do you play in selecting the inmates?

B. Do the inmates have any freedom to refuse to work in the program?

C. Is the method of selection of inmates for work in your programs essentially similar to the selection of inmates for work in other prison industries?

D. What differences exist with regard to the selection of inmates for work in your programs and the selection of inmates for work in other prison industries?

E. What sanctions are applied against a prisoner who refuses to work in your program?

ANSWER TO NO. 6:

The prison classification committee assigns inmates to the Clinic.

A. Usually none. On occasion Parke Davis has requested of the committee that a specific inmate be assigned to the Clinic.

B. Any freedom given to refuse assignment to the Clinic is strictly up to the committee.

C. Selection process for Clinic assignments is presumably identical to all other assignments for inmates.

D. Since all assignments are made by the prison classification committee, Parke Davis & Company is not qualified to answer this question.

E. Any sanctions applied against inmates for refusal of assignment is strictly up to the prison assignment committee.

INTERROGATORY NO. 7:

Do you know of any other drug company with similar programs in the United States?

A. If so, what method of payment is followed by that drug company, if you know, in its programs.

B. Name the drug company or companies and the place or places where such programs are carried on.

ANSWER TO NO. 7:

Yes.

A. Presumably the same method is followed by The Upjohn Co. Information with respect to other companies is not known by Parke Davis & Company.

B. The Upjohn Co., Southern Michigan Prison. Others are unknown.

INTERROGATORY NO. 8:

What statutes of the State of Michigan will you rely on at the trial of this cause to authorize your use of prison labor?

ANSWER TO NO. 8:

This question is objected to.

INTERROGATORY NO. 9:

What members of the Department of Corrections for the State of Michigan own stock in your company?

A. Name them,

B. Give the amount of stock for each person,

C. Give the same information for any past member of the Department of Corrections since your program went into effect.

ANSWER TO NO. 9:

This question is objected to.

INTERROGATORY NO. 10:

Are you a profit making organization?

A. Do you market drugs in interstate commerce?

B. Do you market drugs which are tested at the State Prison of Southern Michigan in interstate commerce?

C. Do you sell such drugs for profit?

D. Are drugs used in testing at the prison shipped in interstate commerce?

E. State your profit for your last complete fiscal year.

ANSWER TO NO. 10 and 10A:

Yes (see answer to paragraph 3 of complaint). Remainder of question is objected to.

INTERROGATORY NO. 11:

For each job classification which inmates perform at the State Prison of Southern Michigan, give the rate of pay a civilian would receive for performing the job for you including overtime rates of pay.

ANSWER TO NO. 11:

This question is objected to.

INTERROGATORY NO. 12:

How are the amounts paid to or for the benefit of the prisoners at the State Prison of Southern Michigan reflected in your federal income tax return?

A. Answer the same question for your state income tax return,

B. Answer the same question for your city income tax return if you, in fact, file one,

C. Are any amounts withheld for income tax purposes at any level?

D. Are any amounts withheld for social security benefits?

ANSWER TO NO. 12:

Amounts referred to in answer to Interrogatory No. 2 are shown as research expense in federal income tax return.

A. Same as above.

B. Same as above.

C. No.

D. No.

INTERROGATORY NO. 13:

Who determines the number of hours an inmate works for you?

A. Have you ever rejected an inmate considered by you for work in your clinic?

B. Have you ever sought replacement of an inmate because of unsatisfactory conduct?

C. Give the names and details as far as you are able for the prior two questions.

ANSWER TO NO. 13:

Assignment hours are regulated by prison authorities. There is no set number of hours for the performance of any tasks.

A. No inmate assigned to clinic has been rejected by Parke Davis.

B. No, except in a few instances where Parke Davis made request for assignment change at the request of the inmate or because the inmate was unable or unwilling to perform the duties assigned to him.

C. Mr. Allen
Mr. Bale
Mr. Blower
Mr. Fowler
Mr. Mack
Mr. Stearns

INTERROGATORY NO. 14:

On what facts do you rely in denying that this is a proper class action in your answer to Plaintiffs' complaint in this lawsuit?

ANSWER TO NO. 14:

A class action in this case is not authorized either by statute or the Federal Rules of Civil Procedure.

INTERROGATORY NO. 15:

Who constructed the building in which your operations are carried on at the prison?

A. Who built the building?

B. What was the cost?

C. Who owns the building now?

D. If the present owner is different from the original owner, how was title transferred?

E. How was the transaction treated by you for federal income tax purposes?

F. Attach copies of all documents involved in the title transfer or state them word for word as part of the answer to this interrogatory.

G. Who is responsible for the maintenance of said buildings?

H. Who does the maintenance work?

ANSWER TO NO. 15:

The architect was J & G Daverman Company.

A. Banta Brooks Company.

B. Approximately $232,000.00.

C. State of Michigan.

D. Not applicable.

E. Depreciation expense.

F. Not applicable.

G. State of Michigan and Parke Davis & Company.

H. Prison inmates and Parke Davis & Company employees or contractors.

INTERROGATORY NO. 16:

If you do not want a prisoner to continue working for you, is there any requirement that you keep them anyway?

ANSWER TO 16:

Assignments of inmates to Clinic are within the exclusive authority of prison authorities.

INTERROGATORY NO. 17:

Are there any custodial employees from the prison at your building?

ANSWER TO 17:

Yes.

INTERROGATORY NO. 18:

Are the civilians employed by your company in the same job classifications as the prisoners members of any union?

A. State the union.

B. Attach a copy of any applicable collective bargaining agreement.

C. List all fringe benefits including but not limited to vacation pay, pension plan, etc.

ANSWER TO NO. 18:

None of Parke Davis & Company's employees working at the Clinic are union members.

INTERROGATORY NO. 19:

State in detail the history of the commencement of the clinics within the walls of Jackson Prison by your company.

A. State the names of your representatives and agents who carried on the negotiations.

B. State the names of the persons representing the Department of Corrections who carried on negotiations for the State of Michigan.

C. Attach copies of all correspondence and intercompany memoranda relating to the aforesaid negotiations and the contract signed between you and the prison if one was, in fact, signed.

ANSWER TO NO. 19:

Copy of the agreement dated November 13 and November 18, 1963 is attached. Remainder of this question is objected to.

INTERROGATORY NO. 20:

State whether or not you sought legal advice as to the legality of the clinics under Michigan law.

A. Attach a copy of any legal opinion you have received in connection with said question.

B. Attach all correspondence relating to any such legal opinion.

ANSWER TO NO. 20:

This question is objected to.

INTERROGATORY NO. 21:

Give the names of any inmates who have refused job assignments for your company.

ANSWER TO NO. 21:

Mr. Dooms is known to have refused assignment to the Clinic. Other instances are not known by Parke Davis & Company.

INTERROGATORY NO. 22:

Have any inmates who worked for you in prison upon their release gone to work for you?

ANSWER TO NO. 22:

No.

INTERROGATORY NO. 23:

Outline the chain of command or administration of your employees in the clinic within the prison walls.

ANSWER TO NO. 23:

John H Conlin, administrator, and George D Wood, assistant to the administrator, perform the necessary administrative and supervisory functions to operate the Clinic and to conduct research studies.

INTERROGATORY NO. 24:

Have you ever written a letter of recommendation for any inmate who worked for you in the prison clinic to aid him in obtaining another job upon his release?

ANSWER TO NO. 24:

Yes.

INTERROGATORY NO. 25:

Give the complete name and court case number of all other suits involving any of the questions in this suit in which you are named a defendant.

A. Attach a copy of the complaint and answer in each such suit.

B. Attach a copy of any motion to dismiss filed by you and the answer thereto.

ANSWER TO NO. 25:

This question is objected to.

INTERROGATORY NO. 26:

Have there ever been discussions between your representatives or agents or representatives of the Department of Corrections involving the payment of wages to inmates for work done in the clinics in accordance with the provisions of the federal minimum wage law or the state minimum wage law.

A. Give the details of any such discussions.

ANSWER TO NO. 26:

This question is objected to.

INTERROGATORY NO. 27:

In connection with your program, have you paid any money to any members of the Department of Corrections or any employees of the Department of Corrections for any reason?

A. If so, state the details of anysuch transaction.

ANSWER TO NO. 27:

Yes.

A. Parke Davis has occasionally contracted with prison staff members to administer restricted medication during nonduty hours.

Miller, Canfield, Paddock and Stone

By WOLFGANG HOPPE
Wolfgang Hoppe
Attorneys for Defendant Parke Davis & Company
2500 Detroit Bank & Trust Building
Detroit, Michigan 48226 963-6420

Dated: October 14, 1970

Name	Assignment Classification	Approximate Periods of Assignment	Total Charges by The State Department of Corrections (as of September 12, 1968)
Allen, R.	Porter, Chief Porter and Runner	4/28/66 - 10/21/66	73.45
Bailey, R.	Cook, Nurse Supervisor, Chief Technician, Chief Cook	3/16/64 - 12/12/66 1/13/68 - Still on Assign.	951.90
Cleary	Technician Trainee, Trained Technician, Chief Cook	11/15/66 - Still on Assign.	465.60
Davis	Kitchen Assistant, Chief Cook	12/1/67 - Still on Assign.	151.30
Holnagel	Trained Technician, Maintenance Man	2/21/67 -- Still on Assign.	330.90
Inman	Trained Technician, Chief Technician, Nurse Supervisor	7/22/66 - 1/8/68	513.95
Kelton	Technician Trainee, Trained Technician	7/15/65 - 12/12/66	325.30
Lord, T.	Clerk, Technician Trainee, Chief Technician, Chief Clerk	4/29/66 - 12/14/67	589.30
Mack, J.	Maintenance Man	11/20/67 - 4/2/68	62.95
McGhee	Porter, Kitchen Assistant	9/30/65 - 8/24.66	122.25
Sims, C.	Trained Technician, Clerk, Chief Clerk	1/6/67 - Still on Assign.	493.95
Spells, B.	Kitchen Assistant, Porter, Chief Cook	9/16/66 - Still on Assign.	439.60
Williams, B.	Clerk, Technician Trainee, Trained Technician, Chief Technician, Chief Cook, Cook	7/28/66 - 11/12/67	316.55
Williams, H.	Kitchen Assistant, Porter, Head Porter, Nurse Supervisor	8/17/66 - Still on Assign.	422.05

Contract No. JC-12

AGREEMENT

The following agreement covers the method of construction, the operation and the ownership of a Clinical Research Building at the State Prison of Southern Michigan at Jackson:

1. The Parke-Davis Company will retain the services of an architect, and will contract for the construction of a Clinical Research Building at the State Prison of Southern Michigan.

2. The Parke-Davis Company will pay the entire expense of planning and constructing the building.

3. The plans and specifications for the Clinical Research Building must be approved by both the Department of Corrections and the Parke-Davis Company.

4. The Parke-Davis Company will purchase all necessary equipment for the building, and the portable research equipment will remain the property of the company.

5. Upon acceptance of the completed project by the Department of Corrections, the building and fixed equipment shall become the property of the State of Michigan. The proceeds of any insurance protection on the building or contents against damage shall be used to restore the facility, such insurance shall be provided by the Parke-Davis Company.

6. In the event of abandonment of a partially completed project, any materials and equipment at the construction site shall become the property of the Department of Corrections.

7. The Parke-Davis Company will heat, light, administer, maintain the building, and provide necessary supervision at its own expense. However, custody and security will be the responsibility of the Department of Corrections.

8. The Parke-Davis Company and only the Parke-Davis Company will have the right to use the building for clinical research so long as clinical research is conducted by any organization or corporation at the State Prison of Southern Michigan.

9. The Parke-Davis Company will be responsible for the conduct of the clinical research in the Clinical Research Building. They will abide by the policies of the Department of Corrections and the laws of Michigan and the United States.

Contract No. 10-12

10. The Department of Corrections will take all reasonable steps to facilitate the conduct of clinical research by the Parke-Davis Company. The Department of Corrections will permit prisoners to volunteer to participate as subjects in the clinical research.

11. The Department of Corrections will appoint a Medical Advisory Committee composed of several qualified faculty members from Michigan Medical Schools which will review the operations on a yearly basis. The Committee will either approve or suggest changes in the procedures used in the clinical research.

12. The Parke-Davis Company agrees to indemnify the State of Michigan for any additional expenditures incurred as a result of a volunteer inmate suffering from a drug incurred illness or disability.

13. The Parke-Davis Company agrees to continue to clear all of its research projects with the Department of Corrections before initiating them at the prison.

PARKE, DAVIS & COMPANY

Nov. 13, 1963
Date

A. Loynd
President

MICHIGAN DEPARTMENT OF CORRECTIONS

11/18/63
Date

Director

UNITED STATES DISTRICT COURT

For the Eastern District of Michigan

Southern Division

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VELBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS, and RALPH R. WARNER,

Plaintiff,

-vs-

PARKE DAVIS & CO., a Michigan Corporation, and THE UPJOHN CO., a Delaware Corporation,

Defendants.
_____/

CIVIL CASE NUMBER 31172

JUDGE FREEMAN

MOTION FOR SUMMARY JUDGMENT BY PLAINTIFFS PURSUANT TO RULE 56 OF THE FEDERAL RULES OF CIVIL PROCEDURE

Plaintiffs through counsel respectfully move the Court pursuant to rule 56 of the Federal Rules of Civil Procedure to enter judgment under Count III of Plaintiffs' amended complaint as to liability only against Defendants and in favor of Plaintiffs on the grounds that it appears from Defendants' answers (attached hereto as Exhibit "A"), Defendants' answers to interrogatories (attached hereto as Exhibit "B") and the affidavit of Calvin Sims (attached hereto as Exhibit "C") that there is no genuine issue as to any material fact and that Plaintiffs are entitled as a matter of law to Judgment under Count III of Plaintiffs' complaint as to liability only.

The concurrence of opposing counsel in the relief sought has been denied, (October 24, 1969).

Plaintiffs hereby request that any answers to interrogatories or written admissions given by Defendants subsequent to the date hereof but prior to a ruling hereon by the Court be considered along with the materials attached hereto in support hereof.

LEITSON, DEAN, DEAN, SEGAR & HART, P.C.
Attorneys for Plaintiff

BY: _____
Robert L. Segar

DATED: _____, 1969.

LAW OFFICES
LEITSON, DEAN, DEAN, SEGAR, & HART, P.C.
808 DETROIT STREET
FLINT, MICH. 48503
238-5691

Filed: Oct. 30, 1969

UNITED STATES DISTRICT COURT

For the Eastern District of Michigan

Southern Division

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McCHEE, VERNON D. MEVIS, RALPH R. WARNER,

Plaintiffs,

-vs-

PARKE DAVIS & CO., a Michigan Corporation and THE UPJOHN CO., a Delaware Corporation,

Defendants.

CASE NUMBER 31172

JUDGE FREEMAN

AFFIDAVIT IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

STATE OF MICHIGAN
SS
COUNTY OF GENESEE

CALVIN SIMS, being first duly sworn, deposes and says as follows:

1. This affidavit is made upon the basis of the personal knowledge of affiant of the following matters and affiant is competent to testify to the matters stated herein.

2. Affiant is one of the named Plaintiffs herein and has worked in the drug clinic building constructed by Parke Davis & Co. at the State Prison of Southern Michigan. Further, he is familiar with the remaining named Plaintiffs and other inmates of said prison who worked in the said clinic as well as in the clinic constructed by the Upjohn Company.

3. The hours which he worked were comparable to those which would be worked by anyone on a regular civilian job and in fact some times he worked seven (7) days a week. The time worked each day varied from a few hours up to sixteen (16) hours in a twenty-four (24) hour period.

4. He and others worked directly under the supervision of civilian employees of the drug companies.

5. Representative examples of the work which was done in the clinics include the following:

A. Drawing blood samples and running them through a centrifuge to separate plasma from red cells.

B. Accurately typing labels for vials.

C. Taking and analyzing urine samples.

D. Taking the temperature and blood pressure of those persons being used in drug tests.

E. Administering electrocardiograms and electroencephalograms.

F. Keeping records of important bodily functions.

6. He and others working at the clinics did so because they were ordered to do so by representatives of the Department of Corrections just as they would be ordered to work in any other prison industry and a refusal to work as directly would have resulted in penalties to them and such coercion and threat, was under the circumstances, clearly implied if not expressly stated.

7. Examples of the drugs tested in said clinics are:

A. Dilantin,
B. Chloromycetin
C. Ponstel
D. Benadryl
E. Albuspan
F. Ambodryl

CALVIN SIMS

Subscribed and sworn to before me this 30th day of October 1969.

Penelope L. Wellman Notary Public
Genesee County, Michigan
My commission expires:
May 15, 1971

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
804 DETROIT STREET
FLINT, MICH. 48503
235-5031

Filed: Nov. 3, 1969

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

CALVIN SIMS, et al

vs. Case No. 31172

PARKE DAVIS AND COMPANY,
and THE UPJOHN COMPANY

_____/

MOTION FOR ORDER THAT PLAINTIFFS' ACTION SHALL NOT BE MAINTAINED AS A CLASS ACTION

NOW COMES Defendant, The Upjohn Company, by its attorneys, Dykema, Wheat, Spencer, Goodnow & Trigg, and respectfully moves that the Court enter its Order that Plaintiffs' Action Shall Not be Maintained as a Class Action.

This Motion is made pursuant to Rule 23 (c) (1), Fed. R. Civ. Procedure, and is supported by the attached Brief.

DYKEMA, WHEAT, SPENCER, GOODNOW & TRIGG

By: Timothy K. Carroll
Attorneys for The Upjohn Company
2700 Penobscot Building

CERTIFICATE OF SERVICE

I, Timothy K. Carroll, hereby certify that one copy of the above Motion for Order that Plaintiffs' Action Shall Not be Maintained as a Class Action, with supporting Brief, was this day served, by first class mail, upon:

Robert L. Segar, Esq.
604 Detroit Street
Flint, Michigan 48503

Timothy K. Carroll

Subscribed and sworn to before me this 3rd day of November, 1969.

Ellen Adair Russell
Notary Public, Wayne County, Mich. My Com. Exp.: March 31, 1973.

Filed: Nov. 3, 1969

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

CALVIN SIMS, et al

vs. Case No. 31172

PARKE DAVIS AND COMPANY, and THE UPJOHN COMPANY

/

MOTION TO DISMISS COUNT II OF COMPLAINT

NOW COMES, Defendant, The Upjohn Company, by its attorneys, Dykema, Wheat, Spencer, Goodnow & Trigg, and respectfully moves that Count II of Plaintiffs' Complaint be dismissed in its entirety, as Count II fails to state a claim upon which relief can be granted.

This Motion is made pursuant to Rule 12, Fed. R. Civ. Procedure, and is supported by the attached memorandum.

DYKEMA, WHEAT, SPENCER, GOODNOW & TRIGG

Timothy K. Carroll
Attorneys for The Upjohn Company
2700 Penobscot Building

CERTIFICATE OF SERVICE

I, Timothy K. Carroll, hereby certify that one copy of the above Motion for Order that Plaintiffs' Action Shall Not be Maintained as a Class Action, with supporting Brief, was this day served, by first class mail, upon:

Robert L. Segar, Esq.
804 Detroit Street
Flint, Michigan 48503

Timothy K. Carroll

Subscribed and sworn to before me this 3rd day of November, 1969.

Notary Public, Wayne County, Michigan
My Commission expires: March 31, 1973.

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARLY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,

Plaintiffs,

-vs-

Civil Action No. 31172

PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN COMPANY, a Delaware corporation,

Defendants.

CLERK

ANSWERS OF PARKE, DAVIS & COMPANY
TO ADDITIONAL INTERROGATORIES

NOW COMES PARKE, DAVIS & COMPANY, a Michigan corporation, and answering plaintiffs' Additional Interrogatories, says:

INTERROGATORY NO. 1:

List the name and address of every witness who you may rely on at the trial of this cause.

ANSWER TO NO. 1:

The witnesses whom Parke, Davis may call at the trial have not yet been determined.

INTERROGATORY NO. 2:

State the subject matter of the testimony of each witness named in the preceding question.

ANSWER TO NO. 2:

The subject matter of the proposed testimony of trial witnesses will not be known until their identity is established.

INTERROGATORY NO. 3:

List the name and address of each of your employees who have knowledge of the workings and procedures of your prison clinic.

ANSWER TO NO. 3:

Parke, Davis & Company does not know all those who may have some knowledge of the workings and procedures of their clinic at Jackson Prison but at present Mr. George D. Wood is probably the one Parke, Davis employee who is best acquainted with the "workings and procedures" of the prison clinic.

INTERROGATORY NO. 4:

List the name and address of each of your employees who have knowledge of the original negotiations leading to the establishment of your clinic at the prison.

ANSWER TO NO. 4:

Parke, Davis & Company does not know all those who may have some knowledge of the original negotiations leading to the establishment of their clinic at Jackson Prison but the agreement preceding the commencement of operation of the clinic was executed on behalf of Parke, Davis & Company by its then president, Harry J. Loynd, 610 Neff Road, Grosse Pointe, now retired.

INTERROGATORY NO. 5:

List the name and address of any person other than your employee who you have reason to believe has such knowledge.

ANSWER TO NO. 5:

Parke, Davis & Company does not know all those who may have some knowledge of the original negotiations leading to the establishment of their clinic at Jackson Prison but the agreement preceding the commencement of operation of the clinic was executed on behalf of the Michigan Department of Corrections by its Director, Mr. Gus Harrison.

INTERROGATORY NO. 6:

State the name and address of the person in charge of personnel for your company.

ANSWER TO NO. 6:

J. W. Matheus, Director of Personnel Relations, 1563 Edmonton, Grosse Pointe, Michigan.

INTERROGATORY NO. 7:

What is the pay scale for civilians employed by you outside the prison who are engaged in drug testing?

A. State all fringe benefits available to such employees.

B. What is the overtime rate of pay for such employees?

C. What is the standard work week for such employees?

D. Are they members of any union?

ANSWER TO NO. 7:

This question is objected to.

PARKE, DAVIS & COMPANY

By _____
John A. Bradshaw
Assistant Secretary

State of Michigan)
) ss.
County of Wayne)

John A. Bradshaw, being first duly sworn, on oath deposes and says as follows:

1. That he is Assistant Secretary of defendant Parke, Davis & Company, a Michigan corporation; and

2. That he has read the foregoing answers to interrogatories by defendant Parke, Davis & Company, and such answers are true and correct to the best of his knowledge, information and belief.

John A. Bradshaw
Assistant Secretary

Subscribed and sworn to before me
this 11th day of December, 1969
Mary L Cumberworth
Notary Public, Wayne County, Michigan
My commission expires: June 5, 1970

Filed: Jan. 21, 1970

UNITED STATES DISTRICT COURT

For the Eastern District of Michigan

Southern Division

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS, RALPH R. WARNER,

Plaintiffs,

-vs-

PARKE DAVIS & CO., a Michigan Corporation and THE UPJOHN CO., a Delaware Corporation, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C. J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON, and GUS HARRISON,

Defendants. /

CASE NUMBER 31172

JUDGE FREEMAN

AMENDED COMPLAINT

Plaintiffs complaint of Defendants as follows:

COUNT I

1. Jurisdiction of this Court is grounded upon:

Title 29 United States Code Annotated: Sec. 216 (6) (Sec. 16(b) of the Fair Labor Standards Act of 1938 as amended),

Title 28 United States Code Annotated: Sec. 1337 giving the District Court original jurisdiction of "Any civil action or proceedings arising under any Act of Congress regulating commerce" without regard to citizenship of the parties or amount in controversy.

Title 28 United States Code Annotated: Sec. 1343

Title 42 United States Code Annotated: Sec. 1983

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Thirteenth Amendment to the United States Constitution.

Fourteenth Amendment to the United States Constitution.

2. This action is brought in part (Count I) pursuant to Sec. 16 (6) of the Fair Labor Standards Act of 1938 (29 U.S.C.A., Sec. 201-219) to recover from Defendants unpaid minimum wages and overtime compensation, interest on said amounts since due, an equal additional amount as liquidated damages, Court costs and a reasonable attorney's fee.

3. Plaintiffs are or have been inmates of the State Prison of Southern Michigan at Jackson, Michigan, at all times relevant to this cause of action. Defendant Parke Davis & Co. is a Michigan Corporation for private profit engaged in the drug industry and Defendant The Upjohn Company is a Delaware Corporation for private profit similarly engaged. Both Defendants are doing business throughout the State of Michigan, and in interstate commerce. Defendant Department of Corrections is a corporation formed by and pursuant to Act Number 232 of the Public Acts of 1953 and is charged by said act with supervising, controlling and managing the administration of penal institutions in general and prison labor and industries in particular. The individual members named are or have been members of said Department of Corrections at times relevant to Plaintiffs' cause of action. Defendant Harrison is the Director of said Department.

4. There are numerous other people who either are or have been inmates in the State Prison of Southern Michigan at Jackson, Michigan, who have the same cause of action as hereinafter set forth on the part of the named Plaintiffs, and the

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named Plaintiffs adequately represent such unnamed people. This action is brought pursuant to Rule 23 A of the Federal Rules of Civil Procedure on behalf of all such people whose number make it impractical to have them join as Plaintiffs. The named Plaintiffs adequately represent said class.

5. In 1963 the named Defendants Parke Davis & Co. and The Upjohn Co. erected within the State Prison of Southern Michigan at Jackson, Michigan, research clinics for the private profit making purposes of said corporations and said clinics have been continuously and are currently in operation. The activities in said clinics among other things include the clinical testing of drugs not presently on the market as well as the testing of drugs currently being produced for, sold, transported, shipped and delivered in interstate commerce throughout the United States. Defendants are enterprises engaged in interstate commerce within the meaning of 29 U.S.C.A., Sec. 203.

6. Certain inmates of said prison including Plaintiffs were picked by Defendants Parke Davis & Co. and The Upjohn Co. in conjunction with representatives of the Michigan Department of Corrections to be employed by Defendants Parke Davis & Co. and The Upjohn Co. at the aforesaid research clinics. The work therein by said inmates is carried on under the sole direction and supervision of Defendants Parke Davis & Co.'s and The Upjohn Co.'s representatives, and said employees work on a regular basis up to as much as one hundred twelve (112) hours per week.

7. The work carried on by the named Plaintiffs and other inmates is exactly the same work that would be required of nonprison personnel working in comparable capacities. The wages paid by the respective private corporate Defendants to each

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worker range from Thirty-Five Cents ($0.35) to One Dollar and 25/100 ($1.25) per day and all other costs of running the clinic are paid by said Defendants, such as power, heat and water.

8. Among the job classifications of the inmates are the following: Chief Technician (in each classification); Trained Technician (in all classified areas); Technician Trainees (in all classified areas); Chief Clerk; Clerks; Nurse Supervisor; Nurse; Chief Cook; Kitchen Assistant; Kitchen Pot and Pan Man; Maintenance Man; Head Porter.

9. All of the activity by Plaintiffs inures to the benefit of the stockholders of Defendant private corporations and involves work which if not accomplished by said inmates would have to be accomplished by civilian help paid in accordance with applicable federal and state laws.

10. Plaintiffs were and are employees of Defendants Parke Davis & Co. and The Upjohn Co. within the meaning of the Fair Labor Standards Act of 1938 as amended, 29 U.S.C.A., Sec. 201 et seq. and were and are entitled to be paid the minimum wages provided for in said act. All of the acts and actions complained of by Plaintiffs were accomplished by the agreement and cooperation of all the Defendants, both corporate and individual, named herein; and the illegal utilization of Plaintiffs' labor inured to the benefit of all Defendants. Further, said actions constituted in fact or in law an attempt to evade, avoid and violate the laws of the State of Michigan regarding the use of prison labor for private profit, and the laws of Michigan and the United States regulating the minimum wage to be paid for labor.

11. Plaintiffs are entitled to recover from Defendants the difference between the amounts received by each Plaintiff

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and the minimum wage guaranteed by said law; all overtime compensation that may be due; an equal additional amount as liquidated damages; courts costs and a reasonable attorney's fee as well as interest due on said back wages since they were due.

12. The number of hours and the amount of overtime worked by each Plaintiff as well as the amounts actually paid to each Plaintiff is within the knowledge of the Defendants through the records which they keep regarding Plaintiffs' employment.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars plus interest, costs and attorney's fee.

COUNT II

1. Plaintiffs refer to and by such reference hereby incorporate as though expressly repeated herein the allegations of paragraphs one (1) through twelve (12) of Count I hereof.

2. The employment of Plaintiffs by Defendants as alleged aforesaid is in violation of Act Number 154 of the Public Acts of 1964 of the State of Michigan commonly known as the Minimum Wage Law of 1964 being Sec. 408.381 of the compiled laws of the State of Michigan.

3. Should this Court determine that the Fair Labor Standards Act of 1938 as amended does not apply to Defendant employers herein then the Minimum Wage Law of the State of Michigan would apply as set out in Sec. 14 thereof, and this action is based in part upon Sec. 13 of said act and seeks recovery of the difference between the amounts paid to Plaintiffs and the minimum wage provided by said Minimum Wage Law and for

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an equal additional amount as liquidated damages together with interest, costs and a reasonable attorney's fee.

4. Defendants are employers and Plaintiffs employees within the meaning of said Minimum Wage Law.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars plus interest, costs and attorney's fee.

COUNT III

1. Plaintiffs refer to and by such reference incorporate herein as though expressly repeated the allegations of paragraphs one (1) through twelve (12) of Count I hereof.

2. The utilization of the labor of said inmates by Defendants is expressly contrary to the law of the State of Michigan and particularly Sec. 800.305 of C.L. 48 which provides in pertinent part. . .

> "Nor shall the labor of prisoners be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction, maintenance or operation of public works, ways, or property as directed by the Governor;"

and Sec. 800.310 C.L 48 which provides in pertinent part:

> "It is hereby declared to be the intent of this act:
> (A) To provide adequate, regular, diversified and suitable employment for prisoners of the State consistent with proper penal purposes;
>
> (B) To utilize the labor of prisoners exclusively for self maintenance and for reimbursement of State for expenses incurred by reason of their crimes and imprisonment;
>
> (C) To eliminate all competitive relationships between prisoner, labor or prison products and free labor or private industry;
>
> (D) To affect the requisitioning and disbursement of prison labor and prison products directly through established state authorities with no

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233-5031

possibility of private profits therefrom and with the minimum of intermediating financial considerations, appropriations or expenditures; . . ."

3. The utilization of the services and labor of Plaintiffs for Defendants own private profit and interest has resulted in and is resulting in the unjust enrichment of Defendants in the amount by which the reasonable value of Plaintiffs' services exceeds the amount paid by Defendants to Plaintiffs. The labor of Plaintiffs has been and is being utilized by Defendants with full knowledge that they are benefiting unjustly and illegally by the difference between the amount paid to Plaintiffs and the reasonable value of their services.

4. In addition, Defendants other than Parke Davis & Co. and The Upjohn Co. have been unjustly enriched and benefited from the illegal use of Plaintiffs' labor by the acquisition for the State Prison of Southern Michigan of a building (i.e. the structure housing the clinic) which cost approximately $300,000.00 to construct and whose replacement cost would be far greater today.

5. Plaintiffs' labor was utilized as alleged by Defendants without Plaintiffs' consent and under coercion and implied threat of retribution if they did not work for Parke Davis & Co. and The Upjohn Co. as ordered.

6. The reasonable value of Plaintiffs' services is at least the amount which would be due them under the Minimum Wage Laws of the State of Michigan and the United States of America.

7. Plaintiffs have, therefore, been unjustly deprived of their labor and the fruits thereof in violation of the laws of the State of Michigan as hereinbefore set forth.

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238-5551

8. The contracts existing between Plaintiffs and Defendants and between Defendants and any other party are void because of violation of the statutes of the State of Michigan regarding prison labor already set forth.

9. Plaintiffs are, therefore, entitled to recover from Defendants the reasonable value of their services in excess of the amounts paid by Defendants to Plaintiffs for same.

10. Plaintiffs are entitled to interest on the amount due to them under this count from the dates said amounts were due.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars, plus interest, costs and attorney's fee.

COUNT IV

1. Plaintiffs refer to an by such reference incorporate herein the allegations of paragraphs one (1) through twelve (12) of Count I hereof.

2. The illegal utilization and exploitation of Plaintiffs' labor by all Defendants and the payment by Defendants Parke Davis & Co. and The Upjohn Co. of nominal wages less than those required by law has resulted and is resulting in a deprivation of the liberty and property of Plaintiffs without due process of law and in violation of the Fourteenth Amendment.

3. Said conduct has also resulted and is resulting in the holding of Plaintiffs in involuntary servitude contrary to the Thirteenth Amendment to the Federal Constitution.

4. Said conduct was carried out under color of the laws of the State of Michigan dealing with supervision of prisoners.

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DEAN, SEGAR,
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235-8031

5. Also as a result of said conduct Plaintiffs have been denied equal protection of the laws guaranteed by the Fourteenth Amendment, in that Plaintiffs have been and are being arbitrarily discriminated against in the amount of wages paid to them for their labor since others doing the same work or performing any service for private profit making corporations would be entitled to collect a reasonable wage therefor.

6. Jurisdiction under this court is grounded upon Sec. 1983 of Title 42 and Sec. 1343 of Title 28 of United States Code Annotated.

7. The actions complainted of have proximately caused damages to Plaintiffs in the amount of One Million ($1,000,000.00) Dollars.

WHEREFORE, Plaintiffs seek judgment against Defendants in the amount of One Million ($1,000,000.00) Dollars, plus interest, costs and attorney's fee.

LEITSON, DEAN, DEAN, SEGAR & HART, P.C.
Attorneys for Plaintiffs

BY: _____
Robert L. Segar

DATED: Feb. 30, 1969.

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
804 DETROIT STREET
FLINT, MICH. 48503
235-5631

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

Calvin Sims, Richard Allen, Frank Rogers, Billy Lee Williams, Walter Lee, Boyd Slager, Peter George Mills, Lee D. Walker, Clemont Dedeaux, Ordell Vilburn, William Cleary, Herbert Williams, Fred Holnagel, Benny Spells, Kenneth Inman, Raymond L. Bailey, Orcean Davis, Jerry Mack, Boyd Kelton, Thomas H. Lord, Ralph Watson, Chester A. Sawicki, Phillip McGhee, Vernon D. Mevis, Ralph R. Warner,

Plaintiffs

-vs-

Civil Action File No. 31172

Parke Davis & Co., a Michigan corporation and The Upjohn Co., a Delaware corporation, Eleanor Hutzel, James E. Wadsworth, Ernest C. Brooks, Max Biber, C. J. Farley, John W. Rice, Duane L. Waters, Florence Crane, Joseph J. Gross, G. Robert Cotton, and Gus Harrison,

Defendants

ANSWER TO COMPLAINT

COUNT I

Now come Eleanor Hutzel, James E. Wadsworth, Ernest C. Brooks, Max Biber, C. J. Farley, John W. Rice, Duane L. Waters, Florence Crane, Joseph J. Gross, G. Robert Cotton, and Gus Harrison, by their attorney, Frank J. Kelley, Attorney General of the State of Michigan, by Solomon Bienenfeld, Assistant Attorney General, and answer as follows:

1. Defendants deny the applicability of the statutes and constitutional provisions to the alleged cause of action. Plaintiffs were lawfully convicted of crimes against the State of Michigan and are serving prison terms in Jackson Prison, Jackson, Michigan. Therefore, they have not been denied of any constitutional or statutory rights.

2. Defendants deny

3. Defendants admit that plaintiffs have been inmates of Jackson Prison. Admit that defendants Parke Davis & Co. and The Upjohn Company are engaged in the drug industry for private profit. Defendants deny that the Department of Corrections is a corporation and state that it is an agency of the State of Michigan established by Act 380, PA 1965, pursuant to Article V, Section 2 of the Michigan Constitution of 1963. Members of the Michigan Corrections Commission named as defendants are state officers and have at all times acted in their capacity as state officers thereby protecting themselves with immunity under such circumstances. Defendant Gus Harrison is the director of the said department and is similarly protected by immunity of state officers.

4. Defendants deny that Rule 23 A of the Federal Rules of Civil Procedure is applicable. Other inmates have previously filed actions in federal district court based upon the same or similar circumstances; Earl F. Mink v. Paul Chase, et al., United States District Court for the Eastern District of Michigan, Southern Division, Civil Action File No. 31480; The United States of America, ex rel, for Coleridge Taylor Mason, Jr., by Coleridge Taylor Mason, Jr., v. The Michigan Department of Corrections, et al., United States District Court for the Eastern District of Michigan, Southern Division, Civil Action No. 29260.

5. Defendants admit.

6. Defendants deny and attach hereto affidavits of Ralph F. Willy and George A. Kropp filed in conjunction with Civil Action No. 29260, referred to in paragraph 4 above, stating the circumstances under which inmates participate in the work assignments relating to the Parke Davis & Co. and the Upjohn Co. facilities.

7. Defendants deny.

8. Defendants neither admit nor deny but leave plaintiffs to their proof.

9. Not applicable to defendants other than Parke Davis & Co. and The Upjohn Co.

10. Defendants deny.

11. Defendants deny.

12. Defendants deny.

COUNT II

1. Defendants refer to and by such reference hereby incorporate answers to paragraph 1 through 12 of Count I hereof.

2. Defendants deny.

3. Defendants deny that either the Fair Labor Standards Act of 1938 or the Minimum Wage Law of the State of Michigan are applicable to activities carried on by inmates of a state prison.

4. Defendants deny.

COUNT III

1. Defendants refer to and by such reference hereby incorporate answers to paragraphs 1 through 12 of Count I hereof.

2. Defendants deny.

3. Defendants deny.

4. Defendants deny.

5. Defendants deny.

6. Defendants deny.

7. Defendants deny.

8. Defendants deny.

9. Defendants deny.

10. Defendants deny.

COUNT IV

1. Defendants refer to and by such reference hereby incorporate answers to paragraphs 1 through 12 of Count I hereof.

2. Defendants deny.

3. Defendants deny. The 13th amendment to the Federal Constitution provides:

> "Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction."

As plaintiffs have been duly convicted of crimes against the people of the State of Michigan, they are not subject to the protection of the 13th amendment.

4. To the extent that plaintiffs were convicted of crimes pursuant to the laws of the State of Michigan and are incarcerated in Jackson Prison as punishment for the commission of such crimes, their controlled activities within the prison were carried out under color of the laws of the State of Michigan.

5. Defendants deny.

6. Defendants deny.

7. Defendants deny.

WHEREFORE defendants ask that plaintiffs' complaint be dismissed with prejudice and with costs.

Eleanor Hutzel, James E. Wadsworth, Ernest C. Brooks, Max Biber, C. J. Farley, John W. Rice, Duane L. Waters, Florence Crane, Joseph J. Gross, G. Robert Cotton, and Gus Harrison

By FRANK J. KELLEY, Attorney General

Solomon Bienenfeld, Assistant Attorney General

Attorney for Defendants

Seven Story Office Building
525 W. Ottawa
Lansing, Michigan

Telephone: (517) 373-1178

Dated: February 6, 1970

UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

THE UNITED STATES OF AMERICA, ex rel, for COMMISSIONER TAYLOR HASON, JR., by COLEMAN TAYLOR MASON, JR.,

Plaintiff,

v.

Civil Action No. 29260

THE MICHIGAN DEPARTMENT OF CORRECTIONS, GUS HARRISON, GEORGE A. KROPP, PAUL HENDERSON, ROBERT H. BOOSE, A. R. SVANSON, GERALD L. HANSEN, DR. F. L. BARTHOLOC, JOHN UNKER,

-and-

THE UPJOHN COMPANY, HAROLD L. UPJOHN, DR. ALAN E. VANLEY, DONALD POWERS, RALPH F. WILLY,

-and-

PARKE DAVIS & COMPANY, JOHN H. COMLEY, DR. ALEXANDER E. LANE, DALE K. BOYERS,

Defendants.

AFFIDAVIT OF ADMINISTRATOR
RALPH F. WILLY

STATE OF MICHIGAN)
) ss.
COUNTY OF JACKSON)

Ralph F. Willy, after first being duly sworn, deposes and says as follows:

1. That he is employed by The Upjohn Company as Administrator of the Upjohn research clinic, located within the confines of the State Prison for Southern Michigan, 4000 Cooper Street, Jackson, Michigan, and has been so employed as Administrator since approximately February 3, 1964.

2. That his duties as Administrator of said clinic include general supervision of the technical and administrative aspects of research conducted therein.

3. That neither he nor any other Upjohn representative connected in any manner whatsoever with the Research Clinic in Jackson Prison have power or authority to assign any inmate to work in the clinic.

4. That inmates of the prison have, from time to time, expressed an interest to him in being assigned to work in the clinic.

5. That in none of those cases in which a particular inmate has expressed an interest in being assigned to the clinic, he has requested that the particular inmate be so assigned.

6. That all such requests have been directed to the Director of Treatment or the Classification Committee of the prison, which affiant believes, are the only parties within the prison having authority to make such assignments.

7. That some of the aforementioned requests have been denied while others have been granted.

8. That there have been instances in which inmates have been assigned by the Director of Treatment or the Classification Committee to work in the research clinic without the prior knowledge or approval of any Upjohn personnel.

9. That in some such instances in which inmates have been so assigned they have been designated by the Classification Committee to perform specific tasks and to fill specific positions.

10. That in some instances in which the inmates have been so designated to perform specific tasks and to fill specific positions, the research clinic had no need for such additional inmate personnel.

11. That on one specific occasion he requested that a certain inmate's assignment to the clinic be rescinded and that such request was denied.

12. That once an inmate has been assigned to perform services at the research clinic, the hours during which such inmate is to be present at the clinic must be approved by the Inside Deputy Warden.

13. That once an inmate has been assigned to the research clinic, he may be given time off in accordance with prison rules by the prison authority for purposes of attending meetings, studying, recreation or other reasons without approval of Upjohn personnel;

14. That once an inmate has been assigned to the research clinic, all specific instructions by Upjohn personnel are subject to approval by the prison authority for administrative and security reasons.

15. That some specific instructions and job assignments by Upjohn personnel have been vetoed by the prison authority.

16. That inmates who have been assigned to the research clinic may be reassigned by the Director of Treatment or the Classification Committee to other assignments within the prison, such as the laundry or the bakery.

17. That such reassignments have occurred without the approval of Upjohn personnel.

18. That inmates have been reassigned to Double "O" or "OO" (back to cell) by the prison authority without knowledge or approval of Upjohn personnel.

19. That Upjohn personnel have requested the Classification Committee or Director of Treatment to reassign inmates to other assignments on various occasions.

20. That such requests have in some instances been denied so that an inmate has continued on the research clinic assignment against the express wishes of Upjohn personnel.

21. That the per diem wage rates for all inmate assignments are set by the Department of Corrections, and that such per diem wages are paid by the State of Michigan.

22. That, as Administrator of the research clinic, he may suggest changes in the per diem rates for those inmates assigned to the research clinic.

23. That any such request must be directed to the Warden whose is may or may not be acted upon.

24. That Upjohn maintains records reflecting the days worked by inmates at the research clinic.

25. That such records are kept upon standard prison forms, as are the days worked by inmates on other prison assignments.

26. That The Upjohn Company reimburses the State of Michigan for the per diem wages of inmates who have been assigned to work in the research clinic, pursuant to agreement with the Department of Corrections.

27. That the prison has assigned a guard to provide security at the Upjohn research clinic.

28. That such guards as may be so assigned are paid by the State of Michigan.

29. That The Upjohn Company reimburses the State of Michigan for the wages paid any such guards for duty at the research clinic, pursuant to agreement between The Upjohn Company and the Department of Corrections.

I make this affidavit on the basis of my own knowledge.

Ralph F. Willy

Subscribed and sworn to before me this _____ day of FEB 16 1967, 1967.

Paul J. LaDow

Notary Public, _____ County, Mich.

My Commission Expires: _____

PAUL J. LADOW
NOTARY PUBLIC, Jackson County, Mich.
My Commission Expires April 5, 1969.

UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

THE UNITED STATES OF AMERICA, ex rel, for COLERIDGE TAYLOR KNOX, JR., by COLERIDGE TAYLOR KNOX, JR.,

Plaintiff,

v.

Civil Action
No. 29200

THE MICHIGAN DEPARTMENT OF CORRECTIONS, GUS HARRISON, GEORGE A. KNOPP, PAUL HENDELSON, ROBERT M. BOOSE, A. R. SVANSON, GERALD L. KNOX, DR. F. L. BARTHOLOW, JOHN WHEED,

-and-

THE UPJOHN COMPANY, HAROLD L. UPJOHN, DR. ALAN B. VARLEY, DONALD POWERS, RALPH F. WILEY,

-and-

PARKE DAVIS & COMPANY, JOHN H. COWLES, DR. ALEXANDER Z. LANE, DALE K. BOYLES,

Defendants.

AFFIDAVIT OF WARDEN
GEORGE A. KNOPP

STATE OF MICHIGAN)
) ss.
COUNTY OF JACKSON)

George A. Knopp, after first being duly sworn, deposes and says as follows:

1. That he is Warden of the State Prison for Southern Michigan (Jackson Prison), 4000 Cooper Street, Jackson, Michigan, and that he has been Warden since February 1, 1963.

2. That, as Warden, he is the chief institutional officer within the prison and is head of all internal operations.

3. That, as the chief institutional officer within the prison, he has various other institutional officers responsible directly to him.

4. That one such officer, G. L. Hanna, is employed in the position of Director of Treatment, and has the day to day responsibility of proper assignment and direction of all inmates in their respective tasks, study and recreation.

5. That the Director of Treatment, acting with the assistance of a Classification Committee, makes each and every assignment of inmates to their respective tasks within the prison, such as assignments to the prison laundry, the prison hospital and the Upjohn research clinic.

6. That in making such assignments the decision of the Director of Treatment is binding in all instances unless, for security, administrative or custodial reasons, such decision is rescinded by the Inside Deputy Warden, John Kinquant.

7. That no supervisor or head of any assignment within the prison has the power or authority to have an inmate placed on his assignment.

8. That requests for particular inmates from the various supervisors or directors of the assignment are frequently received by the Classification Committee or the Director of Treatment.

9. That such requests have been received from the Upjohn research clinic and some have been granted and others have been denied.

10. That the Director of Treatment has the power and authority to place individual inmates on particular assignments, including the Upjohn research clinic assignment, without the approval of the director, administrator or supervisor of the assignment involved.

11. That another institutional officer responsible directly to him as Warden is Inside Deputy Warden John Kinquant, and has the day to day responsibility of insuring proper security and

custody of inmates within the confines of the prison.

12. That the inside Deputy Warden, acting with the assistance of Assistant Deputy Warden H. W. Tucker, has the power and authority to disapprove the hours worked by inmates on any assignment, as well as the particular task an inmate performs on assignment itself, and that it is his duty to disapprove certain hours, tasks and/or assignments in proper situations.

13. That the inside Deputy Warden has, on occasion, disapproved certain hours for inmates assigned to the Upjohn research clinic and certain tasks to be performed by inmates on the Upjohn assignment.

14. That while on the Upjohn research clinic assignment, an inmate is subject to call at anytime by any institutional official.

15. That the administrator or director of the Upjohn research clinic assignment must comply with all such calls and release the particular inmate to the institutional official making such call.

16. That the Director of Treatment has the authority and power to reclassify an inmate, thereby removing him from a particular assignment and placing him on another.

17. That the Director of Treatment has the power and authority to make such reclassifications without the approval of the supervisor or director of the particular assignment from which the inmate is removed.

18. That the inside Deputy Warden may remove an inmate from a particular assignment without the knowledge or approval of the supervisor or director of such assignment, and even against the wishes of the supervisor or director.

19. That inmates have been so removed from the Upjohn research clinic assignment without the prior knowledge or approval of Upjohn personnel.

20. That the supervisor or director of an assignment, including the Upjohn research clinic, may request that an inmate be removed.

21. That all such requests must be directed to G. I. Hansen, Director of Treatment, where they may be granted, denied or returned for further clarification.

22. That the attached memorandum, marked exhibit "A", is a prison publication which describes the function and operations of the Classification Committee within the State Prison for Southern Michigan.

23. That the attached memorandum, marked exhibit "B", is a prison publication containing Prison Regulation 5-100 which is now in effect, and has been in effect at all times since the establishment of the Upjohn research clinic.

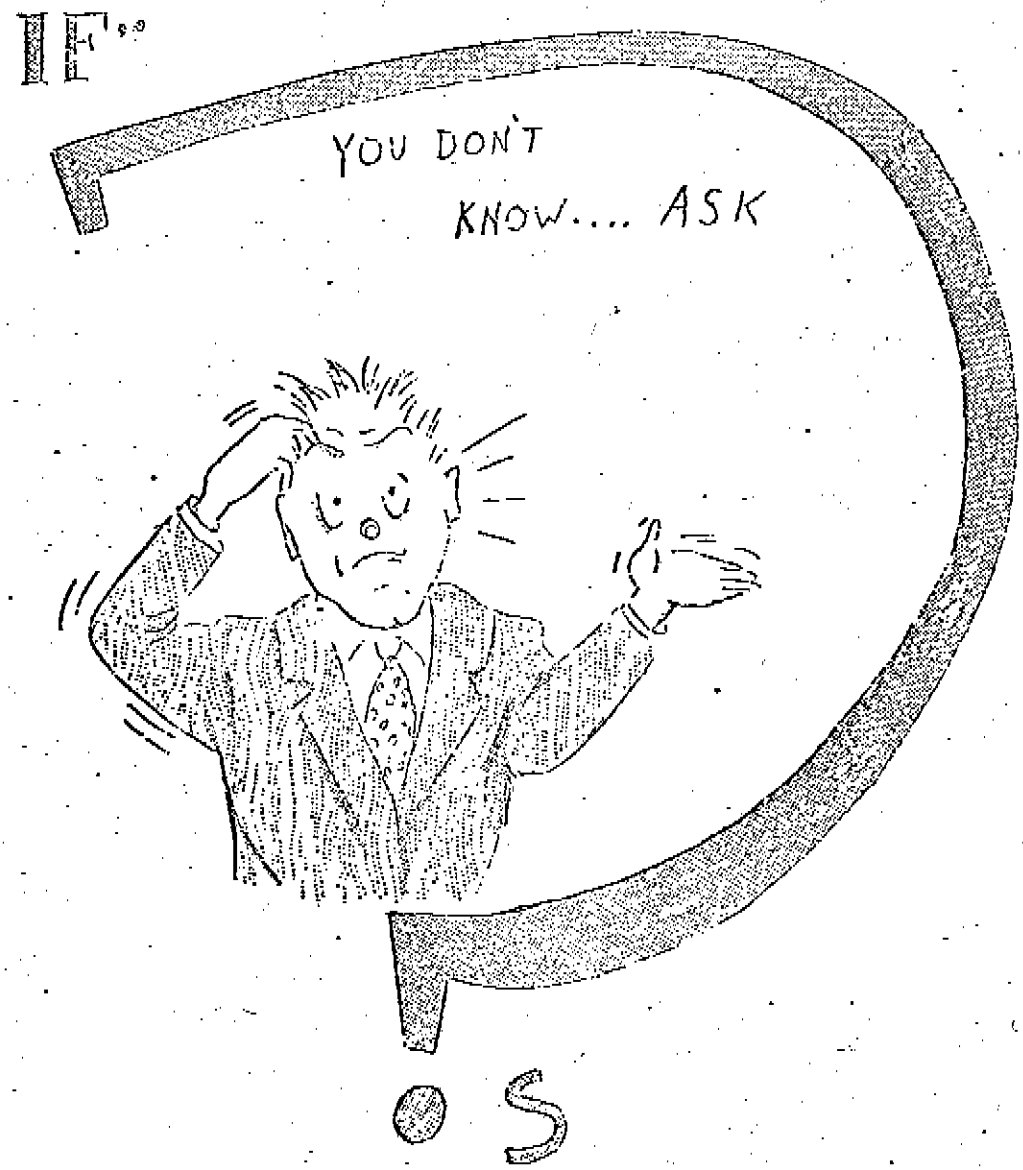
I made this affidavit on the basis of my own knowledge.

_____
George A. Kropp

Subscribed and sworn to before me this_____day of _____, 1967.

_____
Notary Public,_____County, Mich.
My Commission Expires:_____

INITIAL CLASSIFICATION INSIDE SPSM



The Classification Committee is responsible for the assignment of inmates to the various programs available in this institution.

I INITIAL CLASSIFICATION INSIDE SPSM

A. The Director of Classification shall be responsible under the direction of the Director of Treatment, for the coordination, preparation, and execution of the work of the classification committee.

B. All initial classification committees shall be composed of the Director of Classification, who will act as chairman, one member of the custodial staff (members to be provided by the Deputy-Warden,) and one member from the Maintenance or Industrial staffs (from a list to be provided by the Chief Engineer and Industries Manager). All decisions of placement by the classification committee are in the form of recommendation to the Director of Treatment who has the responsibility for final assignment.

1. All classification committee shall bear in mind that the discussion between themselves and the inmate shall be confined to subjects bearing directly on his institutionalprogram.

2. It shall be clearly understood that information learned from the inmate is confidential and will not be made subject of discussion where inmates or institutional personnel outside the classification staff may overhear.In other words, confidential information shall be so treated.

3. Special attention shall be paid to recidivistic inmates in order to insure that this type of offender does not receive preferential treatment because he is known in the institution.

4. Special effort shall be made to initiate and follow the recommendations made by the Reception Diagnostic Center, whenever this cannot be initiated immediately it is the responsibility of the associate counselor and the re-classification committee to arrange for such at a later date.

5. Close attention shall also be paid to the Medical requests, either of physical or mental illnesses, and in all cases of doubt, clearance shall be obtained from the Medical department or psychiatric clinic before establishinga program for the inmate.

6. The decision and findings of the Classification committee will be recorded and made part of the permanent inmates record--they will also when possible outline future programing plans. The recording is the responsibility of the classification director.

II RE-CLASSIFICATION

A. The re-classification committee entails the same membership as the initial classification with one addition, that being the associate counselor.

B. Generally speaking, an associate counselor may, at any time, refer a case fro re-classification. Counselors shall attend representing their written referrals as committee members. Certain designated meeting dates will be scheduled so each counselor can appear and represent the inmates on his case load.

C. The written re-classification referral from the associate counselor will be made available to the inmates treatment counselor for his comments as to the relationship of change of assignment to the treatment program.

D. The re-c. .sification committee shall ma. .ain the following objectives:

1. Provide unity of aim and effort of various personnel who must supervise the inmates daily life.

2. To determine whether the original pogram as recommended by the Reception Diagnostic Center, is being followed and or whether a change is indic ted.

3. To provide recognition or reward for inmates who canbe judged by some objective means to have gained in knowledge or in degree of self-control. This may be accomplished by assigning inmates to jobs of responsibility or to lesser-restrictive types of work on the basis of their accomplishment and by insuring that individual favoritism or outside influence receive negative consideration.

4. To make specific recommendations for the increase or decrease of custodial watchfullness.

5. To recommend changes in program suggested by medical or psychiatric findings.

6. To insure that information received about inmates subsequent to the original evaluation by the Reception Diagnostic Center and the initial classification committees be given proper emphasis.

7. To relate more closely the inmates institutional program with the counselor's treatment objectives.

III OPERATION

A. It is suggested that during classification meetings the custodial officer give the committee the benefit of his observation of the disciplinary adjustment of the inmate; that the industries or maintenance member discuss the occupational adjustment, and the Director and the counselor attempt to synthisize all elements of the problem. The largest measure of success of the committee operation will be obtained if each member uses his own professional knowledge and skill.

B. Since the degree of custodial supervision neccessary to insure the safe keeping of an inmate is basic to all questions of program making, it will receive first consideration of all committees.

1. The expression maxium supervision will be used only when it is implied that the inmate must live in the most secure housing facilities and will be eligible only for assignment and activities which provide constant supervision.

2. Close supervision will be used when it is believed the inmate may be assigned to ordinary housing facilities and is eligible for regular assignments and activities which provide constant supervision.

3. Medium and Minimum supervision implies that the inmate be assigned to the trusty division. The Reception Diagnostic Center may transfer new inmates directly to that unit. He may also and generally be Screened through the Outside Placement Committee which operates under the office of the Director of Outside Placement.

However, the Committee may also review the cases and recommend reduced supervision.

C. It is understood that custodial recommendations by the Classification Committee are advisary.

D. Recommendation of transfer of inmates to other institutions within the system are reviewed and final approval given by the Deputy Director in charge of institutions.

IV CLASSIFICATION (Administration)

The Classification director shall be held responsible for the orderly processing, by Classification and Re-classification methods, of all inmates. He shall have authority to make such arrangements, plans and schedules neccessary to properly carry out his responsibilities.

A. He shall be responsible for the supervision of the Classification Labor Pool, assisted by the Classification Secretary and the Labor Pool Clerk.

1. Assignment of all inmates will br processed through the Labor Pool Office.

2. Every inmate within the institution shall have a Labor Pool card. This card will record his present and past assignment status. It is the responsibility of the Classification Secretary and Labor Pool Clerk to maintain these records.

3. The Labor Pool Office will also provide information to any institutional staff employee as to the assignments of any inmate confined within the walls at this institution.

4. The Labor Pool Staff under the supervision of the Classification Director, will maintain and prepare statistical reports and other pertinent reports routinely or as requested.

5. Classification Secretary assembles meetings on inmates transferred from Reception Diagnostic Center, Camp Program, other institutions, etc. He shall maintain records of all transfers to, and from this institution.

Exhibit B

CLASSIFICATION AND ASSIGNMENT

CLASSIFICATION COMMITTEE: The Classification Committe shall be comprised of at least four members who shall be identified by name and title on each of the Committee's transactions.

1. The Director of Classification who shall serve as its Chairman.
2. A representative from Custody assigned by the inside Deputy Warden.
3. A representative from Industries assigned by the Industries Manager.
4. A counselor, preferably the one to whom the inmate is assigned if administratively convenient.

CLASSIFICATION: All inmates transferred from the Reception-Diagnostic Center or other institutions to the general population inside the walls shall appear before the Classification Committee for classification. In each case, this Committee shall take into consideration the inmate's treatment needs and capacity as well as the original recommendations of the Reception-Diagnostic Center so that, wherever institutional demands will permit, these treatment interests will be best served. The decisions of this Committee regarding programming within this institution are binding unless rescinded for custodial reasons by the inside Deputy Warden. Wherever possible, this Committee should comply with the recommendations made by the Psychiatric Clinic for outpatients directly under their care. Transfer recommendations to other institutions from inside will be made by the Classification Committee and signed by the Classification Director.

Initial classification shall refer to those inmates received on transfer and reclassification to inmates who are changing their programs within the institution itself. Referrals for initial classification are automatic and should be made by the Secretary of Classification on a regularly scheduled basis. The reclassification request must be referred through the inmate's counselor to the Committee.

LABOR POOL: The Director of Treatment will maintain a Labor Pool and an active assignment file. Assignment of inmates will be made on the basis of merit of the individual case without reference to color, race, or creed. Therefore, men will be placed in and withdrawn from the assignment Labor Pool in chronological sequence. A daily list of initial assignments and changes will be provided the following offices:

1. Main Hall Office
2. Sub-Hall Office
3. Record Office
4. Inmate Accounting Office
5. Deputy Warden's Ofice

and to such other departments as are designated by the Director of Treatment. Reuests by supervisors to remove inmates from their assignment will be made on the forms provided and are subject to the approval of the Director of Treatment.

The Deputy Warden, or his representative, may at any time remove from an assignment for disciplinary or custodial reasons by so notifying the Labor Pool.

TRUSTY DIVISION CLASSIFICATION: Inmates transferred to the Trusty Division will immediately be screened by the Trusty Division Classification Committee for Camp placement or other assignment. If the Trusty Division Classification Committee feels that any inmate is unsuited for Minimum and Medium security, they have the discretion to return these men to the main prison. Following initial classification of these men, reclassification must also be channelled through the Committee. The work supervisor wishing this reclassification may make referral by notifying the Trusty Division Labor Pool of his replacement needs.

Selection of candidates for Upper Peninsula trusty assignment shall be made by the Trusty Division Classification Director.

A daily list of assignment changes will be prepared by the Trusty Division Classification Director and provided for distribution to the Trusty Division Deputy Warden, #16 Block Hall Master, and such distribution as is used by the inside Labor Pool.

NOTE: The Trusty Division Deputy Warden or his representative may remove men from any assignment or return them to the main prison for disciplinary or custodial reasons. When this action is taken, the inmates affected should be referred for reclassification to a more suitable assignment.

George A. Kropp
Warden

Revised 12-31-63 from 7-1-57 (PR 5-200)

DISTRIBUTION B:

Filed: Feb. 12, 1970

UNITED STATES DISTRICT COURT

for the

EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS AND RALPH R. WARNER,

Plaintiffs,

vs.

PARKE DAVIS & CO., a Michigan Corporation and THE UPJOHN CO., a Delaware Corporation,

Defendants.

CASE NO. 31172

JUDGE FREEMAN

AFFIDAVIT IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

STATE OF MICHIGAN)
) ss.
COUNTY OF JACKSON)

Boyd Slager, being first duly sworn, deposes and says as follows:

1. This affidavit is made upon the basis of the personal knowledge of affiant of the following matters and affiant is competent to testify to the matters stated herein.

2. Affiant is one of the named Plaintiffs herein and has worked in the drug clinic building constructed by the Upjohn Co., at the State Prison of Southern Michigan. Further, he is familiar with the remaining named Plaintiffs and other inmates of said prison who worked in the said clinic as well as in the clinic constructed by the Parke Davis & Co.

3. The hours which he worked were in excess of the hours worked by anyone on a regular civilian job and, in fact, the detail upon which he was able to be released from his Cell and allowed to remain in the clinic proper read from 4:45am till 10:30pm. And that said detailed hours were effective seven (7) days per week, including holidays.

4. He and others worked directly under the supervision of civilian employees of the drug companies. And that he personally was under the direct supervision of the civilian employees whos[illegible] Dr. Lloyd LeZotte, Ralph F. Willy and William J. Hessler.

5. Representative examples of the work which was done in the clinic include the following:

A. Drawing blood samples and running them through a centrifuge to separate plasma from red cells.

B. Accurately typing the labels for vials.

C. Taking and analyzing urine samples.

D. Taking the temperature and blood pressure of those persons being used in drug tests.

E. Administering electrocardiograms and electroencephalograms.

F. Keeping records of important bodily functions.

G. Dispensing the drugs to be tested.

6. Affiant worked in the Upjohn Clinic from August 1964, until July 1967, during which time he performed the function of acting pharmacist, under the direct supervision of Dr. Lloyd LeZotte, Ralph F. Willy, William J. Hessler, and the Doctors who came to the clinic to supervise the various Protocols (studies) of which they were the Monitors.

7. That during the time span contained in the foregoing paragraph, and while acting in the capacity of pharmacist, it was his duties to dispense medications, maintain accurate records in conjunction with the dispensing of the medications, keep accurate records concerning the receiving and sending of medications between the Company in Kalamazoo and the Prison Clinic, and also to keep an inventory of the restricted drugs used for emergencys.

8. That during the time period set forth in paragraph number six (6), affiant, sometimes in the presence of the civilian employees of the drug company, but generally in their absence, did dispense the various drugs according to the requirements of the study being conducted. And that a partial listing of the medications (drugs) so dispensed is as follows:

a. Thorazine
b. Librium
c. Pheno-barbital
d. Equanil
e. Darvon 65
f. Dilantin
g. Cafergot
h. Dexedrine
i. Lincocin
j. Panalba
k. Measurin
l. Metopirone
m. Synalar (Topical)
n. Medrol Acetate (Topical)
o. Neo-Medrol Acetate (Topical)
p. Heparin
q. Tetracyclanes
r. Benedryl
s. Orinase
t. Pamine

That in addition to the above designated medications, affiant was also required to dispense drugs that were known only by the Upjohn Company's Code Name, e.g., U-11,100A, U-22020, etc.

9. Affiant was placed in the Upjohn Clinic for purposes of work by the following method:

In June of 1964, while working in the Main Hall Office of the State Prison of Southern Michigan as a Count Clerk on the

Night Shift. Affiant was offered or made aware of an opening in the Upjohn Medical Research Clinic, located inside the Walls of the Prison, by the then Inmate Clerk, John Outz. I then requested and was granted an interview with the Clinic Administrator, Mr. Ralph F. Willy. After that interview, a request was made to the Prison Classification Director Mr. Schmeige (now retired), and in the fore part of July 1964 I was taken before the Classification Committee and it was decided that the Prison Officials had no objection to the transfer and it was approved, provided that I stayed on to help break another Inmate in on the Main Hall Office job. This was done and in August of 1964, an Assignment Change Order was signed by Mr. G.L. Hansen, Director of Treatment, indicating that I was to go to work at the Upjohn Clinic. On August 19, 1964, I started work at the Clinic on a full time basis which continued untill July 1967.

10. That untill July 1967, I was under the impression that should I quit my job at the Clinic, without requesting that I be allowed to do from the Prison Officials, I would be placed in solitary. At that time, I was informed to the contrary and immediately quit.

Boyd Sleger

FEB 2 - 1970

Subscribed and sworn to before me this _____ day of _____, 1970.

Paul J. LaDow
Notary Public in and for the
County of Jackson, Michigan

My commission expires:

PAUL J. LaDOW
NOTARY PUBLIC, Jackson County, Mich.
My Commission Expires March 10, 1973

Filed: Feb. 16, 1970

UNITED STATES DISTRICT COURT
for the
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS and RALPH R. WARNER,
Plaintiffs,

vs.

PARKE DAVIS & CO., a Michigan corporation and THE UPJOHN CO., a Delaware corporation,
Defendants.

CASE NO. 31172

JUDGE FREEMAN

AFFIDAVIT IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARYJUDGMENT

STATE OF MICHIGAN
JACKSON ss.
COUNTY OF ~~GENESEE~~

Chester A. Sawicki , being first duly sworn, deposes and says as follows:

1. This affidavit is made upon the basis of the personal knowledge of affiant of the following matters and affiant iscompetent to testify to the matters stated herein.

2. Affiant is one of the named Plaintiffs herein and has worked in the drug clinic building constructed by The Upjohn Co. at the State Prison of Southern Michigan. Further, he is familiar with the remaining named Plaintiffs and other inmates of said prison who worked in the said clinic as well as in the clinic constructed by the Parke Davis & Co.

3. The hours which he worked were comparable to those which would be worked by anyone on a regular civilian job and, in fact, sometimes he worked seven (7) days a week. The time worked each dayvaried from a few hours up to sixteen (16) hours in a twenty-four (24) hour period.

4. He and others worked directly under the supervision of civilian employees of the drug companies.

LAW OFFICES
LEITSON, DEAN, DEAN, SEGAR, & HART, P.C.
1616 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
238-8631

5. Representative examples of the work which was done in the clinics include the following:

A. Drawing blood samples and running them through a centrifuge to separate plasma from red cells.

B. Accurately typing labels for vials.

C. Taking and analyzing urine samples.

D. Taking the temperature and blood pressure of those persons being used in drug tests.

E. Administering electrocardiograms and electroencephalograms.

F. Keeping records of important bodily functions.

6. He and others working at the clinics did so because they were ordered to do so by representatives of the Department of Corrections just as they would be ordered to work in any other prison industry and a refusal to work as directly would have resulted in penalties to them and such coercion and threat, was under the circumstances, clearly implied if not expressly stated.

7. Examples of the drugs tested in said clinics are:

A. Dilantin,
B. Chloromycetin
C. Ponstel
D. Benadryl
E. Albuspan
F. Ambodryl

Hector A. Lawalski

FEB 6 - 1970

Subscribed and sworn to before me this _____ day of _____

Paul J. LaDow
Notary Public
~~Genesee~~ County, Michigan
My commission expires:

PAUL J. LaDOW
NOTARY PUBLIC, Jackson County, Mich.
My Commission Expires March 10, 1973

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
804 DETROIT STREET
FLINT, MICH. 48503
235-5021

Filed: Feb. 16, 1970

UNITED STATES DISTRICT COURT
for the
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS and RALPH R. WARNER,
Plaintiffs,

vs.

PARKE DAVIS & CO., a Michigan corporation and THE UPJOHN CO., a Delaware corporation,
Defendants.

CASE NO. 31172

JUDGE FREEMAN

AFFIDAVIT IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARYJUDGMENT

STATE OF MICHIGAN
JACKSON ss.
COUNTY OF ~~GENESEE~~

Clemont M. DeDeaux, being first duly sworn, deposes and says as follows:

1. This affidavit is made upon the basis of the personal knowledge of affiant of the following matters and affiant iscompetent to testify to the matters stated herein.

2. Affiant is one of the named Plaintiffs herein and has worked in the drug clinic building constructed by The Upjohn Co. at the State Prison of Southern Michigan. Further, he is familiar with the remaining named Plaintiffs and other inmates of said prison who worked in the said clinic as well as in the clinic constructed by the Parke Davis & Co.

3. The hours which he worked were comparable to those which would be worked by anyone on a regular civilian job and, in fact, sometimes he worked seven (7) days a week. The time worked each dayvaried from a few hours up to sixteen (16) hours in a twenty-four (24) hour period.

4. He and others worked directly under the supervision of civilian employees of the drug companies.

LAW OFFICES
LEITSON, DEAN, DEAN, SEGAR, & HART, P.C.
1616 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
238-5631

5. Representative examples of the work which was done in the clinics include the following:

A. Drawing blood samples and running them through a centrifuge to separate plasma from red cells.

B. Accurately typing labels for vials.

C. Taking and analyzing urine samples.

D. Taking the temperature and blood pressure of those persons being used in drug tests.

E. Administering electrocardiograms and electroencephalograms.

F. Keeping records of important bodily functions.

6. He and others working at the clinics did so because they were ordered to do so by representatives of the Department of Corrections just as they would be ordered to work in any other prison industry and a refusal to work as directly would have resulted in penalties to them and such coercion and threat, was under the circumstances, clearly implied if not expressly stated.

7. Examples of the drugs tested in said clinics are:

A. Dilantin,
B. Chloromycetin
C. Ponstel
D. Benadryl
E. Albuspan
F. Ambodryl

Elmer F. McCrump

FEB 6 - 1970

Subscribed and sworn to before me this _____ day of _____

Paul J. LaDow
Notary Public
~~Genesee~~ County, Michigan
My commission expires: _____

PAUL J. LaDOW
NOTARY PUBLIC, Jackson County, Mich.
My Commission Expires March 10, 1973

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
804 DETROIT STREET
FLINT, MICH. 48503
235-5631

UNITED STATES OF AMERICA
THE DISTRICT COURT OF THE UNITED STATES
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,
Plaintiffs,

-vs-

PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN CO., a Delaware Corporation.
Defendants.

Case No. 31172

/

ANSWERS OF THE UPJOHN COMPANY
TO ADDITIONAL INTERROGATORIES

Now comes The Upjohn Company, a Delaware Corporation, and answering Plaintiffs' additional Interrogatories states as follows:

INTERROGATORY NO. 1:

List the name and address of every witness who you may rely on at the trial of this cause.

ANSWER TO NO. 1:

The witnesses The Upjohn Company may call at trial, if trial is held, have not been determined.

INTERROGATORY NO. 2:

State the subject matter of the testimony of each witness named in the preceding question.

ANSWER TO NO. 2:

The general subject matter of testimony which The

Upjohn Company would present would probably be the workings and procedures of the Jackson Prison Clinic operated by The Upjohn Company.

INTERROGATORY NO. 3:

List the name and address of each of your employees who have knowledge of the workings and procedures of your prison clinic.

ANSWER TO NO. 3:

Upjohn personnel most familiar with workings and procedures:

Herbert H. Schweem, M.D.
1703 Poole Drive
Jackson, Michigan 49201

A.B. Varley, M.D.
2146 Treehaven Drive
Kalamazoo, Michigan

Ralph F. Willy
5895 South Jackson Road
Jackson, Michigan 49203

Lloyd A. LeZotte, M.D.
Calle Roma C-11
Ext. Villa Caparra
Guaynabo, Puerto Rico 00936

William J. Hessler
1112 Woodview
Portage, Michigan 49081

H.V. Demissianos, M.D.
1230 Little Drive, Apt. 302A
Kalamazoo, Michigan 49007

INTERROGATORY NO. 4:

List the name and address of each of your employees who have knowledge of the original negotiations leading to the establishment of your clinic at the prison.

ANSWER TO NO. 4:

Harold L. Upjohn
7000 Portage Road
Kalamazoo, Michigan

Gerard Thomas
7000 Portage Road
Kalamazoo, Michigan

Ralph F. Willy
5895 South Jackson Road
Jackson, Michigan 49203

R.T. Parfet
7000 Portage Road
Kalamazoo, Michigan

Carl L. Schlagel
301 Henrietta Street
Kalamazoo, Michigan

Dale J. Chodos
7000 Portage Road
Kalamazoo, Michigan

R.S. Schreiber
7000 Porgage Road
Kalamazoo, Michigan

Lloyd A. LeZotte
Calle Roma C-11
Ext. Villa Caparra
Guaynabo, Puerto Rico 00936

INTERROGATORY NO. 5:

List the name and address of any person other than your employee who you have reason to believe has such knowledge.

ANSWER TO NO. 5:

Gus Harrison
Director of Corrections
Lansing, Michigan

Harold Oster
Jackson, Michigan

Dean William Hubbard
University of Michigan Medical School
Ann Arbor, Michigan

INTERROGATORY NO. 6:

State the name and address of the person in charge of personnel for your company.

ANSWER TO NO. 6:

H. E. Turbeville
7000 Portage Road
Kalamazoo, Michigan

INTERROGATORY NO. 7:

What is the pay scale for civilians employed by you outside the prison who are engaged in drug testing?

ANSWER TO NO. 7:

Defendant, The Upjohn Company, objects to Interrogatory No. 7.

The Upjohn Company

By _____

STATE OF MICHIGAN)
) SS.
COUNTY OF KALAMAZOO)

Gerard Thomas being first duly sworn, deposes and states as follows:

1. That he is the Vice President, Secretary and General Counsel of Defendant, The Upjohn Company, a Delaware corporation.

2. That he has read the foregoing answers to Interrogatories and that such answers are true and correct to the best of his knowledge and belief.

Gerard Thomas

Subscribed and sworn to before me this 9th day of February, 1970.

Edward D. Kallman

Notary Public, Kalamazoo County, Michigan
My Commission expires: November 7, 1971

UNITED STATES OF AMERICA
THE DISTRICT COURT OF THE UNITED STATES
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,

Case No. 31172

Plaintiffs,

-vs-

PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN CO., a Delaware Corporation,

Defendants.

/

AFFIDAVIT IN SUPPORT OF ANSWERS OF THE UPJOHN COMPANY TO INTERROGATORIES

STATE OF MICHIGAN)
) SS.
COUNTY OF KALAMAZOO)

Gerard Thomas, being first duly sworn, deposes and says as follows:

1. That he is the Vice President, Secretary and General Counsel of The Upjohn Company, a Delaware corporation.

2. That he has reviewed the answers of The Upjohn Company to Plaintiffs' Interrogatories, which answers are dated October 14, 1968.

3. That such answers were at the time of such filing

true to the best of his information, knowledge and belief.

Subscribed and sworn to before me
this 9th day of February, 1970.

Notary Public, Kalamazoo County, Michigan
My commission expires: November 7, 1971

Filed: 8-17-70

UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, et al,

Plaintiffs,

v.

PARKE DAVIS & CO., and
THE UPJOHN COMPANY,

Defendants.

Civil Action
No. 31172

DEFENDANTS MOTION FOR SUMMARY JUDGMENT ON COUNT I OF COMPLAINT

Now come Defendants, The Upjohn Company and Parke Davis and Company, by their respective attorneys, DYKEMA, WHEAT, SPENCER, GOODNOW & TRIGG, and MILLER, CANFIELD, PADDOCK & STONE, and respectfully move this Court, pursuant to Rule 56 of the Federal Rules of Civil Procedure, to enter a Summary Judgment in their favor on Count I of the Complaint on the ground that there is no genuine issue as to any material fact and Defendants are entitled to Judgment as a matter of law.

This Motion is based upon the pleadings and the Affidavits of Warden George A. Kropp and Mr. Ralph F. Willy in support of Defendants' Motion for Summary Judgment.

DYKEMA, WHEAT, SPENCER, GOODNOW & TRIGG

By Timothy K. Carroll
Timothy K. Carroll
For the Firm and Individually
2700 Penobscot Building
Detroit, Michigan 48226
963-6040
Attorneys for the Defendant,
The Upjohn Company

MILLER, CANFIELD, PADDOCK & STONE

By Wolfgang Hoppe
Wolfgang Hoppe
2500 Detroit Bank & Trust Building
Detroit, Michigan 48226
963-6420
Attorneys for the Defendant,
Parke Davis and Company

DATED: August 19, 1970

Filed: 8-17-70

UNITED STATES DISTAICT COURT
FOR THE EASTERN DISTAICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARLY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEYER,	:	
Plaintiffs,	:	
-vs-	:	Civil Action No. 31172
PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN COMPANY, a Delaware corporation,	:	
Defendants.	:	

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH RESPECT TO COUNT III

NOW COME Defendants, Parke, Davis & Company and The Upjohn Company, by their respective attorneys, Miller, Canfield, Paddock and Stone and Dykema, Wheat, Spencer, Goodnow & Trigg, and respectfully move for summary judgment with respect to Count III of Plaintiffs' Amended Complaint on the grounds that there is no genuine issue as to any material fact and that defendants are entitled to judgment as a matter of law.

This motion is based on the pleadings and other documents filed in this cause.

Miller, Canfield, Paddock and Stone

By /s/
Wolfgang Hoppe
Attorneys for Defendant Parke, Davis & Company
2500 Detroit Bank and Trust Building
Detroit, Michigan 48226
963-6420

Dykema, Wheat, Spencer, Goodnow & Trigg

By
Timothy K. Carroll
Attorneys for The Upjohn Company
2700 Penobscot Building
Detroit, Michigan 48226
963-6040

Dated: August 4, 1970

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILIS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARLY, HERBERT WILLIAMS, FRED HOLNAGEL, BEENY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,	:	
Plaintiffs,	:	
-vs-	:	Civil Action No. 31172
PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN COMPANY, a Delaware corporation,	:	
Defendants.	:	

DEFENDANTS' MOTION FOR SUMMARY JUDGMENT WITH RESPECT TO COUNT IV

NOW COME Defendants, Parke, Davis & Company and The Upjohn Company, by their respective attorneys, Miller, Canfield, Paddock and Stone and Dykema, Wheat, Spencer, Goodnow & Trigg, and respectfully move for summary judgment with respect to Count IV of Plaintiffs' Amended Complaint on the grounds that there is no genuine issue as to any material fact and that defendants are entitled to judgment as a matter of law.

This motion is based on the pleadings and other documents filed in this cause.

Miller, Canfield, Paddock and Stone

By _____
Wolfgang Hoppe
Attorneys for Defendant Parke, Davis & Company
2500 Detroit Bank and Trust Building
Detroit, Michigan 48226
963-6420

Dykema, Wheat, Spencer, Goodnow & Trigg

By _____
Timothy K. Carroll
Attorneys for The Upjohn Company
2700 Penobscot Building
Detroit, Michigan 48226
963-6040

Dated: August 14, 1970

Filed: 8-17-70

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARLY, HERBERT WILLIAMS, FRED HOLNAGEL, DENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A SAWICKI, PHILLIP McGHEE and VERNON D. MEVIS,	:	
Plaintiffs,	:	
-vs-	:	Civil Action No. 31172
PARKE, DAVIS & COMPANY, a Michigan corporation, and THE UPJOHN COMPANY, a Delaware corporation,	:	
Defendants.	:	

AFFIDAVIT OF WARDEN
GEORGE A. KROPP

STATE OF MICHIGAN)
: ss.
COUNTY OF JACKSON)

George A. Kropp, after first being duly sworn, deposes and says as follows:

1. That he is Warden of the State Prison for Southern Michigan (Jackson Prison), 4000 Cooper Street, Jackson, Michigan, and that he has been Warden since February 1, 1963.

2. That all statements made in this affidavit apply to the years 1964-1969 unless otherwise indicated.

3. That, as Warden, he is the chief institutional officer within the prison and is head of all internal operations.

4. That, as the chief institutional officer within the prison, he has various other institutional officers responsible directly to him.

5. That one such officer is employed in the position of Director of Treatment, and has the day to day responsibility of proper assignment and direction of all inmates in their respective tasks, study and recreation.

6. That the Director of Treatment, acting with the assistance of a Classification Committee, makes each and every assignment of inmates to their respective tasks within the prison, such as assignments to the prison laundry, the prison hospital and the Parke, Davis and Upjohn research clinics.

7. That in making such assignments the decision of the Director of Treatment is binding in all instances unless, for security, administrative or custodial reasons, such decision is rescinded by the inside Deputy Warden.

8. That no supervisor or head of any assignment within the prison has the power or authority to have an inmate placed on his assignment.

9. That requests for particular inmates from the various supervisors or directors of the assignment are frequently received by the Classification Committee or the Director of Treatment.

10. That such requests have been received from the Parke, Davis and Upjohn research clinics and some have been granted and others have been denied.

11. That the Director of Treatment has the power and authority to place individual inmates on particular assignments, including the Parke, Davis and Upjohn research clinic assignments, without the approval of the director, administrator or supervisor of the assignment involved.

12. That the Inside Deputy Warden has the day to day responsibility of assuring proper security and custody of inmates within the confines of the prison.

13. That the Inside Deputy Warden, acting with the assistance of the Assistant Deputy Warden has the power and authority to disapprove the hours worked by inmates on any assignment, as well as the particular task an inmate performs on assignment itself, and that it is his duty to disapprove certain hours, tasks and/or assignments in proper situations.

14. That the Inside Deputy Warden has, on occasion, disapproved certain hours for inmates assigned to the Parke, Davis and Upjohn research clinics and certain tasks to be performed by inmates on these assignments.

15. That while on the Parke, Davis or Upjohn research clinic assignment, an inmate is subject to call at anytime by any institutional official.

16. That the administrators or directors of the Parke, Davis and Upjohn research clinic assignments must comply with all such calls and release the particular inmate to the institutional official making such call.

17. That the Director of Treatment has the authority and power to reclassify an inmate, thereby removing him from a particular assignment and placing him on another.

18. That the Director of Treatment has the power and authority to make such reclassifications without the approval of the supervisor or director of the particular assignment from which the inmate is removed.

19. That the inside Deputy Warden may remove an inmate from a particular assignment without the knowledge or approval of the supervisor or director of such assignment, and even against the wishes of the supervisor or director.

20. That inmates have been so removed from the Parke, Davis and Upjohn research clinic assignments without the prior knowledge or approval of Parke, Davis or Upjohn personnel.

21. That the supervisors or directors of an assignment, including the Parke, Davis and Upjohn research clinics, may request that an inmate be removed.

22. That all such requests must be directed to the Director of Treatment, where they may be granted, denied or returned for further clarification.

23. That there are in effect schedules of payment to inmates adopted by the Corrections Commission pursuant to §11 of the former Prison Industries Act.

24. The schedules so adopted include daily rates applicable to assignment to the Parke, Davis and Upjohn research clinics.

25. That the monies credited to the accounts of the plaintiffs by the Corrections Commission while plaintiffs were on assignment to the Parke, Davis and Upjohn research clinics were based on the schedules in effect at the particular time.

26. That the daily rates for assignment to the Parke-Davis and Upjohn research clinics are somewhat higher than the daily rates for comparable assignments.

27. That the working conditions at the Parke, Davis and Upjohn research clinics are superior as compared with other prison assignments because the research facilities are relatively new and inmates on clinic assignment have special recreation facilities, at times better food, more freedom and more contact with non-prison personnel than have inmates on most other prison assignments.

28. That assignments to the Parke, Davis and Upjohn research clinics are regarded by most inmates as being highly desirable.

29. That many of the specific classifications in the Parke-Davis and Upjohn clinic assignments were considered to be valuable educational and rehabilitative opportunities by the Corrections Commission.

30. That in many instances inmates voluntarily request a particular assignment and frequently requests are made by inmates for assignment to the Parke, Davis or Upjohn research clinics.

31. That the attached memorandum, marked exhibit "A", is a prison publication which describes the function and operations of the Classification Committee within the State Prison for Southern Michigan.

32. That the attached memorandum, marked exhibit "B", is a prison publication containing Prison Regulation 5-100 which is now in effect, and has been in effect at all times since the establishment of the Parke, Davis and Upjohn research clinics.

The facts stated in this affidavit are true and accurate to my best knowledge.

George A. Kropp, Warden
State Prison of Southern Michigan

Subscribed and sworn to before me this 22nd day of December, 1959.

Notary Public, Jackson County, Michigan

My Commission Expires:

MERCENE GAUT
NOTARY PUBLIC, Jackson County, Mich.
My Commission Expires May 27, 1973

INITIAL CLASSIFICATION INSIDE SPSM

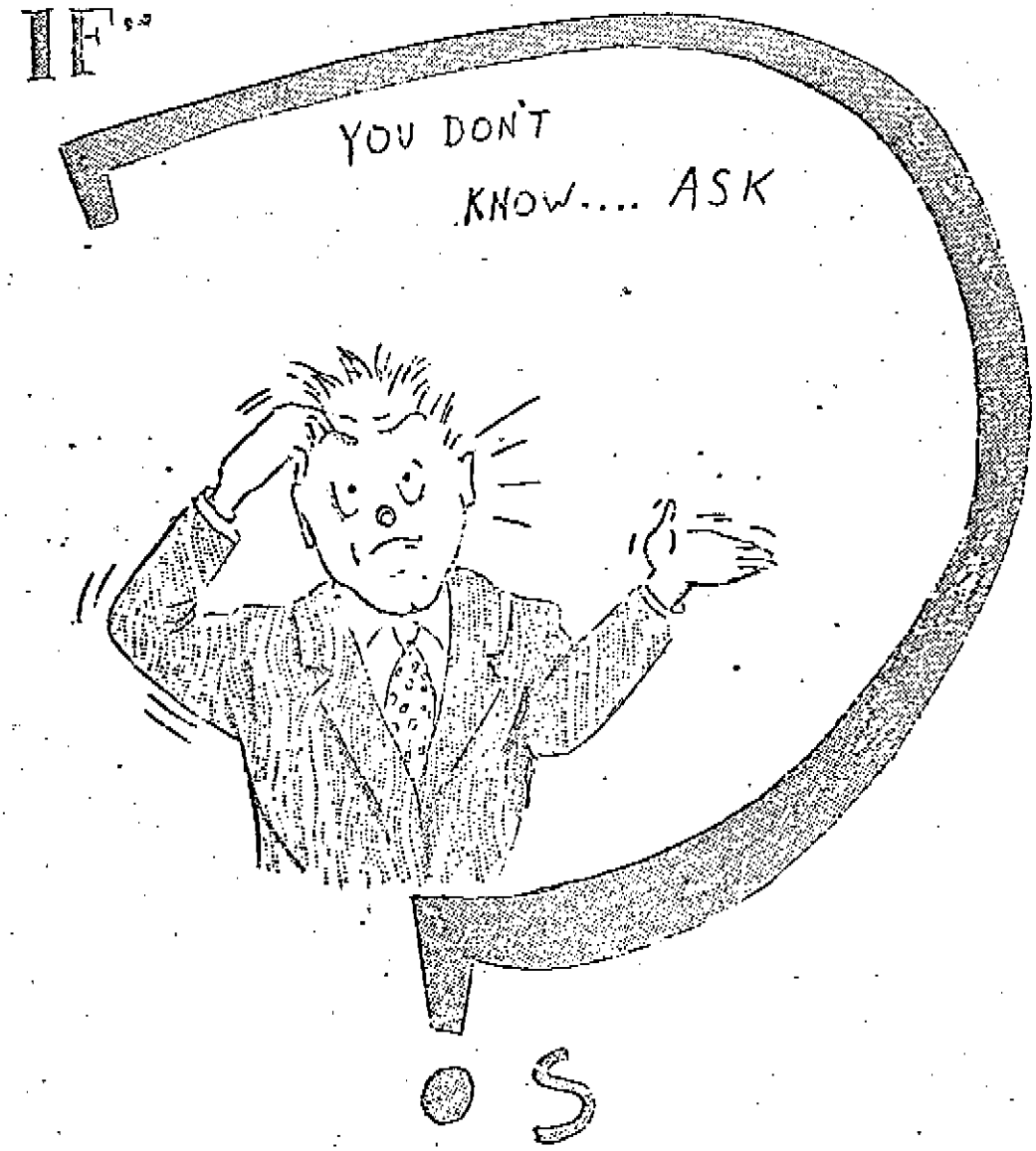


EXHIBIT A

The Classification Committee is responsible for the assignment of inmates to the various programs available in this institution.

I INITIAL CLASSIFICATION INSIDE SPSM

A. The Director of Classification shall be responsible under the direction of the Director of Treatment, for the coordination, preparation, and execution of the work of the classification committee.

B. All initial classification committees shall be composed of the Director of Classification, who will act as chairman, one member of the custodial staff (members to be provided by the Deputy-Warden,) and one member from the Maintenance or Industrial staffs (from a list to be provided by the Chief Engineer and Industries Manager). All decisions of placement by the classification committee are in the form of recommendation to the Director of Treatment who has the responsibility for final assignment.

1. All classification committee shall bear in mind that the discussion between themselves and the inmate shall be confined to subjects bearing directly on his institutional program.

2. It shall be clearly understood that information learned from the inmate is confidential and will not be made subject of discussion where inmates or institutional personnel outside the classification staff may overhear. In other words, confidential information shall be so treated.

3. Special attention shall be paid to recidivistic inmates in order to insure that this type of offender does not receive preferential treatment because he is known in the institution.

4. Special effort shall be made to [illegible] recommendations made by the Reception Diagnostic Center, whenever this cannot be initiated immediately it is the responsibility of the associate counselor and the re-classification committee to arrange for such at a later date.

5. Close attention shall also be paid to the Medical requests, either of physical or mental illnesses, and in all cases of doubt, clearance shall be obtained from the Medical department or psychiatric clinic before establishing a program for the inmate.

6. The decision and findings of the Classification committee will be recorded and made part of the permanent inmates record--they will also when possible outline future programing plans. The recording is the responsibility of the classification director.

II RE-CLASSIFICATION

A. The re-classification committee entails the same membership as the initial classification with one addition, that being the associate counselor.

B. Generally speaking, an associate counselor may, at any time, refer a case fro re-classification. Counselors shall attend representing their written referrals as committee members. Certain designated meeting dates will be scheduled so each counselor can appear and represent the inmates on his case load.

C. The written re-classification referral from the associate counselor will be made available to the inmates treatment counselor for his comments as to the relationship of change of assignment to the treatment program.

D. The re- ssification committee shall m tain the following objectives:

1. Provide unity of aim and effort of various personnel who must supervise the inmates daily life.

2. To determine whether the original pogram as recommended by the Reception Diagnostic Center, is being followed and or whether a change is indic ted.

3. To provide recognition or reward for inmates who canbe judged by some objective means to have gained in knowledge or in degree of self-control. This may be accomplished by assigning inmates to jobs of responsibility or to lesser-restrictive types of work on the basis of their accomplishment and by insuring that individual favoritism or outside influence receive negative consideration.

4. To make specific recommendations for the increase or decrease of custodial watchfullness.

5. To recommend changes in program suggested by medical or psychiatric findings.

6. To insure that information received about inmates subsequent to the original evaluation by the Reception Diagnostic Center and the initial classification committees be given proper emphasis.

7. To relate more closely the inmates institutional program with the counselor's treatment objectives.

III OPERATION

A. It is suggested that during classification meetings the custodial officer give the committee the benefit of his observation of the disciplinary adjustment of the inmate; that the industries or maintenance member discuss the occupational adjustment, and the Director and the counselor attempt to synthisize all elements of the problem. The largest measure of success of the committee operation will be obtained if each member uses his own professional knowledge and skill.

B. Since the degree of custodial supervision neccessary to insure the safe keeping of an inmate is basic to all questions of program making, it will receive first consideration of all committees.

1. The expression maxium supervision will be used only when it is implied that the inmate must live in the most secure housing facilities and will be eligible only for assignment and activities which provide constant supervision.

2. Close supervision will be used when it is believed the inmate may be assigned to ordinary housing facilities and is eligible for regular assignments and activities which provide constant supervision.

3. Medium and Minimum supervision implies that the inmate be assigned to the trusty division. The neception Diagnostic Center may transfer new inmates directly to that unit. He may also and generally be Screened through the Outside Placement Committee which operates under the office of the Director of Outside Placement.

However, the Committee may also review the cases and recommend reduced supervision.

C. It is understood that custodial recommendations by the Classification Committee are advisary.

D. Recommendation of transfer of inmates to other institutions within the system are reviewed and final approval given by the Deputy Director in charge of institutions.

IV CLASSIFICATION (Administration)

The Classification director shall be held responsible for the orderly processing, by Classification and Re-classification methods, of all inmates. He shall have authority to make such arrangements, plans and schedules neccessary to properly carry out his responsibilities.

A. He shall be responsible for the supervision of the Classification Labor Pool, assisted by the Classification Secretary and the Labor Pool Clerk.

1. Assignment of all inmates will br processed through the Labor Pool Office.

2. Every inmate within the institution shall have a Labor Pool card. This card will record his present and past assignment status. It is the responsibility of the Classification Secretary and Labor Pool Clerk to maintain these records.

3. The Labor Pool Office will also provide information to any institutional staff employee as to the assignments of any inmate confined within the walls at this institution.

4. The Labor Pool Staff under the supervision of the Classification Director, will maintain and prepare statistical reports and other pertinent reports routinely or as requested.

5. Classification Secretary assembles meetings on inmates transferred from Reception Diagnostic Center, Camp Program, other institutions, etc. He shall maintain records of all transfers to, and from this institution.

(Auth: DCR Regulation 619, dated July 20, 1969)

PR 5-100

September 29, 1969

CLASSIFICATION

Classification and Assignment

PR 5-100, dated March 1, 1967 and PR 5-104 are hereby rescinded and the following shall be in effect; (PR 5-104 is dated 5-8-67)

1. Classification: The purpose of classification is to assist in the implementation of an efficient correctional program and includes the identification and sharing of all relevant information concerning the offender. The objective of the classification process is the development and administration of an integrated and realistic program of treatment for the individual, with procedures for changing the program when indicated. Classification should be the process through which all the resources of the correctional system can be aplied effectively to the individual case. The Classification Committee will be responsible for incorporating the above-mentioned concepts in it functioning. The Classification Committee will be limited to no more then 4 members with the Classification Director or equivalent serving as Committee Chairman. Treatment, custody and the work assignments should be represented in this Committee.

2. The Classification Committee will assign inmates to various programs based upon the individual's social history and other background information; RDC recommendation; anticipated length of stay; available programs; individual motivations; and institutional needs. Security factors along with counselor and other staff recommendations must be given due consideration by the Classification Committee.

3. Reclassification: All inmates of this institution will be scheduled for classification review once a year by the Classification Committee. The Classification Committee will discuss with the inmate, specific ways in which he can continue to improve himself, point out areas of weakness and make every effort to encourage the inmate. In all instances, reports will be made for all files. Note: If a parole eligibility report is due the same month as the review, the PER will, in effect, become the formal review report and will be so noted.

4. The treatment staff may recommend reclassification prior to the above review dates and should do so if it will contribute to institutional adjustment and enhance the offender's chances of success upon his eventual release. The classification of an offender should be viewed as a treatment plan which is subject to change as progress or lack of progress is noted. Reclassification recommendations may include the resources of other institutions and programs can be anticipated by the Committee in the form of an inter-institutional transfer request. During the review process, the offender's progress, strengths and weaknesses should be discussed. This information combined with the Committee findings and recommendations should be recorded on a Classification Committee Half-sheet in clear concise professional language accurately describing the case.

EXHIBIT B

5. Labor Pool: The Director of Classification will maintain a Labor Pool and an active reassignment file. Assignment of inmates will be made on the basis of merit of the individual case without reference to color, race or creed. Therefore, men will be placed in and withdrawn from the assignment Labor Pool in chronological order.

6. A daily list of initial assignments and changes will be provided the following: Main Hall Office, Sub-Hall Office, Record Office, Inmate Accounting, Deputy Warden's Office, Quartermaster, Food Service Department, Laundry and to such other departments as are designated by the Director of Treatment.

7. Requests by supervisors to remove inmates from their assignments will be made on the forms provided and are subject to the approval of the Director of Treatment.

8. Any lay-in from a work assignment that exceeds 3 days will be reported by the supervisor to the Labor Pool on a regular CO form specifying CO lay-in and giving the reason why this move is necessary.

George A. Kropp
Warden.

GAK-las

DISTRIBUTION B:
Deputy Director, NCP (1)
Warden (1)
Deputy Warden - Main Prison (32)
Deputy Warden - Treaty Div. (19)
Treatment Director (32)
Business Manager (11)
Chief Engineer (5)
Farm Supt. (5)
Medical Director (5)
Psychiatric Clinic (1)
Reception Center Supt. (2)
Personnel (1)
Telephone Office (1)
Transfer Lt. (1)
Information Desk (1)
Chaplains (3)
COS (6)
Industries Mgr. (10)
Research Clinics (2)

UNITED STATES DISTRICT COURT
FOR THE
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, et al,

Plaintiffs,

v.

PARKE DAVIS & CO., and
THE UPJOHN COMPANY,

Defendants.

Civil Action
No. 31172

AFFIDAVIT OF RALPH F. WILLY

STATE OF MICHIGAN)
) SS.
COUNTY OF)

Ralph F. Willy, after first being duly sworn, deposes and says as follows:

1. That he was employed during all periods relevant to the above-captioned proceeding by The Upjohn Company as Administrator of the Upjohn research clinic, located within the confines of the State Prison for Southern Michigan, 4000 Cooper Street, Jackson, Michigan, commencing approximately February 1, 1964.

2. That his duties as Administrator of said clinic included general supervision of the technical and administrative aspects of research conducted therein.

3. That he is familiar with the workings and procedures of the Parke Davis and Company clinic located at Jackson Prison, and that said workings and procedures are essentially identical to the workings and procedures of The Upjohn Clinic.

4. That neither he nor any other Upjohn representative connected in any manner whatsoever with the Research Clinic in

Jackson Prison had power or authority to assign any inmate to work in the clinic.

5. That inmates of the prison had, from time to time, expressed an interest to him in being assigned to work in the clinic.

6. That in some of these cases in which a particular inmate had expressed an interest in being assigned to the clinic, he had requested that the particular inmate be so assigned.

7. That all such requests were directed to the Director of Treatment or the Classification Committee of the prison, which affiant believes, were and are the only parties within the prison having authority to make such assignments.

8. That some of the aforementioned requests were denied while others have been granted.

9. That there were instances in which inmates were assigned by the Director of Treatment or the Classification Committee to work in the research clinic without the prior knowledge or approval of any Upjohn personnel.

10. That in some such instances in which inmates were so assigned they were designated by the Classification Committee to perform specific tasks and to fill specific positions.

11. That in some instances in which the inmates were so designated to perform specific tasks and to fill specific positions, the research clinic had no need for such additional inmate personnel.

12. That on one specific occasion he requested that a certain inmate's assignment to the clinic be rescinded and that such request was denied.

13. That once an inmate was assigned to perform services at the research clinic, the hours during which such inmate was present at the clinic were first approved by the inside Deputy Warden.

14. That once an inmate was assigned to the research clinic, he could be given time off in accordance with prison rules

by the prison authority for purposes of attending meetings, studying, recreation or other reasons without approval of Upjohn personnel.

15. That once an inmate was assigned to the research clinic, all specific instructions by Upjohn personnel were subject to approval by the prison authority for administrative and security reasons.

16. That some specific instructions and job assignments by Upjohn personnel were vetoed by the prison authority.

17. That inmates who were assigned to the research clinic could be reassigned by the Director of Treatment or the Classification Committee to other assignments within the prison, such as the laundry or the bakery.

18. That such reassignments could occur without the approval of Upjohn personnel.

19. That inmates were reassigned to Double "0" or "00" (back to cell) by the prison authority without knowledge or approval of Upjohn personnel.

20. That Upjohn personnel requested the Classification Committee or Director of Treatment to reassign inmates to other assignments on various occasions.

21. That such requests were in some instances denied so that an inmate has continued on the research clinic assignment against the express wishes of Upjohn personnel.

22. That the per diem wage rates for all inmate assignments were set by the Department of Corrections, and that such per diem wages were paid by the State of Michigan.

23. That, as Administrator of the research clinic, he could suggest changes in the per diem rates for those inmates assigned to the research clinic.

24. That any such request would be directed to the Warden, who would accept or reject such suggestion.

25. That Upjohn maintained records reflecting the

assignment days of inmates to the research clinic.

26. That such records were kept upon standard prison forms, similar to those utilized for inmates on other prison assignments.

27. That The Upjohn Company reimbursed the State of Michigan for the per diem wages of inmates who were assigned to the research clinic, pursuant to agreement with the Department of Corrections.

28. That the prison assigned a guard to provide security at the Upjohn research clinic.

29. That such guards were paid by the State of Michigan.

30. That The Upjohn Company reimbursed the State of Michigan for the wages paid any such guards for duty at the research clinic, pursuant to agreement between The Upjohn Company and the Department of Corrections.

I make this affidavit on the basis of my own knowledge.

Ralph F. Willy

Ralph F. Willy

Subscribed and sworn to before me this ___ day of FEB 9- 1970, 1970.

Paul J. LaDow

Notary Public, County, Michigan

My commission expires:

PAUL J. LaDOW
NOTARY PUBLIC, Jackson County, Mich.
My Commission Expires March 10, 1973

Filed: October 1, 1970

LIST OF EXHIBITS AND DISCRIPTION
OF EACH DOCUMENT

Exhibit Letter	
A	Entitled "INMATE DETAIL": Request for Approval of Routine Monthly Work Detail Effective Date December 1, 1966 thru January 31, 1967. 4:45 A.M. to 10:00 P.M. Seven (7) days per week, HOLIDAYS INCLUDED UPJOHN CLINIC. This REQUEST shall apply to the following inmate GLANCY #50593, 20-1-12 UPJOHN HEAD BLOOD ROOM NURSE (To attend Week-end and Holiday movies as the work load permits. ORIGINATOR OF REQUEST: Mr. R. F. Willy, Administrator Upjohn Clinic and Approved by H. W. Tucker, Deputy Warden.
A-1	Same, except #104742 Marlin, 45-4-12, Upjohn Head Clerk & E.E.G. Technician (On 24 Hour Call by Clinic Officer) 6:30 a.m. to 10:30 p.m.
A-2	Same except effective date Sept. 1 thru Nov. 30, 1966, Upjohn Chief Clerk #104742 Marlin, 45-4-12.
A-3	Same, except Effective date July 1 thru Aug. 31, 1966.
A-4	Entitled "INMATE DETAIL": Request for Approval of Special Work and Movement Detail, Effective date December 5 thru December 20, 1966, 4:45 a.m. to 6:30 a.m. Daily, UPJOHN CLINIC (Upjohn E.E.G. Technician has special work (Pharacology) for fifteen days. ORIGINATOR OF REQUEST, Mr. R. F. Willy, Approved H.W. Tucker, Deputy Warden.
A-5	INTRADEPARTMENTAL CORRESPONDENCE Dated 8-17-65 From desk of W. J. Hessler, TO: Classification, Subject: 104742 Marlin. Pertinent portion reads as follows: "The above named inmate has applied to this office for employment in the UPJOHN CLINIC. I have interviewed this man and feel he would make a good man for this assignment. Therefore, if it is agreeable in your opinion, and that of the classification committee, I respectfully request that he be re-classified for the 1011-U Assignment." Signed: W.J. Hessler, Asst. Administrator, UPJOHN CLINIC.
A-6	ASSIGNMENT CHANGE ORDER #104742 Marlin. "Mr. Willy: The above inmates have been placed on the 1011-U Assignment dated 8-27-65, signed G.L. Hansen, Director of Treatment.
A-7	THE UPJOHN CLINIC PERSONNEL ROSTER: Name-MARLIN #104742 JOB: Clerk (Chief) DATE OF ASSIGNMENT: 8-26-66; STARTING PAY: $0.30 MAXIMUM PAY $0.75 ($1.25).
B	Letter to Deputy Kircher, dated January 18, 1965 and signed by Mr. R. F. Willy, Administrator Upjohn Clinic. Paragraph 7 first page discussed RESPONSIBILITIES GIVEN INMATE EMPLOYEES. AND ON PAGE 2, paragraph 2, the following is taken verbatim: "In one respect, the relationship of the INMATE EMPLOYEES to the UPJOHN CLINIC is unique-the Clinic demands, of necessity, standards of performance which are similar to those maintained at the UPJOHN COMPANY. Our Work at the clinic would have little value if this cannot be done." Signed by: R. F. Willy, Upjohn Clinic Administrator.

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
1618 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
238-8631

Exhibit Letter

C ORIGINAL INVOICE NO. 8485, STATE PRISON OF SOUTHERN MICHIGAN, INSTITUTIONAL. SOLD TO: UPJOHN CLINIC ADDRESS: ATTEN: MR. WILLY, JACKSON, MICHIGAN 10/27/66. "EXPENSES DUE STATE OF MICHIGAN AS PER THE ATTACHED STATEMENT -$4,253.78. Please make check payable to State of Michigan, 4000 Cooper Street, Jackson, Michigan. FORWARDED TO KALAMAZOO, FOR PAYMENT ON 11/7/66 By W.J. Hessler, Asst. Administrator, Upjohn Clinic. Page 2 UPJOHN CLINIC BILLING SEPTEMBER 1966, INMATE WAGES $557.75 Forwarded to Kalamazoo for Payment by W.J. Hessler, Asst. Administrator Upjohn Clinic. Page 3, INMATE PAY 1011-Upjohn Assignment MONTHLY SUMMARY-GRAND TOTAL $557.75. Item 2 of listing, #50593 GLANCY Received $31.50 @ $1.05 per day for 30 days. Item 26 of listing #104742 Marlin Received $37.50 @ $1.25 per day for 30 days. CERTIFIED BY R.F.WILLY. UPJOHN CLINIC ADMINISTRATOR.

D 5 pages of Upjohn Company Kalamazoo, personal telephone directory listing all SUBSIDIARIES: LISTING 30 FOREIGN OFFICES (In Foreign Countries) and 29 PHARMACEUTICAL SALES OFFICES AND DISTRIBUTION CENTERS with office addresses in States outside the territorial boundries of the State of Michigan.

E LAKE CENTRAL AIRLINES, INC., Indianapolis, Indiana AIR FREIGHT DOMESTIC AIRBILL NO. 20-YIP-161-993 - SHIPPER: UPJOHN RESEARCH CLINIC, 4000 Cooper Street, Jackson, Michigan-TO: CONSIGNEE: Dr. James O'Donnel, Gastric Laboratory, Cincinnati General Hospital, Cincinnati, Ohio. DESCRIPTION OF SHIPMENT: 2 boxes Blood Specimens. PAID (FREIGHT BILL) 1/25/66 with CHECK NO. 226. TOTAL CHARGES $7.90.

F LETTER: Date November 2, 1965, TO: Warden George A. Kropp, State Prison of Southern Michigan, 4000 Cooper Street Jackson, Michigan. See last paragraph: "This letter is intended to serve formal notice of our interest in securing an outpatient Clinic in the Trusty Division, and to ask that the Corrections Department be so informed that a decision can be made." Signed by: Ralph F. Willy, Clinic Administrator.

F-1 FLOOR PLANS FOR REMODELING, Tearing out and rebuilding of cells in 10-Block and entitled "CELL BLOCK CLINIC, S.P.S.M. JACKSON, MICHIGAN, Dated Nov. 19, 1965 DWG No. CSK-99 by SKIDMORE, OWINGS & MERRILL ARCHITECTS-ENGINEERS.

F-2 LETTER: STATE OF MICHIGAN, DEPARTMENT OF CORRECTIONS: Dated January 14, 1966. MEMO TO: John Conlin, Director, Parke-Davis Clinic and Ralph Willy, Director, Upjohn Clinic. CONTENTS: "It has been agreed that your companies Will be permitted to construct in 10-Block a Clinic for the purpose of conducting some types of drug and medical research." From the Desk of George A. Kropp, Warden.

LAW OFFICES
LEITSON, DEAN, DEAN, SEGAR, & HART, P.C.
5616 GENESEE TOWERS
ONE S. FIRST STREET
FLINT, MICH. 48502
235-5631

Exhibit
Letter

F-3 INVOICE: HUNGERFORD CONSTRUCTION COMPANY, General Contractors, 1425 Woodward Avenue, P.O. Box 507, Jackson, Michigan. INVOICE No. 6798, Job No. 859. Your No. 341427 Dated October 6, 1966, TO: Dr. Lloyd A. LeZotte, Director Upjohn Research Clinic, State Prison of Southern Michigan, Jackson, Michigan: "For: 1/2 of Painting Contract REMOVE FIVE CELLS AND CONVERT INTO CLINIC ---$350.00

F-4 THE UPJOHN COMPANY, JACKSON CLINIC, January 20, 1966: PROPOSE FURNITURE AND EQUIPMENT NEEDS FOR THE TRUSTY DIVISION CLINIC. Signed: Ralph F. Willy, Administrator Upjohn Clinic.

G Job Classification with suggested pay scale, Dated June 11, 1965wherein reference is made to "HIRE INMATES". Signed by: Ralph F. Willy, Upjohn Clinic and John Conlin, Parke-Davis Clinic. Letter attached Dated July 15 on Department of Corrections Letterhead Addressed to Warden George A. Kropp and signed by Gus Harrison, wherein Mr. Harrison gives his approval to new pay scale suggested by the two Clinic Administrators.

G-1 LETTER: DEPARTMENT OF CORRECTIONS Letterhead: dated March 26, 1964, Addressed to Mr. Gus Harrison, Director; ATTENTION: Mr. Robert Boase; Re: INMATE PAY CONFERENCE. Signed George A. Kropp, Warden. cc: Mr. Conlin, Mr. Willy, A.R. Swanson, J. White.

G-2 MEMORANDUM: Dated Dec. 11, 1965: TO: Mr. Robert Boase, Finance Officer, Department of Corrections, RE: OPERATION OF UPJOHN & PARKE-DAVIS LABORATORIES AT SPSM. See Item III (First page) INMATE WAGES...Regular Inmate Payroll: Bill drug firms, collect and deposit with State Treasurer. From the desk of F.M.McLaury, Director of Accounting Division.

G-3 MEMORANDUM: Follow-up to the meeting held in the Parke-Davis Clinic on March 12, 1964 and is intended to cover matters which were understood at the time of that meeting. The particular participants in the March 12,meeting were: Dale K. Boyles, John H. Conlin, Dr. A.Z. Lane for PARKE-DAVIS COMPANY, Dr. Carl Slagle and Ralph F. Willy for UPJOHN COMPANY: George A. Kropp, Dr. F.W. Bartholic,A.R. Swanson and John White for the Department of Corrections, State Prison of Southern Michigan; Gus Harrison and R.M. Boase for the Department of Corrections. Items discussed were: Item #3 INMATE PAY FOR INMATES ASSIGNED TO THE CLINIC JOBS. Other items discussed pertaining to COMPANY EXPENSES for CUSTODIAL COVERAGE: BUILDING MAINTENANCE: LAUNDRY: PROTOCOL COMMITTEE: UTILITIES CHARGES; Signed By: Gus Harrison, Director Department of Corrections. NOTE: State pays custodial officers assigned to Clinics on Straight hourly basis and collects on straight time and one-half hourly basis from the two companies.

LAW OFFICES
-EITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
1618 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
235-5631

Exhibits
Letter

G-4 MEMORANDUM: Report of meeting held in the Office of the Department of Corrections on February 25 to discuss the operation of the Medical Research Clinics at Southern Michigan Prison. Items Discussed: 1. Custodial Coverage-reimbursement by companies for security personnel provided by the prison (Civil Service). 2. Inmates, Clinical Personnel. Reimbursement by companies for INMATE WAGES. See item 6 "The prison could supply all linens and laundry service for linens and levy a reasonable charge against the companies. However, it may be preferable for each Company to supply its own linen and laundry service." See item 9, Insurance: "The Department of Corrections will list the buildings with the State Insurance Fund. The Companies will insure the buildings and contents with Commercial Carriers. "Signed: Gus Harrison, Director, Department of Corrections.

H Entitled: JOB DESCRIPTION, Staff Physician-Jackson Prison Research Clinic: OBJECTIVES: The primary objectives of the Staff Physician assigned to the Jackson Prison Research Clinic are: (See item 4, page 2) FOR HIRING AND RELEASING OF INMATE HELP.

I LETTER: DEPARTMENT OF CORRECTION LETTERHEAD, Dated December 3, 1965, addressed to Mr. F. M. McLaury, Director Accounting Division Department of Administration, Lansing, Michigan; ATTENTION Mr. Donald L. Powers: Subject: Heating Charges to PARKE-Davis and UPJOHN Clinics. Letter commences: "When arrangements were originally made in March, 1964 for CHARGING THOSE DRUG FIRMS FOR HEAT FURNISHED THEIR CLINIC BUILDINGS....." Signed: A.R. Swanson, Business Manager.

J MEMORANDUM: Dated August 18, 1965, TO: INMATE EMPLOYEES RESEARCH CLINICS- Effective Date August 16, 1965: "Any INMATE EMPLOYEE Assigned to the UPJOHN or PARKE-DAVIS CLINIC who is off assignment for a period exceeding three days shall not be compensated at his DAILY RATE OF SALARY, starting with the first day of the absenteeism. "Signed: Ralph F. Willy, Upjohn Clinic and John H. Conlin, Parke-Davis Clinic.

K MEMORANDUM: TO: BLOCKS 5-11-12-4-6: SUBJECT: Upjohn Clinic Protocol #56. See second paragraph: "An INMATE EMPLOYEE of the Clinic....." Signed M.S. Kircher, Deputy Warden.

L LETTER: Dated February 22, 1966, addressed to Mr. Gerald Hansen, Director of inmate Affairs, SPSM. Wherein mention is made to "INMATES OF OUR EMPLOYMENT" and signed by: Ralph F. Willy, Administrator, Upjohn Clinic.

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
1618 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
235-5031

Exhibits
Letter

M INTEROFFICE MEMORANDUM: To: L.A. LeZotte,FROM A.B. Varley, SUBJECT: September 29, 1966 Meeting with Gus Harrison; Date of October 3, 1966: Copies to W.J. Hessler;See:Next to last paragraph wherein reference is made to"...We should have a file here in KALAMAZOO containing copies of all letters and memos which originate at JACKSON and which per tain to the function of OUR UNIT." and, last paragraph in full: "Finally, I wonder if you would begin to consider what civilian personnel we would need to run the Jackson Unit efficiently if INMATE LABOR IS IN THE FUTURE DENIED AS A RESULT OF THE PRESENT FEDERAL MINIMUM WAGE LITIGATION. It is Mr. Harrison's opinion that they could continue to supply us with inmate help for maintenance inasmuch as the building is the property of the State. "NOTE: This letter dated a month prior to the filing of Civil Action #29149.

N Copy of Protocol #88, Jackson, Michigan, Pretaining to U-21, 251F,LINCOSIN.

O Copy of Protocol #96 (Dated May 23, 1966) pertaining to the Drug ORINASE.

LAW OFFICES
LEITSON, DEAN,
DEAN, SEGAR,
& HART, P.C.
1810 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
235-5831

INMATE DETAIL

REQUEST FOR APPROVAL

XXXX ☐ Routine Monthly Work Detail.
☐ Routine Monthly Odd-Hour Detail.
☐ Special Work & Movement Detail.
☐ Leaving Prison Property Detail.

Effective Date
Dec. 1, 1966 Thru Jan. 31, 1967. 4:45 A.M. To 10:00 P.M.
Seven (7) Days Per Week,
HOLIDAYS INCLUDED.
UPJOHN CLINIC

This request shall apply to the following inmates:

No.	Name	Lock	No.	Name	Lock
50593	Glancy	20-1-12			
	Upjohn Clinic Counts				
	Upjohn Head Blood Room Nurse				
	To attend Week End and Holiday Movies as the Work				
	Load permits.				
	cc: 12 Block				
	Upjohn Research Clinic				

Men to be in charge of and returned by _____

Originator of request MR. R.F. WILLY R.F.Willy
ADMINISTRATOR
UPJOHN CLINIC

Verified By _____

Approved by _____
Warden, Deputy Warden, Asst. Dep. Warden (Institution)

NOTE: Any specific and/or special instructions shall be noted hereon.

I-303 020

EXHIBIT-A

INMATE DETAIL

REQUEST FOR APPROVAL

XXXX ☐ Routine Monthly Work Detail.
☐ Routine Monthly Odd-Hour Detail.
☐ Special Work & Movement Detail.
☐ Leaving Prison Property Detail.

Effective Date

Dec. 1, 1966 Thru Jan. 31, 1967. 6:30 A.M. To 10:30 P.M. Seven (7) Days Per Week, HOLIDAYS INCLUDED. UPJOHN CLINIC

This request shall apply to the following inmates:

No.	Name	Lock	No.	Name	Lock
104742	Marlin	45-4-12			

Upjohn Clinic Counts
Upjohn Head Clerk & E.E.G. Tech.

(ON 24 HOUR CALL BY THE CLINIC OFFICER!)

To attend Week End Movies and Holiday Movies as the Work Lead permits.

cc: 12 Block
Upjohn Research Clinic

Men to be in charge of and returned by _____

Originator of request MR. R.F. WILLY
ADMINISTRATOR
Verified By UPJOHN CLINIC

Approved By _____
Warden, Deputy Warden, Asst. Dep. Warden (Institution)

NOTE: Any specific and/or special instructions shall be noted hereon.

303 020

Exhibit 9-1

TCrump JMIT 0138

INMATE DETAIL

REQUEST FOR APPROVAL

- [X] Routine Monthly Work Detail.
- [ ] Routine Monthly Odd-Hour Detail.
- [ ] Special Work & Movement Detail.
- [ ] Leaving Prison Property Detail.

Effective Date

Sept. 1 thru Nov. 30, 1966 - UPJOHN CLINIC
6:30 am to 10:30 pm
7 days per week, holidays included.

This request shall apply to the following inmates:

No.	Name	Lock	No.	Name	Lock
104742	Marlin	45-4-12	x/x/x/	/x/x/x/x/x/x/x/x/	/x/x
/x/x/x/	/x/x/x/x/x/x/x/x/x/	/x/x/x/			
	Upjohn Counts				
	Upjohn Chief Clerk				
	To attend the sunday and holiday movies as the				
	work load permits.				
	ON 24 HOUR CALL BY THE CLINIC OFFICER.				
	cc: 12 Block				
	Upjohn (2)				

Men to be in charge of and returned by _____

Originator of request R.F. Willy R F Willy

Verified By _____

Approved By _____
Warden, Deputy Warden, Asst. Dep. Warden (Institution)

NOTE: Any specific and/or special instructions shall be noted hereon.

1-303 020

EXHIBIT - A-2

INMATE DETAIL

REQUEST FOR APPROVAL

- ☐ Routine Monthly Work Detail.
- ☐ Routine Monthly Odd-Hour Detail.
- XXXX☒ Special Work & Movement Detail.
- ☐ Leaving Prison Property Detail.

Effective Date

Dec. 5, Thru Dec. 20, 1966
4:45 A.M. To 6:30 A.M.
DAILY - UPJOHN CLINIC

This request shall apply to the following inmates:

No.	Name	Lock	No.	Name	Lock
104742	Marlin	45-4-12			
	(UPJOHN E.E.G. TECH.)				
	The E.E.G. Technician named above has special work				
	(Pharmacology) for fifteen consecutive days.				
	cc: 12 Block				
	Upjohn Research Clinic				

Men to be in charge of and returned by _____

Originator of request MR. R.F. WILLY

Verified By _____

Approved By _____
Warden, Deputy Warden, Asst. Dep. Warden (Institution)

NOTE: Any [illegible] and/or special instructions shall be noted hereon.

Exhibit A-3

I-303 D20

Exhibit A-3

INMATE DETAIL

REQUEST FOR APPROVAL

- [x] Routine Monthly Work Detail.
- [ ] Routine Monthly Odd-Hour Detail.
- [ ] Special Work & Movement Detail.
- [ ] Leaving Prison Property Detail.

Effective Date

July 1 thru August 31, 1966 - UPJOHN CLINIC
6:30 am to 10:30 pm
7 days per week, holidays included.

This request shall apply to the following inmates:

No.	Name	Lock	No.	Name	Lock
104742	Marlin	45-4-12	/x/x/x/	x/x/x/x/x/x/x/x/	x/x/x
x/x/x/x/	x/x/x/x/x/x/x/x/x	/x/x/x/			
	Upjohn Counts				
	Upjohn Head Clerk				
	To attend the Sunday and Holiday movies as the work load permits.				
	ON 24 HOUR CALL BY THE CLINIC OFFICER.				
	cc: 12 Block				
	Upjohn (2)				

Men to be in charge of and returned by ____________________

Originator of request R. E. Willy *R. Will*

Verified By ____________________

Approved By *[signature]*
Warden, Deputy Warden, Asst. Dep. Warden (Institution)

NOTE: Any specific and/or special instructions shall be noted hereon.

I-303 O20 *EXHIBIT - A-4* *4-3*

INTRADEPARTMENTAL CORRESPONDENCE

Date: 8-17-65

From desk of: W.J. HESSLER

To: Classification

Subject: 104742 Marlin

The above named inmate has applied to thda office for employment in the UPJOHN CLINIC.

Ihave interviewed this man and feel he would make a good man for this assignment. Therefore if it is agreeable in your opionion, and that of the classification committee, I respectfully request that he be re-classified for the 1011-U assignment.

I have talked with Mr. Don Young personaly and he is willing to release this man immediatly.

Sincerely
W.J. Hessler

W.J. Hessler
Asst. Administrator
UPJOHN CLINIC

WJH/gw

A-5

EXHIBIT - A-5

ASSIGNMENT CHANGE ORDER

NUMBER	NAME	COLOR	REMARKS
104742	Marlin	W	

Mr. Willy : the above inmates have been placed on the 1011-U assignment.

Assignment Clerk

Date 8-27-65, 19 APPROVED:

G. L. HANSEN
Director of Treatment

EXHIBIT - A-6

THE UPJOHN CLINIC

PERSONNEL ROSTER

NAME GLANCY NUMBER 50593 LOCK 20-1-12

JOB BLOOD ROOM NURSE (Head) DATE OF ASSIGNMENT 10-5-65

STARTING PAY $0.30 MAXIMUM PAY $0.75 ($1.25)

Date	Rate	Date	Rate	Date	Rate
5-65	55	6/1/66	90		
1-1-66	60	7/1/66	95		
12-1-65	65	8/1/66	100		
1-31-66	70	9/1/66	105		
2-28-66	75				
4-30-66	80				
5-31-66	85				

Exhibit A-7

-139a-

January 18, 1965

Deputy Kircher:

Friday (1-15-65), while in Kalamazoo, I had a talk with Dr. Varley. We discussed the Jackson Clinic at length. Among the problems we covered was that of our relationship with Custody. I indicated that I have expressed on many occasions the desire to cooperate completely with this department; Dr. Varley was of the opinion that this interest in cooperation should be formalized in a letter to you.

The Parke-Davis and Upjohn Clinics are unique to the Prison and present special problems to custody. I shall concern myself only with the UPJOHN Clinic in the discussion which follows.

The problems arising in the operation of the Clinic, which are a concern to Custody and to us, can be divided into several catagories -

1. Building Design
2. Security of Supplies
3. Responsibilities Given Inmate Employees
4. Responsibilities of Custodial Officers in the Clinic

BUILDING DESIGN - The UPJOHN Clinic was designed purely as an efficient Clinical facility in which a wide variety of Research problems could be handled. From a custodial standpoint the building presents a number of problems - i.e. - large number of rooms with doors, many storage areas, limited vision for large areas of the building.

SECURITY OF SUPPLIES - The nature of our work at the Clinic involves the use of equipment and drugs which are often classified as "High Security" items by Custody. Some maintenance and Lab. equipment is also of concern to Custody. We use special procedures for handling such items and make use of our safest facilities for storing these items.

While I've never been made aware of the loss of any of the special security items, the potential is always present and perhaps it would be of some profit to everyone if procedures, facilities and reporting systems be reviewed by Custody. Perhaps expierence gained in the Prison Hospital should be taken into consideration.

RESPONSIBILITIES GIVEN INMATE EMPLOYEES - The mission of the UPJOHN Clinic involves not only large numbers of inmate subjects, but also much of the work is very involved. For this reason the inmate staff is large - the large staff of nurses, technicians require a large supporting staff.

Exhibit - B

Exhibit B

ORIGINAL

VOICE No. 8485

STATE PRISON OF SOUTHERN MICHIGAN

INSTITUTIONAL

SOLD TO UPJOHN CLINIC
ADDRESS ATTN: MR WILLY

JACKSON, MICH. 10/27/66

ORDER NO.

EXPENSES DUE STATE OF MICHIGAN AS PER THE ATTACHED STATEMENT	$4,253.78

Please make check payable to State of Michigan, 4000 Cooper Street, Jackson, Michigan 49201

FORWARDED TO KAL. FOR PAYMENT ON 11-7-66
W Hobsler

Exhibit C

UPJOHN BILLING
SEPTEMBER, 1966

Inmate Wages - September			557.75
Salaries & Wages of Custodial Personnel assigned to Upjohn for period of September, 1966			
600 hours @ 3.16	1,896.00		
300 hours @ 3.16 (Overtime)	948.00	2,844.00	
Plus 9.76% to cover cost of Civil Service and employee retirement 2,844.00 x .0976		277.57	3121.57
Postage for September			1.35
Installation and service of telephone extension 239			4.47
Utilities:			
Electricity-28,960 KWH @ .017 per KWH			492.32
Cold Water-50,625 gal @ .4085 per 750 gal 67.50 x .1085		7.32	27.55
Hot Water-33,825 gal @ .4485 per 750 gal. (misc. 4.89, salt 2.12, Fuel 13.22) 45.10 x .4485		20.23	
Sewerage-84,450 gal @ .0912 per 750 gal 112.60 x .0912		10.27	
Heat-40.2 milliom BTU @ .5783 per million		23.17	48.24
Plus - 40.2 million BTU @ .6237 per million to cover cost of incidentals and overhead		25.07	
	Total		4,263.52
NOTE: Credit due Upjohn Clinic on electricity charges due to correction factor supplied SPSM by Consumers Power Company for period March, 1966 thru August, 1966			9.74
	Total		4,253.78

FORWARDED TO KAL. FOR PAYMENT ON 11-7-66

W J Kessler

INMATE PAY 1011-UpJohn
Assignment

P. P. S. M.

GRAND TOTAL $557.

MONTHLY SUMMARY

September 19
Month

NUMBER	NAME	AMOUNT	RATE	DAYS	NUMBER	NAME	AMOUNT	RATE	D
48733	Sawicki	15 00	.50	30	107000	Bailey	15 00	.50	
50593	Glancy	31 50	1.05	30	107143	Angers	6 30	.30	
52145	Danielson	15 00	.50	30	107254	Holnagel	7 50	1.25	
55191	May	22 50	.75	30	110782	Brook	21 00	.70	
61569	Davidson	15 00	.50	30	118886	McNamara	21 00	.70	
65238	Lee	37 50	1.25	30					
66180	Slager	37 50	1.25	30					
74593	Mink	12 75	.75	17					
75606	Dake	10 50	.35	30					
76929	Mevis	4 80	.30	16					
80512	Kearns	5 40	.60	9					
80918	Craig	22 50	.75	30					
81245	DeDeaux	27 00	.90	30					
85965	Hill	15 00	.50	30					
86921	Walker	15 00	.50	30					
87776	Simer	22 50	.75	30					
89513	Galbreath	22 50	.75	30					
89679	Grenillo	4 50	.90	5					
91018	Ward	18 00	.60	30					
91681	Phillips	18 00	.60	30					
92690	Spann	18 00	.60	30					
93561	Vilborn	22 50	.75	30					
96507	Nawrocki	10 50	.35	30					
96773	Brown	22 50	.75	30					
104247	Mason	3 50	.50	7					
104742	Marlin	37 50	1.25	30					

Instructions:
Arrange all inmate numbers numerically at end of month. One Name Only per Line. List (name, Inter Amount, Days, Rate from Inmate Time Sheet. One copy only, submit with Time Sheets at end of month. Show Grand Total of currency on front page only.

Certified by R E Will

SUBSIDIARIES

ARGENTINA
LABORATORIOS UPJOHN ANODIA S.A.
Ruta 202, Km. 15,200
San Miguel (Provincia Buenos Aires)
TELEPHONE: 657–1955, 657–0202
CABLE: UPJOHN Buenos Aires (Argentina)
Correspondence Address:
Casilla de Correo N° 79
San Miguel, Buenos Aires
Argentina

AUSTRALIA
UPJOHN PTY. LIMITED
55–73 Kirby Street
P.O. Box 138
Parramatta, New South Wales, Australia
TELEPHONE: 638–0531
CABLE: FRIABLE Sydney (Australia)

BELGIUM
UPJOHN S.A.
Puurs, Belgium
TELEPHONE: Area (3) 77.11.45/46/47/48/49
CABLE: FRIABLE Puurs (Belgium)

BRAZIL
UPJOHN PRODUTOS FARMACEUTICOS LTDA.
Rua General Julio Marcandes Salgado, 24
Caixa Postal 1100
Sao Paulo, Brazil
TELEPHONE: 51–2118, 2119, 2110
CABLE: UOOBRAFA Sao Paulo (Brazil)

RIO BRANCH
Rua Rezende, 69
Rio de Janeiro, Guanabara
Brazil
TELEPHONE: 52-0477

CANADA
THE UPJOHN COMPANY OF CANADA
865 York Mills Road
Don Mills, Ontario, Canada
TELEPHONE: Area Code 416 444–4433

DEPOTS:

Vancouver	Montreal
1635 W. 4th Avenue	375 Laurentian Blvd.
Vancouver, B.C., Canada	P.O. Box 555
TEL: Regent 3–1712	(Montreal 9)
	Quebec, Canada

CANADA
A.H. HOWARD CHEMICAL COMPANY LTD.
3 McCarthy Street
Orangeville, Ontario, Canada
TELEPHONE: Code 519 941–1030

CHILE
UPJOHN COMPANIA LTDA.
Monjitas 404
Clasificardo 1106
Correo Central
Santiago, Chile
TELEPHONE: 397218
CABLE: UPJOHN, Santiago, Chile

COLOMBIA
COMPAÑIA UPJOHN S.A.
Carera 42 Nos. 1544 y 1554
Apartado Aereo No. 8589
Bogota, Cundinamarca, Colombia
TELEPHONE: 47–65–02
CABLE: UDECOL Bogota (Colombia)

ENGLAND
UPJOHN LIMITED
Fleming Way, Crawley
Sussex, England
TELEPHONE: Crawley 2–6011
CABLE: FRIABLE Crawley (England)

FRANCE
UNION CHIMIQUE ATLANTIQUE, S.A.
1, Place d'Estienne d'Orves
Paris 9e, France
TELEPHONE: 744–6359
CABLE: FRIABLE Paris (France)

LABORATOIRES UPJOHN S.A.R.L.
1, Place d'Estienne d'Orves
Paris 9e, France
TELEPHONE: 744–6359
CABLE: FRIABLE Paris (France)

GERMANY
UPJOHN GmbH
Graf von Galenstrasse 12
6148 Heppenheim/Bergstrasse
Germany
TELEPHONE: Heppenheim 2057/58/59
Area Code: 06252
CABLE: UPJOHN HEPPENHEIM

GREECE
UPJOHN L.L.C.
Plateia Omonoias 16
P.O. Box 122
Athens, Greece
TELEPHONE: 315–786
CABLE: UPJOHN Athens (Greece)

Exhibit D-3

Exhibit D

GUATEMALA
COMPANIA FARMACEUTICA UPJOHN S.A.
Edificio Panamericano 13
Apartment #308
Apartado Postal 991
Guatemala City, Guatemala
TELEPHONE: 20088, 24213, 21245, & 29096
CABLE: COFUSA Guatemala

HONG KONG
UPJOHN COMPANY S.A. HONG KONG BRANCH
Tung Kin Factory Building, 7th Floor
Tsat Tse Mui Road, North Point
P.O. Box 4124
TELEPHONE: 700-248
CABLE: UPJOHN Hong Kong

ITALY
UPJOHN S.p.A.
Via Don Orione, 10
Milan, Italy
TELEPHONE: 289-2710, 289-3834
CABLE: UPJOHN Milano (Italy)

JAPAN
JAPAN UPJOHN LIMITED
(5th floor) Toyota Hanbai Building
No. 3, 2-Chome, Kudan, Chiyoda-ku
Tokyo, Japan
TELEPHONE: 265-8140
CABLE: JAPANUPJOHN Tokyo

MEXICO
UPJOHN S.A. DE C.V.
Calzada de Tlalpan 2962
Apartado 156
Mexico D.F., Mexico
TELEPHONE: 49-34-20
CABLE: UDEMEX (Mexico)

MEXICO
C.P. CONTINENTAL S.A.
Miguel Angel No. 35
Apartado Postal 31136
Mexico 19, D.F., Mexico
TELEPHONE: 34-8140
CABLE: MISSUKY (Mexico)

PANAMA
UPJOHN COMPANY S.A.
P.O. Box 536
Colon Free Zone
Colon, Republic of Panama
TELEPHONE: Colon Free Zone 7-1960
CABLE: UPJOHN Colon (Panama)

PERU
UPJOHN INTER-AMERICAN CORPORATION
PERU BRANCH
Avenida Salaverry No. 674
Oficina 603
Apartado 4825
Lima, Peru
TELEPHONE: 34697
CABLE: UPJOHN (Peru)

PHILIPPINES
UPJOHN, INC.
Makati Building
Makati, Rizal
Republic of the Philippines
P.O. Box 3029
TELEPHONE: 88-74-05, 88-72-43
CABLE: UPJOHN Manila, Philippines

PUERTO RICO
UPJOHN INTER-AMERICAN CORPORATION
PUERTO RICO BRANCH
Calle A - Bloque # 17
Urbanizacion Industrial Dr. Mario Julia
Guaynabo, Puerto Rico
TELEPHONE: 766-3058, 766-1280 & 766-1281
CABLE: UPJOHN San Juan (Puerto Rico)

SOUTH AFRICA
TUCO (PROPRIETARY) LIMITED
255 Jeppe Street
Johannesburg, South Africa
P.O. Box 7779
TELEPHONE: 23-9541
CABLE: UPJOHN Johannesburg (South Africa)

SPAIN
LABORATORIOS UPJOHN S.A.
Mateo Inurria, 35
Madrid 16, Spain
TELEPHONE: 259.38.07
CABLE: UPJOHN Madrid, Spain

UNITED STATES
UPJOHN INTER-AMERICAN CORPORATION
320 Portage Street
Kalamazoo, Michigan

UPJOHN INTERNATIONAL, INC.
320 Portage Street
Kalamazoo, Michigan

VENEZUELA
UPJOHN INTER-AMERICAN CORPORATION
VENEZUELA BRANCH
Calle Los Laboratorios, Edif. Oficea
Urbanizacion Los Ruices
Apartado del Este No. 4752
Caracas, Venezuela
TELEPHONE: 34,36,69 34,37,81 & 34,35,73
CABLE: UDEVENE Caracas (Venezuela)

D-cont'd

PHARMACEUTICAL SALES AREAS AND DISTRIBUTION CENTERS

ATLANTA
Area Code 404 451–4422
P.O. Box 529
Chamblee, Georgia 30005
Pharmaceutical Sales Area
Robert C. Ferguson, Sales Mgr.
E.R. Kimsey, Contactor
Distribution Center
John F. Graves, Mgr.
A.C. Emminger, Office Supv.
E.C. Anderson, Shipping Supt.

BOSTON
Area Code 617 449–0440
P.O. Box 184
Needham Heights, Massachusetts 02194
Pharmaceutical Sales Area
Donald E. Johnson, Sales Mgr.
W.J. Kennedy, Contactor
Distribution Center
A.J. Mendles, Mgr.
John Mercurio, Office Supv.
Joseph J. Passanesi, Shipping Supt.

BUFFALO
Area Code 716 634–0001
P.O. Box 1108
Buffalo, New York 14240
Pharmaceutical Sales Area
Robert L. Stevenson, Sales Mgr.
Distribution Center
Joseph D. Bachraty, Supv.

CHICAGO
Area Code 312 654–3300
P.O. Box 4632 Main Post Office
Chicago, Illinois 60680
Pharmaceutical Sales Area
Edward R. Barnett, Sales Mgr.
Distribution Center
M.C. McDonnell, Mgr.
Thomas J. Hilliard, Office Supv.
P.B. Loonam, Shipping Supt.

CINCINNATI
Area Code 513 242–4573
P.O. Box 28, Annex Station
Cincinnati, Ohio 45214
Pharmaceutical Sales Area
Vincent R. Facciuto, Sales Mgr.
Robert C. Bentley, Asst. Mgr.
R.W. Taylor, Contactor
Distribution Center
W.F. Weiss, Mgr.
R.L. Fullerton, Office Supv.
A.J. Jackson, Shipping Supt.

CLEVELAND
Area Code 216 267–4100
P.O. Box 6476
Cleveland, Ohio 44101
Pharmaceutical Sales Area
H.E. Crissman, Sales Mgr.
Edwin H. Sypolt, Jr., Contactor
Distribution Center
C. DeWain Milham, Mgr.
John P. Milner, Office Supv.
L.H. Knoll, Shipping Supt.

DALLAS
Area Code 214 824–3027
P.O. Box 5451
Dallas, Texas 75222
Pharmaceutical Sales Area
Gerald M. Bear, Sales Mgr.
T.H. Tanner, Contactor
Distribution Center
Melvin A. Smith, Mgr.
E.A. Blamire, Office Supv.
W.K. Hodges, Shipping Supt.

DENVER
Area Code 303 355–7391
P.O. Box 5307
Denver, Colorado 80217
Pharmaceutical Sales Area
W. Leslie LaFortune, Sales Mgr.
E.C. Karuzas, Contactor
Distribution Center
Richard L. Kramer, Mgr.
R.E. Winsell, Office Supv.
L.G. Heller, Shipping Supt.

HARTFORD
Area Code 617 449–0440
P.O. Box 184
Needham Heights, Massachusetts 02194
Pharmaceutical Sales Area
Donald E. Johnson, Sales Mgr.

HONOLULU
Tel: 581–181
P.O. Box 491
Honolulu, Hawaii 96809
(Served by San Francisco Area)
Distribution Center
Takashi Okubo, Shipping Supv.

KALAMAZOO
Area Code 616 345–3571
7171 Portage Road
Kalamazoo, Michigan 49001
Pharmaceutical Sales Area
J.S. Campbell, Sales Mgr.
B.A. Otto, Asst. Sales Mgr.
M.E. Wykoff, Contactor
Distribution Center
Duane Schwenn, Mgr.
P.D. Olsen, Office Supv.
E.J. Ennis, Shipping Supt.

KANSAS CITY
Area Code 816 361–2286
P.O. Box 108
Kansas City, Missouri 64141
Pharmaceutical Sales Area
Vance E. Vandiver, Sales Mgr.
M. Norman Hague, Contactor
Distribution Center
W. Bryant Upjohn, Mgr.
Kenneth D. Selvidge, Office Supv.
F.H. Debus, Shipping Supt.

LONG ISLAND
Area Code 516 747–1970
205 Glen Cove Road
Carle Place, Long Island, N.Y. 11514
Pharmaceutical Sales Area
Lewis V. Smith, Sales Mgr.
Leroy Kellogg, Asst. Mgr.
J.T. Elsele, Contactor
Distribution Center
H.R. Gruber, Mgr.
E.E. Starnes, Office Supv.
J.C. Staszek, Shipping Supt.

LOS ANGELES
Area Code 213 463–8101
P.O. Box 2916, Terminal Annex
Los Angeles, California 90054
Pharmaceutical Sales Area
Homer J. Hammond Sales Mgr.
K.H. Laird, Contactor
Karl D. Zorn, Mgr., Western Region Pharm. Sales
Distribution Center
Lyman E. Williams, Mgr.
E.A. Troup, Office Supv.
F.S. Baldwin, Shipping Supt.

D-Cont'd

Exhibit D Cont'd

MEMPHIS
Area Code 901 683–3566
P.O. Box 2525
Memphis, Tennessee 38102
Pharmaceutical Sales Area
Frank P. Fletcher, Jr., Sales Mgr.
D.W. Gamble, Contactor
Benjamin F. Dover, Mgr., Southern Region Pharm. Sales

Distribution Center
J. Lee Vestal, Mgr.
L.E. Wallace, Office Supv.
J.T. Parks, Shipping Supt.

MIAMI
Area Code 305 757–3578
P.O. Box 1297
Little River Station
Miami, Florida 33138
Pharmaceutical Sales Area
M.G. Rogers, Jr., Sales Mgr.
Distribution Center
Jack P. Teagle, Supv.

MINNEAPOLIS
Area Code 612 588–2786
P.O. Box 1205
Minneapolis, Minnesota 55440
Pharmaceutical Sales Area
Arthur Sailer, Sales Mgr.
J.C. Berthel, Sales Mgr.
D.M. Coxell, Contactor
Distribution Center
Howard J. White, Mgr.
D.O. Stjei, Office Supv.
J.E. McGinnis, Shipping Supt.

NEW ORLEANS
Area Code 504 254–3450
P.O. Box 29128
Michoud Station
New Orleans, Louisiana 70129
Pharmaceutical Sales Area
C.H. Cobb, Sales Mgr.

NEW YORK
Area Code 212 924–2440
Village Station, P.O. Box 40
New York, New York 10014
Pharmaceutical Sales Area
Valdemar Christensen, Sales Mgr.
M.H. Munson, Contactor
Distribution Center
Donald Johnson, Mgr.
J.N. Schermerhorn, Office Supv.
W.J. Turner, Shipping Supt.

PHILADELPHIA
Area Code 215 265–2100
P.O. Box M
King of Prussia, Pennsylvania 19406
Pharmaceutical Sales Area
J.E. Baumgardner, Sales Mgr.
Jack C. Bower, Asst. Mgr.
A.B. Griggs, Contactor
Distribution Center
V.J. Rainey, Mgr.
Wayne J. Wisdom, Office Supv.
R.E. Buck, Shipping Supt.

PITTSBURGH
Area Code 412 921–4130
Four Parkway Center
Pittsburgh, Pennsylvania 15220
Pharmaceutical Sales Area
R.J. Deckert, Sales Mgr.

PORTLAND
Area Code 503 236–2133
P.O. Box 4071
Portland, Oregon 97208
Pharmaceutical Sales Area
A.E. Knight, Sales Mgr.
J.L. Stewart, Contactor
Distribution Center
Fred O. Chapman, Mgr.
H.B. Chugg, Office Supv.
C.E. Todd, Shipping Supt.

ST. LOUIS
Area Code 314 994–3040
P.O. Box 7032
St. Louis Missouri 63177
Pharmaceutical Sales Area
Clyde E. Whitley, Sales Mgr.
Jack L. Belcher, Contactor
Distribution Center
H.J. Stiller, Supv.

SAN DIEGO
Area Code 714 454–7169
P.O. Box 2247
La Jolla, California 92037
Pharmaceutical Sales Area
E.V. Lindstrom, Sales Mgr.

SAN FRANCISCO
Area Code 415 322–5301
120 Scott Drive
Menlo Park, California 94025
Pharmaceutical Sales Area
Dwight O. Moore, Sales Mgr.
W.T. Biggs, Contactor
Distribution Center
George L. Hamidia, Mgr.
Gerald Dayharsh, Office Supv.
K.R. Walker, Shipping Supt.

WASHINGTON
Area Code 202 882–6163
P.O. Box 7710
Washington, D.C. 20013
Pharmaceutical Sales Area
Byron J. Pence, Sales Mgr.
J.R. Perry, Asst. Mgr.
B.G. Weis, Contactor
Femen E. Fox, Mgr., Mid-Atl. Region
Distribution Center
K.W. Ellis, Mgr.
G.F. Gallagher, Office Supv.
A. Pecoraro, Shipping Supt.

D-Cont'd

Exhibit D-Cont'd

THE UPJOHN COMPANY
Carwin Organic Chemicals
Area Code 203 288-7471
410 Sackett Point Road
North Haven, Connecticut 06473

THE UPJOHN COMPANY
Polymer Chemicals Division
Area Code 713 479-1541
La Porte Plant, P.O. Box 685
La Porte, Texas 77536
C.J. Thomas, Director

CPR, DIVISION OF THE UPJOHN COMPANY
Area Code 213 320-3550
555 No. Alaska Ave.
Torrance, California 90503
T.P. Dougan, President

D-Cont'd

Exhibit D-Cont'd

LAKE CENTRAL AIRLINES, INC.
Indianapolis, Indiana
AIR FREIGHT DOMESTIC AIRBILL
NON NEGOTIABLE

RECEIVED BY CARRIER AT: ☐ SHIPPER'S DOOR ☐ CITY TERMINAL ☒ AIRPORT TERMINAL

ROUTING: AIRLINE ROUTING APPLIES UNLESS SHIPPER INSERTS SPECIFIC ROUTING HERE

CHARGES ☒ PREPAID ☐ COLLECT

DELIVERY will be made to the consignee at a point where delivery service is available unless instructions to deliver to city terminal or airport terminal are specified in "Instructions to Carrier" below.

LETTERS SIGNIFY AIRPORT OF DEPARTURE

20- Y/P 161-993

IMPORTANT: Carrier will complete all items below bold line EXCEPT SHIPPER'S C.O.D. Weights and classifications are subject to correction.

FROM: SHIPPER: UPJOHN RES CLINIC
STREET ADDRESS: 7000 COOPER ST,
CITY: JACKSON, ZONE STATE: MICH 49201
SHIPPER OR SHIPPER'S AGENT — SHIPPER'S NUMBER

(circled: 1-25-66 CK # 226)

TO: CONSIGNEE: DR, JAMES O'DONNELL
STREET ADDRESS: GASTRIC LABORATORY CINCINNATI GENERAL HOSPITAL
CITY: CINCINNATI, ZONE STATE: OHIO
DESTINATION AIRPORT CODE: CVG
CONSIGNEE'S NUMBER

IT IS MUTUALLY AGREED THAT THE GOODS HEREIN DESCRIBED ARE ACCEPTED IN APPARENT GOOD ORDER (EXCEPT AS NOTED) FOR TRANSPORTATION AS SPECIFIED HEREIN, SUBJECT TO GOVERNING CLASSIFICATIONS AND TARIFFS IN EFFECT AS OF THE DATE HEREOF WHICH ARE FILED IN ACCORDANCE WITH LAW. SAID CLASSIFICATIONS AND TARIFFS, COPIES OF WHICH ARE AVAILABLE FOR INSPECTION BY THE PARTIES HERETO, ARE HEREBY INCORPORATED INTO AND MADE PART OF THIS CONTRACT.

CARRIAGE HEREUNDER IS SUBJECT TO THE RULES RELATING TO LIABILITY ESTABLISHED BY THE CONVENTION FOR THE UNIFICATION OF CERTAIN RULES RELATING TO INTERNATIONAL CARRIAGE BY AIR, SIGNED AT WARSAW, OCTOBER 12, 1929, UNLESS SUCH CARRIAGE IS NOT "INTERNATIONAL CARRIAGE" AS DEFINED BY THE CONVENTION (SEE CARRIER'S TARIFF FOR SUCH DEFINITION). AGREED STOPPING PLACES ARE THOSE PLACES (OTHER THAN THE PLACE OF DESTINATION) SHOWN UNDER ROUTING OR AIRLINE ROUTING AND/OR THOSE PLACES SHOWN IN CARRIER'S TIMETABLES AS SCHEDULED STOPPING PLACES FOR THE ROUTE.

NO. PCS PKGS.	DESCRIPTION OF PIECES AND CONTENTS MARKS - PACKING - NUMBERS	WEIGHT	COMMODITY OR CL. NO.	ROUTING TO	ROUTING VIA	RATE
2	BOXES BLOOD SPEC.	68		CVG	LC	9¢

INSTRUCTIONS TO CARRIER
DLVRY TO CVG
GENERAL HOSPITAL

☒ CASH ☐ CREDIT

DECLARED VALUE agreed and understood to be not more than the value stated in the governing tariffs for each pound on which charges are assessed unless a higher value is declared and applicable charges paid thereon.

DECLARED VALUE $ 200.00 — AMT. COLL. $

NO. PKGS. — LENGTH X WIDTH X DEPTH = CU. IN. — DIMENSIONAL WGT. LBS.

	PREPAID CHARGES	COLLECT CHARGES
INSURANCE	$	$
WEIGHT-RATE	600	
WEIGHT-RATE		
WEIGHT-RATE		
PICKUP		
DELIVERY	160	
EXCESS VALUE TRANSPORTATION CHARGE	30	
ADVANCES		
SHIPPER'S C.O.D.		
C.O.D. FEE - OTHER		
TOTAL CHARGES	$ 7.90	$

20- Y/P 161-993
LETTERS SIGNIFY AIRPORT OF DEPARTURE

EXECUTED BY LAKE CENTRAL AIRLINES, INC. (AGENT): Miller
AT: Y/P
DATE: 1-25-66
TIME: 0830 A.M. / P.M.

PRINTED IN U.S.A.

Paid 25 Jan 66 CK # 226

FORM AC-1
AIR CARGO, INC.
WASHINGTON, D. C.

1 — **1. SHIPPER'S RECEIPT (NOT AN INVOICE)**

Exhibit E

November 2, 1965

Warden George A. Kropp
State Prison of Southern Michigan
4000 Cooper Street
Jackson, Michigan

Dear Warden Kropp:

The Upjohn Clinic is very interested in establishing a Research Clinic in the Trusty Division. The demand for volenteers fr om the inside population has been so great of late that our expanding programs are being slowed down.

The estalishment of an outpatient Clinic in the Trusty Division would allow us to shift certain studies from the present inside facility and remove much of the pressures for volenteers.

We have examined 10 block and visualize our space requirements to be 4 cells - located near the present Trusty Division, 1st aid and pharmacy.

The Upjohn Company would remodel the cells to meet the needs of the ~~pro~~ program. The plans, of course, would be subject to the approval of the corrections department.

The Upjohn Clinic in the Trusty Division would be considered an extension of the Upjohn Clinic operating within the walls and would be operated in the same manner, subject to same administrative procedures, under same rules regarding the inmate participation, and under similar medical supervision.

Parke Davis has been informed of our intrest in establishing a Clinic in the Trusty Division and have been invited to share in the costs and in the operation of the facility. They will indicate their intentions within the present Month.

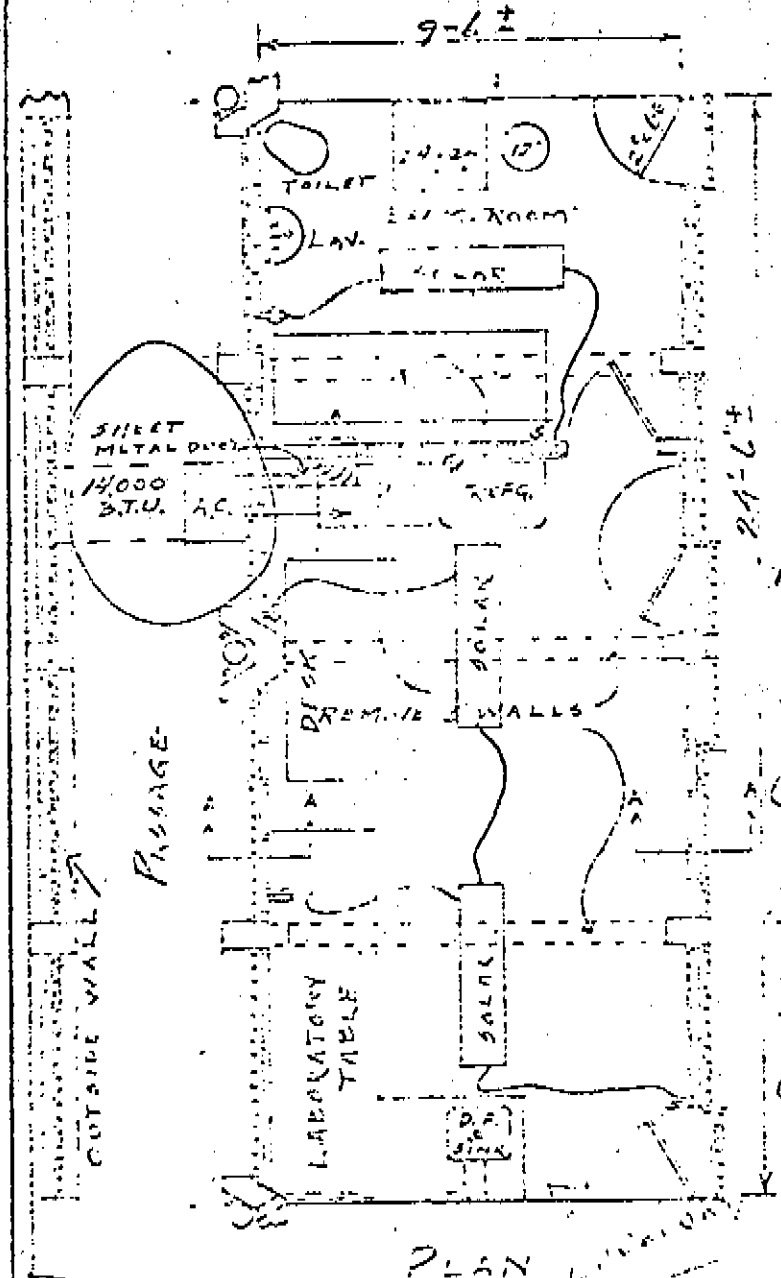
This letter is intended to serve formal notice or our interest in securing an outpatient Clinic in the Trusty Division, and to ask that the Corrections Department be so informed that a decision can be make.

Sincerely yours,

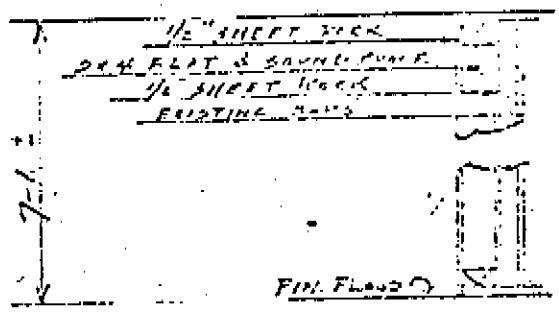
Ralph F. Willy,
Clinic Administrator

RFW/gw
cc: File

Exhibit 7



PLAN
1/4" = 1'-0"



SEC. A-A

NOTE

1. ALL SHEET ROCK WALLS TO BE 2 5/16" O.C. FOR ALL ON USING 2x4 FLAT SIDE. 16" O.C.
2. INSTALL BAT TYPE SOUND MATERIAL IN ALL WALLS.
3. FLOOR TO BE ARMSTRONG EXCELON TILE 1/8 INCH NO 719 SAUTERNE BEIGE.
4. ELECTRIC FIXTURE TO BE SOLAR 9A2HC.
5. ALL WALLS TO RECEIVE 3 COATS CEILING - 2 COATS.
6. EXISTING TOILET & LAVATORY TO REMAIN IN EXAM. ROOM. OTHERS TO BE REMOVED AND AND OPENINGS SEALED.
7. ALL DOOR HARDWARE TO BE RUSSWIN - FLUSH SLIDING LOCK NO F127 REPEATED FRONT CYLINDER TWIN BOLTS AND MASTER KEYED ALIKE.
8. [illegible]

SKIDMORE, OWINGS & MERRILL ARCHITECTS ENGINEERS NEW YORK CHICAGO SAN FRANCISCO PORTLAND			CELL BLOCK CLINIC F.M.S.P. JACKSON, MICHIGAN		
DRAWN:	CHECKED:	APPROVED:	DATE:	JOB NO.:	DWG. NO.:

STATE OF MICHIGAN

DEPARTMENT OF CORRECTIONS

STATE PRISON OF
SOUTHERN MICHIGAN
4000 Cooper Street
Jackson, Michigan
49201

GEORGE ROMNEY
GOVERNOR

January 14, 1966

COPY

MEMO TO: John Conlin, Director
Parke-Davis Clinic

Ralph Wi:ly, Director
Upjohn Clinic

It has been agreed that your companies will be permitted to construct in 10-Block a clinic for the purpose of conducting some types of drug and medical research. You will take four cells on base of this block and remove walls so as to make one room to house your equipment, conduct tests, etc. The area will, of course, remain prison property. We see no need to measure the electricity or heat used in this area as it is inside the block and should cause the institution no additional expense.

GAK-las

George A. Kropp
Warden.

Exhibit F-2

INVOICE

HUNGERFORD CONSTRUCTION COMPANY

1425 WILDWOOD AVENUE • P. O. BOX 507 • JACKSON, MICHIGAN 49204

STATE 9-8144

General Contractors

To: Dr. Lloyd A. LeZotte, Director
Upjohn Research Clinic
State Prison of Southern Michigan
Jackson, Michigan

Invoice No. 6798

Job No. 859

Your No. 341427

DATE October 6 196 6

For: 1/2 of Painting contract
REMOVE FIVE CELLS AND CONVERT INTO CLINIC

1/2 Amount for Completion of Painting ----------$350.00

Exhibit - 7-3

THE UPJOHN COMPANY
JACKSON CLINIC

January 20, 1966

PROPOSED FURNITURE AND EQUIPMENT NEEDS FOR THE TRUSTY DIVISION CLINIC.

1. Freezer-Refrigerator
2. Desk
3. Examination Table
4. Two (2) Storage Cabinets
5. Typewriter
6. Desk Chair
7. 2 or 3 Chairs
8. Strong (Security) Cabinet for Medication (2-?)
9. Floor Lamp
10. Radio
11. Scale
12. Peg Board For Drying Glass Ware
13. Desk Lamp

Ralph F. Willy

Ralph F. Willy,
Upjohn Clinic
Administrator

cc/rm

Exhibit - 7 - 4

STATE OF MICHIGAN

DEPARTMENT OF CORRECTIONS

Stevens T. Mason Building
Lansing, Michigan 48926

GEORGE ROMNEY
GOVERNOR

July 15, 1965

Warden George Kropp
State Prison of Southern Michigan
Jackson, Michigan

Dear Warden Kropp:

I have no objection to the new pay scale proposed by Upjohn-Parke Davis.

You may implement it if you wish.

Sincerely,

DEPARTMENT OF CORRECTIONS

Gus Harrison, Director

GH:jl

Copies made for Mr. Willy and Mr. Conlin on 7-16-65.

Exhibit - G

STATE OF MICHIGAN

DEPARTMENT OF CORRECTIONS

STATE PRISON OF SOUTHERN MICHIGAN
[illegible] COOPER STREET
JACKSON, MICHIGAN

GEORGE ROMNEY
GOVERNOR

March 26, 1964

Mr. Gus Harrison, Director
Department of Corrections
Lansing, Michigan

Attention: Mr. Robert Bosse

Dear Director:

We have just had a conference with Mr. Conlin and Mr. Willy and reviewed the proposed scales for inmate pay in the various job categories. These have been agreed upon as follows:

Porters	20¢ to 30¢ (top limit 20%)
Clerks	35¢ to ~~60¢~~ .55
Chief Clerk and Technicians	75¢ to $1.00
Technician Trainees	35¢ to ~~60¢~~ .55
Cook	25¢ to ~~60~~ 55¢ (top limit 25%)
Maintenance man	~~30~~ 35¢ to 50¢
Nurses	30¢ to 50¢ (top limit 30%)

Very truly yours,

STATE PRISON OF SOUTHERN MICHIGAN

Geo. A. Kropp
Warden

ARS/al
cc: Mr. Conlin
Mr. Willy
A. D. Swanson
J. White

Exhibit G-1

WARDEN KROPP'S - INMATE PAY

Job Classification	Approved Pay Scale April, 1954	Suggested Pay Scale
Chief Cook	.23 - .55	.55 - .80
Kitchen Assistant	*	.40 - .55
Kitchen Pot & Pan Man	*	.25 - .40
Maintenance Man	.30 - .30	.35 - .60
Head Porter	*	.40 - .60
Porters	.20 - .30	.23 - .40

* Classifications not previously noted.

Thank you very much.

Sincerely,

Ralph F. Willy
The Upjohn Company

John H. Conlin
Parke, Davis & Company

Copies:
(1) John H. Conlin
(1) Ralph F. Willy
(1) Gordon Kropp

June 22, 1965

George A. Kropp, Warden
State Prison of Southern Michigan
Jackson, Michigan

Dear Sir:

Since the joint research facilities of Parke Davis and Upjohn Clinics have been in operation for over a year, we find it necessary to re-evaluate the pay scale for inmates working in the clinics. We offer the following reasons:

On occasion, we have found it difficult to hire inmates with the qualifications we require, because it is possible for these men to get equal or more pay for fewer hours of work and less personal responsibility. The standard of performance of the companies must, in turn, be required of inmate help in the clinics. The Industries, Computer Center, and Psychiatric units recognize the performance of their inmate employees with higher pay.

The working hours are, of necessity, longer than those considered normal by other assignments. Such hours are recognized by the State Industries with special pay awards.

After joint consultation and considerable discussion in these related matters, we offer this suggested daily pay scale in hopes that it will meet with your approval:

Job Classifications:	Approved Pay Scale April, 1964	Suggested Pay Scale
Chief Technician	.75 - 1.00	
- in each classification	*	.75 - 1.25
Trained Technician	*	
- in all classified areas	*	.50 - .75
Technician Trainees	.35 - .55	
- in all classified areas	*	.35 - .50
Chief Clerk	.75 - 1.00	.75 - 1.25
Clerks	.35 - .55	.40 - .75
Clerk, Mrs' Room	*	.40 - .75
Nurse Supervisor	*	.50 - 1.00
Nurse	.30 - .50	.30 - .50

(Continued)

It is necessary to delegate responsibility to the inmates. However I don't believe there are any examples of delegated responsibility which are unique to the UPJOHN Clinic.

In one respect, the relationship of the Inmate employees to the UPJOHN Clinic is unique - the Clinic demands, of necessity, standards of performance which are similiar to those maintained at the UPJOHN Company. Our work at the Clinic would have little value if this cannot be done.

RESPONSIBILITIES OF CUSTODIAL OFFICERS - in the Clinic - The UPJOHN Clinic as a Custodial Post is a real challenge - Building design, large staff, large numbers of subjects, a great variety of "situations" involving security, clinical emergencies, and administration problems.

The Clinic recognizes and insists that the primary duty of the officers is Custody. And any requests or suggestions made by the officers and their superiors will be respected.

Frequent inspections are requested for our mutual security. No "courtisies" are expected. It might be helpful if a special officer be assigned the task of inspection of technical materials - i.e. drugs, needles, etc., so that he could be introduced to our system of inventory - this would make inspection more meaningful.

SUMMING UP - Mutual satisfaction for the operation of the UPJOHN Clinic requires close cooperation and understanding. Anything which we can do to help will be done. Perhaps a meeting with some of the Captains, Inspectors, and Officers would be profitable.

Unrelated to the discussion above, but affecting the operation of the Clinic, was Dr. Varley's information that in addition to the administrative assistant we will have two more civilians working full time at the Clinic within a year - an M.D.-Ph.D. and a Lab. Technician. It is a little uncertain when these men will be hired and installed. The M.D. probably by June, and the Lab. Technician in September.

I thank you for your attention.

Sincerely,

R. F. Willy

R.F. Willy,
UPJOHN Clinic
Administrator

Dec. 11,1965

Mr. Robert Beaco
Finance Officer
Department of Correcticns
Steven T. Mason Bldg.,
Lansing Michigan

Dear Mr. Beaco:

Operation of Upjohn and Parke
Davis Laboratories at SPSM

The two drug firms have been operating laboratories at the Prison of Southern Michigan under an agreement which calls for them to pay for the expenses of operating and maintaining the laboratories. Since March 1964 reimbursements to the Prison for expences paid by it in the first instance have been handled in accordance with a tentative Draft of principles issued by Mr. Powers. The purpose of this letter is to finalize these principles and make them a matter of record.

The principles on which certain expenses will be paid and reimbursements credited are as follows:

I. Protocol committed members:
Fee for members of committee to be handled through Correcticns Department Control Office. Gifts,bequests and donaticns account will be used. Drugs firms will pay to Central Office. Central Office will pay committee members.

II. Inmate Volunteers

Drug firms will pay directly into State Prison of Southern Michigan inmate accounts for the individual volunteer. Procedure is the same as that presently in effect.

III. Inmate wages for clerks,nurses,janitors,etc.

State Prison of Southern Michigan will include on regular inmate payroll and credit inmates' accounts. Will bill drug firms,collect and deposit with State Treasurer. Will be classified as expenditures credits.

EXHIBIT G-2

IV. Custody

A. On overtime basis: Pay custodial staff on regular payroll. Must have Civil Service Commission's approval. Bill drug firms, collect and deposit with State Treasurer. Gross salaries will be classified as expenditure credit, object code 120. No charge will be made for State's contribution for sponsored insurance. Bill drug firm for 9.8% for 1963-64 and 1964-65 of gross salaries to cover State's financing of Civil Service and retirement. This will be collected, deposited and credited to receip account 107-113-941.

B. Additional staff on full time basis: Handle as for overtime, and in addition bill drug firms for contribution for sponsored insurance, collect, deposit and classify as expenditure credit.

V. Utilities

Drug firms will be billed and money deposited with the State Treasurer. Rates, procedure and credits are shown below:

A. Electricity and gas for the laboritios are metered separately.

Rates will be those charged by Consumers Power.

Currently, deposit to credit of SPSH Misc. revenue account. At the end of the fiscal year, expenditure credit will be allowed for the annual total, but not to exceed the amount SPSH is Charged by MSU, if any, on the annual settlement for MSU consumption of electrical energy and gas.

B. Cold water and sewerage

Rates will be those charged by the city.

Credit will be to miscellaneous revenue.

C. Hot water for consumption.

Rates will be cold water rate plus softner salt and fuel for heating.

Expenditure credit will be given for salt and fuel. Portion representing cold water will be credited to miscellaneous revenue.

D. Heating (not hot water)
Rate will be established after consultation with Building Division. Portion of reimbursement representing fuel will be expenditure credit, balance will be miscellaneous revenue.

We understand that the two Laboratories are installing flow meters for the measurement of BTU's and water consumed for heating each laboratory. After this has been accomplished and a formula worked out with the Building Division to determine the amount and value of fuel represented in the BTU'S consumed, we would like Mr. Swanson to so advise us.

Very truly yours,

/
P. H. McLaury, Director
Accounting Division

cc: A.E. Swanson State Prison
R. Cooley, Building Div.
W.A. Neumann, Pre-Audit
Procedures File

In addition, three determinations of FBS will be performed at weekly intervals to ascertain that the level of fasting true glucose is < 100 mg%.

b. On days prior to treatment, i.e. Day 0, Day 7, and Day 14: all subjects will start fast at 4:00 pm.

c. On the days of drug administration, i.e. Day 1, Day 8, and Day 15: all subjects will remain in the fasting state through 4:00 pm. True blood glucose will be determined at 5:00 am, 6:00 am, 7:00 am, 8:00 am, 10:00 am, and 12:00 noon, 2:00 pm and 4:00 pm. Drug will be administered as a single dose of four tablets at 6:00 am and subjects will continue fasting thereafter being allowed only intake of water.

The overall scheme of the study may be outlined as follows:

	WEEK			DAY					
	-3	-2	-1	0	1	7	8	14	15
BS	+	+	+	Fast - 4 pm	BSx8 Rx - 6 am End Fast - 4 pm	Fast - 4 pm	BSx3 Rx - 6 am End Fast - 4 pm	Fast - 4 pm	BSx8 Rx - 6 am End Fast 4 pm
SGPT			+						
Total Bilirubin			+						
Alkaline Phosphatase			+						

PRECAUTIONS

Since the dose of Pyrazinamide administration here is within the recommended range for clinical use, it is not felt that any unusual reactions need be anticipated in this essentially single dose experiment. However, the subjects should be carefully followed and any untoward reactions reported. As is known, Pyrazinamide is hepatotoxic after prolonged administration at 2-3 gm day; it is not anticipated that any difficulties along these lines will be encountered in this acute experiment. If there is evidence of adverse effect on the liver, then the liver battery should be performed again at the end of treatment and repeated at intervals until liver-function tests return to normal.

H. V. Demissianos, M.D.

H. Oster, M.D.

R. E. Medlar, M.D.

HVD:hb
5-6-66

~~Re: Clinic~~
Mr. Conlin ons

7-14-6

This report is a follow-up to the meeting held in the Parke, Davis Clinic on March 12, 1964, and is intended to cover matters which were discussed at the time of that meeting. The participants in the March 12 meeting were:

Dale K. Boyles - Parke, Davis & Co.
John H. Conlin - " " "
Dr. A. Z. Lane - " " "
Dr. Carl Slaglo - The Upjohn Co.
Ralph F. Willy - " " "
George A. Kropp - Southern Michigan Prison
Dr. F. W. Bartholic - " " "
A. R. Swanson - " " "
John White - " " "
Gus Harrison - Department of Corrections
R. M. Doase - " " "

1. Custodial Coverage

Custodial coverage will be provided by regular prison personnel working on an overtime basis. Charges to the companies will be on a straight pay basis to which will be added a billing of 9.2% of gross salaries to cover the State's financing of Civil Service and Employees' Retirement.

If it should ever be necessary to acquire additional staff on a full-time basis, this would be handled the same as for overtime, except that it would be necessary also to bill the companies for sponsored insurance and any other applicable fringe costs.

2. Inmate Volunteers

Attached is a schedule of currently approved research activities including the amounts to be paid for inmate participation. The companies will pay directly into the appropriate inmate account.

3. Inmate Pay

The following rates of pay have been established for inmates assigned to clinic jobs:

Porters	20¢ to 30¢ per day.
Clerks	35¢ to 55¢
Chief Clerk & Technicians	75¢ to $1.00
Technician Trainees	35¢ to 55¢
Cook	25¢ to 55¢
Maintenance Man	30¢ to 50¢
Nurses	30¢ to 50¢

It is assumed that new help will always be started at the bottom of the range.

EXHIBIT C-3

Following is a report of the meeting held in the office of the Director of Corrections on February 25 to discuss the operation of the Medical Research Clinics at Southern Michigan Prison.

Present were:

Dale E. Boyles - Parke, Davis & Co.
John M. Conlin - " " " "
Dr. A. Z. Lane - " " " "
Dr. Alan B. Varley - The Upjohn Co.
Ralph F. Milly - " " "
George A. Kropp, Southern Michigan Prison
Dr. F. W. Bartholic - " " "
A. R. Swanson - " " "
John White - " " "
Gus Harrison - Department of Corrections
R. M. Cease - " " "

1. Custodial Coverage

All parties agreed it will be more satisfactory to have security personnel provided by the prison. It was felt that each building should have one officer assigned during the morning and afternoon shifts. At night, perhaps one officer can cover both Clinics. It was understood this would apply on a 7 day week basis.

The Department of Corrections will work out a schedule of custodial coverage and a suggested plan of reimbursement. This will be reviewed with the companies.

2. Inmates

Clinical personnel - estimated needs for the start of operation were 7 inmates for Parke, Davis and 15 to 20 for Upjohn. Both companies understand they will have to go through the Classification Committee for inmate help. Both companies will reassess their inmate needs and advise the Department of Corrections.

Reimbursement - Department of Corrections will work out an inmate pay schedule which will be equitable and workable. The companies will make out inmate payrolls and submit them to the prison business office where they will be credited to the appropriate inmate accounts. A copy of the same payroll will be processed through the companies' business offices to serve as the basis for reimbursing the institution.

Volunteers - 2 panels will be compiled - the healthy and the restricted. The roster of healthy inmates will come from volunteers who will be cleared by the prison hospital on a medical basis only. The restricted panel will be supplied by the hospital at the companies' request. Both companies will draw inmates from one central roster or pool - always, if possible,

EXHIBIT - G-4

JOB DESCRIPTION

Staff Physician - Jackson Prison Research Clinic

OBJECTIVES

The primary objectives of the staff physician assigned to the Jackson Prison Research Clinic are:

1. To develop this direct clinical testing unit of the Upjohn Clinical Pharmacology Group into a capable, trained and experienced clinical pharmacology unit.

2. To expeditiously supervise the testing and evaluation of new Upjohn drugs appropriate to study at this institution.

3. To devise new methods for clinical pharmacologic evaluation of new drug entities.

4. To develop mutual liaison between the clinical pharmacology unit at the Jackson Prison Research Clinic and the clinical pharmacology units of one or more university medical centers.

RESPONSIBILITIES

1. Primary responsibility is to the research project at the Research Clinic to assure that protocols are appropriate, well designed and meaningful and meet standards of safety and ethics of community.

2. Responsibility to develop a capable, appropriately trained and expert clinical pharmacology staff--both inmate and civilian.

3. Responsibility to the Jackson Prison Administration--to assure that Clinic is operated according to security and personnel and administrative policies of the Jackson Prison Administration.

4. To develop new methods for evaluating and screening new drug candidates.

5. To supervise the actual running of studies designed by other members of the Upjohn Medical Staff as requested by the Medical Staff.

6. To represent Upjohn at Protocol Review Committee meetings and at Prison administrative meetings.

7. To develop an original clinical research program and make original contributions.

AUTHORITIES

1. Final Upjohn review of all protocols run at Prison.

2. Scheduling all studies conducted at the Jackson Prison Research Clinic.

EXHIBIT - H

3. Medical judgments during study—for stopping a drug or discontinuing a study for safety or other reason.

4. For hiring and releasing of inmate help.

5. To represent the Company to Prison Administration and the Protocol Review Committee.

ABV:pko
2-8-65

STATE OF MICHIGAN

DEPARTMENT OF CORRECTIONS

STATE PRISON OF SOUTHERN MICHIGAN
4000 Cooper Street
Jackson, Michigan
49201

GEORGE ROMNEY
GOVERNOR

December 3, 1965

COPY

Mr. F. M. McLaury, Director
Accounting Division
Department of Administration
Lansing, Michigan

Attention: Mr. Donald L. Powers

Gentlemen: Subject: Heating charges to Parke-Davis and Upjohn Clinics

When arrangements were originally made in March, 1964 for charging these drug firms for heat furnished their clinic buildings, it was of necessity based on amount of fuel consumed, because of absence of BTU meters.

BTU meters have now been installed and we have the readings on that basis for the month of November. We would, therefore, like to have you advise us as soon as possible what the rate of charge should be, and how distributed as to accounts. Perhaps Mr. Ralph Seeley of the Building Division should be consulted.

Will you kindly advise us as soon as possible?

Very truly yours,

STATE PRISON OF SOUTHERN MICHIGAN

A. R. Swanson
Business Manager

ARS/cl
cc: Mr. Bosco
Mr. Conlin
Mr. Willy

EXHIBIT - I

August 16, 1965

To: Inmate Employees, Research Clinics

Effective: August 16, 1965

Any inmate-employee assigned to the Upjohn or Parke, Davis Clinic who is off assignment for a period exceeding three days shall not be compensated at his daily rate of salary, starting with the first day of the absenteeism.

Examples effecting this policy are:

Custodial detention

OO'd from assignment

Clinic Check-in Studies

Ralph F. Willy
Upjohn Clinic

John H. Conlin
Parke, Davis Clinic

File - Clinic Parke Davis - Foreman

RFW/rhj
cc: John H. Conlin

EXHIBIT - J

TO: BLOCKS, 5 - 1 - 12 - 4 - 6

SUBJECT: UP-JOHN CLINIC PROTOCOL #56

Each of the above blocks recently received a letter from Mr. Willy, Up-John Clinic Adm. regarding the medicating of certain inmate's in the block. This is being done to eliminate some traffic and a list of names and numbers of those to be medicated is attached hereto.

An inmate employee of the Clinic who locks in the block has been designated to do the medication and details covering his release at the proper time have been completed. He will pick up the medication at the Clinic and return to the block to medicate the inmate's designated.

Slager, #6180, 9A-3-5 --- in 5-block.
His present detail permits an unlock to medicate the men at 5:00 A.M. and 9:30 P.M.

Grienillo, #89479 - 20-4-12 - in 12-block.
Details have been issued for him.

Brown, #96773, 19-2-11 -- in 11-Block.
Details have been issued for him.

This procedure will begin at 5:00 A.M., Monday, June 28th, and custodial personnel will be expected to cooperate fully.

M. S. Kipcher

Deputy Warden

cc: Captain Chamberlain - 6-2 Shift
Captain Baldwin 2-10 Shift
Captain Jackson 10-6 Shift
Mr. Willy, Up-John Clinic.
File

February 22, 1966

Mr. Gerald Hansen,
Director of Inmate Affairs
SPSM

Dear Mr. Hansen:

The Upjohn Company, in pursuit of our program of offering special training programs to the inmates of our employment, has enrolled Mr. Holnagel #107254 and Mr. Barry #71212 in the RCA Home Study Course No. I, Electronics.

The Upjohn Company has assumed the entire cost of this program.

Sincerely,

Ralph F. Willy,
Administrator-
Upjohn Clinic

rm

cc: File

EXHIBIT-L

INTEROFFICE MEMORANDUM

COPIES TO:

TO: L. A. LeZotte

SUBJECT: September 29, 1966, Meeting With Gus Harrison

WJHessler

FROM: A. B. Varley

DATE: October 3, 1966

At the meeting on September 29 with Gus Harrison, the subject of gifts to inmates and Department of Corrections personnel was brought up by Mr. Harrison. While I am sure that we have not been guilty of this practice, I think it would be worth reemphasizing again the conclusions I reached from Mr. Harrison's comments:

1. There shall be no gifts of any kind given to either inmates or State personnel for their participation in any way with our research program. This includes candy and cigars at Christmas time.

2. The State is particularly sensitive about distribution and even, I suspect, possession of cigarettes by inmates working in our building or on our research studies. I think that we should be particularly cognizant of this inasmuch as cigarettes are a medium of exchange within the Prison.

3. Coffee to inmates assigned to work in our building is permissible. I understand that it is a Parke-Davis policy not to make coffee available to outpatients in the building for study purposes only, and I believe it would be well for us to follow a similar policy.

4. Lunches for State employees if not excessively frequent and when clearly in the line of business are permissible.

5. I gather that Parke-Davis throws some kind of an annual banquet for some of the State personnel working or involved with their research program. If this can be done in a legitimate way as an information-disseminating function, it is permissible in Harrison's opinion.

Our discussion also led me to conclude that we should have a file here in Kalamazoo containing copies of all letters and memos which originate at Jackson and which pertain to the function of our unit. Would you arrange to have a copy of such documents forwarded to Kalamazoo and have Margo set up a file system so that we can have a complete record of all transactions and communications from Jackson.

Finally, I wonder if you would begin to consider what civilian personnel we would need to run the Jackson unit efficiently if inmate labor is in the future denied us as a result of the present Federal Minimum Wage litigation. It is Mr. Harrison's opinion that they could continue to supply us with inmate help for maintenance inasmuch as the building is the property of the State.

pko

EXHIBIT - M

Exhibit M

CLINICAL PHARMACOLOGY PHASE I

State Prison of Southern Michigan

Protocol No. 88, Jackson, Michigan

U-21,251F (7-Chlorolincomycin Hydrochloride) - Protocol No. 002

Single Dose Blood Level, Urinary Excretion and Fecal Excretion Study

INVESTIGATORS:

H. L. Oster, M.D.
R. E. Medlar, M.D. Jackson, Michigan

MONITOR:

	Phone	Home
J. G. Wagner, Ph.D.	616, 345-3571 Ext. 7689	616, FI 9-4689

PURPOSE:

To compare serum levels, urinary excretion and fecal excretion following 250 and 500 mg. single oral doses of 7-chlorolincomycin hydrochloride and 500 mg. single oral doses of lincomycin hydrochloride in different subjects than employed in the previous Protocol 001 (SPSM Protocol No. 71) study. This study is desirable before proceeding to multiple dose studies in man which will require more extensive animal toxicology than presently available.

INTRODUCTION:

In the previous Protocol 001 (SPSM Protocol No. 71) study U-21,251F was administered in increasing doses (5-500 mg.) to thirty-six normal male volunteers to determine the single dose tolerance, serum levels, urinary excretion and fecal excretion.

No consistent gross changes in vital signs (temperature, pulse, blood pressure and respiration) were observed and no statistically significant differences from lincomycin were found. Headache occurred in nine subjects (seven on U-21,251F and two on placebo). Four subjects treated with a single oral dose of 500 mg. (two on U-21,251F and two on lincomycin hydrochloride) were noted to have a loose stool. One subject treated with a single dose of U-21,251F had mild abdominal cramps thirty minutes after drug administration. No other evidence for toxicity or untoward side effects were observed.

The significantly higher peak serum level response, the significantly greater urinary excretion of bioactivity and the significantly lower fecal excretion of bioactivity following U-21,251F compared with lincomycin hydrochloride in the 001 Study suggested that U-21,251F should be investigated further.

Exhibit A1

Protocol No. 96
Author: H.V. Demiesianos, M.D.
Investigator: H. Oster, M.D.
R.E. Medlar, M.D.

Hypoglycemic Activity
Pyrazinamide - Orinase

State Prison of Southern Michigan
Jackson, Michigan

The purpose of this study is to evaluate in an acute experiment the possible hypoglycemic effect of Pyrazinamide. This drug is currently marketed for the treatment of tuberculosis. Experimental work in our laboratory shows that it and its analogues produce hypoglycemic activity in animals; we would like, therefore, to know if Pyrazinamide itself acts similarly in man.

SUBJECTS

Thirty-six healthy adult volunteers will be selected from among the prison population of the State Prison of Southern Michigan. They should not be diabetic and should consistently demonstrate a FBS < 100 mg%. Moreover, it should be emphasized that these subjects have normal liver function tests (SGPT < 35; total bilirubin < 1 mg; alkaline phosphatase < 12 K.A.). Subjects will be assigned to three equal groups of twelve each and will be matched so that the means of FBS levels of the three groups are as similar as possible.

PLAN OF STUDY

The overall plan of the study is as follows:

	DAY OF Rx				
	1	2-7	8	9-14	15
Group I	Pyrazinamide 2 gm.	nil	Placebo	nil	Orinase 1 gm.
Group II	Placebo	nil	Orinase 1 gm.	nil	Pyrazinamide 2 gm.
Group III	Orinase 1 gm.	nil	Pyrazinamide 2 gm.	nil	Placebo

The medication will be administered as a single dose of four capsules on each treatment day and in double blind fashion.

EXPERIMENTAL PROCEDURES

a. Screening prior to entry into the study: all subjects will be screened for normal liver functions -

SGPT
Alkaline Phosphatase
Total Bilirubin

SUBJECTS:

Fifteen normal adult male volunteers with no known gastrointestinal or renal disease who are non-obese (weighing 130-200 lbs.) and between the ages of 21-40 with normal vital signs will be selected.

Vital Signs	Normal Range
Temperature	$<100.6^{o}F$
Pulse	60-100
Respiration	10-20
BP	90/50 to 140/90

All subjects should have received no medication for 30 days preceding the study. Subjects should be assigned numbers 1 to 15 randomly and divided into 3 groups; namely, 1 to 5, 6 to 10 and 11 to 15. The prison number, initial and surname, body weight, age, height, body build and race of each subject should be written opposite these subject numbers on the attached report form #1.

Note: If a subject is absent for any collection or drops from the study inform J. G. Wagner by phone immediately.

MEDICATION:

A - H.F.C. U-21,251, 250 mg. (as the hydrochloride) - One (1) capsule
B - H.F.C. U-21,251, 500 mg. (as the hydrochloride) - One (1) capsule
C - H.F.C. Lincocin, 500 mg. (as the hydrochloride) - One (1) capsule

DOSAGE SCHEDULE:

Group	Subjects in Group	Week I	Week II	Week III
1	1, 2, 3, 4, 5	A	B	C
2	6, 7, 8, 9, 10	B	C	A
3	11, 12, 13, 14, 15	C	A	B

STUDY CONDITIONS:

Subjects will fast overnight and for four hours post administration of medication. "Fasting" includes not only the absence of food, but also no other beverage than water.

Each capsule should be taken orally with 6 fl. oz. of water at zero time.

There will be one week elapsed time between treatments.

Water may be taken ad lib up to one hour prior to drug ingestion, but only the prescribed 6 fl. oz. of water (taken with the capsule) should be taken from one hour prior to drug ingestion to four hours post drug ingestion. From 4 hours post drug administration beverages and food may be taken ad lib. Breakfast may be provided at The Upjohn Clinic if necessary.

Smoking is permitted.

The subjects should be in The Upjohn Research Clinic wards during the 4-day collection period of feces if at all possible.

The subjects should not engage in any hazardous or strenuous occupations or athletic activities during the day of, or on the day following drug administration.

SAMPLING:

It is vitally important to collect all samples scheduled. Any failure to do so should be immediately reported to J. G. Wagner by phone.

Blood: 50 ml. of blood should be withdrawn at zero time in each phase of the crossover from each subject. It is vitally important that 25 ± 5 ml. of serum be shipped to The Upjohn Company from this zero time drawing for each subject for each treatment. Ten (10) ml. of blood is to be taken at 3/4, 1-1/2, 3, 4-1/2, 6, 8, 10, 12 and 14 hours post administration. Serum is to be harvested from all bloods and the serum frozen. Frozen serum should be shipped to W. C. Bell for transfer to C. G. Chidester (783-41-2).

Urine: The bladder must be emptied at zero time; the pH of this zero hour urine should be determined immediately and recorded. Then the urine collections may be discarded.

Two 24-hour urines are to be collected (0-24 and 24-48 hours) in polyethylene containers containing one milliliter of toluene as preservative. The bladder must be emptied at 24 hours post dosing and this urine added to the 0-24 hour collection. The bladder must be emptied at 48 hours post dosing and this urine added to the 24-48 hour collection. Urine should be stored in the refrigerator at 4°C until the final volume for each collection is obtained.

At the end of each collection period, the urine collection should be mixed by rotation of the capped bottle, the pH and volume determined and recorded on the attached report form #2 (there is one page for each week); a 20 ml. aliquot of each urine collection should be frozen and shipped to W. C. Bell for transfer to C. G. Chidester (783-41-2) for bioassay. The remainder of each urine collection should be frozen and shipped to W. C. Bell for transfer to T. E. Eble (711-25-4) for possible attempted isolation of metabolites.

Feces: Subjects should be encouraged to have a bowel movement in the morning prior to dosing but no laxatives are to be employed. All stools will then be collected quantitatively for 4 days (96 hours) post dosing. Stools must be collected in plastic bags and the stools frozen in the bags. The stools for each subject for each period (0-24, 24-48, 48-72 and 72-96 hours) and each treatment should be packed in individual cardboard containers. For example, if subject #1 had two (2) bowel movements during the 0-24 hour period after treatment A on Week I then these two stools should be in

separate polyethylene bags, but both of these bags should be frozen and placed in the same cardboard container for shipment. Subjects should be encouraged to have a bowel movement in the morning of the fourth day before the termination time (96 hours) but again no laxatives are to be employed.

All frozen fecal samples should be shipped to W. C. Bell for transfer to C. G. Chidester (783-41-2). The time and character of bowel movements should be recorded on report form #3 (there is a separate page for each week). See instructions for completing report form #3 with the forms.

LABELING OF SAMPLES:

Each container of serum, urine and feces should be clearly labeled with subject number (1 through 15), treatment (A, B or C), week (I, II or III) and time or time period of collection. Care should be taken that all numbers are legible and the legibility and accuracy of the labeling of each item should be checked by at least two people.

SIDE EFFECTS:

Subjects should be questioned at 2 and 4 hours post administration of medication to determine if there are any side effects of the medication. The question asked should be - "Have you noticed any effects of the medication?" Please report these side effects or absence of side effects on the attached report form #4.

SUPPLIES:

Capsules: J. G. Wagner to Dr. L. A. LeZotte or R. Willy.

These will be available on or before March 16, 1966.

John G. Wagner Feb 22, 1966

John G. Wagner, Ph.D., F.C.P.C. Date

bw

Filed: Nov. 9, 1970

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

CALVIN SIMS, et al,

Plaintiffs,

vs.

PARKE, DAVIS & COMPANY, A Michigan Corporation, and THE UPJOHN COMPANY, a Delaware Corporation, et al,

Defendants.

CIVIL ACTION NO. 31172

AFFIDAVIT OF GAYLORD LEE ESPICH IN SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND PLAINTIFFS' ANSWER TO DEFENDANTS' MOTIONS FOR SUMMARY JUDGMENT UNDER COUNTS I, III AND IV OF PLAINTIFFS' COMPLAINT AND AMENDED COMPLAINT

STATE OF INDIANA:
SS:
COUNTY OF Allen

GAYLORD LEE ESPICH, being first duly sworn, deposes and says as follows:

1. This Affidavit is made upon the basis of the personal knowledge of Affiant of the following matters and Affiant is competent to testify to the matters stated herein.

2. Affiant is one of the main Plaintiffs herein and has worked in the drug clinic buildings constructed by The Upjohn Company at the State Prison of Southern Michigan. Furthermore, he is familiar with some of the other named Plaintiffs and other inmates of said prison who worked in the said clinic.

3. Representatives of Defendant, The Upjohn Company, personally approved all inmates who worked at the said clinic and persons could not work there unless they were so approved.

4. Inmates who were not working at one of the drug company clinics and who were involved in prison jobs doing piece work could make more money at such a job than was earned by the inmates working at the clinics.

LAW OFFICES
LEITSON, DEAN, DEAN, SEGAR, & HART, P.C.
1616 GENESEE TOWERS
ONE E. FIRST STREET
FLINT, MICH. 48502
235-5631

5. Inmates who utilized their individual skills for such things as painting pictures were allowed to sell them and keep ~~XXX~~ the money representing the proceeds from such sale. Further, the prices for such articles as pictures or handicraft items were set by the inmates who produced said articles.

6. Affiant had advanced education and laboratory experience prior to being ordered to work in the clinic for Upjohn, and his experience and ability were of great value to The Upjohn Company.

7. Part of ~~/XX~~ the time Affiant was employed by Upjohn there were work release programs in existence which paid far more to those prisoners placed thereon than could be earned by those prisoners working at the clinics.

Gaylord Lee Espich
Gaylord Lee Espich

Subscribed and sworn to before me, a Notary Public, this 27th day of October, 1970.

Jacqueline Jo Groves
Jacqueline Jo Groves
Notary Public, Allen County
My Commission Expires: 8-10-71

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Filed Jan. 5, 71

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS, RALPH R. WARNER, RONALD D. KENNEDY, PAUL ROSS, HERMAN HEAD, GERALD G. NORMAN, PAUL MILLER, THOMAS U. MULLIGAN, LONNIE PAYNE, ROBERT MASON, and KENNETH R. MARSHALL,

Plaintiffs,

vs.

Civil Action
No. 31172

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C. J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants.

MEMORANDUM OPINION

Plaintiffs were convicted of crimes under the laws of Michigan and are serving, or have served, terms in the State Prison of Southern Michigan, at Jackson, Michigan, (hereafter referred to as Jackson Prison). Two of the defendants, Parke Davis & Company and The Upjohn Company, are private corporations engaged in the interstate manufacture of drugs. A third defendant, the Department of Corrections of the State of Michigan, has "exclusive jurisdiction over . . .: (c) penal institutions. . . prison labor and industry. . ." Mich. Com. Laws §791.204. The defendants Eleanor Hutzel, James E. Wadsworth, Ernest C. Brooks, Max Biber, C. J. Farley,

John W. Rice, Duane L. Waters, Florence Crane, Joseph J. Gross and G. Robert Cotton are, or were, members of the Michigan Corrections Commission which supervises the Department of Corrections. Mich. Com. Laws §§ 791.201-791.203. The defendant Gus Harrison is Director of the Department of Corrections. Jurisdiction is based upon Title 29 U.S.C. § 216(6); Title 28 U.S.C. §§ 1337, 1343; and Title 42 § 1983.

The background facts giving rise to the present complaint are not in dispute. In November of 1963 the Michigan Department of Corrections entered into two separate agreements with defendant Upjohn Company and defendant Parke Davis & Company. Pursuant to those agreements, each drug company was permitted to construct, at its own expense, ". . . a Clinical Research Building at the State Prison of Southern Michigan." Both buildings were subsequently completed and, under the terms of the contracts, became "the property of the State of Michigan," with the defendant drug companies retaining the right to use the buildings they constructed "for clinical research so long as clinical research is conducted by any organization or corporation at the State Prison of Southern Michigan."

The "clinical research" presently carried on in those buildings involves the testing of drugs on volunteers among the Jackson inmates. The plaintiffs, however, and the class plaintiffs seek to represent, were not used as subjects in drug experiments; instead, they performed various services in connection with the operation of the clinics. Those services were grouped together under the following job classifications:

Parke Davis & Company

Classification:	Services Performed:
Chief Clerk	Preparation of prison details
Clerk	Double check labels
Chief Cook	Cooking and other kitchen duties
Head Porter	Janitor and Messenger
Maintenance Man	Maintenance and minor repairs
Porter and Nurse Supervisor	Night Janitor and Attendant

The Upjohn Company

Classification:	Services Performed:
Chief Technician	Performs specific tasks such as operation of EEG machine
Technician	Same as above
Technician Trainee	Same as above
Chief Clerk	Clerical tasks
Clerk	Clerical tasks
Nurse Supervisor	Acts as nurse in connection with clinical tests
Nurse	Same as above
Chief Cook	Cooks and serves food
Cook	Same as above
Kitchen	Assists in kitchen
Kitchen Pot and Pan	Assists in kitchen
Maintenance Man	Maintenance and minor repairs
Head Porter	Janitorial tasks
Porter	Janitorial tasks

Plaintiffs allege that they, as well as other Jackson inmates, were forced by "defendants Parke Davis & Company and The Upjohn Company in conjunction with representatives of the Michigan Department of Corrections" to work in those classifications "on a regular basis up to as much as one hundred twelve (112) hours per week" at wages ranging "from Thirty-Five ($0.35) to One Dollar and 25/100 ($1.25) per day."

On the basis of these allegations, plaintiffs conclude in Count I of their amended complaint that they are entitled to recover from the defendant drug companies the difference between the compensation received for their labor and the minimum wage prescribed by the Fair Labor Standards Act of 1938 (FLSA), as amended, 29 U.S.C. § 201 et seq. In Count II of their amended complaint, plaintiffs contend that if the Fair Labor Standards Act is found to be inapplicable, then plaintiffs are entitled to recover from the defendant drug companies the difference between the compensation they received for their labor and the minimum wage as prescribed by the Michigan Minimum Wage Law of 1964, Mich. Com. Laws § 408.381.

Count III of the amended complaint alleges that the utilization of the plaintiffs' labor by the drug companies is illegal under Section 800.305 Mich. Com. Laws and "has resulted in . . . the unjust enrichment of Defendants [drug companies] in the amount by which the reasonable value of Plaintiffs' services exceeds the amount paid by Defendants to Plaintiffs." Plaintiffs also contend in Count III that the "Defendants other than Parke Davis & Company and The

Upjohn Company have been unjustly enriched. . . from the illegal use of Plaintiffs' labor by the acquisition for the State Prison of Southern Michigan of a building (i.e., the structure housing the clinic.)".

In Count IV, plaintiffs allege that "the illegal utilization. . . of Plaintiffs' labor by all Defendants and the payment by Defendants Parke Davis & Company and The Upjohn Company of nominal wages less than those required by law" has resulted and is resulting in: (1) deprivation of the property of plaintiffs without due process of law; (2) the holding of plaintiffs in involuntary servitude contrary to the Thirteenth Amendment to the Federal Constitution; and (3) the denial to plaintiffs of equal protection of laws as guaranteed by the Fourteenth Amendment. For these alleged violations of their Constitutional rights, plaintiffs seek one million dollars in damages from defendants.

Plaintiffs have now filed a motion for summary judgment on Count III. The defendants Upjohn Company and Parke Davis Company have, in turn, filed motions for summary judgment on Counts I, III, IV; a motion to dismiss Count II as failing to state a claim upon which relief can be granted; and a motion for an order that plaintiffs' action cannot be maintained as a class action. Defendant Department of Corrections, its Director, and the members of the Corrections Commission have also filed a motion to dismiss the complaint as to them. All of these motions are now before the court.

PARKE DAVIS AND UPJOHN'S MOTION
FOR AN ORDER THAT
PLAINTIFFS' SUIT CANNOT BE MAINTAINED AS A CLASS ACTION

In their complaint, plaintiffs state:

> "There are numerous other people who either are or have been inmates in the State Prison of Southern Michigan at Jackson, Michigan, who have the same cause of action as hereinafter set forth on the part of the named Plaintiffs, and the named Plaintiffs adequately represent such unnamed people. This action is brought pursuant to Rule 23 A of the Federal Rules of Civil Procedure on behalf of all such people whose number make it impractical to have them join as Plaintiffs. The named Plaintiffs adequately represent said class."

Defendant Upjohn Company, however, has filed a motion for an order declaring that the present case cannot be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure.

Rule 23 requires a plaintiff who wishes to bring a class action to overcome two hurdles. First, he must satisfy all the conditions of Rule 23(a), which are:

> "(1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class."

After satisfying the court that all the conditions of Rule 23(a) have been met, the litigant must establish that his action is appropriate under one of the three subdivisions of Rule 23(b). Rule 23(b) provides that:

> "(b). . . An action may be maintained as a class action if the prerequisites of subdivision (a) are satisfied, and in addition:
>
> (1) the prosecution of separate actions by or against individual members of the class would create a risk of
>
> (A) inconsistent or varying adjudications with respect to individual members of the class which would establish incompatible standards of conduct for the party opposing the class, or
>
> (B) adjudications with respect to individual members of the class which would as a practical matter be dispositive of the interests of the other members not parties to the adjudications or substantially impair or impede their ability to protect their interests; or
>
> (2) the party opposing the class has acted or refused to act on grounds generally applicable to the class, thereby making appropriate final injunctive relief or corresponding declaratory relief with respect to the class as a whole; or
>
> (3) the court finds that the questions of law or fact common to the members of the class predominate over any question affecting only individual members, and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy. The matters pertinent to the findings include: (A) the interest of members of the class in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already commenced by or against members of the class; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; (D) the difficulties likely to be encountered in the management of a class action."

Once a plaintiff has demonstrated that his suit comes within the requirements of Rule 23, he can then pursue the action not only on his own behalf, but also on behalf of all other

persons similarly situated, although those persons are not parties to the litigation.

Claims for minimum wages under the Fair Labor Standards Act, however, cannot be maintained as a class action under Rule 23. That is because 29 U.S.C. § 216(b) limits the binding effects of a judgment adjudicating rights under the FLSA to persons who have filed a written consent to become parties to the suit:

> "Any employer who violates the provisions of section 206 or section 207 of this title shall be liable to the employee or employees affected in the amount of their unpaid minimum wages, or their unpaid overtime compensation, as the case may be, and in an additional equal amount as liquidated damages. Action to recover such liability may be maintained in any court of competent jurisdiction by any one or more employees for and in behalf of himself or themselves and other employees similarly situated. No employee shall be a party plaintiff to any such action unless he gives his consent in writing to become such a party and such consent is filed in the court in which such action is brought. . . ." (Emphasis added.) 29 U.S.C. § 216(b).

Hence, plaintiffs concede that since Count I of their complaint alleges a claim under the FLSA, it cannot be maintained under Rule 23, and those inmates not filing written consents can neither benefit from nor be bound by any judgment rendered on Count I.

Nevertheless, plaintiffs contend that Counts II, III and IV of their complaint are maintainable as a Rule 23 class action. Yet assuming Rule 23, rather than 29 U.S.C. § 216(b), is applicable to the remaining Counts, as plaintiffs argue, the requirements of that rule have not been met.

The first prerequisite to a Rule 23 action is a class ". . . so numerous that joinder of all members is impracticable. . . ." 23(a)(1). The resolution of what constitutes "impracticability" depends ". . . upon all the circumstances surrounding a case. . . . Courts should not be so rigid as to depend upon mere numbers as a guideline to the practicability of joinder." Demarco v. Edens, 390 F.2d 836, 845 (2nd Cir. 1968).

On the other hand, while the number of prospective class members is not determinative of the impracticability of joinder: ". . . it is a significant factor to be considered." Fidelis Corp. v. Litton Industries, Inc., 293 F.Supp. 164, 170 (S.D.N.Y. 1968); accord, Philadelphia Electric Co. v. Anaconda American Brass Company, 43 F.R.D. 452 (E.D.Pa. 1968). But that factor cannot be examined in the present case, for plaintiffs have failed to even allege the approximate size of the class they seek to represent. Instead, their pleadings merely contain the conclusionary statement that "there are numerous other people who. . . have the same cause of action . . ." and ". . . whose number make it impracticable to have them join as plaintiffs." The only information this court has been given on class size was supplied by plaintiffs' attorney during oral argument, when he commented that the class would probably contain between 70 and 200 persons. Since this estimate was unsupported by any materials before the court, it must be deemed purely speculative, and speculation cannot be used to establish that a prospective class

is so numerous as to make joinder impracticable under the surrounding circumstances. Demarco v. Edens, supra, at 845; Matthies v. Seymour Mfg. Co., 23 F.R.D. 64, 75 (D.Conn. 1958), rev. on other grounds, 270 F.2d 365 (2nd Cir. 1959); See, Lucas v. Seagrave Corp., 277 F.Supp. 338, 348 (D.Minn. 1967).

Because more than speculation as to class size is required for a court to determine if the requirement of 23(a)(1) is met does not mean, however, that plaintiffs have to establish class size with precision. It simply means that some information must be presented by plaintiffs from which the approximate number of class members can be ascertained before the court can decide if joinder of all those members would be impracticable.

Since plaintiffs have failed to show that the requirement of 23(a)(1) has been satisfied, Counts II, III, and IV are not maintainable as a class action. Thus, defendants' motion for an order declaring those Counts cannot be pursued as a class action is granted, subject to possible revision if plaintiffs later demonstrate that their suit complies with Rule 23(a)(1). Defendants' motion for a similar order that Count I cannot proceed as a Rule 23 class action is also granted for the reasons previously stated.

MOTION FOR SUMMARY JUDGMENT ON COUNT I
FILED BY DEFENDANT DRUG COMPANIES

In Count I of their amended complaint, plaintiffs allege that they are entitled to recover from defendant drug companies the difference between the amounts plaintiffs received for their labor in the research clinics and the minimum wage, plus overtime compensation, prescribed by the Fair Labor Standards Act of 1938, as amended, 29 U.S.C. §201 et seq. Defendant drug companies have moved for summary judgment on this Count pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, which provides:

> "The judgment sought shall be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."

Plaintiffs maintain that there are genuine issues of material fact to be decided in Count I, and, thus, under Rule 56(c), defendants' motion for summary judgment must be denied. Defendants, on the other hand, contend that the affidavits they have filed, as well as their answers to interrogatories, are uncontroverted by sworn testimony submitted by plaintiffs and must, therefore, be viewed as presenting undisputed facts. It is defendants' position that on those facts the applicable law entitles them to judgment.

Although the parties disagree on the factual posture of Count I, they are in accord that the only question of law

raised by this Count is whether plaintiffs are "employees" of either defendant within the meaning of the Fair Labor Standards Act. That Act, as amended, defines "employee" as:

> ". . . any individual employed by an employer, except that such term shall not, for the purposes of subsection (u) of this section include--
>
> (1) any individual employed by an employer engaged in agriculture if such individual is the parent, spouse, child, or other member of the employer's immediate family, or
>
> (2) any individual who is employed by an employer engaged in agriculture if such individual (A) is employed as a hand harvest laborer and is paid on a piece rate basis in an operation which has been, and is customarily and generally recognized as having been, paid on a piece rate basis in the region of employment, (B) commutes daily from his permanent residence to the farm on which he is so employed, and (C) has been employed in agriculture less than thirteen weeks during the preceding calendar year." 29 U.S.C. § 203(e).

An employer is defined as:

> ". . . any person acting directly or indirectly in the interest of an employer in relation to an employee but shall not include the United States or any State or political subdivision of a State (except with respect to employees of a State, or a political subdivision thereof, employed (1) in a hospital, institution, or school referred to in the last sentence of subsection (r) of this section, or (2) in the operation of a railway or carrier referred to in such sentence), or any labor organization (other than when acting as an employer), or anyone acting in the capacity of officer or agent of such labor organization." 29 U.S.C. § 203(d).

To employ, in turn, means ". . . to suffer or permit to work." 29 U.S.C. § 203(g).

A literal application of those definitions contained in the Act would, as the parties note, "encompass all employed humanity." Walling v. Sanders, 136 F.2d 78, 80 (6th Cir. 1943). For this reason, courts have been forced to devise a more meaningful test to determine when an employment relationship exists within the meaning of the FLSA. That test is one of "economic reality," [Goldberg v. Whitaker House Cooperative, Inc., 366 U.S. 28, 33 (1960)] and is not limited to the technical concepts ". . . pertinent to an employer's legal responsibility to third persons for acts of his servants." United States v. Silk, 331 U.S. 704, 713 (1946).

Plaintiffs do not contest the applicability of the economic reality test to Count I of their complaint, but instead allege that this test involves considerations of a peculiarly factual nature which preclude summary judgment treatment. Plaintiffs, however, have failed to cite any legal authority to support their contention that summary judgment is inappropriate in cases raising the question of whether an employment relationship exists under the FLSA. And while the United States Supreme Court in Kennedy v. Silas Mason Company, 334 U.S. 249 (1948), did vacate a summary judgment where that very issue was involved, the Court specifically noted that summary disposal would have been proper if the record had presented ". . . a more solid basis of findings. . . or a comprehensive statement of agreed facts." 334 U.S. at 257.

Subsequent to the Kennedy decision, the District Court for the Eastern District of Texas summarily adjudicated rights under the Fair Labor Standards Act, after finding the defendants were not independent contractors. The Fifth Circuit Court of Appeals affirmed on the ground that the uncontroverted facts before the lower court were sufficient to warrant its ultimate finding:

> ". . . that appellee was not an independent contractor. . . . A reasonable inference fairly deduced from an uncontroverted. . . number of facts may establish the existence of an ultimate fact that entitles one of the parties to judgment as a matter of law. When this happened, as it did in this case, and summary judgment is sought, Rule 56(c) requires that 'judgment. . . shall be rendered forthwith.'" Creel v. Lone Star Defense Corp., 171 F.2d 964, 968 (5th Cir. 1948), rev'd. on other grounds, 339 U.S. 497 (1950).

Under Kennedy, supra, and the reasoning of the Fifth Circuit Court of Appeals, defendant drug companies would be entitled to summary judgment if the present record contains sufficient uncontroverted facts from which this court can conclude that in economic reality plaintiffs are not "employees" of defendants. On the other hand, if the sworn testimony on material facts is contradictory, or if the record does not contain a sufficiently comprehensive picture of plaintiffs' relationship to defendants, then defendants' motion for summary judgment must be denied.

In deciding whether the inmates working at the Jackson research clinics are, in economic reality, employees of defendants, both parties agree that the court must consider

the extent to which defendants can hire, fire and control those inmates. Walling v. Sanders, supra. It is the position of defendants that they can exercise only limited control over the inmates and that they have no authority over hiring and firing. To support their contentions, defendants have filed the affidavit of George A. Kropp, Warden of the State Prison of Southern Michigan.

In his affidavit, Warden Kropp swears that the Director of Prison Treatment, acting with the prison Classification Committee, determines every work assignment of inmates, including assignments to the research clinics. The Director of Treatment and the Classification Committee, however, will consider requests from Parke-Davis and Upjohn for the assignment of certain inmates, although prison officials can place inmates at work in the clinics over the objections of the drug companies.

Moreover, according to Warden Kropp, the Director of Treatment is similarly responsible for the removal of inmates from their work assignments and has removed inmates from clinic assignments without the knowledge or approval of the drug companies. As in the case of assignments, the drug companies may request that the Director of Treatment remove particular inmates from the research clinics, but those requests can be denied. Finally, Warden Kropp maintains that his Deputy Warden has the power to disapprove the hours worked and the particular tasks performed by inmates on all work assignments and has exercised that power in the case of certain inmates assigned to the clinics.

The defendant Upjohn Company has also introduced the affidavit of Ralph F. Willy, Administrator of the Upjohn clinic at Jackson. Willy's affidavit is to the same effect as Warden Kropp's and states that: (1) inmates were in some instances assigned by the prison Classification Committee to perform specific tasks at the Upjohn clinic, although the clinic had no need for additional help; (2) inmates assigned to the Upjohn clinic took time off from their tasks pursuant to prison rules without the approval of their Upjohn supervisor; (3) specific instructions by Upjohn personnel to inmates were sometimes vetoed by prison authorities; and (4) requests by Upjohn filed with the Classification Committee to remove inmates from the clinic were in some instances denied.

The answers to interrogatories of both Upjohn and Parke-Davis, which may be examined in a summary judgment proceeding, further buttress the affidavits of Willy and Kropp. According to those answers, neither drug company was ever permitted to select an inmate for assignment to the research clinic (Interrogatory Answer No. 6); the prison authorities could require the companies to keep an inmate working in the clinic over drug company objections (Interrogatory Answer No. 16); and the hours worked by inmates assigned to the clinics were regulated by prison authorities (Interrogatory Answer No. 13).

Plaintiffs' attorney, however, contends that defendants' affidavits and interrogatory answers concerning clinic assignments and the direction of the clinic work force are controverted by sworn testimony submitted by plaintiffs. Thus, plaintiffs conclude that Count I must be tried since summary judgment proceedings cannot be used to resolve a conflict among affidavits. Yet, an examination of the materials filed by plaintiffs in opposition to the summary judgment motion fails to reveal such a conflict.

The affidavit of Gaylord Lee Espich, which plaintiffs allege contradicts Upjohn's sworn testimony that it did not select the inmates to work in the clinic, cannot be considered by the court. As Upjohn correctly notes, Rule 56(e) requires affidavits ". . . be made on personal knowledge, . . . and . . . show affirmatively that the affiant is competent to testify to the matters stated therein." While affiant Espich states he is competent to testify from personal knowledge that "the Upjohn Company, personally approved all inmates who worked in the said clinic and persons could not work there that were not so approved," his competency and firsthand knowledge of these facts is unsupported by anything contained in his affidavit. Espich does not, "in his affidavit or otherwise reveal how he knew these facts. Inasmuch as summary judgment procedure lacks the safeguard of cross-examination of an affiant, it is important that it be shown that he is competent to testify to the matters therein stated." American Security Co. v. Hamilton Glass Co.,

254 F.2d 889, 893-894 (7th Cir. 1970); Accord, Green v. Benson, 271 F.Supp. 90 (E.D.Pa. 1967). Indeed, since Espich is simply one of the inmates who worked in the Upjohn laboratory, it is difficult to see how he could be competent to testify from firsthand knowledge on whether Upjohn "personally approved all inmates who worked" in its clinic. Hence, that portion of Espich's affidavit referring to Upjohn's selection of inmates will be stricken as failing to conform with Rule 56(e).

Plaintiffs' attorney has filed four other affidavits of Jackson inmates, Boyd Slager, Clemont M. DeDeaux, Chester A. Sawicki, and Calvin Sims, who worked in the research clinics and who are parties to the present suit. Portions of those affidavits support, rather than contradict, defendants' sworn testimony that prison authorities, not the drug companies, selected the inmates for work in the research clinics.

Affidavit of Boyd Slager:

> "9. Affiant was placed inthe Upjohn Clinic for purposes of work by the following method:
>
> "In June of 1964, while working in the Main Hall Office of the State Prison of Southern Michigan as a Count Clerk on the Night Shift. Affiant was offered or made aware of an opening in the Upjohn Medical Research Clinic, located inside the Walls of the Prison, by the then Inmate Clerk, John Dutz. I then requested and was granted an interview with the Clinic Administrator, Mr. Ralph F. Willy. After that interview, a request was made to the Prison Classification Director Mr. Schmeige (now retired), and in the fore part of July 1964 I was taken before the Classification Committee and it was decided that the Prison Officials had no objection to the transfer and it was approved,

provided that I stayed on to help break another Inmate in on the Main Hall Office job. This was done and in August of 1964, an Assignment Change Order was signed by Mr. G. L. Hansen, Director of Treatment, indicating that I was to go to work at the Upjohn Clinic. On August 19, 1964, I started work at the clinic on a full time basis which continued until July 1967."

Affidavits of Clemont M. DeDeaux, Chester A. Sawicki, and Calvin Sims:

"6. He and others working at the clinics did so because they were ordered to do so by representatives of the Department of Corrections just as they would be ordered to work in any other prison industry and a refusal to work as directly would have resulted in penalties to them and such coercion and threat, was under the circumstances, clearly implied if not expressly stated."

The affidavits of Sims, DeDeaux, Sawicki, and Slager also say that the affiants "worked directly under the supervision of civilian employees of the drug companies." According to plaintiffs' attorney, those statements contradict defendants' sworn testimony concerning the drug companies' lack of control over inmates assigned to the clinics. Defendants, however, admit that their agents directly supervised the inmates in the day-to-day performance of clinic work (Defendants' Brief on Count I, p. 4), and the affidavits submitted by defendants do not claim to the contrary. Rather, those affidavits indicate that defendants' day-to-day supervision over inmates was always subject to the overriding authority of prison officials, who frequently exercised their authority to disapprove the drug companies' instructions to

inmates. Hence, the fact that clinic inmates were supervised in the routine performance of their tasks by defendants is simply another uncontroverted fact for the court to consider in analyzing the extent to which defendants actually control the inmates working in the clinic.

Finally, plaintiffs' attorney maintains that a letter co-signed by Upjohn and Parke-Davis officials and referring to the "hiring" of inmates at the research clinics contradicts defendants' sworn testimony on the drug companies' inability to select inmates for work in the clinics. [Exhibit G-1, letter signed by J. P. Conlin of Parke-Davis and R. Willy of Upjohn]. We cannot agree with plaintiffs on this point. To show there is a material fact in dispute on the present summary judgment motion, plaintiffs must produce a factual description of the procedures by which defendants acquire inmate help, and such description must be different from the one presented by defendants' affiants. The word "hiring" is not a factual description, but simply a shorthand notation that is often used by businessmen to connote any variety of procedures resulting in the attainment of a work force.

Moreover, the letter containing the reference to hiring is only one in an exhibit of many letters signed by drug company personnel or by prison officials, which plaintiffs have submitted for our examination. [Defendants have stipulated to the court's consideration of that entire exhibit for the purposes of the present motion.] The content of those letters, when read together, indicate that even

though defendants' personnel might occasionally refer to the hiring of inmates, the assignment of inmates to the clinics was determined by prison authorities. [See, e.g., Exhibit G-4 and A-5].

Having carefully reviewed all the admissible affidavits, documents, and interrogatories submitted by both parties, this court concludes that the following facts have been established by uncontroverted sworn testimony: (1) prison officials, not the drug companies, decide which inmates will work in the clinics, and inmates have been assigned to the clinics despite the disapproval of the drug companies; (2) prison authorities, not the drug companies, determine when inmates will be removed from their assignment to the clinics, and inmates have been so removed without the approval of the drug companies; (3) the particular tasks performed by inmates working in the clinics must be approved by prison officials; (4) the hours worked by inmates are subject to the approval of prison officials; (5) inmates working in the clinics may be given time off from their tasks by prison officials without the consent or knowledge of defendant drug companies; (6) the inmates are supervised by defendant drug companies in the day-to-day performance of their work at the clinics. From these uncontroverted facts, the court must conclude that neither Upjohn nor Parke-Davis had the right to hire or fire inmates, and that the companies' supervision of inmates' work performance was always subject to final control by prison officials.

But the fact that defendants could not hire, fire or finally control inmates working in the clinics is not determinative on the issue of whether plaintiffs are employees of the drug companies under the economic reality test. The entire fabric of plaintiffs' relationship to the companies must be considered.

A comprehensive picture of that relationship, excluding the elements already discussed, is presented by defendants' answers to interrogatories, portions of Warden Kropp's affidavit, and the parties' judicial admissions. They establish that plaintiffs are, or were, lawfully convicted criminals, serving sentences in Jackson prison. As prisoners, plaintiffs were ordered by prison authorities to perform services for defendant drug companies, just as they would be ordered to work in any other prison industry. Those services, which have previously been described, were performed inside the prison walls in a clinic operated by the drug companies and owned by the State of Michigan. Plaintiffs were paid for their services to the drug companies by the Department of Corrections at per diem rates established by the Department. The drug companies, in turn, reimbursed the Department for its payments to inmates working at the clinics. The drug companies never contracted with the inmates for the payment of compensation.

A case involving an almost identical relationship between prisoners and a private corporation was decided under the Fair Labor Standards Act by the Federal District Court for

the Western District of Michigan in 1948. That case, Huntley v. Gunn Furniture Company, 79 F.Supp. 110 (W.D.Mich. 1948), also had certain inmates of Jackson Prison as plaintiffs claiming to be entitled to the Federal Minimum Wage.

In Huntley, plaintiffs alleged that the Michigan Corrections Commission entered into a contract with defendant, a private manufacturing corporation, whereby the State of Michigan would supply defendant with a convict labor force to work on the assembly of shell casings. Pursuant to that contract, plaintiffs were allegedly assigned to work in the prison stamping plant upon those shell casings. According to the complaint, plaintiffs' work was supervised by prison employees, who were paid by the defendant and who were under the defendant's direction. Plaintiffs further alleged that defendant reimbursed the State of Michigan for the inmates' per diem compensation, which was paid by the State of Michigan.

On the basis of the above allegations, Judge Starr dismissed the prisoners' complaint, saying:

> ". . . the complaint in the present case fails to allege facts showing that plaintiffs were employees of the defendant within the meaning of the words 'employ' and 'employee' as used in the Act [Fair Labor Standards Act]. In fact, the complaint affirmatively shows that the plaintiffs were employees of the Michigan prison industries and not of the defendant. In view of this conclusion, it is unnecessary to determine the question of the validity of the contract between the defendant and the prison industries."
> 79 F.Supp. at 116.

Plaintiffs, however, would distinguish the Huntley case from the present suit because here the defendant drug companies exercised a degree of supervision over inmates

assigned to the clinics, while in Huntley, only prison employees directed the convict work force. To distinguish the cases on this ground would ignore the allegation in Huntley that the prison employees who supervised the inmates in their work in the stamping plant were "under the supervision and direction of the defendant." 79 F. Supp. at 112. Since those allegations had to be accepted as true for the purposes of the motion todismiss, the Huntley court was required to assume that the defendants' agents supervised plaintiffs in their routine work at the stamping plant. That assumption corresponds to the uncontroverted facts now before the court.

In our opinion, Judge Starr's decision that the prisoners there were not employees of the defendant manufacturing corporation within the meaning of the FLSA was correct. Similarly, in our case, we believe that the economic reality of the present situation, based on uncontroverted facts, requires a finding that the present plaintiffs are not employees of the defendant drug companies.

The economic reality is that plaintiffs are convicted criminals incarcerated in a state penitentiary. As state prisoners, they have been assigned by prison officials to work on the penitentiary premises for private corporations at rates established and paid by the State. In return for the use of this convict labor, the private corporations have relinquished their normal rights: (1) to determine when, and whether, their enterprises need additional help; (2) to select the members of their work force; (3) to remove from their work force members with whom they are dissatisfied;

(4) to control that labor force except in the most routine matters. To find on those facts that an employment relationship exists between the prisoners and private corporations is contrary to the economic reality of their relationship.

Moreover, we do not think that Congress intended the Fair Labor Standards Act to cover the present situation. The setting of wages for incarcerated prisoners working on assignment by prison officials requires the consideration of many variables which are unique to that situation and which directly affect government policy on rehabilitation of criminals. It is unlikely that Congress considered any of those variables at the time it adopted general legislation designed to give employees the right to a subsistence wage. Fair Labor Standards Act, 81 Cong. Rec. 7652, 7672, 7885; 82 Cong. Rec. 1386, 1395, 1491, 1505, 1507; 83 Cong. Rec. 7283, 7298, 9260, 9265. See also H. Rep. No. 1452, 75th Cong. 1st Sess., p. 9; S. Rep. No. 884, 75th Cong., 1st Sess., pp. 3-4. Congress has, however, recognized the possibility of convict labor being used to compete with the free labor market and made it a crime to:

> "(a) . . . knowingly transport in interstate commerce. . . any goods, wares, or merchandise manufactured, produced, or mined, wholly or in part by convicts or prisoners, except convicts or prisoners on parole or probation, or in any penal or reformatory institution, ...
>
> "(b) This chapter shall not apply to . . . commodities manufactured in a Federal, District of Columbia, or State institution for use by the Federal Government, or by the District of Columbia, or by any State or Political subdivision of a State." 18 U.S.C. § 1761.

Nevertheless, the court does not now hold that any prisoner who is assigned by prison officials to perform work for a private corporation on the penitentiary premises is, because of his prisoner status, outside the coverage of the Fair Labor Standards Act. We only find that on the present facts plaintiffs are not in economic reality employees of defendant drug companies as that word is defined in the Act. Hence, defendants' motion for summary judgment on Count I is granted.

DEFENDANT DRUG COMPANIES' MOTION TO DISMISS COUNT II

In Count II, plaintiffs set forth a claim under the Michigan Minimum Wage Law of 1964, Mich. Com. Laws, § 408.381. That claim involves allegations identical to those contained in Count I of the complaint and is before the court under its pendent jurisdiction; Siler v. Louisville and Nashville R. Co., 213 U.S. 175 (1909); Hurn v. Oursler, 289 U.S. 238 (1933); United Mine Workers v. Gibbs, 383 U.S. 715 (1966). Defendants Upjohn and Parke-Davis have filed a motion to dismiss Count II for failing to state a claim upon which relief can be granted under the Michigan Minimum Wage Law. The Michigan Minimum Wage Law, Section 14, provides:

> "The provisions of this act shall not apply to any employer who is subject to the minimum wage provisions of the federal fair labor standards act of 1938, as amended, except in any case where application of such minimum wage provisions would result in a lower minimum wage than provided in this act . . . . M.S.A. § 17.255(14).

Defendants contend that under this language, the Michigan Minimum Wage Law is inapplicable to the present suit because both drug companies, as interstate manufacturers, are jurisdictionally subject to the Fair Labor Standards Act of 1938, which act provides for higher wages than the Michigan law. Plaintiffs, on the other hand, would construe Section 14 to mean only that employers who are required to pay the federal minimum wage under the FLSA are not subject to the Michigan Minimum Wage Law, provided the federal wage rate is the higher of the two. Hence, if a Michigan employer were jurisdictionally subject to the FLSA, due to the interstate nature of its enterprise, but were excused from paying the federal minimum wage rate for some reason, then that employer would be subject to the Michigan Minimum Wage Law.

Neither plaintiffs nor defendants have cited any cases in support of their respective constructions of Section 14. It would seem, however, that public policy favors plaintiffs on this point. The narrower construction defendants advocate would permit Michigan employers who escape paying the federal minimum wage to also escape paying the Michigan minimum wage. Such a result is not required under the doctrine of federal pre-emption.

Yet while the court holds that defendant drug companies are jurisdictionally subject to the Michigan Minimum Wage Law, it further finds plaintiffs are not employees within the meaning of that word as defined in the Act:

> "'Employee' means an individual between the ages of 18 and 65 years employed by an employer on the premises of the employer or at a fixed site designated by the employer." M.S.A. § 17.255(2)(b).

Employ, in turn, means ". . . to engage, suffer or permit to work." M.S.A. § 17.255(2)(d).

Although those definitions, enacted in 1964, have never been construed, the Michigan Supreme Court has ruled that the common law test of a master-servant relationship is not determinative of whether one person is employed by another under the State's Workmen's Compensation Act and Employment Security Act. Instead, the Michigan Supreme Court directed that in deciding if an employment relationship exists, ". . . for the purpose of remedial social legislation, . . ." the total factual situation surrounding the relationship must be examined; the test is one of "economic reality." Goodchild v. Erickson, 375 Mich. 289, 293 (1965); Tata v. Muskovitz, 354 Mich. 695, 699 (1959); Foster v. Employment Security Commission, 15 Mich. App. 96, 99-101 (1968).

Since the Michigan Minimum Wage Law is remedial legislation, the reasoning of the Michigan Supreme Court under the Employment Security Act and the Workmen's Compensation Act would apply equally as well to it, and the entire fabric of plaintiffs' relationship to defendants must be examined in determining whether plaintiffs are, in economic reality, employees of defendants within the meaning of the Michigan Minimum Wage Law.

But the court has already made such an examination under Count I and decided on the affidavits submitted by the parties that plaintiffs are not employees of defendants within the meaning of the Fair Labor Standards Act. Since the economic reality test is likewise applicable to plaintiffs' claim under the Michigan Minimum Wage Law, defendants are similarly entitled to summary judgment on Count II. Thus, the court will treat defendants' motion to dismiss Count II as one for summary judgment under Rule 12(c) which provides:

> "If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, . . ."
> Rule 12(c) F.R.C.P.

PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON COUNT III; DEFENDANT DRUG COMPANIES' CROSS-MOTION FOR SUMMARY JUDGMENT ON COUNT III; MOTION TO DISMISS FILED BY DEFENDANT DEPARTMENT OF CORRECTIONS, THE DIRECTOR OF THE DEPARTMENT OF CORRECTIONS, AND MEMBERS OF THE CORRECTIONS COMMISSION.

Count III of the amended complaint alleges a claim for damages under Michigan law which involves factual allegations similar to those raising a federal question in Count IV and is before the court under its pendent jurisdiction. In Count III, plaintiffs state that their services were utilized by defendant drug companies pursuant to agreements between the drug companies and the Michigan Department of Corrections which are illegal under Section 5

of the Michigan Prison Industries Act, 210 P.A. 1935, Com. Laws 1948, § 800.305:

> ". . . nor shall labor of prisoners be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction, maintenance or operation of public works, ways, or property as directed by the Governor; . . ." (§ 28.1525 M.S.A.)[1]

Because of the alleged illegality of those labor contracts under Section 5, plaintiffs conclude that they have a cause of action under Michigan law, in either tort or implied contract, for the reasonable value of their services against the defendant drug companies, the defendant Department of Corrections, its Director and the individual members of the Corrections Commission.

Plaintiffs have now moved for summary judgment on Count III, while defendant drug companies have filed a cross-motion for summary judgment on this Count. In addition, defendant Department of Corrections, its Director, Gus Harrison, and the individual members of the Michigan Corrections Commission have filed a motion to dismiss Count III on the ground that plaintiffs have failed to state a claim entitling them to relief. Since, however, that motion to dismiss has been accompanied by another affidavit of Warden Kropp, the court will treat it as one for summary

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[1] Section 5 of the Michigan Prison Industries Act, 210 P.A. 1935, Com. Laws 1948, § 800.305, is now Section 6 of the Michigan Correctional Industries Act, 15 P.A. 1968, Com. Laws, § 800.326.

judgment under Rule 12(c), which provides:

> "If, on a motion for judgment on the pleadings, matters outside the pleadings are presented to and not excluded by the court, the motion shall be treated as one for summary judgment and disposed of as provided in Rule 56, . . ." Rule 12(c) F.R.C.P.

The question raised by the above motions is whether on the uncontroverted facts, as already discussed in Count I, any of the parties are entitled to judgment as a matter of Michigan law. Those facts are:

1. Plaintiffs are or were legally incarcerated in Jackson Prison (Plaintiffs' Stipulation on Oral Arguments).

2. Pursuant to contracts between defendant drug companies and defendant Department of Corrections, the latter "furnished labor" to the drug companies for use in the research clinics built by the companies in the prison, but owned by the State of Michigan. (Plaintiffs' Brief of October 30, 1969, p. 3).

3. The plaintiff inmates worked in the clinics by order of the Department of Corrections just as "they would be ordered to work in any other prison industry." (Plaintiffs' Brief of October 30, 1969, p. 4).

4. Defendant drug companies paid certain sums to the State of Michigan for the labor of the inmates assigned to the clinics, according to monthly charges made by the Department of Corrections. (Plaintiffs' Brief of October 30, 1969, p. 5).

On those facts, defendants maintain that even if the labor contracts were illegal under Section 5 of the Michigan Prison

Industries Act, plaintiffs do not have a cause of action against any of the defendants for the reasonable value of their services, and that defendants are, therefore, entitled to judgment as a matter of Michigan law.

Although no Michigan court has ever decided whether a violation of Section 5 of the Michigan Prison Industries Act gives rise to a claim for damages, we believe that such a violation by defendants would not, on the present facts, create a cause of action for money damages in favor of plaintiffs. Instead, that Act authorizes criminal prosecution as the remedy for its willful violations:

> "Violations. Sec. 14. Wilful violation of any of the provisions of this act by an officer of the state or of any political subdivision thereof, or by any officer of any institution of either, shall be sufficient cause for removal from office; and such officer shall also be subject to prosecution as hereinafter provided." M.S.A. § 28.1534.[2]

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[2] Section 14 of the Michigan Prison Industries Act is now Section 13 of the Michigan Correctional Industries Act, which provides:

> "Wilful violations of any of the provisions of this act by an officer of the state or of any political subdivision thereof, or by any officer of any institution of either shall be sufficient cause for removal from office, and subject such officer to prosecution as provided in section 14." Com. Laws, § 800.333, M.S.A. § 28.1540(13).

> "Penalty. Sec. 15. Any person, firm or corporation who shall wilfully violate any of the provisions of this act, shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than one hundred [100] dollars nor more than five hundred [500] dollars, or by imprisonment in the county jail for a period of not more than ninety [90] days, or by both fine and imprisonment, at the discretion of the court." M.S.A. § 28.1535.[3]

While an action for damages may be inferred from a criminal statute even though that statute does not expressly authorize a civil damage suit, nevertheless it is generally recognized that a plaintiff must first demonstrate he falls within the class of persons the criminal statute was intended to protect before he can base a civil action for damages on a violation of criminal law. Wyandotte Co. v. United States, 389 U.S. 191, 202 (1967).

Section 5 of the Michigan Prison Industries Act, however, was never intended to protect inmates incarcerated in Michigan prisons from being compelled to perform services for private corporate profit. Rather, the primary purpose of that Section is, in pertinent part:

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[3] Section 15 of the Michigan Prison Industries Act is now Section 14 of the Michigan Correctional Industries Act, which provides:

> "Any person, firm or corporation who willfully violates any of the provisions of this act is guilty of a misdemeanor." Com. Laws, § 800.334, M.S.A. § 28.1540(14).

> "(c) to eliminate all competitive relationships between prisoner labor . . . and free labor. . . ." Section 10, Michigan Prison Industries Act, Com. Laws, § 800.310(c), M.S.A. § 28.1530.[4]

Hence, it is the work force outside the prison walls, not prison inmates, that the Michigan legislature was attempting to protect by the enactment of Section 5. Since plaintiffs are not the intended beneficiaries of Section 5, they cannot pursue an action for damages based on a violation of that Section.

There is a second reason why plaintiffs cannot recover damages from defendants on the present facts. That is because defendants' allegedly illegal utilization of plaintiffs' labor did not, as plaintiffs contend, deprive them of any property to which they were entitled. Instead, the thrust of the Michigan Prison Industries Act[5] is that

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[4] Section 10 of the Michigan Prison Industries Act is now Section 11 of the Michigan Correctional Industries Act, Com. Laws, § 800.331, M.S.A. § 28.1540 (11).

[5] The Michigan Prison Industries Act, 210 P.A. 1935, Com. Laws, §§ 800.301-319, has been repealed by the Michigan Correctional Industries Act, 15 P.A. 1968, Com. Laws. §§ 800.321-335. The 1968 Act, however, is substantially identical in content to the 1935 Act.

the labor of inmates lawfully incarcerated in Michigan penitentiaries and working on the order of prison officials belongs to the State, rather than to the inmates. This construction of the Act earlier received the approval of the Federal District Court for the Western District of Michigan in Huntley v. Gunn Manufacturing Co., supra, when Judge Starr concluded on almost identical facts:

> "[i]t is clear that the labor of the plaintiffs as inmates of the State prison belonged to the State of Michigan." 79 F.Supp. at 113 .

Since plaintiffs had no right to their own labor, or to its fruits, at the time they were ordered to perform the services they now challenge as being illegal, plaintiffs are not entitled to recover the reasonable value of those services under any theory of action recognized by Michigan law.

Plaintiffs, however, would have the court construe Section 5 of the Michigan Prison Industries Act as conferring on inmates the right to the fruits of their labor when that labor has been illegally used, through no fault of the inmates, in competition with private industry. But, as already noted, the purpose behind the enactment of Section 5 was to protect the free labor market, not to give incarcerated criminals any rights regarding the disposition of their labor.

The only case suggesting that a violation of a state statute regulating the uses of prison labor may create an

action for damages in favor of the prisoners whose labor was unlawfully used is Sloss Iron and Steel Company v. Harvey, 116 Ala. 656, 22 So. 994 (1897). In Sloss, the Alabama Supreme Court denied the plaintiff prisoners' claim for relief ex contractu, but said, in dicta, that defendants' acts in extracting work from the prisoners on Sunday, in violation of a statute prohibiting such Sunday labor, was tortious. Yet, Sloss is distinguishable from the present situation because there the court found that the law prohibiting Sunday labor by prisoners, ". . . was enacted for the benefit of the convict," 116 Ala. at 657.

Since Section 5 of the Michigan Prison Industries Act was not intended to protect inmates, and since plaintiffs as inmates have not been deprived of any property belonging to them under Michigan law by defendants' utilization of their labor, the court concludes that defendants are entitled to judgment on the stipulated facts. Summary judgment will, therefore, be entered for defendants on Count III.

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DEFENDANT DRUG COMPANIES' MOTION FOR SUMMARY JUDGMENT ON COUNT IV AND MOTION TO DISMISS FILED BY DEFENDANT DEPARTMENT OF CORRECTIONS, ITS DIRECTOR, AND THE MEMBERS OF THE MICHIGAN CORRECTIONS COMMISSION

In Count IV of their complaint, plaintiffs ask for money damages under 42 U.S.C. § 1983, alleging that the "illegal utilization . . . of plaintiffs' labor by all the Defendants and the payment by Defendants Parke, Davis and Company and the Upjohn Company of nominal wages less than those required by law" has resulted in: (1) the deprivation of plaintiffs' property without due process of law as required by the Fourteenth Amendment; (2) the holding of plaintiffs in involuntary servitude contrary to the Thirteenth Amendment to the Federal Constitution; and (3) the denial to plaintiffs of equal protection of laws as required by the Fourteenth Amendment. Defendant drug companies have moved for summary judgment on this count. In addition, the Michigan Department of Corrections, its Director, and the members of the Michigan Corrections Commission have filed a motion to dismiss Count IV as failing to state a claim entitling plaintiffs to relief. That motion to dismiss will be treated as one for summary judgment for the reasons already discussed under Count III.

The facts relevant to a determination of the present motions are those previously enumerated under Count III, and some additional facts established by uncontroverted statements in an affidavit of Warden Kropp. According to Warden Kropp: (1) inmates performing labor in the research clinics are paid

at somewhat higher daily rates than are inmates performing similar labor in other prison industries; (2) the recreational facilities and, at times, the food available to inmates working in the research clinics are superior to the recreational facilities and the food available to prisoners working in other prison industries; (3) inmates working in the research clinics are given more freedom by prison authorities than are inmates working in most other prison industries. On these facts, defendants maintain that they are entitled to a judgment as a matter of law. We agree.

Plaintiffs' claim that their work in the research clinics constitutes a form of involuntary servitude is without merit. Lawfully convicted criminals may be required to work by prison authorities for: "There is no federally protected right of a state prisoner not to work while imprisoned after conviction. . . .[t]his is not the sort of involuntary servitude which violates Thirteenth Amendment rights." Draper v. Rhay, 315 F.2d 193, 197 (Ninth Cir. 1963). Indeed, the Thirteenth Amendment expressly excepts punishment for a crime from its prohibitions against involuntary servitude:

> "Neither slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction."

Since plaintiffs do not maintain that they were illegally convicted, their claim that they have been held in involuntary servitude by defendants is groundless.

On oral argument, plaintiffs' attorney indicated that the due process and equal protection claims raised by Count IV are based wholly on the alleged unlawfulness under Michigan law of defendants' utilization of plaintiffs' labor. As we now understand the legal argument underlying Count IV, it is that a violation of the Michigan statute prohibiting competition between prison labor and free labor automatically deprives the prisoners whose labor is used contrary to this mandate of their Fourteenth Amendment rights.

Yet, merely because penal officials have treated state prisoners at variance with the applicable state law does not, in itself, constitute a violation of the due process or equal protection rights of those prisoners. That was the precise conclusion reached by the Courts of Appeal for the Eighth and Ninth Circuits in two decisions which we elect to follow. Draper v. Rhay, 315 F.2d 193, 197 (9th Cir. 1963); Sigler v. Lowrie, 404 F. 2d 659, 662 (8th Cir. 1968). If the rule were otherwise, every erroneous decision on state law matters would come before the federal court as a Constitutional question. Hughes v. Heinze, 268 F. 2d 865, 870 (9th Cir. 1959).

But even if the allegations in Count IV are construed more broadly than plaintiffs' attorney suggested on oral argument, they still do not present a cause of action under 42 U.S.C. § 1983 for the denial of due process rights. To raise such a claim, those allegations, or the facts already established, must indicate that plaintiffs have been deprived of some fundamental Constitutional right which follows them into their prison cells.

> "Lawful incarceration brings about the necessary withdrawal or limitation of many privileges and rights, a withdrawal which is justified by the considerations underlying our penal system. To argue that the incarcerated person can only be incarcerated and not be deprived of the average person's ordinary rights as he would have had them if the prisoner were not convicted and sentenced and confined is, as a matter of common ordinary logic, absurd. It is only where fundamental, humane and necessary rights are breached that the constitutional protections become involved." Ray v. Commonwealth of Pennsylvania, 263 F.Supp. 630, 631 (W.D. Pa. 1967).

A failure, however, to pay plaintiffs for their labor in the clinics at its reasonable value is not a denial of such a fundamental Constitutional right. Sigler v. Lowrie, supra at 661.

Plaintiffs have likewise failed to contend that defendants purposefully discriminated against them, as opposed to other prisoners in the same class, when defendants allegedly used prison labor contrary to Section 5 of the Michigan Prison Industries Act. That purposeful discrimination is a necessary element in the present case under the equal protection clause of the Fourteenth Amendment:

> "Appellant asserts. . . that he is being held in the state penitentiary, and that in accordance with state law, he should be in the county jail . . . . No denial of equal protection is shown unless there is shown intentional or purposeful discrimination between persons or classes." Draper v. Rhay, supra at 198.

Moreover, the uncontroverted facts already discussed show that the effects of the alleged violation of Michigan law

was to confer tangible benefits on inmates like plaintiffs who received clinic assignments, for they received higher wages, more freedom, and labored under better working conditions than did the inmates performing similar work but in different prison industries.

In view of the above findings, it is unnecessary to determine whether defendants have, in fact, violated Section 5 of the Michigan Prison Industries Act or whether each defendant has acted under color of law sufficient to subject it to liability under 42 U.S.C. § 1983. Rather, we hold only that even if defendants used plaintiffs' labor contrary to Michigan law, and even if defendants acted under color of state law in so doing, plaintiffs have suffered no denial of federally protected rights. For this reason, defendants' motions for summary judgment on Count IV are granted.

Appropriate orders may be submitted.

Ralph M. Freeman
Chief Judge

Dated: Detroit, Michigan
January , 1971.

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Filed: Feb. 2, 1971

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS, RALPH R. WARNER, RONALD D. KENNEDY, PAUL ROSS, HERMAN HEAD, GERALD G. NORMAN, PAUL MILLER, THOMAS U. MULLIGAN, LONNIE PAYNE, ROBERT MASON, and KENNETH R. MARSHALL,

Plaintiffs,

vs.

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C.J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants.

A TRUE COPY
FREDERICK W. JOHNSON, Clerk
By Josephine Williams
DEPUTY CLERK

Civil Action
No. 31172

ORDER GRANTING DEFENDANTS' MOTIONS PERTAINING TO CLASS ACTION, TO DISMISS AND FOR SUMMARY JUDGMENT AND DENYING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

At a session of said Court held in the Federal Building, Detroit, Michigan on the 2 day of February A.D., 1971.

PRESENT: RALPH M. FREEMAN
United States District Judge

The parties herein having filed various motions described below, and

The Court having considered the pleadings in this cause and the extensive briefs and oral arguments pertaining to such motions, and

The Court having filed its opinion herein on January 5, 1971, setting out its findings of fact and conclusions of law, and

The Court being fully advised in the premises.

NOW, THEREFORE, IT IS HEREBY ORDERED AS FOLLOWS:

1. Defendants' (Parke Davis & Co. and The Upjohn Company) Motion For Order That Plaintiffs' Action Shall Not Be Maintained As A Class Action is hereby granted.

2. Defendants' (Parke Davis & Co. and The Upjohn Company) Motion For Summary Judgment On Count I Of Complaint is hereby granted.

3. Defendants' (Parke Davis & Co. and The Upjohn Company) Motion To Dismiss Count II Of Complaint (treated as a motion for summary judgment pursuant to Rule 12(c), F.R.C.P.) is hereby granted.

4. Defendants' (Parke Davis & Co. and The Upjohn Company) Motion For Summary Judgment With Respect To Count III, and Defendants' (other than Parke Davis & Co. and The Upjohn Company) Motion To Dismiss Count III (treated as a motion for summary judgment pursuant to Rule 12(c), F.R.C.P.) are hereby granted.

5. Defendants' (Parke Davis & Co. and The Upjohn Company) Motion For Summary Judgment With Respect To Count IV and Defendants' (other than Parke Davis & Co. and The

Upjohn Company) Motion To Dismiss Count IV (treated as a motion for summary judgment pursuant to Rule 12(c), F.R.C.P.) are hereby granted.

6. The Motion For Summary Judgment By Plaintiffs Pursuant To Rule 56 Of The Federal Rules Of Civil Procedure (pertaining to Count III) is hereby denied.

RALPH M. FREEMAN

Ralph M. Freeman, Chief Judge

Approved as to form:

Robert L. Segar, Esq.
Leitson, Dean, Dean, Abram, Segar & Hart
804 Detroit Street
Flint, Michigan 48503 235-5631
Attorneys for Plaintiffs

EXPERIMENTS BEHIND BARS

Doctors, drug companies, and prisoners

by Jessica Mitford

"Criminals in our penitentiaries are fine experimental material--and much cheaper than chimpanzees."

Before a new drug can be marketed in the United States, it must, according to Food and Drug Administration rules, be tested on human beings. In recent years, most of the early testing of our increasingly exotic drugs has been done in prisons. And prisoners have been the subjects of other medical experiments as well.

For some time, international medical societies have attempted to prohibit the use of prisoners as subjects, but these efforts have been effectively frustrated by American medical experimenters. The World Medical Association proposed in 1961 that prisoners "being captive groups should not be used as the subject of experiments." The recommendation was never formally adopted, largely because of the opposition of American doctors. "Pertinax" writes in the *British Medical Journal* for January, 1963: "I am disturbed that the World Medical Association is now hedging on its clause about using criminals as experimental material. The American influence has been at work on its suspension." He adds wistfully, "One of the nicest American scientists I know was heard to say, 'Criminals in our penitentiaries are fine experimental material—and much cheaper than chimpanzees.' I hope the chimpanzees don't come to hear of this."[1]

Although few involved in prison experiments like to talk openly about them, alarming stories crop up in the press with sufficient regularity to give some indication of the scope and nature of the experiments. In 1963, *Time* magazine reported that the federal government was using prisoner "volunteers" for large-scale research, dispensing rewards ranging from a package of cigarettes to $25 in cash plus reduction of sentence; that prisoners in Ohio and Illinois were injected with live cancer cells and with blood from leukemia patients to determine whether these diseases could be transmitted; that doctors in Oklahoma were grossing an estimated $300,000 a year from deals with pharmaceutical companies to test out new drugs on prisoners; that the same doctors were paying prisoners a quart for blood which they retailed at $15.

In July, 1969, Walter Rugaber of the New York *Times* reported that "the Federal Government has watched without interference while many people have died and some died in an extended series of drug [illegible] and blood plasma operations . . . the immediate damage has been done in the penitentiary systems of three states. Hundreds of inmates in voluntary programs have been stricken with serious disease. An undetermined number of the victims have died."

The stakes in prison research are high. The drug companies, usually operating through private physicians with access to the prisons, can ob-

[1] See M. H. Pappworth, M.D., *Human Guinea Pigs*, Beacon Press, 1967.

The participating physician cashes in on the programs in various ways.

healthy human subjects living in controlled conditions that are difficult, if not impossible, to duplicate elsewhere. In addition, the companies can buy these for a fraction—less than one-tenth, according to many medical authorities—of what they would have to pay medical students or other "free-world" volunteers. They can conduct experiments on prisoners that would not be sanctioned for student-subjects at any price because of the degree of risk and pain involved. Guidelines for human experimentation established by HEW and other agencies are easily disregarded behind prison walls.

When the studies are carried out in the privacy of prison, if a volunteer becomes seriously ill, or dies, as a result of the procedures to which he is subjected, the repercussions will likely be smaller than they would be on the outside. As Rugaber discovered when trying to trace deaths resulting from the "voluntary programs," prison medical records that might prove embarrassing to the authorities have a habit of conveniently disappearing. There is minimal risk that subjects disabled by the experiments will bring lawsuits against the drug companies. Prisoners are often required to sign a waiver releasing those responsible from damage claims that may result. Such waivers have been held legally invalid as contrary to public policy and are specifically prohibited by FDA regulations, but the prisoner is unlikely to know this. The psychological effect of signing the waiver, along with the general helplessness of prisoners, make lawsuits a rarity.

For the prisoner, the pittance he gets from the drug company—generally around $1 a day for the more onerous experiments—represents riches when viewed in terms of prison pay scales: $30 a month compared with the $2 to $10 a month he might make in an ordinary prison job.

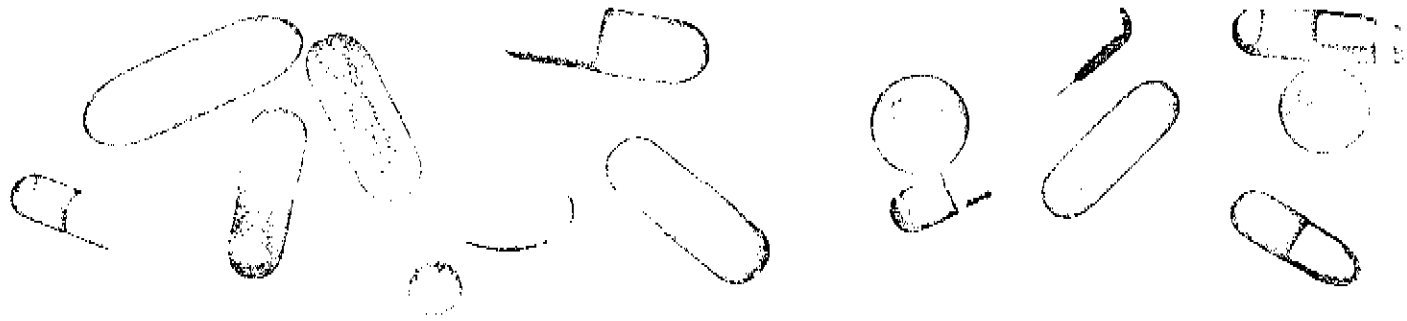
Dr. Robert Batterman, a clinical pharmacologist, told me, "The prisoner-subject gets virtually nil." He cited an estimate given him for experimenting on prisoners in Vacaville, California: $15 a month for three months to be *lowered* to $12.50 a month should the experiment run for six months. "We would normally do it the other way around with free-world volunteers. We'd give them more money if the experiment ran longer." Dr. Batterman makes considerable use of student-subjects from a nearby Baptist divinity school. For a comparatively undemanding experiment—one requiring a weekly withdrawal of blood—he would pay a student at least $100 a month, he said.

However, the problem as seen by some leaders of the American medical profession is not that the prisoner-subjects are paid too little, but rather that they may be paid too much. That a dollar-a-day stipend to a healthy adult can be so overwhelmingly attractive as to invalidate the results of medical research is a possibility only in the topsy-turvy world of prisons. Yet the fear that this will happen is precisely what is expressed by some spokesmen for the profession. Thus Dr. Herbert L. Ley, Jr., then commissioner of the Food and Drug Administration, testified in 1969 before the Senate Select Committee on Small Business:

"The basic problem here, Mr. Chairman, is that the remuneration to the prisoner was too much. This meant that the prisoner had a very strong pressure not to report and not to withdraw from the study. Therefore he would decline to say that he felt any adverse reactions. This is bad for the prisoner in that it exposes him to unnecessary risk, it is bad for our records in that it does not provide us full information."

Prisoners do indeed view the small sums paid as largesse. In a series of interviews conducted in 1969 at Vacaville prison, California, by Martin Miller, a graduate student at the University of California Department of Criminology, some of the prisoners commented: "Yeah, I was on research but I couldn't keep my chow down. Like I lost about thirty-five pounds my first year in the joint, so I started getting scared. I hated to give it up because it was a good pay test." . . . "Hey, man, I'm making $30 a month on the DMSO thing [Chronic Topical Application of Dimethylsulfoxide]. I know a couple of guys had to go to the hospital who were on it—and the burns were so bad they had to take *everyone* off it for a while. But who gives a shit about that, man? Thirty is a full canteen draw and I wish the thing would go on for years—I'd be lost without it." . . . "I was on DMSO last year. It paid real good and it was better than that plague thing [Bubonic Plague Vaccine Immunization Study] that fucked with guys last year. There was a lot of bad reactions to DMSO but I guess that's why it paid so good." Of DMSO Morton Mintz, staff writer for the Washington *Post*, had written three years earlier: "Human testing has now been severely curbed by FDA because of reports of serious adverse effects" (Washington *Post*, July 24, 1966).

The participating physician cashes in on the programs in various ways. He may make a direct deal with the drug company for financial backing, out of which he pays the expenses of research and pockets the rest as his fee. An individual research grant might run from $5000 to more than $50,000, enabling a doctor with good prison contacts to double or triple his regular income. Or if he is, as many are, a faculty member in a medical school,



he can route the grant through his university, to the acclaim of his colleagues. His prestige will be enhanced when the results of his research appear in a professional journal.

Some of the vicissitudes that the medical researcher may expect to encounter in his quest for prisoner-subjects are described by Dr. Robert F. Hodges in the November 6, 1971, issue of the *Journal of the American Medical Association.* In the late forties, Dr. Hodges and his colleagues reached a "verbal working arrangement" with Iowa prison officials enabling them to canvass the prison population for volunteers who would submit to prolonged hospitalization in university hospitals as research subjects. "We knew this procedure was not specifically permitted by law," writes Dr. Hodges. "But neither was it specifically prohibited." Eventually the experiments came to the attention of Iowa's Attorney General: "In his judgment, it was not legal for us to accept prison volunteers for medical research." There followed two fallow years in which the experiments were halted, but Dr. Hodges during this time "sought and obtained enactment of a specific law permitting the use of prisoners for medical research at university hospitals." The path thus cleared, a total of 224 convicts were in the course of time delivered over to Dr. Hodges and his colleagues at the university hospitals.

Speculating on the "incentives and motives" that induce prisoners to volunteer for research studies "which are usually somewhat unpleasant and in a few instances involve distinct risks," Dr. Hodges surmises that "for some, it probably represents a new experience which takes them away from the monotony and oppressiveness of prison routine." The relief from monotony: "They have eaten strange diets, swallowed tubes, submitted to repeated venipunctures, and participated in a wide variety of physiological tests. . . ."

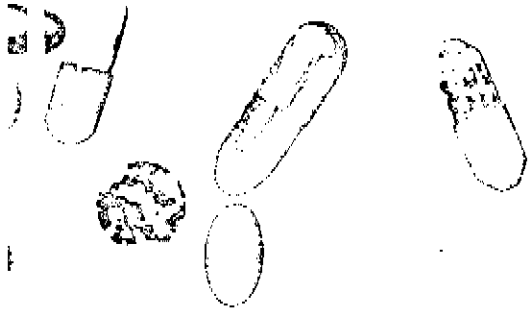
For some prisoners, "monetary gain may be the incentive, though inmates are paid only one dollar daily." Iowa prisoners are not supposed to receive reduction of sentence in return for volunteering, but Dr. Hodges routinely sent a thank-you letter to the warden for each subject: "It is possible that this letter in the prisoner's file may favorably influence the parole board." As for the incentives and motives of researchers, Dr. Hodges reports that more than eighty scientific publications resulted from the Iowa studies on prisoners.

Dr. Hodges becomes almost lyrical in his discussion of the moral and ethical aspects of such experimentation. The prisoner-volunteers, he says, are "our companions in medical science and adventure"; the subject "in whatever degree derelict or forlorn has sacred rights which the physician must always put ahead of his burning curiosity." Dr. Hodges, without elaborating on these sacred rights, concludes: "A system of voluntary participation firmly based on legal and ethical standards has provided a rich opportunity for clinical investigators who wish to study metabolic, physiologic, pharmacologic, and medical problems. This has been a rewarding experience both for the physicians and for the subjects."

One such experience is described by Dr. Hodges in one of his papers: "Clinical Manifestations of Ascorbic Acid Deficiency in Man," in the *American Journal of Clinical Nutrition* of April, 1971. The object: "to define the metabolism of this vitamin in the face of severe dietary deficiency." For the study, which consisted of experimentally induced scurvy, five companions in medical science and adventure were recruited from the Iowa State Penitentiary "and their informed consent was obtained." For periods ranging from 84 to 97 days they were fed by stomach tube a liquid formula free of ascorbic acid: "Because of the unpalatability of this formula, the men took it thrice daily via polyethylene gastric tube." They were exposed in a cold-climate "control room" to a temperature of fifty degrees for four hours each day. The volume of blood drawn "for laboratory purposes" was large enough to "cause mild anemia in all the men." In a throwaway line, Dr. Hodges observes that "the mineral supplement [recommended by the National Research Council] was inadvertently omitted from the diets during the first 34 days of the depletion period."

The experiment was a great success. It was the second of its kind, Dr. Hodges having tried it once before with far less favorable results: "Despite a somewhat shorter period of deprivation in the second scurvy study, the subjects in the second study developed a more severe degree of scurvy . . . although none of the subjects in the first scurvy study developed arthralgia, this was a complaint in four out of five men who participated in the second scurvy study. Joint swelling and pain made themselves evident in Scurvy II, but had not been observed in the subjects participating in Scurvy I."

The gradual onset of scurvy in the five prisoners is traced by Dr. Hodges with some enthusiasm. "The first sign of scurvy to appear in both studies was petechial hemorrhage [hemorrhages in the skin]. Coiled hairs were observed in two of the men and first appeared on the 42nd and 74th days, respectively. The first definite abnormalities of the gums appeared between the 43rd and 84th



"We knew this procedure was not specifically permitted by law. But neither was it specifically prohibited."

days of depletion and progressed after the plasma ascorbic acid levels fell. . . . The onset of joint pains began between the 67th and 96th days. . . . Beginning on the 88th day of deprivation there was a rapid increase in weight followed by swelling of the legs in the third man, who had the most severe degree of scurvy."

By the time it was all over, Dr. Hodges was able to chalk up these significant accomplishments: all five subjects suffered joint pains, swelling of the legs, dental cavities, recurrent loss of new dental fillings, excessive loss of hair, hemorrhages in the skin and whites of the eyes, excess fluid in the joint spaces, shortness of breath, scaly skin, mental depression, and abnormalities in emotional responses. The youngest, a twenty-six-year-old, "became almost unable to walk as a result of the rapid onset of arthropathy [painful joints] superimposed on bilateral femoral neuropathy [disease in both large nerves to the thighs and legs plus hemorrhage into nerve sheaths]. The onset of scurvy signaled a period of potentially rapid deterioration." Dr. Hodges' anticlimactic conclusion: "Once again our observations are in accord with those of the British Medical Research Council."

To other doctors, the "Ascorbic Acid Deficiency" study appears as a senseless piece of cruelty visited on the five volunteers. "This study was totally pointless," Dr. Ephraim Kahn of the California Department of Public Health said of Dr. Hodges' publication. "The cause and cure of scurvy have been well known in the medical profession for generations. Some of the side effects he lists may well be irreversible - the young man who had the most severe case of scurvy may never have recovered. There's a clue here to the degree of competence of these so-called 'researchers'--they 'inadvertently' omitted a mineral supplement from the diets. This no doubt weakened the men and exacerbated the other side effects. It might cause them to go into shock, and to suffer severe cardiac abnormalities." Among effects of the experiment recorded in the publication that could be permanent, Dr. Kahn cited heart damage, loss of hair, damage to teeth, hemorrhage into femoral nerve sheaths the latter is "terribly painful and could lead to permanent nerve damage."

I asked Dr. Hodges, now a professor of internal medicine at the University of California medical school at Davis, how much he had paid the scurvy test volunteers. "I think it was one dollar or maybe two dollars a day," he replied. "Over the years, when I was in Iowa, as the cost of cigarettes and razor blades went up, we increased prisoners' pay somewhat. It's unethical to pay an amount of money that is too attractive. Oh, we had the money, we could have paid much more, of course but we weren't just being cheap, we were considering the ethics of the situation. The prisoners got a bit extra for really unpleasant things--if we had to put a tube down their throats for several hours, or take a biopsy of the skin the size of a pencil eraser, we'd give them a few dollars more."

Doctors with whom I have discussed the matter agree unanimously that FDA regulations requiring drugs to be tested on humans before being marketed are sound and necessary. But human experimentation, they say, must be conducted within a framework of stringent rules for the protection of the human subject.

Since World War II a number of "guiding principles" and "codes of ethics" have been developed by the medical profession to govern the conduct of experiments. An American Medical Association resolution of 1946 on human research was in turn followed by FDA regulations of 1962 and the Helsinki Declaration of 1966.

These are largely repetitive. All affirm that human experiments must be based on prior laboratory work and research on animals, emphasize the grave responsibility of investigator to subject, and exhort him to avoid experiments that are of no scientific value or that subject humans to unnecessary pain and risk. Above all, the "informed consent" of the subject must be obtained.

In 1972 the U.S. Department of Health, Education and Welfare issued a set of comprehensive and detailed regulations, incorporating principles of the previous codes, entitled "The Institutional Guide to DHEW Policy on Protection of Human Subjects."

The Guide expresses a "particular concern" for "subjects in groups with limited civil freedom. These include prisoners . . ." Having uttered this praiseworthy sentiment, HEW has apparently let the matter drop. Dr. D. T. Chalkley, chief of the Institutional Relations Branch, Division of Research Grants, and signer of the Guide, tells me that HEW does not even maintain a list of prisons in which HEW-financed research programs are in progress and has "no central source of information" on the scope of medical experiments on prisoners by drug companies--in any event, the regulations set forth in the Guide apply only to HEW studies, and not to those sponsored by private industry. "The FDA has some data on prisoner usage by drug houses, but I doubt if this is collated."

"If the prisons closed down tomorrow, the pharmaceutical companies would be in one hell of a bind."

What efforts have been made by HEW to enforce its guidelines in HEW-financed medical research behind prison walls? "We do give some grants that involve prisoners. But there's no convenient way of recovering the information as to whether our guidelines are being followed," said Dr. Chalkley. "That responsibility lies with the principal investigator." I asked him about a letter I had received from Dr. Richard B. Hornick, director of the Division of Infectious Diseases, University of Maryland School of Medicine, who is currently conducting cholera, typhoid fever, viral respiratory, and viral diarrhea studies at the Maryland House of Correction under a grant from the National Institutes of Health, a division of HEW. "We can predict how many people will get sick following a particular dose of bacteria," Dr. Hornick wrote. "With cholera or with typhoid we will use a dose of organisms that will produce disease in 25 to 30 percent of the control [unvaccinated] population." He had furnished me with a copy of the consent form prisoner-subjects in these studies are required to sign, in which the prisoner agrees to "release and forever discharge" the principal investigator and everybody else involved in the experiment "from liability for any injury which may result directly or indirectly from the performance of these investigations." "Oh *damn!*" said Dr. Chalkley. "I was aware of this form two years ago I thought they said they were going to quit using it. I don't know. Give us hell; I guess we deserve it." Has HEW ever brought any action to enforce its regulations in any prisons anywhere? "None, to date."

Dr. Alan Lisook, of FDA's Office of Scientific Evaluation, said: "We've no list of prisons where drug research is going on. We know it does go on in certain prisons. The way we learn of it is through the IND [Investigational New Drug] submissions by the pharmaceutical companies. It's a touchy area, probably confidential information under the Trade Secrets Act. I suggest you make a written request say the magic words 'Freedom of Information Act'—and I will get an opinion from counsel as to whether we can compile the information for you." I did so, and in the course of time I obtained a list of prisons. "It is without doubt imperfect since this information is not routinely abstracted in a retrievable form," wrote Dr. Lisook. He was unable to furnish the names of drug companies experimenting in these prisons, or numbers of inmates involved.

A forthright explanation of the secrecy surrounding prison research was furnished by a vice president of Wyeth Laboratories, who asked me not to use his name. "Almost all our Phase I testing is done in prisons," he said. "The locations of the prisons in which we do research—that's fundamentally confidential information. *Where* we get our clinical work done is just as much a trade secret as *what* we're doing. There are industrial spies everywhere. If we let the names of the prisons out, our competitors could easily get a pipeline to what we're doing, and the secret would be out." Mr. Paul Stessel, public relations man for Lederle Laboratories, advanced a further reason for keeping mum. I asked him whether his company has a policy against disclosing names of prisons where it does research: "Yes, as a matter of fact." Why is that? "The prison administrators might get upset if there was publicity about it." [2]

Drug testing on human beings occurs in three stages: In Phase I, the new compound is tried out for effectiveness and possible toxic properties on a small group of normal, healthy individuals. If these survive without serious side effects and the drug appears promising, it is passed into Phase II, in which several hundred normal subjects are given the compound and the dosage is gradually increased until the experimenter decides the limit of safety has been reached. Once this is established, the drug is ready for Phase III, in which it is given as medication to patients to test its efficacy as a remedy for illness.

From my conversations with drug company executives and physicians involved in research, I learned that prisons today furnish virtually the entire pool of subjects for Phase I testing. "If the prisons closed down tomorrow, the pharmaceutical companies would be in one hell of a bind," said one medical researcher. (The drug houses, are, however, casting eyes in the direction of the "underdeveloped" nations as potential reservoirs of

[2] Missing from Dr. Lisook's imperfect list is Patuxent Institution, Maryland. Phil Stanford, writing in the New York *Times* Magazine (September 17, 1972), reports that Johns Hopkins, the University of Maryland, and the National Institute of Mental Health are conducting a number of experimental "behavioral control" drug programs in the institution. "It's no sweat getting volunteers because all of these programs pay volunteers," a staff member told him. Stanford cites a Johns Hopkins experiment in which an inmate is getting dosages of a female hormone, "presumably to counteract his 'supermasculinity,'" and quotes the following exchange between Edward Tomlinson, a law professor, and members of Patuxent's professional treatment staff:

Tomlinson: Does he understand the effects of the drug?

Dr. Harold M. Boslow, director of Patuxent: Yes, we explained the whole thing to him. We don't want any misunderstanding.

Tomlinson: Well, what are the effects?

Dr. Arthur Kandel, associate director: We don't know. That's what they're trying to find out.

human experimental material.) Most pharmaceutical concerns have to queue up for available prison populations on which to experiment, but two of the biggest—Upjohn and Parke, Davis—are in the enviable position of having acquired exclusive rights to Michigan's Jackson State Prison. In what Charles Mangee, public relations spokesman for Upjohn, calls "a beautiful operation run in a highly ethical fashion," the two companies maintain fully equipped laboratories built at a cost of half a million dollars, complete with hospital bed space within the prison for forty inmate subjects. Upjohn says that these facilities incorporate greater safeguards against injuries to prisoners than is common in experiments conducted through private researchers. A group of three physicians, for example, reports directly to the Department of Corrections and any one of them may order an experiment stopped at any moment. Pay scales, however, are much the same as elsewhere.

Until recently, inmates have also served as laboratory workers in the Upjohn–Parke, Davis clinics. In 1968, some of them brought suit against the companies and the Department of Corrections, alleging that "the drug companies are obtaining or have obtained hundreds of thousands of dollars' worth of labor free. . . ." The inmates, who frequently put in a sixteen-hour day, were paid a wage ranging from thirty-five cents a day for a nurse to $1.25 a day for a chief technician. (Although the allegations with respect to wage levels were not in dispute, the case was decided in favor of the defendants on other grounds.)

Over the past ten years a brisk traffic in human subjects for drug company experimentation has grown up in the California Medical Facility at Vacaville, a prison specifically designated for men deemed by the authorities to be in need of psychiatric treatment. Vacaville has a population of some 1500, of whom from 300 to more than 1000 may be in the volunteer medical research program at any given time.

The medical experiments are organized under the aegis of an organization called the Solano Institute for Medical and Psychiatric Research (SIMPR), with headquarters in the prison. I discovered that even such prison knowledgeables as faculty members at the School of Criminology in Berkeley, and California legislators who have devoted years to studying prison conditions, were but dimly aware of the existence of SIMPR and had no idea of the extent and the nature of its activities.

Unlike the Upjohn-Parke, Davis operation, which

A GUIDE TO PRISON RESEARCH

Following is a list of U.S. prisons, furnished by the Food and Drug Administration, where medical experiments are conducted.

Alabama: Alabama State Prison System, Montgomery.

Arkansas: Arkansas State Prison, Cummins.

California: California Institution for Women, Chino; California Medical Facility, Vacaville.

Connecticut: Connecticut State Prison, Somers; Connecticut Correctional Institution, Montville.

Florida: Avon Park Correctional Institution, Avon Park; Florida State Prison, Raiford; Glades Correctional Institution, Belle Glades; Lowell Correctional Institution, Lowell; Largo Prison Farm, St. Petersburg.

Georgia: U.S. Federal Penitentiary, Atlanta.

Illinois: Joliet Prison, Joliet.

Indiana: Indiana State Prison, Michigan City; Marion County Jail, Indianapolis.

Iowa: Anamosa State Men's Reformatory, Iowa City.

Louisiana: Orleans Parish Prison, New Orleans.

Maryland: Maryland House of Correction, Jessup.

Massachusetts: Massachusetts Correctional Institution, Norfolk.

Michigan: Southern Michigan State Prison, Jackson; Detroit House of Corrections, Plymouth.

Missouri: Missouri State Penitentiary, Jefferson City.

Montana: Montana State Prison, Deer Lodge.

New Jersey: Essex County Prison, Caldwell.

New York: Attica State Prison, Attica; Sing Sing Prison, Tarrytown.

Ohio: Cincinnati City Jail, Cincinnati; Ohio Correctional Institution, Lebanon.

Oklahoma: Oklahoma State Penitentiary, McAlister.

Oregon: Oregon State Penitentiary, Salem.

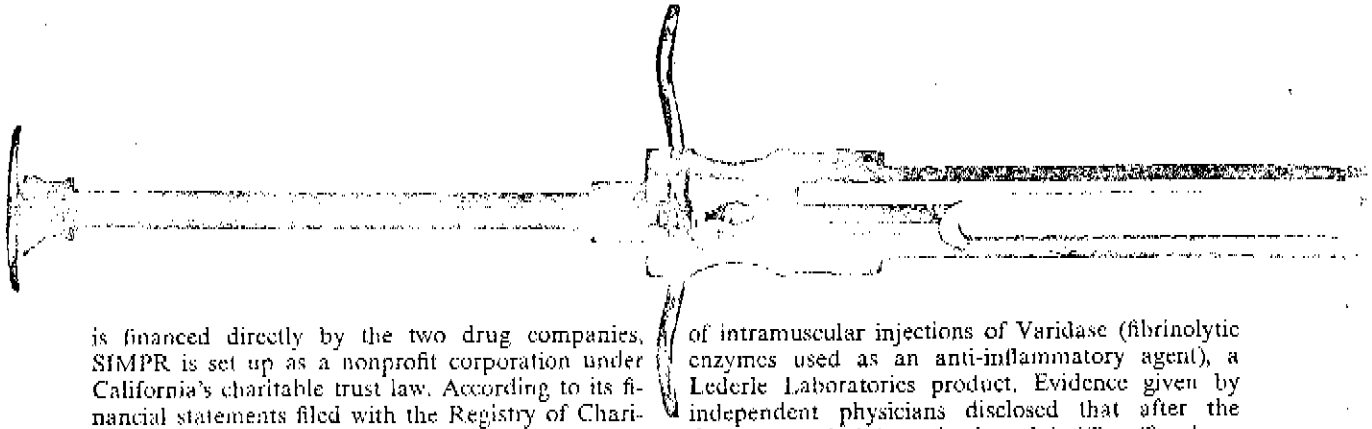
Pennsylvania: Bucks County Prison, Doylestown; Lancaster County Prison, Lancaster; Holmesburg Prison, Philadelphia; Philadelphia House of Corrections, Philadelphia; Berks County Prison, Reading; Northampton Prison, Easton; Chester County Farm, Westchester; Delaware County Prison, Thornton; Lebanon County Prison, Lebanon.

Rhode Island: Adult Correctional Institution, Howard.

Texas: Texas State Penitentiary, Huntsville.

Vermont: Vermont State Prison, Windsor.

Virginia: Virginia State Penitentiary, Richmond; Lorton Reformatory, Lorton.



is financed directly by the two drug companies, SIMPR is set up as a nonprofit corporation under California's charitable trust law. According to its financial statements filed with the Registry of Charitable Trusts, SIMPR's income from "various researchers" rose from $47,000 in 1963, its first year of business, to $266,000 in 1971. I asked Mr. Ralph Urbino, SIMPR administrator, which drug companies had paid over this money. He seemed quite shocked at the question: "We couldn't receive funds from drug companies," he said. "As a nonprofit organization we are barred from receiving money from private business concerns. Our income is derived from the physicians who have been given research grants for the purpose."

The "various researchers," then, for the most part faculty members from neighboring University of California medical schools, are a conduit for tax-exempt payments from giant pharmaceutical concerns, including Lederle, Wyeth, Dow Chemical, Roche, Abbott, and Smith, Kline & French. According to a 1972 SIMPR publication addressed to potential customers, "One research team from the University of California has been continuously active since the inception of our program here. . . . There have been no deaths or serious sequelae resulting from drug research at this institution . . . the reservoir of volunteer subjects offers investigational possibilities not found elsewhere."

Checking on SIMPR's claim that there have been no deaths or "serious sequelae" is not easy, since SIMPR maintains it is not required, under the California Public Records Act, to disclose medical data. But something of the modus operandi of the prison experimenters can be gleaned from records subpoenaed and depositions taken in a lawsuit, eventually settled out of court for $6000, that arose out of a 1962 experiment. The two principal defendants in that suit are prime operatives in SIMPR today. Dr. William C. Keating, Jr., then superintendent of Vacaville prison, was a founder of SIMPR and serves on its board of directors; Dr. William L. Epstein, chairman of the dermatology department at the University of California, conducted the experiment in question together with a colleague, Dr. Howard I. Maibach. Drs. Epstein and Maibach are the self-same "continuously active" research team featured in the 1972 SIMPR publication.

The plaintiff, who according to Dr. Keating had been classified as psychotic and sent to Vacaville for "psychiatric programming and treatment," was one of twenty subjects selected to undergo what Dr. Epstein calls "pain tolerance studies" consisting of intramuscular injections of Varidase (fibrinolytic enzymes used as an anti-inflammatory agent), a Lederle Laboratories product. Evidence given by independent physicians disclosed that after the drug was administered, the plaintiff suffered an agonizing, near fatal disease of the muscles, in the course of which his weight dropped from 140 to 75 pounds. He subsequently developed chronic stomach ulcers as a result of being treated for his condition with steroids.

From the depositions of the doctors in charge, it appears that nobody involved knew much about Varidase except that it can make people very ill. The purpose of the experiment, as explained by Dr. Epstein, was to find out just how ill and to learn more about adverse side effects caused by the drug: "The reason we did the experiment was the pain and the fever . . . what we were looking for was pain, discomfort, aching in the arm. We were told [by Lederle] they might also have fever, malaise, and chills." Dr. Keating recalled that the only information available to him on the drug was "a little brochure that comes with the preparation" containing "a bit of medical cautions, but at the time I read them . . . this was not a significant concern." Could the Varidase injections have caused the plaintiff's condition? "There was the possibility that this could have been due to the drug," said Dr. Epstein. "I think that looking back on it now it is a possibility, a better possibility than I thought initially because I never heard of this thing. . . ."

As to his role as principal investigator in overseeing the experiment, Dr. Epstein could not remember if he had been present when the subjects were chosen or when the injections were given—they were given by inmate nurses, he said. His visits to Vacaville were infrequent, once a week or once every two weeks. . . . No signed consent was required of the prisoner-subjects, said Dr. Keating. Asked in his deposition whether "the dangers of any of those possible medical problems were mentioned or explained to any of the potential volunteers for this project," he answered: "I don't know. I would think not." A "large fund" was granted by Lederle for the research, said Dr. Epstein. Compensation to the plaintiff for taking part: "He received four dollars, three spendable and one to retention funds."

If pain, discomfort, fever, and chills were what Dr. Epstein was looking for, he was not disappointed. In a letter to his sponsors at Lederle he wrote: "I am enclosing a rough copy of the comments from one of the subjects. I thought you might enjoy his description of the symptomatology;

"It was a potential time bomb for the Department of Corrections."

it's fairly representative of what all the men experienced." Among the descriptions that Lederle might have enjoyed, given by the nineteen subjects who did not sue, and subpoenaed by the plaintiff as part of the record: "Cold chills, sweated, nauseated throughout the night." "Sharp abdominal pains." "I have a headache and my stomach feels terrible." "My body feels weak all over, right arm hurts worse than ever." "My head feels as if it will fall off." "Chilled, feverish, weak and exhausted." "Lost 4 lbs. in three days—Dr. Epstein said it was a natural reaction except it was more severe in my case for some reason but not to worry." (What eventually became of the nineteen—whether they made full recovery—history does not relate. That nobody bothers to follow up the subsequent medical history of research subjects in prison can be inferred from Dr. Epstein's deposition to plaintiff's counsel Malcolm Burnstein: "Since [the plaintiff] cleared the initial experiment, it was forgotten, because like all the other people they were just let go. . . . And he came back, I couldn't tell you how soon, complaining of aching. . . .")

Thorough researcher that he is, Dr. Epstein was soon at it again. He writes to Lederle a month after the plaintiff was stricken: "We are planning this week to try four more men and I am prepared to give them some steroids when the severe symptomatology starts."

From my discussion with Mr. Urbino, a genial, retired Air Force man who is SIMPR's only full-time "free-world" employee, I concluded that SIMPR evolved in a somewhat haphazard fashion and is run on highly informal lines. For the first four years of its existence, SIMPR lived off the bounty of the prison (and hence the taxpayers), paying no rent or prison personnel wages. "It was a potential time bomb for the Department of Corrections," said Mr. Urbino. "Besides, they saw SIMPR as a very prosperous operation; they wanted to get their hands on some of that money." In 1966 SIMPR entered into a permit agreement with the Department. The corporation now pays an annual rent of $1000 plus "custodial coverage" (guards' wages) of about $14,000 a year, and provides moonlighting jobs for other state employees to the tune of some $17,000.

SIMPR also hires convict labor technicians, nurses, para-medical and clerical personnel—for wages in the range of five to eight dollars a month, about one-hundredth of what free personnel would command in these positions. (As Ken E. Haden pointed out in a 1963 report on the Vacaville operation to the U.S. National Institute of Mental Health: "Without this reservoir of skilled technicians, laboratory aides, clerical help, medical research could not be more than a token activity in a prison setting.") In SIMPR's first four financial reports, this item, between $700 and $800 a year for work worth $70,000 to $80,000 outside the walls, shows up as "Inmate Salaries." Thereafter it is no longer itemized but is merged along with most other cost items into a general category labeled "cost of goods sold." Could these inmate salaries be another potential time bomb for the Department of Corrections? The California constitution specifically prohibits the contracting out of convict labor "to any person, copartnership, company, or corporation," which would seem to cover the SIMPR operation. Mr. Urbino, who is not a lawyer, was unaware of the constitutional prohibition.

Payment to the prisoner-subjects of the experiments is variously recorded in SIMPR's financial statements as "honoraria," "donations," "benefits to recipients under charitable trust." Spiraling upward with the fortunes of SIMPR, these honoraria, donations, or charitable benefits rose from $34,000 in 1963 to $150,000 in 1970. The nine-year total is $787,000. Thus, assuming the drug companies would have had to compensate free-world volunteers at ten times what they pay convicts, they obtained some $7.8 million worth of research for their $787,000.

Who establishes the amount of pay for each experiment? "I do," said Mr. Urbino. "Several factors go into it: number of times we bleed the man, number of times he has to report to the lab on any given day." Sample payments range from $15 a month for a two-month study of inflammatory dermatophytosis (fungi described in the protocol as "one of the most prevalent health hazards to military personnel stationed in Southeast Asia") to $30 for one day for Cleocin HFC levels, an experiment run by Dr. Epstein in which a gram of muscle tissue is removed. If unusually adverse side effects are anticipated, the pay goes up accordingly. "We're in the middle of one now, conducted by Dr. Howard I. Maibach, a Wyeth safety study, WY-21,743. It pays sixty dollars a month." What side effects might be expected? Mr. Urbino, who is not a medical man, did not know. (I subsequently asked the Wyeth vice president what mysterious WY-21,743 consists of. His reply: "That's confidential information in the Investigational New Drug file. I wouldn't tell my own mother about it!" Nor would FDA reveal the formula. Dr. Li-

Systematically impoverished by his keepers, denied a decent wage, the prisoner is reduced to bartering his body for cigarette and candy money.

sook told me, "The Freedom of Information Act specifically prohibits such disclosure. Our new regulation says 'the very existence of an IND is confidential.' ")

Why does the Department of Corrections tolerate the SIMPR presence--is it because the rent money and payment to guards (who would have to be paid anyway) is a nice financial cushion for the institution? "That's part of it," said Mr. Urbino. "But the main benefit to the Department is that the research programs cut down on disciplinary problems. A man has to have a relatively infraction-free record to qualify as a volunteer subject. And the Department figures if he has thirty dollars a month to spend on canteen, he'll be a lot cooler." Systematically impoverished by his keepers, denied a decent wage, the prisoner is reduced to bartering his body for cigarette and candy money.

Presumably to insure against any repetition of the 1962 lawsuit, SIMPR now requires each convict-subject to sign a consent form and waiver, stating, "I hereby fully and forever release, acquit and discharge" all state agencies involved, plus SIMPR, "from any and all liability which may accrue" from participation in the research project.

To my question whether the waiver is not in clear violation of HEW guidelines, I got the following answers. Dr. Alan Lisook, who had twice inspected the SIMPR operation on behalf of FDA, said he was not aware that such a waiver was being used. "Although we require a consent form in all drug experimentation, we do not require that the wording be cleared with us, nor that copies be submitted. It would be very difficult to enforce the prohibition against exculpatory clauses." The Wyeth vice president: "The medical monitor of Wyeth is in charge of that." (The name of the medical monitor is, however, confidential, he said.) Mr. Paul Stessel, public relations spokesman for Lederle: "It's the responsibility of the investigator to follow the guidelines and obtain a proper consent form. We don't dictate to the clinician how he runs these things. I'm sure you're aware that the more prestigious the clinician is, the more convinced he is that he knows what he's doing. If you use him, you have little choice but to trust what he says he does." Dr. Howard I. Maibach, principal investigator for many SIMPR experiments: "Yes, I'm familiar with the consent form used at Vacaville. It's in a period of change, a state of flux. . . ."

Theoretically, the University of California medical schools exercise considerable control over faculty member researchers through committees on human experimentation, consisting of medical professors and laymen, established by the president of the university in 1966. These are supposed to review and pass on the protocol for each proposed study under University of California sponsorship "regardless of funding source"—in the light of HEW and FDA standards.

At a meeting of the University of California Medical Center Committee on Human Experimentation, I was told that few SIMPR protocols had ever been submitted to the committee. "Prison research that comes before this committee is extremely rare," said one member. "The minute a Vacaville study comes in, the red flag goes up!" Although both Dr. Epstein and Dr. Maibach are on the Medical Center faculty, the committee had never heard of most of the experiments they are currently conducting at Vacaville. Of another team of doctors, listed in SIMPR's 1971 report as faculty members of the Medical Center and principal investigators in current research studies, I was told that one had been "severed" by the university in 1966 and the other had died in 1968.

The California Department of Corrections publishes an annual research review, in one section of which some thirty experiments conducted under the auspices of SIMPR are set forth in précis form. Since these are couched in the language of pharmacology and medicine, the nature of the experiments is for the most part obscure to the layman. (An exception is the Aedes Mosquito Study, in which "freshly grown, unfed female mosquitoes in carefully prepared biting cages are applied to the forearms of volunteers for a period of ten minutes," which seems explicit enough.)

Seeking clarification, I showed a copy of the 1971 research review to Dr. Sheldon Margen, a physician with wide experience in human research, who, as chairman of the Department of Nutritional Sciences at the University of California, uses students and other free-world volunteers as experimental subjects. Dr. Margen read with fascination and mounting indignation the experiments described in the review. He translated the procedures for me, interjecting a frequent "Wow!" or "Brother!" or "God, that kills me!" Some of the studies, he said, are innocuous; others, extremely painful and potentially dangerous.

He mentioned, as an example, Dr. Epstein's study of Cleocin HFC levels, for which "ten healthy normal volunteers" were selected; its purpose, "to determine antibiotic levels in various tissues and/or fluids." Each subject gets "150 mg of

Cleocin q.i.d. for a single day," following which he will be relieved of "sebum, 2-4 ml; sweat, 4-5 ml; semen, amount of normal ejaculation; and muscle tissue, 1 gm. In addition, a 15 cc blood sample will be drawn. . . ." "Here's what happens to these ten guys," said Dr. Margen. "First they make them masturbate to collect the semen. Then they cut into the arm or go through the flesh to get the gram of muscle tissue. That's the horrific part. The experiment itself may be totally justified -the drug presents virtually no risk but this procedure is cockeyed. It would never be approved for student-subjects." Nor had it ever been approved by the University of California Medical Center Committee on Human Experimentation. Dr. Leslie Bennett, chairman of the University of California committee, told me "there's no evidence this was ever submitted for review."

The Organic Phosphates Toxicity Study, the purpose of which is "to determine the threshold of incipient toxicity in human subjects of organic phosphates currently in wide use as insecticides," involves the use of the most dangerous and poisonous of all pesticides, said Dr. Margen. Would this be approved for experimentation on students? "Are you kidding?" Possible hazards of other experiments described in the research review include, he said, cardiac failure, total loss of blood flow resulting in neurological damage and loss of fingers, fungus infection, allergic reactions . . .

In 1947 fifteen German doctors, all distinguished leaders of their profession, were tried and convicted at Nuremberg for their cruel and frequently murderous "medical experiments" performed on concentration camp inmates. The barbarity of these crimes is of course unparalleled, but the Nuremberg tribunal established standards for medical experimentation on humans, which, if observed, would end altogether the practice of using prisoners as subjects: "The voluntary consent of the human subject is absolutely essential. This means the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice . . . and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding, enlightened decision." Are prisoners, stripped of their civil rights when they enter the gates, subjected to years or decades of confinement, free agents capable of exercising freedom of choice? Can we trust that they are furnished by the experimenters with "knowledge and comprehension" to enable them to make "understanding and enlightened" decisions? To ask these questions is, I believe, to answer them. □

HISTORY OF ALCHEMY

All the gold that exists was transmuted once
by men learning to change themselves
who broke it and buried it
those who found it
took it for a metal
wanted it for its own sake
to have rather than to foresee
and for them it was evil
and they declared that transmuting it was impossible
and evil

by W. S. Merwin

THE UNIVERSITY OF MICHIGAN
COLLEGE OF PHARMACY

JOHN G. WAGNER, PH.D.
PROF. OF PHARMACY
ASS'T. DIR. FOR RAD. PHARMACY SERVICE
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October 20, 1972

Mr. Robert Manning
Editor-in-Chief
Atlantic Monthly
8 Arlington Street
Boston, Massachusetts 02116

Dear Mr. Manning:

This letter is in response to the copy of a letter I received from Dr. William S. Apple directed to you.

Concerning use of prisoners as subjects in drug studies I suggest you write the following:

1. Alan B. Varley, M. D.
   Medical Director, Pharmaceutical Marketing
   The Upjohn Company, Building 88
   Portage Road
   Kalamazoo, Michigan 49001

2. Stephen N. Preston, M.D.
   Director, Clinical Investigation Department
   Parke, Davis & Co.
   Research Laboratories
   2800 Plymouth Road
   Ann Arbor, Michigan 48105

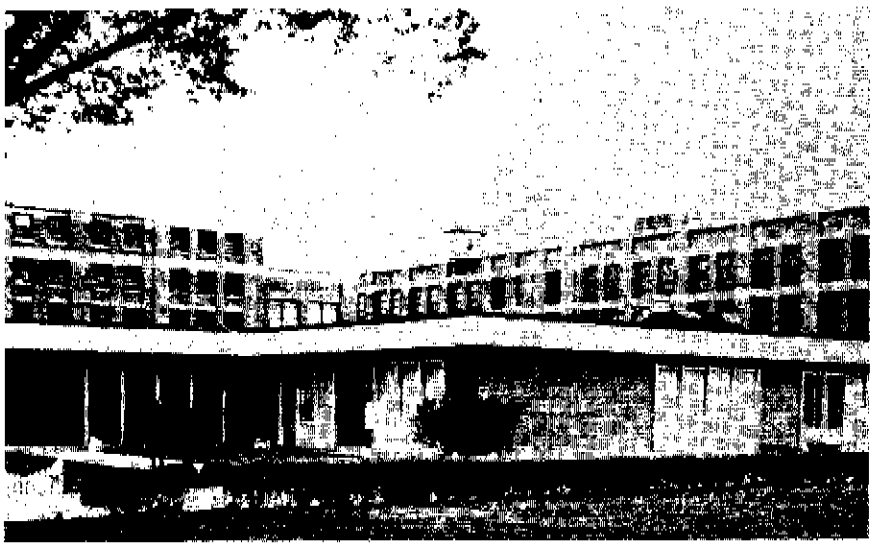
Both the Upjohn Company and Parke, Davis & Co. have built hospital facilities behind the walls of Jackson Prison, Jackson, Michigan, and the above two gentlemen know the most about use of these facilities.

Sincerely,

John G. Wagner

John G. Wagner, Ph.D.

Copy:
William S. Apple, M.D.
Executive Director
American Pharmaceutical Association
2215 Constitution Ave. N.W.
Washington, D. C. 20037



The Research Clinic inside the Southern Michigan State Prison.

In 1964 the State of Michigan through its Department of Corrections established an unbiased Research Protocol Review Committee which has functioned for the State as a scientifically knowledgeable peer review and advisory committee concerning human research in the prison population. Policies for clinical research involving volunteers from the prison population were firmly established. The unique cooperation of existing state agencies and the medical colleges permitted the formation of an over-all advisory committee which included representatives of the State Department of Corrections, the State Health Department, and the two Michigan Medical Colleges. The establishment and functioning of the Research Protocol Review Committee are described. After the committee was established Phase I studies were permitted within the prison population. Since the formation of the Research Protocol Review Committee, in several hundred Phase I and other studies, no serious adverse reaction has yet occurred.

A Research Protocol Review Committee For the State of Michigan

BY ROSS V. TAYLOR, M.D., JACKSON
CHRIS J. D. ZARAFONETIS, M.D., ANN ARBOR
EDWARD A. CARR, JR., M.D., ANN ARBOR
LAWRENCE H. POWER, M.D., DETROIT
PARK W. WILLIS, III, M.D., ANN ARBOR
PHILIP A. RILEY, JR., M.D., JACKSON

During the past few years new regulations have led to a marked increase in the influence of the Food and Drug Administration on the study and use of drugs in this country. While some problems remain to be resolved, the pharmaceutical industry, the academic community and practicing physicians have, for the most part, made excellent progress towards a satisfactory adjustment to these new regulations.

Unfortunately, it now appears that this complex system may be further complicated by legislative action at the state or national level. Legislation introduced in the New York State Legislature last year would have established a State Commission with authority to control all research involving human subjects.[1] It was proposed that this Commission on Medical Research consist of a

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chairman, appointed by the Governor, and 11 other members. The act further provided that "not less than six of those 11 other members shall at all times be non-members of the medical profession." The implications of such legislation are far-reaching and of concern to all who are responsible for developments in clinical pharmacology and therapeutics. The New York State proposal would have placed control of human research in the hands of "non-members of the medical profession." It would also have created an administrative and review mechanism which would intrude on the area of responsibility and authority of hospital directors and professional staffs, deans of medical schools and their faculties (including their respective Committees to study Clinical Research and Investigation Involving Human Beings, and which follow guidelines set forth by the Public Health Service) and prison commissioners and their boards in those situations where inmates volunteer to participate in such studies. Chaos would result should all 50 states create differing laws regulating research on human beings.

ON THE NATIONAL SCENE the recent problems disclosed in the *New York Times*, May 31, 1969, concerning the necessity for the Alabama Board of Corrections to order a halt to the drug testing programs being conducted in the state prisons, resulted in wide-spread adverse publicity and editorials concerning drug testing and research throughout the nation.

The *Medical World News* in the August 29, 1969 issue, page 13, states: "Partly as a result of recent 'disclosures' in the *New York Times*, mostly a rehash of earlier stories in the Montgomery (Ala.) *Advertiser*, and a critical report by the Medical Association of the State of Alabama, FDA Commissioner Herbert L. Ley, Jr., was called before the Senate Monopoly Subcommittee of Sen. Gaylord Nelson (D.-Wis.). Dr. Ley testified that the agency would seek to have expert reviewers examine protocols at prisons and other institutions conducting drug studies and monitor the evaluations."

In the *American Medical News* August 25, 1969 it was reported that Dr. Ley in questioning by a Senate Small Business Subcommittee stated that he planned "to issue a regulation requiring that drug testing in prisons and hospitals be screened by 'peer groups' of physicians, lawyers, and clergymen."

Senator Nelson has introduced a bill that would create a federal center, under FDA auspices, to do all such work.

THESE COMMENTS are not to be construed as criticism of the Legislature of the Commonwealth of New York, which is properly attempting to assure maximum protection for those participating as subjects in human research. In New York, Alabama, and in many other states, there appears to be a need for some means by which drug investigation in humans can continue with adequate safeguards for volunteer subjects outside of university medical centers. At the present time all university medical centers and most hospitals where research involving human beings is performed have review committees assigned this responsibility. But there remains a large group of normal volunteers, often prisoners, for whom similar supervision and protection must be provided. However, the placement of research guidance under uninformed laity would seem ill-advised and impractical.

The State of Michigan has provided safeguards for over five years for its Department of Corrections through its Protocol Review Committee. This description of the history and function of the Committee is presented here in the hope that it may be helpful to others searching for a means of dealing with this problem.

BACKGROUND

The effective use in preceding years of volunteers from the prison population for human research at the Southern Michigan State Prison led to the suggestion by the Upjohn Company in 1961 that a research facility be constructed inside the prison. This suggestion was of interest to the Department of Corrections because serious space problems had limited the research programs that could be conducted in the prison hospital. In November, 1961, Harold L. Upjohn, M.D. and William N. Hubbard, Jr., M.D., Dean of the University of Michigan Medical School, met with the Corrections Commission of the State of Michigan and outlined proposals for the general research program and for the construction of a Medical Research Building within the Southern Michigan State Prison.[2]

In December, 1961, the Corrections Commission

Part of the laboratory and examining rooms of the special facility for research projects at Southern Michigan State Prison.

approved[3] in principle recommendations relative to:

1. Construction of a facility.
2. Participation of inmates. Guidelines stated that participation must:
   a. Be voluntary in all instances.
   b. Be based upon informed consent. An agreement between each volunteer and The Upjohn Company informing the inmate of the nature of his participation and the possible associated hazards.
   c. Include the right to voluntary withdrawal from a study at *any* time.
   d. Stipulate the rate of compensation for volunteers.
   e. Be based on the non-discriminatory inmate participation policy.
3. Waiver of liability on the part of the State, the Commission, and its employees.
4. Liability insurance.
5. Special diet responsibilities.
6. Proposed research project review procedure.
7. Cost of construction.
8. Possession of title of the building.
9. Professional staff and custodial control.

In April 1962, the Corrections Commission asked the Director of the Department of Corrections to inform the Parke, Davis Company that the Department was proceeding with the Upjohn Proposal,[4] and in May advised the Director to proceed with the Upjohn Project.[5] In August, the Director reported to the Commission that meetings had been held with the architect to initiate planning for the construction of a Research Building.[6] In March, 1963, the Commission reviewed the request of the Parke, Davis Company to join The Upjohn Company in the construction of the Research Building and recommended to the Director that the request be approved.[7]

EARLY IN 1964, Harold L. Oster, M.D., an Upjohn Company research investigator, and Harold L. Upjohn, M.D., became concerned that the only review of research protocols was within the research department of the Company. An unbiased review mechanism seemed desirable for several reasons including a desire to improve the safety factors of volunteers for the studies, and also the recognition of the problem that in the advent of an adverse drug reaction there might well be criticism of the absence of an unbiased review of the safety of any proposed project prior to initiation of the study. This concern of The Upjohn Company officers coincided with that of the Department of Corrections for the State of Michigan, which has primary responsibility for the safety of all prisoners as wards of the State.

On March 3, 1964, Alexander Z. Lane, M.D., Edward L. Holmes, M.D., Harold L. Oster, M.D., Robert E. Mellar, M.D., Alan B. Varley, M.D., and Mr. Ralph Willy met to discuss the important responsibility of the Company and the State for the safety of inmate volunteers participating in these research projects. They recommended the formation of a Protocol Review Committee to evaluate all medical research projects to be conducted in the State of Michigan within the jurisdiction of the Department of Correction.[8] In May, 1964, the Commission approved the appointment of an advisory Protocol Review Committee to assist the Department of Corrections by reviewing research proposals to be carried out on volunteers under jurisdiction of the Department.[9]

In April, 1964, Mr. Gus Harrison, Director, Department of Corrections, invited five physicians,

One of the ward rooms for in-patient volunteers at the prison research station.

Edward A. Carr, M.D., Joseph A. Preston, M.D., Philip A. Riley, Jr., M.D., Ross V. Taylor, M.D., and Chris J. D. Zarafonetis, M.D., to become members of a Protocol Review Committee.* All accepted and Dr. Taylor was appointed Executive Secretary and was asked to serve as Chairman of the Committee. Each member had skills and knowledge in specific areas which, it was anticipated, would be of importance to the work of the Committee.

1964 In May 1964, Alan B. Varley, M.D., Alexander Z. Lane, M.D., and Chris J. D. Zarafonetis, M.D., met with the Commission to discuss experiences with the development of new drugs. The Commission agreed to volunteer participation by prisoners in experiments involving new compounds if the inmates were fully informed in non-scientific terms of the nature of the experiment and were given permission to withdraw at any time.[5]

THE COMMISSION ALSO recommended the appointment of a special advisory committee to assist in determination of policies concerning human research. This advisory committee was to consist of representatives of the Michigan Department of Corrections, Michigan Department of Health, and the then existing two schools of Medicine. Ernest D. Gardner, Ph.D., Dean of the Wayne State University College of Medicine, William N. Hubbard, M.D., Dean of the University of Michigan School of Medicine and Albert E. Heustis, M.D., Director of the Michigan Department of Health, agreed to serve on this Advisory Committee. Commissioner Duane L. Waters, M.D., was appointed to represent the Commission.

CONSTITUTION OF THE REVIEW COMMITTEE:

The complete statement of purpose and functions of the Protocol Review Committee was as follows:

I. PURPOSE: To review and render an opinion to the Director of the Department of Corrections on the safety and suitability of research protocols submitted by the Parke, Davis or Upjohn companies on studies to be conducted in the prison system of the State of Michigan.

II. MEMBERS: The Committee will be appointed by the Director of the Department of Corrections, shall report directly to him, and will consist of three to five physicians with previous research experience, located in the Michigan area. One member of the Committee shall be appointed Executive Secretary and shall be responsible for the administration of Committee functions.

*Dr. Allen R. Hennes was added to the Committee to represent the Wayne State University Medical School. Following Doctor Hennes' untimely death, Dr. Lawrence H. Power was appointed to the Committee. Park W. Willis, M.D., joined the Committee to fill the vacancy created when Dr. Joseph Preston moved to another state.

Defibrillator monitor in Southern Michigan Prison room for special studies.

III. DUTIES: The Committee shall meet once monthly to review all protocols forwarded to the Director of the Department of Corrections by the involved companies. At the discretion of the Executive Secretary, Protocols representing repetition of previously approved studies, studies of previously reviewed drugs with only minor protocol changes, diagnostic procedures, or studies involving no drug or commercially available drugs may be reviewed informally by letter. In such instances recommendation for approval or disapproval may be communicated to the Director of the Department of Corrections without a formal Committee meeting. All protocols involving drugs new to the prison system shall be formally reviewed by the Committee.

IV. STIPENDS: Stipends and expenses (travel) use of consultants, etc. are paid by the State Board of Corrections from a general operating fund provided equally by the Upjohn and Parke, Davis companies.

OPERATIONS OF THE PROTOCOL REVIEW COMMITTEE

The general plan for proposal review and implementation of protocols is as follows:

a. The company or individual wishing to initiate a research project forwards an appropriate number of copies of the proposed protocol with necessary information to the Director of the Department of Corrections.

b. One copy remains in the Director's office and copies are forwarded to the Executive Secretary of the Committee for distribution to Committee members.

c. The Committee reviews the protocol for evidence of medical safety and suitability; one or more representatives of the sponsoring company are present at meetings involving review of protocols submitted by that company and provide any additional information needed by the Committee in its consideration of the protocol.

d. The Executive Secretary forwards the recom-

mendation of the Committee for approval or disapproval (with a brief explanatory note) to the Director of the Department of Corrections as promptly as possible.

e. The Director of the Department of Corrections, after review of the Committee's recommendations, approves or disapproves the protocol by letter to the proposer.

DISCUSSION:

As far as can be ascertained, this working partnership between separate units of State government for the advancement of human research is unique to Michigan. The wisdom of such a partnership is obvious if one considers the responsibilities of each of the concerned agencies. The Department of Health must be concerned with all aspects of public health, the Department of Corrections must be entirely responsible for the imprisoned "wards of the State," and the Medical Schools must be continuously concerned with all aspects of medical research and education.

1964 The first meeting of the Protocol Review Committee on May 22, 1964 was an organizational one. Since June 1, 1964, the Committee has met at monthly intervals to review research protocols and make recommendations concerning them to the Department of Corrections. Protocols have been primarily submitted by the Parke, Davis Company and The Upjohn Company, but also by the R. P. Scherer Corporation, The University of Michigan and the Henry Ford Hospital.

The majority of the protocols have come from two Michigan based pharmaceutical companies. One hundred and thirty-eight (138) protocols from the Parke, Davis Company and 174 from The Upjohn Company were approved in the first five years.

The usual procedure has been for the Committee and representatives of each pharmaceutical firm to meet together as a group for general discussion. Then the Committee and representatives of each company in turn have a closed session for consideration of the protocols submitted by that firm. Protocols of one company are not, of course, discussed with representatives of other companies. Frequently the Committee has suggestions for modifying protocols to make them more safe for the subjects or to improve the information yield from the study.

It should also be noted that approval of a protocol by the Michigan Protocol Review Committee does not *ipso facto* allow a research project to be initiated. Even after approval by this committee, the recommendation and comments on safety and suitability of the proposed research are given to the Director of the Department of Corrections and his final approval is required before the study can be initiated.

PARTICIPATION BY the prisoners in these investigations within the prison is entirely voluntary. No individual inmate is asked to participate. Advertisements are placed in the prison newspaper and volunteers are obtained exclusively by this avenue. Volunteers must initiate their own participation by sending in a request as explained in the advertisement. Inmate participation in such research programs has no influence in consideration for parole or pardon. Payment to volunteers has been set at a low level so that it cannot be viewed as a strong inducement to participation. The attitude of the volunteers, although difficult to evaluate, is in general one of making a contribution to society.

Since April 1, 1964, 18,278 men have been "screened" as possible participants in drug studies. If an inmate meets the medical requirements, he is then eligible for participation in studies at either the Parke, Davis Clinic or Upjohn Clinic.

THROUGH 1968 there were 174 studies involving 5,296 subjects in the Upjohn Clinic. (Table 1.) In the year 1967, as an example of the distribution of the studies, the Upjohn Research Clinic performed 18 Phase I studies, 6 Phase II studies, and 3 Phase III studies. Together these involved 989 subjects for a total of 29,751 man-days.

The Parke, Davis Clinic since March 16, 1964 has had 5,641 volunteers participate in studies.

TABLE 1
THE UPJOHN CO. RESEARCH ACTIVITIES
SOUTHERN MICHIGAN STATE PRISON

Year	No. Studies	No. Subjects
1964	41	1299
1965	33	802
1966	42	1216
1967	27	989
1968	31	990
Totals	174	5296

TABLE 2
PARKE, DAVIS & CO. RESEARCH ACTIVITIES
SOUTHERN MICHIGAN STATE PRISON

Year	No. Studies	No. Subjects
1964	32	838
1965	28	1629
1966	24	1204
1967	20	774
1968	34	1396
Totals	138	5841

TABLE 3
ALL CLINICAL RESEARCH ACTIVITIES
SOUTHERN MICHIGAN STATE PRISON

Year	No. Studies	No. Subjects
1964	73	1937
1965	61	2431
1966	66	2420
1967	47	1763
1968	65	2386
Totals	312	10937

(Table 2) lists the number of studies and subjects at the Parke, Davis Research Clinic tabulated by year. There were 31,907 patient days involving 1,201 subjects in 1966, and 22,102 patient days involving 1,396 subjects in 1968.

From (Table 3) it can be seen that 10,937 volunteer subjects have participated in 312 protocol studies from the inception of the Protocol Review Committee through 1968.

SOME STUDIES do not require screening and some volunteers are used in more than one study. Many volunteers are screened three or four times a year. The physical examinations done prior to a study are sometimes an added bonus to the volunteers through the detection of disease not previously known. At any given time, there are about 1,200 inmates participating in the research program.

Prior to the establishment of the Protocol Review Committee, the study of new compounds was not permitted at the Southern Michigan State Prison. However, since the formation of the Committee, a majority of the protocols have been concerned with Phase I tests. It should be noted further that despite the large number of Phase I studies not a single serious adverse drug reaction has been encountered among the test subjects.

SUMMARY

Whenever prison inmates serve as volunteer subjects in research, safeguards against coercion and careful consideration of the safety of the studies are particularly necessary. As wards of the State, prisoners are entitled to the protection afforded by the existence of a reviewing body comprised of scientifically qualified individuals.

The Michigan Protocol Review Committee is offered as an example of such a reviewing body. The policies and operations of such a reviewing body should be established and monitored by an advisory group of representatives of the concerned governmental and scientific agencies. This insures the qualifications of the members of the reviewing committee and protects against possible coercive practices in the selection of subjects. The advisory group in Michigan has included representatives of the State Department of Correction, State Department of Health, and two of the schools of medicine.

There are alternative arrangements to insure that those conducting research among prison volunteers are held to careful public accountability. One alternative is exemplified by the New York State proposal to which reference was made at the outset of this article. The arrangement has as one of its important features the establishment of an entirely new group not composed of experienced scientific investigators and not deriving its authority from agencies or institutions already existing in the state.

The successful operation of a Protocol Review Committee in the State of Michigan, under policies established by an advisory group of representatives of established state agencies and medical schools suggests that the mechanisms such as outlined in the New York proposal, are unnecessary. Without additional legislative action most states could probably establish research review committees similar to Michigan's under authority already implied in their existing legal structures.

That the formula devised in Michigan is successful is attested by the fact that in an experience of over five years duration and in several hundred research studies frequently involving new drugs administered to humans for the first time, no serious adverse reactions have occurred. As far as can be ascertained the State of Michigan was the first to recognize its responsibilities and establish an adequate mechanism which protects the participating volunteers and yet permits the properly directed and necessary continuing human clinical research.

REFERENCES

1. State of New York Senate -- Assembly February 20, 1968 S.4015-A A.5586-A
An Act: To amend the public health law, in relation to human research.
2. Minutes of meeting of the State of Michigan Corrections Commission, November 1-2, 1961.
3. Minutes of meeting of the State of Michigan Corrections Commission, December 6-7, 1961.
4. Minutes of meeting of the State of Michigan Corrections Commission, May 2-3, 1962.
5. Minutes of meeting of the State of Michigan Corrections Commission, May 2-3, 1962.
6. Minutes of meeting of the State of Michigan Corrections Commission, August 1-2, 1962.
7. Minutes of meeting of the State of Michigan Corrections Commission, March 6-7, 1963.
8. Holmes, F. L.: Personal correspondence, 1968.
9. Minutes of meeting of the State of Michigan Corrections Commission, May 6-7, 1964.
10. Minutes of meeting of the State of Michigan Corrections Commission, June 17-18, 1964.

SUBCHAPTER C—DRUGS

PART 130—NEW DRUGS

Subpart A—Procedural and Interpretative Regulations

Subpart B—Drugs Exempted From Prescription-Dispensing Requirements

Subpart C—Final Orders Effecting Suspension or Withdrawal of Approval of New-Drug Applications

AUTHORITY: The provisions of this Part 130 issued under secs. 502, 505, 701, 52 Stat. 1051, 1052, 1055, as amended; 21 U.S.C. 352, 355, 371, unless otherwise noted.

SOURCE: The provisions of this Part 130 appear at 28 F.R. 6377, June 20, 1963, unless otherwise noted.

CROSS REFERENCES: For other regulations in this chapter concerning new drugs, see also §§ 1.106, 3.46, 3.511, 3.512, and 121.7.

Subpart A—Procedural and Interpretative Regulations

§ 130.1 Definitions and interpretations.

As used in this part:

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act, as amended (secs. 201–902, 52 Stat. 1040 et seq., as amended; 21 U.S.C. 321–392).

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Secretary" means the Secretary of Health, Education, and Welfare.

(d) "Commissioner" means the Commissioner of Food and Drugs.

(e) The term "person" includes individuals, partnerships, corporations, and associations.

(f) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

(g) "New-drug substance" means any substance that when used in the manufacture, processing, or packing of a drug, causes that drug to be a new drug, but does not include intermediates used in the synthesis of such substance.

(h) The newness of a drug may arise by reason (among other reasons) of:

(1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component.

(2) The newness for drug use of a combination of two or more substances, none of which is a new drug.

(3) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug.

(4) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body, even though such drug is not a new drug when used in another disease or to affect another structure or function of the body.

(5) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

(i) "Animals used only for laboratory research" and "laboratory research animals" mean individual animals or groups of animals used solely for laboratory research purposes regardless of species and does not include animals intended to be used for any food purposes or animals intended to be kept as domestic pets or livestock.

(j) The term "sponsor" means the person or agency who assumes responsibility for an investigation of a new drug, including responsibility for compliance with applicable provisions of the act and regulations. The "sponsor" may be an individual, partnership, corporation, or Government agency and may be a manufacturer, scientific institution, or an investigator regularly and lawfully engaged in the investigation of new drugs.

(k) The phrase "related drugs(s)" includes other brands, potencies, dosage forms, salts, and esters of the same drug moiety, including articles prepared or manufactured by other manufacturers; and any other drug containing a component so related by chemical structure or known pharmacological properties that, in the opinion of experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, it is prudent to assume or ascertain the liability of similar side effects and contraindications.

(l) [Reserved]

(m) "Designated journal(s)" means journals listed in § 130.38.

[28 F.R. 6377, June 20, 1963, as amended at 31 F.R. 4891, Mar. 24, 1966; 32 F.R. 8080, June 6, 1967]

§ 130.2 Biologics; products subject to license control.

(a) A new drug shall not be deemed to be subject to section 505 of the act if it is a drug licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.).

(b) A new drug produced and distributed in accordance with §§ 103.1 to 103.3 of Title 9 of the Code of Federal Regulations, issued under the animal virus, serum, and toxin law of March 4, 1913 (37 Stat. 832; 21 U.S.C. 151 et seq.) shall not be deemed to be subject to section 505 of the Federal Food, Drug, and Cosmetic Act.

[29 F.R. 7820, June 19, 1964]

§ 130.3 New drugs for investigational use in human beings; exemptions from section 505(a).

(a) A shipment or other delivery of a new drug shall be exempt from section 505(a) of the act if all the following conditions are met:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use."

(2) The person claiming the exemption has filed with the Food and Drug Administration a completed and signed "Notice of Claimed Investigational Exemption for a New Drug" in triplicate, with the information shown below in form FD–1571; and not less than 30 days have elapsed following the date of receipt

of the notice by the Food and Drug Administration; and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects. The 30-day delay requirement may be waived by the Food and Drug Administration upon a showing of good reason for such waiver.

Form FD 1571

Department of Health, Education, and Welfare, Food and Drug Administration

Notice of Claimed Investigational Exemption for a New Drug

Name of sponsor _____
Address _____
_____
Name of investigational drug _____
To the Secretary of Health, Education, and Welfare,
For the Commissioner of Food and Drugs,
Washington 25, D.C.

Dear Sir:

The sponsor, _____, submits this notice of claimed investigational exemption for a new drug under the provisions of section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3 of Title 21 of the Code of Federal Regulations.

Attached hereto are:

1. The best available descriptive name of the drug, including to the extent known the chemical name and structure of any new-drug substance, and a statement of how it is to be administered. (If the drug has only a code name, enough information should be supplied to identify the drug.)

2. Complete list of components of the drug, including any reasonable alternates for inactive components.

3. Complete statement of quantitative composition of drug, including reasonable variations that may be expected during the investigational stage.

4. Description of source and preparation of any new-drug substances used as components, including the name and address of each supplier or processor, other than the sponsor, of each new-drug substance.

5. A statement of the methods, facilities, and controls used for the manufacturing, processing, and packing of the new drug to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug.

6. A statement covering all information available to the sponsor derived from preclinical investigations and any clinical studies and experience with the drug as follows:

a. Adequate information about the preclinical investigations, including studies made on laboratory animals, on the basis of which the sponsor has concluded that it is reasonably safe to initiate clinical investigations with the drug: Such information should include identification of the person who conducted each investigation; identification and qualifications of the individuals who evaluated the results and concluded that it is reasonably safe to initiate clinical investigations with the drug and a statement of where the investigations were conducted and where the records are available for inspection; and enough details about the investigations to permit scientific review. The preclinical investigations shall not be considered adequate to justify clinical testing unless they give proper attention to the conditions of the proposed clinical testing. When this information, the outline of the plan of clinical pharmacology, or any progress report on the clinical pharmacology, indicates a need for full review of the preclinical data before a clinical trial is undertaken, the Department will notify the sponsor to submit the complete preclinical data and to withhold clinical trials until the review is completed and the sponsor notified. The Food and Drug Administration will be prepared to confer with the sponsor concerning this action.

b. If the drug has been marketed commercially or investigated (e.g. outside the United States), complete information about such distribution or investigation shall be submitted, along with a complete bibliography of any publications about the drug.

c. If the drug is a combination of previously investigated or marketed drugs, an adequate summary of preexisting information from preclinical and clinical investigations and experience with its components, including all reports available to the sponsor suggesting side-effects, contraindications, and ineffectiveness in use of such components: Such summary should include an adequate bibliography of publications about the components and may incorporate by reference any information concerning such components previously submitted by the sponsor to the Food and Drug Administration. Include a statement of the expected pharmacological effects of the combination.

7. A copy (one in each of the three copies of the notice) of all informational material, including label and labeling, which is to be supplied to each investigator: This shall include an accurate description of the prior investigations and experience and their results pertinent to the safety and possible usefulness of the drug under the conditions of the investigation. It shall not represent that the safety or usefulness of the drug has been established for the purposes to be investigated. It shall describe all relevant hazards, contraindications, side effects, and precautions suggested by prior investigations and experience with the drug under investigation and related drugs for the information of clinical investigators.

8. The scientific training and experience considered appropriate by the sponsor to qualify the investigators as suitable experts to investigate the safety of the drug, bearing in mind what is known about the pharmacological action of the drug and the phase of the investigational program that is to be undertaken.

9. The names and a summary of the training and experience of each investigator and of the individual charged with monitoring the progress of the investigation and evaluating the evidence of safety and effectiveness of the drug as it is received from the investigators, together with a statement that the sponsor has obtained from each investigator a completed and signed form, as provided in subparagraph (12; or (18) of this paragraph, and that the investigator is qualified by scientific training and experience as an appropriate expert to undertake the phase of the investigation outlined in section 10 of the "Notice of claimed investigational exemption for a new drug." (In crucial situations, phase 3 investigators may be added and this form supplemented by rapid communication methods, and the signed form FD 1573 shall be obtained promptly thereafter.)

10. An outline of any phase or phases of the planned investigations, as follows:

a. *Clinical pharmacology.* This is ordinarily divided into two phases: Phase 1 starts when the new drug is first introduced into man—only animal and in vitro data are available—with the purpose of determining human toxicity, metabolism, absorption, elimination, and other pharmacological action, preferred route of administration, and safe dosage range; phase 2 covers the initial trials on a limited number of patients for specific disease control or prophylaxis purposes. A general outline of these phases shall be submitted, identifying the investigator or investigators, the hospitals or research facilities where the clinical pharmacology will be undertaken, any expert committees or panels to be utilized, the maximum number of subjects to be involved, and the estimated duration of these early phases of investigation. Modification of the experimental design on the basis of experience gained need be reported only in the progress reports on these early phases, or in the development of the plan for the clinical trial, phase 3. The first two phases may overlap and, when indicated, may require additional animal data before these phases can be completed or phase 3 can be undertaken. Such animal tests shall be designed to take into account the expected duration of administration of the drug to human beings, the age groups and physical status, as for example, infants, pregnant women, premenopausal women, of those human beings to whom the drug may be administered, unless this has already been done in the original animal studies.

b. *Clinical trial.* This phase 3 provides the assessment of the drug's safety and effectiveness and optimum dosage schedules in the diagnosis, treatment, or prophylaxis of groups of subjects involving a given disease or condition. A reasonable protocol is developed on the basis of the facts accumulated in the earlier phases, including completed and submitted animal studies. This phase is conducted by separate groups following the same protocol (with reasonable variations and alternatives permitted by the plan) to produce well-controlled clinical data. For this phase, the following data shall be submitted:

i. The names and addresses of the investigators. (Additional investigators may be added.)

ii. The specific nature of the investigations to be conducted, together with information or case report forms to show the scope and detail of the planned clinical observations and the clinical laboratory tests to be made and reported.

iii. The approximate number of subjects (a reasonable range of subjects is permissible and additions may be made), and criteria proposed for subject selection by age, sex, and condition.

iv. The estimated duration of the clinical trial and the intervals, not exceeding 1 year, at which progress reports showing the results of the investigations will be submitted to the Food and Drug Administration.

(The notice of claimed investigational exemption may be limited to any one or more phases, provided the outline of the additional phase or phases is submitted before such additional phases begin. This does not preclude continuing a subject on the drug from phase 2 to phase 3 without interruption while the plan for phase 3 is being developed.)

Ordinarily, a plan for clinical trial will not be regarded as reasonable unless, among other things, it provides for more than one independent competent investigator to maintain adequate case histories of an adequate number of subjects, designed to record observations and permit evaluation of any and all discernible effects attributable to the drug in each individual treated, and comparable records on any individuals employed as controls. These records shall be individual records for each subject maintained to include adequate information pertaining to each, including age, sex, conditions treated, dosage, frequency of administration of the drug, results of all relevant clinical observations and laboratory examinations made, adequate information concerning any other treatment given and a full statement of any adverse effects and useful results observed, together with an opinion as to whether such effects or results are attributable to the drug under investigation.

11. A statement that the sponsor will notify the Food and Drug Administration if the investigation is discontinued, and the reason therefor.

12. A statement that the sponsor will notify each investigator if a new-drug appli-

cation is approved, or if the investigation is discontinued.

13. If the drug is to be sold, a full explanation why sale is required and should not be regarded as the commercialization of a new drug for which an application is not approved.

14. A statement that the sponsor assures that clinical studies in humans will not be initiated prior to 30 days after the date of receipt of the notice by the Food and Drug Administration and that he will continue to withhold or to restrict clinical studies if requested to do so by the Food and Drug Administration prior to the expiration of such 30 days. If such request is made, the sponsor will be provided specific information as to the deficiencies and will be afforded a conference on request. The 30-day delay may be waived by the Food and Drug Administration upon a showing of good reason for such waiver.

Very truly yours,

_____
(Sponsor)

Per _____
(Indicate authority)

(This notice may be amended or supplemented from time to time on the basis of the experience gained with the new drug. Progress reports may be used to update the notice.)

Provided, however, That where a new drug limited to investigational use is proposed for shipment to a foreign country and the circumstances are such that the submission of the "Notice of Claimed Investigational Exemption for a New Drug" (Form FD 1571) is not feasible, the Commissioner may authorize the shipment of the drug if he receives, through the U.S. Department of State, a formal request to allow such shipment from the government of the country to which the drug is proposed to be shipped. This request should specify that said government has adequate information about the drug and its proposed use and is satisfied that the drug may legally be used by the intended consignee in that country.

(3) Each shipment or delivery is made in accordance with the commitments in the "Notice of claimed investigational exemption for a new drug."

(4) The sponsor maintains adequate records showing the investigator to whom shipped, date, quantity, and batch or code mark of each such shipment and delivery, until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration has been so notified. Upon the request of a scientifically trained and properly authorized employee of the Department at reasonable times, the sponsor makes the records referred to in this subparagraph and in subparagraph (2) of this paragraph available for inspection, and upon written request submits such records or copies of them to the Food and Drug Administration.

(5) The sponsor monitors the progress of the investigations and currently evaluates the evidence relating to the safety and effectiveness of the drug as it is obtained from the investigators. Accurate progress reports of the investigations and significant findings, together with any significant changes in the informational material supplied to investigators, shall be submitted to the Food and Drug Administration at reasonable intervals, not exceeding 1 year. All reports of the investigation shall be retained until 2 years after a new-drug application is approved for the drug; or, if an application is not approved, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the Food and Drug Administration so notified. Upon request of a scientifically trained and properly authorized employee of the Department, at reasonable times, these reports shall be made available for inspection, and on written request copies of these reports shall be submitted to the Food and Drug Administration.

(6) The sponsor shall promptly investigate and report to the Food and Drug Administration and to all investigators any findings associated with use of the drug that may suggest significant hazards, contraindications, side-effects, and precautions pertinent to the safety of the drug. If the finding is alarming, it shall be reported immediately and the clinical investigation discontinued until the finding is adequately evaluated and a decision reached that it is safe to proceed.

(7) If the investigations adduce facts showing that there is substantial doubt that they may be continued safely in relation to the drug's potential therapeutic effects, the sponsor shall promptly discontinue the investigation, notify all investigators and the Food and Drug Administration, recall all stocks of the drug outstanding, and furnish the Food and Drug Administration with a full report of the reason for discontinuing the investigation. The Food and Drug Administration will be prepared to confer with the sponsor on the need to discontinue the investigation.

(8) The sponsor shall discontinue shipments or deliveries of the new drug to any investigator who has repeatedly or deliberately failed to maintain or make available his records or reports of his investigations.

(9) The sponsor shall not unduly prolong distribution of the drug for investigational use but shall submit an application for the drug pursuant to section 505(b) of the act (or give reasons for not submitting such application, or a statement that the investigation has been discontinued and the reasons therefor):

(i) With reasonable promptness after finding that the results of such investigation appear to establish the safety and effectiveness of the drug; or

(ii) Within 60 days after receipt of a written request for such an application from the Commissioner.

(10) Neither the sponsor nor any person acting for or on behalf of the sponsor shall disseminate any promotional material representing that the drug being distributed interstate for investigational use is safe or useful for the purposes for which it is under investigation. This regulation is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay communications media; its sole intent is to restrict promotional claims of safety or effectiveness by the sponsor while the drug is under investigation to establish its safety or effectiveness.

(11) The sponsor shall not commercially distribute nor test-market the drug until a new-drug application is approved pursuant to section 505(b) of the act.

(12) The sponsor shall obtain from each investigator involved in clinical pharmacology a signed statement in the following form:

Form FD 1572

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator (Clinical Pharmacology)

Name of investigator _____
Date _____
Name of drug _____
To supplier of the drug:
Name _____
Address _____

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3 of Title 21 of Code of Federal Regulations as a condition for receiving and conducting clinical pharmacology with a new drug limited by Federal (or United States) law to investigational use.

1. A statement of the education and training that qualifies me for clinical pharmacology.

2. The name and address of the medical school, hospital, or other research facility where the clinical pharmacology will be conducted.

3. The expert committees or panels responsible for approving the experimental project.

4. The estimated duration of the project, and the maximum number of subjects that will be involved.

5. A general outline of the project to be undertaken. (Modification is permitted on the basis of experience gained without advance submission of amendments to the general outline.)

6. The undersigned understands that the following conditions generally applicable to new drugs for investigational use govern his receipt and use of this investigational drug:

a. The sponsor is required to supply the investigator with full information concerning the preclinical investigation that justifies clinical pharmacology.

b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantity, and use by subjects, and if the clinical pharmacology is suspended or terminated to return to the sponsor any unused supply of the drug.

c. The investigator is required to prepare and maintain adequate case histories designed to record all observations and other data pertinent to the clinical pharmacology.

d. The investigator is required to furnish his reports to the sponsor who is responsible for collecting and evaluating the results, and presenting progress reports to the Food and Drug Administration at appropriate intervals, not exceeding 1 year. Any adverse effect which may reasonably be regarded as caused by, or is probably caused by, the new drug shall be reported to the sponsor promptly; and if the adverse effect is alarming it shall be reported immediately. An adequate report of the clinical pharmacology should be furnished to the sponsor shortly after completion.

e. The investigator shall maintain the records of disposition of the drug and the case reports described above for a period of 2 years following the date the new-drug application is approved for the drug; or if no application is to be filed or is approved until 2 years after the investigation is discontinued and the Food and Drug Administration so notified. Upon the request of a

scientifically trained and specifically authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The names of the subjects need not be divulged unless the records of the particular subjects require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual studies or do not represent actual results obtained.

f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him, _____, and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

g. The investigator certifies that he will inform any patients or any persons used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

Very truly yours,

_____
(Name of investigator)

_____
(Address)

_____

(13) The sponsor shall obtain from each investigator involved in clinical trials a signed statement in the following form:

Form FD 1573

Department of Health, Education, and Welfare, Food and Drug Administration

Statement of Investigator

Name of investigator _____
Date _____
Name of drug _____
To supplier of drug:
Name _____
Address _____

Dear Sir:

The undersigned, _____, submits this statement as required by section 505(i) of the Federal Food, Drug, and Cosmetic Act and § 130.3 of Title 21 of the Code of Federal Regulations as a condition for receiving and conducting clinical investigations with a new drug limited by Federal (or United States) law to investigational use.

1. The following is a statement of my education and experience:

a. Colleges, universities, and medical or other professional schools attended, with dates of attendance, degrees, and dates degrees were awarded.

b. Postgraduate medical or other professional training: Dates, names of institutions, and nature of training.

c. Teaching or research experience: Dates, institutions, brief description of experience.

d. Experience in medical practice or other professional experience: Dates, institutional affiliations, nature of practice, or other professional experience.

e. Representative list of pertinent medical or other scientific publications: Titles of articles, names of publications and volume, page number, and date.

(If this information has previously been submitted to the sponsor, it may be referred to and any additions made to bring it up to date.)

2. If any hospital, institutional, and clinical laboratory facilities, etc., are available and will be employed in connection with the investigation, an identification of each follows:

(If this information has previously been submitted to the sponsor, reference to the previous submission will be adequate.)

3. The investigational drug will be used by the undersigned or under his supervision in accordance with the plan of investigation described, as follows: (Outline the plan of investigation, including approximation of the number of subjects to be treated with the drug and the number to be employed as controls, if any; clinical uses to be investigated; characteristics of subjects by age, sex, and condition; the kind of clinical observations and laboratory tests to be undertaken prior to, during, and after administration of the drug; the estimated duration of the investigation; and a description or copies of report forms to be used to maintain an adequate record of the observations and tests results obtained. This plan may include reasonable alternates and variations, and should be supplemented or amended when any significant change in direction or scope of the investigation is undertaken.)

4. The undersigned understands that the following conditions, generally applicable to new drugs for investigational use, govern his receipt and use of this investigational drug:

a. The sponsor is required to supply the investigator with full information concerning the preclinical investigations that justify clinical trials, together with fully informative material describing any prior investigations and experience and any possible hazards, contraindications, side-effects, and precautions to be taken into account in the course of the investigation.

b. The investigator is required to maintain adequate records of the disposition of all receipts of the drug, including dates, quantities, and use by subjects, and if the investigation is terminated to return to the sponsor any unused supply of the drug.

c. The investigator is required to prepare and maintain adequate and accurate case histories designed to record all observations and other data pertinent to the investigation on each individual treated with the drug or employed as a control in the investigation.

d. The investigator is required to furnish his reports to the sponsor of the drug who is responsible for collecting and evaluating the results obtained by various investigators. The sponsor is required to present progress reports to the Food and Drug Administration at appropriate intervals not exceeding 1 year. Any adverse effect that may reasonably be regarded as caused by, or probably caused by, the new drug shall be reported to the sponsor promptly, and if the adverse effect is alarming, it shall be reported immediately. An adequate report of the investigation should be furnished to the sponsor shortly after completion of the investigation.

e. The investigator shall maintain the records of disposition of the drug and the case histories described above for a period of 2 years following the date a new-drug application is approved for the drug; or if the application is not approved, until 2 years after the investigation is discontinued. Upon the request of a scientifically trained and properly authorized employee of the Department, at reasonable times, the investigator will make such records available for inspection and copying. The subjects' names need not be divulged unless the records of particular individuals require a more detailed study of the cases, or unless there is reason to believe that the records do not represent actual cases studied, or do not represent actual results obtained.

f. The investigator certifies that the drug will be administered only to subjects under his personal supervision or under the supervision of the following investigators responsible to him, _____, and that the drug will not be supplied to any other investigator or to any clinic for administration to subjects.

g. The investigator certifies that he will inform any subjects, including subjects used as controls, or their representatives, that drugs are being used for investigational purposes, and will obtain the consent of the subjects, or their representatives, except where this is not feasible or, in the investigator's professional judgment, is contrary to the best interests of the subjects.

Very truly yours,

_____
(Name of investigator)

_____
(Address)

_____

(This form should be supplemented or amended from time to time if new subjects are added or if significant changes are made in the plan of investigation.)

(b) A shipment or other delivery of a new drug that is being imported or is offered for importation into the United States shall be exempt from the requirements of section 505(a) of the act if the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New drug—Limited by Federal (or United States) law to investigational use"; and

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has prior to such shipments and deliveries completed and submitted signed copies to the Food and Drug Administration of the "Notice of claimed investigational exemption for a new drug"; and acts as the sponsor of the clinical investigation to assure compliance with the conditions prescribed by paragraph (a) of this section; or

(3) The drug is shipped directly to a scientific institution with adequate facilities and qualified personnel to conduct clinical pharmacology and is intended solely for such use in such institutions and a "Notice of claimed investigational exemption for a new drug" covering this activity has been filed.

(4) Not less than 30 days have elapsed following the date of receipt of the notice by the Food and Drug Administration; and the Food and Drug Administration has not, prior to expiration of such 30-day interval, requested that the sponsor continue to withhold or to restrict use of the drug in human subjects. The 30-day delay requirement may be waived by the Food and Drug Administration upon a showing of good reason for such waiver.

(c) (1) Whenever the Food and Drug Administration has information indicating that an investigator has repeatedly or deliberately failed to comply with the conditions of these exempting regulations outlined in Form FD-1572 or FD-1573 (set forth in paragraph (a) (12) and (13) of this section), or has submitted to the sponsor of the investigation false information in his Form FD-1572 or FD-1573 or in any required report, the Director of the Bureau of Medicine will furnish the investigator written notice of the matter complained of in general terms and offer him an opportunity to explain the matter in an informal conference and/or in writing. If an explanation is offered but not accepted by the Bureau of Medicine, the Commissioner will provide the investigator an opportunity for an informal hearing on the question of whether the investigator is entitled to receive investigational-use drugs, if the hearing is requested within 10 days after receipt of notification that the explanation is not acceptable.

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(3) After evaluating all available information, including any explanation and assurance presented by the investigator, if the Commissioner determines that the investigator has repeatedly or deliberately failed to comply with the conditions of the exempting regulations in this section or has repeatedly or deliberately submitted false information to the sponsor of an investigation and has failed to furnish adequate assurance that the conditions of the exemption will be met, the Commissioner will notify the investigator and the sponsor of any investigation in which he has been named as a participant that the investigator is not entitled to receive investigational-use drugs with a statement of the basis for such determination.

(4) Each "Notice of Claimed Investigational Exemption for a New Drug" (Form FD–1571 set forth in paragraph (a)(2) of this section) and each approved new-drug application containing data reported by an investigator who has been determined to be ineligible to receive investigational-use drugs will be examined to determine whether he has submitted unreliable data that are essential to the continuation of the investigation or essential to the approval of any new-drug application.

(4) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are inadequate to support a conclusion that it is reasonably safe to continue the investigation, he will notify the sponsor and provide him with an opportunity for a conference and an informal hearing in accordance with paragraph (d) of this section. If an imminent hazard to the public health exists, however, he shall terminate the exemption forthwith and notify the sponsor of the termination. In such event the Commissioner, on request, will afford the sponsor an opportunity for an informal hearing on the question of whether the exemption should be reinstated.

(5) If the Commissioner determines after the unreliable data submitted by the investigator are eliminated from consideration that the data remaining are such that a new-drug application would not have been approved, he will proceed to withdraw approval of the application in accordance with section 505(e) of the act.

(6) An investigator who has been determined to be ineligible may be reinstated as eligible to receive investigational-use drugs when the Commissioner determines that he has presented adequate assurance that he will employ such drugs solely in compliance with the exempting regulations in this section for investigational-use drugs.

(d) If the Commissioner of Food and Drugs finds that:

(1) The submitted "Notice of claimed investigational exemption for a new drug" contains an untrue statement of a material fact or omits material information required by said notice; or

(2) The results of prior investigations made with the drug are inadequate to support a conclusion that it is reasonably safe to initiate or continue the intended clinical investigations with the drug; or

(3) There is substantial evidence to show that the drug is unsafe for the purposes and in the manner for which it is offered for investigational use; or

(4) There is convincing evidence that the drug is ineffective for the purposes for which it is offered for investigational use; or

(5) The methods, facilities, and controls used for the manufacturing, processing, and packing of the investigational drug are inadequate to establish and maintain appropriate standards of identity, strength, quality, and purity as needed for safety and to give significance to clinical investigations made with the drug; or

(6) The plan for clinical investigations of the drugs described under section 10 of the "Notice of claimed investigational exemption for a new drug" is not a reasonable plan in whole or in part, solely for a bona fide scientific investigation to determine whether or not the drug is safe and effective for use; or

(7) The clinical investigations are not being conducted in accordance with the plan submitted in the "Notice of claimed investigational exemption for a new drug"; or

(8) The drug is not intended solely for investigational use, since it is being or is to be sold or otherwise distributed for commercial purposes not justified by the requirements of the investigation; or

(9) The labeling or other informational material submitted for the drug as required by section 7 of the "Notice of claimed investigational exemption for a new drug" or any other labeling of the drug disseminated within the United States by or on behalf of the sponsor fails to contain an accurate description of prior investigations or experience and their results pertinent to the safety and possible usefulness of the drug, including all relevant hazards, contraindications, side-effects, and precautions; or any promotional material disseminated within the United States by or on behalf of the sponsor contains any representation or suggestion that the drug is safe or that its usefulness has been established for the purposes for which it is offered for investigations; or

(10) The sponsor fails to submit accurate reports of the progress of the investigations with significant findings at intervals not exceeding 1 year; or

(11) The sponsor fails promptly to investigate and inform the Food and Drug Administration and all investigators of newly found serious or potentially serious hazards, contraindications, side-effects, and precautions pertinent to the safety of the new drug;

he shall notify the sponsor and invite his immediate correction or explanation. A conference will be arranged with the Bureau of Medicine if requested. If the Bureau of Medicine does not accept the explanation and/or the correction submitted by the sponsor, the Commissioner will provide the sponsor an opportunity for an informal hearing on the question of whether his exemption should be terminated. If the hearing is requested within 10 days after receipt of notification that the explanation or correction is not acceptable. After evaluating all the available information including any explanation and/or correction submitted by the sponsor, if the Commissioner determines that the exemption should be terminated he shall notify the sponsor of the termination of the exemption and the sponsor shall recall unused supplies of the drug. If at any time the Commissioner concludes that continuation of the investigation presents an imminent hazard to the public health, he shall terminate the exemption forthwith and notify the sponsor of the termination. The Commissioner will inform the sponsor that the exemption is subject to reinstatement on the basis of additional submissions that eliminate such hazard(s) and will afford the sponsor an opportunity for an informal hearing, on exemption should be reinstated. The sponsor shall recall the unused supplies of the drug upon notification of the termination.

(e) Where drugs were under clinical trial on man on or after August 10, 1962, the sponsor shall, within 30 days after these regulations become effective, submit a list of such investigational drugs, and within 120 days after such effective date shall submit to the Food and Drug Administration the completed "Notice of claimed investigational exemption for a new drug" or a new-drug application. Failure to do so shall automatically terminate the exemption. If any such clinical trials have been discontinued, the sponsor is requested to submit a statement of why the investigation was discontinued.

(f) [Reserved]

(g) A "Notice of Claimed Investigational Exemption for a New Drug" which pertains to a product subject to the licensing provisions of the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.), should be submitted initially to the Division of Biologics Standards, National Institutes of Health, Public Health Service, rather than to the Commissioner of Food and Drugs. Also, amendments of or supplements to such notice, and progress reports, consultations or other communications with regard to the investigation, should be directed to the Division of Biologics Standards, which monitors the development of biological products subject to license under section 351 of the Public Health Service Act. A sponsor for a "Notice of Claimed Investigational Exemption for a New Drug" pertaining to such biologic should substitute in reading this § 130.3 the unit "Division of Biologics Standards" for "Food and Drug Administration" and the person "Director, Division of Biologics Standards" for "Commissioner" or "Commissioner, Food and Drug Administration," wherever they appear.

(h) Any requirement by this section for the submission of information or data that has been submitted previously may be incorporated by reference.

[28 F.R. 179, Jan. 8, 1963; 28 F.R. 319, Jan 11, 1963, as amended at 28 F.R. 10573, Oct. 12, 1963; 31 F.R. 4691, Mar. 24, 1966; 32 F.R. 8381, June 6, 1967; 33 F.R. 8338, June 5, 1968; 34 F.R. 6776, Apr. 23, 1969; 35 F.R. 12391, Aug. 14, 1970]

NOTE: Order of the Commissioner of Food and Drugs published at 28 F.R. 183, Jan. 8, 1963, provides as follows:

"That, § 130.3 (28 F.R. 179) shall not apply to radioactive new drugs, until further notice, provided the radioactive new drugs for investigational use are being shipped in complete conformity with the regulations issued by the Atomic Energy Commission."

§ 130.3a New drugs for investigational use in animals; exemptions from section 505(a).

(a) *New drugs for tests in vitro and in laboratory research animals.* (1) A shipment or other delivery of a new drug intended solely for tests in vitro or in animals used only for laboratory research purposes shall be exempt from section 505(a) of the act if it is labeled as follows:

Caution—Contains a new drug for investigational use only in laboratory research animals, or for tests in vitro. Not for use in humans.

(2) The person or firm shipping new drugs for tests in vitro or in animals used only for laboratory research purposes under this exemption shall use due diligence to assure that the consignee is regularly engaged in conducting such tests and that the shipment of the new drug will actually be used for tests in vitro or in animals used only for laboratory research.

(3) The person who introduced such shipment or who delivered the drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the expert to whom the drug is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times, he shall make such records available for inspection and copying.

(4) The exemption allowed in this paragraph shall not apply to any new drug intended for in vitro use in the regular course of diagnosing or treating disease, including antibacterial sensitivity discs impregnated with any new drug or drugs, which discs are intended for use in determining susceptibility of micro-organisms to the new drug or drugs.

(b) *New drugs for clinical investigation in animals.* A shipment or other delivery of a new drug intended for clinical investigational use in animals shall be exempt from section 505(a) of the act if all the following conditions are met:

(1) The label shall bear the statements:

Caution—Contains a new drug for use only in investigational animals in clinical trials. Not for use in humans.

Edible products of investigational animals are not to be used for food unless authorization has been granted by the U.S. Food and Drug Administration or by the U.S. Department of Agriculture.

In the case of containers too small or otherwise unable to accommodate a label with sufficient space to bear the caution statements required by paragraphs (a) or (b) of this section, the statements may be included on the carton label and other labeling on or within the package from which the drug is to be dispensed.

(2) The person or firm shipping the new drug shall use due diligence to assure that the drug will actually be used for tests in animals and not in humans.

(3) The person who introduced such shipment or who delivered the drug for introduction into interstate commerce shall maintain adequate records showing the name and post office address of the investigator to whom the drug is shipped, date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment and delivery. Upon the request of a properly authorized employee of the Department at reasonable times such records shall be made available for inspection and copying.

(4) Prior to the shipment of the drug for clinical tests in animals, the sponsor of the investigation shall submit in triplicate to the Food and Drug Administration a signed statement containing the following information:

(i) The identity of the drug.

(ii) All labeling and other pertinent information to be supplied to the investigators.

(iii) The name and address of each clinical investigator.

(iv) The approximate number of animals to be treated (or if not available, the amount of drug to be shipped).

(v) If the drug is given to food-producing animals, the statement or a supplemental statement shall contain the following additional information:

(a) A commitment that the edible products from such animals shall not be used for food without prior authorization in accordance with § 121.75 of this chapter.

(b) Approximate dates of the beginning and end of the experiment or series of experiments.

(c) The maximum daily dose(s) to be administered to a given species, the size of animal, maximum duration of administration, method(s) of administration, and proposed withdrawal time, if any.

(5) Authorization for use of edible products derived from a treated food-producing animal may be granted under the provisions of this section and § 121.75 of this chapter when the following specified conditions are met, except that in the case of an animal administered any unlicensed experimental veterinary biological product regulated under the viruses, serums, toxins statute (21 U.S.C., Chapter V, sec. 151 et seq.) the product shall be exempt from the requirements of this section and § 121.75 when U.S. Department of Agriculture approval has been obtained as provided in § 103.2 of Title 9, Code of Federal Regulations. Conditional authorization may be granted in advance of identification of the name(s) and address(es) of the clinical investigator(s) as required by subparagraph (4) (iii) of this paragraph. Information required for authorization shall include, in addition to all other requirements of this section, the following:

(i) Data to show that consumption of food derived from animals treated at the maximum levels with the minimum withdrawal periods, if any, specified in accordance with subparagraph (4) (v) (c) of this paragraph, will not be inconsistent with the public health; or

(ii) Data to show that food derived from animals treated at the maximum levels and with the minimum withdrawal periods, if any, specified in accordance with subparagraph (4) (v) (c) of this paragraph, does not contain drug residues or metabolites.

(iii) The name and location of the packing plant where the animals will be processed, except that this requirement may be waived, on request, by the terms of the authorization.

Authorizations granted under this subparagraph do not exempt investigational animals and their products from compliance with other applicable inspection requirements.

(6) On written request of the Food and Drug Administration, the sponsor shall submit any additional information in his possession with respect to the investigation deemed necessary to facilitate a determination of whether there are grounds in the interest of public health for terminating the exemption.

(7) The sponsor shall assure himself that the drug is shipped only to investigators who:

(i) Are qualified by scientific training and/or experience to evaluate the safety and/or effectiveness of the drug.

(ii) Shall maintain complete records of the investigations.

(iii) Shall furnish adequate and timely reports of the investigation to the sponsor.

(8) The sponsor:

(i) Shall retain all reports received from investigators for 2 years after the termination of the investigation or approval of a new-drug application and make such reports available to a duly authorized employee of the Department for inspection at all reasonable times.

(ii) Shall provide for current monitoring of the investigation by a person qualified by scientific training and experience to evaluate information obtained from the investigation, and shall promptly investigate and report to the Food and Drug Administration and to all investigators any findings associated with use of the drug that may suggest significant hazards pertinent to the safety of the drug.

(iii) Shall not unduly prolong distribution of the drug for investigational use.

(iv) Shall not, nor shall any person acting for or on behalf of the sponsor, represent that the drug is safe or effective for the purposes for which it is under investigation. This requirement is not intended to restrict the full exchange of scientific information.

(v) Shall not commercially distribute nor test-market the drug until a new-drug application is approved pursuant to section 505(c) of the act.

(9) If the shipment or other delivery of the new drug is imported or offered for importation into the United States for clinical investigational use in animals, it shall also meet the following conditions:

(i) The importer of all such shipments or deliveries is an agent of the foreign exporter residing in the United States or the ultimate consignee, which person has, prior to such shipments and deliveries, informed the Food and Drug Administration of his intention to import the new drug as sponsor in compli-

Interview, DT Chalkely, 301-496-7005. 5 Oct, 1972

Q. How are guidelines enforced? A. ~~Xxxxx~~ see page 1. We can terminate the project -- we haven't done it yet. Oh, yes we have oh two occasions -- niether involved prisoners -- in which we found the exps. unethical, we wouldn't approve them. See also p. 17 -- but it didn't involve prisoners, Mex-Americasn. We can terminate the exp. if we disapprove of it.

We have ~~xxxx~~ grants that involve prisoners. But there's no convenient way of recovering the information as to whether our guidelines are being followed. That responsibility lies with the chief investigator. For example, if you give a toy whiphto your small son -- you've no way of checking on what use he puts it to -- ~~x~~ you wouldn't give it to him, then check up on him to see he isn't sticking it in some lion's mouth (etc)

Q. I have a letter from Dr. Richard B. Norwick, director ~~xfxSix~~ of Div. of Infectious Disease, U. of Md. Med School. He has conducted studies at ~~Mx~~ Md. House of Corr. since 1959. "Cholera, viral respitory studies, viral diarrhea studies are supported by the NIH..." And he sends copies of consent form: "hereby release & forever discharge" doctor, U of Md etc. from liability.

A. Oh damn! I was aware 2 years ago of this form -- I thought they said they were goint to quit it. I don't know. Give us hell!

Q. Page 7 your guide says "should include no exculpl language." A. We wanted to say "must." We asked counsel, who said it would be improper in a fed. document to impose a requirement that might be contrary to state or municipal law., so we used "should" not "must." FDA has changed theirs to "must". Most institutions have complied with FDA regulations. We are changing ours from "should" to "must".

We have practicailly so little NIH research in prisons -- our efforts aren't concentrated in this area. We're aware of the problem, it's been brought to our attention any number of times. Q. By whom? A. Mr. John Bowers, mostly.
Q. Have you brought any action at all to enforce yr. regulations in any prisons anywhere? A. None, to date.

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Med exp
Dec notes

Interview with Charles Mangee, Upjohn company, 616-382-4000

Michigan,
We have a lab. in Jackson prison,/within the prison walls. It's a beautiful operation. All under the direction of a review committee, composed of a combination of university professors and private physicians.

Q. How long has it been going? A. Don't know -- at least 10 years or longer.

Q. Before that, who did Upjohn use for exprs? A. Don't know.

Q. Numbers of prisoners involved? A. Don't know.

Q. How compensated? A. Don't know -- I think by Dept. of Corrections.

Q. Do you reimburse Dept. of Corr. for a) convict payment, b) rent, guards wages etc? A. Don't know.

Q. Consent form? A. Will try to find.

Q. Any lawsuits? A. Not out of experiments; some of the trustees in the clinic brought a suit, they lost in court.

Q. Details of that -- name of lawyer for plaintiff? Date of suit? A. Don't know.

I have an intuitive feeling your story is going to have a negative twist to it.

Med exp
Doc notes

Interview with Dr. Howard Maibach, 666-9000

Phase I on normal subjects got big after WW II, malaria experiments. Bigger now in prisons. Cld. find out nationally.

Q. Are your experiments funded through UC? A. Cld be highly variable -- could happen either way.
Q. What's WY 21,743? A. Anti-inflammatory drug. In between aspirin and cortisone. Non-steroidal material. Q. Who decides compensation to convicts? A. That's an interesting study in itself. If you offered to pay $1,000 or $500, could be too much inducement -- much concern if the fee is out of line, it would upset the system and seem like luring somebody to participate.
Q. What side effects anticipated in WY study? A. None.
Q. Did it ever come before Human Experimentation Comm?
A. If the study in any way is done in the medical center it comes before the commmittee, not if it's done entirely at Vacaville. It's in a state of flux. There's a very good chance that with concern re. human volunteers, it's likely to get to the point where it's too tough to continue.
Q. How is doctor compensated by drug company? A. The classical way is if the study being done in pharm. industry, they'd budget $X for the program. Within budget ~~##~~ $X, so much for the volunteers, the lab work, recompense to the physician. Sometimes they pay the Dr. a fee on top
Q. How often do you go to Vacaville? A. Once a week for part of a day.
Q. Is formula of WY 21,743 availab.e? A. Yes, it's available to me, but not for publication.
Q. Why does this test pay $60? A. I'd guess because of taking blood samples. To recompense the volunteers for the inconvenience.
Q. What follow-up on volunteers? A. I saw them throughout the study -- one, I kept seeing over again. (had some side effects).
Q. Do ~~##~~ any of your Vacaville experiments come before the Human Exp. committee? A. I can't generalize. Any work done at the school~~s~~ goes through the committee. I'm giving considerable thought to giving up the Vacaville experiments.
Q. Are you familiar with the consent form signed at Vacaville?
A. Yes, I'm familiar with it. Obviously it's in a period of change I'm changing mine to a new one without exculp. clause.
Q. When did you start using consent forms? A. Can be checked -- must have been used from the beginning.
Q. Have your subjects ever had to be hospitalized, or suffered bad side effects? A. We might have had to put a man to bed for a day or half a day . Can't recall any bad cases.
Q. Horrowitzz/? A. Don't remember. (Will look up lawsuit at Vacaville).
Kept suggesting other Drs. to inteview, esp. Dr. Albert Kligman, Phila.
Works ½ day week in private practice.

* * * * * *

Aileen! Please put all Lisocki together, ditto other interviews with the smashing new paperclips

Dec notes
med-exp -

Interview with Dr. Allan Lissock, asst. to Frances Kelsey, FDA, 301-443-1727 -- Aug. 30, 1972

Q. What prisons have drug company testing? A. We've no list as such. Through experience we know of certain prisons. It's a touchy area. The way we find out is they are submitted in the IND submission. It's probably confidential information. Suggest you make a written request? Telegram? go via Freedom of Information Act. I'll ~~take~~ take yr. request to the General Counsel. I doubt there are 20 prisons that do it. Q. Could you furnish numbers of prisoners involved? A. That would be very difficult, probably unavailable. Q. History of Phase I testing and types of subject used? A. There's always been Phase I testing. Q. Didn't term "phase I, II, III" arise out of 1962 FDA regulations? A. It was formalized then. Q. Are students used much? A. In a few isolated examples. Now, it's overwhelmingly done in prisons. Q. What is/isnt confidential? Why confidential? A. We're in a difficult position, are writing guidelines about public information. Most things that are not pure mfg. processes are public info. under Freedom of Information Act. Q. Are you aware Vacaville has exculp. clause in its consent form? A. I've been out there twice, wasn't aware. Don't know if FDA regulations prohibit exculp. clause. Q. Do you get info. about what convicts get paid? A. We're aloof to the question of payment. Q. Any lawsuits? A. Must be some. Q. Testing overseas? A. Tremendous amount. Most drug companies have affiliates overseas. We don't necessarily OK the results, as the rules are more lax.

****

Jim Dan address
2) Ja?
3) Research etc?

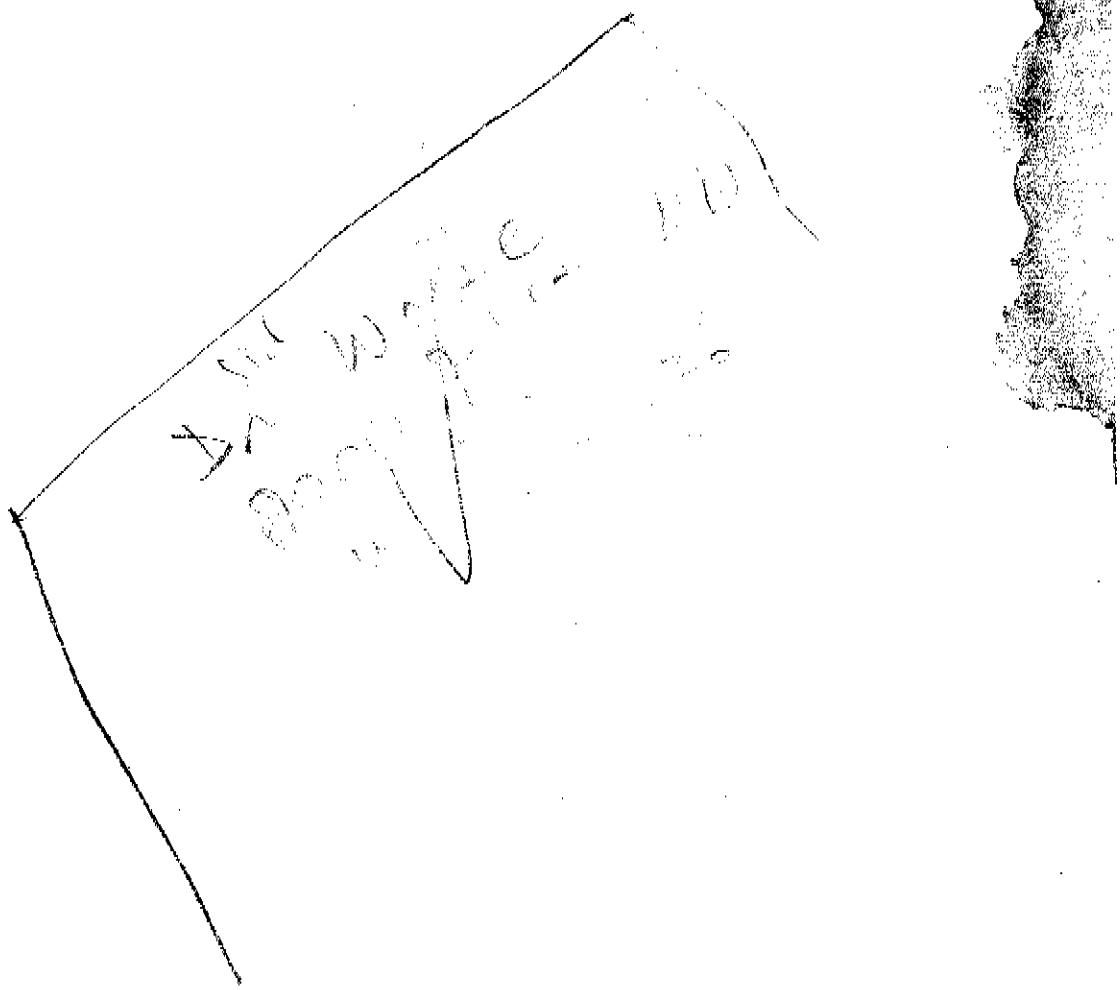
Dick Silberman
547-7575

facilities
tax-saving device since investors can benefit from short life depreciation deduction -
do get extra cost write-off

Dec notes

BEN GORDON, 202-225-8489. Leg. asst to Sen. Gaylord Nelson. via Jeff Cowan. 30 Aug, 1972

Don't know if there is any list of prisons. According to law, trade secrets means processes and methods of manufacturing. FDA interprets this statute to mean testing for safety and efficacy. A problem: the drug compnay selects the tester, choses its own friends. Our bill would create a drug testing and evaluation center -- essentially nationalize testing, but don't quote that! Too explosive. Gaylord Nelson bill provides ~~xxx~~ no drug can be tested on any human unless approved by the secretary of HEW (FDA). It takes the whole thing away from the drug companies. Bill says: "Methodology, results and conclusions of all tests and investigations under this section with any new drug shall be made public..."



Warden Charles Eggler, 517-782-0301, Aug. 30, 1972

Compensation to prisoner is set by agreement with head of clinics -- two clinics, Upjohn and Park-Davis. Upjohn has about 10 employees, Drs. and technicians. They built the facilities and turned them over the DOC. They pay officer supervision. Numbers involved -- a maximum of 80 or 90? Between two, 40 to 50 live-ins, also 200 walk-ins. Q. How much pay? A. Dr. Schweem would know. Pretty good money. Maybe $20 a test for the live-ins? Don't know abt. lawsuit.

Dr. Herbert Schweem, 517-787-5533

No, I'm sorry, it's the policy of the company to refer all questions to public relations. Those are strict reuglations, I must insist. (But did allow as how there are 1200 in research).

Dr. Leslie Bennett, U.C. (phone interview)

Head of Human Experimentation Comm. at U.C.

The experiments don't necessarily involve UC. Some exps. listed are dead, some have left.

Q. Where does SIMPR's money come from?
A. I'd be curious to know myself.

Chairmn of SIMPR board is Dr. Henry W. Elliott of Irvine, UC

Certain ~~ex~~ studies are cleared by university. We have files on projects reviewed by this campus.

The problem is more subtle -- the use of prisoners? Shouldnt be used. See ACLU article, July 1972, Irwin Feinberg.

We insist on knowing how much they pay convicts. There's a perfectly dreadful consent form -- it says if you dont complete the experiment you wont get paid.

For research, you need a reliable, stable population. It's easy on a hospital research ward.

A. Hance MD is chief of Davis comm. on human experimentation.

Q. Payment? Answer: No firm guidelines. Cons get $7 for giving blood.

Our files would not show permanent harm to the individual.
1971 Research
Manual: (p. 66) J. Alfred Rider severed from UC in 66,
Meeller died June 1968
Cleocin HFC (p.67) Epstein: no evidence ever submitted for review.
Abbott 35616, Charles H. Hine, M.D., Hine Lab. Inc.: Know nothing about it.
SK&F, page 84: not reviewed.
Safety study, Wyeth, p.86 -- not before committee.
p.88, Solu-cortef: don't recognize.

Interview with Dr. Batterman, 2030 Haste, Berk. July 2[illegible], 1972

Goes to Vacaville [illegible] once a month, clinic, internal medicine.

Q. How do doctors get paid for drug experiments? A. Depends on doctor, and type of study. Could be a two-way basis: the drug companies are the only ones that have the drugs, so the investigator could approach them and ask them to finance a study. He would furnish protocol and budget. If he has an in at the prison -- is involved with the university -- would do Toxicity Phase I. Phase I is very big in prisons. He would say it will cost me X dollars to do the study, including prison utilization, staff time etc. The Dr's fee depends on his experience -- could be up to $10,000 or $15,000. The drug compnay might approach him, if they've got a new drug they want tested for human use. FDA prefers Phase I to be on in-patient basis, they figure there's better control in an in-patient situation. Can't be done in hospitals as such -- the only place available for toxicity studies is prison. The vast majority of drugs -- more than 90% -- never get into medical practice, they prove too toxic. They drop by the wayside in Phase II. Upjohn set up and paid huge sums of money in Jackson prison (Mich) with their own staff, company's own doctor.

Experiemtns are means for prisons to get extra money that doesn't show up in the prison budget -- for example, the guards are already paid but they charge the experimenter for guards' wages and overtime, it gives gravy for more personnel.

The prisoner gets practically nil. Q. What would a student get for similar experiment? A. It depends. For example, if the experimenter was making a comparison between two aspirin, and the student had to give blood samples every 15 minutes for 2 hours -- he'd get about $25. Or, if he's taking a drug every day and comes in once a week for a month for blood, he might get $100. The investigator decides on the pay. We get volunteers from Baptist divinity school etc.

In my Xerox sample protocol, the prisoner would get $15 a month -- practically nothing. For the longer time, 6 months instead of 3, it drops to $12.50 a month -- we do it the other way around, give <u>more</u> money if the experiment takes longer.

There are very few places to do Phase I experiments -- prisons are ideal.

Write to Upjohn for published accounts of their Jackson experiments. Kalamazoo, Michigan.

Q. Manufacturers of prison-used drugs:

A. Prolixin - Squibb. Anectine - Burroughs Wellcome. Lithium-carbonate: a lot of companies. Prisons buy durgs on bid system. May get hospital rates?

Q. What about Varidase, Mal's case? A. It's off the market. It should never have been given by injection, if Epstien knew anything about this drug.

Q. What SIMPR records would be confidential? A. Their research would be confidential until submitted to FDA. All research must be filed with FDA, then it should be availbee to the public. (Note: I think he's wrong? See John Bowers file).

Q. What sort of supervision does the principal inv. provide? A. Complete. He's totally responsible. My view: when I was conducting exps. at Vacaville I saw the cases myself, did my own lab. tests. I stopped all research at Vacaville because the data is worthless, there's totally inadqueate supervision. When you sign a protocol you've assumed total responsibility, it's your responsibility, not that of your staff.

Q. Just how do doctors profit from the "publish or perish" business? A. Two aspects: 1) the publicity iss important in terms of getting tenure etc. You become an authority in the field. There's a double advantage in the publicity: you bring money into the department via government or industry. 2) On a personal basis you can be a consultant without doing any research -- for example, you might be asked to review data for the FDA. Q. Fee? A. Depends -- could be $50, could be $2,000.

Q. Has there been a rise in drug co. use of prisoners? A. They've always used prisoners. There's better control now. Drug studies began in mid-thirties when a host of new drugs came into being. You had to prove safety -- the law of 1938 applies, not the 1962 law.

Q. In Dr. Hodges scurvy study -- what is consequence of inadvertently omitting mineral supplement? A. Can have serious toxicity by omitting min. supplement. Min. supplement means all minerals. They could have severe cardiac abnormalities as a result, or go into shock. Q. After 34 days? A. Sure, it depends on the patient.

Q. Eph said he thought DSMO was never released for general use? A. Correct, not for gen. use, only for partial use.

Tom Brylke, 31 Beverly Rd, Kensington July 1972 interview

DSMO study done via Esptein/Maybeck. At least 30-40 inmates (70 more
for 6 months or more. In form of a jelly; once or twice
a deay smear over body, early a.m. and late ev ning. Each 1 mo.
week blood samples taken, each 30 days, bone marrow biopisies.
All on a semi-formal contract basis: got $30 month, bonus of
$75 for staying 6 months.

Not actual burns -- infusion of blood to surface of skin.
5% to 10% got ill. Two smells: bad oysters, rotten asparagus.

(One man used vaseline -- found empty tube of DSMO)

If we picked up, via liver profile, toxis, there were 2
alternatives: notify the doctor, or notify the inmate.
subject
If we notify dr. of side effects, he may ask/patient "How
do you feel?" If answer is "Fine!" doctor may reduce
dosage.

Q. How is the money raised? A. Bennett says he doesn't know.
SIMPr bought property on retarded children's home to sell
at profit. They only do experiments on prisoners.

FDA (?)

Q. How much paid for spinal tap? A. Maximum of $25. He'd
be hospitalized for 24 hours after. DMSO: $30 month
including drug, blood tests, spnals, bone marrow etc.
Discontinued in 1968. Was given clean bill of health for Squibb.

Q. How is informed consent obtained -- what explanation of
experiment? A. It's very informal -- the doctor himself
doesn't know what the risks and side-effects are! He'll
be told "possibly some discomfort".

Leslie Bennett asst at UC med-school

Cyclamates: a crash program at Vacaville. In manufactureres
bottles, Abbott Labs, 10 to 12 days. Then drug was taken
off market. Payment: $10 for 10 days. High level toxicity.
A Maibach/Epstein experiment. They do 85% of the research.

Q. How do chief investigators supervise the experiment?
A. Epstein comes in at least two ½ days a week. Maibach,
½ day a week. Experimenters give up control to the inmate-
researcher who hands out medication, takes blood, analyses
blood, gives result to physician in charge. Investigators
only see patients they believe are in toxic state.
Q. What if subject gets ill? A. If the resident physician
diangoses an illness he'll notify the experimenters. Q. Is
a lot of illness caused by research? A. More than I think
is necessary. I've seen lots get ill. Many hide symptoms to
stay on program. Experimenters review the test results, look
for toxic levels, bring new stuff to be tested. Protocols
are v. general; name of drug, tests to be done, amt. of pay.
Noone really knows what protocols mean -- vague medical jargon.

vice-president, Research & Development

Interview with Dr. R. Bogash, Wyeth company, MU 8 4400 (215)

Q. Where do you go Phase I testing? Main populations? A. Tell me the reason for your question. Q. Prisons? To what extent do you use prisoners, in which prisons, numbers of volunteers involved? A. That's fundamentally confidential information. The reason is, where we get our clinical work done is just as much a trade secret as what we're doing. There are industrial spies everywhere, our competitors have a pipeline to what we are doing. If we let out the names of the prisons the secret would be out, as we have numbers of volunteers -- if two people have a secret, it's still a secret. If more have it, (volunteers might spill beans). Q. Where is most of the Phase I testing done? A. I assume you are not going to quote anybody in the article? Q. (a reassuring hmmmm). A. In Phase I, in the US, it's mostly prisoners. In other countries, they only use patients. Other countries do better with patients. Q. Phase I means normal, healthy volunteers, excludes patients by definition? A. That's true in the US. Only in special situations we use other than prisoners -- for example, cancer patients. Q. Do you use other large-scale populations -- students, for instance -- for Phase I? A. Offhand, I'd say no. Q. Could you tell me about 2 experiments currently being conducted at Vacaville prison: WY 8678 and WY 21,743? A. That's confidential information in the IND (means Investigational New Drug) files -- I wouldn't tell my own mother about it. It's filed with FDA, which is in the same bind of confidentiality. Q. The volunteers for WY 21,743 get $60 a month compared with av. of $30, according to Mr. Urbino -- he said because riskier side-effects? A. I don't know anything about the compensation, that's between the prisoner and the prison. Q. Any lawsuits against Wyeth? A. You're asking essentially confidential information. Q. Does Wyeth assume any responsibility for adhering to FDA/HEW guidelines? A. All our protocols are reviewed with this in mind. We work hard at this kind of thing. Q. Who does? A. The medical monitor in Wyeth does. Q. Are you aware that Vacaville exacts a waiver from volunteers, in violation of FDA rules? A. No, the medical monitor would never permit that. Q. What is the name of the medical monitor? A. Goodbye.

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Med Outpatients

on problem of prisoner not reporting side effects:

Dr. Ley: The basic problem here, Mr. Chairman, is that the the remuneration to the prisoner was too much. This meant that the prisoner had a very strong pressure not to report and not to withdraw from the study. Therefore, he would decline to say that he felt any adverse reactions. This is bad for the prisoner in that it exposes him to unnecessary risk, it is bad for our records in that it does not provide us full information.

(report): The presence of drug testing programs in a prison affords another means of rehab. through the provision of a channel by which the prisoners can make both a humane and financial contribution to society and their families.

Sen. Dole: I also understand that he made ref. to a certain prisoner in Ala. who perhaps was pd. too much for participation in testing. I am wonderwith what he was paid, what the going rate was in Ala....

Sen. Neslon: $1 a day.

Dr. Ley: Dr. Liseok tells me that the fee varies depending on the test, and I suspect, as usually is the case, on the number of times the pris. has to be bled. But an av. figure across the board would be somwhere about $1 a day. (above, drug hearings)

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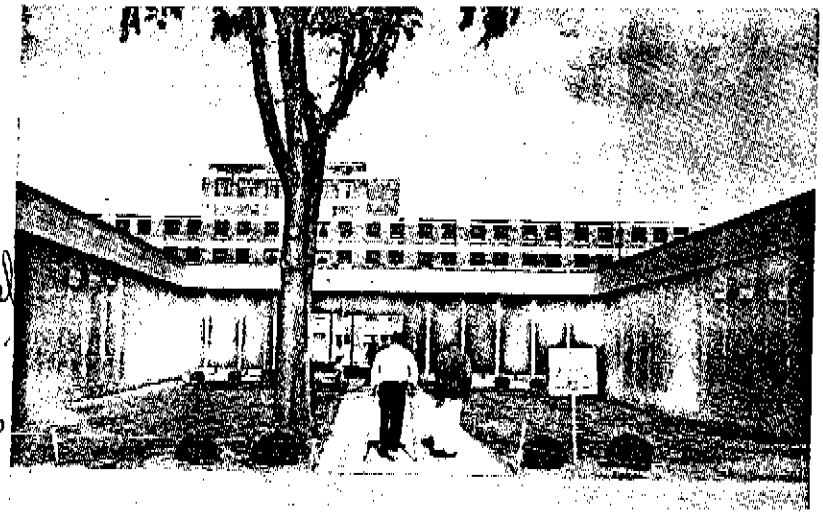
Interview with Dr. Hodges: Q. How much did scurvy test subjects get paid? A. $1 or $2 a day -- the pay increased as the cost of cigarettes went up. It's unethical to pay an amount of money that is too attractive. Oh, we had the money, we could have paid much more, of course -- but we weren't being cheap, we were considering the ethics of the situation. Q. Have you done similar experiments on students? A. Not the same one. We've used students to test diets. Q. How are they compensated? A. They get their meals free, and $1 each time we stick them with a needle.

The prisoners got extra for really unpleasant things -- if we had to put a tube down their throats for several hours we'd give them a few dollars more. $5 for a biopsy of the skin the size of a pencil eraser.



New laboratories of Upjohn and Parke-Davis stand between prison hospital and Cell Block 9 at State Prison of Southern Michigan, in Jackson, Mich.

Prisoner's mouth is checked to be sure he

RESEARCH

Drug tests behind bars

Upjohn and Parke-Davis have broken precedent in building their own labs in huge Jackson (Mich.) prison, where they can run better clinical tests than ever before on new drugs

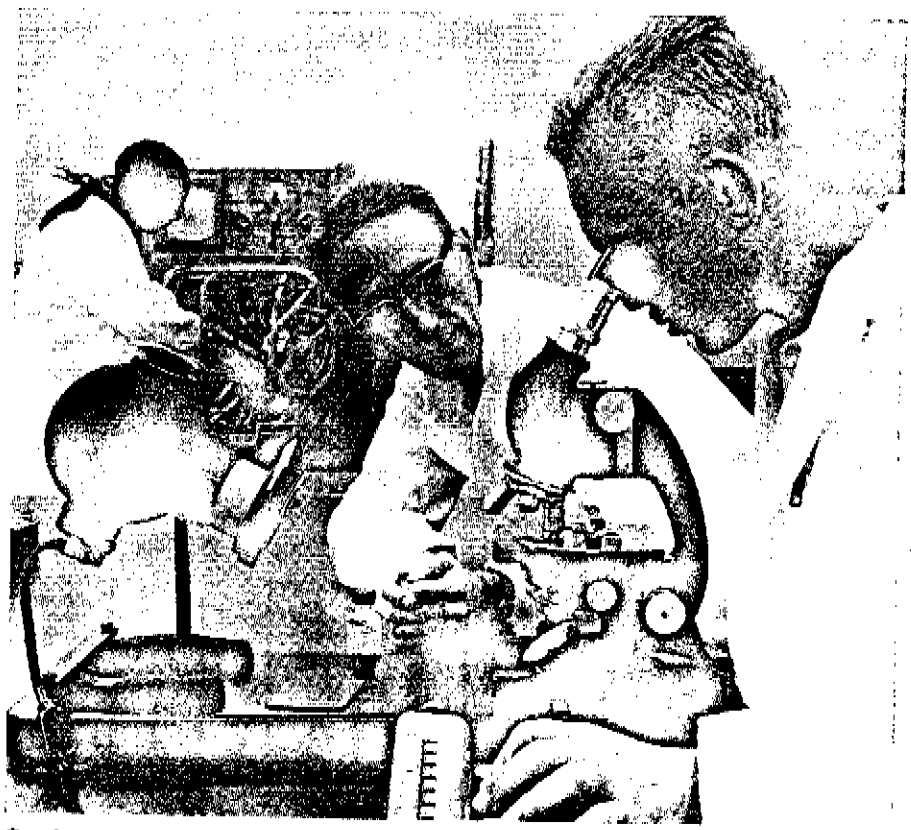
If you wanted to test a new drug on hundreds of human volunteers who have much the same sort of life and who can be continuously supervised for months or years, what better place to look than in a prison?

For many years, drug companies and the National Institutes of Health have had cooperative agreements with penal institutions all over the country, permitting them to run clinical tests on inmates. But they have generally been barred from installing labs at the institutions.

Now, Upjohn Co. and Parke, Davis & Co. have broken into prison in a big way, with half a million dollars' worth of lab facilities (pictures) at the State Prison of Southern Michigan. This prison, at Jackson, is rated as the world's largest walled penitentiary, enclosing 57 acres and 4,141 prisoners.

The two companies' laboratories, adjacent to the prison hospital, are said to be the first such facilities ever built by drug companies inside U.S. prison walls. They were completed this spring at a cost of $266,000 for Upjohn's labor and $226,000 for Parke-Davis, and title was then turned over to the state.

Research dream. From the outside, the two buildings, connected by a covered walk, aren't too impressive. Yet research people in both com-



One inmate technician watches another counting blood cells. Inmates learn lab techniques; this gives them chance to gain skills useful in outside world.

swallowed pill. A tranquilizer, for example, can fetch two packs of cigarettes if it can be smuggled out to the yard

Inmate technicians take blood samples from prisoner volunteers in drug tests.

Guard checks volunteers into the waiting room of Upjohn's lab. Room seats 100 inmates, is made to look professional, cheerful.

Gus Harrison, Michigan's director of corrections, pressed the lab idea

panies say the setup is a dream come true. It will permit, for the first time, what they call optimum control testing of new drugs.

The companies expect testing at Jackson to permit unsuitable drugs to be detected and discarded in as little as one month, compared with a standard three to five years for conventional clinical testing. They also expect far more accurate findings on how drugs affect cells and enzymes. The groundwork for a cure for the common cold or for cancer might well be laid at Jackson.

Drugs these days are accomplishing remarkable results partly because they are so much more powerful and so specifically formulated for their tasks. But as their potency increases, so does their inherent risk. Thus, accurate testing on human volunteers is ever more vital.

Personnel problem. It is also increasingly difficult to find enough volunteers—or even enough clinical investigators to test all the new drugs coming out of the laboratory.

With the spread of medical insurance, charity wards in hospitals are disappearing. These were traditionally an area for studies of new drugs as well as for the teaching of medical students. Drug tests can still be run much more cheaply in foreign countries, but companies admit a risk of inadequate controls and of a political backfire.

Through doctors who are competent clinical investigators, tests can also be run on patients all over the country, though it's a slower process than with mass volunteers and requires more contact work. There is a severe shortage of top researchers for routine testing jobs.

"There are a lot of doctors who are superb doctors," says Dr. Harold L. Upjohn, Upjohn's director of clinical research. "But they do not have the time, the knowledge (although they do not know it), or the patients to test drugs adequately."

Yet the drug companies must respond to the strict 1963 amendments to the Food, Drug & Cosmetics Act that empower the Food & Drug Administration to require a fuller accounting on all drug testing.

Finding an answer. Many a clinical test of a new drug turns up an aberrant finding that leaves the drug researchers uneasy even after the drug has been licensed. It might be a freakish reaction to a compound, a genuine effect of the drug, or a technician's sloppiness.

"We can never erase doubt in our own minds," a technician says. The prison labs are a step toward eliminating such doubts.

At Jackson, with laboratory facilities now available for substantial expansion of the testing program, Upjohn and Parke-Davis are tapping a rich source of volunteers for round-the-clock experiments under round-the-clock supervision. Prisoners are volunteering by the hundreds for testing purposes.

Willing help. Many want the money, which ranges from a few cents to as much as $15 a day on a scale set by the prison board. Some are saving up for their parole period when a small bankroll can mean the difference, as it did for one prisoner recently, between getting out or being kept in prison for lack of a job or friends outside. Some send money to their families, too.

Prisoners also get a valuable feeling of self-respect. For some, it is the first time they have ever done anything to benefit society; some even

learn the trade of lab technician, with a chance to find an honest job in a hospital later.

"I'm helping other people," says one inmate technician, "and I've never felt like this in my life."

Selling the idea. Testing of drugs in U. S. prisons dates back to 1906, when Pres. Theodore Roosevelt pressed for the first food and drug controls. It increased during World War II. Parke-Davis has been testing at Jackson prison for 30 years, Upjohn for eight.

Three years ago, Dr. Harold Upjohn broached the idea of company laboratories at the prison to Gus Harrison, director of the Michigan Board of Corrections. He and Harrison took the idea to the Prison Commission with the argument that research labs could be considered an extension of prison work shops and other activities geared to rehabilitation of prisoners.

The commission approved, and the state issued invitations to other Michigan drug companies to participate in the project. Parke-Davis accepted.

How it works. Under their agreement with the prison board, the companies are training inmates to run the tests that can be handled in the prison labs. Other tests are completed in their respective headquarters facilities, Parke-Davis in Ann Arbor and Upjohn at Kalamazoo.

The Board of Corrections decides which drugs may be tested at the prison. Each case is reviewed by a board of five doctors and a blue-ribbon committee that includes the deans of the state's medical schools. Right now, the two companies are testing a broad range of drugs at Jackson, including anti-coagulants, analgesics, anesthetics, steroids, tranquilizers, and deodorants.

With their new ability to keep close laboratory controls on tests with prisoners, Parke-Davis and Upjohn expect soon to start testing drugs that have never been tried on human subjects. Tests at the prison are designed primarily to measure the toxicity of a drug, rather than its efficacy.

Initial doses are as low as 1/1000th of LD 50 (the lethal dose for 50 out of 100 laboratory animals, adjusted to man's weight). They are then built up gradually to the point where adverse reactions appear.

Much faster. At Jackson, a large number of persons can be run quickly through the early stages of toxicity testing, revealing the specific reactions that must be explored. In the past, much of a researcher's time in checking on the toxicity of

Each volunteer gets a physical, and about half are eliminated from testing.

a new drug had to be spent in running around the country, coordinating clinical investigators.

"We're willing to stick our necks out on an unsuitable drug in a month now," says a Parke-Davis researcher. The Jackson project is hailed by Dr. P.F.R. de Caires, Parke-Davis director of clinical investigation, as a great aid to speed and accuracy in pinning down the areas for further study.

Since the lab opened, Parke-Davis has already eliminated two new chemicals designed to reduce blood cholesterol level.

Deeper, too. Dr. Upjohn is particularly interested in depth studies of a drug's reaction on a given prisoner, revealing basic facts about drugs generally. Upjohn is stressing two 10-bed metabolic wards at its lab for near-absolute control in drug studies that may last three or four days or several months at a time.

These studies will attempt to chart blood level, absorption and excretion of drugs, as well as toxicity, in selected healthy men. This is the element that is missing in many drug tests elsewhere.

"How can you tell when you test whole wards of little old ladies with broken hips if their reaction to a drug will be the same as that of a 17-year-old girl?" asks Dr. Alan Varley, manager of clinical research for Upjohn.

With prisoners, researchers can precisely set the odds in drug tests. "You can devote your entire attention to safety," says Varley, "and learn considerably more about a drug."

In the outside world, test subjects balk drug researchers at every turn, albeit unintentionally. "People are not reliable when they are asked to take medicine," Dr. Upjohn says. In a prison setup, they can be checked to be sure they have followed instructions precisely. **End**

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Discussion

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My discussion is about three committees on which I serve at the University of Michigan. Perhaps this will help to establish some principles with a few specific examples. The committee meetings must keep a certain confidentiality, which is easily solved here by omitting individuals' and investigators' names. Also, I'll confine myself to classes of compound rather than specific ones.

Students as a group do not participate in all these committee actions, and this introduces certain difficulties. These students, whom we are expected to teach, have strong, diverse opinions. If we get one student on a committee, it may be good for his political standing with his fellows, but it doesn't teach the whole class. I wish the whole class were involved in committee discussions, but then we would destroy the confidentiality. So, much of the *teaching* aspect so important in these committee discussions is not available to the students.

Regarding the first committee with which I have worked, the Radioisotope Committee, a primary principle is that the pharmacology of a compound has a great deal to do with decisions as to what is permissible in investigations. In 1947, this type of committee might be considered the grandfather of the peer review committees. By 1952, the Atomic Energy Commission had formal arrangements for regulating the use of radioisotopes in human beings, and radiation policy committees were set up in the universities, with subcommittees on human use. Our committee in Michigan started in 1952.

Table I shows a problem with an investigational drug using tritium. If 100 microcuries of tritium is given in the form of water, the whole body dose is only about 8 millirads, which is about the dosage one gets from cosmic radiation in about one month in most parts of the United States. In general it isn't a very high dose. On the other hand, along came an application to use a congener of cytarabine because studies in animals didn't clearly indicate how the human being would dispose of it. A company wanted to investigate this in human beings, using 100 microcuries of tritiated cytarabine congener, which was not used in the previous 20 protocols. This posed problems. The drug is not like other tritiated compounds, for the genetic material would take it up. It is very difficult to estimate how much this use would increase the radiation dose to the genetic material. Estimates ranged from 15- to 1,000-fold increased biologic effectiveness in this instance. We decided it just could not be done except in people who could, for some reason, eventually benefit by it. This was an antiviral compound and certain people with malignant diseases would be in serious trouble if they contracted a viral disease; this particular compound might prove to be very helpful to them. Therefore, it

be justifiable in those instances to them to participate as research subjects. In fact, this study was not initiated at Michigan after all the discussions were completed.

Table II illustrates another principle, namely, that in certain circumstances you can proceed with an investigational tool on the basis that the subject has little to gain but nothing to lose. Consider first objections to use of ^{131}I in the form of radioiodinated serum albumin intrathecally. From the suggested 100 μc of this compound (^{131}I-iodoalbumin), the whole body dose would be in the range of 30 to 150 millirads with much higher local dose.

If one wanted to give 50 millicuries of an ^{131}I-chloroquine analogue the whole body dose would be almost 100 rads at the highest—a big whole body dose. Why was this permitted? Because the people in whom the investigators wished to use this analogue had disseminated malignant melanoma, no other therapy was available and this was an attempt to treat them; in other words, it was intended for their own immediate good.

Now, there were questions as to whether it would help them, for melanoma is not a radiosensitive tumor (relatively) and, second, even in the usual black melanoma, not all cells are melanotic. Therefore, it was questionable whether these people would really get a cure from malignant melanoma or get tremendous benefit. On the other hand, it was considered unethical to refuse them this possibility. One could sit and watch them die or let this investigator try to do something for them. The choice was obvious.

There are two ways to look at this: We have to consider the pharmacology of the compound and use clinical common sense as to what can be allowed and what cannot. Thus, either we can find measures that are of such low risk that we don't have to think a great deal about whether the investigation is likely to help or not, or we find situations in which the patient has so little to lose that it would be wrong to deny him this one chance in a thousand of being helped. However, most of the time it isn't that simple and one has to make other decisions. We come now to the third principle, in situations involving the second review committee.

Table I. *The case of the dangerous radioisotope*

Prior to 1970, the Subcommittee on Human Use of Radioisotopes had approved 20 protocols using tritium in doses ranging from 2μc to 2mc.
Application No. 21 requested the use of 100 μc to study the metabolic disposition of a congener of cytarabine

Table II. *The "hopeless" case*

The Subcommittee on Human Use of Radioisotopes restricted the use of ^{131}I-iodoalbumin (intrathecal) to special diagnostic problems (e.g., CSF leaks), even though the established whole body dose from the administered 100μc = 30 to 150 mrads. The spinal cord might receive a local dose as high as 40 to 60 rads
Yet this Subcommittee approved administration of 50 mc. of an experimental ^{131}I-chloroquine analogue systemically to certain patients. Their *whole body dose* is 70 to 95 rads

By February 1966, the Surgeon General's edict, with which you are all familiar, had been issued, and by the end of March 1966, we had a standing committee that dealt with various forms of human investigation, quite apart from the Radioisotope Committee.

Table III lists some examples of cases that plagued this review committee. A study that in itself was safe might frighten the subject. The otologists were interested in obtaining audiograms to test the hearing of people who had terminal illnesses, in the event that some of them would come to autopsy. They might then be able to compare the findings in the inner ear with the audiograms. Not everyone with a terminal illness is miserable and in pain at that time. The investigators were quite careful to stay away from anyone who was in pain or would in any way be harassed

Table III. *Cases that plague review committees*

No.	*Cases*
1	Studies that are themselves safe and reasonable but may still be frightening to the subject
2	Studies that are themselves safe and reasonable but may still be embarrassing to the subject
3	Invasion of the body by indwelling catheters, etc.
4	Studies during pregnancy and delivery
5	Anesthesia

by the procedure. The patient was, of course, not told he was being studied because of his condition. While the procedure had no benefit to him, the investigators were very careful to make sure it would not affect the patient's treatment, and, since an audiogram is a painless procedure, it is the kind of thing that could be allowed rather easily. However, by the "hospital grapevine," it would eventually become known that the audiograms were being used for this purpose and would frighten the persons concerned. Therefore, we just couldn't allow the investigators to select their subjects, no matter how careful they were with the terminally ill patients.

Since it was a painless and harmless test and since the investigators were not doing this for anything except hearing research, we allowed them to do it provided they also sought out *other* people at random. Our concern was that they do nothing to frighten the subjects.

We also had to deal with situations that involved embarrassment. For example, a psychiatrist wished to do something that required a follow-up of what had been done in the past. This meant following up people who had been seen in the student health center by a psychiatrist in previous years. The questionnaire they proposed was not unreasonable and the people were not in any way coerced to answer it. We had one problem, however. Many people are sent to psychiatrists in college for one thing or another. The psychiatrist may find it to be a minor problem. Five years later, and after the person has left the college, suppose a letter arrives making reference to the fact that this person had been seen in psychiatry. Suppose his secretary or his wife opens the letter—it is like a voice out of the past!

Although there was nothing in the letter that one would find offensive, it might be opened by someone other than the rightful recipient and cause embarrassment. Therefore, we didn't think this should be allowed, even though it was a very mild request—simply a letter asking for certain follow-up information from the subject himself.

Number three in the list of problems before the review committee is much stickier. It involved investigation of hearing by a new method. It is very important to find out if a young child has normal hearing, to determine whether problems are associated with deafness or with mental retardation. Many children unfortunately are called mentally retarded even though they are very bright; the problem is with their poor hearing. In the younger age group, the proposed method of testing hearing was by evoked cochlear potential and involved putting electrodes in the middle ear. The investigators wanted to start with adults. We felt as follows: No matter how much they told the person and no matter how unequivocally he consented, we wouldn't permit puncturing the eardrum solely for research purposes, even if the subject understood exactly what was being done. Therefore, initially they had to start with people who already had punctured eardrums from previous disease or who had no eardrums.

Now, what happens when you finally decide that this is a useful method and you wish to use this in an infant? Then it will require a myringotomy for the purpose of trying to help the infant. On the other hand, the first infant in whom this is done is still an experimental subject. How does one know the first time around that this investigation will actually help the child?

The switching from adults to children is very difficult. What are the rights of a parent to commit children to investigation? Taking an example from obstetrics, what are the rights of a parent to commit a fetus to investigation? Do they have such rights? These are serious problems to deal with.

Nevertheless, we can't stop all the progress in obstetrics. In the long run, this would be to the disadvantage of pregnant women. Recently, some of us were prepared to veto a proposal to monitor the use of a prostaglandin as a method of inducing labor after the standard oxytocic hormone had failed. One investigator wanted a catheter in the uterus through the abdominal wall. We said, "Ridiculous, we can't allow a thing like that." It turned out that obstetricians in many places used that type of monitoring routinely in trying to induce labor. It can be part of medical practice to put a catheter in the uterus to monitor the progress of labor and their answer was, "Do you want to deprive a patient of an investigational drug—after the standard drug has failed—using the same protective monitoring that goes on with the standard drug?" Obviously, the answer then was "no."

As to the fifth problem, we feel that general anesthesia should not be induced routinely purely for investigational purposes. But what happens if you want to do early studies on a new anesthetic agent? Are you going to start with sick people? Are they to be the first to receive a new general anesthetic?

We had this problem in a prison study and we finally permitted short general anesthesia to be given for a few minutes as a Phase I study. It was administered by a professor of anesthesiology, with a professor of pharmacology doing the monitoring. Under these conditions we would allow it, and no adverse effects resulted. Nevertheless, we are always worried about general anesthetics.

Subject selection requires careful consideration. In my own experience, I've found four types that constitute poor selections (Table IV). People who are psychiatrically borderline are not good research subjects unless the study has to be done on psychiatrically borderline people. The first one listed was an individual who was regularly "on" all sorts of drugs on campus. He would make a very poor volunteer for a drug study, even though he'd be delighted to take any drug that we would give him.

Table IV. *The case of the poor selections*

No.	*Subjects who were poor candidates for drug studies*
1	A drug-seeking hippie
2	A "volunteer" under family pressure
3	An attorney (!)
4	A patient in danger of sudden death

The second was a so-called volunteer, but after I talked to him I discovered he was frightened and did not wish to participate in research but was doing it under family coercion. Of course, we did not use him.

Litigious persons are not good subjects. Maybe it's unfair to assume that attorneys involve *themselves* in lawsuits more than other people.

Another poor selection would be a patient in danger of sudden death, e.g., one who might have a sudden myocardial infarct, even if the study had nothing in it that could precipitate a cardiac arrest. If you think the volunteer is in such danger, he is a very poor subject to select.

A very interesting case was presented to our committee by an investigator who wanted to do endocrine studies using students as subjects. He wasn't studying contraception specifically, but he wanted to learn the effect of contraceptive drugs on certain endocrine functions. These girls were students, minors, unmarried, and they were told that they were going on contraceptives. But in the original plan they would not have been specifically told that the study would be controlled by placebo. This protocol received a fast veto (Table V).

A series of studies has been conducted, beginning in 1964, in prison units similar

Table V. *A case of poor planning*

No.	*An investigator proposed to the Committee to Study Clinical Research in Humans that he be allowed to conduct a study of oral contraceptives, using subjects who were:*
1	Unmarried
2	Minors
3	Students
4	Also to be given placebo controls

Table VI. *The case of the successful protocol review committee*

The clinical research activities at Southern Michigan State Prison in the first 5 years of operation (1964-1968) included 312 studies using 10,037 subjects

In the most recent year (1970) 64 studies, using 2,930 subjects, were conducted

No instance of death or serious injury from a study has occurred since the beginning of the program

in type to Deer Lodge in Montana. The units were established by Upjohn and Parke Davis at the Michigan State Prison in Jackson. Some statistics are given in Table VI. By using protocol review committees it has been possible to conduct a large number of studies and, as of 1970, there has not been a death or serious injury since the beginning of the program.

These are mostly Phase I studies. One advantage of having a committee meet rather regularly is that with time it becomes unnecessary to reject very many protocols. The investigators soon learn what is and is not acceptable. After a while the acrimony tends to disappear, I believe, because certain things are known to be forbidden, and these are not proposed. This is the way it is done at Southern Michigan State Prison: When an inmate is admitted to that prison he receives a notice which he can send in if he wishes. Nobody approaches him directly to ask if he wishes to be part of the drug experimentation group. Very few people volunteer initially. They wait until they have talked to other

Table VII. *Cases of change in protocol*

From August 1969 through August 1971 the Michigan Protocol Review Committee modified submitted protocols for Phase I studies as follows:

Modifications	*Instances*
Improved monitoring of subjects	34
Exclusion of certain subjects	14
Improved design and logistics of study	6
Submission of additional preliminary data	3
Improved informed consent	1

Table VIII. *Improved monitoring of subjects*

Improvements	*Instances*
Amount of blood withdrawn	8
Additional liver function studies	7
Additional coagulation studies	5
Change in dose schedule	4
Electrocardiography	3
Slit lamp examination	2
Additional blood counts	2
Miscellaneous	3

prisoners to find out whether they should participate. If they do volunteer they are interviewed by the people concerned with the drug study. When the protocol is developed it has to be reviewed by a protocol review committee consisting of physicians from the University of Michigan and others in private practice in Jackson, Michigan. There is also a physician from Wayne State University, and now an attorney has been added. A few statistics from the last two years' activities of that committee are shown in Table VII.

The most common objections we have made refer to monitoring. In several instances we have insisted on closer monitoring. In Phase I studies, the most important thing is to watch the subjects carefully for signs of adverse effect from the drug, signs of disturbed function of any kind. Then one must stop the medication. There is no way to raise the dose by increments in a Phase I study without very careful monitoring of the subjects.

Table IX. *Exclusion of subjects*

Exclusion	*Reason*
Previous reaction	Vaccine to be used in the study
Previous psychosis	Steroid to be used in the study
Previous phlebitis	Steroid to be used in the study
Previous exposure	Chloramphenicol to be used in the study
Previous liver disease	Creatinine phosphokinase determinations important
Multiple allergies	High risk of sensitization
Recent trauma	Heparin to be used
Recent blood donor	Many blood samples needed
Eye disease	Long-term antilipid drug to be used
Normal VDRL	Requires LP
Cardiac abnormality	Antimalarial to be used
Abnormal ECG	CO exposure
Infection	Sulfonamide to be used
Gynecomastia	Steroid to be used

Table VIII shows 34 protocols in which the monitoring was modified. The biggest problem was that the investigators might take too much blood. In a pharmacokinetic study, blood is taken serially and if one adds up the total amount, one may end by taking more blood than one would from a blood donor. This problem is now controlled by careful limitation of the amount of blood withdrawn. These people are also given iron supplementation where indicated (Table VIII).

Another aspect of a study is the exclusion of certain subjects. In one study the investigators wanted to obtain spinal fluid. It was necessary to explain what a spinal tap was; nevertheless, we were reluctant to approve it, as it represented invasion of the body. On the other hand, in a prison there may be many people who need lumbar punctures because of a positive serologic test for syphilis. Therefore these people could be available and they would themselves benefit from the procedure (Table IX).

Summary

In summary, this was an attempt to set down some principles based on the work of three committees on which I have served. By means of some practical examples I have tried to suggest a few guidelines for conducting research with volunteers. I believe that such principles, illustrated by practical examples, are useful to investigators and aid in the guidance of committees in their function as review bodies.

Any set of guidelines should be just that; if they are too rigid they are likely to lead to serious difficulty. If rigid guidelines are put into law and interpreted not only by various federal agencies at the top level but by middle bureaucrats and lower echelon bureaucrats, bad mistakes are likely. A truism in this work is the need for individualizing each case to avoid the risk of mistakes arising from strict and inflexible application of the guidelines. It is my hope that we can keep guidelines as aids for peer review groups in making individual decisions, rather than as rigid rules.

CONDUCTING INVESTIGATIONAL DRUG STUDIES FOR INDUSTRY

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Any discussion of the methodology for evaluation of a new drug should be prefaced by a presentation of the procedure that must take place in making a decision that the new substance merits clinical trial in man. I shall restrict my remarks to procedures employed in the clinical trial of an entirely new substance, and I shall not attempt to discuss problems related to evaluation of changes in formulation.

Let us assume that the chemists and pharmacologists have produced evidence that a new compound possesses some properties that might have therapeutic application in man. At this time, tests in several species of experimental animals will be undertaken for the purpose of determining any potential toxicity. In addition to undergoing acute tests for lethality, the drug will be administered to animals at regular intervals in the maximum dose they can tolerate, and it will be given by the same route to be used in man. During the administration of the drug, laboratory tests of organ function will be performed at regular intervals. These tests will be terminated at varying times depending on the number of doses planned to be administered in the initial clinical trial. Some of the animals will be sacrificed and subjected to thorough postmortem examination, including careful microscopic examination of tissues. The remainder will continue to receive the drug and be kept under close observation. It is important to keep in mind that the goal of this toxicological testing is to give the drug in sufficient amounts to uncover any undesirable actions. The difference between the quantity of the drug required to produce the desired pharmacologic action in animals and the amount that may cause toxic effects is an important criterion in deciding if a drug merits clinical trial. The occurrence of toxic manifestations in animals when the dosage level is many times the anticipated therapeutic dose should not be held as evidence against initiating a clinical study. However, it is essential that the clinician who will be asked to consider undertaking the clinical trial be informed of all evidence of toxicity and of any abnormalities in organ function that may have been observed during the preclinical studies.

It is obvious that we must always weigh the potential for harm against the anticipated benefit that might occur as a result of the addition of a new drug to our therapeutic armamentarium. The first review of these data for this purpose will be made by the research staff that participated in their production and by a physician from the company's medical research staff who will be responsible for the clinical trial programs. This group will present recommendations to research administration for approval. An important consideration affecting a decision that a new drug merits clinical trial is its intended use. If the new substance would enable us to treat a disease in man for which there is no satisfactory therapy, we would certainly be willing to accept greater potential risk in the clinical trial program than if the drug was intended to

treat a symptom that in itself is not life-threatening. Finally, the economic factors involved in clinical trial must be considered by management. The prolongation of the tests for toxicity in animals and the extension and repetition of clinical studies have contributed to an increase in the cost of drug evaluation. Perhaps if we can ascertain the metabolic pathway of the drug in man during the early stages of the clinical trial and then select as the species of animal for chronic toxicity testing those animals metabolizing the drug in the same manner as man, it may be possible to reduce the duration of the toxicity testing. Furthermore, attention to the design of the clinical studies will give us more meaningful information than might be obtained by widespread investigation in which many factors may not be adequately controlled. It should be noted, however, that when there are instances in which a new drug offers therapy for a heretofore invariably fatal disorder, industry would undertake a clinical trial regardless of the cost or the ability to produce material on a satisfactory scale.

Today the advances in our technology and the recognition of the importance of investigating the metabolism of the drug have made it desirable for the initial study to be conducted by a trained clinical pharmacologist working in a well-equipped laboratory with adequate technical staff so that maximum safety for the subjects or patients may be provided. Under these conditions it is possible to obtain a great deal of information from a limited number of observations, and this information will be utilized in planning the total program for the evaluation of the drug.

Let us assume that a decision has been reached that a new compound merits at least a limited clinical evaluation. The data must be assembled for submission to the Food and Drug Administration, and the clinical trial will actually begin when an Investigational New Drug number is received from Washington.

In the past, it was customary for a physician assigned as monitor by the manufacturer to seek out several investigators who would be willing to "try the new drug." Today we must consider the feasibility of the manufacturer's establishing clinical research units with a full-time technical staff under the supervision of a competent clinical pharmacologist and investigator. Some of these units have been placed in prisons, but the ideal place for such a facility is a hospital with close association with a medical school.

In some quarters, the participation of a clinician who receives his entire financial support from a pharmaceutical manufacturer has not been looked upon with favor because it was the consensus that the clinical trial might be biased. It was reasoned that the physician would be unduly influenced by the desire of management for a favorable answer. In my opinion, this is not true. It has been my observation that most industry-based investigators exhibit, if anything, a lower level of "positive bias" than exists among physician-investigators who would be supported by grants. Present FDA regulations require that the initial clinical studies be undertaken by individuals experienced in drug evaluation. Certainly it would be ill advised and would show poor judgment to permit undue pressure to influence the conduct of the clinical studies. If an initial study is conducted in a haphazard manner, it is possible that a valuable therapeutic agent may be discarded and might not be rediscovered.

In 1926 Eli Lilly and Company established a modest research unit in the Indianapolis General Hospital (now Marion County General Hospital) for the evaluation of liver extract in the treatment of primary pernicious anemia. The laboratory has been in continuous operation since then and has become

involved in several fields of interest. Today, the Lilly Laboratory for Clinical Research occupies 69,000 square feet at this hospital, which is affiliated with the Indiana University School of Medicine. The hospital is about two miles from the main research laboratories of Eli Lilly and Company. Clinic physicians can confer with their colleagues in research, and vice versa. In 1968 we occupied a new wing in the hospital, and the facility was expanded so that we now have space for 52 patients or subjects in a special ward, which includes excellent equipment for preparation of special diets and continuous electronic monitoring of vital signs. In addition to the ward, there are laboratories for the conduct of special tests, including liquid gas chromatography, isotope studies, and all the usual standard hospital laboratory equipment. Examining rooms and other facilities are available for outpatient studies. The unit is closely associated with the departments of pharmacology and medicine at the Indiana University School of Medicine. At the present time, almost all of our initial clinical trials and a portion of the continuing studies for effectiveness and safety are being conducted in the Lilly Clinic by physicians with the assistance of technical staff, all of whom are full-time members of this research component.

Subjects and patients come from several sources. It is essential to have an ample number of volunteers. These individuals should be healthy young adults. We have developed a satisfactory arrangement with the Board of Correction of the State of Indiana whereby young male adults who have been serving a prison term in a state institution near Indianapolis may volunteer as subjects for the clinical trial of new drugs.

In Indiana there is frequently a period of time between the approval of parole and the actual date of release of the individual. This interval provides a satisfactory time for this person to participate in drug studies. In addition to the monetary gain that may accrue to these men, participation in our clinical trial program at the hospital provides an opportunity for the subject to "test himself" in a different environment. This experience has been helpful in aiding in his readjustment to society. After these men have volunteered they are interviewed carefully, and the nature of the proposed study is explained in great detail. The administration of the institution has not only approved their participation in the study but also will permit their transfer to the Lilly ward for clinical research in Marion County General Hospital. Since they are due to be paroled within a matter of weeks, there is no incentive to escape. Each volunteer is given a very thorough physical examination, and a complete battery of laboratory tests is performed to ascertain that all organ function is normal. At the time of the admission to the research ward, the protocol of a proposed study is explained in detail and in lay language by the clinical pharmacologist. Each volunteer must then sign a written consent form. Our criteria for establishing that these volunteers have been as adequately informed as possible would be determined by their ability to describe in their own words the nature of the tests and the goals and any adverse experience that might be anticipated.

A copy of the proposed protocol is filed with the superintendent of the institution and is reviewed by the medical director at the prison. During their stay in the hospital, the volunteers are provided with equipment for exercise. They are visited regularly by an occupational therapist of the hospital. The money they are paid for their effort is held in escrow until they are paroled.

At the hospital they may have visitors (15 years of age and over). Prospective employers may interview them.

We have found this arrangement to be far more satisfactory than attempting to conduct the clinical trial program in the prison. The Lilly research unit has been nicknamed the "Halfway House." The volunteer subjects are especially helpful in the conduct of increasingly important metabolic studies of new drugs.

In some instances, the patients with a relevant disease will be used in the initial phase of a clinical trial program, rather than normal volunteers. For example, for evaluation of a relatively toxic drug in cancer chemotherapy we would use patients with advanced disease. Similarly, in evaluation of an antihypertensive drug there is ample opportunity to make observation of its safety in patients with mild hypertension and at the same time obtain information as to its effectiveness.

Special clinics such as diabetic, cardiovascular, and gastroenterological ones are conducted by Lilly physicians in Marion County General Hospital, both in the outpatient area and in the research unit. Thus, they collect a group of patients with carefully documented records of their disease. We have had no trouble attracting these patients as volunteers following their treatment and observation in our clinics.

A special committee, which includes members in the departments of medicine and pharmacology as well as senior members of the company's clinical research staff, carefully reviews each protocol prior to every proposed clinical trial. As you are well aware, the initial trial of a new drug always entails some risk to the subject. We have made a maximum effort to reduce this to a minimum. The clinical pharmacologist must devote time and effort to these programs. Personal attention is essential, and responsibility cannot be delegated. A well-trained, competent graduate nurse is indispensable for maximum efficiency.

In addition to determining dose range, it is often possible to investigate the metabolism of the new drug in the course of the initial study. Methods for measuring concentration of the drug and its metabolites usually will have been developed in the course of the studies in experimental animals. Often they will be applicable to human subjects during Phase I.

There is increasing recognition of the need to establish the metabolic pathways of a new drug as soon as possible in the course of a clinical trial. As we have stated, this will be helpful in selecting species of animals for long-term chronic toxicity studies.

All of the data from the initial studies will be reviewed by the research staff. All information that is known, including chemistry, pharmacology, toxicology, and clinical data will be compiled into a loose-leaf notebook for distribution to clinical investigators when they express an interest in further evaluation of the drug. As the information is accumulated, additional pages can be added to this book under the proper section.

Now let us assume that we have evidence that the new drug has not caused serious side effects in subjects or patients; also, we have found the drug to be capable of producing in man the same desirable pharmacologic changes observed in animals. We are now ready to undertake a limited number of studies to demonstrate further evidence of therapeutic effectiveness. For these studies the physician-monitor may select four or five clinicians known to have an interest in the disease under study. The drug would be placed with them.

After they have also accumulated some experience with the new substance,

we would sponsor a conference in a central location such as Chicago with representatives of the Lilly research staff and the investigators who have participated in the preliminary study. The combined effort of this group would be brought to bear on the design for further studies at this seminar. Guidelines and ground rules would be spelled out for the next phase of the clinical trial. Emphasis now would be placed on the kinds of tests and the nature of the observations required to establish effectiveness. At this stage, it is desirable to limit the scope of the program and attempt only to collect data to support several major claims. For example, if we were to evaluate an antibiotic shown to have activity in *in vitro* testing against a number of organisms in both the gram-positive and gram-negative categories, and if, following oral administration, there is evidence that the substance is well absorbed, we would first plan to limit its use to treatment of infections in the upper and lower respiratory tracts, urinary tract, and soft tissues. Thus, at this stage in the clinical trial we would not expect to be able to establish a claim for effectiveness in such diseases as bacterial endocarditis or osteomyelitis.

Following this conference between the research staff of industry and the several investigators, we would prepare forms for case reports that would include data needed for dosage recommendation and establishment of diagnoses. The proposed study also would be programmed for data processing.

The necessity to use report forms has created some irritation and has been a problem with some investigators. Formerly it was customary to permit each investigator to report his data as he wished. Data collected in this manner did not lend themselves to the data-processing programs. However, the participation of several investigators in the design of the research plan has made the use of standard report forms acceptable to other investigators when they are invited to join in the second stage of our clinical trial program.

During the time of the preliminary clinical trial and the development of the master plan for the second phase of the evaluation, the pharmaceutical development and control laboratories will be expected to have established a satisfactory formulation and set up specifications for assuring maximum uniformity in material to be used in the clinical trial. Each bottle of medicine will bear a date after which the material should not be used. In the clinical trial period, the maximum expiration date should be no more than six months. When material is reassayed, the dating can be extended by the manufacturer if there has been no significant change in potency.

We must emphasize the importance of using material of uniform potency and composition in clinical trial. An apparently minor detail such as micronizing the ingredients may improve the uniformity of distribution of active drug when filled into capsules or in forming tablets. It is of little value to expend great effort on carrying out very carefully controlled clinical trials if there is great variation in the composition of the pharmaceutical forms used. The manufacturer may spend large sums on support for clinical studies and the supporting research, but, unless adequate attention is given to the pharmaceutical preparation of material, the variation in results arising from the difference in material may be responsible for a difference of opinion among investigators regarding the effectiveness of the new drug. All of the information regarding specifications for clinical trial material, as well as plans for the study, including report forms, are submitted to the FDA as part of the continuing process of updating the Investigational New Drug application.

As the investigation gets under way and case reports are received, it is possi-

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ble to give all investigators reports at frequent intervals on results of the study to date. The occurrence of any adverse experience also can be communicated promptly to all investigators. Prior to the use of data-processing equipment it was often impossible to know the status of a clinical trial until all the reports were received and tabulated by the physician-monitor. Today, even in a large-scale clinical trial program, we are able to have a printout of all the data every three weeks. A few investigators have objected to preparing detailed reports. However, when the advantages of the system are made known to them, they have accepted the task of reporting each case as the treatment is completed.

By use of data-processing methods we can ascertain with considerable accuracy when we have accumulated sufficient data to undertake preparation of the New Drug Application. The work entailed in preparation of this document also has proliferated. The manufacturer is expected to assemble all data and provide summaries of each section of the application. Any abnormalities found in laboratory tests must be isolated and attention called to them.

The performance of laboratory tests of certain organ functions, which are necessary to establish safety, presents a major problem for evaluation of new drugs by industry. If a laboratory performs tests in a careless fashion, or if an error in technic occurs, data will appear in the New Drug Application that may cause the FDA to consider the application incomplete and request additional studies. A satisfactory solution to this problem does not exist. One proposal has been to have the specimens shipped by air mail to a central laboratory, so that all tests can be performed in a uniform manner. Obviously, this program presents many difficulties and obstacles. Additional experience may enable industry to develop a procedure for overcoming problems such as those due to variation in technic in clinical laboratories.

In some instances, sufficient data can be obtained from the clinical trial performed in hospitals, but for some drugs, such as materials for use in dermatology, analgesics, or any antihypertensive drugs that will ultimately be used in office practice, it is essential to have a period of clinical trial in which the drug is used under these conditions. This type of study has been designated as a Phase III investigation. Obviously, the use of the drug cannot be well controlled, and we must depend on the patient to follow instructions. One safeguard can be employed to ascertain whether the patient has taken all of the prescribed medicine: A small excess of tablets or capsules is placed in a bottle, and the patient is asked to bring the container of the medicine to the physician's office or clinic at the next visit. The number of tablets or capsules is carefully counted each time. If doses have been missed, too many tablets will be left. The patient is not to be aware that his cooperation is being checked each time.

In studies for effectiveness, especially when the only criterion is relief of symptoms, the double-blind technic is needed. In many instances this procedure can reduce bias. It should be noted, however, that despite our best effort, it is sometimes difficult to be sure that neither the patient nor the physician has been inadvertently made aware of when a placebo or when the active medicine is being used.

Considerable controversy has surrounded the use of the placebo. In our opinion, a great deal of useful information can be obtained if we use a positive control, rather than a blank. One technic is to provide the patients with two tablets or capsules for each dose. They need not be similar in appearance. One will be an active drug and the second will be a placebo. Thus, we can alternate between active drugs without the patient or physician's being aware of the

change. This technic makes it possible to compare two marketed preparations that are unlike in their appearance and still employ a double-blind technic.

It is advisable to have a lapse between the use of two active drugs and two placebo preparations. This procedure provides for a "washout period" of the drug effects.

We hope that if studies for drug evaluation are carefully designed and then conducted according to the plan with assurance of high quality of materials employed, perhaps the duration of the clinical trial may be shortened.

Large sums are being spent on drug evaluation. We are of the opinion that our most pressing problem is to increase the number of adequately trained clinical pharmacologists. When a greater number of these individuals becomes available, it will be possible to improve the efficiency of the industry in the drug-trial programs.

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STATEMENT OF ISSUES PRESENTED FOR REVIEW

DID THE DISTRICT COURT ERR IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON THE GROUND THAT THE PLAINTIFFS HAVE NO STANDING TO RECOVER WAGES FOR WORK PERFORMED AS CONVICTS WITHIN THE CONFINES OF A STATE PRISON?

The District Court answered "No."

The Appellants say "Yes."

The Appellees say "No."

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 71-1170

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS, RALPH R. WARNER, RONALD D. KENNEDY, PAUL ROSS, HERMAN HEAD, GERALD G. NORMAN, PAUL MILLER, THOMAS U. MULLIGAN, LONNIE PAYNE, ROBERT MASON, GAYLORD L. ESPICH and KENNETH R. MARSHALL,

Plaintiffs-Appellants

v.

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C.J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants-Appellees

APPEAL FROM THE DISTRICT COURT OF THE UNITED STATES

FOR THE EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

BRIEF FOR ATTORNEY GENERAL OF THE STATE OF MICHIGAN

INTRODUCTORY STATEMENT

This brief is filed by the Attorney General of the State of Michigan on behalf of the defendants who were added as parties by order of the district judge on November 18, 1969. In particular these defendants are the Department of Corrections of the State of Michigan, ten individuals who served as members of the Michigan Corrections Commission, and the Director of the Department of Corrections, all of whom acted in their official capacities as officers of the State of Michigan.

The appellants have raised five issues in their brief but the Attorney General will only address the fourth issue because it is believed that this issue is controlling and dispositive of the claim of the appellants and also because the other issues are adequately addressed by appellees Upjohn Company and Parke Davis & Company. The Attorney General therefore hereby adopts the arguments contained in the briefs of Upjohn Company and Parke Davis & Company.

FACTS RELEVANT TO THE ISSUES PRESENTED FOR REVIEW

Plaintiffs were duly convicted of crimes under the laws of the State of Michigan and were sentenced to serve prison terms in the State Prison of Southern Michigan at Jackson, Michigan. This institution, as well as other state prisons, is under the jurisdiction of the Michigan Department of Corrections. 1953 PA 232; MCLA 791.201 et seq. The commission is empowered by Section 3 of 1953 PA 232, to appoint a director of corrections who is qualified by training and experience in penology. The director is the chief administrative officer of the commission and is responsible to the commission for the exercise of powers and duties assigned to the commission by statute.

Section 1 of 1935 PA 210; MCLA 800.301, authorizes and empowers the state prison commission "to use, purchase, erect, equip and maintain buildings, machinery, boilers and equipment which may be necessary to provide for the employment of prison labor in the several state prisons or penal institutions of this state * * *."

Section 6 of 1935 PA 210, imposes a duty upon the prison commission to provide "as fully as practicable for the employment of prisoners confined in the prisons of this state in tasks consistent with the penal and reformatory purposes of their imprisonment and with the public economy * * *."

Prohibitions on the use of prison labor are imposed by Section 5 of 1935 PA 210 with certain exemptions from these prohibitions contained therein.

Effective April 5, 1968 the 1935 prison industries act was repealed and a new act known as the "correctional industries act" was passed. 1968 PA 15; MCLA 800.321 et seq. Section 4 of the new act continued the powers and duties of the state corrections commission to use, equip and maintain buildings, machinery, boilers and equipment which may be necessary to provide for the employment of inmate labor. Section 4 of 1968 PA 15; MCLA 800.324. The new act also contains provisions regulating the sale of products and labor of prison inmates. Section 6 thereof, in pertinent part provides:

> " * * * Nothing in this act shall be deemed to prohibit the sale at retail of articles made by inmates for the personal benefit of themselves or their dependents or the payment to inmates for personal services rendered in the penal institutions, subject to regulations approved by the corrections commission, * * *."

Section 7 of 1968 PA 15, supra, continuing the policy of the former prison industries act, provides that the corrections commission shall provide "as fully as practicable for the employment of inmates in tasks consistent with the penal and rehabilitative purposes of their imprisonment and with the public economy."

In November, 1963, the Michigan Department of Corrections entered into agreements with Upjohn Company and Parke Davis & Company pursuant to which these companies were permitted to construct a clinical research building within the confines of the state prison at Jackson, Michigan. Upon completion, these buildings became the property of the State of Michigan and the drug companies retained the right to use these structures for clinical research.

The clinical research conducted at Jackson Prison involves the testing of drug products for efficacy and potential harmful effects upon inmate-volunteers. These inmate-volunteers are not parties in this matter. The claims are brought by inmates who performed various services in connection with the operation of the clinics. These services include maintenance and minor repairs of the facility, preparation of food in the facility, and specific tasks connected with clinical tests. Assignments of inmates to the clinic are made by a classification committee which also makes every assignment of inmates to tasks performed within the prison by inmates, such as assignments to prison laundry, prison hospital and various prison industries conducted within the confines of the prison. Requests for particular inmates to perform services at the clinic are received by the classification committee or the director of treatment and, an independent determination is made by prison officials of whether to grant the request. Full power and authority to determine the hours to be worked by inmates on any assignment are retained by prison officials and an inmate is subject to call

at any time by institutional officials.

All inmates who perform services at the prison receive compensation and the compensation paid to those who are assigned to the clinics are paid amounts commensurate with those paid to other inmates. Pursuant to agreement, however, the drug companies reimburse the state for the amount paid to inmates who are assigned to work in the clinics.

ARGUMENT

THE PLAINTIFFS HAVE NO STANDING TO RECOVER STATUTORY MINIMUM OR QUANTUM MERUIT WAGES FOR WORK PERFORMED BY THEM AS CONVICTS WITHIN THE CONFINES OF A STATE PRISON.

Michigan statutes prior and subsequent to the enactment of the correctional industries act, 1968 PA 15, supra, and 1935 PA 210, supra, specifically provide for the employment of prison inmates in tasks consistent with the penal and rehabilitative purposes of their imprisonment. The requirement that prisoners perform labor while in confinement is recognized as justifiable, not only for the purpose of punishment, but as a means of enforcing prison discipline and of maintaining the health and well-being of the prisoners. 41 Am Jur, Prisons and Prisoners, § 27, p. 903. This is true even though their services may be uncompensated. As held in Opinion of Justices, 211 Mass 605, 98 NE 334, employment of the inmate serves to conserve his health, teach him a useful trade, and is in keeping with intelligent humanitarianism in the treatment of persons under sentence for violation of criminal law. It has also been said that such employment is justifiable as a means of defraying the expense of maintaining support and custody of the prisoner. Shenandoah Lime Co. v Governor, 115 Va 865, 80 SE 753.

As stated in 41 Am Jur, Prisons and Prisoners, § 27, p. 903:

> "The requirement of labor is regarded in many ways as a valuable addition to the forces of law and order. Its imposition is neither cruel nor unusual. It operates, when rightly regulated, as a mitigation rather than an aggravation of the punishment involved in imprisonment, and is not of itself disgraceful or degrading, but, on the contrary, is beneficial and humane."

Thus the willingness of the state to compensate inmates for services performed is a privilege which serves an additional humanitarian purpose of adding dignity and reward which, in turn, has its own rehabilitative effect. But the fact that such provisions are made by the state should not be used to elevate the relationship between state and prisoner to the status of employer-employee relationship. As pointed out in Huntley v Gunn Furniture Co., 79 F Supp 110 (1948), the labor of prison inmates belongs to the state and, as a result of their conviction of a crime, they have lost their right to liberty and the right to the fruits of their labor.

Although appellants argue that the imposition upon prison inmates of any requirement that they perform services constitutes a violation of their Thirteenth and Fourteenth Amendment rights, the Thirteenth Amendment clearly regards involuntary servitude as a punishment for a crime for which a person has been duly convicted as permissible. This amendment states:

> "Neither slavery nor involuntary servitude, except as a punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction." (emphasis added)

Appellants base their arguments on the theory that a prisoner is entitled to the fruits of his labor and, in support of this assumption, point to the provisions of Michigan statutes which limit the use of prison labor for certain purposes. The difficulty with this logic is that the limitation on the use of prison labor was enacted solely for the benefit of free labor which might suffer from any competition from the products or services performed by prison labor. That this is the purpose of the statutory limitation on the use of prison labor is clearly indicated by history of such provisions in this state. Thus in OAG 1941-42, No 21939, p 443, the Michigan Attorney General ruled that inmate barbers could not render services to officers of the institution at cut-rate prices because, he said, such services would be in competition with the established barber shops in the community.

It is therefore quite clear that the Michigan prison industries act was never enacted for the benefit of prison inmates and was never intended to give rise to a cause of action to recover either the reasonable value for their services or a minimum wage established by federal or state government. Rather, its purpose has been to protect free labor from potential competition by prison labor. Section 10 of 1935 PA 210 and Section 11 of 1968 PA 15. Both of these statutory provisions clearly indicate that the purpose of such statutes is to provide diversified and suitable employment for inmates without threatening the interests of free labor or

private industry. Discretion to determine activities which fulfill this legislative intent is vested in the department of corrections by Section 6 of 1968 PA 15, and the program established by the department of corrections and the drug companies is in fulfillment of these objectives. It must be emphasized that these work activities are carried on within the prison walls and that much of the activity consists in maintaining janitorial services, feeding prisoners and performing other kinds of work that are normally carried on within the confines of a prison. Thus there has been no deprivation of any constitutional or statutory right of any prisoner by virtue of the arrangement made between the department of corrections and the drug companies.

As pointed out by the district judge (Appendix for Plaintiffs-Appellants 217a & 218a) the uncontroverted statements contained in the affidavit of Warden Kropp demonstrate that the inmates performing services in the research clinics receive somewhat higher daily rates than other inmates, enjoy more freedom, have available better recreational facilities and at times better food than other inmates in the prison. Generally assignments to the clinics are treated by institutional authorities in the same manner as other work assignments.

Despite suggestions to the effect that the arrangement between the department of corrections and the drug companies may be in violation of Michigan law, this point is not conceded by the Attorney General. A fair interpretation of the statute would seem to allow the department of corrections to enter into an arrangement of this nature where it honestly believed that such an arrangement would provide prisoners with adequate, regular, diversified and suitable employment for prisoners of the state. These criteria are established by the legislature and by public policy and there is no doubt that the department acted in good faith and in the full belief that it was carrying out its statutory duties and responsibilities in establishing this program. In the footnote on page 42 of appellants' brief it is stated that "throughout all of the pleadings and the arguments in this case, never once have Defendants' counsel asserted that the arrangement is lawful under the applicable Michigan statutes." Yet this same footnote cites the case of Mink v Parke Davis Company, Mich Court of Appeals No. 2684, Nov. 21, 1966, Leave to appeal denied, 379 Mich 773 (1967); Cert Denied, 392 US 934 (1968), in which an inmate sought to have this arrangement declared illegal and the court of appeals discussed the action stating:

> "IT IS ORDERED that the complaint be, and the same is hereby DENIED for lack of meritorious grounds for the relief sought."

Appellees therefore do take the position that the arrangement does not violate applicable Michigan statutes.

CONCLUSION

In summary, it is clear that the State of Michigan has imposed upon the Michigan department of corrections and its director the duty of finding diversified and suitable employment for prisoners of the state consistent with proper penal purposes. In establishing such employment the department of corrections has agreed to permit the drug companies to engage in clinical research within the confines of the prison and has assigned inmates to perform services within the clinics. As a convicted prisoner is required to be employed and as the State of Michigan is entitled to the fruits of his work, the prisoners may not recover either the minimum wage established by federal fair labor standard acts or the Michigan minimum wage law for the value of their services nor are they entitled to the reasonable value of their services on a quantum meruit basis.

Respectfully submitted.

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Dated: June 11, 1971

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Law Review Commentaries

Solitary confinement of prisoners based on religious beliefs. 60 Mich.L. Rev. 643 (1962).

Library References

Prisons ⇐4. C.J.S. Prisons § 5.

800.292 Duty of keeper

Sec. 2. It shall be the duty of such keeper or other person in control, during the time fixed, in pursuance of the first section of this act, to give free access to any clergyman of any religious denomination, and to furnish such clergyman all reasonable facilities for interviews with the inmates named in the first section: Provided however, That the keeper or other persons, having the control of said prison or jail, almshouse, workhouse, house of correction, hospital or poorhouse shall first be satisfied that such clergymen are in good and regular standing in their profession, and are pastors of any church or religious congregation in this state.

Historical Note

Source:

P.A.1859, No. 185, § 2, Eff. May 18.
C.L.1871, § 8190.
How. § 9902.
C.L.1897, § 2154.
C.L.1915; § 1833.
C.L.1929, § 17659.

PRISON INDUSTRIES ACT

P.A.1935, No. 210, Eff. Sept. 21

AN ACT to provide for the employment of prison labor in the penal institutions of this state; to establish a state use system of prison industries; to define the powers and duties of the prison commission, the governor and other officers and employes in relation thereto, and to provide for the abolition of certain employe positions; to provide for the requisitioning and disbursement of prison products; to provide for the sale and/or purchase of certain prison equipment; to create a revolving fund and otherwise provide for the disposition of the proceeds of said industry; to provide for purchasing and accounting procedures; to prohibit the sale, exchange or other distribution of prison products made in or transported into this state, except as herein provided; to provide for the requisitioning and/or purchase and supply of prison products for use or consumption by certain institutions and departments; to provide penalties for violations of this act; and to repeal certain acts and parts of acts.

The People of the State of Michigan enact:

800.301 Prison industries; employment of state prison labor; materials and equipment; director of prison industry, appointment; assistants

Sec. 1. The state prison commission is hereby authorized and empowered to use, purchase, erect, equip and maintain buildings, machinery, boilers and equipment which may be necessary to provide for the employment of prison labor in the several state prisons or penal institutions of this state for the manufacture of goods, wares and merchandise, to purchase new material to be used in the manufacture of goods, wares and merchandise, and to dispose of such manufactured products in such manner as shall have been or may be otherwise provided by law; and is hereby authorized and empowered to continue to use and maintain the buildings, machinery, boilers and equipment and the manufacture of goods, wares and merchandise in the manner now in operation at the time of the effective date of this act. The commission is hereby authorized to appoint a director of prison industry and to employ such other agents and assistants as may be necessary to carry out the purpose of this act.

Historical Note

Source:

P.A.1935, No. 210, § 1, Eff. Sept. 21.

Cross References

State department of corrections, see § 791.201 et seq.

Library References

Convicts ⇐10(2). C.J.S. Convicts § 17.

Notes of Decisions

1. In general

Prison inmates who were assigned by prison officials to work in prison stamping plant upon parts and assemblies of shell casing which were furnished to war department by manufacturer which had contracted with the Michigan prison industries to pay prison industries a fixed sum per day for every inmate assigned to such work, were not "employees" of manufacturer within wage and hour provisions of Fair Labor Standards Act. Huntley v. Gunn Furniture Co. (D.C.1948) 79 F. Supp. 110.

It was a legal and constitutional provision that "no mechanical trade shall hereafter be taught to convicts in the state prison, except the making of those articles of which the chief supply for the consumption of the country is imported from other states or countries." The agent of the prison alone had power to decide what trades are within the prohibition, and the court refused to control his discretion by mandamus. People ex rel. Russell v. State Prison Inspectors (1856) 4 Mich. 187.

Reformatory barber shop may not render barber shop services to public in competition with established barber shops in that vicinity. Op.Atty.Gen. 1941–42, No. 21939, p. 443.

800.301a Short title

Sec. 1a. This act shall be known and may be cited as "The prison industries act."

Historical Note

Source:
P.A.1935, No. 210, § 1a, added by P.A.1943, No. 215, Imd. Eff. April 20, 1943.

800.302 Receipts credited to general fund; revolving fund

Sec. 2. All moneys in any state account prison industry fund at the time of the effective date of this act, and all moneys collected by the state from the sale or disposition of goods, wares and merchandise heretofore or hereafter manufactured by prison labor in accordance with the provisions of this act, shall be forthwith turned over to the treasurer of the state of Michigan to be credited to the general fund, and shall be paid out only as otherwise provided for by law: Provided, however, That out of said moneys on hand at the time of the effective date of this act, or out of the first moneys collected from the sale of such goods, wares and merchandise, there is hereby created a revolving fund of 500,000 dollars to be used solely for the purchase of manufacturing supplies, equipment, machinery and materials to be used in said industry, by or under the direction and approval of the state purchasing agent, or his successor. Such revolving fund shall be maintained at all times in the state treasury not in excess of 500,000 dollars and any proceeds from the sale or disposition of such goods, wares and merchandise in excess of said fund shall be paid out of the general fund of the state only as may be provided for by law.

Historical Note

Source:
P.A.1935, No. 210, § 2, Eff. Sept. 21.

Cross References

Revolving funds, see § 21.10.

Library References

Convicts ⇐13.

C.J.S. Convicts § 26.

Notes of Decisions

1. Revolving fund

Prison industries revolving fund is for working capital and may not be used to pay for building erected by Prison Commission even though Commission had authority to erect such building. Op.Atty.Gen.1935-36, No. 139, p. 343.

800.303 Bonds of officers or agents

Sec. 3. The state prison commission is hereby authorized and directed to require of such officers or agents of the commission as may have the possession and control of the moneys, machinery, materials, supplies and equipment herein referred to, a good and sufficient bond to the people of the state of Michigan in a penal sum not to exceed 50,000 dollars conditioned upon the faithful and prompt accounting for and paying over all moneys and other property which shall come into his possession in carrying out the provisions of this act.

Historical Note

Source:
P.A.1935, No. 210, § 3, Eff. Sept. 21.

800.304 Definitions

Sec. 4. The term "prison products," as used in this act, shall be construed to mean all goods, wares and merchandise manufactured, produced, or mined, wholly or in part, and either within or outside of this state, by convicts or prisoners, except convicts or prisoners on parole or probation, or in any penal and/or reformatory institution, except commodities manufactured in federal penal and correctional institutions for use by the federal government.

The term "prisons of this state" shall be construed to mean the state prison at Jackson, the branch state prison at Marquette and the state reformatory at Ionia.

The authority and duties herein vested in the prison commission or in the state purchasing agent or his successor shall be construed as subject in all respects to the control and supervision of the governor.

Historical Note

Source:
P.A.1935, No. 210, § 4, Eff. Sept. 21.

Library References

Convicts ⇨13.
C.J.S. Convicts § 26.

M.L.P. Convicts and Prisons § 3.

800.305 Unlawful sale of prison products; exceptions; prison labor on farms

Sec. 5. From and after 60 days after this act shall become law it shall be unlawful to sell or exchange or to offer for sale or exchange, or to purchase any prison products, except pure bred livestock raised on the several prison farms and sold for breeding pur-

poses, otherwise than for use or consumption in the penal, charitable and/or other custodial institutions of this state or for departments of this state, or political subdivisions thereof, or the federal government or agencies thereof, or otherwise as specifically provided in this act; nor shall the labor of prisoners be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction, maintenance or operation of public works, ways or property as directed by the governor; except that the prisoners of a county or of a city may be used on the public works, ways or property of said county or city as directed by the constituted authority thereof: Provided, That nothing in this act shall be deemed to prohibit the sale at retail, of articles made by prisoners for the personal benefit of themselves or their dependents, or the payment to prisoners for personal services rendered in the penal institution, subject to regulations approved by the prison commission, or the manufacture, sale or purchase of binder twine, rope and cordage used in agricultural production, or to the use of prison labor upon agricultural land which has been rented or leased by the department of corrections upon a share cropping or other basis: Provided, That in no case shall any prison products be sold or offered for sale at a price below cost of production which cost of production shall include materials, labor, supervision, distribution and selling, heat, light, power and all other expenses connected therewith. As amended P.A.1956, No. 42, § 1, Imd. Eff. March 28.

Historical Note

Source:

P.A.1935, No. 210, § 5, Eff. Sept. 21.
P.A.1937, No. 95, Imd. Eff. June 21.
P.A.1937, No. 299, Imd. Eff. July 23.
P.A.1943, No. 215, Imd. Eff. April 20.
P.A.1945, No. 107, Imd. Eff. April 19.

Authority for use of prison labor on certain agricultural land was added in 1956.

Library References

Convicts ⇐13.
C.J.S. Convicts § 26.

M.L.P. Convicts and Prisons § 3.

Notes of Decisions

1. Construction and application

The words "cost of production", in prohibition against sale of prison products at a price below cost of production, do not include the items of food, clothing and maintenance of inmates of prison. Op.Atty.Gen.1947–48, No. 481, p. 376.

Reformatory barber shop may not render barber shop services to public in competition with established barber shops in that vicinity. Op.Atty.Gen. 1941–42, No. 21939, p. 443.

2. Sale of prison products

Prison products may not be sold to foreign purchasers either public or private. Op.Atty.Gen.1949-50, No. 958a, p. 224; Op.Atty.Gen.1949–50, No. 958, p. 211.

It is unlawful to sell, except as permitted by the Prison Industries Act (section 800.301 et seq.) prison products produced in penal institutions of Michigan to agencies of other states. Op.Atty.Gen.1955–56, No. 2846, p. 788.

Provision for sale of prison goods to federal government or agencies thereof would warrant the sales to private corporations under contract with the federal government in matters relating to "the war effort". Op.Atty.Gen. 1947–48, No. 481, p. 376.

Prison products may not be sold to Michigan municipal league as jobber for resale to Michigan municipalities. Op. Atty.Gen. 1947–48, No. O–5314, p. 133.

Under Prison Industries Act (sections 800.301 et seq.) goods may not be sold to sectarian or private organizations regardless of charitable or nonprofit character. Op.Atty.Gen. 1945–46, No. O–4517, p. 653.

Highways signs manufactured in prison shop are prison products and sale thereof to County Road Commission [prior to 1937 amendment of G.A.1935, No. 210, § 5] was forbidden. Op.Atty. Gen. 1935–36, No. 142, p. 346.

Agricultural products produced with prison labor on prison farms, including livestock raised thereon, are prison products and may not be sold on the open market. Op.Atty.Gen. 1935–36, No. 140, p. 344.

3. Employment of prisoners

Sharecropping contracts for use of prison labor are unlawful in absence of legislative authority therefor. Op.Atty. Gen. 1947–48, No. 659, p. 533.

Under P.A.1935, No. 210, § 5 (now this section) which related to unlawful sales of prison products or labor it was unlawful for a private party to employ prison labor for personal and private purposes and it was unlawful for prison industries to purchase raw materials and equipment for resale to employees, private individuals and corporations. Op.Atty.Gen. 1947–48, No. 481, p. 376.

Department of corrections was not authorized to permit or allow inmates of state prisons to work for privately supported non-profit institutions. Op. Atty.Gen., 1943–44, No. O–870, p. 421.

Prison labor may not be sold, hired, leased, loaned or used unless the use made thereof is on a public work, way or property and unless such use is directed by the governor. Op.Atty.Gen. 1941–42, No. 22908, p. 544.

800.306 Types and priority of employment of prison labor

Sec. 6. It shall be the duty of the prison commission to provide as fully as practicable for the employment of prisoners confined in the prisons of this state in tasks consistent with the penal and reformatory purposes of their imprisonment and with the public economy and of the types and approximately in the order of priority as follows:

1. Routine, maintenance and constructive activities contributing to the conduct of the several prisons in a manner most favorable to their penal and reformatory purposes and to the minimum costs to the state therefor.

2. Educational and/or rehabilitation activities, whether formal or through productive or socialized activities, determined on the basis of individual needs and educability.

3. Labor assignments on state public works, ways or properties when and as requisitioned by the governor or on county, township or district roads when requested by the commissioners thereof in accordance with section 800.102 of the Compiled Laws of 1948.

4. Productive or maintenance labor on or in connection with the prison farms, or other agricultural land rented or leased by the de-

partment of corrections upon a share cropping or other basis, factories, shops or other available facilities for the production and supply of foods, clothing and/or other supplies, materials or equipment properly required for the maintenance and operation of or for consumption in the prisons of the state or for distribution for other state purposes, or the manufacture, sale or purchase of binder twine, rope and cordage used in agricultural production, through the state purchasing agent or his successor, as provided in this act. As amended P.A.1956, No. 42, § 1, Imd. Eff. March 28.

Historical Note

Source:

P.A.1935, No. 210, § 6, Eff. Sept. 21.

In 1956, in subsec. 3, a reference to C.L.1948 replaced an earlier reference to C.L.1929; and in subsec. 4, the reference to agricultural land was inserted.

Library References

Convicts ⇐10(3)

C.J.S. Convicts § 16.

Notes of Decisions

1. Authority to regulate

Labor of inmates of state prison belong to the state and they can be lawfully employed only by the state. Huntley v. Gunn Furniture Co. (D.C. 1948) 79 F.Supp. 110.

Sharecropping contracts for use of prison labor are unlawful in absence of legislative authority therefor. Op.Atty. Gen. 1947–48, No. 659, p. 533.

800.307 Requisition, production and distribution of prison products for state purposes; duty of state purchasing agent

Sec. 7. Requisition, production and distribution of prison products for state purposes. It shall be the duty of the state purchasing agent, or his successor, to prepare annually in advance an itemized estimate of the supplies, materials and equipment required for proper use and consumption in the penal, charitable and/or other custodial institutions and for the departments of state government for which he may be the legally designated or the delegated purchasing authority; and he shall have the authority to require of the superintendent, warden or other official in control of each of said institutions and departments such reports and/or requisitions as may be necessary for the purposes of such estimate; and it shall be the duty of the state purchasing agent, or his successor, to make requisition upon the prison commission, subject to the approval and acceptance of said commission, for all of said estimated supplies, materials and equipment insofar as it shall be deemed practicable to produce or manufacture same with the available prisoner labor and equipment of the prisons of this state; and it shall be the duty of the prison commission to provide for and to require the production, manufacture, supply and delivery of said

requisitioned supplies, materials and equipment to the fullest extent consistent with the regular and suitable employment of the prisoner labor and of the equipment and facilities available in the prisons of this state. The state purchasing agent, or his successor, shall prescribe specifications, standards, quality tests, methods and conditions of packaging and conditions and times of deliveries, and shall have authority to inspect, accept or reject said requisitioned prison products to the same extent as if the same were purchased from other sources.

Historical Note

Source:

P.A.1935, No. 210, § 7, Eff. Sept. 21.

Library References

Convicts ⇨13. C.J.S. Convicts § 26.

Notes of Decisions

1. In general

Contracts for the purchase of sand and highway signs made by the highway department, and with which the department of administration had nothing to do with were void, and approval by the administrative board did not give them life. Op.Atty.Gen. 1949–50, No. 1037, p. 308.

800.308 Contracts for additional supplies; exchange with other states; printing exemption

Sec. 8. (a) After provision has been made for the employment of prisoners as fully as practicable as provided for in sections 6 and 7 of this act,[1] and in case it shall appear that further means of prisoner employment may be necessary to prevent idleness, the prison commission may make contracts with the proper purchasing authorities to supply to penal, charitable or other custodial institutions or departments of this state additional prison products of the kinds produced and delivered under the provisions of section 7 of this act[2]: Provided, That all such contracts shall be made in advance of actual production or manufacture and that no unrequisitioned surplus shall be produced or sold under the provisions of this section. Such contracts shall make proper provision for payment to the state by the purchaser for said prison products at prices to be fixed by the prison commission which prices shall be sufficient to reimburse the state for the costs of production and shall be uniform and non-discriminating; and the proceeds of the sale of such prison products under such contracts aforesaid shall be disbursed by the prison commission for prison purposes after or for the purpose of defraying the production costs thereof. No such contract for the sale of prison products shall subject the state or any department or institution thereof to any claim for damages or indemnification for non-delivery or for non-fulfillment of contract nor shall any such claim be valid, but the right of the purchaser to accept

or to reject for sufficient cause the products contracted for is not hereby abrogated.

(b) In the further accomplishment of the purposes of this section as aforesaid, and so far as applicable under the same conditions and methods of procedure provided in subsection (a) hereof, the state purchasing agent, or his successor, may make further requisition for additional prison products from the prisons of this state and exchange same for the prison products of prisons of counties or cities of this state or of the prisons of other states: Provided, Said prison products from prisons other than those of this state or equivalent substitutes therefor, cannot be produced in the prisons of this state with the equipment available: And provided, Said products shall be required for and distributed to the institutions or departments of this state as provided for in section 4 of this act [3] in the same manner as the products of the prisons of this state. In the construction of this act nothing herein contained shall allow printing to be done for counties or political subdivisions of the state.

[1] Sections 800.306, 800.307.
[2] Section 800.307.
[3] Section 800.304.

Historical Note

Source:

P.A.1935, No. 210, § 8, Eff. Sept. 21.
P.A.1937, No. 95, Imd. Eff. June 21.

Cross References

Penalties, see § 800.315.
Requisition production and distribution of prison products for state use, see § 800.319.
State department of corrections, see § 791.201 et seq.

Library References

Convicts ⇐10(1). C.J.S. Convicts § 16.

Notes of Decisions

Construction and application 1
Sale of prison products 2

1. Construction and application

Prison Commission may employ psychiatrists and pay for them from funds available under P.A.1935, No. 210 §§ 8, 13 (now sections 800.308, 800.313). Op.Atty.Gen., 1935–36, No. 140, p. 344.

2. Sale of prison products

Prison products may not be sold to Michigan municipal league as jobber for resale to Michigan municipalities. Op. Atty.Gen., 1947–48, No. O–5314, p. 133.

800.309 Local penal institutions; disposal of prison products

Sec. 9. It shall be lawful for a penal institution now maintained by a political subdivision of this state to sell or otherwise dispose of its

prison products to the institutions or departments of the county or political subdivision in which said penal institution is located. The provisions of sections 7 and 8 of this act [1] shall not apply to such penal institutions of such a political subdivision. None of the provisions of this act shall apply to the Detroit house of correction.

[1] Sections 800.307, 800.308.

Historical Note

Source:
P.A.1935, No. 210, § 9, Eff. Sept. 21.

Library References

Convicts ⇐13. C.J.S. Convicts § 26.

800.310 Intent of act

Sec. 10. It is hereby declared to be the intent of this act:

(a) to provide adequate, regular, diversified and suitable employment for prisoners of the state consistent with proper penal purposes;

(b) to utilize the labor of prisoners exclusively for self-maintenance and for reimbursing the state for expenses incurred by reason of their crimes and imprisonment;

(c) to eliminate all competitive relationships between prisoner labor or prison products and free labor or private industry;

(d) to effect the requisitioning and disbursement of prisoner labor and prison products directly through established state authorities with no possibility of private profits therefrom and with the minimum of intermediating financial considerations, appropriations or expenditures; and to these ends

The governor shall require the state purchasing agent, or his successor, to establish suitable methods of purchasing and of accounting which shall provide as may be necessary or advisable

(e) for the purchasing and supply on account of the consuming institutions and/or departments, separately or collectively, of supplies and materials necessary for the prison manufacture or production of the prison products requisitioned therefor in accordance with sections 4, 5 and 6 of this act.[1]

(f) for crediting prison accounts and debiting accounts of consuming institutions or departments for products requisitioned and disbursed, at prices fixed to indicate fairly the true costs of maintenance and efficiency of management of said prisons, institutions and departments: Provided, That said prices or the requisitioning or disbursement of said prison products shall in no case be determined by or contingent upon competitive bidding from other sources;

(g) for the purchase of all commodities or requirements other than prison products as provided for in this act, by competitive bidding or

other methods established by law or approved practice: Provided, That no bids may be asked or received except for commodity requirements which it has been definitely decided shall not be supplied by requisitioning of prison products as hereinbefore provided.

[1] Sections 800.304–800.306.

Historical Note

Source:

P.A.1935, No. 210, § 10, Eff. Sept. 21.

Cross References

State revenue, disposition and accounting, see § 21.10.
Statistical details relating to labor in penal institutions, collection and compilation, see § 408.52.
Supervisor of industrial plants, see § 791.271.

Library References

Convicts ⇨8. C.J.S. Convicts § 13.

Notes of Decisions

1. Sale of prison products

Prison products may not be sold to Michigan municipal league as jobber for resale to Michigan municipalities. Op. Atty.Gen. 1947–48, No. O–5314, p. 133.

Under Prison Industries Act, goods may not be sold to sectarian or private organizations regardless of charitable or nonprofit character. Op.Atty.Gen. 1945–46, No. O–4517, p. 653.

800.311 Schedule of payments or allowances to prisoners

Sec. 11. The prison commission may adopt a schedule of payments or allowances to prisoners or to their dependents from such funds as may be provided therefor, but such payments shall be made on the basis of need or of motivation of or reward for industry or behavior and shall not be related to profits to the state from the activities to which said prisoners may be assigned.

Historical Note

Source:

P.A.1935, No. 210, § 11, Eff. Sept. 21.

800.312 Abolition of positions or offices of prison industries inconsistent with this act

Sec. 12. All positions or offices heretofore created or established for the sale or distribution of prison products or for the conduct of prison industries which may be inconsistent with the operation of this act, shall be abolished within 30 days after this act shall have become law.

Historical Note

Source:

P.A.1935, No. 210, § 12, Eff. Sept. 21.

800.313 Equipment; sale, price, terms, conditions

Sec. 13. The prison commission is hereby empowered to sell such of the present equipment of the prisons as cannot be utilized under the provisions of this act and to determine the prices, terms and conditions of such sale in the best interests of the state: Provided, That so far as practicable such sales shall be the means of establishing, extending or encouraging private or cooperative industry in this state; and the said prison commission is empowered to expend the proceeds of such sales, as may be deemed wise or necessary, in the provision of such other equipment or facilities as shall be required for making effective to the fullest possible extent the purposes and provisions of this act.

Historical Note

Source:

P.A.1935, No. 210, § 13, Eff. Sept. 21.

Notes of Decisions

1. Construction and application

Prison Commission may employ psychiatrists and pay for them from funds available under P.A.1935, No. 210, §§ 8, 13 (now sections 800.308, 800.313). Op.Atty.Gen. 1935–36, No. 140, p. 344.

800.314 Violations

Sec. 14. Wilful violation of any of the provisions of this act by an officer of the state or of any political subdivision thereof, or by any officer of any institution of either, shall be sufficient cause for removal from office; and such officer shall also be subject to prosecution as hereinafter provided.

Historical Note

Source:

P.A.1935, No. 210, § 14, Eff. Sept. 21.

800.315 Penalty

Sec. 15. Any person, firm or corporation who shall wilfully violate any of the provisions of this act, shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than 100 dollars nor more than 500 dollars, or by imprisonment in the county jail for a period of not more than 90 days, or by both fine and imprisonment, at the discretion of the court.

Historical Note

Source:

P.A.1935, No. 210, § 15, Eff. Sept. 21.

Cross References

Misdemeanor, see §§ 750.8, 750.9.

Secs. 16, 17, P.A.1935, No. 210

These sections, a repealer and a severability clause, were repealed by P.A. 1945, No. 267, Imd. Eff. May 25. Section 16 repealed the following:

P.A.1909, No. 140 (C.L.1929, §§ 17608–17613).
P.A.1911, No. 150 (C.L.1929, §§ 17614–17623).
P.A.1911, No. 151 (C.L.1929, §§ 17624–17631).
P.A.1917, No. 202 (C.L.1929, §§ 17632–17636).
P.A.1921, No. 343 (C.L.1929, § 17644).
P.A.1907, No. 291 (C.L.1929, § 17645).

800.318 Provisions in conflict with national prison labor authority void

Sec. 18. Any provision contained in this act which is in conflict with the rules and regulations of the national prison labor authority is hereby declared void.

Historical Note

Source:

P.A.1935, No. 210, § 18, Eff. Sept. 21.

800.319 Requisition, production and distribution of prison products for state use; state administrative board, duties

Sec. 19. Requisition, production and distribution of prison products for state use. It shall be the duty of the state administrative board to prepare annually in advance an itemized estimate of the articles and materials required for proper use by the institutions, departments and offices of the state which may be produced by prison industry; and the state administrative board shall have the authority to require of each of said institutions, departments and offices such reports as may be necessary for the purposes of such estimate. It shall be the duty of the state administrative board to issue purchase orders to the prison commission for all of said estimated articles and materials insofar as the prison commission shall deem it practicable to produce same with prison labor; and it shall be the duty of the prison commission to fulfill such purchase orders as requisitioned in strict conformity with the specifications upon which they are based. After consultation with the prison commission and the officials in control of said institutions, departments or offices of the state, the state purchasing agency shall prescribe the specifications for prison products, and shall have authority to inspect, accept or reject said prison products to the same extent as if the same were purchased from other sources.

Historical Note

Source:

P.A.1935, No. 210, § 19, Eff. Sept. 21.

Library References

Convicts ⇐13.

C.J.S. Convicts § 26.

PRISON INDUSTRIES ACT

800.301 to 800.319 Repealed. P.A.1968, No. 15, § 15, Imd. Eff. April 5, 1968

TABLE

Showing where the subject matter of sections repealed by P.A.1968, No. 15, § 15 is covered by new sections.

Repealed Section	New Section
800.301	800.324
800.301a	800.321
800.302	800.325
800.303	———
800.304	800.322
800.305	800.326
800.306	800.324, 800.327
	800.327
800.307	800.328, 800.329
800.308	———
800.309	800.330
800.310	800.331
800.311	800.332
800.312	———
800.313	———
800.314	800.333
800.315	800.334
800.316	———
800.317	———
800.318	———
800.319	800.327

CORRECTIONAL INDUSTRIES ACT [NEW]

Library References

Convicts ⊂=7. C.J.S. Convicts § 13.

P.A.1968, No. 15, Imd. Eff. April 5

AN ACT to provide for the employment of inmate labor in the correctional institutions of this state; to define the powers and duties of the corrections commission, the governor and other officers and employees in relation thereto; to provide for the requisitioning and disbursement of correctional industries products; to provide for the disposition of the proceeds of the industries; to provide for purchasing and accounting procedures; to regulate the sale or disposition of inmate labor and products; to provide for the requisitioning and purchases and supply of correctional industries products for use or consumption by certain institutions and departments; to provide penalties for violations of this act; and to repeal acts and certain parts of acts.

The People of the State of Michigan enact:

800.321 Short title

Sec. 1. This act shall be known and may be cited as the "correctional industries act".

P.A.1968, No. 15, § 1, Imd. Eff. April 5.

The subject matter of this act was formerly covered by sections 800.301 to 800.319.

800.322 Definitions

Sec. 2. The term "correctional institution products" as used in this act, means all services provided, goods, wares and merchandise manufactured or produced, wholly or in part, by inmates in any state correctional institution.

P.A.1968, No. 15, § 2, Imd. Eff. April 5.

800.323 Corrections commission

Sec. 3. The authority and duties herein are vested in the corrections commission.

P.A.1968, No. 15, § 3, Imd. Eff. April 5.

Deletions from text indicated by asterisks * * *

800.324 Power and duties of commission

Sec. 4. The state corrections commission may:

(a) Use, equip and maintain buildings, machinery, boilers and equipment which may be necessary to provide for the employment of inmate labor in the state correctional institutions for the manufacture of goods, wares and merchandise and the operation of services.

(b) Purchase new material to be used in the manufacture of goods, wares, merchandise and operation of services.

(c) Dispose of such manufactured products or to provide services in such manner as provided by law.

(d) Continue to use and maintain the buildings, machinery, boilers and equipment in the manufacture of goods, wares and merchandise in the manner now in the operation at the time of the effective date of this act and use such facilities in the operation of service programs.

(e) To employ such agents and assistants as may be necessary to carry out the purposes of this act.

P.A.1968, No. 15, § 4, Imd. Eff. April 5.

Library References

Prisons ⇐12. C.J.S. Prisons § 17.

800.325 Proceeds from inmates' labor; revolving fund; disbursements

Sec. 5. All moneys collected from the sale or disposition of goods, wares and merchandise manufactured by inmate labor, or received for services provided by inmate labor in the correctional institutions in accordance with the provisions of this act, shall be turned over to the state treasurer and credited to the correctional industries revolving fund, and shall be paid out only for inmate wages, contractual services, supplies, materials and equipment representing direct and indirect costs of carrying out the purpose of this act and to comply with the provisions of Act No. 250 of the Public Acts of 1941, being sections 21.121 to 21.130 of the Compiled Laws of 1948, or as otherwise provided by law.

P.A.1968, No. 15, § 5, Imd. Eff. April 5.

800.326 Regulation of sale of products and labor

Sec. 6. No correctional institution products, except purebred livestock raised on the several institutional farms and sold for breeding purposes, shall be sold, exchanged, offered for sale or exchange, or purchased other than for use or consumption in the penal, charitable or other custodial institutions of this state or political subdivision thereof, or the federal government or agencies thereof, or otherwise as specifically provided in this act. The labor of inmates shall not be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any purpose other than the construction, maintenance or operation of public works, ways or property as directed by the governor. Nothing in this act shall be deemed to prohibit the sale at retail of articles made by inmates for the personal benefit of themselves or their dependents or the payment to inmates for personal services rendered in the penal institutions, subject to regulations approved by the corrections commission, or the use of inmate labor upon agricultural land which has been rented or leased by the department of corrections upon a sharecropping or other basis.

P.A.1968, No. 15, § 6, Imd. Eff. April 5.

Library References

Convicts ⇐13. C.J.S. Convicts § 26.

800.327 Types of employment; priority

Sec. 7. The corrections commission shall provide as fully as practicable for the employment of inmates in tasks consistent with the penal and rehabilitative purposes of their imprisonment and with the public economy. The types of employment in the order of their priority shall be as follows:

(a) Routine, maintenance and constructive activities contributing to the conduct of the several institutions in a manner most favorable to their correctional and rehabilitative purposes and to the minimum costs to the state.

(b) Educational and rehabilitation activities, whether formal or through productive or socialized activities, determined on the basis of individual needs and educability.

(c) Productive or maintenance labor on or in connection with the institution farms, or other land rented or leased by the department of corrections on a sharecropping or other basis, factories, shops or other available facilities for the production and supply of foods, clothing and other supplies, materials or equipment, and the performance of services properly required for the maintenance and operation of or for consumption in the correctional institutions of the state or which may be made available upon request to other federal, state or local units of government. Correctional industries may produce such items and may maintain an inventory compatible with sales volume and good business practice.

(d) Labor assignments on state public works, ways or properties when and as requisitioned by the governor or on county, township or district roads when requested by the commissioners thereof in accordance with section 1 of Act No. 181 of the Public Acts of 1911, being section 800.101 of the Compiled Laws of 1948.

P.A.1968, No. 15, § 7, Imd. Eff. April 5.

800.328 Conditions and inspection of packaging and delivery of products

Sec. 8. The director of the department of administration shall prescribe specifications, standards, quality tests, methods and conditions of packaging and conditions and times of delivery, and may inspect, accept or reject correctional institution products to the same extent as if they were purchased from other sources.

P.A.1968, No. 15, § 8, Imd. Eff. April 5.

Library References

Convicts ⇐13. C.J.S. Convicts § 26.

800.329 Purchase and resale of goods by corrections commission; purpose

Sec. 9. The corrections commission, with the specific approval of the director of the department of administration, may purchase finished goods, materials or equipment of the same type as ordinarily produced by correctional industries. The commission may then sell such items to those governmental entities for whom production by correctional industries is permitted by this act. The purpose of this section is to provide for the completing of orders when production is not sufficient or for other reasons of economy and good business practice which may make such purchases beneficial to the state.

P.A.1968, No. 15, § 9, Imd. Eff. April 5.

Library References

Convicts ⇐13. C.J.S. Convicts § 26.

800.330 Correctional institutions maintained by a political subdivision; application of act

Sec. 10. A correctional institution now maintained by a political subdivision of this state may sell or otherwise dispose of its correctional institution products to the institutions or departments of the county or political subdivision in which the institution is located. The provisions of sections 8 and 9[1] shall not apply to a correctional institution of a political subdivision. None of the provisions of this act shall apply to the Detroit house of correction.

P.A.1968, No. 15, § 10, Imd. Eff. April 5.

[1] Sections 800.328, 800.329.

Library References

Convicts ⇐13. C.J.S. Convicts § 26.

800.331 Purpose and intent of act

Sec. 11. It is the intent of this act:

(a) To provide adequate, regular, diversified and suitable employment for inmates of the state consistent with proper penal purposes.

(b) To utilize the labor of inmates exclusively for self-maintenance and for reimbursing the state for expenses incurred by reason of their crimes and imprisonment.

(c) To eliminate all competitive relationships between inmate labor or correctional industries products and free labor or private industry.

(d) To effect the requisitioning and disbursement of inmate labor and correctional industries products directly through established state authorities with no possibility of private profits therefrom and with the minimum of intermediating financial considerations, appropriations or expenditures, and to these ends the governor shall require the director of the department of administration to establish suitable methods of purchasing and of accounting which shall provide as may be necessary or advisable:

(i) for the purchasing and supply of supplies and materials necessary for the institutional manufacture or production of the correctional industries products in accordance with sections 2, 6 and 7.[1]

(ii) for crediting corrections industries accounts and debiting accounts of consuming institutions or departments for products requisitioned and disbursed, at prices fixed as nearly as practicable to recapture direct and indirect costs exclusive of supervisory costs and to indicate fairly the true costs of maintenance and efficiency of the management of correctional institutions, provided that the prices or the requisitioning or disbursement of correctional industries products shall in no case be determined by or contingent upon competitive bidding from other sources.

(iii) for the purchase of all commodities or requirements other than correctional industries products as provided in this act, by competitive bidding or other methods established by law or approved practice, but no bids may be asked or received except for commodity requirements which it has been definitely decided shall not be supplied by requisitioning of correctional industries products as provided in this act.

P.A.1968, No. 15, § 11, Imd. Eff. April 5.

[1] Sections 800.322, 800.326, 800.327.

800.332 Adoption of schedule of payments or allowances; basis

Sec. 12. The corrections commission may adopt a schedule of payments or allowances to inmates or to their dependents from such funds as may be provided therefor, but such payments shall be made on the basis of need or of motivation or of reward for industry or behavior and shall not be related to profits to the state from the activities to which the prisoners may be assigned.

P.A.1968, No. 15, § 12, Imd. Eff. April 5.

800.333 Violations and penalties; public officer

Sec. 13. Wilful violations of any of the provisions of this act by an officer of the state or of any political subdivision thereof, or by any officer of any institution of either, shall be sufficient cause for removal from office, and subject such officer to prosecution as provided in section 14.[1]

P.A.1968, No. 15, § 13, Imd. Eff. April 5.

[1] Section 800.334.

Library References

States ⊂=52. C.J.S. States §§ 49, 79, 95.

800.334 Violations and penalties; person, firm or corporation

Sec. 14. Any person, firm or corporation who wilfully violates any of the provisions of this act is guilty of a misdemeanor.

P.A.1968, No. 15, § 14, Imd. Eff. April 5.

800.335 Repeal of Prison Industries Act

Sec. 15. Act No. 210 of the Public Acts of 1935, as amended, being sections 800.301 to 800.319 of the Compiled Laws of 1948, is repealed.
P.A.1968, No. 15, § 15, Imd. Eff. April 5.

CHAPTER 801

CORRECTIONS—JAILS AND WORKHOUSES

COUNTY JAILS, AND THE REGULATION THEREOF

COUNTY JAILS, AND THE REGULATION THEREOF

801.4a Municipal ordinance violations, county jail charges and expenses, payment

Sec. 4a. All charges and expenses of safekeeping and maintaining persons in the county jail charged with violations of city, village or township ordinances shall be paid from the county treasury if a district court of the first or second class has jurisdiction of the offense.
R.S.1846, c. 171, § 4a, added by P.A.1969, No. 274, § 1, eff. Sept. 1, 1969

P.A.1969, No. 274, § 2 provided that the Act should take effect September 1, 1969. It was ordered to take immediate effect and was approved August 11, 1969.

CHAPTER 802

CORRECTIONS—HOUSES OF CORRECTION

DETROIT HOUSE OF CORRECTION

DETROIT HOUSE OF CORRECTION

P.A.1961, No. 104

AN ACT to establish the Detroit house of correction and authorize the confinement of convicted persons and persons awaiting trial or sentence.
Amended by P.A.1970, No. 183, § 1, Imd. Eff. Aug. 3.

802.8a Agreement between county and city of Detroit, custody of persons awaiting trial or sentence; expenses, payment

Sec. 8a. The board of county commissioners of any county having a population of 500,000 or more may enter into an agreement with the common council of the city of Detroit, or with any authorized agent or officer on behalf of the city and the common council of the city of Detroit or any authorized agent or officer of the city so authorized shall have the authority to enter into an agreement with a county whereby the Detroit house of correction is authorized to receive and keep in custody any person detained in custody and awaiting trial or sentence pursuant to court order. The agreement shall provide that the county shall pay all reasonable expenses incurred by the city for such custodial incarceration.
P.A.1961, No. 104, § 8a, added by P.A.1970, No. 183, § 1, Imd. Eff. Aug. 3.

Deletions from text indicated by asterisks * * *

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UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

NO. 71-1170

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Plaintiffs-Appellants,

v.

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C. J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants-Appellees.

APPEAL FROM THE DISTRICT COURT OF THE UNITED STATES FOR THE EASTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

BRIEF FOR DEFENDANTS-APPELLEES, PARKE DAVIS & COMPANY AND THE UPJOHN COMPANY

COUNTERSTATEMENT OF ISSUES PRESENTED

I Was the District Court correct in ruling that Counts II, III and IV of Plaintiff inmates' Complaint are not maintainable as a Class Action under Rule 23, Fed.R.Civ.P.?

II Was the District Court correct in granting Defendants' Motion for Summary Judgment on Count I because uncontroverted facts established that the inmates were not "employees" of Defendant drug companies within the meaning of the Fair Labor Standards Act?

III Was the District Court correct in granting Defendants' Motion for Summary Judgment on Count II because the uncontroverted facts established that inmates were not "employees" of Defendant drug companies within the meaning of the Michigan Minimum Wage Law of 1964?

IV Was the District Court correct in granting Defendants' Motion for Summary Judgment on Count III because under the uncontroverted facts, lawfully confined prison inmates in Michigan do not own their own labor and do not have a private cause of action for damages by reason of their work assignment to research clinics located within the prison walls, allegedly in violation of a Michigan

statute designed to protect free labor from competition by prison labor?

V Was the District Court correct in granting Defendants' Motion for Summary Judgment as to Count IV because, even assuming that the utilization of inmates' labor was contrary to Michigan law, they suffered no denial of any rights protected by the United States Constitution?

COUNTERSTATEMENT OF THE CASE

For purposes of this appeal only, Defendants-Appellees, Parke Davis & Company and The Upjohn Company, (hereafter Parke Davis and Upjohn, or, simply, "Defendants") accept Plaintiff inmates' Statement of the Case set forth in their Brief. In addition, however, the following uncontroverted facts are relevant to the issues presented for review.

The research conducted at the clinics consist of very carefully planned and supervised testing of drugs, as required by the Federal Drug Administration. Only inmates who volunteer and who are in excellent physical condition are accepted for the test programs. These inmate volunteers have no complaints and are not part of the lawsuit.

The test programs are developed and monitored by highly experienced medical and scientific personnel of the drug companies. The tests are actually run under the supervision of technical personnel of the drug companies who work at the clinics in Jackson Prison. The Michigan Prison Commission has assigned prison inmates to work at the research clinics to perform various tasks ranging from common labor (e.g., janitorial tasks) to semi-technical work (e.g., clerical tasks, operating EEG machine) (App. to Plaintiffs-Appellants' Brief 25a, 36a (hereafter "App.")). See Business Week, June 27, 1964, pp. 58 et seq. (copy attached). All the Plaintiffs are members

of this latter group. In this law suit they seek compensation in addition to the pay credited to their respective accounts by the Michigan Prison Commission.

The imprisonment and detention of all inmates involved in this proceeding was legal. (Brief for Plaintiffs-Appellants (hereafter "Plaintiffs' Brief") p.41.) The research facilities operated by Parke Davis and Upjohn are located within the walls of Jackson Prison (App. 60a) and generally provide conditions superior to other prison assignments because the facilities are relatively new. Inmates on clinic assignment enjoy special recreation facilities, at times better food, more freedom and more contact with non-prison personnel than inmates on most other prison assignments. (App. 112a) Assignment to the clinics, therefore has been regarded by the inmates to be highly desirable -- in fact, inmates frequently requested to be assigned to work at the research clinics. (App. 112a) On the other hand, many of the specific classifications in the clinics have been considered valuable, educational and rehabilatative opportunities by the State Corrections Commission. (App. 112a)

Daily rates for assignment to the research facilities, which were paid by the Corrections Commission into the respective inmates' accounts, were established by the Corrections Commission and are somewhat higher than rates for comparable work on other prison assignments. (App.111a-12a)

The actual assignment of each and every inmate to their respective tasks within Jackson Prison is made by the Prison Director of Treatment, acting with the assistance of the Classification Committee. (App. 109a) Requests for certain named inmates have been made by Parke Davis and Upjohn; some were granted by the prison authorities and some were denied. (App. 109a, 123a-24a) Conversely, certain inmates have been assigned to the research clinics without the prior knowledge or approval of the clinic administrators (App. 110a, 124a), while others have been removed without their prior knowledge or approval. (App. 29a, 42a, 111a, 125a) Indeed, certain inmates have been assigned to research facility tasks and others have been removed against the express wishes of the clinic administrators. (App. 124a-25a)

Once an inmate had been assigned to either the Parke Davis or Upjohn research facility, he was subject to call at any time by any prison official (App.110a), his hours were subject to the approval by prison authority (App. 28a, 39a-40a, 124a), and he could be given time off for various reasons by the prison authority without the approval of the research clinic administrator. (App. 124a-25a) Specific instructions and tasks assigned by the research facilities could be and, in fact, were vetoed by the prison authority. (App. 125a)

In short, as noted by the District Court, the day-to-day supervision by Parke Davis or Upjohn of inmates assigned to the research facilities was always subject to the overriding authority of prison officials who frequently exercised their authority to disapprove the drug companies' instructions to inmates.

ARGUMENT

I

THE DISTRICT COURT WAS CLEARLY CORRECT IN RULING THAT COUNTS II, III AND IV OF PLAINTIFFS' AMENDED COMPLAINT ARE NOT MAINTAINABLE AS A CLASS ACTION UNDER RULE 23, FED.R.CIV.P.

The basis for the ruling of the District Court that the inmates could not pursue Counts II, III and IV of their Complaint as a Class Action was simply that they had failed to demonstrate that the requirement of Rule 23 (a)(1) was satisfied, i.e., that "the class is so numerous that joinder of all its members is impracticable."

Plaintiffs' action is not automatically maintainable as a Class Action merely because their Complaint designates it as such. The burden is, of course, on the Plaintiffs to establish, to the reasonable satisfaction of the trial court, that the action is one contemplated by the Rules, and that all prerequisites of Rule 23 have been met. See 3B Moore, Fed. Prac. ¶ 23.02-2 (2d ed. 1969). A threshhold requirement of Rule 23 (a) is that the members of the alleged class be so numerous as to make joinder impracticable.

The ruling by the District Court on this point was clearly correct. Not until oral argument did counsel for Plaintiff inmates provide the Court with any hint as to the

approximate size of the alleged class, and counsel's comment was based upon pure speculation. As the District Court noted in its opinion, however, "speculation cannot be used to establish that a prospective class is so numerous as to make joinder impracticable under the surrounding circumstances," citing Demarco v. Edens, 390 F.2d 836 (2d Cir. 1968); Matthies v. Seymour Mfg. Co., 23 F.R.D. 64 (D.Conn. 1958), Rev. on other grounds, 270 F.2d 365 (2d Cir. 1959); Lucas v. Seagrave Corp., 277 F.Supp. 338 (D.Minn 1967). (App. 189a-90a).

The Court left open the possibility of revising its Order should Plaintiff inmates later demonstrate that their action complies with the requirements of Rule 23. Upjohn and Parke Davis respectfully submit that the District Court's Order was proper and should be affirmed.

II

THE DISTRICT COURT WAS CLEARLY CORRECT IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNT I. THE UNCONTROVERTED FACTS ESTABLISHED THAT, AS A MATTER OF LAW, PLAINTIFF INMATES WERE NOT "EMPLOYEES" OF THE UPJOHN COMPANY OR PARKE DAVIS & CO. WITHIN THE MEANING OF THE FAIR LABOR STANDARDS ACT.

After reviewing pleadings, affidavits and answers to interrogatories, the District Court concluded that the following facts had been established by uncontroverted sworn testimony:

> "(1) prison officials, not the drug companies, decide which inmates will work in the clinics, and inmates have been assigned to the clinics despite the disapproval of the drug companies; (2) prison authorities, not the drug companies, determine when inmates will be removed from their assignment to the clinics, and inmates have been so removed without the approval of the drug companies; (3) the particular tasks performed by inmates working in the clinics must be approved by prison officials; (4) the hours worked by inmates are subject to the approval of prison officials; (5) inmates working in the clinics may be given time off from their tasks by prison officials without the consent or knowledge of defendant drug companies; (6) the inmates are supervised by defendant drug companies in the day-to-day performance of their work at the clinics." (App. 20la)

Based upon those uncontroverted facts,* the District Court ruled that, as a matter of law, the inmates were not "employees" of the drug companies within the meaning of the Fair Labor Standards Act, 29 U.S.C. §§ 201-19, as amended 29 U.S.C. §§ 251-62 (hereafter "FLSA").

Since the passage of FLSA the issue whether a given individual was the employee of a particular firm or another person has been litigated often. We therefore have available a body of judicial interpretations of the terms "employer", "employee" and "employ" upon which to rely.

The FLSA itself defines an "employer" as including:

> "...any person acting directly or indirectly in the interest of an employer in relation to an employee..." FLSA § 3(d), 29 U.S.C. § 203(d).

An "employee" includes:

> "...any individual employed by an employer." FLSA § 3(e), 29 U.S.C. § 203(e).

And finally, the term "employ" includes:

> "...to suffer or permit to work." FLSA § 3(g), 29 U.S.C. § 203(g).

A literal application of the definitions contained in the Act would "encompass all employed humanity." Walling v.

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* The inmates' contention that the Espich affidavit presented a genuine issue of material fact (Plaintiffs' Brief pp. 17-18) is without merit and was properly disposed of by the District Court. (App. 197a-98a) There is no hint whatsoever in the Espich affidavit as to how he allegedly obtained personal knowledge or the competency to testify with respect to the internal administrative regulation of Jackson Prison or the terms or conditions of the Upjohn-Parke Davis relationship with the prison authority. (App. 178a-79a)

Sanders, et al, 136 F.2d 78, 81 (6th Cir. 1943), and courts, therefore have developed more meaningful tests for application to this issue. In the more recent judicial opinions on point, the proper test is expressed in terms of "economic reality". Goldberg v. Whitaker House Co-operative, Inc., 366 U.S. 28, 33 (1961); Wirtz v. Silbertson, 217 F. Supp. 148, 154 (E.D. Pa. 1963); Mitchell v. Northwestern Kite Co., 130 F. Supp. 835, 837 (D. Minn. 1955). The economic realities of the situation control, rather than legal technicalitites. Further, the "economic reality" test is not an absolute yardstick, but rather appears to be a synonym for plain "common sense".

What is the "economic reality" of the situation involved in the instant case? What does common sense here dictate? Parke Davis and Upjohn respectfully submit that to classify the inmate help assigned by the prison authority to the research clinics as "employees" of Parke Davis or Upjohn is to ignore economic reality and to defy common sense. Lawfully incarcerated prisoners, whose labor belongs to the State of Michigan, who may be assigned by the State to Defendants' research clinics without their knowledge or consent, who are controlled by Parke Davis or Upjohn personnel while so assigned only within the framework of rules established by the State of Michigan, who may be removed by the State at any time, who cannot be "fired" by Parke Davis or Upjohn and with whom there is no agreement for compensation, express or implied, cannot possibly be "employees" of Parke Davis or Upjohn within the meaning of the FLSA.

Many factors have been suggested and discussed in various cases involving this "employee" issue, all of which are relevant in determining the employment status of particular individuals. The most important of these factors to be considered is who has the right to hire and fire the persons in question. Walling v. Sanders, et al supra; Van Hee, et al v. Elmer C. Breuer, Inc., et al, 10 LC Par. 62,826 (N.D. Ohio 1945). In Walling v. Sanders, which involved the question of whether drivers of beer trucks were the employees of the beer distributor or whether they were employed by the retail salesmen who actually hired and paid them, this Court stated:

> "The usual test by which, in common experience, men determine the employer is to ascertain who has authority on his own account to hire and fire." 136 F.2d at 81.

After ruling, that, as a matter of law, the drivers were not employed by the distributor, the Court went on to comment on the definitions provided in the Act, as follows:

> "In so broadly defining the word "employ" congress undoubtedly had a purpose to relieve complainants of the necessity of proving a contract of employment. The administrator desires us to construe employees so as to include not only those who work for an accused employer, but also those who work for anybody else. Manifestly, this would encompass all employed humanity." 137 F.2d at 81.

In the instant situation, Parke Davis and Upjohn have neither the right to hire nor the right to fire the inmates assigned by the State. Inmates have been assigned to the clinics by the Director of Treatment without the prior knowledge or approval of Parke Davis or Upjohn personnel; inmates have been removed from assignments without the prior knowledge or approval of Parke Davis or Upjohn personnel; inmates who were requested have been assigned elsewhere; an inmate Upjohn had requested be removed, remained on the Upjohn assignment. Clearly, Parke Davis and Upjohn have no right or power to hire or fire these convicts. Judged by this, the most common test, the drug companies do not employ the inmates assigned to the clinics. The inmates simply were not "employees" of Parke Davis or Upjohn as that term is used in the FLSA.

The direction and control of the working force is also a relevant factor, although by no means conclusive. See, e.g., Van Hee, et al v. Elmer C. Breuer, Inc., supra. In the day-to-day performance of their tasks, inmates assigned to the research clinics, are, within very strict limits, directed and controlled by Parke Davis or Upjohn. The various duties are necessarily established by Parke Davis or Upjohn on a routine basis. But even the routine direction of the inmates is always subject to approval of the prison authority, and performance is subject to interruption by frequent calls from institutional officials, which calls must be honored.

This further emphasizes the reality of the situation. Appellants are inmates of a State prison who are under constant direction and control by the prison authority. These men are not in the Trusty Division, nor on outside work assignments. The prison authority has made the determination that these men must be confined within the walls of Jackson Prison, and any control by Upjohn or Parke Davis, therefore, is completely limited by prison rules, even during the hours the inmates are assigned by the prison authority to the clinics.

Moreover, the hours during which an inmate may work are subject to approval by the inside Deputy Warden who is charged with the security and custody of inmates within the prison. More than once he has disapproved the hours of assignment, and has disapproved the particular job of an inmate who was assigned to a research clinic. In short, it is clear that Parke Davis and Upjohn "direct and control" the inmates assigned by the prison authority in only a very narrow sense.

Another factor of importance involves the payment of wages or other compensation. This factor is really comprised of two aspects: first, is there any obligation to pay, i.e., is there a wage liability at all, and second, who if anyone, actually makes the payments for work performed?

Dealing with these aspects in that order, it is

clear that, under Michigan law, a private party has no liability to inmates for labor performed by them under arrangement with the State. In Thompson v. Bronk, 126 Mich. 455, 85 N.W.1084 (1901), the defendant had a contract with the Warden of Jackson Prison for the labor of 300 convicts to be used in the manufacturing of shirts. After his release from prison, plaintiff sued defendant for the value of his services on 576 days of labor, basing his suit on the allegation that he had been unlawfully incarcerated. The Supreme Court of Michigan, in holding for the defendant, stated:

> "If the law raises an implication of a promise to pay plaintiff for these services, it cannot be an implication of fact, but a fiction. It is clear that defendants had no thought of accepting services from plaintiff, to be compensated in any other way than under their express contract with the warden. It is said in some cases, where the defendant is guilty of a wrong, that the law will recognize an implied, or more accurately speaking, a constructive, contract and enforce it. [citation omitted] But, where the circumstances repel all implication of a promise in fact, the law will not imply a promise, unless something has been done on which an implication of a promise can be rested, as in the case of a sale of personal property by a tort feasor, who then became liable to an action for money had and received. [citation omitted] These defendants contracted with a third party for laborers. Under such contract, the third party furnished certain laborers - among them, the plaintiff. The defendants paid to the third party the contract price for the labor so supplied. No contract relations existed between the parties to this suit. There was no

> privity between them. They were not consenting bargainors, coming together in contract relations manifested by some intelligible conduct, act, or sign; and the whole transaction was brought about and accounted for by circumstances repelling every possible implication of contract relations." 127 Mich. at 456-57.

In Dugas et al v. Nashua Mfg. Co., 62 F. Supp. 846, (D.N.H. 1945), appeal dismissed, 154 F.2d 655, (1st Cir. 1946), the Court was faced with the issue of whether certain guards, hired and trained by the City of Nashua, but assigned to protect defendant's premises, were employees of defendant. In holding that they were not, the Court noted that:

> "The purposes and aims of the [Fair Labor Standards Act] are social and remedial. It was not its purpose to create new wage liabilities, but where such existed, to measure them by the standards fixed by law." 62 F. Supp. at 849 (Emphasis added.)

Upjohn and Parke Davis respectfully submit that the Act is inapplicable to the instant situation. To hold otherwise would be to create a new wage liability where none existed. Dugas et al v. Nashua Mfg. Co., supra. See also Helena Glendale Ferry Co. v. Walling, 132 F.2d 616 (8th Cir. 1942) where the Court noted:

> "The Act defines an employee as 'any individual employed by an employer', and the word 'employ' as used in the Act includes 'to suffer or permit to work'. But since the obvious purpose of the Act is to establish

> minimum wages and maximum hours, the words last quoted cannot be interpreted to include as an employee one over whose hours of labor the employer has no control, and to whom the employer is under no obligation to pay wages." 132 F.2d at 620. (Emphasis added.)

The United States Supreme Court has ruled that trainees, to whom the alleged employer had not expected to make any payments, could not recover under the FLSA. Walling v. Portland Terminal Co., 330 U.S. 148 (1947). Language from Justice Black's opinion clearly indicates that the inmates assigned to the clinics are not covered by the FLSA in part for the very reasons expressed in Portland Terminal:

> "Section 3(g) of the Act defines 'employ' as including 'to suffer or permit to work' and § 3(e) defines 'employee' as 'any individual employed by an employer'. The definition 'suffer or permit to work' was obviously not intended to stamp all persons as employees who without any express or implied compensation agreement, might work for their own advantage on the premises of another. Otherwise, all students would be employees of the school or college they attended, and as such entitled to receive minimum wages. So also, such a construction would sweep under the Act each person who, without promise or expectation of compensation, but solely for his personal purpose or pleasure, worked in activities carried on by other persons either for their pleasure or profit. But there is no indication from the legislation now before us that Congress intended to outlaw such relationships as these. The Act's purpose as to wages was to insure that every person whose employment contemplated compensation should not be compelled to sell his services for less than the prescribed minimum wage. The definitions of 'employ' and of 'employee' are broad enough to accomplish this. But, broad as they are, they cannot be interpreted so as to make a person whose work serves only his own interest an employee of another person who gives him aid and instruction." 330 U.S. at 152. (Emphasis added.)

Defendants' counsel believes that only two reported cases arising under the FLSA thus far involved prisoners as plaintiffs. Hudgins v. Hart et al, 65 L.C. ¶ 32,486 (E.D.La. March 18, 1971) (copy attached); Huntley v. Gunn Furniture, 79 F. Supp. 110 (W.D. Mich. 1948).

Hudgins v. Hart et al involved a situation remarkably similar to the one at hand. Plaintiff Hudgins, an inmate of the Louisiana State Penitentiary, was assigned to perform certain technical and clerical duties for defendants in connection with their business of extracting blood plasma from other inmates who volunteered. Hudgins alleged a violation of the FLSA and sought $17,000 in minimum wages for work performed during a three year period. In granting defendants' motion for summary judgment, the Court commented:

> "...there was no contractual agreement, oral or written, between the inmate plaintiff and either of the defendants. There was simply no employer-employee relationship between any of these parties. All contractual arrangements in this case were between the defendants, Hyland and Hart, and the Louisiana State Penitentiary, and the Louisiana Department of Corrections. The plaintiff was an inmate at the penitentiary, and as such his labor belonged to the penitentiary. It was the penitentiary that assigned him to work for Hyland and/or Hart, and it was the penitentiary that decided what Hyland and/or Hart would pay to the penitentiary for that labor. The fact that the penitentiary deposited all or part of the money paid by Hyland and/or Hart for the services of plaintiff to the account of the inmate does not make the plaintiff an employee of the defendants." (Emphasis in original.)

In Huntley v. Gunn Furniture, supra, cited and followed by the Court in Hudgins v. Hart et al and by the District Court in this case, plaintiffs were inmates of Jackson Prison who had been assigned by the prison authority to work in the prison stamping plant. Defendant was an outside contractor who had an arrangement with the State of Michigan whereby the contractor would supply the equipment and materials for the manufacture of parts and assemblies of shell casing which it sold to the government. The inmates worked under the supervision of prison employees who were, in turn, supervised and paid by the defendant. Defendant also paid the utilities involved, and reimbursed the State for the inmates' per diem compensation. The inmates assigned to the project were selected by the prison authority.

Assuming for purposes of argument that the arrangement did not comply with the applicable State regulations dealing with prison labor, the Court concluded that, as a matter of law, the inmates were not the employees of the defendant contractor.

The circumstances in Hudgins v. Hart et al, supra, in Huntley v. Gunn Furniture, supra and in this case are almost identical. Parke Davis and Upjohn do not "employ" the inmates assigned by the prison officials to the clinics. The "economic realities" of the instant situation make clear the frivolous nature of the inmates' allegations and theories. Upjohn and Parke Davis respectfully submit that the Judgment of the District Court on Count I of the inmates' Complaint must be affirmed.

III

THE DISTRICT COURT WAS CLEARLY CORRECT IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNT II OF THE INMATES' COMPLAINT. THE UNCONTROVERTED FACTS ESTABLISHED THAT THE INMATES WERE NOT "EMPLOYEES" OF PARKE DAVIS & COMPANY OR THE UPJOHN COMPANY WITHIN THE MEANING OF THE MICHIGAN MINIMUM WAGE LAW OF 1964.

The definition of the term "employ" set forth in the Michigan Minimum Wage Law of 1964 is almost identical to that set forth in the Fair Labor Standards Act.

> "(d) 'Employ' means to engage, suffer or permit to work"
> M.C.L. 408.382 (d), M.S.A. 17.255 (2)(d).

The District Court noted that the definitions contained in the Minimum Wage Law, enacted in 1964, have never been judicially construed in a reported decision. Under Michigan's Workmens' Compensation Act and Employment Security Act, however, "the test is one of economic reality". Goodchild v. Erickson, 375 Mich. 289, 293, 134 NW2d 191, (1965); Tata v. Muskovitz, 354 Mich. 695, 699, 94 NW2d 71, (1959); Foster v. Employment Security Commission, 15 Mich. App. 96, 99-101, 166 NW2d 530, (1968). And since the Minimum Wage Law of 1964 is also remedial social legislation, the test developed under the Workmens' Compensation Act and the Employment Security Act would seem equally applicable. Under the test of "economic

reality", however, Appellant inmates cannot be deemed employees of Parke Davis or Upjohn, for the reasons set forth above with respect to the Fair Labor Standards Act, to which the same test of "economic reality" is applicable.

Apparently recognizing this problem, Appellant inmates urge that the Michigan Minimum Wage Law should be extended in scope and coverage beyond the relationships sought to be covered by the Fair Labor Standards Act because "the clear intention of the Michigan Act [was] to take up the slack where federal law does not apply and for that reason, taking into consideration the remedial nature of the legislation, the word 'employee' in the state law should be interpreted and would be interpreted by the Michigan Courts, even more broadly than under the federal law." (Plaintiffs' Brief p.28). This argument, advanced without supporting citation is totally without merit and ignores various restrictions in coverage contained in the Michigan Act, which are not found in the Federal Act.

For example, the State Act is inapplicable to employees under age 18 or over age 65, and is inapplicable to employees performing their duties at locations other than on the employer's premises or a fixed site designated by the employer. M.C.L. 408.382(b) M.S.A. 17.255 (2)(b).

Moreover, the State Act contains no provision for overtime premium pay, such as is found in the Fair Labor

Standards Act. (FLSA §7).

Only one decision has been found dealing with the status of an inmate under a state minimum wage law. Dice v. Board of County Commissioners of Coffey County, 178 Kan. 523, 289 P.2d 782 (1955). Dice was a prisoner in a county jail, having been sentenced to 45 days confinement on a misdemeanor. At his suggestion, he performed certain carpentry work on county buildings for the sum of $2.00 per day. Upon his release, Dice filed a claim under the minimum wage laws of the State of Kansas.

The court affirmed the trial court's denial of recovery.

> "...we think it may not be said that in the enactment of our minimum wage law...the legislature ever intended that it should apply to a situation such as we have here. No good purpose would be served by setting out its provisions or discussing them in detail.... We simply hold that the minimum wage law has no application to a 'contract of employment' such as we have in this case." 289 P.2d at 784.

Parke Davis & Company and The Upjohn Company respectfully submit that the Judgment of the District Court with respect to Count II of Appellant inmates' Complaint was clearly correct and must be affirmed.

IV

THE DISTRICT COURT WAS CLEARLY CORRECT IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNT III AND IN CONCLUDING THAT LAWFULLY CONFINED PRISON INMATES IN MICHIGAN DO NOT OWN THEIR OWN LABOR AND DO NOT HAVE A PRIVATE CAUSE OF ACTION FOR DAMAGES BY REASON OF THEIR WORK ASSIGNMENT TO RESEARCH CLINICS LOCATED WITHIN THE PRISON WALLS, ALLEGEDLY IN VIOLATION OF A MICHIGAN STATUTE DESIGNED TO PROTECT FREE LABOR FROM COMPETITION BY PRISON LABOR

A. Summary Of Argument

Plaintiffs' theory with respect to Count III of the Amended Complaint boils down to a claim that they have a private common law cause of action for damages by reason of the utilization of their labor allegedly in violation of Section 5 of the former Michigan Prison Industries Act (M.C.L. 800.301 et seq., M.S.A. 28.1521 et seq.). That section provides in pertinent part as follows:

> ". . . nor shall the labor of prisoners be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction, maintenance of operation of public works, ways or property as directed by the Governor; . . ."
> (M.C.L. 800.305, M.S.A. 28.1525)

The Plaintiff inmates contend that their work assignment to the research clinics was prohibited under the Act and thus was illegal. They further claim that under the common law, persons illegally compelled to work are entitled to damages

(measured by the reasonable value of the labor) either on a tort or on an implied contract theory.

This common law proposition is inapplicable to the instant case. There has been no invasion of any personal rights of the Plaintiff inmates, and Plaintiffs have not been damaged in any way.

The essence of Plaintiffs' argument appears to be as follows:

1. Convicted felons imprisoned in Michigan's Jackson Prison own their labor and have a constitutional right to dispose of their labor as they please (including working at the prison research clinics) and to receive compensation therefor, except to the extent to which that right has been lawfully taken away from them. (Plaintiffs' Brief, pages 30, 31 and 48)

2. The Michigan Prison Industries Act prohibits the utilization of inmate labor at the prison research clinics.

3. Plaintiffs' underlying constitutional right to work at the research clinics or to the fruits of such work cannot lawfully be taken away from them in view of the statutory prohibition.

4. Thus: Plaintiffs have a constitutional right to receive compensation for work prohibited by the statute (work

at the research clinics) as if they were not prison inmates.

This theory is so "novel" that there appears to be no case law in point.

At the outset it should be made very clear that Defendants emphatically deny that Plaintiffs' work assignment to the research clinics is in violation of the Prison Industries Act. The Defendant drug companies recognize, however, that a determination of that legal issue might involve fact issues. Solely to avoid that procedural problem, Defendants assume, for purposes of their Motion For Summary Judgment and this appeal only, that the work assignments are in violation of the Act.

Defendants submit that all the labor of lawfully convicted prison inmates in Michigan "belongs" to the State of Michigan by necessary implication of their confinement and pursuant to statutory mandate. No "residue" of their former right to work remains during the period of lawful incarceration. The principal purpose and effect of the Prison Industries Act was to protect free labor from competition by prison labor, not to "return" to prison inmates the right to dispose of their labor in the proscribed area, or to limit the loss of the right to their own labor. Not having the underlying right to dispose of their labor as they please and, on the contrary, being expressly subject to be put to hard labor as part of

their imprisonment, the Plaintiff inmates have not been injured in any way by their work assignment at the reserach clinics even if that assignment was contrary to Michigan law. Without injury, Plaintiffs thus clearly are not entitled to damages either on a tort or implied contract theory.

B. In Michigan The Labor Of Lawfully Confined Prisoners Belongs To The State Of Michigan

Lawfully convicted inmates confined to the Michigan prison in Jackson are by necessary implication of their confinement deprived of all opportunity and consequently of the "right" to "dispose of their labor as they please" except to the extent to which that opportunity ("right") may be granted them by the State.

This general proposition was recognized by this Court in Coffin v. Reichard, 143 F.2d 443 (6th Cir. 1944) in which this Court stated (at 445):

> "A [prisoner] retains all the rights of an ordinary citizen except those expressly, or by necessary implication, taken from him by law." (Emphasis added.)

In addition, however, a prisoner's loss of his right to his labor is specifically covered by statute in Michigan. The power and duty of the Prison Commission to compel prisoners to work and to determine their compensation, and the corresponding loss of the right by prison inmates not to work or to dispose of their labor as they see fit while in prison are clearly set out

in Section 6 of the Prison Industries Act as follows:

> "It shall be the duty of the Prison Commission to provide as fully as practicable for the employment of prisoners confined in the prisons of this state in tasks consistent with the penal and reformatory purposes of their imprisonment and with the public economy and of the types and approximately in the order of priority as follows . . ." (M.C.L. 800.306, M.S.A. 28.1526)

Similarly, M.C.L. 800.38, M.S.A. 28.1407 provides:

> "All convicts other than such as are confined in solitude for misconduct in the prison shall as far as practicable be kept constantly employed at hard labor at an average of not less than 10 hours a day, (Sundays excepted), unless incapable of laboring by reason of sickness or other infirmity."

In Section 11, the Prison Industries Act further provides with respect to compensation of prisoners that:

> "The prison commission may adopt a schedule of payments or allowances to prisoners or to their dependents from such funds as may be provided, therefore, but such payments shall be made on the basis of need or of motivation of or reward for industry or behavior and shall not be related to profits to the state from the activities to which said prisoners may be assigned." (M.C.L. 800.311, M.S.A. 28.1531)

The obvious conclusion to be drawn from this statutory scheme was stated by Judge Starr in Huntly v. Gunn Furniture Co., supra, as follows:

> "It is clear that the labor of the plaintiffs as inmates of the state prison belong to the State of Michigan." 79 F. Supp. at 113.

This proposition has been recognized in cases in other states. Thus, in Anderson v. Salant, 38 R.I. 463, 96 A. 425 (1916) relied upon by Plaintiffs (Plaintiffs' Brief at 39), the Rhode Island court made the following observation:

> "As to the benefit or profit from his services, his labor was a part of his sentence, and was furnished to the contractor by the state for a compensation fixed in the contract. His inability to dispose of his person, or services, did not arise from the contract, but from his status as a convict under sentence in prison. His services being a part of his sentence could not be disposed of or controlled otherwise than by the state. His disabilities in regard to the disposal of his property are due to the provisions of the statutes, applicable alike to all convicts, and were not imposed by the contract made under said section 21 of chapter 825 of the Public Laws of 1912." 38 R.I. at 478 (Emphasis added)

In Dice v. The Board of County Commissioners of Coffey County, supra, the court concluded:

> "[1] In the first place, the legislature, by the enactment of G.S. 1949, 62-2109, dealt with the subject of 'employment' of those persons who have been convicted of misdemeanors and are serving sentences in the county jail. Under the first provision of that section plaintiff could have been compelled to work at hard labor for eight hours of every working day while so confined and for which he would not have been entitled to receive payment." 289 P.2d at 783 (Emphasis added)

By the same token, in Hudgins v. Hart, et al, supra, the court said:

> "The plaintiff was an inmate at the penitentiary, and as such his labor belonged to the penitentiary. It was the penitentiary that assigned him to work for Hyland and/or Hart, and it was the penitentiary that decided what Hyland and/or Hart would pay to the penitentiary for that labor." (Emphasis added)

It is therefore, clearly apparent that by necessary implication of their confinement, by legislative mandate and under applicable case law, Plaintiffs' labor belonged to the State of Michigan. Plaintiffs did not have the right not to work while imprisoned, nor the right to work or dispose of their labor as they saw fit, nor the right to receive compensation for any work the State compelled them to perform. Accordingly, Plaintiffs have not been deprived of any right, nor injured in any way by having been assigned to the research clinics (for example, to work as cooks there) rather than to some other prison industry (such as the general prison kitchen), and thus are not entitled to compensatory damages.

C. The Michigan Prison Industries Act Does Not Provide A Direct Or Indirect Basis For A Private Damage Remedy

Although Plaintiffs disclaim reliance on the Act as the basis for their purported private damage action (Plaintiffs' Brief, page 43), it is evident that they are attempting to do indirectly what they admit they cannot do directly. A discussion of the Act, therefore, appears appropriate.

1. Stated Purposes of the Act

The stated purposes of the Michigan Prison Industries Act compels the conclusion that the Act was not intended to serve as the basis for a civil action for damages by prison inmates. In fact, permitting it to serve as such a basis would contravene its purposes. Section 10 of the Act, M.C.L. 800.310, M.S.A. 28.1530, explicitly sets out the purposes of the legislation:

> "Intent of Act. Section 10 It is hereby declared to be the intent of this act:

> (a) to provide adequate, regular, diversified and suitable employment for prisoners of the state consistent with proper penal purposes;
> (b) to utilize the labor of prisoners exclusively for self-maintenance and for reimbursing the state for expenses incurred by reason of their crimes and imprisonment;
> (c) to eliminate all competitive relationships between prisoner labor or prison products and free labor or private industry; . . ."

Subsection (b) clearly indicates that it is one of the purposes of the Act that the labor of prisoners is to be utilized exclusively for the benefit of the State. This language thus supports the proposition that, in Michigan, the labor of prison inmates belongs to the State of Michigan. In addition, however, this language indicates an intent that the labor of prisoners is not to be utilized for their own private profit. To permit Plaintiffs to use the Act, although indirectly, as a vehicle to collect compensatory damages would thus contravene one of the express purposes of the Act.

Subsection (c) further indicates that one of the primary purposes of the Act was ". . . to eliminate all competitive relationships between prisoner labor . . . and free labor . . . ." Plaintiffs recognize this important purpose and emphasize, in their brief, that:

> "[i]t would certainly be absurd for men convicted for serious crimes to be given work that would in effect deprive those living a just and lawful life of the right to earn a living." Plaintiffs' Brief at 36.

Thus, as Plaintiffs themselves point out, the intended beneficiaries of this noncompetition policy are those living lawful lives and seeking a lawful income.

Further, any compensation to prison inmates for labor performed by them is totally ". . . by grace of the state." Sigler v. Lowrie, 404 F.2d 659 (8th Cir. 1968). In Michigan, Section 11 of the Prison Industrics Act specifically covers the question of compensation to be paid to inmates for their labor as follows:

> "Schedule of payments or allowances to prisoners. Sec. 11. The prison commission may adopt a schedule of payments or allowances to prisoners or to their dependents from such funds as may be provided therefor, but such payments shall be made on the basis of need or of motivation of or reward for industry or behavior and shall not be related to profits to the state from the activities to which said prisoners may be assigned." (M.C.L. 800.311, M.S.A. 28.1531)

This provision clearly commits the matter of compensation to the sound discretion of the prison commission and negates any inference that any person or entity other than the commission is to be called upon to compensate prison inmates. In sum, therefore, the Act itself negates any direct or indirect use of its terms by prison inmates as a vehicle for recovery of compensation beyond the allowances paid by the prison commission.

2. Express Penalties Under The Act

The penalties expressly provided under the Act omit any mention whatsoever of a civil damage remedy available to inmates. Rather, the following specific penalties are provided:

> "Violations. Section 14. Wilful violations of any of the provisions of this act by an officer of the state or of any political subdivision thereof, or by any officer of any institution of either, shall be sufficient cause for removal from office; and such officer shall also be subject to prosecution as hereinafter provided."
> (M.C.L. 800.314, M.S.A. 28.1534)
>
> * * *
>
> "Penalty. Section 15. Any person, firm or corporation who shall wilfully violate any of the provisions of this act, shall be deemed guilty of a misdemeanor and, upon conviction thereof, shall be punished by a fine of not less than 100 dollars nor more than 500 dollars, or by imprisonment in the county jail for a period of not more than 90 days, or by both fine and imprisonment, at the discretion of the court."
> (M.C.L. 800.315, M.S.A. 28.1535)

Conspicuously absent from the above provisions is any reference to a private damage remedy in favor of those prisoners whose labor was required to be performed pursuant to a contract allegedly in violation of the Act.

3. Plaintiffs Do Not Have A Private Damage Remedy Under The Act

Defendants recognize that in certain circumstances, a statutory violation constituting a crime may also give rise

to a cause of action for damages. However, this doctrine is not applicable to the Plaintiff inmates in the present case.

It has long been recognized that civil remedies are not to be lightly inferred from criminal statutes. Thus, in Beegle v. Thomson, 138 F.2d 875 (7th Cir. 1943), cert. denied, 322 U.S. 743 (1944), which involved a civil action for damages based upon a criminal provision contained in an anti-trust statute, the court concluded:

> "Plaintiff urges that the second paragraph of Section 20, which fixes criminal responsibility for violation of the Act, creates also a cause of action, if open bidding is prevented, irrespective of whether an interlocking relationship exists. We think this construction unjustified. Statutory remedial causes of action must find express basis in congressional act; they do not arise by implication from a provision for a criminal penalty." 138 F.2d at 880. Accord: Mezullo v. Maletz, 331 Mass. 233, 238, 118 NE2d 356 (1954).

Where no express statutory basis for a civil damage remedy is provided, the United States Supreme Court has required that it be shown that (1) ". . . criminal liability was inadequate to ensure the full effectiveness of the statute . . .," (2) ". . . the interest of the plaintiffs . . . fell within the class that the statute was intended to protect . . ." and (3) ". . . the harm that had occurred was of the type that the statute was intended to forestall. . . ." Wyandotte Co. v. United States, 389 U.S. 191, 202 (1967). See also Lepard v. Michigan Central Railroad Co., 166 Mich. 373, 130 N.W. 668 (1911);

Bolden v. Grand Rapids Operating Corporation, 239 Mich. 318, 214 N.W. 241 (1927).

Defendants submit that Judge Freeman correctly concluded that Plaintiffs in this case have failed to satisfy the Wyandotte criteria. First, there is no allegation nor proffered proof that the criminal penalties provided under the Act have been inadequate or ineffective.* Second, it is patently clear that the interests of the Plaintiff inmates were not those intended to be protected under the express "purposes" provision of the Act. Third, the harm which the Act seeks to prevent is injury to free labor by prison inmate competition, whereas the alleged "harm" for which Plaintiffs seek recovery is simply the fact that they were compelled by the State to perform labor under an allegedly illegal contract between the Michigan Department of Corrections and Parke Davis and Upjohn.

In these circumstances, Plaintiffs' attempt to base a purely private and compensatory remedy either directly, or indirectly, upon the Michigan Prison Industries Act, a statute designed to regulate the administration of state prison industries and providing purely public remedies to redress public wrongs, is wholly inappropriate.

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* The characterization of the Mink case (Mink v. Parke Davis Company, Mich. Court of Appeals No. 2684, Order of November 23, 1966; leave to appeal denied, 379 Mich. 773 (1967); cert. denied, 392 U.S. 934 (1968) in the footnote on p. 42 of Plaintiff's Brief is not supported by the record. The denials of Mr. Mink's mandamus action by the Michigan courts are extremely summary. The pleadings and briefs indicate that the denials were probably based on procedural grounds.

D. Plaintiffs Do Not Have A Cause Of Action In Tort

It is hornbook law that the field of torts ". . . is concerned with the compensation of losses suffered by private individuals in their legally protected interests, through conduct of others which is regarded as socially unreasonable." Prosser, Torts 1 (2d ed. 1955). Defendants submit that Plaintiffs possess no legally-protected interest which was in any way invaded by the actions of Defendant drug companies.

Plaintiffs contend that the allegedly illegal utilization of their labor by Defendants constituted a tort against them, by ". . . invading a protected property interest of the prisoners." Plaintiffs' Brief at 31.

This contention has already been answered in the first two sections of this portion of Defendants' Brief. However, it appears appropriate to discuss the authorities cited by Plaintiffs which are claimed to hold that the illegal compulsion of prison labor constitutes a tort against the prisoner.

At page 31 of their Brief, Plaintiffs quote from 98 C.J.S., Work and Labor, Section 12, as follows:

> ". . . and where one party wrongfully compels another to render him valuable services, a promise to pay their value is implied. So, a promise to pay for services rendered will be implied against a wrongdoer who never intended to pay, or who intended deceitfully to avoid payment, and whether the rendition of such services is secured through duress, compulsion, or fraud makes no difference. Where, without legal authority, one is compelled to perform work for another, the law raises an implied contract for compensation for the value of the services rendered."

Parke Davis and Upjohn submit that this statement of the law is too broad in that it assumes the crucial fact, absent in the present case, that a party was injured by a wrongful invasion of a right possessed by that party.

Similarly, the quotation from 41 Am. Jur., Prison and Prisoners, Section 34 (Plaintiffs' Brief at 38)

> "It seems agreed that a lessee of convict labor who knowingly receives the services of a convict illegally compelled to perform such labor is guilty of a tort toward such convict for which he is liable."

is based on cases which do not support the quoted proposition or involve facts which are significantly different from those in the instant case.

Thus in Anderson v. Salant, supra, (Plaintiffs' Brief at 39) it was simply decided that the Rhode Island Prison Labor Statute did not contravene the Rhode Island Anti-Slavery provision in the Constitution.

The case of Greer v. Critz, 53 Ark. 247, 13 S.W. 764 (1890) referred to in the Anderson case involved a determination of alleged error in jury instructions in light of two different Arkansas statutes. The court affirmed, finding "no error", on the basis of a very short, conclusionary opinion citing no authority whatever. Whatever the Greer case may stand for, it is submitted that the Anderson characterization of Greer (quoted in Plaintiffs' Brief at 39) is inaccurate and goes far beyond the holding in Greer.

The cases of Chattahoochee Brick Co. v. Goings, 69 S.E.865 (Ga. 1910) (expired sentence); Patterson v. Prior, 81 Am. Dec. 367 (Ind. 1862) (void conviction) and Tennessee Coal, Iron and R. Co. v. Butler, 65 So. 804 (Ala. 1914) (expired term) all cited in Plaintiffs' Brief at 39-41, involved plaintiffs who had been compelled to labor while illegally imprisoned or confined. In other words, in these cases the state itself was not entitled to the labor which the prisoners had been required to perform for the various defendants; and the prisoners, therefore, had been wrongfully deprived of something that belonged to them. These cases stand for the proposition that persons injured through a wrongful deprivation of their right to dispose of their own labor are entitled to recovery from the tort-feasors who caused or participated in causing the injury. The unmistakable point of distinction between these cases and the present case is, of course, that in the present case "the labor of the plaintiffs . . . belong to the State of Michigan", Huntley v. Gunn Furniture Co., supra; and the Plaintiffs, therefore, have not been injured by the State's disposition of that labor, even if that disposition violated a statute designed to protect free labor from competition by prison labor.

Similarly none of the other authorities relied upon by Plaintiffs in their brief constitute precedent for the damage

relief sought by them under Count III in this case.*

It is respectfully submitted that the cases and authorities relied upon by Plaintiffs do not support the claimed right to a damage remedy on a tort theory and that that contention is not legally supportable in the context of the present case.

E. Plaintiffs Are Precluded From Recovery Under An Implied Contract Theory

The doctrine is clear that no contract will be implied where this same contract, if express, would be illegal. Succinctly stated, the rule is that: "[t]he law will not imply an agreement which would be illegal, if it were express." Cardozo, J., in Andrews v. Haas, 214 N.Y. 255, 259, 108 N.E. 423 (1915). See also: Dumphy v. Ryan, 116 U.S. 491 (1885). Application of this doctrine to the facts of the case at bar indicates the crucial

*It should be noted that many of the cases cited by Plaintiffs are injunction cases. Such actions by the intended beneficiaries of the Michigan Prison Industries Act might be quite proper. See, for example, Matheny v. Vincent, 145 Mich. 327, 108 N.W. 667 (1906) cited at page 35 of Plaintiffs' Brief, in which representatives of labor and manufacturers in the Michigan broom industry were successful in obtaining an injunction against prison officials restraining them from performance of a contract for the manufacture of brooms by prison inmates. The decision was based on a former Michigan constitutional provision prohibiting the teaching of mechanical trades to prison inmates and a determination by the court that the constitutional provision was intended for the benefit of the plaintiffs in that case.

inconsistency in Plaintiffs' case. An express agreement between Plaintiffs and Defendants would clearly have been invalid. Plaintiff inmates were not free to contract with anyone with respect to their labor because their labor belonged to the State. In addition, the very statute upon which Plaintiffs rely would prohibit such an agreement. In short, no promise on the part of Parke Davis and Upjohn to pay Plaintiffs for the value of their services can be implied, since even had Defendants expressly promised to pay Plaintiffs for their labor, such express promise would have been illegal.

Further, implying such a promise would violate public policy. No promise of compensation may be implied where public policy would be frustrated thereby. Berka v. Woodward, 125 Cal. 119, 57 P. 777 (1899); Barngrover v. Pettigrew, 128 Iowa 533, 104 N.W.904 (1905). Nevertheless, Plaintiffs seek to obtain compensation higher than provided for under Michigan law for labor performed by persons confined in prison as a consequence of their conviction of serious crimes. To permit such recovery would, of course, negate the very deprivation of benefits which forms an integral part of the punishment which the Michigan prison system levies upon those convicted of crimes. Defendants submit that to grant the relief which Plaintiffs seek herein would violate both statutory mandate and public policy and would subvert, rather than promote, the interest of justice.

F. Plaintiffs Have Not Sustained And Cannot Show Recoverable Damages

In order to recover damages on a statutory, tort or implied contract theory, Plaintiffs would, of course, have to show that they have been damaged. This they cannot do.

As has already been pointed out, Plaintiffs simply have not been injured by being assigned by the State of Michigan to various tasks at the research clinics rather than to the prison laundry or some other prison industry.

Further, even if some theoretical right to money damages existed in this case, Plaintiff inmates do not and cannot satisfy the applicable rule relating to the measure of damages. The law is very clear that the reasonable value of services.

> ". . . is determined largely by the nature of the work and the customary rate of pay for such work in the community . . . [where] the work was performed." 58 Am. Jr. Work and Labor §10 at 518 (Emphasis added.)

Thus, in Morehouse v. Shepard, 183 Mich. 472, 150 N.W. 112 (1914), the court held it proper to consider ". . . the usual commission charged and received by real estate agents and brokers in Paw Paw . . ." (183 Mich. at 474) in an action by a broker for the reasonable value of his services.

The community within which the work here in question was performed is circumscribed by the walls of Jackson Prison.

Plaintiffs' situations thus must be considered in relation to the situation of other prisoners. As appears from the uncontroverted facts set forth in Warden Kropp's affidavit, (App. 111a, 112a) Plaintiffs suffered no harm or disadvantage at all. Paragraphs 26 and 27 of the affidavit indicate that Plaintiffs were and are paid at a higher rate than are prisoners assigned to other comparable prison industries and that the working conditions at the research clinics are superior. Since the prison commission is required, pursuant to Section 6 of the Act, to provide for employment of prisoners, it is apparent that if Plaintiffs had not been assigned to the research clinics, they would have been assigned to some other task -- at a lower rate and with comparatively inferior working conditions.

Plaintiffs not having been damaged in any way, they are not entitled to an award of money damages in this case.

G. Conclusion

In Count III of the Amended Complaint, Plaintiffs allege a claim for relief sounding in tort. Plaintiffs further claim that, by waiving the tort and suing on implied contract, they are

entitled to the reasonable value of services rendered to Parke Davis and Upjohn, as measured by statutory minimum wage provisions. Defendants respectfully submit that, as a matter of law, Plaintiffs have failed to state a claim in tort or implied contract upon which relief can be granted, that Plaintiffs are not entitled to further compensation or any theory and that the Summary Judgment in favor of Defendants granted by Judge Freeman should be affirmed.

V

THE DISTRICT COURT WAS CORRECT IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON COUNT IV, BECAUSE EVEN ASSUMING THAT THE UTILIZATION OF PLAINTIFFS' LABOR WAS CONTRARY TO MICHIGAN LAW, PLAINTIFFS DID NOT SUFFER A DENIAL OF ANY RIGHTS PROTECTED BY THE UNITED STATES CONSTITUTION

It is difficult to see what Count IV of Plaintiffs' Amended Complaint (purportedly alleging violations of rights under the 13th and 14th Amendments) adds to the argument under Count III in the present litigation.

On page 47 of their Brief, Plaintiffs state their theory under Count IV as follows:

> "Appellants begin from the basic assumption that the right of an individual to the fruits of his own labor belongs to him alone and is a constitutionally protected property right under the Fourteenth Amendment except to the extent it is lawfully taken away from him. The residue of that right after part of it is carved out and given to the state by applicable state law, belongs to the prisoner."

This contention appears to be identical to Plaintiffs' argument under Count III. As has already been stated, under Michigan law a lawfully convicted felon detained within Jackson Prison must be put to hard labor pursuant to statute and thus has no right to his own labor, or to dispose of it as he may see fit, except as that right may be granted him by grace of the State. In Michigan a prisoner completely forfeits his

freedom to work as he chooses and to receive compensation therefor.

It is true that Section 5 of the Michigan Prison Industries Act, (M.C.L. 800.305, M.S.A. 28.1525) in effect directs the State, which has the sole right to dispose of the labor of prison inmates, not to utilize their labor for certain purposes in order to avoid competition with free labor. This statutory restraint on the State does not alter the fact that the State and only the State has the basic right to compel and dispose of prison labor in Michigan. Further, this statutory restraint on the State certainly does not "return", so to speak, the right to their labor to the prison inmates when the labor allegedly is utilized in violation of the Act. At the risk of being redundant, Defendants again submit that it is plainly absurd that Plaintiffs should have a constitutional (or other) right to their labor at the research clinics because, and only because, the work is in violation of criminal statute which prohibits that very labor.

Plaintiff inmates expressly agree with Judge Freeman's conclusion that, as lawfully convicted prison inmates, they may constitutionally be compelled to work (Plaintiffs' Brief, page 47). Draper v. Rhay, 315 F.2d 193 (9th Cir. 1963); Fallis v. United States, 263 F. Supp. 780 (M.D. Pa. 1967). Another way of putting the proposition is to say that prison inmates may constitutionally be deprived of their labor and the fruits thereof. That is exactly what the State of Michigan

has done by statute. Thus, pursuant to M.C.L. 800.306, M.S.A. 28.1526 and M.C.L. 800.38, M.S.A. 28.1407, prison inmates must be put to hard labor and whatever rights to their labor they had prior to lawful detention in Jackson Prison belong to the State while Plaintiffs are confined in prison. Huntley v. Gunn Furniture Co., supra.

Plaintiffs further concede that a mere violation of State law by prison officials does not, in itself, constitute a violation of Federal constitutional rights (Plaintiffs' Brief, page 47). Sigler v. Lowrie, 404 F.2d 659 (8th Cir. 1968) and cases cited therein. Thus, even though the utilization of Plaintiffs' labor by prison officials is assumed to be in violation of Michigan law, it is submitted that Judge Freeman was correct in concluding that Plaintiffs' constitutional rights have not been violated.

Whatever constitutional limitations may exist on the power of prison officials to compel work of prisoners or dispose of their labor, those limitations are not involved in the present case. Arguably, it may be constitutionally improper to compel prison labor involving creativity or individuality (Davis v. Superior Court In and For County of Martin, 345 P.2d 513 (Cal. 1959)) such as compelling Muhammed Ali to fight for the heavyweight championship or requiring an artistic prison inmate to paint pictures, as suggested in Plaintiffs' Brief (p. 31). Plaintiffs here, however, do not and cannot contend

that their work assignments at the prison research clinics involved anything but ordinary labor, albeit of varying degrees of skill.

It is respectfully submitted that the constitutional contentions of Plaintiffs are insubstantial and that Judge Freeman was correct in granting Summary Judgment for Defendants on Count IV of Plaintiffs' Amended Complaint.

VI

RELIEF REQUESTED

Defendants Parke Davis and Upjohn respectfully submit that Judge Freeman's Order entered in this case on February 2, 1971 (App. 223a) should be affirmed by this Court.

Respectfully submitted,

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Dated: Detroit, Michigan
June 15, 1971

ADDENDUM

Rule 23, Fed.R.Civ.P. Class Actions

(a) Prerequisites to Class Action.

One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

State of Michigan Minimum Wage Law of 1964

M.C.L. 408.382(b), M.S.A. 17.255(2)(b)

"Employee" means an individual between the ages of 18 and 65 years employed by an employer on the premises of the employer or at a fixed site designated by the employer.

In The

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 71-1170

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL WILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. LEWIS, RALPH R. WARNER, RONALD D. KENNEDY, PAUL ROSS, HERMAN HEAD, GERALD G. NORMAN, PAUL MILLER, THOMAS H. HOLLIGAN, LONNIE PAYNE, ROBERT MASON, GAYLORD L. ESPICH and KENNETH R. MARSHALL,

Plaintiffs-Appellants,

v.

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C.J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRAWFORD, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants-Appellees.

APPEAL FROM THE DISTRICT COURT OF THE UNITED STATES FOR THE EASTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

BRIEF FOR PLAINTIFFS-APPELLANTS

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STATEMENT OF ISSUES PRESENTED FOR REVIEW

I.

DID THE DISTRICT COURT ERR IN RULING THAT COUNTS II, III AND IV OF PLAINTIFFS' AMENDED COMPLAINT ARE NOT MAINTAINABLE AS A CLASS ACTION BECAUSE OF PLAINTIFFS' FAILURE TO SUFFICIENTLY ESTABLISH THE SIZE OF THEIR CLASS?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

II.

DID THE DISTRICT COURT ERR IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT UNDER COUNT I OF PLAINTIFFS' AMENDED COMPLAINT BECAUSE PLAINTIFFS' WERE NOT "EMPLOYEES" WITHIN THE MEANING OF THE FAIR LABOR STANDARDS ACT?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

III.

DID THE DISTRICT COURT ERR IN GRANTING SUMMARY JUDGMENT TO DEFENDANTS ON COUNT II OF PLAINTIFFS' AMENDED COMPLAINT BECAUSE PLAINTIFFS WERE NOT EMPLOYEES WITHIN THE MEANING OF THE MICHIGAN MINIMUM WAGE LAW?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

IV.

DID THE DISTRICT COURT ERR IN GRANTING SUMMARY JUDGMENT TO DEFENDANTS ON COUNT III OF PLAINTIFFS' AMENDED COMPLAINT BECAUSE PLAINTIFFS WERE NOT DEPRIVED OF PROPERTY UNDER MICHIGAN LAW AND BECAUSE PLAINTIFFS WERE NOT INTENDED BENEFICIARIES UNDER THE MICHIGAN PRISON INDUSTRIES ACT?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

V.

DID THE DISTRICT COURT ERR IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO COUNT IV OF PLAINTIFFS' AMENDED COMPLAINT, BECAUSE EVEN ASSUMING THE ILLEGAL USE OF PLAINTIFFS' LABOR CONTRARY TO MICHIGAN LAW, THEY SUFFERED NO DENIAL OF FEDERALLY PROTECTED RIGHTS?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

UNITED STATES COURT OF APPEALS

FOR THE SIXTH CIRCUIT

No. 71-1170

CALVIN SIMS, RICHARD ALLEN, FRANK ROGERS, BILLY LEE WILLIAMS, WALTER LEE, BOYD SLAGER, PETER GEORGE MILLS, LEE D. WALKER, CLEMONT DEDEAUX, ORDELL VILBURN, WILLIAM CLEARY, HERBERT WILLIAMS, FRED HOLNAGEL, BENNY SPELLS, KENNETH INMAN, RAYMOND L. BAILEY, ORCEAN DAVIS, JERRY MACK, BOYD KELTON, THOMAS H. LORD, RALPH WATSON, CHESTER A. SAWICKI, PHILLIP McGHEE, VERNON D. MEVIS, RALPH R. WARNER, RONALD D. KENNEDY, PAUL ROSS, HERMAN HEAD, GERALD G. NORMAN, PAUL MILLER, THOMAS U. MULLIGAN, LONNIE PAYNE, ROBERT MASON, GAYLORD L. ESPICH and KENNETH R. MARSHALL,

Plaintiffs-Appellants,

v.

PARKE DAVIS & CO., a Michigan Corporation, THE UPJOHN CO., a Delaware Corporation, DEPARTMENT OF CORRECTIONS OF THE STATE OF MICHIGAN, ELEANOR HUTZEL, JAMES E. WADSWORTH, ERNEST C. BROOKS, MAX BIBER, C.J. FARLEY, JOHN W. RICE, DUANE L. WATERS, FLORENCE CRANE, JOSEPH J. GROSS, G. ROBERT COTTON and GUS HARRISON,

Defendants-Appellees.

APPEAL FROM THE DISTRICT COURT OF THE UNITED STATES

FOR THE EASTERN DISTRICT OF MICHIGAN

SOUTHERN DIVISION

PLAINTIFFS - APPELLANTS' BRIEF

Filed April 1970

STATEMENT OF THE CASE

A. Nature of the Case

This is a class action filed by people who are or have been prisoners at the State Prison of Southern Michigan, seeking recovery for their labor in drug clinics operated by Parke Davis & Co. and The Upjohn Co., at the prison. The complaint filed on April 23, 1968, and the amended complaint filed on January 21, 1970, seek recovery under four theories. The first count alleges Plaintiffs are entitled to protection under the Fair Labor Standards Act and Count II alleges similar protection under the Minimum Wage Law of the State of Michigan. Count III seeks recovery on a quantum meruit theory, while Count IV seeks damages based on violations of Plaintiffs' rights under the Fourteenth Amendment. (58a)

The gravamen of the action under Counts I and II is that Plaintiffs were actually employees of the drug companies in economic reality, despite the fact of custodial control by the Michigan Department of Corrections. The core of Count III and IV is the alleged illegal (under Michigan law) utilization of Plaintiffs' labor and the resultant deprivation of their property. (58a)

The pleadings allege a conspiracy on the part of the drug companies and the members of the Michigan Corrections Department

to illegally utilize Plaintiffs' labor without proper payment therefor. (61a)

After answers were filed by all Defendants and interrogatories by Plaintiffs had been answered, Plaintiffs' moved for summary judgment as to liability only under Count III and Defendant drug companies moved for summary judgment under Counts I, III and IV. They also moved to dismiss Count II. (53a) Defendant Department of Corrections and its individual members moved to dismiss Plaintiffs' amended complaint in its entirety. (3 a) Defendant drug companies also moved the Court for an order that Plaintiffs' action could not be maintained as a class action (52a)

The District Court granted Defendants' motion regarding the class action, finding that Plaintiffs had not sufficiently established the size of the class. (190a) The Court, further, treating the motions to dismiss as motions for summary judgment, granted summary judgment to Defendants on all counts by order filed February 2, 1971. (224a)

From this order Plaintiffs' filed a Claim of Appeal. (3 a)

B. Facts Relevant to the Issues Presented for Review

Plaintiffs are or have been inmates at the State Prison of Southern Michigan at Jackson, Michigan (sometimes hereafter referred to as "Jackson"). (59a) The Upjohn Company (hereafter referred to as "Upjohn") and Parke Davis & Company (hereafter referred to as "Parke Davis") are corporations organized for profit

engaged generally in the drug manufacturing industry. Parke Davis is a Michigan Corporation, while Upjohn is organized under the laws of the State of Delaware; but both companies are doing business throughout the State of Michigan and in interstate commerce. There are other Plaintiffs besides those named in this complaint who either are or have been inmates at Jackson and who have the same claim as do the named Plaintiffs. (59a)

Defendant Michigan Department of Corrections is a corporate body organized originally under Act Number 232 of the Public Acts of the State of Michigan of 1953* (Sections 28.2271-28.2341 M.S.A.) and has exclusive jurisdiction over the administration of all penal institutions; and specifically over the management and control of prison labor and industry (Sec. 28.2274 M.S.A.). The individual Defendants** in this case all are or have been members of the Michigan Corrections Commission at times relevant to Plaintiffs' claim, except for Gus Harrison who has been the Director of the Commission.** (59a)

Both Defendant drug companies have been carrying on drug research at Jackson for some years, the activities of Parke Davis dating back to 1934. (36a)

* Whose powers were transferred to the Department of Corrections created by Sec. 275 of the Executive Organization Act of 1965 (Sec. 3.29 (1) et seq M.S.A.) pursuant to Section 277 of said act.

** The Department of Corrections is administered by The Corrections Commission, consisting originally of six members which number was reduced to five by the Executive Organization Act of 1965. The principal executive officer of the Department of Corrections is its director, who is appointed by the Commission.

1963 DOC/drug agreement

Generally, volunteers from among the prisoners are used as guinea pigs to engage in drug testing and in finishing and refining products which are ultimately sold by Parke Davis and Upjohn in interstate commerce. These drug testing programs are administered or have been administered in great part by labor furnished by the Department of Corrections from Jackson pursuant to agreement with the drug companies. (181a) On November 18, 1963, an agreement was signed between Parke Davis and the Department of Corrections relating to the construction of a building for the conducting of the clinical research at the prison. (47a) On November 21, 1963, a similar agreement was executed between The Upjohn Company and the Michigan Department of Corrections. (32a)

These agreements generally require the drug companies to retain an architect and to pay the entire expense of planning and constructing clinical research buildings at the prison, although the Department of Corrections is given a right to approve the plans before construction. The building is to be equipped completely by the drug companies; and as soon as the completed project is accepted by the Department of Corrections all of the building and fixed equipment is to become the property of the State of Michigan. Any insurance proceeds are to be used to restore the building and in the event of abandonment of the building when partially completed, all the materials and equipment on the construction site are to become the property of the Department of Corrections. The drug companies are given the right to use the building for clinical research only as long as that sort of research is conducted at the

Pay

prison. The agreements further make the drug companies responsible for the conduct of clinical research in the building. The Department of Corrections agrees to take "all reasonable steps" to facilitate the conduct of clinical research by the drug companies. The agreements have been carried out in accordance with their terms and it is during the period subsequent to their execution that the acts complained of by Plaintiffs occurred. (33a)

All the named Plaintiffs, as well as others who worked in the drug testing clinics organized and run by Defendant drug companies, worked as part of the administrative or drug testing staff and not as so called voluntary guinea pigs. The prisoners thus working did so because they were ordered to do so by the representatives of the Department of Corrections just as they would be ordered to work in any other prison industry and a refusal to work as directed would have resulted in penalties to them and such a coercion or threat was clearly implied if not expressly stated. (94a)

Many different job classifications have existed at the drug clinic facilities and they are listed as follows with the rate of pay per day opposite each. (182a)

THE UPJOHN COMPANY

Job Classification	Duties	Daily Rate of Pay
Chief Technician	Ordinarily performs specific tasks such as operation of EEG machine	$.76 - $1.25
Technician	Same as Chief Technician	$.50 - $ .75
Technician Trainee	Same as Chief Technician	$.35 - $ .50
Chief Clerk	Clerical tasks	$.75 - $1.25
Clerk	Clerical tasks	$.40 - $ .75
Nurse Supervisor	Acts as nurse in connection with clinical tests	$.50 - $1.00
Nurse	Same as Nurse Supervisor	$.30 - $ .50

Chief Cook	Cooks and serves food	$.55 - $ .80
Cook	Same as Chief Cook	
Kitchen	Assists in kitchen	$.40 - $ .55
Kitchen Pot & Pan	Assists in kitchen	$.25 - $ .40
Maintenance Man	Maintenance and minor repairs	$.35 - $ .60
Head Porter	Janitorial tasks	$.40 - $ .60
Porter	Janitorial tasks	$.25 - $ .40

PARKE DAVIS & COMPANY

Job Classification	Duties	Rate of Pay
Chief Clerk	Preparation of labels for blood, urine, etc. sample containers; prison details; call slips; inmate workers and volunteer payrolls	$1.25
Clerk	Double checks labels	$ .75
Chief Cook	Cooking and other kitchen duties	$ .80
Head Porter	Janitor and messenger	$ .60
Maintenance Man	Maintenance and minor repairs	$ .60
Porter and Nurse Supervisor	Night janitor and attendant	$1.00

The above noted daily rates are paid by check by each of the drug companies to the State of Michigan and then the amounts due to each prisoner are assigned to the prisoner's account by the Department of Corrections. (35a) Plaintiffs worked long hours in this program and had tasks involving substantial responsibility. (91a) Other than the nominal payment noted above, Plaintiffs received no compensation for the services rendered by them. (60a)

The research clinics involved in this case are utilized for the private profit-making purposes of Defendants Upjohn and Parke Davis and their shareholders; and their activities, among other things, include the clinical testing of drugs not presently on the market as well as the testing of drugs currently being produced for, sold, transported, shipped and delivered in interstate commerce throughout the United States. (60a)

57 employees

SUMMARY OF ARGUMENT

I.

Plaintiffs may properly maintain this action as a class action under Rule 23(a) of the Federal Rules. Because of the circumstances it is impossible for them to know the number of people similarly situated with certainty and, in fact, such knowledge is peculiarly within the knowledge of the Defendants. Moreover, the record shows that a class of at least fifty-seven people exists which is sufficient a number to meet the requirements of class litigation.

II.

Under Count I of their amended complaint, Plaintiff inmates seek recovery of wages under the Fair Labor Standards Act for the difference between the normal amounts paid them by Defendant drug companies and the amount required to be paid employees under Federal law. The economic realities of the situation at the drug clinics at which Plaintiffs worked are that except for ultimate custodial control, Plaintiffs were under the direction and supervision of the drug companies and worked just as civilian employees would for their economic benefit. The Fair Labor Standards Act was remedial legislation and is to be liberally construed. The arrangements between the drug companies and the State of Michigan is nothing more than an attempt to avoid the minimum wage requirements with resultant benefit to the State of Michigan and the employers.

III.

The purpose of the Michigan Minimum Wage Act was to cover those people not protected by the Federal law, and if Plaintiffs are found not to be within the protection of the latter, the Michigan act applied to them.

IV.

Plaintiffs, as every other person, have a right to the fruits of their own labor except to the extent such right is legally taken from them. The Legislature of Michigan has expressly denied the Corrections Department the right to utilize the labor of inmates in the fashion done in this case. A person illegally deprived of the fruits of his labor has been deprived of a property right and may recover the reasonable value thereof, and the fact that Plaintiffs are or have been prisoners does not negate this right.

V.

The right to the fruits of one's labor is a property right protected under the Fourteenth Amendment and illegal deprivation of that right constitutes a denial of due process. The actions of Defendants in this case were illegal under Michigan law in that they deprived Plaintiffs of a property right for which Plaintiffs are entitled to damages.

ARGUMENT

I.

DID THE DISTRICT COURT ERR IN RULING THAT COUNTS II, III AND IV OF PLAINTIFFS' AMENDED COMPLAINT ARE NOT MAINTAINABLE AS A CLASS ACTION BECAUSE OF PLAINTIFFS' FAILURE TO SUFFICIENTLY ESTABLISH THE SIZE OF THEIR CLASS?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

In Paragraph 4 of their amended complaint (containing four counts) Plaintiff inmates allege that:

> "There are numerous other people who either are or have been inmates in the State Prison of Southern Michigan at Jackson, Michigan, who have the same cause of action as hereinafter set forth on the part of the named Plaintiffs and the named Plaintiffs adequately represent such unnamed people. This action is brought pursuant to Rule 23A of the Federal Rules of Civil Procedure on behalf of all such people whose number make it impractical to have them join as Plaintiffs. The named Plaintiffs adequately represent said class." (59a)

Defendant Upjohn Company moved the trial court to find that the action was not properly brought as a class action under Rule 23 of the Federal Rules of Appellate Procedure. Several grounds of non-qualification under the Rule were alleged. (52a) Plaintiffs agreed that Count I, containing a claim under the Fair Labor Standards

Act, was ruled by the provision of that Act limiting the effect of a judgment thereunder to persons who have filed a written consent to become parties to an action. However, as to Counts II, III and IV, Plaintiffs' contended that the requirements of Rule 23 were met.

The District Court granted Defendants' motion as to Counts II, III and IV, and this ruling was predicated solely on Rule 23(a)(1) which required that the class be:

> ". . . so numerous that joinder of all members is impracticable." (190a)

The District Judge found insufficient evidence of the size of the class involved to enable him to determine whether or not a class action was appropriate, stating that:

> "The only information this court has been given on class size was supplied by Plaintiffs' attorney during oral argument, when he commented that the class would probably contain between 70 and 200 persons. Since this estimate was unsupported by any materials before the court, it must be deemed purely speculative, and speculation cannot be used to establish that a prospective class is so numerous as to make joinder impracticable under the surrounding circumstances." (Cit. omit.) (189a)

It is necessary to look at the whole record in this case to determine whether or not the Court was correct. First of all, both in their complaint and amended complaint, Plaintiff inmates alleged:

> "There are numerous other people who either are or have been inmates in the State Prison of Southern Michigan at Jackson, Michigan, who have the same cause of action as hereinafter set forth on the part of the named Plaintiffs, and the named Plaintiffs adequately represent such unnamed people. This action is brought pursuant to Rule 23A of the Federal Rules of Civil Procedure on behalf of all such people whose number make it impractical to have them

join as Plaintiffs. The named Plaintiffs adequately represent such class." (52a)

The answer of the Department of Corrections and its individual members, filed by the Attorney General of the State of Michigan, while denying that Rule 23(a) is applicable, does not deny the allegation as to the number of the alleged Plaintiffs. (68a) Thus, for purposes of the record on behalf of those Defendants, that allegation is admitted.

The answers of both Parke-Davis (15a) and Upjohn (20a) state that they neither admit nor deny the allegation, thus leaving Plaintiffs to their proofs. Very significantly, however, they do not state, as required by Rule 8(b) of the Federal Rules, that they are without knowledge or information sufficient to form a belief as to the truth of the averment. Nor could they possibly do so when all of the information is within their knowledge, since all of the inmates involved performed services for them. Based upon this fact, their statement in their answers should not have the effect of a denial. (Iceplant Equipment Co. v. Martocello, 43 F.Supp. 281 (D.C. Pa., 1941)

Therefore, it is Appellants' position that on the present state of the pleadings the fact that there are numerous other inmates involved who would be members of the alleged class is admitted. However, it is not necessary to rest on the state of the pleadings to demonstrate this. There are now thirty-five specifically named Plaintiffs, whereas there were originally nineteen, the difference resulting from parties requesting to be added as the suit progressed.

Furthermore, Exhibit C*, filed as part of the record in this case, lists thirty-one names of inmate employees working for the drug companies, twenty-two of which are different from those named in this action, making a class at least fifty-seven in number. (141a) The lower court could certainly have taken judicial notice of the fact that people are not incarcerated permanently, and that it would be most difficult for the Plaintiffs to gather a list of all those who might have a cause of action in this case. Moreover, federal law has made clear that the size of the class in this case has already been sufficiently established, so that that alone is no bar to maintaining a class action.

For example, in Citizens Banking Co. vs. Monticello State Bank, 143 F2d 261 (8th Cir., 1944) an action by twelve of forty holders of collateral trust notes against a trustee for restoration of trust funds was held to be a proper class action. In Fidelis Corporation v. Litton Industries, Inc., 293 F.S. 164 (S.D.N.Y., 1968) a class of between thirty-five and seventy stockholders was determined to be sufficient to have a proper class action.

A class of eighteen was held sufficient in Cypress vs. Newport News General and Non-Sectarian Hospital Association, 375 F2d 648 (4th Cir., 1967).

Similarly see Tisa v. Potofsky, 90 F.S. 175 (U.S.D.C., 1950) where an executive board of more than fifty members was sufficiently numerous to make it impractical to bring them all before the Court.

* Exhibit C is a summary of inmates wages paid by Upjohn in September, 1966.

The Courts have pointed out on numerous occasions that the word "impracticability" as used in Rule 23(a) does not mean "impossibility" but only the difficulty or inconvenience of joining all members of the class. (Harris v. Palm Springs Alpine Estates, Inc., 329 F.2d 909, 9th Cir. (1964); Goldstein v. New Jersey Trust Co., 39 F.R.D. 363, D.C.N.Y., (1966.))

In the instant situation, several things result in the impracticability of joining all the plaintiffs. First of all, many of this group of potential plaintiffs may be uneducated and illiterate, and they lack knowledge of their rights. Secondly, they may be afraid of taking action because of possible reprisals against them by prison authorities.

Finally, it seems to Appellants that in this case, since all of the knowledge with regard to the size of the class is clearly within the possession of Appellees and that it would have been easy enough for them to bring it to the attention of the Court, whereas it would be difficult for Appellants to put forth such information, that the lower court was wrong in ruling that the record did not contain sufficient evidence of the size of the class so that that alone required him to grant Appellees motion for an order that this action could not be maintained as a class action. Certainly, it is in the interests of the orderly administration of justice that this action be decided once and for all and that all of the people having this cause of action be brought before the Court at one time, which is really the main rationale behind the class action procedures.

Appellants urge that the District Court erred in ruling that Counts II, III and IV of their complaint could not be properly maintained as a class action under Rule 23.

II.

DID THE DISTRICT COURT ERR IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT UNDER COUNT I OF PLAINTIFFS' AMENDED COMPLAINT BECAUSE PLAINTIFFS' WERE NOT "EMPLOYEES" WITHIN THE MEANING OF THE FAIR LABOR STANDARDS ACT?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

A. The Question To Be Decided

Plaintiff inmates seek recovery under Count I of their complaint and amended complaint on the ground that they are "employees" of Defendant drug companies and entitled to the protection of the Fair Labor Standards Act. (61a) Defendant drug companies moved for summary judgment, arguing that as a matter of law, Plaintiffs were not "employees" of either themselves or the State of Michigan within the meaning of that statute. (103a)

The relevant terms used in the Act are the following. An "employee" is defined as:

> " . . . any individual employed by an employer." (29 U.S.C. Sec. 203(e))

The term "employer" is defined as:

> " . . . any person acting directly or indirectly in the interest of an employer in relation to an employee . . ." (29 U.S.C. Sec. 203(d))

To "employ" means:

> " . . . to suffer or permit to work."
> (29 U.S.C. Sec. 203(g))

Because of the breadth of the above language and the fact that its literal application would "encompass all employed humanity", (Walling v. Sanders, 136 F.2d 78, 80; 6th Cir. 1943) the Courts have applied a narrower test, the test of "economic reality" to determine the status of one as an employee or non-employee. (Goldberg vs. Whitaker House Cooperative, Inc., 366 U.S. 28, 33, 1960) The District Court, after considering the affidavits filed by all parties and applying this criterion (agreed by all parties to be the correct one) ruled as a matter of law that Plaintiffs were not "employees" of the drug companies within the meaning of the Fair Labor Standards Act. (206a)

B. The Right To Hire And Fire

The basis of his ruling was, in part, his conclusion that:

> ". . . defendants could not hire, fire or finally control inmates working in the clinics . . . " (202a)

The substance of the affidavits of Ralph F. Willy, Administrator of the Upjohn Clinic at Jackson, (123a) and of Warden Kropp of the State Prison of Southern Michigan (108a), filed by Defendants, as well as the Defendants' answers to interrogatories (24a), as analyzed and relied upon by the District Court, is that the prison authorities control assignment to the clinics and removal therefrom and the regulation of hours worked by the inmates.

The Court determined that affidavits filed by Plaintiffs support the proposition that they were under the ultimate control of the Department of Corrections, and thus reached the conclusion that the affidavits filed by the parties are not factually in conflict. (197a)

However, the Court expressly disregarded the affidavit of Gaylord Lee Espich which states:

> "Representatives of Defendant, The Upjohn Company, personally approved all inmates who worked at the said clinic and persons could not work there unless they were so approved." (178a)

The reason for this, according to Judge Freeman, was:

> "While affiant Espich states he is competent to testify from personal knowledge that 'the Upjohn Company, personally approved all inmates who worked in the said clinic and persons could not work there that were not so approved,' his competency and firsthand knowledge of these facts is unsupported by anything contained in his affidavit. Espich does not, 'in his affidavit or otherwise reveal how he knew these facts. Inasmuch as summary judgment procedure lacks the safeguard of cross-examination of an affiant, it is important that it be shown that he is competent to testify to the matters therein stated.' . . . Indeed, since Espich is simply one of the inmates who worked in the Upjohn laboratory, it is difficult to see how he could be competent to testify from firsthand knowledge on whether Upjohn 'personally approved all inmates who worked' in its clinic. Hence, that portion of Espich's affidavit referring to Upjohn's selection of inmates will be stricken as failing to conform with Rule 56(e)." (197a)

This despite the fact that Affiant Espich also stated:

> "1. This Affidavit is made upon the basis of the personal knowledge of Affiant of the following matters and Affiant is competent to testify to the matters stated herein.

> 2. Affiant is one of the main Plaintiffs herein and has worked in the drug clinic buildings constructed by The Upjohn Company at the State Prison of Southern Michigan. Furthermore, he is familiar with some of the other named Plaintiffs and other inmates of said prison who worked in the said clinic." (178a)

The Court appears to be saying that nobody except a representative of one of Defendants could have the knowledge as to how employees were selected for employment at the drug companies. There is no reason that this has to be true. The knowledge of an employee, who himself was selected, certainly should rate some standing with the Court. Appellants' believe the Court was in error in striking that portion of the Affidavit of Plaintiff Espich dealing with the method of selecting inmates.

Plaintiffs do not dispute that legally the Michigan Department of Corrections had custodial control of them. The question raised is rather, acknowledging this control, did the Department of Corrections subordinate their wishes to those of the drug companies so that in fact the latter controlled the work assignments. This is a factual issue which cannot be decided on the basis of the affidavits filed in this case. Moreover, Plaintiffs do not see that the existence of custodial control by the state negates the possibility of "employment" by a third party. Furthermore, as the Court notes in his opinion, it is uncontroverted that the inmates were supervised in the routine performance of their tasks by the drug companies. (201a) In short, aside from the actual ultimate legal right to determine whether they worked there or not, Plaintiffs were directed in the actual services they rendered by representatives of the Defendants, just as civilian employees would have been.

The Court gave no weight to the exhibits filed by Plaintiffs. (200a) Taken as a whole, while indicating ultimate control of inmate assignment in the prison, they quite clearly show that it was in fact the representatives of the drug company that originated requests in many cases for reassignment or for permission for time off or for hiring new inmates. (132a) Exhibit "H", containing a job description of the staff position at the prison clinic, indicates that one of his "authorities" is "for hiring and releasing of inmate help." (166a) Several of the exhibits speak of such things as "inmate employees" and "daily rate of salary". (140a) Especially interesting is a letter dated June 11, 1965, to George A. Kropp, Warden, from Mr. Willy of the Upjohn Clinic, which states as follows:

> "Dear Sir:
>
> Since the joint research facilities of Parke Davis and Upjohn Clinics have been in operation for over a year, we find it necessary to re-evaluate the pay scale for inmates working in the clinics. We offer the following reasons:
>
> On occasion, we have found it difficult to hire inmates with the qualifications we require, because it is possible for those men to get equal or more pay for fewer hours of work and less personal responsibility. The standard of performance of the companies must, in turn, be required of inmate help in the clinics. The Industries, Computer Center, and Psychiatric units recognize the performance of their inmate employees with higher pay." (158a)

The Court disregards this sort of comment in the letters as being mere "shorthand" notations "often used by businessmen to connote any variety of procedures resulting in the attainment of a work force". Appellants

believe, however, that they do constitute one of the factors to be considered in determining whether or not there is a factual issue to be resolved and are, in fact, admissions of at least the attitude of the defendant drug companies toward the relationship in issue.

Appellants' believe that the District Court was mistaken in determining as a matter of law that the right to hire, fire, and control inmates working in the clinics resided in the Department of Corrections because Appellants' believe the realities of the situation should rule. Only a trial would show those realities and Appellants further believe that the reality is that the defendant drug companies were allowed by the Department of Corrections to have almost as free a hand with the inmates as they would with their own civilian employees.

C. Other Factors Pertaining to Application of "Economic Reality" Test

Having determined that the drug companies had neither the right to hire nor fire inmates and that custodial supervision of the inmates was always subject to the final control of prison officials, the District Court recognized, however, that this fact alone is not determinative of the employment issue; and that "the entire fabric of Plaintiff relationship to the companies must be considered." (202a) He then found the "economic reality" to be that:

> "In return for the use of this convict labor, the private corporations have relinquished their normal rights: (1) to determine when, and whether, their enterprises need additional help; (2) to select the members of their work force; (3) to

> remove from their work force members with whom they are dissatisfied; (4) to control that labor force except in the most routine matters." (204a)

Appellants' urge that the record simply does not support such a finding as a matter of law and that, indeed, it is a factual issue, regardless of the technicalities of the matter, whether the private corporations have really given up any of those rights or whether, in fact, they exercise them for the most part just as they would in the normal employment situation. Particularly, Appellants' believe the Court is erroneous in finding that the drug companies have control of the labor force only in the "most routine matters" since it seems clear on the record that as far as the actual work that is done, they have absolute control and supervision as to method carried out, as to method utilized and the task to be carried out.

In fact, the economic reality of the situation indicates that defendant drug companies are obtaining or have obtained hundreds of thousands of dollars worth of labor free by use of the device here involved. It hardly lies in the mouths of defendants to claim, as they did in one of their briefs submitted to the lower court:

> "It is submitted that on its face a corporation employing thousands of persons is not interested in the assistance of a few inmates because of a saving of labor costs."

Despite the fact that the District Court found, that the inmates were paid for their services by the Department of Corrections at per diem rates established by the Department, the economic

reality is that the cost of their employment is borne by the drug companies and, as indicated by the exhibits already referred to, the drug companies have a great deal to say about what amount they pay.

The fact that the inmates are subject to custodial control of the prison authorities does not mean that they cannot be employees. In fact, an analogous situation exists with every unemancipated minor who works at a job. There is no question that he is subject to control of his parents, yet this does not prevent him from being an employee of another. It may be that he could not work without the permission of his parents and that they could make him quit the job at any time. No one would say that he is not employed because of this, however. Similarly, a person can be subject to two employers and have two jobs and the control of one doesn't necessarily interfere with the control of the other.

The entire reasoning of the Court in applying the economic reality test seems circular. The prisoners are not employees because they don't meet the test of being employees. They do not meet the test of being employees because they are prisoners and subject to custodial control. All the authority vested in the prison officials and the decisions made are natural and to be expected when a third-party employer suffers or permits the prisoners to work for them. It is the most natural thing in the world that there should be rules, regulations and oversight by the prison officials when private companies use prisoners to work. It is clear that custodial control is the real basis of the lower court's finding that the prisoners are not employees, yet the Court states at page 26 in his opinion:

> "Nevertheless, the court does not now hold that any prisoner who is assigned by prison officials to perform work for a private corporation on the penitentiary premises is, because of his prisoner status, outside the coverage of the Fair Labor Standards Act. We only find that on the present facts plaintiffs are not in economic reality employees of defendant drug companies as that word is defined in the Act." (206a)

It is hard to imagine in what situation the Court would hold prisoners to be within the Fair Labor Standards Act. Undisputedly, the supervision at their job is by the defendant drug companies. It is clear not only that the cost of their services is borne by the drug companies, but also the value of their services inures to the drug companies, and is substantial in amount. The substance of the transaction is that they, in fact, work for the drug companies. Further, all of the arguments applicable to the situation in this case would apply to prisoners who are allowed to participate in a "work release" program and yet such prisoners are paid the going rate for civilian labor, even though still incarcerated and subject to control by the Corrections Department and indeed no one, it seems, would argue that they are not employees of the particular concern they work for.*

D. Application of Huntley v. Gunn

The District Judge obviously placed great reliance on the case of Huntley vs. Gunn Furniture Co., 79 F.Supp. 110 (W.D. Mich. 1948) However, this case is clearly distinguishable from the

* In fact, Michigan law provides that even a prisoner on parole "shall remain in the legal custody and under control of the commission". (Sec. 28.2308 M.S.A.) Yet obviously, parolees are not kept from being "employees" by such custody and control.

instant one. In summarizing the facts, the Court in Huntley stated that the allegations of the complaint:

> "show that plaintiffs were inmates of a State prison; that they were under the sole control, direction, and supervision of the Michigan prison industries and prison officials; . . . " (emph. add.)

The Court went on to state:

> "The complaint does not allege or intimate that there was any collusive arrangement between defendant and Michigan prison industries for the intent and purpose of evading the law of the State or the application of the Act."

The above two statements both show facts strikingly different from this case. Here we have alleged and sworn statements that Plaintiffs were subject to direct control of supervision of the Defendants, and Plaintiffs have alleged that there is a conspiracy between the Defendants to avoid the application of the law of the State of Michigan. Paragraph 10 of Plaintiffs' amended complaint states:

> "All of the acts and actions complained of by Plaintiffs were accomplished by the agreement and cooperation of all the Defendants, both corporate and individual, named herein; and the illegal utilization of Plaintiffs' labor inured to the benefit of all Defendants. Further, said actions constituted in fact or in law an attempt to evade, avoid and violate the laws of the State of Michigan regarding the use of prison labor for private profit, and the laws of Michigan and the United States regulating the minimum wage to be paid for labor." (61a)

The District Judge stated in his opinion that Plaintiffs were incorrect in trying to distinguish the Huntley case on the

basis that the drug companies exercise supervision over the inmates in the instant case, while in Huntley, only prison employees directed the convict work force. His opinion stated that to make such a distinction would:

> ". . . ignore the allegation in Huntley that the prison employees who supervised the inmates in their work in the stamping plant were 'under the supervision and direction of the defendant.' 79 F. Supp. at 112. Since those allegations had to be accepted as true for the purposes of the motion to dismiss, the Huntley court was required to assume that the defendants' agents supervised plaintiffs in their routine work at the stamping plant. That assumption corresponds to the uncontroverted facts now before the court." (204a)

Appellants' believe that the District Judge was simply in error in stating the above. The complete quotation from the Huntley case relevant to the point raised by the District Judge is as follows:

> "They alleged that the superintendent, general foreman, night superintendent, paint foreman, superintendent of the tool room, and other employees of the prison industries (all of whom were not inmates and not involved in the present suit) were to be paid by the defendant for their services in supervising the inmates in their work in the stamping plant; and that these employees of the prison industries were under the supervision and direction of defendant." (Emph. add.)

To Appellants this language seems clearly to indicate that the inmates were at all times, both in terms of their custody and their everyday routine work, under the control of representatives or employees of the prison industries. The fact of their supervision at work, in doing their work, by prison authorities, Appellants' believe is a

crucial factor distinguishing this case from the Huntley case and bearing on the question of whether or not they were employees of the drug company. After all, the right to control persons in their work has always been considered, if not the sole, at least a crucial element in determining their status as employees.

E. Conclusion

Finally, in his opinion, the District Judge speaks about the intention of Congress. Appellants think it is clear that the Congress intended a broad coverage, as noted earlier, of this act and the development of this coverage has been on a case by case basis. The very criminal statutes quoted by the Court would seem to make clear that Federal policy and Congressional policy would be not to define the term "employee" in such a way so as to encourage private corporations to violate its policy toward the competition between convict and free labor.

Despite the claims of defendant drug companies and the finding of the lower court, there are serious factual issues in this case and it is not one, with regard to Count I, in which the Court should have made a decision on the basis of a summary judgment. Furthermore, were such a decision proper Appellants' urge that it should be made in their favor under the circumstances of this case.

III.

DID THE DISTRICT COURT ERR IN GRANTING SUMMARY JUDGMENT TO DEFENDANTS ON COUNT II OF PLAINTIFFS' AMENDED COMPLAINT BECAUSE PLAINTIFFS WERE NOT EMPLOYEES WITHIN THE MEANING OF THE MICHIGAN MINIMUM WAGE LAW?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

Count II of Plaintiffs' complaint and amended complaint set forth a claim under the Minimum Wage Law of the State of Michigan (Sec. 17.255(1)-17.255(16) M.S.A.) Sec. 17.255(14) of that Act provides in pertinent part:

> ". . . provisions of this act shall not apply to any employer who is subject to the minimum wage provisions of the federal fair labor standards act of 1938, as amended, . . ."

The Act contains the following relevant definitions in Sec. 17.255(2):

> "(b) 'Employee' means an individual between the ages of 18 and 65 years employed by an employer on the premises of the employer or at a fixed site designated by the employer.
>
> (c) 'Employer' means any person, firm or corporation, including the state and its political subdivisions, agencies and instrumentalities, and any person acting in the interest of such employer, who employs 4 or more employees at any one time within any calendar year. Such employer shall be subject to this act during the remainder of such calendar year.

(d) 'Employ' means to engage, suffer or permit to work."

There have been no cases in Michigan construing these provisions.

The District Court found that the drug companies are "jurisdictionally subject" to the Michigan Minimum Wage Law, but found further that Plaintiffs were not "employees" within the meaning of that word as defined in the act. (207a) His opinion correctly pointed out that the test in Michigan of the employee status is not the common law definition of the master-servant relationship, but rather, the total factual situation surrounding the relationship, including the economic reality of it. The Court then found, based on his reasoning under Count I with reference to the Fair Labor Standards Act, that Plaintiff inmates were not employees under the Michigan Minimum Wage Law. (209a) Appellants urge that for all of the reasons stated with regard to Count I, they should be considered employees within the meaning of the Michigan Minimum Wage Law; or at the very least, that there is a factual issue created by the record in this case.

Further, Appellants urge that it was the clear intention of the Michigan Act to take up the slack where federal law does not apply and for that reason, taking into consideration the remedial nature of the legislation, the word "employee" in the state law should be interpreted and would be interpreted by the Michigan Courts, even more broadly than under the federal law. In the absence of a determination by the Michigan Courts, the District Court was bound to make its own determination.

The dissenting opinion of Justice Talbot Smith in Powell v. Employment Sec. Comm., 345 Mich. 455 (1956) has become the law of Michigan on this subject.

> "The test employed is one of economic reality. It looks at the task performed, whether or not it is a part of a larger common task, 'a contribution to the accomplishment of a common objective.' (Cit. omit.) The test is far from the common-law test of control, since 'the act concerns itself with the correction of economic evils through remedies which were unknown at the common law.' (Cit. omit.) The test, rather, looks at the workmen, to see whether or not their work can be characterized 'as a part of the integrated unit of production,' (Cit. omit.) and whether 'the work done, in its essence, follows the usual path of an employee.' (Cit. omit.) In applying such test, control is only one of many factors to be considered. The ultimate question is whether or not the relationship is of the type to be protected.
>
> . . .
>
> Tested by those standards, Rebecca Cohen was clearly an employee. Her work, in essence, followed the usual path of an employee. It was an integral part of her employers' business. It was a contribution to the common objective. And if 'control' remains the test, it is clear that her employers exercised over her all of the control her work demanded."

Applying this concept to the instant case, the District Court should have found that the defendant drug companies, if not subject to the federal act, were subject to the Michigan Minimum Wage Law; or at the very least, that a factual issue existed with regard thereto. The District Court erred in granting summary judgment to Defendants under Count II of Plaintiffs' amended complaint.

IV.

DID THE DISTRICT COURT ERR IN GRANTING SUMMARY JUDGMENT TO DEFENDANTS ON COUNT III OF PLAINTIFFS' AMENDED COMPLAINT BECAUSE PLAINTIFFS WERE NOT DEPRIVED OF PROPERTY UNDER MICHIGAN LAW AND BECAUSE PLAINTIFFS WERE NOT INTENDED BENEFICIARIES UNDER THE MICHIGAN PRISON INDUSTRIES ACT?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

Plaintiffs sued under Count III of their Amended Complaint for the reasonable value of their services of which they were illegally deprived by the conduct of Defendants. (63a) The District Court also granted Defendants' motion for summary judgment on this count. (216a)

A. Plaintiffs' Theory of Recovery

It is necessary to start out with the general proposition that the labor of every person in this county belongs to that person. It seems unnecessary to cite the Fourteenth Amendment, the Declaration of Independence and other basic legal documents or theory to substantiate that statement.

When a person is lawfully incarcerated the statutes of the State of Michigan authorize the Department of Corrections to requisition and use their labor to a certain extent and the conditions

under which that labor can be utilized are carefully spelled out. To this extent a prisoner's labor is given to the State but only to this extent.

It is clear that inmates are not deprived of all their rights to their own labor. For example, would anyone contend that the Department of Corrections could compel Muhammed Ali to fight for the heavyweight championship or fight exhibitions with the money to go to the State? Can the State require a person with artistic ability to paint pictures or an author to write stories for the benefit of the State? It seems to Plaintiffs that the answer is clearly no. As a matter of fact, the State Prison of Southern Michigan has an arts and crafts shop from which work of the inmates is sold at prices set by the inmates. (179a) Nobody has ever claimed or could claim that the State is entitled to the profits of this sort of work. To repeat to the extent the right is legally given, the State has the right to requisition the labor of prisoners. Beyond that it is acting illegally and invading a protected property interest of the prisoners. Although this is a novel situation, the principles applicable to it are clear. Since Plaintiffs were entitled to the fruits of their labor, except in so far as it was legally taken from them, they were deprived of property in this case.

The general rule is formally stated as follows:

> ". . .and where one party wrongfully compels another to render him valuable services, a promise to pay their value is implied. So, a promise to pay for services rendered will be implied against a wrongdoer who never intended to pay, or who intended deceitfully to avoid

> payment, and whether the rendition of such services is secured through duress, compulsion, or fraud makes no difference. Where, without legal authority, one is compelled to perform work for another, the law raises an implied contract for compensation for the value of the services rendered." (98 C.J.S. Work and Labor Sec. 12, Page 737)

B. The Law of Michigan

In Michigan the law will imply a promise to pay for the performance of labor or the rendering of services where they were performed or rendered at another's request or with his knowledge and assent. Moreover, such a promise will be implied under appropriate circumstances even though no tortious act is involved. A leading Michigan authority states the rules this way:

> "At common law, a tort arising out of a contractual relation between the parties, or consisting of a conversion of property into money or money's worth, may be waived and suit may be brought in assumpsit, on a contract or promise implied by law, notwithstanding the fact that an action of trespass on the case might have been brought. Under the statute, the right to waive a tort and to maintain assumpsit, on a contract or promise implied by law, is extended to . . .cases of the conversion of personal property into money."

And further, the same authority states:

> "Assumpsit generally lies where labor has been performed or services rendered pursuant to a contract, express or implied, . . .although the contract is not binding upon plaintiff because of frauds or mistakes of defendant or its terms are not enforceable because of the statute of frauds.
>
> In the absence of an express contract for labor or services and payment of compensation, as where labor was performed at another's request, or with his knowledge and assent, and there is no evidence of a contract price, or where services were rendered and accepted with full knowledge of the facts, assumpsit may ordinarily be maintained for the reasonable value of the labor performed or services rendered, upon an implied promise to pay the reasonable value thereof." (Callaghan's Michigan Pleading and Practice, Vol. 8, Sections 62.10 and 62.20)

The cases supporting this proposition are legion and a few citations will suffice as examples. In Donovan vs. Halsey Fire Engine Company, 58 Mich.38(1885) Plaintiff recovered for labor performed in an action of assumpsit against Defendant and the Court sustained a judgment for Plaintiff holding that:

> "Some point was made on the hearing that by the by-laws of the company no debt could be contracted except by order of the board of directors. There is nothing, however, in this point. There seems to have been no question about the legal existence of the defendant, or the fact that it did business and employed the services of these men whose claims were held by the plaintiff, . . .
>
> There is no pretense that the company did not receive good and valuable service for the amount of claims sought to be recovered, and that it was for the benefit of the company and with its knowledge. The implied assumpsit alone, under such facts, is sufficient to create the liability."

Similarly, in Davis vs. School District, 81 Mich. 214, (1890) Plaintiff sued Defendant School District to recover for services rendered as Superintendent during the school year. Defendant resisted the claim on the basis that he was not a qualified teacher because he had no certificate and the lower court directed a verdict on that ground and refused the Plaintiff's offer of proof to show that the services rendered by him were performed with knowledge by the Board of Trustees. On appeal the case was reversed and the Michigan Supreme Court stated:

> "Where a municipal corporation receives money or property of a party under such circumstances that the law, independent of express contract, imposes the obligation upon the corporation to do justice with respect to the same, it has been held that it may be liable to an action."

statute prohibiting [illegible]

The following language was approved by the Michigan Supreme Court in Detroit vs. Highland Park, 326 Mich. 78 (1949) at page 100:

> " 'There are two kinds of implied contracts: One implied in fact, and the other implied in law. The first does not exist unless the minds of the parties meet, by reason of words or conduct. The second is quasi or constructive, and does not require a meeting of minds, but is imposed by fiction of law, to enable justice to be accomplished, even in case no contract was intended.
>
> 'In order to afford the remedy demanded by exact justice and adjust such remedy to a cause of action, the law sometimes indulges in the fiction of a quasi or constructive contract, with an implied obligation to pay for benefits received. The courts, however, employ the fiction with caution, and will never permit it in cases where contracts, implied in fact, must be established or substitute one promise or debtor for another.' "

C. The Illegality of Defendants' Acts

There remains only the question of whether Plaintiff inmates were, in fact, illegally deprived of their labor.

It is the law and policy of the State of Michigan that the labor of prisoners shall not be used for private or corporate profit. This mandate is expressly and clearly spelled out in the Michigan Statutes regulating prison labor as follows:

> "From and after 60 days after this act shall become law it shall be unlawfull to sell or exchange or to offer for sale or exchange, or to purchase any prison products, except pure bred livestock raised on the several prison farms and sold for breeding purposes, otherwise than for use or consumption in the penal, charitable and/or other custodial institutions of this state or for departments of this state, or political subdivisions thereof, or the federal government or agencies thereof, or otherwise as specifically provided in this act; nor shall the labor of prisoners be sold, hired, leased,

> loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction, maintenance or operation of public works, ways or property as directed by the Governor; . . . (Sec. 28.1525, M.S.A.) (Emph. added)

This mandate is further expressed in Sec. 28.1530* M.S.A. which states:

> "It is hereby declared to be the intent of this act:
> (a) to provide adequate, regular, diversified and suitable employment for prisoners of the state consistent with proper penal purposes;
>
> (b) to utilize the labor of prisoners exclusively for self-maintenance and for reimbursing the state for expenses incurred by reason of their crimes and imprisonment;
>
> (c) to eliminate all competitive relationships between prisoner labor or prison products and free labor or private industry;" (Emph. added)

* * * * *

This public policy is one recognized in many if not all of the states in this country and one which has a rather ancient history. For example, Sec. 3 of Article 18 of the Michigan Constitution in effect in 1906 provided:

> "No mechanical trade shall hereafter be taught to convicts in the State prison of this State, except the manufacture of those articles of which the chief supply for home consumption is imported from other States or countries."

In the case Manthey vs. Vincent, 145 Mich. 327 (1906) the Supreme Court of this state enjoined the warden and the Board of Control of the Michigan State Prison from performing a contract for the manufacture of brooms by inmates because such activity violated the

* The Correctional Industries Act (Act 15, 1968) repealed the former Prison and Labor Industries Act, but the new act contains substantially similar provisions for purposes of this case.

constitutional provision in question. That such a state policy is valid (i.e. the prevention of competition between convict labor and free labor) was established by the United States Supreme Court long ago (Kentucky Whip & Collar Co. vs. Illinois Cr. Co., 299 U.S. 334 (1936)). Even in the days when the labor of convicts could legally be leased the prescribed method of doing so had to be followed exactly or a contract for this purpose was void (Agent of State Prison vs. Lathrop, 1 Mich. 438 (1850)).

One cogent reason motivating the legislature in this regard is so clear as to require no detailed exposition.* It would certainly be absurd for men convicted for serious crimes to be given work that would in effect deprive those living a just and lawful life of the right to earn a living. Yet that is exactly what is being done in this case in clear violation of the statutes and policy of this state. In addition, regulation of inmate employment so as to prevent its abuse and to limit the temptation to prison officials for possible gain through its improper utilization and valid legislative objects. Similarly, the desire to provide proper rehabilitation opportunities. In short, the interest of prisoners are also a concern of the State.

Other states have not hesitated to strike down or refuse to enforce contracts in violation of similar laws and a similar policy where their jurisdiction was concerned. For example,

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* Indeed the congress of the United States has seen fit for analogous reasons to establish a criminal penalty for knowingly transporting in interstate commerce convict or prisoner made goods. (U.S.C.A. Title 18, Sec. 1961)

the Illinois Supreme Court refused a petition for mandamus to compel the Secretary of State to secure through the Department of Public Welfare car license plates to be used for drivers in Illinois where they were to be manufactured by convict labor. The writ was denied because the plates were not to be manufactured for use of the State and the applicable statute required the Department of Public Welfare to avoid the products of prison labor being sold on the open market and their competition with free labor (People vs. Hughes, 18 N.E. 2nd 453 (Ill., 1938)).

In Arkansas a suit was brought to restrain members of the Board of Penitentiary Commissioners from hiring out and leasing convicts for the purpose of constructing a dam. The Plaintiffs appealed from a lower court decree dismissing their suit and the Supreme Court of Arkansas reversed the decision, and in so doing stated:

> "It is urged that the convicts have not been leased within the meaning of the statute because their physical control is under the supervision and direction of guards and wardens appointed by the penitentiary commission. The physical custody of the convicts by the guards and wardens appointed by the penitentiary commission does not and cannot prevent the contract from being one of hiring out or leasing the convicts. Such a construction of the statute would in effect render it useless and ineffectual for the purpose for which it was enacted. The public policy of the state, as shown by the legislative will, was to prevent letting of the convicts to persons or corporations to be worked by them for private gain. To allow the contracts to stand would be contrary to the policy of the law as tending obviously to result in the violation of the purpose and spirit of our statute prescribing the rules and regulations which are to govern the penitentiary board in the control and working of the state convicts. (Green vs. Jones, 261 Southwestern 43 (Ark., 1924)).

A situation very similar to the instant case was involved in Price vs. Mabey, 218 Pac. 724 (1923) in which the Utah Supreme Court held void a contract by the State Board of Corrections which provided for the installation by a shirt and overall manufacturer of manufacturing equipment in the state prison and the purchase by the manufacturer from the state of all shirts and overalls manufactured therein with prison labor under the supervision of the warden. The Utah constitution prohibited the contracting of convict labor and the Utah Supreme Court granted a writ of prohibition restraining the defendants from carrying out the agreement. Similarly, see Bromwell Brush & W. G. Co. vs. State Board of Charities, 286 F. 737 (D.C.E.Ky., 1922).

D. Illegal Utilization of Plaintiffs' Labor By Defendants Constituted a Tortious Act

Although the cases are not many in this area the general rule concerning illegal utilization of convict labor is succinctly stated by one legal authority as follows:

> "It seems agreed that a lessee of convict labor who knowingly receives the services of a convict illegally compelled to perform such labor is guilty of a tort toward such convict for which he is liable." (41 Am Jur, p. 908)

The relatively few cases which have discussed this question have agreed that an action of assumpsit based upon a quantum meruit theory will lie where prison labor is utilized in violation of law; and where the labor of a convict has been received by a contractor through an illegal agreement the law will raise an implication of a promise upon the basis of the tort

so committed by the contractor. (Anderson vs. Salant, 96 A. 425 (R.I., 1916)) As the Rhode Island Supreme Court stated in the last cited case at page 427:

> "Where the labor of a convict has been received by a contractor under a contract which was illegal, either through want of authority to make the contract, or a void commitment, or holding to labor after a valid commitment had expired, it has been held that the law will raise an implication of a promise upon the basis of the tort so committed by the contractor. Thus in Greer v. Critz, 53 Ark. 247, 13 S.W. 764, the statute placed the management and control, and the hiring of convicts under the jurisdiction of the county courts. Under a contract with the judge of the county court, in vacation of the court, the convict was delivered to the contractor to work out his fine, and worked for the contractor under said contract. The court held that there was no power or authority given by the statute to the judge of the county court, in vacation of said court, to make a contract for that purpose, which could be done alone by the order of the court itself, and held that the defendant, being a party to the contract, was bound to know of this lack of authority, and that as he had the benefit of the plaintiff's services he was obliged to pay for them."

In Chattahoochee Brick Co. vs. Goings, 69 S.E. 865 (Ga., 1910) a convict whose labor had been leased out by state authorities brought suit for work performed for the defendant contractor after his lawful sentence had run out. On appeal the Georgia Supreme Court held that the demurrer to Plaintiff's petition had been properly overruled. The Court further held that if the Plaintiff's detention was illegal and he was compelled to work for the Defendant, who knew that his detention was illegal and continued to get the benefit of it, then the Defendant was a participant in a wrong and a joint tort-feasor. The Court stated further that the fact that the act was committed by order of an executive officer of

the state didn't make it lawful or prevent the Defendant from being liable. As the Court summarized at page 867:

> "If the detention of the plaintiff beyond the term of his sentence was an illegal deprivation of his liberty, and he was compelled to work for the defendant, and the latter, knowing that his sentence had terminated and that his detention was illegal, continued to furnish maintenance, to receive the benefit of such wrong, to have the plaintiff unlawfully compelled to work for it, and to take part therein, it was a participant in the wrong done and was a joint tort-feasor with the principal wrongdoer. 'In all cases he who maliciously procures an injury to be done to another, whether it be an actionable wrong or a breach of contract, is a joint wrongdoer, and may be sued either alone or jointly with the actor.' Civ. Code 1895, Sections 3873, 3853. 'One who aids, abets, or incites, or encourages or directs, by conduct or words, in the perpetration of a trespass, is liable equally with actual trespassers.' 28 Am. & Enc. Law (2nd Ed.) 566, 567. In 2 Add. Torts (Wood's Ed.) Section 1321, it is said: 'Whoever willfully assists in the doing of an unlawful act becomes answerable for all the consequences of such act.'"

Similarly, in Patterson vs. Prior, 81 Am. Dec. 367 (Ind., 1862) the Plaintiff prisoner had been convicted by a court without jurisdiction and his labor had been leased to the Defendant. The appellate court held that a tort is committed by one accepting labor forced on the Plaintiff and that the employer was presumed to know the state law. It was further held that Plaintiff could waive the tort and sue in assumpsit; because the person utilizing his labor and benefiting from it was deemed to have assented to its performance. The court held that the law implies a promise to pay for such labor what it is reasonably worth and affirmed a judgment for the Plaintiff against the lessee of the Plaintiff's labor. In the words of the Court at page 442:

> "At the time the appellee was convicted and sent to the penitentiary, the court of common pleas had no jurisdiction in that behalf; hence the conviction and judgment were nullities, and furnish appellants no protection for the tort committed in confining him in the penitentiary. Patterson vs. Crawford, 12 Ind. 241. The appellants must be presumed to have known the law, and that they had no legal right to imprison the appellee, or cause him to labor. That they may have been responsible to him in some form cannot be doubted. They undoubtedly committed a tort, and the question here is whether the tort can be waived, and an action maintained on an implied assumpsit? We will first examine this question so far as it relates to Patterson. He, it seems, was the lessee of the penitentiary, and received all the benefit of the appellant's labor. He must be presumed to have assented to the performance of the labor, and, being benefited, thereby, the law implies a promise to pay what it is reasonably worth. * * * In our opinion, so far as Patterson is concerned, the tort may be waived, and an action be maintained on the implied assumpsit. The case, however, is entirely different as to Miller, the warden of the penitentiary. He received no benefit of the plaintiff's labor, and not having been benefited, there is, as to him, no consideration to support an implied assumpsit to pay."

See also Tenn. Coal, Iron & R. Co. vs. Butler, 65 So. 804 (Ala. 1914).

In the instant case, even though the detention of plaintiffs was legal, the members of the Michigan Department of Corrections as well as the Department of Corrections as such committed a tortious act in depriving plaintiffs of property by illegally utilizing their labor for the private profit making purposes of said drug companies. This agreement and the act of such utilization, known to be illegal by defendant, is actionable by plaintiffs.

E. The Basis of the District Court's Ruling

The District Judge granted summary judgment to Defendants on Count III on two grounds. The first was that, in

his opinion, the relevant Michigan Statutes governing prison industries do not give rise to a claim for damages; and that a Plaintiff must first demonstrate he falls within the class of persons a criminal statute was intended to protect before he can base a civil action for damages on its violation, citing Wyandotte Co. v. United States, 389 U.S. 191 (1967). (213a)

The Wyandotte case sets forth three criteria which must be met before a civil damage remedy will be implied in a statute where it is not expressed. Those three criteria are the following:

1. Criminal liability is inadequate to insure the full effectiveness of the statute.

2. The interests of the Plaintiffs fall within the class that was intended to be protected by the statute.

3. The harm that had occurred was of the type that the statute was intended to forestall.

Even though Appellants do not rely on any such "statutory cause of action", it seems that all those requirements are present in this case.

First of all, it is patently clear that the potential criminal liability under the Prison Industries Act is inadequate to insure its full effectiveness. The very existence of the arrangement being questioned here is plain proof of that.*

* It is interesting to note that throughout all of the pleadings and the arguments in this case, never once have Defendants' counsel asserted that the arrangement is lawful under the applicable Michigan statutes.

It is also interesting that an attempt by a prisoner to halt the conduct complained of through mandemus was ineffective and denied by the Michigan Courts.

Mink vs. Parke Davis Company, Mich Court of Appeals No. 2684, Order of Nov. 21, 1966; Leave to appeal denied, 379 Mich 773 (1967); Cert Denied, 392 U.S. 934 (1968.

Further, the harm that has occurred is exactly the type of harm that the statute was intended to forestall, and, finally, it seems to Plaintiff inmates for the reasons already stated that they are a major concern of the legislation in question and that, for at least some purposes, their interests fall within the class of interests that the statute was intended to protect.

Be that as it may, Appellants do not rely on a cause of action stated by the statute but rather are suing under the common law. However, violation of the Act by Defendant drug companies does establish that their conduct is illegal, thus establishing that one element of Plaintiffs' common law cause of action does exist. It is similar to the situation where a violation of a statute governing the operation of automobiles may establish a breach of duty in a negligence action. The statute does not establish the cause of action but its violation is evidentiary on an element of that cause of action.

The second ground of the District Court's decision was that even if the utilization of Plaintiffs' labor was illegal, such utilization did not deprive them of any property to which they were entitled. The Court based this conclusion on the belief that the labor of inmates lawfully incarcerated belongs to the prison officials of the State and he relied for this belief, in part, on Huntley vs. Gunn Manufacturing Company, Supra.

For the reasons already stated, Appellants simply do not agree with this broad statement of the law. Rather, the labor of the inmates belongs to the State of Michigan only insofar

as that labor has been legally requisitioned by the State. This right of the inmates does not come from Section 5 of the Michigan Prison Industries Act, but from the right of every person to the fruits of their labor unless it is legally taken away. One authority has stated that right as follows:

> "It has repeatedly been held that the right of the laborer to enter into contracts for his services is property within the meaning of the constitutional guaranties; that the constitutional right of every man lawfully to acquire property includes the right of making contracts for personal services as a means of acquiring property; and that each person is entitled to make such contracts in reference to such lawful business or occupation as he may choose, free from hindrance or obstruction by his fellow men, except for the protection of equal or superior rights on their part. The constitutional right to liberty also embraces the right to contract regarding employment. The right of a workman freely to use his hands and to use them for whom he pleases, upon such terms as he may choose, is an absolute right, of which he cannot be deprived. Every man may engage to work for or to deal with, or to refuse to work for or to deal with, any man or class of men, as he sees fit, whatever his motive or the resulting injury, without being held in any way accountable therefor. A laborer, then, has a right, under the law, to full freedom in disposing of his own labor according to his own will, and at terms agreeable to him, except so far as this right may be restricted by valid statutes enacted in the exercise of the police power of a state. Moreover, the right to dispose of the compensation received under contracts of labor, is, under ordinary circumstances, a property right within the constitutional guaranties." (48 Am. Jur. 2d: Labor and Labor Relations, Sec. 8, page 55 (1970).

Insofar as the Huntley case deviates from this principle, Appellants believe it is in error and it should be noted that the theory of

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Count III of the amended complaint issued herein was not even raised or argued in the Huntley case.

It is admitted that in this case the labor of Plaintiffs was furnished by the Department of Corrections for utilization by Defendant drug companies, and further that said companies knowingly accepted the benefits of that labor which accrued in substantial fashion to their economic interests and that of their shareholders. Moreover, the Michigan Department of Corrections also benefited significantly by the acquisition of two buildings with an original cost of roughly five hundred fifty thousand dollars and with undoubtedly a much bigger replacement cost today. There can be no misunderstanding of the law with regard to such contracts for the usage of prison labor in this State because of the explicitness of the statutory references already detailed above. Having knowingly and illegally accepted the direct benefits of Plaintiffs' labor (as well as those accruing therefrom in the case of the Department of Corrections) Defendants are responsible to pay Plaintiffs the reasonable value thereof.

The District Court erred in granting Defendants' motion for summary judgment as to Count III; and further, under the undisputed facts as noted above Appellants believe that their motion for summary judgment as to liability only under Count III should have been granted.

V.

DID THE DISTRICT COURT ERR IN GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO COUNT IV OF PLAINTIFFS' AMENDED COMPLAINT, BECAUSE EVEN ASSUMING THE ILLEGAL USE OF PLAINTIFFS' LABOR CONTRARY TO MICHIGAN LAW, THEY SUFFERED NO DENIAL OF FEDERALLY PROTECTED RIGHTS?

The District Court answered "No".

The Appellants say "Yes".

The Appellees say "No".

Under Count IV of their amended complaint, Plaintiff inmates seek recovery for violation of their constitutional rights under the Thirteenth and Fourteenth Amendments. In Paragraph 10 of Count I of Plaintiffs' amended complaint, Plaintiffs alleged:

> ". . . All of the acts and actions complained of by Plaintiffs were accomplished by the agreement and cooperation of all the Defendants, both corporate and individual, named herein; and the illegal utilization of Plaintiffs' labor inured to the benefit of all Defendants. Further, said actions constituted in fact or in law an attempt to evade, avoid and violate the laws of the State of Michigan regarding the use of prison labor for private profit and the laws of Michigan and the United States regulating the minimum wage to be paid for labor." (61a)

In granting Defendants' motion for summary judgment on Count IV, the District Judge held that assuming Defendants used

Plaintiffs' labor contrary to Michigan law and acted under colour of state law in so doing, "Plaintiffs have suffered no denial of federally protected rights". (221a) The Court relied primarily on the language of the Thirteenth Amendment in connection with the claim of involuntary servitude and on the cases of Draper vs. Rhay, 315 F.2d 193 (9th Cir., 1963); and Sigler vs. Lowrie, 404 F.2d 659 (8th Cir. 1968) in reaching this conclusion. Appellants begin from the basic assumption that the right of an individual to the fruits of his own labor belongs to him alone and is a consitutionally protected property right under the Fourteenth Amendment except to the extent it is lawfully taken away from him. The residue of that right after part of it is carved out and given to the state by applicable state law, belongs to the prisoner.

Appellants do not disagree with the broad generalization contained in Draper vs. Rhay supra, that:

> "There is no federally protected right of a state prisoner not to work while imprisoned after conviction, even though that conviction is being appealed."

Nor do they argue that being imprisoned in the State Penitentiary rather than the County Jail necessarily involves violation of a prisoner's constitutional rights, which also was the holding of the last cited case. Nor do they take issue with the statement of Judge Freeman at page 39 of his memorandum opinion in this case, wherein he states:

> "Yet, merely because penal officials have treated state prisoners at variance with the applicable state law does not, in itself, constitute a violation of the due process or equal protection rights of those prisoners." (219a)

The trouble with that statement is that it doesn't go far enough to cover this case. What Appellants are saying is that in this case Plaintiff inmates have been treated at variance with state law and that as a result of that treatment they have been deprived of a constitutionally protected right, namely, the right to dispose of their labor as they please except to the extent that it has been lawfully taken away from them. Obviously, there are many other cases where treating prisoners at variance with state law would constitute a violation of due process, depending on the particular treatment involved and rights violated.

Judge Freeman stated at page 40:

> "A failure, however, to pay plaintiffs for their labor in the clinics at its reasonable value is not a denial of such a fundamental Constitutional right. Sigler v. Lowrie, supra at 661." (220a)

In Sigler vs. Lowrie the Court of Appeals for the Eighth Circuit found that the Warden of a Nebraska State Penitentiary did not act improperly in taking a prisoner's pay to reimburse the State of Nebraska for certain expenses resulting from his escape and return to prison. However, in that case, the Court was careful to point out that the monies used by the Warden had never taken on vested characteristics to the prisoner, stating:

> "However, prospective cancellation of a conditional grant, although seemingly inconsistent with the intent of the statute, is nevertheless not a deprivation of a federal constitutional right. The statutory provision for cancellation makes explicit that the 'spending account' never takes on vested characteristics. And assuming the prisoner's cancellation of a future credit is in violation of the statute, this does not properly state a claim for relief under the Civil Rights Act."

* * *

> "It is true that the attorney general stipulated that the warden did not 'cancel' the credit but actually 'fined' the prisoner. However, we feel, in view of the fact that the prisoner's vested interests are not involved, the effect of the warden's action is to 'fine' the prisoner by merely cancelling his conditional credit. As to the plane expense, no money exchanges hands, it is a bookkeeping credit only which is cancelled. In this instance it is not the choice of words but the measured action induced which becomes relevant. When such action fails to encroach upon federal rights an essential ingredient of our jurisdiction is missing."

The Court clearly seemed to indicate that if the state law had given the prisoner an absolute right to the money or a vested right to the money as opposed to only a conditional right, his constitutional rights would have been violated. It is Appellants' claim that Plaintiff inmates in this case have a vested right to the fruits of their own labor, a right not given by state law but given by the Federal Constitution; and further that to the extent the state deprives them of it illegally, it has violated their Federal Constitutional rights. (Lee vs. Washington, 390 U.S. 333, 1968; Wright v. McMann, 389 F.2d 519, 2d Cir. 1967; Cooper vs. Pate, 378 U.S. 546, 1964). Regardless of whether the state has the power to take all of the rights of a prisoner to his own labor, in the State of Michigan, the legislature has not done so. The District Court erred in granting summary judgment for Defendants as to Count IV of Plaintiffs' amended complaint.

CONCLUSION

Appellants, therefore, ask this Court to reverse the order of the District Court that this action cannot be maintained as a class action, and granting summary judgment to Defendants on all counts of Plaintiffs' amended complaint. Further, Appellants ask this Court to find that Plaintiffs are entitled to summary judgment as to liability only under Count III and to remand this case to the District Court for trial on damages only or in the alternative to remand the case for a trial on all four counts of the amended complaint.

Respectfully Submitted,

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ADDENDUM CONTAINING RELEVANT STATUTORY PROVISIONS AND RULES

The provisions of Titles 18 and 29 of the United States Code which are involved (in relevant part) are as follows:

> "(a) Whoever knowingly transports in interstate commerce or from any foreign country into the United States any goods, wares, or merchandise manufactured, produced, or mined, wholly or in part by convicts or prisoners, except convicts or prisoners on parole or probation, or in any penal or reformatory institution, shall be fined not more than $1,000 or imprisoned not more than one year, or both.
>
> (b) This chapter shall not apply to agricultural commodities or parts for the repair of farm machinery, nor to commodities manufactured in a Federal, District of Columbia, or State institution for use by the Federal Government, or by the District of Columbia, or by any State or Political subdivision of a State." (18 U.S.C., Sec. 1761)

> "(d) 'Employer' includes any person acting directly or indirectly in the interest of an employer in relation to an employee but shall not include the United States or any State or political subdivision of a State (except with respect to employees of a State, or a political subdivision thereof, employed (1) in a hospital, institution, or school referred to in the last sentence of subsection (r) of this section, or (2) in the operation of a railway or carrier referred to in such sentence), or any labor organization (other than when acting as an employer), or anyone acting in the capacity of officer or agent of such labor organization.
>
> (e) 'Employee' includes any individual employed by an employer, except that such term shall not, for the purposes of subsection (u) of this section include--

(1) any individual employed by an employer engaged in agriculture if such individual is the parent, spouse, child, or other member of the employer's immediate family, or
(2) any individual who is employed by an individual (A) is employed as a hand harvest laborer and is paid on a piece rate basis in an operation which has been, and is customarily and generally recognized as having been, paid on a piece rate basis in the region of employment, (B) commutes daily from his permanent residence to the farm on which he is employed, and (C) has been employed in agriculture less than thirteen weeks during the preceding calendar year.

(g) 'Employ' includes to suffer or permit to work." (29 U.S.C., Sec. 203 (d), (e), (g))

Provisions of Title 17 and Title 28 of the Michigan Statutes Annotated which are involved (in relevant part) are as follows:

"Definitions. As used in this act:
* * * * * * *
(b) 'Employee' means an individual between the ages of 18 and 65 years employed by an employer on the premises of the employer or at a fixed site designated by the employer.
(c) 'Employer' means any person, firm or corporation, including the state and its political subdivisions, agencies and instrumentalities, (and any person acting in the interest of such employer,) who employs 4 or more employees at any one time--(within any calendar year. Such employer shall be subject to this act during the remainder of such calendar year).
(d) 'Employ' means to engage, suffer or permit to work." (17.255 (2) M.S.A.)

"Exemptions; piece rate scales. The provisions of this act shall not apply to any employer who is subject to the minimum wage provisions of the federal fair labor standards act of 1938, as amended, (except in any case where application of such minimum wage provisions would result in a lower minimum wage than provided in this act, or to persons employed in summer camps for not more than 4 months,) or to agricultural fruit growers,

pickle growers and tomato growers, or other agricultural employers who traditionally contract for the harvesting on a piecework basis, as to those employees of such employers used for such harvesting until the board shall have acquired sufficient data to determine an adequate basis for the establishment of a scale of piecework and shall determine such a scale equivalent to the prevailing minimum wage for such employment, which determination shall occur no later than (May 1, 1967, Such piece rate scale shall be equivalent to the minimum hourly wage in that when the payment by unit of production is applied to a worker of average ability and diligence in harvesting a particular commodity he shall receive an amount not less than the hourly minimum wage)." (17.255 (14) M.S.A.)

"Same; unlawful sales of prison products or labor; exceptions, prices.) From and after 60 days after this act shall become law it shall be unlawful to sell or exchange or to offer for sale or exchange, or to purchase any prison products, except pure bred livestock raised on the several prison farms and sold for breeding purposes, otherwise than for use or consumption in the penal, charitable and/or other custodial institutions of this state or for departments of this state, or political subdivisions thereof, or the federal government or agencies thereof, or otherwise as specifically provided in this act; nor shall the labor of prisoners be sold, hired, leased, loaned, contracted for or otherwise used for private or corporate profit or for any other purpose than the construction maintenance or operation of public works, ways, or property as directed by the governor; except that the prisoners of a county or of a city may be used on the public works, ways or property of said county or city as directed by the constituted authority thereof: Provided, That nothing in this act shall be deemed to prohibit the sale at retail, of articles made by prisoners for the personal benefit of themselves or their dependents, or the payment to prisoners for personal services rendered in the penal institution subject to regulations approved by the prison commission, or the manufacture, sale or purchase of binder twine, rope and cordage used in agricultural

production: Provided, That in no case shall any prison products be sold or offered for sale at a price below cost of production which cost of production shall include materials, labor, supervision, distribution and selling, heat, light, power and all other expenses connected therewith." (28.1525 M.S.A.)

"Intent of Act. It is hereby declared to be the intent of this act: (a) to provide adequate, regular, diversified and suitable employment for prisoners of the state consistent with proper penal purposes;
(b) to utilize the labor of prisoners exclusively for self-maintenance and for reimbursing the state for expenses incurred by reason of their crimes and imprisonment;
(c) to eliminate all competitive relationships between prisoner labor or prison products and free labor or private industry;
(d) to effect the requisitioning and disbursement of prisoner labor and prison products directly through established state authorities with no possibility of private profits therefrom and with the minimum of intermediating financial considerations, appropriations or expenditures; and to these ends
The governor shall require the state purchasing agent, or his successor, to establish suitable methods of purchasing and of accounting which shall provide as may be necessary or advisable
(e) for the purchasing and supply on account of the consuming institutions and/or departments, separately or collectively, of supplies and materials necessary for the prison manufacture or production of the prison products requisitioned therefor in accordance with sections four (4), five (5) and six (6) of this act.
(f) for crediting prison accounts and debiting accounts of consuming institutions or departments for products requisitioned and disbursed, at prices fixed to indicate fairly the true costs of maintenance and efficiency of management of said prisons, institutions and departments: Provided, That said prices of the requisitioning or disbursement of said prison products shall in no case be determined by or contingent upon competitive bidding from other sources;

(g) for the purchase of all commodities or requirements other than prison products as provided for in this act, by competitive bidding or other methods established by law or approved practice: Provided, That no bids may be asked or received except for commodity requirements which it has been definitely decided shall not be supplied by requisitioning of prison products as hereinbefore provided." (28.1530 M.S.A.)

"Prisoner on parole; legal custody; warrant for return; parole violators as escaped prisoners; forfeiture of good time; conviction and sentence for crime committed on parole, treatment as to last incurred term; parole as permit.) Sec. 38. Every prisoner on parole--shall remain in the legal custody and under the control of the commission. The assistant director of the bureau of pardons and paroles is hereby authorized, at any time in his discretion and upon a showing of probable violation of parole, to issue a warrant for the return of any paroled prisoner to any penal institution in the state under the control of the commission. Pending hearing--upon any charge of parole violation, the prisoner shall remain incarcerated in such penal institution.

A prisoner violating the provisions of his parole and for whose return a warrant has been issued by the assistant director of the bureau of pardons and paroles shall, after the issuance of such warrant, be treated as an escaped prisoner owing service to the state, and shall be liable, when arrested, to serve out the unexpired portion of his maximum imprisonment, and the time from the date of--(the) declared--(violation) to the date of his-(availability for return to any penal institution under the control of the commission) shall not be counted as any part or portion of the time to be served. The warrant of the assistant director of the bureau of pardons and paroles shall be a sufficient warrant authorizing all officers named therein to-(detain) the paroled prisoner--(in any jail of the state until his return to any penal institution under the control of the commission can be effected).

If any paroled prisoner shall fail to return to the prison enclosure when required by the assistant director of the bureau of pardons and paroles, or if he makes escape while on parole, he shall be treated in all respects as if he had escaped from the prison enclosure, and shall be subject to be retaken as provided by the laws of this state.

The parole board, in its discretion, may cause the forfeiture of all good time to the date of the declared--(violation).

Any prisoner committing a crime while at large upon parole and being convicted and sentenced therefor shall be treated as to the last incurred term, as provided under section 34.

A parole granted a prisoner shall be construed simply as a permit to such prisoner to go without the enclosure of the prison, and not as a release, and while so at large he shall be deemed to be still serving out the sentence imposed upon him by the court, and shall be entitled to good time the same as if he were confined in prison." (28.2308 M.S.A.)

The provisions of Rules 8 and 23 of the Federal Rules of Civil Procedure which are involved (in relevant part) are as follows:

"(b) Defenses; Form of Denials. A party shall state in short and plain terms his defense to each claim asserted and shall admit or deny the averments upon which the adverse party relies. If he is without knowledge or information sufficient to form a belief as to the truth of an averment, he shall so state and this has the effect of a denial. Denials shall fairly meet the substance of the averments denied. When a pleader intends in good faith to deny only a part or a qualification of an averment, he shall specify so much of it as is true and material and shall deny only the remainder. Unless the pleader intends in good faith to controvert all the averments of the preceding pleading, he may make his denials as specific denials of designated averments or paragraphs, or he may generally deny all the averments except such

designated averments or paragraphs as he expressly admits; but, when he does so intend to controvert all its averments, including averments of the grounds upon which the court's jurisdiction depends, he may do so by general denial subject to the obligations set forth in Rule 11." (28 F.R.C. Rule 8 (b))

"(a) Prerequisites to a Class Action. One or more members of a class may sue or be sued as representative parties on behalf of all only if (1) the class is so numerous that joinder of all members is impracticable, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class." (28 F.R.C. Rule 23 (a) Supp.))