OUT OF LINE:
Hepatitis C Treatment Protocols in the California Department of Corrections

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CONTENTS

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Executive Summary

California Prison Focus[1] presents this report to assess the present treatment offered by the California Department of Corrections (CDC) to the estimated 68,000 prisoners suffering with hepatitis C in this state.

The hepatitis C protocols of the CDC, developed in response to the *Plata v. Davis* and *Madrid v. Gomez* litigation, deviate in several important regards from the current medical standard of care for hepatitis C. This paper discusses the CDC's hepatitis C management protocols, identifies their principal deficiencies, and makes recommendations for improvements. While the CDC provides medical treatment at the ordinary standard of care to select inmates, the CDC falls below the ordinary standard of care in its systematic use of exclusionary categories to deny care to patients who would be eligible, and who would receive individualized consideration for treatment, if they were outside the prison gates. The most serious deviations from the medical consensus on care for hepatitis C patients are:

> (1) The CDC excludes HIV-negative patients with stage 1 or 2 fibrosis from receiving combination therapy. In the outside world, a liver biopsy with stage 2 fibrosis is a strong indicator that a patient should receive therapy. Patients with stage 1 fibrosis should be considered for therapy on an individual basis.
>
> (2) The CDC denies biopsies to patients with normal liver enzyme levels, despite a NIH finding that the diagnostic value of liver enzyme tests has not been well documented. The AASLD agrees that therapy is proper in some cases for patients with persistently normal enzyme levels.
>
> (3) The CDC denies therapy to individuals with a history of substance abuse in the past 6-12 months, despite the NIH's endorsement of treatment for current drinkers and drug users. According to the NIH, treatment of injection drug users is especially valuable because of its potential to reduce disease transmission.

[1] California Prison Focus is a fifteen-year-old non-profit organization dedicated to defending and advancing the human and civil rights of prisoners.

(4) CDC protocols refuse re-treatment to patients who have not responded to an initial course of therapy, despite an NIH finding that re-treatment is proper in at least some instances.

CPF's key recommendations:

- The CDC should amend its policies so that stage 2 fibrosis is a strong factor in favor of treatment.

- The CDC should provide individualized consultations for patients with stage 1 fibrosis, normal ALT levels, substance abuse problems, and previous nonresponders. These patients, like all patients with hepatitis C, should receive individualized treatment decisions based on the condition of the liver, the potential side effects of treatment, the likelihood that treatment will be effective, and the presence of comorbid conditions.

I. Background on HCV

Hepatitis C is an inflammation of the liver caused by the Hepatitis C Virus (HCV). The disease has infected approximately 4 millions persons in the United States, of whom 2.7 million are chronically infected. Left untreated, hepatitis C can lead to cirrhosis, decompensated liver disease, liver cancer, and death.[2] It is presently the number-one cause of liver transplantation in the United States and causes 10,000 to 12,000 deaths every year.[3]

According to the Bureau of Justice Statistics, between 27 and 33 percent of state prison inmates are infected with hepatitis C nationwide.[4] In California, a UCSF study found that the HCV incidence among new parolees is 41.5%.[5] This indicates that, out of California's prison population of 163,939, approximately 68,000 have hepatitis C. Since

[2] Salomon, Weinstein, Hammitt and Goldie, *Cost-effectiveness of Treatment forChronic Hepatitis C Infection in an Evolving Patient Population*, in Journal of the American Medical Association [JAMA] (vol. 290, no. 2), July 9, 2003.
[3] *Management of Hepatitis C: 2002*. NIH Consens State Sci Statements. 2002 Jun 10-12; 19(3) 1-46, 11.
[4] *The Inmate Healthcare Challenge: Fixing a Broken System in Light of the Deukmejian Report.* Background Briefing Paper for a Joint Hearing of the Senate Select Committee on the California Correctional System (September 29, 2004), p. 2.
[5] Page-Shafer, Wright, Fox, Currie, Gobidas and Tracy, *HEPCAP II: Hepatitis C in the California Prisons Project.* Center for AIDS Prevention Studies (2004). www.caps.ucsf.edu/pdfs/2004portfolio/Hepcap2.pdf

105,298 CDC prisoners are expected to be paroled from July 2004 to June 2005,[6] this translates into 43,700 prisoners returned to society with hepatitis C this year.

Hepatitis C infection can be acute or chronic. An acute infection disappears in a patient without any treatment a short time after infection, for unknown reasons. When HCV genetic material is detected in a patient's blood for a period of six months that person is diagnosed with chronic HCV infection. Approximately 60 to 85 percent of HCV-infected persons develop chronic infection.[7] It is chronic hepatitis C infection which endangers a patient's health and requires monitoring and treatment.

Even chronic HCV usually progresses very slowly in causing liver damage. Twenty years after infection, approximately 10 to 15 percent of patients will develop liver cirrhosis, a dangerous and often fatal condition. However, many factors increase the risk of cirrhosis, including older age at time of infection, male gender, concurrent infection with HIV or hepatitis B, alcohol use equivalent to 2 beers per day, toxic environmental conditions, taking medications toxic to the liver, and various medical conditions.

HCV manifests six major variations in its genetic code, which are known as genotypes 1 through 6. Genotype 1 accounts for 70 to 75 percent of HCV infections and is the most difficult to treat.[8]

II. CDC Protocols for Prisoners with Hepatitis C

Because of the prevalence of hepatitis in prisons, many states and the federal Bureau of Prisons have adopted written protocols for hepatitis treatment. In March 2004,

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[6] CDC Population Projections Unit, *Population Projections 2004-2009* (Spring 2004), Tables 13-14. www.corr.ca.gov/OffenderInfoServices/Reports/Projections/S04Pub.pdf
[7] *Inmate Healthcare Challenge*, *supra* note 4, p. 10.
[8] *Management of Hepatitis C: 2002*, *supra* note 3.

pursuant to the requirements of a federal lawsuit—*Plata v. Davis*—CDC's Health Care Services Division published policies and procedures for the diagnosis, monitoring and treatment of hepatitis C, in a document titled *Hepatitis C Clinical Management Program* (HCCMP). HCCMP's stated purpose is to ensure "a consistent, appropriate, effective, and efficient approach to the clinical management of persons infected with HCV."[9] The Program divides management of HCV into three phases, corresponding to screening and initial diagnosis (phase I); initial management after diagnosis (phase II); and staging by liver biopsy and combination therapy (phase III). Its policies and procedures govern all prisoners under custody of the CDC, except for those at Pelican Bay State Prison.

Prisoners at Pelican Bay are subject to the *Madrid v. Gomez* litigation rather than *Plata*, and they are covered by a separate document, the Pelican Bay Hepatitis C Program Policy (PBHCPP). The Pelican Bay policy, which resembles the HCCMP in many respects, was approved by Judge Thelton Henderson on June 27, 2002.[10]

The hepatitis C protocols of the California Department of Corrections developed in response to the *Plata* and *Madrid* litigation deviate in several important regards from the current medical standard of care for hepatitis C. While the CDC provides medical treatment at the ordinary standard of care to the inmates whom it decides to treat, the CDC falls below the ordinary standard of care in its systematic use of categories of exclusion to deny care to patients who would be eligible, and who would receive individualized consideration for treatment, if they were outside the prison gates. The most notable deviations from the medical consensus on care for hepatitis C patients are as follows:

[9] California Department of Corrections, Health Care Services, *Hepatitis C Clinical Management Program* (March 2004), p. 1.
[10] Hagar, John. *Special Master's Notice to Inmates Concerning Hepatitis C Disease* (July 2, 2002), p. 7.

(1) the denial of treatment to HIV-negative patients with Stage 2 fibrosis;

(2) the denial of biopsy or treatment to patients under 45 who lack elevated ALT levels;

(3) the denial of treatment to patients with current or recent substance abuse histories;

(4) the denial of retreatment to nonresponders.

A. HCCMP Phase I: Screening and Initial Diagnosis

Various tools are available to diagnose and monitor HCV infections. A gateway test is the enzyme immunoassay (EIA) test, which detects antibodies to HCV. Positive EIA results indicate that a person has been exposed to the virus at some time. Next, various blood tests are available to detect the presence and quantity of the virus itself (viral load tests) and healthy liver function (ALT tests). The ALT test measures levels of alanine aminotransferase, a liver enzyme whose presence at elevated levels in the bloodstream indicates liver damage. A biopsy—the extraction of a small piece of liver for testing—is more invasive, but it is the best method for detecting structural changes to the liver caused by hepatitis.[11]

CDC protocols require that HCV screening be made available to patients who request it, and that HCV screening be offered to patients with a history of intravenous drug use or other risk factors. The screening begins with hepatitis antibody tests and ALT liver function tests. No copayment is assessed for the screening. All patients who test positive for HCV antibodies are then given viral load tests and, sometimes, a second ALT test. The anticipated time period for a prisoner to complete screening and initial diagnosis is three months.[12]

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[11] *Management of Hepatitis C: 2002, supra* note 3, pp. 12-15.
[12] *Hepatitis C Clinical Management Program, supra* note 9, pp. 1-2.

The selectiveness of CDC's screening procedure for HCV is controversial. Because of the high prevalence of hepatitis among prison inmates, some states subject all incoming prisoners to hepatitis C testing. Indiana, for example, requires mandatory screening of all incoming prisoners for HCV and HIV.[13] The Centers for Disease Control recommends expanded or universal testing of inmates when the prevalence of risk factors for infection is greater than 75%, and a high prevalence of HCV exists among inmates who deny risk factors.[14]

B. HCCMP Phase II: Initial Management After Diagnosis of HCV

After a patient has been diagnosed with hepatitis C, s/he enters phase II of the HCCMP. In phase II, the patient receives information about hepatitis C, receives vaccinations against hepatitis A and B, and is evaluated to determine whether s/he qualifies for a liver biopsy. Qualifying patients are counseled about the biopsy requirement, available medical treatments, possible side effects, and likelihood of treatment success. Phase II generally lasts for approximately two months.[15]

During phase II, several categories of patients are disqualified for liver biopsy and treatment. For example, patients under 45 years of age are subjected to monthly ALT tests for three months; if none of the tests show ALT levels at least two times normal, they are not eligible for treatment. Other patients ineligible for biopsy and treatment include patients who will be unable to complete a course of therapy prior to their release date. Because the length of medical treatment depends on the genotype of hepatitis C with which a patient is afflicted, patients with genotype 2 or 3 HCV are ineligible for

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[13] Allen, Scott. *Developing a Systematic Approach to Hepatitis C for Correctional Systems: Controversies and Emerging Consensus* (April 2003). www.idcronline.org/archives/april03/mainarticle.html

[14] Centers for Disease Control and Prevention. *Prevention and Control of Infections with Hepatitis Viruses in Correctional Settings.* MMWR 2003; 52 (No. RR-1): 1-34, 24.

[15] *Hepatitis C Clinical Management Program*, *supra* note 9, pp. 2-4.

treatment if they will be released within ten months of referral for biopsy. Patients with genotype 1, 4 or 6 HCV are ineligible for treatment if they will be released within sixteen months of biopsy referral. Patients are also ineligible for treatment if they have various medical or psychological conditions, if they have a recent history of high-risk behaviors, if they are unable to cooperate with treatment or give informed consent, if they are greater than 60 years old, or if they are pregnant.[16]

Problem #1: Denying Diagnosis and Treatment to Patients with Normal ALT Levels

> ***CDC Deviation from the Ordinary Standard of Care: The blanket exclusion from treatment of patients under 45 without elevated ALT levels is not supported by current medical literature, which recommends individualized therapy decisions that look to ALT levels as only one factor in making a therapy decision.***
>
> ***CPF Recommendation: Because CDC's policy of denying biopsy to patients with normal or slightly elevated ALT levels does not conform with the current medical consensus on treatment of hepatitis C, the policy should be abolished.***

The blanket exclusion from treatment of patients under 45 without elevated ALT levels is not supported by current medical literature, which recommends individualized therapy decisions that look to ALT levels as only one factor in making a therapy decision. According to the National Institutes of Health 2002 Consensus Statement on Management of Hepatitis C, ALT levels are a "relatively insensitive" means of assessing disease activity:

> A single determination of ALT level gives limited information about the severity of the underlying liver disease. In most studies, a weak association exists between the degree of ALT elevation and severity of the histopathological findings on liver biopsy. Serial determinations of ALT levels over time may provide a

[16] *Id.*, Attachment C: Exclusion Criteria for Combination Therapy.

> better means of assessing liver injury, but the accuracy of this approach has not been well documented.[17]

Even for patients with normal levels of ALT liver enzymes, the NIH recommends liver biopsy as an invaluable source of information for making informed treatment decisions:

> Liver biopsy provides a unique source of information on fibrosis and assessment of histology. Liver enzymes have shown little value in predicting fibrosis. . . . Moreover, only liver biopsy provides information on possible contributions of iron, steatosis, and concurrent alcoholic liver disease to the progression of chronic hepatitis C toward cirrhosis. Although unexpected etiologies of liver disease are rarely discovered on liver biopsies from patients undergoing evaluation of chronic hepatitis C, the information obtained on liver biopsy allows affected individuals to make more informed choices about the initiation or postponement of antiviral treatment. Thus, the liver biopsy is a useful part of the informed consent process.[18]

The American Association for the Study of Liver Diseases (AASLD) concurs that ALT levels should not be used to withhold a biopsy or therapy, making the recommendation that

> Regardless of the serum aminotransferase levels, the decision to initiate therapy with interferon and ribavirin should be individualized based on the severity of liver disease by liver biopsy, the potential of serious side effects, the likelihood of response, and the presence of comorbid conditions.[19]

Because CDC's policy of denying biopsy to patients with normal or slightly elevated ALT levels does not conform with the current medical consensus on treatment of hepatitis C, the policy should be abolished.

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[17] *Management of Hepatitis C: 2002, supra* note 3, p. 14.
[18] *Id*., p. 15.
[19] Strader, Wright, Thomas, and Seeff, *Diagnosis, Management, and Treatment of Hepatitis C.* Hepatology (vol. 39, no. 4) April 2004, 1147, 1157.

Problem #2: Withholding Treatment from Patients with Substance Abuse Histories

> ***CDC Deviation from the Ordinary Standard of Care: Patients with a history of substance abuse within the past 6-12 months are excluded from treatment.***
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> ***CPF Recommendation: Because the denial of HCV treatment to patients with substance abuse problems has no therapeutic justification, CDC should abolish the policy of excluding such patients from antiviral treatment, while ensuring that those patients enjoy access to substance abuse treatment.***

CDC's hepatitis C policies are deficient because the policies exclude persons with substance abuse problems from treatment. The HCCMP denies biopsy or treatment to prisoners with "[h]istory of illicit drug use, alcohol or other substance abuse, or other high risk behaviors currently active or within the past 6-12 months."[20] This denial of care has no medical basis, according to the NIH Consensus Statement:

> Recent, albeit limited, experience has demonstrated the feasibility and effectiveness of treating chronic hepatitis C in people who use illicit injection drugs, known as injection drug users (IDUs). This is potentially important because injection drug use is the most common risk factor for new HCV infections in the United States, and successful treatment may reduce transmission. . . . HCV therapy has been successful even when the patients have not abstained from continued drug or alcohol use or are on daily methadone. . . . Thus, it is recommended that treatment of active injection drug use be considered on a case-by-case basis, and that active injection drug use in and of itself not be used to exclude such patients from antiviral therapy.[21]

Indeed, there is an emerging consensus in correctional medicine that prison is a relatively promising environment for hepatitis C treatment for substance abusers and the mentally ill:

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[20] *Hepatitis C Clinical Management Program, supra* note 9, Attachment C.
[21] *Management of Hepatitis C: 2002, supra* note 3, p. 25.

> Sobriety is largely enforced in the correctional setting, making it a more stable environment in which to contemplate medical therapy for HCV infection. . . . A history of substance abuse is no longer a contraindication for treatment of chronic HCV infection. Linking medical therapy with referral to substance abuse treatment, however, is a good idea. Still, the absence of available substance abuse treatment programs in a correctional setting should not be used to justify withholding treatment.[22]

Because the denial of HCV treatment to patients with substance abuse problems has no therapeutic justification, CDC should abolish the policy of excluding such patients from treatment.

C. HCCMP Phase III: Staging by Liver Biopsy and Combination Therapy

Phase III of the HCCMP begins after a qualifying patient signs a liver biopsy authorization. The patient's case is reviewed by the Medical Authorization Review (MAR) HCV sub-committee for approval of the biopsy. Following biopsy, the MAR sub-committee reviews a patient's file for a second time, to make a determination of whether the patient qualifies for medical treatment, in light of the biopsy results. HIV-negative patients qualify for treatment only if their biopsy results show fibrosis greater than stage 2. HIV-positive patients qualify for treatment if their biopsy results show stage 2 fibrosis or greater.[23]

The prevailing standard of care for patients with HCV genotype 1 is combination therapy with pegylated interferon and ribavirin for 48 weeks. For patients with HCV genotypes 2 or 3, the prevailing standard of care is combination therapy with standard

[22] *Developing a Systematic Approach to Hepatitis C for Correctional Systems*, *supra* note 13.
[23] *Hepatitis C Clinical Management Program*, *supra* note 9, pp. 4-7.

interferon and ribavirin for 24 weeks.[24] The CDC follows the prevailing standard of care in administering these medicines to those whom it treats.

Both interferon and ribavirin commonly cause adverse side effects. Interferon's effects include fatigue, headache, myalgias, fever and chills, insomnia, nausea, anorexia, weight loss, alopecia, irritability, depression, injection site reaction, autoimmune disease exacerbation, neutropenia, and thrombocytopenia. The effects of ribavirin include cough, shortness of breath, rash, nausea, anorexia, weight loss, hemolytic anemia, and teratogenicity. HCV treatment is not recommended for patients with decompensated liver disease, pregnancy, active autoimmune disease, severe psychiatric disease (particularly depression), hemolytic anemia, uncontrolled medical disease, poorly controlled diabetes mellitus, seizures, coronary artery disease, chronic obstructive pulmonary disease, or a history of heart failure.[25] CDC policy excludes such contraindicated persons from receiving treatment.

Problem #3: Denying Treatment to Patients with Stage 1 or 2 Fibrosis

> ***CDC Deviation from the Ordinary Standard of Care: Patients with stage 1 or 2 fibrosis are not allowed to receive treatment unless they have stage 2 fibrosis and are HIV-positive.***
>
> ***CPF Recommendation: Patients with stage 2 fibrosis should be eligible for combination therapy, and a finding that a patient has stage 2 fibrosis should weigh in favor of receiving such therapy. Patients with stage 1 fibrosis should be considered for therapy on an individualized basis.***

The Metavir scoring system identifies four stages in the liver deterioration of a patient with Hepatitis C. These stages are based on the extent of fibrous scarring, known as fibrosis. In stage 1, a patient's liver is starting to show fibrosis within the portal

[24] *Management of Hepatitis C: 2002, supra* note 3, pp. 17-18.
[25] Flamm, Steven. *Chronic Hepatitis C Virus Infection*. Journal of the American Medical Association (vol. 289, no. 18), May 14, 2003, 2413, 2416.

regions. In stage 2, fibrous bridges known as septae have developed *between* portal regions of the liver (so-called "bridging fibrosis"). In stage 3, the fibrous septae connect portal regions of the liver to central regions. In stage 4, fibrosis has proceeded to such an extent that the liver has developed cirrhosis, a condition in which the liver is no longer able to perform its usual functions. In lay terms, these four stages of liver decay correspond to mild fibrosis, moderate fibrosis, severe fibrosis, and cirrhosis. Treatment is advised where a patient's liver has developed bridging fibrosis—in other words, where the patient's liver has reached stage 2 in the Metavir system.[26]

According to CDC's *Hepatitis C Clinical Management Program*, "Inmate-patients whose liver biopsy results are consistent with stage 2 fibrosis or less, and inmate-patients who are HIV infected and whose liver biopsy results are consistent with less than stage 2 fibrosis, are currently not eligible for combination therapy. . . ."[27] Similarly, under the Pelican Bay program, "patients with Stage 1 or Stage 2 liver biopsy results are not offered medicine for HCV."[28]

The denial of medicine to patients with stage 2 fibrosis deviates from the current medical consensus. According to the Practice Guideline of the American Association for the Study of Liver Diseases, for example, "[m]ore-than-portal fibrosis on liver biopsy (Metavir $\geq$ 2 or Ishak $\geq$ 3) is an important predictor of future progression of liver disease and the need for HCV treatment."[29] Writing in the Journal of the American Medical Association, Dr. Steven Flamm argued in 2003 that

> Improvements in sustained response rates and better adverse effect management have increased the indications

[26] *Diagnosis, Management, and Treatment of Hepatitis C, supra* note 19, 1150.
[27] *Hepatitis C Clinical Management Program, supra* note 9, p. 5.
[28] *Special Master's Notice to Inmates Concerning Hepatitis C Disease, supra* note 10, p. 5.
[29] *Diagnosis, Management, and Treatment of Hepatitis C, supra* note 19, p. 1151.

> for therapeutic intervention. Patients without contraindications should be considered for therapy. . . . individuals who should strongly be considered for therapy include patients with fibrosis or cirrhosis identified on liver biopsy, patients with genotype 2 or 3, patients with symptoms (eg, fatigue), and those with extrahepatic manifestations.[30]

According to Flamm, therapy should even be contemplated "on an individual basis" for asympomatic patients with genotype 1 and no fibrosis, "particularly in young adults or in highly motivated individuals."[31]

According to the Practice Guideline of the AASLD, treatment of patients with stage 2 fibrosis is "widely accepted."[32] Where a liver biopsy indicates no fibrosis or mild stage 1 fibrosis, treatment may still be appropriate, but the decision to treat should be made on an individual basis.[33] Although the dangers to the liver of a patient with stage 0 or 1 fibrosis are relatively remote, treatment is more likely to be successful the earlier it is undertaken.

At least one leading practitioner of correctional medicine has gone on the record to state that treatment is appropriate for prisoner-patients with stage 2 fibrosis caused by HCV. According to Scott Allen, Medical Director of the Rhode Island Department of Corrections,

> "Clinically appropriate" patients include those with stage 2, 3, and compensated stage 4 liver disease. Stage 1 rapid fibrosers (as determined by serial liver biopsies) may also be considered for treatment. Treatment can safely be deferred in patients with stage 0-1 fibrosis, although the decision should be individualized and based on an informed consultation with the patient.[34]

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[30] *Chronic Hepatitis C Virus Infection, supra* note 25, p. 2416.
[31] *Id.*
[32] *Diagnosis, Management, and Treatment of Hepatitis C, supra* note 19, p. 1155.
[33] *Id.*
[34] *Developing a Systematic Approach to Hepatitis C for Correctional Systems, supra* note 13.

Other state prison systems provide treatment for patients with Stage 2 fibrosis. In the Hawaii prison system, for example, a patient with HCV genotype 1 qualifies for treatment if his liver biopsy shows "portal or bridging fibrosis and at least moderate inflammation and necrosis (Stage 2 or 3)."[35] Patients with HCV genotypes 2 or 3 receive treatment regardless of the stage of their fibrosis.

Problem #4: Denying Re-treatment to Relapsers and Non-responders

> ***CDC Deviation from the Ordinary Standard of Care: Patients who do not respond to an initial course of combination therapy are withdrawn from therapy and categorically excluded from later treatment.***
>
> ***CPF Recommendation: Nonresponding and relapsing patients should be considered for retreatment on a case-by-case basis, in accord with the findings of the NIH Consensus Statement.***

Although treatment for HCV genotype 1 lasts for 48 weeks, the efficacy of treatment can be predicted from the decrease in viral levels in a patient's bloodstream at week 12. The goal of treatment is for a patient to achieve a sustained virologic response (SVR), defined as the absence of HCV in the bloodstream at the end of treatment and six months later. Patients with HCV genotype 1 who achieve an SVR almost always first experience a dramatic reduction in the amount of virus in their blood at week 12. This reduction is known as an early virologic response (EVR). Of those patients who do not have an EVR by week 12, 97% will not achieve an SVR at the end of treatment.[36] Thus, it is standard medical practice to test genotype 1 patients at week 12 to see if they have had an EVR. For patients who have not had an EVR, known as non-responders, therapy

[35] State of Hawaii Department of Public Safety, Health Care Division, *Hepatitis C Screening and Treatment Guidelines* (11/04 update).
[36] *Diagnosis, Management, and Treatment of Hepatitis C, supra* note 19, p. 1154.

is often discontinued. Patients who achieve an SVR at the end of treatment but show HCV in the bloodstream six months later are known as relapsers.

The CDC follows the practice of testing genotype 1 patients three months into combination therapy to determine virologic response. Those patients who do not demonstrate an EVR are thereafter excluded from treatment. According to the HCCMP, "[i]nmate-patients who previously received appropriate combination therapy for HCV but relapsed, or who did not respond to the therapy are currently not candidates for re-treatment."[37]

The CDC's exclusion from re-treatment of relapsers and non-responders does not conform to the ordinary standard of care. According to the NIH Consensus Statement,

> Selected patients who fail to achieve an SVR may benefit from re-treatment with pegylated interferon-based regimens. Decisions regarding re-treatment should be based on (1) previous type of response, (2) the previous therapy and the difference in potency of the new therapy, (3) the severity of the underlying liver disease, (4) viral genotype and other predictive factors for response, and (5) tolerance of previous therapy and adherence.[38]

For example, a patient with HCV genotype 2 or 3 who did not respond to standard interferon plus ribavirin is apparently excluded from retreatment under the HCCMP. The American Association for the Study of Liver Diseases recommends that such patients receive individualized consideration to determine whether they might benefit from an additional course of treatment.[39]

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[37] *Hepatitis C Clinical Management Program, supra* note 9, p. 3.
[38] *Management of Hepatitis C: 2002, supra* note 3, p. 19.
[39] *Diagnosis, Management, and Treatment of Hepatitis C, supra* note 19, pp. 1155, 1156.

Conclusion

CDC medical protocols deviate from the current standard of care for treatment of patients with hepatitis C in four crucial respects relating to exclusion from diagnosis and/or treatment. All four failures wrongfully deny treatment on a categorical basis instead of providing the individualized treatment that is required. Equally disturbingly, under the current medical consensus the presence of stage 2 fibrosis in a patient's liver should be a strong factor in *favor* of administering medical treatment—not a basis for excluding a patient, as it is under CDC protocols.

Persons with stage 1 or 2 fibrosis, substance abusers, persons with normal ALT levels, and non-responders may all benefit from treatment, in light of the totality of the factors in their medical charts. Like all patients with hepatitis C, they are entitled to individualized treatment decisions based on the progression of their liver disease, the potential for side effects, the likelihood that they will respond to treatment, and the presense of co-morbid conditions. To deny these people individual attention is to deprive them of the minimally-acceptable standard of medical care, as articulated in the National Institutes of Health Consensus Statement and the Practice Guideline of the American Association for the Study of Liver Diseases. Not only does this denial infringe on prisoners' fundamental right to medical care, it endangers public health in the entire community.

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