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# Foreword

The *Annals of Health Law and Life Sciences* Editorial Staff is proud to present our Summer 2020 Issue. The issue features articles deriving from our thirteenth annual Annals of Health Law and Life Sciences Symposium: Addressing the Health Care Needs of Justice-Involved Populations. The symposium brought together scholars and practitioners to explore the legal barriers that justice-involved populations face in accessing health care and how those barriers can be alleviated. Each author published in this edition highlights a specific area of the panel topics presented at the Symposium. On behalf of the entire Annals of Health Law and Life Sciences Editorial Staff, I would like to thank our authors for both presenting at Symposium and contributing their knowledge, research, and talent to this outstanding issue.

The Symposium was organized into three separate panels following a special address by Cook County Sheriff's Thomas Dart. Each panel was tasked to discuss different perspectives of health care issues relating to justice-involved populations. The first panel was *Preventing Contact with the Criminal Justice System through Increasing Access to Health Care*, which focused on current health care measures preventing individuals from encountering the criminal system. The second panel was *Increasing Access to Treatment for Incarcerated Populations*, which discussed the legal support and medical treatment of justice-involved populations during the duration of their involvement with the U.S. justice system. The last panel was *Constitutional Issues Relating to the Medical Treatment of Justice-Involved Populations*, which addressed Eighth Amendment and Fourteenth Amendment issues regarding access to medical treatment to medical treatment of justice-involved populations.

I would like to express my sincerest gratitude to my colleagues on the Executive Board: Christina Perez-Tineo, Alesandra Hlaing, Nicolette Taber, Raquel Boton, Hannah Lehmann, and Jacalyn Smith. Additionally, I would like to thank the outstanding efforts of our Senior Editors: Haley Comella, Jan Dervish, Elizabeth Heredia, and Rachel Kemel. Finally, I would like to thank the wonderful faculty at

the Beazley Institute for Health Law and Policy for their continued support of our endeavors. The success of the Symposium and Summer 2020 Issue would not have been possible without the hard work and dedication of everyone involved.

I am proud to present the Summer 2020 issue of *Annals of Health Law and Life Sciences*.

Sincerely,

Isabella Mancini
Editor-in-Chief
*Annals of Health Law and Life Sciences*

# Hepatitis C Litigation: Healing Inmates as a Public Health Strategy

*Robert Katz**

Hepatitis C virus (HCV) is the most lethal infectious disease in the United States. HCV-related deaths exceed the total number of deaths from 60 other infectious diseases combined, including HIV and tuberculosis.[1] HCV can lead to liver failure, liver cancer, and other complications.[2] Around 3.5 million people—an estimated 1 percent of the U.S. population—are infected with HCV.[3] But HCV affects population groups in disparate numbers.

HCV is especially prevalent in America's prisons, as approximately 20 percent of incarcerated persons are infected.[4] Approximately 30 percent of all HCV-infected persons spend at least part of the year in a correctional institution.[5] They are not only at risk of transmitting the disease to one another: more than 90 percent of infected inmates are eventually released and are at risk of transmitting the disease among the general population.[6]

HCV can be cured through treatment with direct-acting anti-viral drugs

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* The author serves as co-counsel in Stafford v. Carter, 117CV00289JMSMJD, 2018 WL 4361639 (S.D. Ind. Sept. 13, 2018). (Thanks to Michael Ray Stafford, Charles Smith, Douglas Smith, Mark W. Sniderman, Peter Erlinder, Peter H. Schwartz, Raj Vuppalanchi, Suthat Liangpunsakul, Diane J. Klein, the Beazley Institute for Health Law and Policy, and the student editors of the *Annals of Health Law*. This article is dedicated to the memory of Eleanor Kinney, who believed in the power of law to improve the health of the most vulnerable.) *See* Robert Katz, *A Tribute to Eleanor D. Kinney*, 17 Ind. Health L. Rev. 1, 1 (2020).

1. AM. ASS'N FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AM., *HCV Testing and Treatment in Correctional Settings*, HCVGUIDELINES.ORG (Nov. 6, 2019), www.hcvguidelines.org/unique-populations/correctional [hereinafter *HCV Testing and Treatment in Correctional Settings*]; *Hepatitis C Kills More Americans than Any Other Infectious Disease*, CTR. FOR DISEASE CONTROL & PREVENTION http://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html (last visited Apr. 11, 2020). These numbers were compiled prior to the COVID-19 pandemic.

2. Stafford v. Carter, 2018 WL 4361639, at *20 (S.D. Ind. Sept. 13, 2018).

3. Ann Pietrangelo, *Hepatitis C by the Numbers: Facts, Statistics, and You*, HEALTHLINE https://www.healthline.com/health/hepatitis-c/facts-statistics-infographic#hepatitis-types (last visited April 6, 2020); Sanjiv Chopra, *Patient Education: Hepatitis C (Beyond the Basics)*, UPTODATE.COM, https://www.uptodate.com/contents/hepatitis-c-beyond-the-basics (last visited April 11, 2020).

4. *HCV Testing and Treatment in Correctional Settings*, *supra* note 1.

5. *Id.*

6. *Id.*

known as DAAs.[7] These drugs are costly—an estimated $25,000 per course of treatment.[8] Their high price, naturally, is a major obstacle to wider treatment.[9] For example, the Indiana Department of Correction (IDOC) estimates that it would cost between $87 million to $100 million to treat all current inmates with chronic HCV.[10] This sum could consume IDOC's entire medical budget for fiscal year 2019.[11] Unsurprisingly, most prison systems are loath to treat infected inmates. In 2015, fewer than 1 percent of Indiana's infected inmates were treated.[12] IDOC treated only 41 of approximately 3,500 infected inmates as of January 2018.[13] The Florida Department of Corrections (FDC) treated only thirteen of approximately 7,000 infected inmates as of November 2017.[14]

Is a prison system's refusal to treat this disease unconstitutional? In recent years, federal class action lawsuits filed around the country have challenged state HCV treatment policies that restrict or deny treatment to HCV-infected inmates. Two of these lawsuits have prevailed on the merits: *Hoffer v. Inch*[15] and *Stafford v. Carter,*[16] which challenged FDC's and IDOC's policies, respectively.[17] *Stafford*'s certified class consists of "all current and future

7. *Stafford*, 2018 WL 4361639, at *9.

8. *Id*.

9. NATIONAL ACADEMIES OF SCIENCES, ENGINEERING, AND MEDICINE, A NATIONAL STRATEGY FOR THE ELIMINATION OF HEPATITIS B AND C. 1, 6 (Strom BL & Buckley GL 2017).

10. Dave Stafford, *Ruling: DOC Violating Rights of Inmates with Hepatitis*, THE IND. LAWYER (Sept. 13, 2018), http://www.theindianalawyer.com/articles/48119-ruling-doc-violating-rights-of-inmates-with-hepatitis.

11. *Stafford*, 2018 WL 4361639, at *13.

12. Adam L. Beckman et al., *New Hepatitis C Drugs Are Very Costly and Unavailable to Many State Prisoners*, 35 HEALTH AFF. 1893, 1896 (Oct. 2016).

13. *See generally Stafford*, 2018 WL 4361639, at *10.

14. Hoffer v. Jones, 290 F. Supp. 3d 1292, 1298 (N.D. Fla. 2017).

15. *See generally* Hoffer v. Inch, 382 F. Supp. 3d 1288 (N.D. Fla. 2019) (Summary judgment partially granted; motion for permanent injunction was approved).

16. *See generally Stafford*, 2018 WL 4361639 (plaintiffs moved for summary judgment on their Eighth Amendment claim, and defendants cross-moved for summary judgment on all claims. Court granted plaintiffs' motion as to liability on the Eighth Amendment claim and denied defendants' cross-motion on all claims).

17. *See generally id.*; *see generally Inch*, 382 F. Supp. 3d 1288. Similar suits have failed on the merits in Kentucky, North Carolina, and Tennessee. *See* Woodcock v. Correct Care Sols., LLC, No. 3:16-CV-00096-GFVT, 2020 U.S. Dist. Lexis 17793 (E.D. Ky. Feb. 04, 2020) (holding that Kentucky state prison's HCV treatment policy does not violate class-action plaintiffs' Eighth Amendment rights); Atkins v. Parker, 412 F.Supp.3d 761, 777 (M.D. Tenn. 2019) (holding that Tennessee state prison's HCV treatment policy does not violate class-action plaintiffs' Eighth Amendment rights). *See also* Buffkin v. Hooks, 1:18-CV-502, 2019 WL 1282785 (M.D.N.C. Mar. 20, 2019) (denying inmates' motion for a preliminary injunction where they failed to show that the Eighth Amendment challenge to North Carolina's HCV treatment policy was likely to succeed on the merits).

prisoners in IDOC custody who have been diagnosed, or will be diagnosed, with chronic HCV, and for whom treatment with DAA medication is not medically contraindicated."[18] *Hoffer*'s class is similarly defined.[19]

*Stafford* and *Hoffer* each challenge a state's HCV treatment policy on grounds that withholding treatment with DAAs violates the infected inmate's Eighth Amendment rights.[20] Each court granted Plaintiffs' motion for summary judgment on their Eighth Amendment claim.[21] In *Stafford*, the court approved a settlement agreement in which IDOC undertook to treat all class members, thereby avoiding the need for injunctive relief.[22] In *Hoffer*, the court has issued two injunctions requiring FDC to commence treatment of class members, and FDC has appealed both.[23]

Several other state prison systems have settled class action lawsuits by agreeing to expand treatment to some or all infected inmates. These include Colorado,[24] Connecticut,[25] Massachusetts,[26] Minnesota,[27] Pennsylvania,[28]and South Carolina.[29] More class action lawsuits are pending in Maine,[30]

18. *Stafford*, 2018 WL 4361639, at *11.

19. *Jones*, 290 F. Supp. 3d at 1296.

20. *See generally Stafford*, 2018 WL 4361639; *See generally Inch*, 382 F. Supp. 3d 1288.

21. *Stafford*, 2018 WL 4361639, at *11; *Jones*, 290 F. Supp. 3d at 1304.

22. *Stafford*, 2018 WL 4361639, at *3.

23. *Jones*, 290 F.Supp.3d at 1306; *Hoffer*, 382 F.Supp.3d at 1315.

24. Kirk Mitchell, *Colorado Approves $41 Million Settlement Ensuring Care of 2,200 State Prisoners with Hepatitis C*, THE DENVER POST (Sept. 12, 2018, 4:46 PM), http://www.denverpost.com/2018/09/12/colorado-settlement-prisoner-care-for-hepatitis-c.

25. Proposed Settlement Agreement and Release at 7–8, Barfield v. Cook , 3:18-CV-1198-MPS (D. Conn. 2020).

26. Fowler v. Turco, No. 1:15CV12298-NMG (D. Mass. Mar. 9, 2018).

27. *Minnesota Prisoners Win Access to New Hepatitis C Medications*, PRISON LEGAL NEWS (July 2, 2019), www.prisonlegalnews.org/news/2019/jul/2/minnesota-prisoners-win-access-new-hepatitis-c-medications.

28. Bobby Allyn, *Pa. Department of Corrections to Provide Costly Hepatitis C Treatment to Nearly 5,000 Inmates*, WHYY (Nov. 19, 2018), www.whyy.org/articles/pa-department-of-corrections-to-provide-cost ly-hepatitis-c-treatment-to-nearly-5000-inmates/.

29. Geissler v. Stirling, No. 4:17-CV-01746-MBS, 2019 WL 3561875, at *6 (D. S.C. Aug. 5, 2019) (approving settlement agreement).

30. NEWS DESK, *Lawsuit Claims Prison Officials Aren't Treating Hepatitis C*, WABI5 (Jun. 28, 2019, 11:24 AM), https://www.wabi.tv/content/news/Lawsuit-claims-prison-officials-arent-treating-hepatitis-C-511951751.html.

Missouri,[31] Texas,[32] and Vermont.[33] Several states are expanding treatment outside the context of a class action lawsuit, including California,[34] Louisiana,[35] Michigan,[36] New Mexico,[37] Washington,[38] and Wyoming.[39]

These lawsuits aim directly at improving the health of infected inmates by vindicating their Eighth Amendment rights. But it is not only inmates who benefit. Their treatment confers broad health benefits on uninfected third parties and the population at large by reducing the risk of disease transmission.

Just as prisons have an outsized role in spreading the HCV epidemic, prisons can play an outsized role in combating it.[40] Public health experts argue that the criminal justice system "presents a critical opportunity to have a substantial effect on this epidemic,"[41] while "failure to scale up treatment

31. ASSOCIATED PRESS, *ACLU Seeks to Force Missouri to Treat Inmates' Hepatitis C*, ST. LOUIS POST DISPATCH (Jun. 24, 2019), https://www.stltoday.com/news/local/metro/aclu-seeks-to-force-missouri-to-treat-inmates-hepatitis-c/article_85f1ecdc-e818-5bc2-83a1-2a375b7c2c7c.html.

32. Gabrielle Banks & Keri Blakinger, *Texas Inmates Sue for Hepatitis C Drug, Alleging Lack of Treatment is 'Cruel and Unusual*', HOUSTON CHRONICLE (Sep. 18, 2019), https://www.houstonchronicle.com/news/houston-texas/houston/article/Texas-inmates-sue-for-hepatitis-C-drug-alleging-14453099.php.

33. Ellie French, *ACLU Sues Corrections Over Denial of Hepatitis C Treatment*, VTDIGGER (May 22, 2019), https://vtdigger.org/2019/05/22/aclu-sues-corrections-denial-hepatitis-c-treatment/.

34. Noreen Marcus, *Hepatitis C Fight Hinges on Prisons*, U.S. NEWS (Feb. 5, 2019), https://www.usnews.com/news/healthiest-communities/articles/2019-02-05/hepatitis-c-fight-hinges-on-prisons-inmate-care ("[In 2018] California lawmakers took the unusual step of putting $105.8 million in the state budget to treat its 22,000 hepatitis C-infected inmates").

35. Ted Alcorn, *Louisiana's Deal for Hepatitis C Drugs May Serve as Model*, WALL STREET J. (Sept. 13, 2019, 9:50 AM), https://www.wsj.com/articles/louisianas-deal-for-hepatitis-c-drugs-may-serve-as-model-11568347621.

36. Mardi Link, *Michigan Aims to End Hep C in Prisons*, RECORD-EAGLE (Mar. 31, 2019), https://www.record-eagle.com/news/local_news/michigan-aims-to-end-hep-c-in-prisons/article_9dc3c401-80aa-5f95-9a59-ef1a9e284e95.html.

37. Ted Alcorn, '*Major Milestone': Governor's Budget Targets Hepatitis C Epidemic in Prisons,* NEW MEXICO IN DEPTH (Jan. 16, 2020) http://nmindepth.com/2020/01/16/major-milestone-governors-budget-target-hepatitis-c-epidemic-in-prisons/ (governor's proposed budget "recommends $30 million in new funding for the Corrections Department for treatment of hepatitis C, with the expectation of curing most inmates by the end of 2024").

38. JoNel Aleccia et al., *Pharma Sells Washington State and Others on 'Netflix Model' to Wipe Out Hep. C. But the Cost is Being Kept from the Public*, SEATTLE TIMES (Oct. 29, 2019), https://www.seattletimes.com/seattle-news/health/pharma-sells-washington-state-and-others-on-netflix-model-to-wipe-out-hep-c-but-the-cost-is-being-kept-from-the-public/.

39. WYOMING NEWS EXCHANGE, *Corrections Department Seeks $4 million for Hepatitis Treatments*, GILLETTE NEWS RECORD (Jan. 6, 2020), https://www.gillettenewsrecord.com/news/wyoming/article_9e863df3-66cd-5cbc-962d-6f153c6010f9.html.

40. Atkins v. Parker, 412 F.Supp.3d 761, 782 (M.D. Tenn. 2019).

41. Josiah D. Rich et al., *Responding to Hepatitis C through the Criminal Justice*

in prisons dooms any effort to eliminate hepatitis C in America".[42] Accordingly, inmate HCV litigation can help promote public health. According to Ross Silverman, Professor of Health Policy and Management at the Indiana University Richard M. Fairbanks School of Public Health:

We've seen a significant rise in the number of HCV cases in Indiana. Slowing and ultimately eliminating HCV infection in our state and across the nation depends upon providing treatment to this otherwise vulnerable and hard-to-reach population of people moving in and out of the prison system.[43]

Successful inmate HCV litigation is thus a strategy for improving the health of multiple populations. It simultaneously vindicates infected inmates' rights and can improve the health of infected and uninfected persons alike. "[*Stafford*] is an important decision in support of justice and the public's health," states Silverman.[44]

These two goals—curing infected inmates and reducing disease transmission—are best achieved by treating all infected inmates regardless of disease stage or symptoms, a.k.a., "universal treatment." Yet such treatment can have a mixed health impact on inmates who are *not* infected with HCV. On one hand, treatment reduces their risk of contracting HCV. On the other hand, requiring prison systems to buy DAAs reduces the funds available to meet inmates' non-HCV-related health needs—that is, unless state legislatures appropriate additional funds for DAAs. Critically, it may be that certain health interventions unrelated to HCV improve inmate health more cost-effectively than treating HCV, especially for those with early-stage or asymptomatic HCV. Universal treatment may best promote the health of infected inmates and the general population. However, unless prison officials are provided additional funds to buy DAAs, they may pay for them through cuts that may reduce the health of uninfected inmates and the inmate population as a whole.

As demonstrated below, courts are well-positioned to enforce an infected inmate's constitutional right to treatment, advance the public's interest in combating the HCV epidemic, protect uninfected persons and populations from disease transmission, and ensure that taxpayers rather than uninfected inmates bear the cost of expanding treatment.

Part I provides information about HCV, the stages of this disease, lifesaving DAAs, the HCV epidemic, and expert recommendations for

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*System*, 370 NEW ENG. J. MED. 1871, 1873 (May 15, 2014).

42. Marcus, *supra* note 34.

43. *IU McKinney Professor and Alumnus Life-Saving Treatment for Inmates*, IU ROBERT H. MCKINNEY SCHOOL OF LAW (Jan. 6, 2020), https://mckinneylaw.iu.edu/news/releases/2020/01/iu-mckinney-professor-and-alumnus-secure-life-saving-treatment-for-inmates.html.

44. *Id.*

treatment. It also explores the tension between the goals of curing HCV-infected inmates and reducing disease transmission.

Part II discusses the Eighth Amendment's guarantee of adequate medical care for inmates, which it secures by prohibiting prison officials from displaying deliberate indifference to an inmate's serious medical needs. The linchpin of the Eighth Amendment guarantee is its connection to a physician's professional judgment. This part also discusses the discredited "defense of inadequate funds," in which prison systems essentially plead poverty in an attempt to avoid providing costly medical care to which inmates are constitutionally entitled.

Part III presents the Eighth Amendment analysis of IDOC and FDC's undertreament of HCV. The *Stafford* and *Hoffer* courts held that chronic HCV is a "serious" medical condition even during the early stages of the disease and without fibrosis or other disease symptoms. The courts looked to the medical standard of care for objective criteria for determining whether a condition is constitutionally "serious." The *Stafford* and *Hoffer* courts also found that prison officials were "deliberately indifferent" because their HCV treatment policies lacked medical foundation.

Part IV details the *Stafford* settlement agreement under which Indiana undertook to treat all class members by July 1, 2023, subject to an appropriation of sufficient funds by the Indiana General Assembly. This amount could be as large as $100 million. Should the General Assembly fail to appropriate these funds, the Plaintiffs may seek enforcement from the court.

Part V examines the *Hoffer* court's decisions to grant injunctive relief and order Florida to commence treating infected inmates. In balancing the hardships, the *Hoffer* court did not consider the unintended harm such relief might visit upon uninfected inmates if prison officials pay for DAAs by diverting funds away from health interventions that are unrelated to HCV and not required by the Eighth Amendment. In finding that an injunction would serve the public interest, the *Hoffer* court focused on how treatment would reduce the risk of disease transmission to uninfected persons.

## I. THE HEPATITIS C VIRUS (HCV)

### *What is the Hepatitis C Virus (HCV)?*

The Hepatitis C virus (HCV) is an infectious disease transmitted through exposure to infected blood.[45] It causes inflammation of the liver that

45. Stafford v. Carter, No. 1:17-CV-00289, 2018 WL 4361639, at *8 (S.D. Ind. Sept. 13, 2018).

frequently results in liver scarring (also called "fibrosis").[46] Such scarring can significantly impair liver function and lead to liver failure, liver cancer, and other complications.[47]

HCV infection occurs in two stages: acute and chronic.[48] Approximately 15 percent to 25 percent of infected persons clear the virus from their bodies without treatment; the remaining 75 to 85 percent move into the chronic phase.[49] Unless treated, chronically-infected individuals remain infected for life.[50] In addition, 10 to 20 percent of people infected with HCV will develop cirrhosis of the liver within 20-30 years.[51] Finally,1 to 5 percent of chronically-infected individuals die within twenty years of becoming infected.[52]

HCV is a progressive disease that becomes more severe over time.[53] Some HCV-infected patients may experience symptoms such as fatigue, joint pain, nerve pain, skin disorders, jaundice, fluid accumulation in the abdomen, confusion, and gastrointestinal bleeding.[54]

The severity of an infection is reflected in the degree of scarring or fibrosis in the liver.[55] Doctors describe the progression of fibrosis with a five-stage scale: F0 (no fibrosis); F1 (mild fibrosis); F2 (moderate fibrosis); F3 (advanced fibrosis); and F4 (cirrhosis).[56] The stage of a patient's fibrosis does not necessarily correspond to their symptoms.[57] For example, some infected individuals with cirrhosis (F4) may have no symptoms for decades.[58] The disease's progression varies from person to person based on a variety of factors including an individual's sex, duration of infection, age, alcohol use,

46. Hoffer v. Jones, 290 F. Supp. 3d 1292, 1294 (N.D. Fla. 2017); *see also* Am. Ass'n for the Study of Liver Diseases & Infectious Diseases Society of Am., *When and in Whom to Initiate HCV Therapy*, HCVGUIDELINES.ORG, www.hcvguidelines.org/evaluate/when-whom (last updated Nov. 6, 2019) [hereinafter *When to Initiate HCV Therapy*].

47. *Jones*, 290 F. Supp. 3d, at 1294.

48. *Stafford*, 2018 WL 4361639, at *8.

49. *Id.* From here on, "HCV" and "chronic HCV" will be used interchangeably, and references to those "infected" mean those chronically infected.

50. *Id.*

51. *Hepatitis C Questions and Answers for Health Professionals - Viral Hepatitis*, CTR. FOR DISEASE CONTROL & PREVENTION, www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Apr. 11, 2020) [hereinafter CDC HEPATITIS C QUESTIONS AND ANSWERS].

52. *Stafford*, 2018 WL 4361639, at *12.

53. *Id.* at *8.

54. *Id.*

55. *Id.* at *9.

56. Atkins v. Parker, 412 F. Supp. 3d 761, 766 (M.D. Tenn. 2019).

57. Hoffer v. Jones, 290 F. Supp. 3d 1292, 1295 (N.D. Fla. 2017).

58. *Jones*, 290 F. Supp. 3d at 1295; CDC HEPATITIS C QUESTIONS AND ANSWERS, *supra* note 51.

and cigarette smoking.[59] It is thus difficult to predict the rate at which an individual's HCV will progress.[60]

There are several methods for measuring the stage of a patient's disease.[61] One method requires a liver biopsy (the METAVIR score).[62] Another method uses routinely available blood tests (the APRI score).[63] A third method, a non-invasive technique called transient elastography, measures liver stiffness.[64] No single method is highly accurate alone.[65]

*The Cure*

HCV can be cured through treatment with direct-acting anti-viral drugs or DAAs.[66] DAAs work by preventing the virus from replicating, eventually eliminating it from the body.[67] Cure, also known as sustained virologic response (SVR), is defined as "the absence of detectable virus for at least 12 weeks after completion of treatment."[68] DAAs are the only effective treatment for HCV.[69]

A course of treatment typically lasts between 8 to 12 weeks.[70] It can cure

59. *See When to Initiate HCV Therapy*, *supra* note 46 ("Fibrosis results from chronic hepatic necroinflammation").

60. *Stafford*, 2018 WL 4361639, at *12.

61. *Id.* at *9.

62. *Id.* at *9; *see generally*, *When to Initiate HCV Therapy*, *supra* note 46 ("Although liver biopsy is the diagnostic standard, sampling error and observer variability limit test performance, particularly when inadequate sampling occurs. Up to 1/3 of bilobar biopsies had a difference of at least 1 stage between the lobes. In addition, the test is invasive and minor complications are common, limiting patient and practitioner acceptance. Although rare, serious complications such as bleeding are well recognized.").

63. *Stafford*, 2018 WL 4361639, at *9; AM. ASS'N FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AM., *HCV Testing and Linkage to Care*, HCVGUIDELINES.ORG, https://www.hcvguidelines.org/evaluate/testing-and-linkage (last updated Nov. 6, 2019), [hereinafter *HCV Testing and Linkage to Care*].

64. *Stafford*, 2018 WL 4361639, at *9; *HCV Testing and Linkage to Care*, *supra* note 63.

65. *When to Initiate HCV Therapy*, *supra* note 46.

66. *Stafford*, 2018 WL 4361639, at *9.

67. *Id.*

68. CDC HEPATITIS C QUESTIONS AND ANSWERS, *supra* note 51, at 2; *When to Initiate HCV Therapy*, *supra* note 46, at 7.

69. *Stafford*, 2018 WL 4361639, at *9; *see generally,* Atkins v. Parker, 412 F. Supp. 3d 761, 767 (M.D. Tenn. 2019) (writing "in the past, the standard treatment for chronic HCV infections involved injections of a drug called interferon, which activates the immune system."); *see also* Alliance for Patient Access, *Hepatitis Therapy Access Physician's Working Group* (last visited Feb. 1, 2020), https://allianceforpatientaccess.org/hepatitis/ (writing that these injections, administered over a period of 24–48 weeks, "offered only a 50 percent success rate and dampened patients' quality of life by introducing side effects such as fatigue and depression"); *see also Atkins*, 412 F. Supp. 3d 761 at 767 (writing "upon the approval of DAAs, interferon treatment for HCV was effectively abandoned").

70. CDC HEPATITIS C QUESTIONS AND ANSWERS, *supra* note 51, at 6.

over 90 percent of HCV-infected persons with minimal side effects.[71] Patients who are cured of their HCV infection experience numerous health benefits including reduced fibrosis, resolution of cirrhosis, reduced risk of liver cancer and liver-related mortality, and improved quality of life.[72]

A course of treatment with DAAs currently costs approximately $25,000,[73] although pharmaceutical manufacturers and payers are developing innovative models for lowering prices. For example, under a subscription-based approach (the "Netflix model") a "state pays a negotiated price for a certain volume of a drug over a specified period of time to increase access in a way that recognizes state budget constraints."[74] Louisiana recently entered into such an agreement with Gilead Sciences, a pharmaceutical company, achieving huge cost savings. Under the agreement, the state pays an annual fee ($35 million) to the company for unlimited access to its DAAs for five years, instead of paying per patient for a total cost of $760 million.[75]

*The HCV Epidemic*

An estimated 3.5 million individuals are infected with HCV in the United States.[76] The incidence of HCV increased "by more than 200 percent in 30 states since . . . 2010-2014."[77] And it is growing. One study reported that without large-scale efforts to treat HCV, "the burden of HCV-associated disease will increase dramatically in the near future, with more than 1 million people expected to die from HCV by 2060."[78]

HCV poses an especially grave threat to incarcerated persons. An estimated 17.4 percent to 23.1 percent are infected with HCV[79] as compared

71. *Id.*

72. *When to Initiate HCV Therapy*, *supra* note 46, at 2.

73. Anne C. Spaulding et al., *Funding Hepatitis C Treatment in Correctional Facilities by Using a Normal Pricing Mechanism*, 25 J. CORRECTIONAL HEALTH CARE 1, 2 (2018).

74. KATE JOHNSON ET AL., NAT'L GOVERNORS ASS'N, PUBLIC HEALTH CRISES AND PHARMACEUTICAL INTERVENTIONS: IMPROVING ACCESS WHILE ENSURING FISCAL SUSTAINABILITY 6, 21–23 (2018); *see also* Mark R. Trusheim et al., *Alternative State Level Financing for Hepatitis C Treatment-The "Netflix Model,"* 320 JAMA, E1 (2018) (describing the subscription based pricing model as the "Netflix" model).

75. *See* ASSOCIATED PRESS, *Gilead Enters Subscription-Based Contract with Louisiana for Hepatitis C Drugs,* MODERN HEALTH CARE, (Mar. 27, 2019), https://www.modernhealthcare.com/government/gilead-enters-subscription-based-contract-louisiana-hepatitis-c-drugs (stating "Louisiana will treat as many Medicaid patients and prisoners as it can [during this period], rather than pay a per-patient treatment price that is so costly it has severely limited access").

76. *HCV Testing and Linkage to Care*, *supra* note 63, at 1.

77. Marcus, *supra* note 34.

78. Rich et al., *supra* note 41, at 1872.

79. *HCV Testing and Treatment in Correctional Settings, supra* note 1, at 1.

to 1 percent of the U.S. adult population.[80] The high prevalence of HCV among inmates is due in part to the fact "that many populations who are most affected by incarceration such as the poor, injection drug users, and the mentally ill, are also more likely to have HCV."[81] In addition, infected inmates can transmit HCV to other inmates. Upon release they can infect members of the general population. However, those patients who are cured can no longer transmit the virus to others.[82] Treating inmates is thus an important population health strategy for combating the HCV epidemic.

*Medical Recommendations for Treating HCV*

Two learned societies jointly have provided healthcare practitioners with guidance on how best to treat patients with HCV.[83] Together, the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) "have developed a web-based process for the rapid formulation and dissemination of evidence-based, expert-developed recommendations for hepatitis C management."[84] These recommendations are contained in an online document entitled "HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C" ("the Guidance").[85]

The Guidance recommends treatment "for *all* patients with acute or chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV therapy, liver transplantation, or another directed therapy."[86] These recommendations are supported by the highest level of medical evidence, *i.e.*, "[e]vidence and/or general agreement that a given. . . treatment is beneficial, useful, and effective."[87] The recommendations also

80. HEPATITIS C PREVALENCE ESTIMATES 2013-2016, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates.html (last visited Nov. 6, 2018).

81. *An Overview of Hepatitis C in Prisons and Jails,* NATIONAL HEPATITIS CORRECTIONS NETWORK (Feb. 22, 2016), http://www.hcvinprison.org/resources/articles-documents/71-main-content/content/191-hepcprison.

82. *When to Initiate HCV Therapy*, *supra* note 46, at 2.

83. AM. ASS'N FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AM., *About the Guidance*, HCVGUIDELINES.ORG, https://www.hcvguidelines.org/about (last visited April 11, 2020).

84. *Id.*

85. *Id.*

86. *When to Initiate HCV Therapy*, *supra* note 46, at 1. ("Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert.") (emphasis added).

87. *See generally* AM. ASS'N FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AM., *Table 2. Rating System Used to Rate Level of Evidence and Strength of Recommendation*, HCVGUIDELINES.ORG, https://www.hcvguidelines.org/contents/methods/table-2 (last visited April 11, 2020)

have the highest level of strength, *i.e.*, the supporting data is "derived from multiple randomized clinical trials, meta-analyses, or equivalent."[88]

The Guidance states that treatment with DAAs "is expected to benefit nearly all chronically infected persons" regardless of their fibrosis stage.[89] It states that practitioners should commence treatment "preferably *early* in the course of chronic hepatitis C before the development of severe liver disease and other complications."[90] Patients who start treatment at an early stage of the disease have better outcomes than those who start at a later stage.[91] For example, one study concludes that waiting to treat HCV until stage F3 and stage F4 results in two and five times higher rates of liver-related mortality, respectively, compared with commencing treatment at stage F2.[92]

*Trade-offs Between Patient Health and Population Health*

The Guidance recognizes that treating infected inmates can improve population health: such treatment "can ultimately reduce the risk of liver-related and extrahepatic complications [among inmates], *and* has the potential to decrease HCV transmission in correctional facilities and the community after release."[93] These population health benefits warrant expanding treatment because "[i]mproving the diagnosis and management of HCV infection in correctional settings will greatly facilitate efforts to eliminate HCV infection in the US."[94]

But these two goals are not identical. The Guidance states that F3 and F4 patients, who have the highest risk for HCV-related complications, realize "the most immediate benefits of treatment."[95] If the primary goal is to reduce the number of inmates who suffer and die from HCV-related complications, then F3s and F4s should be treated first. However, if the primary goal is to improve the general population's health, then inmates facing imminent release should be treated first and without regard to the stage of their disease, as F0s can transmit the disease as readily as F4s.[96]

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(describing the requirements for the different classes and levels of evidence).

88. *Id.*

89. *When to Initiate HCV Therapy*, *supra* note 45 at 1.

90. *Id.* at 2 (emphasis added).

91. *Id.*

92. *Id.* at 3.

93. *HCV Testing and Treatment in Correctional Settings*, *supra* note 1, at 2.

94. *Id*. at 4.

95. *See* AASLD/IDSA HCV Guidance Panel, *Hepatitis C Guidance: AASLD-IDSA Recommendations for Testing, Managing, and Treating Adults Infected with Hepatitis C Virus*, 62 HEPATOLOGY 932, 935-36 (2015) (referencing table 3 which discusses settings of liver-related complications and extrahepatic disease in which HCV treatment is most likely to provide the most immediate and impactful benefits).

96. The Guidance refers to such patients as "those at risk for transmitting HCV or in

In its initial formulation in 2015, the Guidance recommended that even under conditions of scarcity both goals should be pursued simultaneously.[97]

> [W]here resources limit the ability to treat all infected patients immediately as recommended, it is most appropriate to treat first [a] those at great risk of disease complications . . . *and* [b] those at risk for transmitting HCV or in whom treatment may reduce transmission risk.[98]

The Guidance's current treatment recommendations are grounded exclusively on the health benefits of treatment to individual patients.[99] Although the Guidance recognizes the public health benefits of treatment in preventing transmission to non-patients,[100] its recommendations are not grounded on these benefits[101] or on the cost-effectiveness of treatment from a societal perspective.[102] As explained below, an individual inmate's Eighth Amendment right to adequate health care is ultimately grounded on the health benefits the inmate derives from the requested treatment; it does not turn on considerations of whether an individual inmate's treatment will increase the overall health of the inmate or general populations as a whole.

## II. THE EIGHTH AMENDMENT AND THE RIGHT TO ADEQUATE MEDICAL CARE

The Eighth Amendment to the United States Constitution prohibits the government from inflicting "cruel and unusual punishments" on convicts.[103] In *Wilson v. Seiter*, the U.S. Supreme Court explained that this prohibition encompasses "deprivations . . . not specifically part of [a] sentence but . . . suffered during imprisonment."[104]

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whom treatment may reduce transmission." *See id*. at 935.

97. *Id*.

98. *Id*. at 936.

99. *When to Initiate HCV Therapy*, *supra* note 45 at 2.

100. *See id.* at 6 ("Persons who have successfully achieved SVR (virologic cure) no longer transmit the virus to others. As such, successful treatment of HCV infection benefits public health.").

101. *See id.* ("To guide implementation of hepatitis C treatment as a prevention strategy, studies are needed to define the best candidates for treatment to stop transmission. . .").

102. *See* AM. ASS'N FOR THE STUDY OF LIVER DISEASES & INFECTIOUS DISEASES SOCIETY OF AM., *Overview of Cost, Reimbursement, and Cost-Effectiveness Considerations for Hepatitis C Treatment Regimens*, HCVGUIDELINES.ORG www.hcvguidelines.org/evaluate/cost ("the HCV guidance does not utilize cost-effectiveness analysis to guide [treatment] recommendations") [hereinafter AASLD-IDSA OVERVIEW OF COST].

103. U.S. Const., Amend. VIII; *see also* Wilson v. Seiter, 501 U.S. 294, 298 (1991) (discussing the provision of inadequate medical treatment to inmates or its outright denial also implicates inmates' right to due process under the Fifth or Fourteenth Amendments); JOHN PALMER, CONSTITUTIONAL RIGHTS OF PRISONERS § I-10.3 (9th ed. 2009).

104. *Wilson*, 501 U.S. at 297.

*The Estelle Deliberate Indifference Test*

In *Estelle v. Gamble*, decided in 1976, the Supreme Court established that prison officials are constitutionally obliged to provide inmates with adequate medical care.[105] Such officials violate the Eighth Amendment by displaying "deliberate indifference" to an inmate's "serious medical needs."[106] A violation is thus "defined by the seriousness of the prisoner's medical needs and the subjective state of mind of prison officials providing care."[107]

The *Estelle* court's "deliberate indifference" standard has both an objective and subjective prong.[108] First, an inmate must demonstrate that their medical need or condition is sufficiently serious in an objective sense.[109] An inmate's need or condition may be "serious" if it "has been diagnosed by a physician as mandating treatment."[110] It may also be "one that is so obvious that even a layperson would easily recognize the necessity for a doctor's attention."[111] Second, an inmate must show that the responsible prison officials acted with a "sufficiently culpable state of mind."[112] For example, prison officials may act with deliberate indifference by delaying medical treatment for a non-medical reason.[113]

The Eighth Amendment protects inmates from conditions that pose an unreasonable risk of damage to their present or *future* health.[114] In *Helling v McKinney*, Helling's cellmate smoked five packs of cigarettes a day.[115] Helling stated a constitutional cause of action by alleging that prison officials exposed him to unreasonably high levels of environmental tobacco smoke,[116]

105. *Estelle v. Gamble*, 429 U.S. 97, 104 (1976); *see also* West v. Atkins, 487 U.S. 42, 54 (1988) (discussing how prisons have "a constitutional obligation . . . to provide adequate medical care to those whom it has incarcerated").

106. *West*, 487 U.S. at 46.

107. Andrew Brunsden, *Hepatitis C in Prisons: Evolving Toward Decency Through Adequate Medical Care and Public Health Reform*, 54 UCLA L. REV. 465, 484 (2006).

108. Farmer v. Brennan, 511 U.S. 825, 834 (1994); Roe v. Elyea, 631 F.3d 843, 857 (7th Cir. 2011); PALMER, *supra* note 103.

109. *Farmer*, 511 U.S. at 823.

110. MICHAEL B. MUSHLIN, 1 RIGHTS OF PRISONERS § 4:4 (5th ed. 2019).

111. *Id.*

112. *Farmer*, 511 U.S. at 823; Palmer, *supra* note 103, at 229.

113. Baez v. Rogers, 522 F. App'x 819, 821 (11th Cir. 2013) (discussing that conduct that is more than negligence includes delaying treatment for a non-medical reason); Archer v. Dutcher, 733 F.2d 14, 17 (2d Cir. 1984) (delaying treatment as punishment for past breaches of the disciplinary code is an invalid reason); Ancata v. Prison Health Services, Inc., 769 F.2d 700, 704 (11th Cir. 1985) (delaying care as a means to coerce an inmate to pay for their care is an invalid reason).

114. Helling v. McKinney, 509 U.S. 25, 32 (1993); Roe v. Elyea, 631 F.3d 843, 858 (7th Cir. 2011).

115. *Helling*, 509 U.S. at 28.

116. *Id.* at 35.

which increased his risk of respiratory and other ailments. To prevail, Helling was not required to show that he was currently experiencing serious medical problems from such exposure.[117]

*Professional Judgement*

If an inmate has a serious but curable medical condition, prison doctors might respond by (1) prescribing an effective treatment; (2) prescribing an effective but suboptimal or less desirable alternative treatment; (3) denying effective treatment due to an unwise or negligent exercise of professional judgment; or (4) denying effective treatment without exercising professional judgment.

The second scenario, prescribing an effective but suboptimal alternative, does not constitute deliberate indifference. In *Forbes v. Edgar*, a Seventh Circuit case, an inmate with tuberculosis requested that a certain drug therapy be administered daily.[118] Although experts recommended daily administration, a semiweekly or twice-a-week administration was "a satisfactory alternative."[119] The court held that prison doctors, who administered the therapy on a semiweekly basis, did not thereby violate the Eighth Amendment.[120] This case stands for the proposition that an inmate "is not entitled to the best care possible. She is entitled to reasonable measures to meet a substantial risk of serious harm to her."[121]

The third scenario, denying an inmate effective treatment as a result of a prison doctor's mistake or negligence, does not necessarily violate the Eighth Amendment.[122] This aligns with the "error in judgment rule" in medical malpractice, which "exempts a physician from liability if the malpractice is based on the physician's error in judgment in choosing among different methods of treatment or in diagnosing a condition."[123]

J.W. Gamble, the plaintiff in *Estelle*, lost his case on this basis. Gamble injured his back when a bale of cotton fell on him.[124] "The doctors diagnosed his injury as a lower back strain and treated it with bed rest, muscle relaxants, and pain relievers."[125] Gamble complained that "more should have been done by way of diagnosis," such as an x-ray of his lower back, and that an

117. *Id.*
118. *Forbes v. Edgar*, 112 F.3d 262, 265 (7th Cir. 1997).
119. *Forbes*, 112 F.3d at 267.
120. *Id.*
121. *Id.*
122. *Medical Malpractice*, GALE ENCYCLOPEDIA OF AMERICAN LAW (Donna Batten ed., vol. 7, 3rd ed. 2010).
123. *Id.* at 31–32.
124. Estelle v. Gamble, 429 U.S. 97, 99 (1976).
125. *Id.* at 107.

appropriate diagnosis would have led to effective treatment.[126] The Court found that prison doctors who exercise professional judgment in making treatment decisions do not violate the Eighth Amendment, even if the exercise was (simply) negligent.[127]

[T]he question [of] whether an X-ray or additional diagnostic techniques or forms of treatment is indicated is a classic example of a *matter for medical judgment*. A medical decision not to order an X-ray, or like measures, does not represent cruel and unusual punishment. At most it is medical malpractice. . .[128]

In the fourth scenario, prison doctors violate the Eighth Amendment by denying effective treatment *without* exercising professional medical judgment. According to *Estelle*, a prison doctor may display "deliberate indifference" in this way by providing an "easier and less efficacious treatment" without exercising professional judgment.[129] For illustration the *Estelle* court cited *Williams v. Vincent,* a Second Circuit case involving an inmate who lost a large portion of his right ear in a fight.[130] The prison doctor stitched up the inmate's stump rather than reattach the severed portion of the ear.[131] The *Williams* court stated that the doctor's choice of treatment—which was the "easier and less efficacious" one—might be attributed to the doctor's "deliberate indifference towards [the inmate's] medical needs, *rather than* an exercise of professional judgment. . ."[132] The *Williams* court opined that "one would expect a concerned doctor to have tried" to sew the ear back on.[133]

This fourth category also includes cases where prison officials deny treatment for a *non-medical* reason. This is definitional: medical professionals fail to exercise professional medical judgment when they make treatment decisions for a non-medical reason, or for no reason at all.

To determine whether a prison doctor has failed to exercise professional judgment, we ascertain the medical standard of care and assess how far the doctor diverged from it.[134]

For a medical professional to be held liable under the deliberate indifference standard, they must make a decision that is such a substantial

126. *Id*.
127. *Id.* at 106.
128. *Id.* at 107.
129. *Id.* at 104, n.10 (quoting Williams v. Vincent, 508 F.2d 541, 544 (2d Cir. 1974)).
130. *Id.*
131. *See Williams*, 508 F.2d at 543 (discussing that after telling the inmate that he didn't need the severed portion, the doctors threw it away in front of him).
132. *Id.* at 544.
133. *Id.*
134. Youngberg v. Romeo, 457 U.S. 307, 314 (1982).

departure from *accepted professional judgment, practice, or standards*, as to demonstrate that the person responsible actually did not base the decision on such a judgment.[135]

*No "Inadequate Resources" Defense to Injunctive Relief*

There are at least three financial reasons why prison officials might deny inmates a medical treatment to which they are constitutionally entitled.[136] The state legislature may expressly withhold funds for that specific procedure, or appropriate insufficient funds for inmate health care altogether. Or prison officials may choose to deny that treatment in order to fund other priorities.

When inmates move for an injunction to obtain a particular obligatory treatment, prison officials cannot defeat the motion by asserting that the state legislature did not appropriate sufficient funds.[137] This is known as "the defense of inadequate resources."[138] This defense is rejected even if prison officials themselves lack the means or authority to pay for the treatment. First, when prison officials are sued in their official capacity, the real defendant is the state; the officials are simply its agents.[139] The state legislature is responsible for depriving itself and its agents, the prison officials, of sufficient funds to discharge their constitutional duty to provide inmates with adequate health care.[140] As the Eleventh Circuit explained in *Williams v. Bennett*:

[A] state is not required to operate a penitentiary system. If, however, a state chooses to operate a prison system, then each facility must be operated in a manner consistent with the Constitution. Thus, when a court is considering injunctive relief against the operation of an unconstitutionally cruel and unusual prison system, it should issue the injunction without regard to legislative financing.[141]

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135. *Id.*

136. MUSHLIN, *supra* note 110, at n.22; *see also* Michele Westhoff et al., AN EXAMINATION OF PRISONERS' CONSTITUTIONAL RIGHT TO HEALTHCARE: THEORY AND PRACTICE, HEALTH LAW 1 (The ABA Health Law Section vol. 20 2008) ("[P]rison health systems are understaffed, poorly organized, and lacking in adequate equipment and facilities. Often prisoners' access to what meager services are available is limited by whether a guard chooses to allow the inmate to seek treatment.").

137. *See* MUSHIN, *supra* note 110, at § 3:92 (writing that in cases seeking injunctive relief, "courts have consistently held that inadequate funding is not a legitimate defense to constitutional violations").

138. *Id.*

139. *Id*. at nn.12–13 (citing, *inter alia*, Kentucky v. Graham, 473 U.S. 159, 165–66 (1985)).

140. *Estelle*, 429 U.S. at 103–04.

141. Williams v. Bennett, 689 F.2d 1370, 1388 (11th Cir. 1982); *see also* Watson v.

Second, allowing a state to plead insufficient funds would permit the Eighth Amendment's protections to vary from state to state depending on a given state legislature's ability or willingness to raise sufficient funds.[142] In *Harris v. Thigpen*, the Eleventh Circuit expressed concern that "poor states" would use the inadequate resources defense to deny inmates' basic rights:

> We do not agree that 'financial considerations must be considered in determining the reasonableness' of inmates' medical care to the extent that such a rationale could ever be used by so-called 'poor states' to deny a prisoner the minimally adequate care to which he or she is entitled . . . . We are aware that systemic deficiencies in medical care may be related to a lack of funds allocated to prisons by the state legislature. Such a lack, however, will not excuse the failure of correctional systems to maintain a certain minimum level of medical service necessary to avoid the imposition of cruel and unusual punishment.[143]

## III. THE INFECTED INMATE'S EIGHTH AMENDMENT RIGHT TO TREATMENT WITH DAAS

The *Stafford* and *Hoffer* courts held that chronic HCV is a "serious" medical condition even in the early stages of the disease when there may be no fibrosis or symptoms and that prison officials were deliberately indifferent insofar as their HCV treatment policies were not justified on medical

City of Memphis, 373 U.S. 526, 537 (1963) (rejecting argument that city couldn't desegregate parks because of budgetary concerns: "vindication of conceded constitutional rights cannot be made dependent upon any theory that it is less expensive to deny than to afford them"); *see also* Peralta v. Dillard, 744 F.3d 1076, 1083 (9th Cir. 2014) (holding that in a § 1983 action alleging prison officials' deliberate indifference to serious medical needs, "[l]ack of resources is not a defense to a claim for prospective relief because prison officials may be compelled to expand the pool of existing resources in order to remedy continuing Eighth Amendment violations."); Harris v. Thigpen, 941 F.2d 1495, 1509 (11th Cir. 1991); *see also* Smith v. Sullivan, 611 F.2d 1039, 1043-44 (5th Cir. 1980) (entering an order requiring county to remedy unlawful jail conditions is not defeated by county's claim that compliance would require county to "violate its duty to stay within spending limits imposed by state law . . . . It is well established that inadequate funding will not excuse the perpetuation of unconstitutional conditions of confinement"); *see also* Battle v. Anderson, 564 F.2d 388, 396 (10th Cir. 1977) (affirming order requiring state to remedy prison conditions notwithstanding financial constraints; "the lack of financing [is not] a defense to a failure to provide minimum constitutional standards"; "If the State of Oklahoma wishes to hold the inmates in institutions, it must provide the funds to maintain the inmates in a constitutionally permissible manner"); *see also* Holt v. Sarver, 309 F. Supp. 362, 383 (E.D. Ark. 1970) (writing that "the obligation of the Respondents to eliminate existing unconstitutionalities does not depend upon what the Legislature may do, or upon what the Governor may do, or, indeed, upon what Respondents may actually be able to accomplish. If Arkansas is going to operate a Penitentiary System, it is going to have to be a system that is countenanced by the Constitution of the United States.").

142. MUSHLIN, *supra* note 110, at § 3:92.

143. *Harris,* 941 F.2d at 1509.

grounds.

*HCV is a Serious Medical Condition at All Stages*

The *Stafford* and *Hoffer* courts both held that chronic HCV is a "serious medical condition" at every stage of the disease.[144] This finding is grounded on the medical standard of care, which—as articulated by the Guidance—recommends that virtually all chronically infected patients receive treatment with DAAs.[145]

A specific inmate's medical need or condition is constitutionally "serious" if a physician has recommended that it be treated.[146] To determine what a conscientious but hypothetical physician would recommend, we consult the medical standard of care. With respect to a group of individuals with a common medical need or condition, their need is "serious" in the relevant sense if the standard of care is to treat it.[147]

A standard of care, also known as "best practices," consists of "[t]reatment methods for a particular disorder that [(a)] are considered optimal by medical experts and [(b)] that are widely used in [the] treatment of that disorder."[148] The Guidance's recommendations for treating HCV meet both criteria. They represent the informed judgment of two professional societies whose members possess the relevant expertise: the AASLD, comprised of experts in gastroenterology and hepatology, and the IDSA, comprised of infectious disease specialists.[149] Second, "[a] majority of medical providers in the United States who treat HCV follow the AASLD/IDSA Guidance recommendations."[150]

Indiana's IDOC and Florida's FDC's policies for treating HCV purport to prioritize treatment based on the stage of an inmate's disease. IDOC's written policy gives the highest priority to F3 and F4 inmates, intermediate priority to F2 inmates, and low priority to F0 and F1 inmates.[151] IDOC's policy also permits exceptions from the priority criteria based on "a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other

144. *Jones*, 290 F. Supp. 3d at 1299; *Id*. at *12 (citing, *inter alia*, *Jones*, 290 F. Supp. 3d at 1299).

145. *Jones*, 290 F. Supp. 3d at 1296.

146. MUSHLIN, *supra* note 110.

147. *Id.*

148. J.E. SCHMIDT, ATTORNEYS' DICTIONARY OF MEDICINE (Matthew Bender & Company 2019).

149. *Atkins*, 412 F. Supp. 3d 761 at 768.

150. *Id*.

151. Stafford v. Carter, No. 1:17-CV-00289, 2018 WL 4361639, at *10 (S.D. Ind. Sept. 12, 2018) (I translate these APRI scores into the F stage scale).

comorbidities."[152] FDC's policy is similar.[153] In practice, IDOC and FDC's prioritization approach amounted to full-scale denials of treatment, with all but a handful of infected inmates receiving treatment.[154] This state of affairs, observed the *Stafford* court, "can be described in no other way than an effective denial of treatment for those suffering from chronic HCV."[155]

The *Stafford* court expressly rejected the argument that stages F0 and F1 are not "serious" within the meaning of *Estelle*'s deliberate indifference test.[156] This argument was also advanced by the Pennsylvania Department of Corrections (PDOC) in *Chimenti v. Wetzel,*[157] another class action lawsuit challenging a state prison system's HCV treatment policy. PDOC moved for summary judgment on the F0 and F1 inmates' Eighth Amendment claim on grounds that they did not (currently) have serious medical needs.[158] PDOC cited testimony that early-stage inmates "are at low risk for rapid progression to severe liver disease, [and] therefore they are not at imminent risk of physical injury without immediate treatment with DAA therapies."[159]

PDOC's argument in *Chimenti* has a surface plausibility. From a medical perspective, F3 and F4 patients are "at greatest risk of disease complications" and will realize "the most immediate benefits of treatment."[160] On this basis a doctor might say that an F0-F1 inmate's need for DAAs or medical condition is less pressing or "serious" than an F3-F4 inmate's. The confusion arises because the question of seriousness is legal or legal-medical as opposed to strictly medical or clinical. The relevant question is not "Is HCV at stages F3-F4 clinically more serious than at F0-F1?" Rather, the question is "Does the medical standard of care recommend treatment with DAAs for HCV at stages F0-F1?" Because the answer is yes, HCV at stages F0-F1 is a "serious medical condition."

Laypersons can also appreciate the importance of treating patients with early-stage HCV. Delaying patients' treatment significantly increases their risk of liver-related death.[161] Untreated patients experience the stress of

152. *Id.* at *10.
153. *Jones*, 290 Fla. Supp. 3d at 1301.
154. *Stafford*, 2018 WL 4361639, at *12.
155. *Id*. at *20.
156. *Id*. at *19-20.
157. Chimenti v Wetzel, No. 15-3333, 2018 WL 3388305, at *1, *10 (E.D. Pa. July 12, 2018).
158. *Id.*
159. *Id*.
160. AASLD/IDSA HCV Guidance Panel, *supra* note 95 at 935.
161. *See Stafford*, 2018 WL 4361639, at *17 ("[T]he undisputed medical evidence is that delaying treatment for chronic HCV until patients have developed more advanced stage liver fibrosis has been demonstrated to result in two to five times higher rates of liver-related mortality, as compared to those offered treatment at an earlier stage.").

living under a death sentence, *i.e.*, "the certainty that their disease will progress through the stages of infection."[162] Because staging is an imprecise art, a late-stage patient may present as an early-stage one and vice versa.[163] Even if a patient has been accurately staged, it is difficult to predict how quickly a patient's disease will progress. All these factors increase the danger of delaying treatment.

*Defendants Acted with Deliberate Indifference*

*Hoffer* found that Florida's FDC acted with deliberate indifference because it explicitly denied treatment with DAAs for a non-medical reason—FDC's alleged lack of funds.[164]

The *Stafford* court found that Indiana's IDOC officials acted with deliberate indifference by adopting and maintaining a medically unjustified HCV treatment policy.[165] ". . .[I]t is undisputed that there is *no medical justification* for dividing individuals into treatment categories based on the degree of fibrosis or the progression of their disease . . . ."[166] IDOC therefore also withheld treatment on non-medical grounds, although the nature of that non-medical ground is somewhat obscure because IDOC did not claim inadequate resources.[167]

The lack of medical justification for IDOC's policy is reflected in its departure from the standard of care, which recommends treatment for nearly all chronically infected persons.[168] The court held that IDOC officials acted with deliberate indifference because they were aware of the standard of care and knew that their policy departed from it.[169]

IDOC officials claimed they offered alternative treatments for HCV.[170] These consisted of monitoring, patient education, evaluation by clinicians,

162. *Id*. at *20.

163. *See id*. at *17 ("the undisputed medical evidence establishes that the test used by IDOC to estimate the degree of liver fibrosis is not a good predictor at earlier stages of infection.").

164. *Jones*, 290 Fla. Supp. 3d at 1300–01.

165. *Stafford*, 2018 WL 4361639, at *20 (finding "that [the] Plaintiffs have satisfied both the objective and subjective elements of the deliberate indifference standard.").

166. *Id*. at *13.

167. *Id*. ("But Defendants do not contend that the prioritization system was adopted on the basis of cost savings, and indeed they completely eschew cost as the motivating force.").

168. *Id*. at *9.

169. *Id*. at *15 ("[T]he undisputed evidence establishes that Dr. VanNess knew when he drafted HCSD 3.09 [IDOC's HCV treatment policy] that the medical standard of care for treatment for HCV, as indicated by the AASLD Guidance, recommends treatment for all individuals suffering from HCV, except for those for whom DAAs are medically contraindicated. . . Dr. VanNess was also aware that the prioritization policy adopted by IDOC differs from the AASLD Guidance.").

170. *Id*. at *16.

laboratory analysis, discussion of risk strategies, genotypic testing of the HCV infection, counseling, pain medication, and vitamins.[171] Recall that when an inmate requests a specific treatment, prison officials do not display deliberate indifference by prescribing an effective but suboptimal alternative.[172]

The suggestion here is that Plaintiffs were grasping for the best (DAAs) rather than settling for the good enough alternative (monitoring, etc.). What *chutzpah*! Yet Plaintiffs presented undisputed evidence that the measures IDOC proffered as "treatment" could not cure HCV.[173] Ineffective treatment is no treatment at all.[174]

Lastly, IDOC's HCV treatment policy permitted exceptions from the stage-based priority criteria to account for "compelling or urgent need for treatment."[175] IDOC argued that the opportunity for prison doctors to make individualized assessments precluded a finding of deliberate indifference.[176] The *Stafford* court found that a policy that is medically unjustified at its core cannot be remedied by the mere possibility of medically justified exceptions.[177]

## IV. *STAFFORD* SETTLEMENT

After the *Stafford* court granted summary judgment on Plaintiffs' Eighth Amendment claim, a permanent injunction was sought to require IDOC to treat all chronically infected inmates with DAAs immediately.[178] Before the court held a hearing on this motion, the parties jointly submitted a proposed settlement agreement to the court.[179] In an order dated January 2, 2020, the *Stafford* court approved the proposed settlement agreement as "a fair,

171. *Id*. at *5, *6, *16.

172. *See infra* Part IV.

173. Stafford v. Carter, 2018 WL 4361639, at *16.

174. *See id.* at *17 (writing that "there is simply no genuine dispute of material fact on this issue–the only proffered evidence establishes that the actions identified by Defendants do not constitute treatment.").

175. *Id.* at *10.

176. *Id.* at *13.

177. *Id.* at *14 (in particular, the *Stafford* court stated:
"If Defendants' primary concern were the individualized treatment of each inmate for his or her HCV, no categorization or prioritization would be necessary . . . .Without the prioritization system, each individual would be treated without reference to a treatment category, but instead based solely on his own symptoms and medical presentation").

178. Plaintiff's Motion for Permanent Injunction at [*11], *Stafford*, 2018 WL 4361639 (Mar. 26, 2019) (No. 218).

179. Amended Stipulation to Enter into Settlement Agreement Pursuant to 18 U.S.C. § 3626(c)(2) Following Notice to the Class and Fairness Hearing at [*3], *Stafford*, 2018 WL 4361639 (Aug. 12, 2019) (No. 253).

reasonable, and adequate resolution of this matter."[180]

Under the terms of the settlement, IDOC promises to revise its HCV treatment policy to require treatment of all chronically infected inmates.[181] IDOC will phase in treatment over several years based on disease stage.[182] It will treat F2-F4 inmates by July 1, 2020, paying for such treatment out of its existing budget.[183] It will treat F0-F1 inmates by July 1, 2023, subject to an appropriation of the Indiana General Assembly.[184]

IDOC agrees to ask the Indiana General Assembly to appropriate an amount "equal to the number of class members currently incarcerated multiplied by the cost of a standard course of DAA medication . . . ."[185] This amount could be as large as $100 million.[186] If IDOC fails to revise its HCV treatment policy or to request or obtain an appropriation from the Indiana General Assembly, the *Stafford* court retains jurisdiction to enforce the agreement, or to re-open the action and hear the Plaintiffs' motion for a permanent injunction.[187]

## V. *HOFFER* AND THE HEALTH IMPACTS OF INJUNCTIVE RELIEF ON THIRD PARTIES

In November 2017, the *Hoffer* court granted Plaintiffs' motion for a preliminary injunction and ordered FDC to commence treating F2 to F4 inmates within one year.[188] In April 2019, the court granted Plaintiffs' motion for a permanent injunction and ordered FDC to commence treating F0 and F1 inmates within two years.[189] FDC has appealed both rulings.[190]

In deciding whether to grant injunctive relief, a court is obliged to consider the impact of such relief on non-movants.[191] These impacts can be assessed under two doctrinal headings: the balancing of hardships and the public interest.[192] In its balancing-the-hardships analysis, the *Hoffer* court touched

180. Stafford v. Carter, No. 1:17-CV-00289-JMS-MJD, at *5 (S.D. Ind. Jan. 2, 2020) .
181. *Stafford*, 2018 WL 4361639, at *8–9 (Aug. 12, 2019) (No. 253).
182. *Id.* at *9–10.
183. *Id.* at *9.
184. *Id.* at *9–10.
185. *Id.* at *10.
186. Defendant's Pre-Hearing Brief and Response to Plaintiff's Motion for Permanent Injunction at 4, *Stafford,* 2018 WL 4361639 (Apr. 9, 2019) (No. 224).
187. Order at 6, *Stafford*, 2018 WL 4361639, at *6 (Jan. 2, 2020) (No. 282).
188. *Jones*, 290 F. Supp. 3d at 1305–06.
189. *Inch*, 382 F. Supp. 3d at 1316.
190. Docket, Carl Hoffer, et al. v. Secretary, Florida Department, No. 19-11921 (11th Cir. May 17, 2019) (No. 19-11921).
191. *See*, e.g., *Jones*, 290 F. Supp. 3d at 1298 (discussing the procedure for injunctive relief).
192. *Inch*, 382 F. Supp. 3d at 1314–15.

upon, but did not pursue, how requiring the prison system to pay for DAAs would affect its ability to pay for other kinds of inmate health interventions.[193] In finding that an injunction would serve the public interest, the *Hoffer* court focused on how it would reduce the risk of disease transmission to uninfected individuals in the inmate and general populations.[194]

*Balancing the Interests of Infected Inmates with Nonparties*

In deciding a motion for injunctive relief, a court engages in "a balancing of the interests of the parties who might be affected by the court's decision—the hardship on plaintiff if relief is denied as compared to the hardship on defendant if it is granted."[195] A court may also refuse relief in order to avoid imposing a hardship on third persons, *i.e.*, parties other than the defendant.[196]

In granting injunctive relief to Plaintiffs, the *Hoffer* court found that the balance of hardships weighed more heavily on Plaintiffs.[197] On one side were the "great injuries" that Plaintiffs would face due to "the harmful consequences that result from untreated HCV."[198] On the other side, "[t]he only hardship Defendant faces is that FDC will have to spend more money [on DAAs] and treat more [HCV-infected] inmates than it wants to."[199] FDC would also incur "administrative inconvenience."[200]

The *Hoffer* court pits the Plaintiffs' interests against the FDC's interests, which appear inconsequential. In this context, however, prison officials may represent the legitimate interests of nonparties, most notably uninfected inmates whose healthcare may worsen if relief is granted.[201] In *Ward v. Walsh*, the Ninth Circuit denied an Orthodox Jewish inmate's request not to be transported on Shabbat or Jewish holidays.[202] The court credited the warden's testimony that "the health, safety, and welfare of the prisoners is dependent upon the ability to move prisoners quickly and efficiently," and that granting plaintiff's request "could have a significant impact on guards, other inmates, and prison resources."[203] Are HCV-infected inmates like the Orthodox Jewish inmate, where meeting their needs would burden nonparty

193. *Jones.*, 290 F. Supp. 3d at 1304.
194. *Inch*, 382 F. Supp. 3d at 1315.
195. MARY KAY KANE, 11A FEDERAL PRACTICE & PROCEDURE § 2942 (3d ed. 2019).
196. *Id.*
197. *Jones*, 290 F. Supp. 3d at 1304; *Inch*, 382 F. Supp. 3d at 1315.
198. *Jones*, 290 F. Supp. 3d at 1304.
199. *Inch*, 382 F. Supp. 3d at 1315.
200. *Id.*
201. *See* Ward v. Walsh, 1 F.3d 873, 879–80 (9th Cir. 1993).
202. *Id.*
203. *Id.* at 880.

inmates?

Like the warden in *Ward v. Walsh*, FDC officials have rejected the Plaintiffs' request on grounds that granting it would harm the interests of nonparties. FDC "does not have unlimited resources and must be a good steward of public funds"[204]—in this case, taxpayer dollars designated for inmate health care. FDC understands stewardship to mean using its scarce health care dollars in a cost-effective manner. This notion is familiar: "[m]aximization of health benefits within a relatively fixed budget [is] an important social and political value."[205]

Let's assume that some uninfected inmates have greater medical needs than some HCV-infected inmates.[206] If so, then at some point each healthcare dollar spent on non-HCV-related health needs yields more health benefits than if spent on HCV-related health needs. On this account, compelling FDC to treat every HCV-infected inmate would reduce overall inmate health. In FDC's words:

It would be unreasonable to force the FDC to provide DAA drugs to these inmates—who are not at risk of immediate serious harm—where such a requirement would immediately harm the FDC's ability to provide medical care to other inmates with more immediate needs.[207]

FDC does not exactly argue that it cannot pay for DAAs, *i.e.*, it does not invoke a defense of inadequate resources. Rather, it stands by its decision to fund health interventions more cost-effective than treating infected inmates with DAAs. The FDC "must also make policy choices on how to spend its limited resources on its numerous constitutional mandates."[208]

Assuming the size of FDC's budget is fixed (even if fixed by FDC's inaction), any funds spent on DAAs must, according to FDC, be "taken from providing care to other inmates."[209] The *Hoffer* court rejects this: "But that is no excuse. FDC cannot use its constitutional duty to treat a certain group of inmates as a reason not to treat a different group."[210]

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204. Secretary Jones' Response in Opposition to Plaintiff's Motion for Preliminary Injunction at 9, Hoffer v. Jones, 290 F. Supp. 3d 1292 (N.D. Fla. 2017) (No. 4:17-CV-00214-MW-CAS).

205. LAWRENCE O. GOSTIN & LINDSAY F. WILEY, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 63 (3d Ed. 2016).

206. *See* Secretary Jones' Response in Opposition to Plaintiff's Motion for Preliminary Injunction at 9, *Jones,* 290 F. Supp. 3d 1292 (No. 31) ("Under the one-size-fits-all approach requested by Plaintiffs, a prisoner with HCV but without symptoms . . . should be pushed to the front of the line for expenditure of the FDC's limited resources regardless of the need under the Eighth Amendment.").

207. *Id.*

208. *Id.* at 9.

209. *Jones*, 290 F. Supp. 3d at 1304, n.23.

210. *Id.* at 1304; *See also Inch*, 382 F. Supp. 3d at 1315, n.26 ("It is no excuse to cry that resources may be diverted from other medical programs. FDC cannot use its

Is the *Hoffer* court correct? The answer depends on the extent of FDC's constitutional duty to provide health interventions unrelated to HCV. A prison system cannot triage its constitutional obligations: it must meet them all. As the Eleventh Circuit stated in *Williams v. Bennett*, "[i]f . . . a state chooses to operate a prison system, then each facility must be operated in a manner consistent with the constitution."[211] If there is not enough money to fund both constitutionally-obligatory and discretionary health interventions for inmates, FDC may be obliged to stop funding the discretionary ones in order to fund the obligatory ones. This is true even if some discretionary interventions improve inmate health more cost-effectively than those required by the U.S. Constitution.

Contributing to this problem is FDC's unexplained failure to ask the state legislature to provide more funds. Indeed, high-level FDC officials apparently thwarted efforts by lower-level officials to ask the legislature for such funds.[212] FDC cannot fund both DAAs and other interventions without more funds, nor can it fund DAAs without eliminating discretionary interventions it deems more conducive to overall inmate health. From this perspective, the *Hoffer* court is correct to stay focused on the choices of FDC officials—especially their choice to keep the agency under-resourced—and not on the inmates whose health is harmed by those choices.

*The Public Interest*

In assessing a motion for injunctive relief, a court must consider whether granting it would serve (or not disserve) the public interest.[213] The *Hoffer* court found that granting Plaintiffs' motion would serve the public interest by combatting the HCV epidemic.[214]

"[B]oth parties' experts testified that treating HCV inside prisons may have great impacts on reducing the prevalence of HCV outside prisons. . . . So, if anything, it seems that an injunction in this case would actually *serve* the public interest."[215] The case for granting an injunction is bolstered by the indirect health benefits it confers on third parties, most notably the general

constitutional duty to treat one group of inmates as a reason to not treat a different group.").

211. *Bennett*, 689 F.2d at 1388.

212. *Jones*, 290 F. Supp. 3d at 1298 ("In 2015, Mr. Reimers [the FDC administrator responsible for overseeing medical contractors] prepared a legislative budget request of $6.5 million to obtain DAAs for the 2016–17 fiscal year, but the request never made it out of FDC (*i.e.*, someone in FDC denied it). [citation omitted] In 2016, Mr. Reimers prepared a $29 million request for the 2017–18 fiscal year, but that too never made it out of FDC").

213. *See Inch*, 382 F. Supp. 3d at 1314 (stating that to obtain a permanent injunction, Plaintiffs must show [inter alia] that a permanent injunction would not disserve the public interest").

214. *See Jones*, 290 F. Supp. 3d at 1304.

215. *Id.*

population.

## CONCLUSION

When an inmate HCV lawsuit brings about the universal treatment of infected inmates, it simultaneously vindicates the inmates' Eighth Amendment rights and maximally advances the public health goal of eradicating HCV. In order to pay for DAAs, however, prison officials may be tempted to cut spending on health interventions unrelated to HCV that are not constitutionally required. If some of the eliminated interventions improve inmate health more cost-effectively than DAAs, universal treatment may unintentionally reduce the entire inmate population's overall health and possibly the general population's as well.

The *Stafford* and *Hoffer* cases show that courts are well positioned to enforce an infected inmate's constitutional right to treatment, combat the spread of HCV to uninfected individuals, and ensure that taxpayers bear the costs of treatment instead of uninfected inmates.