MAKING A DELIBERATE DIFFERENCE: CREATING A CONSTITUTIONAL SOLUTION TO HEPATITIS C IN PRISONS

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INTRODUCTION

In chronic cases, the hepatitis C virus ("HCV") replicates insidiously by dulling the body's normal immune responses, often

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manifesting its destruction decades after the initial infection.[1] In this way, the virus mirrors the current HCV health crisis in our country's prison systems: Decades of strict drug enforcement policies in the United States have exacerbated the number of drug users in incarceration, and in lockstep, increased the percentage of prisoners infected with communicable-diseases.[2] As for HCV, the infection rate in the noninstitutionalized U.S. population is approximately one percent, while the prevalence among prison inmates is about seventeen percent.[3] It is estimated that one-third of America's HCV population spends part of the year in jail or prison.[4] Recently developed direct-acting antiviral ("DAA") oral treatments present the first simple, efficient, and tolerable treatment for HCV in correctional populations, but the high price of these drugs (retail prices in 2017 are estimated between $84,000 and $94,500) present a major barrier to implementing widespread treatment in correctional facilities.[5]

The unique nature of the disease, combined with the high cost of effective, but impermanent,[6] treatment raises serious questions about the application of the "deliberate indifference" standard under the Eighth Amendment in correctional facilities. The U.S. Supreme Court has recognized basic healthcare for prisoners as a constitutional right, but the current interpretation of the Eighth Amendment guarantees prisoners only

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1. Orla Convery et al., *The hepatitis C virus (HCV) protein, p7, suppresses inflammatory responses to tumor necrosis factor (TNF)- a via signal transducer and activator of transcription (STAT)3 and extracellular signal-regulated kinase (ERK)–mediated induction of suppressor of cytokine signaling (SOCS)3*, 33 THE FASEB J. 8732, 8741 (2019).

2. The U.S. prison and jail population has plateaued since 2007 at approximately 2 million people, and the concentration of communicable diseases remained incredibly high. As of 2017, U.S. prisons contained 1.439 million individuals, Jennifer Bronson & E. Ann Carson, *Bulletin: Prisoners in 2017*, BUREAU OF JUST. STAT., at 6 (April 2019), https://www.bjs.gov/content/pub/pdf/p17.pdf, [https://perma.cc/C9GW-WDPY]; and U.S. county and city jail population at midyear 2017 was 745,200 inmates. Zhen Zeng, *Bulletin: Jail Inmates in* 2017, BUREAU OF JUST. STAT., at 1 (April 2019), https://www.bjs.gov/content/pub/pdf/ji17.pdf. [https://perma.cc/CS8F-U8WC]; In 2011-2012, twenty-one percent of prisoners and fourteen percent of jail inmates reported having blood-borne communicable diseases. Laura M. Maruschak et al., *Medical Problems of State and Federal Prisoners and Jail Inmates, 2011-12*, BUREAU OF JUST. STAT., at 1 (Revised October 2016), https://www.bjs.gov/content/pub/pdf/mpsfpji1112.pdf [https://perma.cc/TK34-VWSY].

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

4. *Id.*

5. *Id.* at 1893–94.

6. Notably, DAAs are not a vaccine. Reinfection is possible even after treatment. *See* Matthew McConnell & Joseph K. Lim, *Hepatitis C Vaccine Development in the Era of Direct-Acting Antivirals*, 12 CLINICAL LIVER DISEASE 118, 118 (2018).

limited access to medical care.[7] A prisoner challenging medical care as inadequate must show "deliberate indifference" by prison officials, a legal standard that entitles prisoners to relief only when prison officials show a conscious disregard for a prisoner's medical needs.[8] In general, courts are hesitant to order expanded access to medical care, deferring instead to prison administration in the formulation of healthcare policy. Therefore, the HCV crisis in prisons presents an incredibly significant challenge, both in protecting public health [9] and in determining the legal duties of state and federal correctional systems under the Eighth Amendment.

Historically, the judiciary's deference to states concerning the medical treatment of prisoners has mired the treatment of new diseases in the correctional setting. Conversely, the recent development of effective HCV treatments has created a wave of inmates seeking judicial intervention to impose greater constitutional obligations on the country's correctional systems.[10] These opposing forces add a new wrinkle to the Eight Amendment's interpretation. Current national HCV guidelines recommend treatment for all inmates who have sufficient time left on their sentences to receive a recommended course of antiviral therapy.[11] Yet many states have implemented less stringent HCV treatment protocols, and others have yet to adopt protocols that account for new antiviral drugs.[12] Prisoners are challenging these protocols across the country, claiming that a failure to provide DAA treatment to prisoners with HCV constitutes deliberate indifference to their medical needs.[13] Much of the current HCV litigation focuses on states' obligations under the Eighth Amendment to test individuals for HCV, whether nonmedical exclusions are appropriate, and if states may precondition treatment for patients with little or no progression of the disease.[14]

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7. In Estelle v. Gamble, 429 U.S. 97, 104–05 (1976), the Supreme Court established that the Eighth Amendment prohibits deliberate indifference to serious medical needs of prisoners.

8. *Id.*

9. H. Stöver et al., *Offering HCV Treatment to Prisoners is an Important Opportunity: Key Principles Based on Policy and Practice Assessment in Europe*, BMC PUB. HEALTH, 2019 at 2. https://bmcpublichealth.biomedcentral.com/track/pdf/10.1186/s12889-018-6357-x [https://perma.cc/34W9-XKWU].

10. *See infra* Part III.

11. *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C,* HCV GUIDELINES.ORG (Nov. 6, 2019), https://www.hcvguidelines.org/unique-populations/correctional [https://perma.cc/2YFC-YX5Z].

12. *See infra* Section I.B.

13. *See infra* Part III.

14. *See* Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 4361639, at *13 (S.D. Ind. Sept. 13, 2018) (finding that the "stage" level of the disease is for evaluating type of treatment, not whether treatment should begin at all); Chimenti v. Wetzel, No. 15-3333, 2018 WL 3388305, at *10–12 (E.D. Penn. July 12, 2018) (at summary judgment level, finding that material issues of fact exist as to whether

This Note argues that prisons do not show deliberate indifference in treating HCV if they establish protocols that provide systematic testing of inmates upon intake, establish medical review boards that make individual treatment determinations, prioritize treatment of individuals based on those determinations, allocate specific funding for the purchase of DAAs and other treatment costs, and allow for third parties to monitor treatment implementation. Part I describes the HCV virus and its treatment, the current standards of HCV care, and the barriers to effective treatment of the disease in prisons. Part II reviews the deliberate indifference standard, how the standard is shaped around individual medical determinations, and court deference to prison policy. Part III examines the status of HCV litigation in prisons in the United States and contrasts two recent U.S. District Court decisions, each pending appeal, that highlight how the Eighth Amendment might apply to the HCV crisis. Part IV examines the focus of HCV litigation and suggests that states can craft treatment policies that comply with the Constitution and effectively address the HCV crisis in prisons.

I. HEPATITIS C

Hepatitis C is a unique disease, both as it compares to other strains of hepatitis and to other infectious diseases. The disease has remained in relative obscurity in part because of its slow-developing nature and invasive testing techniques. However, the development of accurate noninvasive testing and a better understanding of at-risk populations has raised the profile of the disease globally. This section will discuss the characteristics of HCV that make it particularly difficult to treat, the relationship between the disease and prisons, and the complications of introducing recently developed DAA treatments to correctional facilities.

A. A Unique Disease

The hepatitis C virus (HCV) is the most frequently reported bloodborne infection in the United States and a leading cause of liver-related health problems, transplantations, and death.[15] In 2018, a conservative estimate cited over 15,700 U.S. death certificates that listed HCV as an underlying or contributing cause of death.[16] HCV infections are

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inmates at lower stages of the disease have serious medical needs); Buffkin v. Hooks, No. 1:18CV502, 2019 WL 1282785, at *9 (M.D. N.C. Mar. 20, 2019) (finding that genuine issues exist about whether DAAs are required treatment for all prisoners with HCV).

15. Eli S. Rosenberg et al., *Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016*, JAMA NETWORK OPEN (2018).

16. *Hepatitis C Questions and Answers for Health Professionals,* CTR. FOR DISEASE CONTROL (Sept. 7, 2019), https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm #Ref01 [https://perma.cc/G9CF-SMDH].

classified either as acute or chronic.[17] For patients with an acute infection, they are able to spontaneously clear the infection without treatment.[18] However, for approximately 75-85% of people infected with HCV, the disease becomes a chronic infection.[19] It is estimated that 3.5 million people in the United States are living with chronic HCV.[20]

HCV infections cause inflammation in the liver.[21] As the liver regenerates damaged tissue, it causes scarring that eventually decreases the liver's ability to perform its functions.[22] The progress of the disease is based on the level of scarring also known as "fibrosis."[23] In chronic cases, HCV is termed a "silent epidemic" because replications of the virus change to evade the immune response.[24] For most people with chronic HCV, their infections are asymptomatic, or they have non-specific symptoms such as chronic fatigue and depression.[25] Among chronically infected individuals, approximately 10-20% will go on to develop liver cirrhosis over a period of twenty to thirty years.[26] Patients who develop liver cirrhosis then face an annual risk of developing life-threatening liver cancer or liver failure.[27] Critically, prior infection does not protect against reinfection of the same or different variations of the virus.[28]

Historically, HCV infections were tracked over time, often through invasive biopsies to take a static sample of liver fibrosis.[29] Eventually, noninvasive means were developed to evaluate HCV and allow for accurate testing to be performed more frequently.[30] Usually as a preliminary test, a blood sample is taken from an individual to measure liver functionality.[31] Those results are then processed through an algorithm that considers age

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17. *Id.*

18. Approximately 15-20% of patients clear the disease without treatment. The reasons for this are still not well known. *See id.*

19. *Id.*

20. David Powell et al., *A Transitioning Epidemic: How The Opioid Crisis Is Driving The Rise In Hepatitis C*, 38 HEALTH AFF. 287, 287 (2019).

21. *Hepatitis C Questions and Answers for Health Professionals*, *supra* note 16.

22. *Id.*

23. Ramón Bataller & David A. Brenner, *Liver Fibrosis*, 115 J. CLINICAL INVESTIGATION 209 (2005).

24. *Hepatitis C Questions and Answers for Health Professionals*, *supra* note 16.

25. *Id.*

26. *Id.*

27. *Id.*

28. *Id.*

29. Keyur Patel et al., *FibroSureTM and FibroScanTM in relation to treatment response in chronic hepatitis C virus*, 17 WORLD J. GASTROENTEROLOGY 4581, 4582 (2017).

30. *Id.*

31. *Id.* at 4588.

and gender to generate an initial fibrosis level.[32] Often, if this initial test indicates a possibility of an HCV infection, an individual receives a specialized ultrasound of the liver.[33] These tests measure liver scarring caused by HCV by measuring the stiffness of an individual's liver.[34] Doctors use that data to determine a fibrosis score.[35] The rating systems are expressed as follows: F0 to F1: no liver scarring or mild liver scarring; F2: moderate liver scarring; F3: severe liver scarring; F4: advanced liver scarring (cirrhosis).[36]

In 2013, annual HCV-related mortality surpassed the combined number of deaths from sixty other infectious diseases, including HIV, pneumococcal disease, and tuberculosis.[37] The greatest HCV burden falls generally on baby boomers, often infected during medical procedures in the years after World War II when injection and blood transfusion technologies were not safe.[38] However, new infections are often underreported due to the nature of the disease and difficulties in screening.[39] Acute cases of HCV doubled in four years from 2010 to 2014.[40] Predominantly, these cases were "among young, white individuals with a history of injection drug use, living in rural and suburban areas of the Midwest and Eastern United States."[41] There is evidence that this wave of new infections stems directly from the rise of opioid use in the United States.[42] As pain medications like OxyContin were reformulated to prevent abuse, many drug users switched to intravenous drug use like heroin.[43] While the misuse of reformulated pain medications decreased, both HCV infections and heroin deaths increased at similar rates.[44] If drug users are switching to injection methods, there will continue to be an increase in individuals with bloodborne infectious diseases like HCV.[45]

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32. *Id.* at 4582.

33. *Id.* at 4588.

34. *Understanding your FibroScan Results*, MEMORIAL SLOANE KETTERING CANCER CTR. (Feb. 27, 2018), https://www.mskcc.org/cancer-care/patient-education/understanding-your-fibroscan-results [https://perma.cc/P99D-UJMC].

35. *Id.*

36. *Id.*

37. *Hepatitis C Kills More Americans than Any Other Infectious Disease*, CTR. FOR DISEASE CONTROL AND PREVENTION (May 4, 2016), https://www.cdc.gov/media/releases/2016/p0504-hepc-mortality.html [https://perma.cc/GEL6-YT65].

38. *Id.*

39. *Id.*

40. *Id.*

41. *Id.*

42. *See* Powell, *supra* note 20, at 292–93.

43. OxyContin was reformulated in 2010. This version was designed to prevent the pill from being crushed or dissolved in an attempt to deter abuse by inhalation or injection. *Id.* at 288.

44. *See id.* at Exhibit 1, 288.

45. *Id.* at 293.

B. HCV in Prisons

While it is estimated that HCV is prevalent in roughly one percent of the total population, analysis suggests that HCV infects between 17.4% and 23.1% of incarcerated populations.[46] Because the primary means of transmitting HCV is through contact with infected blood, HCV is estimated to be present in between 38.1% and 68% of injection drug users.[47] More than half of state prisoners and two-thirds of sentenced jail inmates met the criteria for drug dependence or abuse.[48] Based in part on the criminalization of drug use in the United States, it is estimated that one-third of Americans with HCV spend at least part of the year in a correctional facility.[49] The high prevalence of HCV in state and federal correctional facilities presents a health threat to both the individual inmates and the public.[50] First, correction facilities contain a high prevalence of individuals with significant medical needs, and second, the reentry of those individuals to society, if left untreated, creates a dangerous risk of transmission to the general population.[51]

The standards for HCV care in prisons are still being developed, based partially on the fairly recent discovery of the diseases,[52] and on the recent development of effective, direct-acting antiviral drugs.[53] A 2015

46. *HCV Guidance*, *supra* note 11.

47. *Hepatitis C Questions and Answers for Health Professionals*, *supra* note 16.

48. Jennifer Bronson et al., *Drug Use, Dependence, and Abuse Among State Prisoners and Jail Inmates*, *2007-2009*, U.S. DEP'T JUSTICE (June 2017), https://www.bjs.gov/content/pub/pdf/dudaspji0709.pdf [https://perma.cc/TQ5E-HYJG].

49. Beckman, *supra* note 3, at 1893.

50. As a personal medical problem, HCV care addresses the health of an individual. As a public health problem, HCV care in correctional facilities is an effective way to treat a large portion of HCV infected individuals. *See* Scott A. Allen et al., *Hepatitis C Among Offenders – Correctional Challenge and Public Health Opportunity*, 67 FED. PROB. J. 22, 24 (2003).

51. Beckman, *supra* note 3, at 1893.

52. *The 25th Anniversary of the Discovery of the Hepatitis C Virus: Looking Back to Look Forward*, CTR. FOR DISEASE CONTROL AND PREVENTION (June 17, 2014), https://www.cdc.gov/grand-rounds/pp/2014/20140617-hepatitis-c.html [https://perma.cc/BE45-VBMX].

53. From the early 1990s until 2011, treatment of Hepatitis C was limited to about 70% effectiveness for genotype I patients. However, in 2013, new direct-acting antiviral drugs increased the effectiveness to 90% for the same genotypes. Kathleen Maurer et al., *Hepatitis C in Correctional Settings: Challenges and Opportunities*, 2 COALITION OF CORRECTIONAL HEALTH AUTHORITIES AM. CORRECTIONAL ASS'N 1, 3 (2015), http://www.aca.org/ACA_PROD_IMIS/Docs/OCHC/HCVinCorrectionalSetting_Final.pdf. [https://perma.cc/7PUN-LL68].

survey[54] of state prisons found that only seventeen of the forty-nine reporting states had routine opt-out testing[55] for hepatitis C, and only ten percent of prisons spent more than $5 million dollars on HCV treatment.[56] Staggeringly, this study reported that only 949 inmates out of the 106,266 inmates with known HCV were receiving any form of treatment as of January 1, 2015.[57] Additionally, states used a variety of factors to prioritize HCV treatment. Forty-one states prioritized patients with cirrhosis for HCV treatment, and twenty-three states prioritized treatment for patients with chronic HCV.[58] States also considered nonclinical criteria, such as the length of time remaining on a prison sentence, the likelihood of recidivism, and the patient's chance of reinfection by engaging in risky behaviors like drug use or fighting.[59] Some states also explained that a prisoner's compliance with treatment for drug use, alcohol abuse, or mental health criteria would also be considered before treatment.[60]

In contrast, current treatment guidelines from healthcare groups suggest complete treatment with DAAs for inmates with sufficient sentence time to complete a regiment.[61] The Federal Bureau of Prisons has guidelines that recommend treating prisoners with HCV with the new DAAs.[62] However, federal prisons in 2017 only contained 183,058 inmates while state prisons house approximately 1.3 million inmates.[63] As a result, states have the incredible burden to treat a large portion of America's HCV problem, and often do so without adequate resources.

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54. Unquestionably, HCV treatment has improved since 2015. However, much of these improvements have come on the heels of litigation discussed in part III. Instead, this study represents the condition of HCV treatment in prisons shortly after the development of DAAs.

55. Meghan D. Morris et al. *Universal opt-out screening for hepatitis C virus (HCV) within correctional facilities is an effective intervention to improve public health,* INT. J. PRISONER HEALTH (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5764160/pdf/intjprisonhealth-13-0192.pdf [https://perma.cc/8KHJ-HFEM]; opt-out testing means that prisoners will be tested unless they request not to be. This is contrasted by opt-in testing, in which a prisoner must request the test be performed.

56. Beckman, *supra* note 3, at 1895.

57. Only 41 states reported the number of prisoners being treated. *Id.* at 1896.

58. *Id*. at 1897.

59. *Id.*

60. *Id.*

61. *HCV Guidance*, *supra* note 11.

62. *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection*, Fed. Bureau Prisons Clinical Guidance (Oct. 2016), at 9–12, https://www.bop.gov/resources/pdfs/hepatitis_c.pdf [https://perma.cc/3BEH-X2QS] (last accessed Jan. 10, 2020).

63. Bronson & Carson, *supra* note 2.

C. The Cost of HCV: Direct-Acting Antiviral Drugs

Treatment options for patients with chronic HCV infections have increased rapidly in the thirty years since the disease was discovered. For approximately twenty years, from 1990 to 2011, the most effective treatment was interferon drugs that inhibit the virus's replication.[64] This treatment only achieved a 40-50% effective treatment rate.[65] Additionally, interferon treatment of HCV produced a number of difficult side effects including fever, headache, depression, joint and muscle pain, and in some cases, serious autoimmune complications.[66] From 2011 until 2013, the introduction of direct-acting antiviral ("DAA") medications increased efficacy rates to almost 70%.[67] Most recently in 2013, several new types of DAAs were introduced that, while extremely costly, give effective treatment of the disease in 90% of cases.[68] Currently, the most common treatment option provides an oral one-pill-per-day regimen with a course of therapy for eight, twelve, or twenty-four weeks.[69]

With such effective treatment, the issue with providing this medication to prisoners becomes one of cost. DAAs are one of the most expensive oral medications in history, with wholesale acquisition prices, or "sticker" prices, ranging from $417 to $1,125 per pill depending on the specific type.[70] These wholesale acquisition prices are substantially higher than the estimated cost of production for the medication.[71] As an example, a twelve-week course of sofosbuvir, a DAA that treats HCV, is $84,000, and the estimated production cost is between $68 and $136.[72] Pharmaceutical companies justify this significant discrepancy between "sticker" price and actual cost based on a need to recoup large expenses incurred during the research and development process for the medication.[73]

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64. Maurer, *supra* note 53.

65. *Id.*

66. Geoffrey Dusheiko, *Side Effects of Alpha Interferon in Chronic Hepatitis C*, 26 HEPATOLOGY 112S, 113S (1997), https://aasldpubs.onlinelibrary.wiley.com/doi/epdf/10.1002/hep.510260720 [https://perma.cc/42N7-N6ER].

67. Maurer, *supra* note 53.

68. *Id.*

69. *Id.*

70. "Sticker" price is the wholesale acquisition cost and is set by the pharmaceutical company. It can vary greatly from the actual cost of the medicine. Sophie L. Woolston and H. Nina Kim, *Cost and Access to Direct-Acting Antiviral Agents*, HEPATITIS C ONLINE 1, 2 (May 31, 2018), https://cdn.hepatitisc.uw.edu/pdf/evaluation-treatment/cost-access-medications/core-concept/all [https://perma.cc/2453-Z9PJ].

71. *Id.*

72. *Id.*

73. *Id.*

Based on a 2015 survey, states paid varying prices for DAA drugs.[74] It remains difficult for state prisons to negotiate drug prices.[75] The federal government receives discounts for drugs under Medicaid, Medicare, and the Veterans Health Administration.[76] However, state prisons are excluded from many of those programs.[77] One program, the federal 340B Drug Discount Program, would offer state prisons discounted drugs if they were able to partner with a federally qualified health center to provide medical treatment.[78] However, of forty-nine states reporting in 2015, only sixteen states attempted this method of price reduction.[79] Three of the four states paying the lowest for sofosbuvir were using this mechanism.[80]

High drug prices have caused many states to balk at providing the best treatment options for individuals facing serious medical conditions. This has led some states to find alternative strategies for reducing the cost of HCV medications. California, as an example, allocated $176 million to expand HCV treatment for low-income patients and state prison inmates.[81] Roughly $106 million will be used to treat state prisoners.[82] California's version of Medicaid will only provide treatment for individuals with stage two or above liver fibrosis, or any stage if they have a qualifying co-morbid condition.[83] Unique among the solutions is Louisiana's adoption of a "Netflix-model" to make HCV treatment more affordable.[84] Through this "Netflix-model," Louisiana agreed with the manufacturer of DAAs to pay a flat-fee for unlimited use of the drug for five years.[85] Louisiana hopes to treat 31,000 of the estimated 39,000 patients and prisoners with the disease

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74. Michigan reported paying the full list price of $84,000 and $94,500 to treat 100 inmates with HCV but was able to negotiate future discounts of 60-65% off. Anna Maria Barry-Jester, *Prisoners with Hep C Get Cured in Some States But Not Others*, FIVETHIRTYEIGHT (OCT. 13, 2016, 7:00 AM), https://fivethirty eight.com/features/prisoners-with-hep-c-get-cured-in-some-states-but-not-others/ [https://perma.cc/7888-T5W6].

75. *Id.*

76. *Id.*

77. *Id.*

78. Beckman, *supra* note 3, at 1899.

79. *Id.*

80. *Id.*

81. Hannah Holzer, *Not All Californians Can Get Life-Saving Hepatitis C Treatment. Governor's Budget Aims to Fix.*, SACRAMENTO BEE (June 27, 2018 11:51 AM), https://www.sacbee.com/news/local/health-and-medicine/article21370 2989.html [https://perma.cc/WB63-XT5T].

82. *Id.*

83. *Id.*

84. Melinda Deslatte, *Louisiana reaches 'Netflix-model' deal to tackle hepatitis C*, AP NEWS (June 26, 2019), https://www.apnews.com/bc074b5c060249 26a5c58163de8bab9d [https://perma.cc/39D6-LZXE].

85. *Id.*

during that time period.[86] According to Louisiana's Health Secretary, this agreement will save the state an estimated $470 million over the next five years.[87]

Internationally, Egypt once had the highest prevalence of HCV in the world.[88] After unknowingly spreading the disease through the mid-20th century through the reuse of needles, one in ten Egyptians developed chronic HCV.[89] At the U.S. market price of $84,000 per patient, treating the entire infected Egyptian population would have cost half a trillion dollars, nearly double the country's gross domestic product.[90] Egypt was in the middle of price negotiations, while also scrutinizing the drug company's application for a patent, and subsequently denied the drug company's patent application.[91] This allowed generic manufacturers to produce the drug, and through competition, the price of DAA treatment in Egypt is only $84 per patient.[92]

In sum, the high price of DAA medications presents the largest barrier to universal treatment of HCV. Without a path forward for discounted drugs, states are forced to spend more of their budget treating HCV, or alternatively, and more likely, states will attempt to save money by providing the lowest level of treatment possible. As a result, many states risk the prospect of running afoul of the Eighth Amendment and inviting judicially-imposed HCV protocols.

II. DELIBERATE INDIFFERENCE

Originally, the Eighth Amendment's protections were based linguistically and conceptually on the English Bill of Rights of 1689, a protection against torture and other barbaric forms of punishment.[93] In the early part of the twentieth century, the Supreme Court began to give the

86. *Id.*

87. *Id.* (it should be noted that the article lists the treatment cost per course at between $20,000 and $30,000).

88. Ted Alcorn, *Why Egypt Is at the Forefront of Hepatitis C Treatment*, ATLANTIC (May 29, 2018), https://www.theatlantic.com/health/archive/2018/05/why-egypt-is-at-the-forefront-of-hepatitis-c-treatment/561305/ [https://perma.cc/PL43-3YZ5].

89. By 2015, HCV accounted for 40,000 deaths per year, approximately 7.6 percent of all deaths. *Id.*

90. *Id.*

91. *Id.*

92. *Id.*

93. Marc J. Posner, *The Estelle Medical Professional Judgment Standard: The Right of Those in State Custody to Receive High-Cost Medical Treatments*, 18 AM. J. L. MED. 347, 348–49 (1992).

Amendment a broader interpretation.[94] Over time, the Court in *Trop v. Dulles* held that the Eighth Amendment "must draw its meaning from the evolving standards of decency that mark the progress of a maturing society."[95] Later, in *Estelle v. Gamble*, the Court found that the Eighth Amendment requires the federal government and, through the Fourteenth Amendment, the states provide medical care for those punished by incarceration.[96] The Court conditioned this holding by describing that only "deliberate indifference to serious medical needs of prisoners" violates the Eighth Amendment.[97]

Subsequent cases have further defined the "deliberate indifference standard." In *Wilson v. Seiter*, the Court clarified that the deliberate indifference test has both an objective component and a subjective component.[98] To satisfy the objective component, inmates must prove a "sufficiently serious" condition as a matter of objective evaluation.[99] To satisfy the subjective component, inmates must prove that prison officials acted with a "sufficiently culpable state of mind."[100] In *Farmer v. Brennan*, the Court specified that the requisite state of mind for proof of deliberate indifference is criminal recklessness.[101] Thus, to establish an Eighth Amendment violation for inadequate medical care, an inmate must show that "the official knows of and disregards an excessive risk to inmate health or safety; the official must both be aware of facts from which the inference could be drawn that a substantial risk of serious harm exists, and he must also draw the inference."[102] This interpretation tolerates objectively inadequate care if it cannot be shown that a prison official acted or failed to act despite his knowledge of a substantial risk of serious harm.[103]

By its nature, a court places considerable weight on the judgment of medical professionals in evaluating a claim of insufficient medical treatment under *Estelle*.[104] By requiring prisoners to prove a "serious medical need," *Estelle* mandates a court's deference when a medical professional has diagnosed the inmate as such, or when an inmate's condition is so obvious that even a layperson could recognize him as

94. *See, e.g.*, Weems v. United States, 217 U.S. 349, 377 (1910) (striking down a fifteen-year hard labor sentence as excessive punishment for the crime of falsifying public documents).

95. Trop v. Dulles, 356 U.S. 86, 100–101 (1958).

96. Estelle v. Gamble, 429 U.S. 97, 103 (1976).

97. *Id.* at 104.

98. Wilson v. Seiter, 501 U.S. 294, 298 (1991).

99. *Id.*

100. *Id.*

101. Farmer v. Brennan, 511 U.S. 825, 839–40 (1994).

102. *Id.* at 837.

103. *Id.* at 842.

104. Posner, *supra* note 93, at 351.

requiring medical attention.[105] Additionally, the determination of "deliberate indifference" also requires a court to defer heavily to the judgment of medical professionals.[106] Because courts have held that a prison official demonstrates deliberate indifference when he or she deviates from prescribed medical treatment, a prisoner is constitutionally entitled to whatever treatment a medical professional deems necessary.[107] Thus, the difference between medical negligence, a constitutionally excusable omission, and deliberate indifference, an unconstitutional offense, hinges on whether a state treats an inmate in accordance with the judgment of a medical professional.[108]

In general, the Court applies considerable deference to prison policymaking decisions when the issue concerns punishment and detention.[109] This deference standard applies a "lesser standard of scrutiny" when evaluating an infringement upon prisoners' rights.[110] In *Turner v. Safley,* the Court held that "when a prison regulation impinges on inmates' constitutional rights, the regulation is valid if it is reasonably related to legitimate penological interests."[111] Thus, *Turner* suggests that, in certain instances, courts may have limited ability to enforce the constitutional rights of prisoners. However, it remained unclear whether *Turner* applied with equal weight to every constitutional right.

Then, in *Johnson v. California*, the Court made clear that deference to prison policies depends on the right at issue.[112] Finding the *Turner* test inapplicable to evaluating a prisoner's Fourteenth Amendment right to be free from racial discrimination, the Court explained that deference is not required when the right "is not [one] that need necessarily be compromised for the sake of proper prison administration."[113] Thus, for similar reasons, the Court declined to provide a similar deference to Eighth Amendment claims because "the integrity of the criminal justice system depends on full compliance with the Eighth Amendment."[114] The Court opted instead to

105. *Id.*

106. *Id.* at 351–52.

107. *Id*. at 352.

108. *Id*. at 352–53; *see also* Andrew Brunsden, *Hepatitis C in Prisons: Evolving Toward Decency Through Adequate Medical Care and Public Health Reform*, 54 UCLA L. REV. 465, 478 (2006).

109. *See* Bell v. Wolfish, 441 U.S. 520, 547 (1979) ("Prison officials must be free to take appropriate action to ensure the safety of inmates and corrections personnel and to prevent escape or unauthorized entry. Accordingly, we have held that even when an institutional restriction infringes a specific constitutional guarantee, such as the First Amendment, the practice must be evaluated in light of the central objective of prison administration, safeguarding institutional security.").

110. Turner v. Safley, 482 U.S. 78, 81 (1987).

111. *Id.* at 89.

112. Johnson v. California, 543 U.S. 499, 510 (2005).

113. *Id.*

114. *Id.* at 511.

judge violations of the Eighth Amendment under the "deliberate indifference" standard.[115]

III. HCV LITIGATION

After the development of DAA treatments, prisoners suing as a class began litigation against state correctional systems, and subsequent settlements in several states have established benchmarks for still-pending litigation. Other states have attempted to meet the problem more directly by either requesting more funding from the state legislature or by modifying their HCV treatment protocol to avoid constitutional challenges.[116] This section summarizes the states' recent HCV settlements and funding requests and analyzes two U.S. District Court cases that illustrate the application of the Eighth Amendment to the HCV crisis in prisons.

A. Settlement Agreements and Budgetary Adjustments

Several states have settled their class action litigation with inmates with HCV. These agreements provide a useful survey of the relief prisoners seek and may provide potential benchmarks that other states can use as a model for their HCV policies.

In 2018, Colorado agreed to settle its HCV class action claim.[117] Under the terms of this agreement, Colorado will spend $41 million, divided equally, over two years to treat prisoners with HCV.[118] Colorado will no longer require inmates to undergo drug or alcohol treatment as a precondition for treatment, and treatment cannot be withheld as a result of a disciplinary action.[119] Additionally, Colorado will provide the prisoners' counsel with quarterly reports concerning the prison population with HCV and prisoners who have been treated.[120]

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115. *Id.*

116. As noted in *Atkins v. Parker*, Tennessee adopted a new HCV treatment protocol likely in response to prior legal history in other cases. *See* Atkins v. Parker, 412 F. Supp. 3d 761, 764 (M.D. Tenn. 2019).

117. Kirk Mitchell, *Colorado approves $41 million settlement ensuring care of 2,200 state prisoners with hepatitis C*, DENVER POST (Sept. 12, 2018), https://www.denverpost.com/2018/09/12/colorado-settlement-prisoner-care-for-hepatitis-c/ [https://perma.cc/QMB3-6GXD].

118. *Id.*

119. *Id.*

120. *ACLU and Colorado Department of Corrections Reach Historic Settlement to Treat All Colorado Prisoners with Hepatitis C,* ACLU COLO., https://aclu-co.org/aclu-and-colorado-department-of-corrections-reach-historic-settlement-to-treat-all-colorado-prisoners-with-hepatitis-c/ [https://perma.cc/Y5SJ-GC55] (last accessed Jan. 24, 2020).

Pennsylvania recently agreed to widespread changes in HCV treatment after its motion for summary judgment was denied.[121] Under the settlement agreement, Pennsylvania will adopt a new HCV protocol that provides DAA medications to prisoners with chronic HCV with fibrosis scores of F2, F3, or F4 within six months.[122] The state will treat a set amount of individuals each year with DAAs based on a priority system established in its HCV protocol.[123]

Minnesota also recently agreed to provide DAA medications to prisoners at all stages of progression.[124] The agreed HCV protocol requires the Minnesota Department of Corrections to provide DAAs to prisoners with advanced HCV or HCV along with other complications.[125] Inmates denied treatment can request re-evaluation every six months, and any inmate with the virus will get treatment after sixteen months of imprisonment.[126]

Additionally, Massachusetts recently settled its pending lawsuit with prisoners who have HCV and agreed to similar protocols as the Pennsylvania agreement.[127] Notably, however, under the Massachusetts agreement, the department of corrections is only required to treat 280 prisoners with the most advanced disease with DAAs.[128] Prisoners with moderate or advanced HCV will be treated on a more expedient timeline, ranging from three to twelve months.[129] Inmates with less advanced stages of the disease will be retested every six months.[130]

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121. Dale Chappell, *Preliminary Settlement in Class-Action HCV Suit Against Pennsylvania DOC*, PRISON LEGAL NEWS (Feb. 4, 2019) https://www.prisonlegalnews.org/news/2019/feb/4/preliminary-settlement-class-action-hcv-suit-against-pennsylvania-doc/ [https://perma.cc/E96Y-EVCM]; *see* Chimenti v. Wetzel, No. 15-3333, 2018 WL 3388305, at *10–12 (E.D. Penn. July 12, 2018).

122. Chappell, *supra* note 121.

123. The settlement ramps up treatment of DAAs from approximately 30 individuals in September 2017 to 1,500 a year from 2019-2021, and 2,000 a year after. *Id.*

124. Brandon Stahl, *In class-action settlement, Minnesota prisoners win access to pricey hepatitis C drugs*, STAR TRIB. (Mar. 18, 2019, 7:58 PM), http://www.startribune.com/in-class-action-settlement-minnesota-prisoners-win-access-to-hepatitis-c-drugs/507322252/ [https://perma.cc/FZ44-K2QB].

125. *Id.*

126. *Id.*

127. *Massachusetts: Settlement w/ Prisoners Prompts New HepC Protocol*, Class Action Reporter, Vol. 22; ISSN: 1525-2272 (Aug. 27, 2018).

128. *Id.*

129. *Id.*

130. Shira Schoenberg, *Massachusetts Department of Correction settles lawsuit on treating inmates with hepatitis C*, MASS LIVE (Mar. 10, 2018), https://www.masslive.com/politics/2018/03/massachusetts_corrections_depa.html [https://perma.cc/KTR3-2XPL].

A judge in South Carolina recently granted preliminary approval of a settlement between the state and inmates with HCV.[131] South Carolina began testing former and current inmates in 2018, and the state legislature allocated $10 million for HCV medication, staffing, equipment, and other expenses related to HCV treatment.[132] The director of South Carolina's correctional facilities states that he believed this settlement would actually save medical treatment costs for taxpayers over time.[133]

There are over a dozen class action lawsuits pending before federal district courts or awaiting appeal from federal district court decisions.[134] In some cases, states facing litigation have begun to make preemptive changes to their HCV treatment policies. Following class certification,[135]

131. *Mandated hep C treatment for SC inmates gets initial consent*, ASSOCIATED PRESS (Jan. 14, 2020), https://apnews.com/4051e68697444fd48b9dc7f2831b8f78 [https://perma.cc/R4UE-K73M].

132. *Id.*

133. *Id.*

134. At this time, there appear to be fourteen pending class action suits against state correctional facilities alleging deliberate indifference to HCV treatment. *See* Matt Clarke, *Federal Class-Action Lawsuit Seeks Hepatitis C Treatment for Texas Prisoners*, PRISON LEGAL NEWS (Feb. 4, 2020), https://www.prisonlegalnews.org/news/2020/feb/4/federal-class-action-lawsuit-seeks-hepatitis-c-treatment-texas-prisoners/ [https://perma.cc/QWP4-3S8X]; Barfield v. Cook, No. 3:18-cv-1198, 2019 WL 3562021, at *13 (D. Conn. Aug. 6, 2019); Atkins v. Parker, 412 F. Supp. 3d 761, 764 (M.D. Tenn. 2019); Woodcock v. Correct Care Solutions, No. 3:16-cv-00096-GFVT, 2019 WL 3068447, at *1 (E.D. Ky. July 12, 2019); Riggleman v. Clarke, No. 5:17-cv-0063, 2019 WL 1867451, at *1 (W.D. Va. Apr. 25, 2019) (class certification denied for inadequate counsel, see 2019 WL 1903795); Buffkin v. Hooks, No. 1:18CV502, 2019 WL 1282785, at *12 (M.D. N.C. Mar. 20, 2019); Turney v. Atencio, No. 1:18-cv-00001-BLW, 2019 WL 254238 (D. Idaho Jan. 17, 2019); Postawko v. Missouri Dept. of Corrections, 910 F.3d 1030 (8th Cir. 2018) (affirming class action certification); Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 1140388, at *1 (S.D. Ind. Mar. 2, 2018); Bayse v. California Dept. of Corrections, No. 2:18-cv-0278 MCE DB P, 2018 WL 827423, at *1 (E.D. Cal. Feb. 12, 2018); Hoffer v. Inch, 290 F. Supp. 3d 1292 (N.D. Fla. 2017); Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 1140388, at *1 (S.D. Ind. Mar. 2, 2018). Additionally, it appears class actions are filed in Maine and Vermont. *See* Lauren Abbate, *Lawsuit claims Maine refused to provide hepatitis C treatment to hundreds of inmates*, WGME (June 26, 2019), https://wgme.com/news/local/lawsuit-claims-maine-refused-to-provide-hepatitis-c-treatment-to-hundreds-of-inmates [https://perma.cc/X5XQ-9KRG]; *CHLPI and ACLU File Class Action Lawsuit Challenging Denial of Lifesaving Hepatitis C Treatment to Hundreds of Vermont Prisoners*, Harv. L. SCH. CTR. FOR HEALTH L. AND POL'Y INNOVATION (May 22, 2019), https://www.chlpi.org/chlpi-aclu-file-class-action-lawsuit-challenging-denial-lifesaving-hepatitis-c-treatment-hundreds-vermont-prisoners/ [https://perma.cc/3NJ8-ZK52].

135. Barfield v. Cook, No. 3:18-cv-1198, 2019 WL 3562021, at *13 (D. Conn. Aug. 6, 2019).

Connecticut recently announced that it would provide both opt-out testing and information to inmates about HCV and how to obtain further HCV tests in the future.[136] Even states without pending or ongoing litigation have made improvements to their HCV protocols or funding. After settling a Medicaid lawsuit, Kansas began to screen all inmates for hepatitis C and will spend $6 million in fiscal 2020 on treating half of its inmates with HCV.[137] Michigan acknowledged that the pattern of class action lawsuits influenced its decisions to provide more aggressive treatment for inmates with HCV.[138] New Jersey has proposed legislation to require opt-out HCV screening for all jail and prison inmates.[139]

In New Mexico, where nearly half of the state prisoners are infected with HCV, the state's governor recommended spending $30 million in new funding for HCV, with a goal of curing every inmate by 2024.[140] Additionally, the medical director for North Dakota's Department of Corrections recently asked the state legislatures for an additional $1.8 million in funding for HCV care even though he estimated it would cost between $4 and $5 million for universal treatment.[141] As mentioned in Part I, California allocated $105.8 million to treat its 22,000 inmates with HCV.[142] Florida[143] and Tennessee[144] have also earmarked budgets specifically for the treatment of HCV.

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136. Keith M. Phaneuf & Kelan Lyons, *Correction Department to begin testing, treating inmates for Hepatitis C*, CONN. MIRROR (Aug. 13, 2019), https://ctmirror.org/2019/08/13/correction-department-to-begin-testing-treating-inmates-for-hepatitis-c/ [https://perma.cc/E29J-KSKP].

137. Cellia Llopis-Jepsen, *Many Kansas Inmates Will Wait For Hepatitis C Treatment Despite Recent Legal Settlement*, KCUR.ORG (June 11, 2019), https://www.kcur.org/post/many-kansas-inmates-will-wait-hepatitis-c-treatment-despite-recent-legal-settlement#stream/0 [https://perma.cc/42ZQ-4X9V].

138. Mardi Link, *Michigan Aims to End Hep C in Prisons*, TRAVERSE CITY REC. 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 [https://perma.cc/GY7L-AFGY].

139. Joe Hernandez, *Proposal would require screening all N.J. Prisoners for hepatitis B and C*, WHYY PBS (Dec. 4, 2019), https://whyy.org/articles/proposal-would-require-screening-all-n-j-prisoners-for-hepatitis-b-and-c/ [https://perma.cc/9E8B-Q4XH].

140. Ted Alcorn, *'Major milestone': Governor's budget targets hepatitis C epidemic in prisons*, N.M. IN DEPTH (Jan 16, 2020), http://nmindepth.com/2020/01/16/major-milestone-governors-budget-target-hepatitis-c-epidemic-in-prisons/ [https://perma.cc/479Z-Y6D4].

141. Noreen Marcus, *Hepatitis C Fight Hinges on Prisons*, U.S. NEWS (Feb. 5, 2019, 5:30 AM), https://www.usnews.com/news/healthiest-communities/articles/2019-02-05/hepatitis-c-fight-hinges-on-prisons-inmate-care [https://perma.cc/WS3L-XDGK].

142. *See supra* Section I.C.

143. Florida set aside $50 million to treat inmates with HCV. *Florida pushes back in prison hepatitis legal battle*, TAMPA BAY TIMES (May 23, 2019),

The sheer volume of pending litigation and settlements illustrates the seriousness of HCV in prisons. Millions of dollars will be spent to treat this disease, even if drug prices continue to drop. The issue then becomes one of control: Will states adopt policies that allow them to control how they utilize their resources, or will they risk judicially-imposed orders that mandate treatment?

B. A Tale of Two Cases

Two cases help to isolate the issues at stake in HCV prison litigation. In *Hoffer v. Jones*[145] and its related case *Hoffer v. Inch*,[146] Florida's Department of Corrections was found deliberately indifferent to the medical needs of inmates with HCV. Alternatively, in *Atkins v. Parker*,[147] Tennessee's Department of Corrections was able to successfully show that its HCV treatment policy was constitutional under the Eighth Amendment. By examining these cases and the judges' rationale, states can adopt key aspects of HCV treatment to avoid constitutional challenges and better serve their infected populations.

1. Hoffer v. Inch

In *Hoffer v. Jones* and the related case, *Hoffer v. Inch*, three named plaintiffs infected with HCV brought suit against the Florida Department of Corrections ("FDC").[148] At the time of filing, all plaintiffs suffered from cirrhosis as a complication of HCV that they allege was left untreated for years.[149] The plaintiffs had received the treatment sought, but certified as a class to seek a preliminary injunction on behalf of all current and future prisoners in FDC custody.[150] The FDC was slow to incorporate direct-acting antiviral drugs because of lack of funds to purchase the drugs or because the request for funds was denied.[151]

On plaintiffs' motion for preliminary injunction, the court evaluated the plaintiffs' Eighth Amendment claim for its substantial

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https://www.tampabay.com/florida-politics/buzz/2019/05/23/florida-pushes-back-in-prison-hepatitis-legal-battle/ [https://perma.cc/L2NK-5CTK].

144. Tennessee's governor sought $24.7 million dollars to treat hepatitis C in the state's prisons. Jonathan Mattise, *Tennessee gov seeking $24.7M to treat hepatitis C in prisons*, ASSOCIATED PRESS (Apr. 16, 2019), https://apnews.com/15a8a493cc0c4424923c6016b1dc115f [https://perma.cc/3S24-EFBU].

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

146. Hoffer v. Inch, 382 F. Supp. 3d 1288 (N.D. Fla. 2019).

147. Atkins v. Parker, 412 F. Supp. 3d 761, 764–65 (M.D. Tenn. 2019).

148. *Jones*, 290 F. Supp. 3d at 1296; *Inch*, 382 F. Supp. 3d at 1294.

149. Jones, 290 F. Supp. 3d at 1297.

150. *Id.* at 1297–98.

151. *Id.*

likelihood of success on the merits.[152] Plaintiffs' claim that the FDC's policies and practices for HCV treatment constituted deliberate indifference required plaintiffs to demonstrate (1) a serious medical need, (2) the FDC's deliberate indifference to that need, and (3) causation between the FDC's indifference and the plaintiffs' injuries.[153]

Following Eleventh Circuit precedent, the court defined a serious medical need as "one that has been diagnosed by a physician as mandating treatment or one that is so obvious that even a lay person would easily recognize the necessity for a doctor's attention," or as an alternative, one in which "a delay in treating the need worsens the condition."[154] In either case, the medical need must be "one that, if left unattended, poses a substantial risk of serious harm."[155] Applying that definition, the court found that plaintiffs (by diagnosis) and the class (by definition) all suffer from a serious medical condition because HCV complications present substantial risks of serious harm.[156]

In evaluating the FDC's deliberate indifference, the court noted that plaintiffs must show the FDC had subjective knowledge of a risk of serious harm and that the FDC's disregard of that risk amounted to more than mere negligence.[157] The court found that the FDC had knowledge of a risk of serious harm because it knew that the plaintiffs were diagnosed with HCV.[158] Thus, the only issue was whether the FDC disregarded that risk by conduct that is more than mere negligence.[159] Eleventh Circuit precedent identifies five examples of conduct that are considered more than mere negligence:

> (1) knowledge of a serious medical need and a failure or refusal to provide care; (2) delaying treatment for non-medical reasons; (3) grossly inadequate care; (4) a decision to take an easier but less efficacious course of treatment; or (5) medical care that is so cursory as to amount to no treatment at all.[160]

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152. *Id.* at 1298.

153. *Id.* at 1299 (citing Goebert v. Lee County, 510 F.3d 1312, 1326 (11th Cir. 2007)).

154. *Id.* (citing Mann v. Taser Int'l, Inc., 588 F.3d 1291, 1307 (11th Cir. 2009)).

155. *Id.* (citing *Mann*, 588 F.3d 1291, 1307 (11th Cir. 2009)).

156. *Id.*

157. *Id.* (citing *Goebert*, 510 F.3d at 1326–27).

158. *Id.* (citing *cf.* Brown v. Johnson, 387 F.3d 1344, 1351 (11th Cir. 2004)).

159. *Id.* at 1299–1300.

160. *Id.* at 1300 (citing Baez v. Rogers, 522 F. App'x. 819, 821 (11th Cir. 2013)).

In evaluating the testimony presented at trial, the court found that a lack of funding resulted in the FDC's failure to provide adequate medical treatment.[161] However, the court reasoned that only evidence of ongoing or future violations can support the plaintiffs' motion for a preliminary injunction.[162]

To evaluate evidence of future violations, the court analyzed the FDC's current HCV-treatment policy and admissions by the FDC's expert and treatment-guidance drafter.[163] The court found that while the treatment policy had been modified to address shortcomings in screening and providing treatment for chronically infected inmates, the FDC was still unable to provide treatment in a timely manner.[164] This reinforced the court's belief that without a court-ordered injunction, the FDC would be unlikely to treat inmates in a constitutionally appropriate manner.[165] The court granted the plaintiffs' motion for a preliminary injunction.[166]

In *Hoffer v. Inch*,[167] the court reevaluated the status of the FDC's treatment of chronically infected individuals fifteen months after the preliminary injunction was granted for the plaintiffs.[168] The court noted that since the preliminary injunction was issued, the FDC had dramatically improved its responses to treat chronic HCV.[169] However, the plaintiffs sought several types of additional relief through a permanent injunction.[170]

First, plaintiffs sought to replace the FDC's opt-in testing method for opt-out testing.[171] Plaintiffs based this request on a belief that FDC's opt-in approach constituted clear indifference because the FDC can knowingly remain ignorant of individuals with the disease.[172] The court agreed in part because the FDC had only identified 7% of the total inmate population as having chronic HCV when even conservative estimates

161. *Id.* at 1300–01.

162. *Id.* at 1301 (citing *See* O'Shea v. Littleton, 414 U.S. 488, 495–96, 94 S. Ct. 669, 338 L.Ed.2d 674 (1974)).

163. *Id.*

164. *Id.* at 1294, 1304.

165. *Id.* at 1305.

166. *Id.*

167. Hoffer v. Inch, 382 F. Supp. 3d 1288, 1294 (N.D. Fla 2019).

168. *Id.* at 1294–95.

169. At the preliminary injunction stage, only thirteen inmates had been treated with DAAs. *See Jones*, 290 F. Supp. 3d at 1298. In the fifteen months that followed, the number of chronically infected inmates being treated with DAAs was 4,901. *Inch*, 382 F. Supp. 3d at 1294.

170. Plaintiffs sought roughly fifteen additional forms of relief. *Inch*, 382 F. Supp. 3d at 1298. For the purpose of this note, some involving technical methods of testing are not being discussed.

171. *Id.*; *See* Morris, *supra* note 55.

172. *Inch*, 382 F. Supp. 3d. at 1299 (citing *See, e.g.*, Lancaster v. Monroe County, 116 F.3d 1419, 1425 (11th Cir. 1997)).

believed 20% of the total inmate population had chronic HCV.[173] In fashioning a remedy for this issue, the court noted that its role was clearly to enforce the rights of prisoners and not to supervise prisons.[174] Thus, the courts would accept either opt-out testing or opt-in testing paired with peer education.[175]

Second, plaintiffs sought to force the FDC to prescribe DAAs to inmates with fibrosis scores of F0 or F1.[176] The FDC's policy only monitored these inmates clinically every six months with laboratory testing and predictive fibrosis scans every twelve months.[177] From the FDC's position, treatment would be inevitable for F0 and F1 inmates, but the FDC believed those inmates could be treated at a later time than prisoners with more advanced stages of the disease.[178] However, the court agreed with plaintiffs that F0 and F1 inmates were facing substantial harm and suffering.[179] The plaintiffs' medical expert explained that HCV symptoms did not correlate with fibrosis stages, and that even F0 and F1 inmates can suffer symptoms.[180] Additionally, both the state's and plaintiffs' medical experts agreed that, even for F0 and F1 inmates, successful treatment of HCV tends to decrease mortality rates.[181] Thus, the court found that the FDC's decision to delay treatment for F0 and F1 inmates, without any medical reason, constituted deliberate indifference.

Third, plaintiffs challenged the FDC's policy to exclude inmates from treatment if they did not have sufficient time left on their sentences to complete a course of DAA treatments.[182] The court limited the framework of this policy to prevent exclusions from being made prior to initial screenings for HCV and to prevent the FDC from excluding inmates who were unable to complete a post-treatment assessment.[183] The court reasoned that limiting this policy ensured that the FDC may only exclude treatment from inmates with confirmed chronic HCV infections for medical reasons.[184]

Fourth, plaintiffs challenged the FDC's policy to exclude from treatment anyone who does not "demonstrate willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high risk

173. *Id.*
174. *Id.* (quoting Cruz v. Beto, 405 U.S. 319, 321 (1979)).
175. *Id.* at 1299–1300.
176. *Id.* at 1302.
177. *Id.*
178. *Id.*
179. *Id.*
180. *Id.*
181. *Id.*
182. *Id.* at 1308.
183. *Id.*
184. *Id.* at 1308–09.

behaviors while incarcerated."[185] As an initial matter, the court found that treatment can only be delayed for a medical reason.[186] The court found that consuming illicit drugs, fighting with other inmates, or using intravenous drugs that risk reinfection of HCV would not be sufficient to exclude treatment unless there are medical reasons.[187] Under this reasoning, the FDC would not be exhibiting deliberate indifference if medical staff at a correctional facility found that there was a medical reason to deny an inmate treatment because of the inmate's illicit drug use or fighting.[188] This policy could only be enforced if the exclusions were temporary and not permanent.[189]

2. Atkins v. Parker

In contrast, Tennessee was successful in defending its HCV treatment policy against a class action challenge from prisoners.[190] In *Atkins v. Parker*, HCV-infected prisoners brought a class action lawsuit against the Tennessee Department of Corrections ("TDOC").[191] The plaintiff's class was defined as all TDOC inmates with HCV who had at least twelve weeks or more remaining on their sentences.[192] Specific to the plaintiff's complaint was that the TDOC's diagnosis, evaluation, and approval for treatment policies did not meet the current medical standard of care, subjected HCV-infected inmates to substantial risk of harm or death, and constituted deliberate indifference in violation of the Eighth and Fourteenth Amendments.[193] The TDOC developed a new, continuously improving HCV treatment protocol ("the Guidance") in 2019 that controls the testing, evaluation, staging, prioritization, treatment, and monitoring of inmates with chronic HCV.[194] This new protocol offered opt-out testing at intake, and allowed any inmate to request HCV testing at any time.[195] Following this blood test, inmates undergo periodic testing to detect comorbid conditions, other possible causes of liver disease, and liver fibrosis

185. *Id.* at 1309.

186. *Id.* (citing Melton v. Abston, 841 F.3d 1207, 1229 (11th Cir. 2016)).

187. *Id.* (comparing favorably to Reid v. Clarke, No. 7:16-cv-00547, 2018 WL 3626122, at *4, n.2 (W.D. Va. July 30, 2018) ("Take a prisoner who cuts his own wrists. A prison would have little basis to refuse treatment on the grounds that he himself had created the harm, or that he might try to commit suicide again.").

188. *Id.* at 1309–10.

189. *Id.* at 1310.

190. Atkins v. Parker, 412 F. Supp. 3d 761, 764–65 (M.D. Tenn. 2019).

191. *Id.*

192. *Id.* at 765.

193. *Id.*

194. *Id.* at 771.

195. *Id.*

scores.[196] The TDOC also provides two forms of fibrosis testing to evaluate a baseline.[197]

The Guidance recommends that all inmates are treated but continues to follow the policy that the sickest inmates should be treated first, and it provides criteria for prioritizing DAA treatment among HCV inmates.[198] Ultimately, a specialized board evaluates HCV inmates and makes "patient-specific" treatment decisions, factoring more than just the fibrosis stage of the inmate.[199] Plaintiffs' medical expert believed that the prioritization structure of the Guidance was below the standard of care because it did not explicitly recommend early DAA treatment of all HCV patients.[200] Additionally, the Guidance requires all HCV inmates to be enrolled in a chronic care clinic and be evaluated every six months.[201]

Despite these improvements, the plaintiffs introduced many examples of the TDOC's failure to treat individuals who likely should have been provided DAA treatment.[202] However, the court found that several of these inmates were now receiving proper treatment and care following the development of the Guidance.[203] Moreover, the court noted that treatment costs had lowered to between $13,000 and $32,000 depending on the brand.[204] The court also noted the increased funding allocated to the new programs and the TDOC's consistent use of budgeting to purchase DAAs.[205]

The court held that the plaintiffs had not met their burden to establish the TDOC's deliberate indifference to their chronic HCV infections.[206] To establish deliberate indifference, the court held that plaintiffs must show both (1) that the alleged wrongdoing was objectively harmful enough to establish a constitutional violation and (2) that the

196. *Id.* at 771–72.

197. Of known HCV-infected inmates that were tested under this guidance, approximately 63% were in the F0 or F1 stage, 9% are in the F2 stage, and 29% are in the F3 or F4 stages. *Id.* at 772.

198. *Id.*

199. Notably, just prior to litigation, the TDOC approved multiple F1/F2 inmates for DAA treatment. *Id.*

200. *Id.* at 773.

201. These reevaluations include education, physical examination, laboratory tests, fibrosis score testing, and for patients with advanced fibrosis or cirrhosis (F3 and F4), an ultrasound to screen for liver cancer. *Id.* at 774.

202. In total, the court found seven individuals who were denied access to DAA treatment. The court noted this behavior was borderline deliberate indifference. *Id.* at 775–76.

203. *Id.* at 776.

204. *Id.* at 777.

205. The TDOC budget for the 2019-20 fiscal year was approximately $31 million, and the court noted the TDOC had run over budget on DAA spending. *Id.*

206. *Id.* at 785.

official acted with a culpable state of mind rising above gross negligence.[207] In evaluating the objective standard, plaintiffs must prove that they have a serious medical need[208] and that the alleged deprivation of medical care was serious enough to violate the Eighth Amendment.[209] The court noted that if a claim is that a particular treatment must be provided, the plaintiffs must demonstrate that "the inmate's symptoms would be alleviated by the treatment and that the inmate's condition requires that treatment."[210] If that is established, the inmate must further show that the treatment being provided is so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness.[211] This burden can be met if plaintiffs can prove (1) that the provided treatment was not adequate medical treatment for the inmate's condition, and (2) the treatment provided had a detrimental effect.[212]

The court also explained that plaintiffs are required to show that the TDOC acted with a sufficiently culpable state of mind.[213] This requires proof that the TDOC consciously exposed inmates to an excessive risk of serious harm.[214] While the court noted that it is entitled to conclude that a prison official knew of a substantial risk from the very fact that the risk was obvious, the plaintiffs must also present sufficient evidence to show that the TDOC was so recklessly ignorant to the risk that officials were deliberately indifferent.[215] The subjective component was to be centered around the "current attitudes and conduct, including attitudes and conduct at the time suit is brought and persisting thereafter."[216] As a key component of this, the court noted it must be deferential to the judgment of medical professionals.[217] If treatment is reasonable, a doctor is not liable under the Eighth Amendment if he or she provides reasonable treatment, even if the outcome of the treatment is insufficient or even harmful.[218]

The court applied these standards individually to both the TDOC's Commissioner and Chief Medical Officer.[219] Beginning first with the Commissioner, the court noted that the plaintiffs failed to establish that the

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207. *Id.* at 777–78 (quoting Rhinehart v. Scutt, 894 F.3d 721, 737 (6th Cir. 2018)).

208. *Id.* at 778 (quoting *Rhinehart*, 894 F.3d at 736 (explaining that serious medical conditions carry with it a serious medical need)).

209. *Id.* (quoting *Rhinehart*, 894 F.3d at 737).

210. *Id.* (quoting *Rhinehart*, 894 F.3d at 749).

211. *Id.* (quoting *Rhinehart*, 894 F.3d at 749).

212. *Id.* (quoting *Rhinehart*, 894 F.3d at 749).

213. *Id.* at 779 (citing Farmer v. Brennan, 511 U.S. 825, 834 (1970)).

214. *Id.* (quoting *Rhinehart*, 894 F.3d at 738).

215. *Id.* (quoting *Farmer*, 511 U.S. at 842; *Rhinehart*, 894 F.3d. at 738).

216. *Id.* at 779 (citing *Farmer*, 511 U.S. at 834 (1970)).

217. *Id.* (citing *Rhinehart*, 894 F.3d at 738).

218. *Id.* (quoting *Rhinehart*, 894 F.3d at 738).

219. *Id.* at 780.

Commissioner, as a supervisory official, violated their Eighth Amendment rights.[220] Plaintiffs could only demonstrate "that a supervisory official 'caused' a violation of his or her constitutional rights by demonstrating that the official 'either encouraged the misconduct, or in some other way directly participated in it.'"[221] At a minimum, the plaintiffs must show that the official "implicitly authorized, approved, or knowingly acquiesced in unconstitutional conduct." [222] Failure to act on its own is not sufficient.[223]

The court found that the plaintiffs failed to establish that the Commissioner encouraged, actively participated in, or knowingly approved any particular aspect of the TDOC's policy concerning treatment of HCV, a finding consistent with the conclusions of other courts on liability of the head of the department of corrections.[224] Additionally, the court found that the plaintiffs failed to establish the subjective component of their claim against the Commissioner because officials who lack "medical training do not act with the necessary culpable state of mind when [they] reasonably defer[] to the medical professionals' opinions."[225] Because the Commissioner had no substantive training or knowledge regarding HCV, he relied reasonably on the medical professionals to create the TDOC's HCV policies, and the Commissioner had not formed the requisite mental state exceeding gross negligence.[226]

The court then considered the liability of the TDOC's Chief Medical Officer.[227] The court did not question that HCV is a serious medical condition.[228] Additionally, the court found that other courts had found HCV to be a serious medical condition, regardless of whether the infection becomes chronic.[229] Plaintiffs demonstrated that HCV was a

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220. *Id.*

221. *Id.* (quoting Thomas v. Nationwide Children's Hosp., 882 F.3d 608, 612 (6th Cir. 2018); Shehee v. Luttrell, 199 F.3d 295, 300 (6th Cir. 1999)).

222. *Id.* (quoting *Shehee*, F.3d at 300).

223. *Id.* (citing *Shehee*, F.3d at 300).

224. *Id.* at 780–81 (noting Pevia v. Wexford Health Source, Inc., No. CV ELH-16-1950 and ELH-17-631, 2018 WL 999964, at *13 (D. Md. Feb. 20, 2018), *aff'd sub nom.* Pevia v. Comm'r of Corr., 731 F. App'x 243 (4th Cir. 2018) (dismissing the commissioner of the department of corrections due to inadequate involvement in HCV treatment policy as a supervisory official); Abu-Jamal v. Kerestes, No. 3:15-cv-00947, 2016 WL 4574646, at *12 (M.D. Pa. Aug. 31, 2016) (dismissing the prison officials not personally involved in the HCV treatment committee, the development, adoption, or implementation of the HCV protocol)).

225. *Id.* at 781 (quoting Olmstead v. Fentress Cty., No. 2:16-cv-46, 2019 WL 1556657, at *8 (M.D. Tenn. Apr. 10, 2019)).

226. *Id.*

227. *Id.*

228. *Id.*

229. *Id.* at 781–82 (citing Hix v. Tenn. Dep't of Corr., 512 F. App'x 350, 356 (6th Cir. 2006) ("[H]epatitis C likely constitutes a serious medical need sufficient to satisfy the objective component of our Eighth Amendment analysis[.]"); Owens

serious medical condition, sufficient to meet the objective component of the deliberate indifference test, and that DAAs are the most effective treatment for the vast majority of HCV patients.[230]

However, the court did not find that the plaintiffs were able to prove that the Guidance was so grossly incompetent, inadequate, or excessive as to shock the conscience or to be intolerable to fundamental fairness.[231] Plaintiffs argued that the recommended treatment and medical expert testimony support administering DAAs to inmates with chronic HCV as soon as possible.[232] Plaintiffs argued that the TDOC's prioritization method may be detrimental to HCV patients in the long-term because earlier treatment of chronic HCV stops the progression of the damage to an inmate's liver and prevents damage to other organs.[233] However, the court found that the recommended treatment and the testimony of the plaintiffs' medical experts provide the "best possible practice," but do not "necessarily determine the standard for judging constitutional deliberate indifference."[234]

Instead, the court found that the Guidance created a multifaceted set of policies and protocols for DAA treatment of chronic HCV inmates that include: evaluation, staging for referral to the review board, consideration and designation for treatment by the board, monitoring and regular testing by the chronic care clinic, and technology to streamline and monitor the treatment of individual inmates.[235] The court found that while this standard was not the "gold standard" of immediate, universal DAA treatment regardless of fibrosis stage recommended by the AASLD/IDSA, the Guidance was not so unreasonable or so contrary to medical standards that no competent medical professional would make similar choices, particularly given the resources available to the TDOC.[236]

The court specifically addressed why its decision differs from other courts' decisions in favor of HCV inmates who challenged state prison

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v. Hutchinson, 79 F. App'x 159, 161 (6th Cir. 2003) (stating that HCV "is an objectively serious medical condition."); Parks v. Blanchette, 144 F. Supp. 3d 282, 314 (D. Conn. 2015) (holding that "[i]t is well established that Hepatitis C is sufficiently serious" for purposes of the objective prong); Hilton v. Wright, 928 F. Supp. 2d 530, 547 (N.D. N.Y. 2013) ("It is well-established that HCV is a serious medical condition[.]")).

230. *Id.* at 782.

231. *Id.* at 783.

232. *Id.*

233. *Id.*

234. *Id.* (citing Buffkin v. Hooks, No. 1:18CV502, 2019 WL 1282785, at *6 (M.D. N.C. Mar. 20, 2019) (noting that the guidelines relied upon by the plaintiffs should not be relied on to suggest a course of treatment for a particular individual, and cautioning against the use of those guidelines as a legal measure of Eighth Amendment deliberate indifference).

235. *Id.*

236. *Id.*

HCV treatment.[237] Contrasting *Abu-Jamal v. Wetzel*, the court found that Pennsylvania Department of Corrections' ("PDOC") policy had two important limitations on DAA treatment: Inmates had to have cirrhosis to be considered for DAA treatment, and they had to suffer from a specific complication related to cirrhosis.[238] PDOC's prioritization was not the problem; those with mild or moderate fibrosis unacceptably "ha[d] no chance of receiving [DAAs]."[239] While the TDOC has a "prioritization system, no inmate is foreclosed from consideration" by the medical review board, and there are no exclusions from DAA treatment.[240]

The court also addressed the decisions of *Hoffer v. Jones* and *Stafford v. Carter*, finding the analysis of the objective components in these cases consisted of no more than deeming chronic HCV to be a serious medical need.[241] The analysis of those courts differed from that of the Sixth Circuit, which requires a determination of the degree to which there has been an objective deprivation of medical care.[242] The court reasoned that it was likely because of the more drastic failures to treat HCV in those cases that a different decision was reached.[243] Again, the court found that the TDOC's policy was intentionally structured to increase the number of HCV inmates treated with DAAs, unlike *Abu-Jamal*, *Hoffer,* or *Stafford*.[244]

The court also found that the plaintiffs failed to prove that the TDOC's Chief Medical Officer acted with the culpable state of mind necessary to meet the subjective component of Eighth Amendment deliberate indifference.[245] Instead, the court found that the Chief Medical Officer used, and continues to use, his medical judgment to provide reasonable care for the TDOC HCV inmates.[246] Because the Chief Medical Officer had consciously used his medical judgment to develop the TDOC's HCV standards, plaintiffs could not prove that he acted with a culpable state of mind approaching "criminal recklessness."[247]

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237. *Id.* at 784.

238. *Id.* (citing Abu-Jamal v. Wetzel, No. 3:16-CV-2000, 2017 WL 34700, at *15 (M.D. Pa. Jan. 3, 2017)).

239. *Id.* (citing *Wetzel*, 2017 WL 34700, at *15).

240. *Id.*

241. *Id.* (citing Hoffer v. Jones, 290 F. Supp. 3d 1292, 1299 (N.D. Fla. 2017); Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 4361639, at *11–12 (S.D. Ind. Sept. 13, 2018)).

242. *Id.* at 784–85.

243. *Id.* at 785.

244. *Id.*

245. *Id.*

246. *Id.*

247. *Id.*

IV. CONSTITUTIONAL GUIDEPOSTS FOR PRISON HCV TREATMENT

From a public health perspective, states would benefit greatly from providing the best possible treatment for prisoners with HCV. However, the Eighth Amendment requires much less from the states. While attempting to balance these competing ideals, states and their respective legislatures are weary of court-ordered structural injunctions that would force states to comply with extremely costly or infeasible treatment plans. By analyzing the outcomes of HCV litigation, clear guideposts exist for states to satisfy their constitutional duty under the Eighth Amendment, without allowing the HCV crisis in prisons to continue. These guideposts include systematic testing for prisoners currently within the state system, evaluation by a medical review board that makes individual determinations, prioritization of treatment based on those determinations, adequate funding set aside for appropriate treatment, and third-party monitoring.

A. Systematic Testing

As an initial step to providing adequate medical treatment to prisoners, states should adopt policies that provide HCV testing upon intake. The benefit of identifying the HCV population at intake is important for two reasons. First, understanding the number of inmates with chronic HCV can provide states with better information to tailor their HCV treatment policies in the most cost-effective ways. A recent study in 2019 found that targeted testing approaches, which might appear cost-effective, likely cost more than other strategies while providing less clinical benefit.[248] In other words, efforts to save money by providing limited or targeted testing strategies "may not lead to the best allocation of limited resources, or to the best population health outcomes."[249] Thus, systematic testing upon intake may ultimately lead to more accurate treatment and cost spending in the future.

Second, a lack of systematic testing may be used as circumstantial evidence of deliberate indifference. A state that fails to provide systematic treatment may be vulnerable to deliberate indifference claims under the Eighth Amendment. In several cases, prisoners as a class have claimed that a lack of systematic testing demonstrates a component of deliberate indifference.[250] In fact, in *Hoffer v. Inch*, the plaintiffs argued precisely that:

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248. Sabrina A. Assoumout et al, *Cost-effectiveness and Budgetary Impact of Hepatitis C Virus Testing, Treatment, and Linkage to Care in US Prisons*, 70 CLINICAL INFECTIOUS DISEASES 1388, 1393 (2020).

249. *Id.* at 1395.

250. *See, e.g.*, Barfield v. Semple, No. 3:18-cv-1198, 2019 WL 3680331, at *5 (D. Conn. Aug. 6, 2019); Hoffer v. Inch, 382 F. Supp. 3d 1288, 1298–99 (N.D. Fl. 2019); Atkins v. Parker, 412 F. Supp. 3d 761, 771 (M.D. Tenn. 2019) (describing Tennessee's shift to opt-out HCV testing at intake).

> [The FDC] knows that there are thousands more prisoners in its care who are infected with HCV and are at serious risk of damage to their health, but has deliberately remained ignorant of their identities, thereby ensuring they will never receive treatment. This "head-in-the-sand" approach amounts to clear deliberate indifference.[251]

The plaintiffs challenging opt-in testing in *Hoffer* were able to draw sharp contrasts between the FDC's population of HCV individuals and the suspected national prevalence of HCV in prisons.[252] While there is not a clear constitutional standard specific to testing inmates for communicable diseases, a lack of sufficient testing for high-risk diseases like chronic HCV may be evidence of deliberate indifference. As Judge Walker pointed out, "To hold otherwise would mean that FDC could avoid treating an insane inmate simply because he is unaware of his condition."[253]

Currently, both the Federal Bureau of Prisons and the American Association for the Study of Liver Diseases recommend opt-out testing for HCV in prisons.[254] Additionally, an opt-out testing strategy informs all prisoners of the health consequences of HCV and improves the overall number of accurate diagnoses.[255] While there is no constitutional requirement for opt-out testing, it likely presents the best solution for both states and prisoners. At the very least, states should adopt some type of systematic testing at intake to monitor their HCV prison populations.

B. Individual Medical Determinations

From solely an Eighth Amendment perspective, individual medical determinations remain the most important aspect of HCV treatment policies. As discussed in Part II, a court evaluating a deliberate indifference claim must rely heavily on the judgments of medical professionals. Thus, prison policies that attempt to provide some categorical restrictions on treatment, absent medical purposes, will likely constitute deliberate indifference.

For this reason, prisons must still evaluate prisoners individually. Often, states implement a board of medical professionals to evaluate

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251. *Inch*, 382 F. Supp. 3d at 1299.

252. FDC identified only 7% of its total population as having chronic HCV. Compared to the national estimate between 16% and 41%, the court believed this amounted to deliberate indifference. *Id.*

253. *Id.* at n.9.

254. *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection*, FED. BUREAU PRISONS CLINICAL GUIDANCE (Oct. 2016), https://www.bop.gov/resources/pdfs/hepatitis_c.pdf [https://perma.cc/3VAG-YCF9]; *HCV Guidance*, *supra* note 11.

255. *HCV Guidance*, *supra* note 11.

individuals for HCV treatment. The typical process is for patients with confirmed chronic HCV to undergo periodic reevaluation to monitor the progress of the disease. States can adopt a comprehensive database of their population so that the board of medical professionals can evaluate patients for appropriate treatments.

The largest responsibility of these medical review boards is the allocation of DAA treatment. Given the unsettled Eighth Amendment requirements for providing DAA treatment to all individuals and speculation as to the prices available to states, most states will likely adopt treatment policies that treat the sickest patients first. However, this determination still relies on the judgment of medical professionals. To avoid deliberate indifference claims brought against the states, these medical boards must work within some guidelines for determining and utilizing funds available to treat as many patients as possible.

Tennessee's HCV policy illustrates a model policy where a medical review board makes treatment decisions at an individual level. The TDOC's 2016 HCV protocol provided that only inmates with fibrosis scores of F3 or F4 should be referred to the medical review board for DAA treatment.[256] While technically this policy evaluated prisoners based on their fibrosis level, it created a nonmedical-based criteria for DAA treatment. Instead, Tennessee modified its 2019 HCV protocol so that all HCV inmates would be eligible for referral to the medical review board regardless of fibrosis stage.[257] Under the 2019 protocol, prisoners with fibrosis stage F3 or F4, cirrhosis, coinfection regardless of fibrosis score, and comorbid conditions regardless of fibrosis score are considered to have the highest level of prioritization for DAA treatment.[258] An intermediate prioritization is given to inmates with "moderate pathology," defined as fibrosis stage F2, or comorbid chronic kidney disease.[259] Ultimately, this policy adheres to the idea that inmates should receive "patient-specific" medical treatment based on the judgment of medical professionals.[260]

In contrast, Florida's policy in *Hoffer v. Inch* had several categorical restrictions on treatment that are not based on individual medical determinations. The FDC did not provide DAA treatment to inmates with fibrosis scores of F0 or F1.[261] Instead, those patients were only reevaluated with laboratory testing every six months and fibrosis elastography scans every twelve months.[262] The plaintiffs challenged, claiming, "[t]he only reasons why [the] FDC [elected] not to provide treatment is due to the cost of treatment, which is per se deliberate

256. Atkins v. Parker, 412 F. Supp. 3d 761, 772 (M.D. Tenn. 2019).
257. *Id.*
258. *Id.*
259. *Id.*
260. *Id.*
261. Hoffer v. Inch, 382 F. Supp. 3d 1288, 1302 (N.D. Fl. 2019).
262. *Id.*

indifference."[263] The court agreed with the plaintiffs and found that delaying treatment absent a medical reason for those decisions constituted deliberate indifference.[264]

The FDC's policy also excluded inmates from treatment if their remaining sentence length was insufficient to complete pre-treatment evaluations, the treatment course itself, and a reassessment twelve weeks after treatment to assess a patient's response.[265] The FDC believed that the reassessment policy insured the program was working and allowed improvements for future use.[266] While the court observed that this might be a worthwhile goal and beneficial for inmates in the future, it was "not a *medical reason* to withhold treatment from a specific inmate in the present."[267]

The FDC's policy also excluded treatment from any inmate who does not "demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high risk behaviors while incarcerated."[268] The FDC claimed that these determinations were made by physicians who consider many factors on a case-by-case basis.[269] The court agreed with the FDC but made it clear that inmates, even those with high risks of re-infection, must only be denied treatment for a "medical reason."[270] Thus, if a medical reason exists to deny an inmate treatment, then withholding treatment is an acceptable decision, but it cannot be a permanent exclusion from treatment consideration.

In sum, it becomes clear from analyzing the decisions in both the Tennessee and Florida cases that individual medical determinations are key to providing constitutionally appropriate treatment to individuals. States attempting to save resources by applying categorical exclusions to treatment that are not based on individual medical determinations will likely be unable to avoid violating the Eighth Amendment. States may vary in how they evaluate inmates on an individual basis, but anything less may be evidence of deliberate indifference.

C. Prioritization

While no court order nor settlement agreement has required universal treatment, it remains unclear how much money a state is required to dedicate to treatment, or if there is a certain population target for treating inmates with HCV. States that require opt-out testing of all inmates upon

263. *Id.*
264. *Id.* at 1303.
265. *Id.* at 1308.
266. *Id.*
267. *Id.* at 1308–09.
268. *Id.* at 1309.
269. *Id.*
270. *Id.*

intake and then again upon request may be able to set plans to treat a percentage of their population each year. With finite resources, states are most likely to prioritize treatment for individuals with the most progressive symptoms.

Outside of the correctional setting, it is almost universally accepted that DAA treatment should be provided for all HCV patients regardless of their liver fibrosis stage.[271] However, even the guidelines that support providing universal treatment also acknowledge that state correctional systems with limited resources may prioritize treatment to provide the best care.[272] This issue may well be shaped by the medical community's understanding of HCV and how it affects the body even in early stages. Experts in some cases were able to show that the disease, even in early stages, could increase the chances of other comorbid conditions.[273] It is also important to consider that HCV treatment alone could swallow the medical budgets of many states. Even at reduced prices, the cost of treating all inmates might mean that states are forced to cut funding to other correctional programs.[274]

The cost of treating this disease cannot be avoided. If it can be shown that prioritization fails to meet the Eighth Amendment's prohibition on cruel and unusual punishment, it may require states to provide further treatment options. As the situation stands currently, however, prioritization is likely the most cost-effective way for states to provide HCV treatment.

D. Dedicated Funding

Without question, the cost of providing adequate treatment for HCV remains the most difficult issue in combating HCV in prisons. States have limited resources and often attempt to mitigate the cost of providing substandard HCV treatment. However, even with limited resources, states may be able to adopt policies that are cost effective.

It remains to be seen if the Eighth Amendment requires universal treatment of prisoners with costly DAA medications. If universal treatment

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271. There are interesting parallels relating to states' denial of HCV treatment for Medicare and Medicaid patients who do not reach a sufficient level of fibrosis, but these parallels are beyond the scope of this article.

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

273. *See, e.g.*, *Inch*, 382 F. Supp. 3d at 1302 (noting that HCV can result in many symptoms regardless of fibrosis stage); Stafford v. Carter, No. 1:17-cv-00289-JMS-MJD, 2018 WL 4361639, at *19–20 (S.D. Ind. Sept. 13, 2018) (noting that the state could not prove individuals at earlier stages of infection do not experience lesser or less severe symptoms).

274. Anne C. Spaulding & Jagpreet Chhatwal, *'Nominal pricing' can help prisons and jails treat hepatitis C without breaking the bank*, STAT NEWS (Jan. 9, 2019), https://www.statnews.com/2019/01/09/nominal-pricing-prisons-jails-treat-hepatitis-c/ [https://perma.cc/8XCW-8QSC].

is not constitutionally required, states will likely continue to adopt prioritization methods that allocate resources to the patients with the most serious complications. Prioritization also raises more questions about how much money a state must allocate, or how many prisoners a state is required to treat annually. Recent drug price reductions may provide some relief to states, but, even at reduced prices, systematic DAA treatment may still be too costly for states.[275] A study, which permutated common HCV treatment protocols, found that testing and treatment for all inmates provided the best "value for money" option, but because HCV is extremely prevalent in prison, it still remains an expensive undertaking.[276]

Even if drug prices continue to decrease, treating HCV in the United States will still be a costly undertaking. In addition to DAA medications, states will need to provide funding for appropriately trained staff to screen inmates, HCV prevention, and linkage to care.[277] National recommendations suggest that the introduction of telemedicine to link inmates to specialists can be effective in underserved settings.[278] Additionally, states may have to establish a comprehensive system for tracking the progress of individual inmates and their treatments. This would assist any medical review boards in evaluating a prioritization system. While litigation rightly focuses primarily on the cost of DAA medications, states will also have to be willing to set aside funding for the associated costs of establishing the corresponding treatment protocols.

A federal solution may be an effective path forward. A coordinated federal approach might be appropriate considering the federal government would likely bear a substantial proportion of the costs of untreated hepatitis C.[279] Any attempt at reducing the HCV epidemic in the United States will have to include more treatment in state correctional facilities. At the same time, state correctional facilities are often barred from federal programs that provide discounted medications.

One solution would be to adopt "nominal pricing" for states to purchase HCV medications. Under federal regulation,[280] the nominal price of a drug must be less than 10% of its average market price.[281] This

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275. According to a 2019 model based on Washington's state prison population with eight-thousand intakes per year, the cost of providing every inmate with testing, treatment, and linkage to care at release would be approximately $11.5 million dollars. That total corresponds to approximately 89% of the total pharmaceutical budget for 2016. Sabrina A. Assoumout et al., *Cost-effectiveness and Budgetary Impact of Hepatitis C Virus Testing, Treatment, and Linkage to Care in US Prisons*, 70 CLINICAL INFECTIOUS DISEASES 1388, 1393–94 (2020).

276. *Id.* at 1394.

277. *HCV Guidance*, *supra* note 11.

278. *Id.*

279. Beckman, *supra* note 3, at 1899.

280. *See* 42 C.F.R. § 447.508 (2020).

281. *See* 42 C.F.R. § 447.502; Spaulding & Chhatwal, *supra* note 274.

discount is extended to "safety-net facilities," including hospitals and clinics that treat patients without insurance or who are homeless.[282] States are allowed to participate in this reduced pricing program if they can partner with federally approved facilities. However, as noted in Part I, very few states are able to qualify for this program because they are unable or unwilling to partner with federally approved facilities. If a federal program eliminated this hurdle from states and extended nominal pricing solely to HCV treatment options, it would save taxpayers billions of dollars.[283] Drug manufacturers would still be able to sell the drug at a profit and would not disrupt the Medicaid market. A federal program that provides discounts for HCV medications would provide relief to states and represent a viable means of controlling the spread of HCV in the United States.

In sum, drug prices will likely continue to decrease, and states will be able to treat more inmates, but the HCV problem, particularly for correctional facilities, remains a consequence of punitive drug policies. Therefore, states will be required to seek affordable methods of providing treatment. If the Eighth Amendment allows for the prioritization of treatment, it will likely be the most cost-effective solution. Regardless, states and taxpayers will have to pay a high price.

E. Monitoring

The common theme in prison HCV litigation is that states have failed to be proactive in treating this disease. Understandably, prisoners, as a class, often seek court ordered or agreed-upon oversight over the implementation of new HCV treatment protocols. The most common form of this oversight is monitoring.

Several states have settled with chronic HCV prisoners to provide monitoring and oversight of the implementation of the settlement agreement. Massachusetts settled its HCV litigation and agreed to hire an independent monitor to ensure that the department is complying with the new protocols.[284] Additionally, Pennsylvania's settlement agreement provided that the attorneys representing the class members would receive reports documenting compliance with the agreement.[285] South Carolina recently settled its HCV litigation, and the agreement provides that a federal magistrate will monitor the state's HCV protocol.[286]

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282. Spaulding & Chhatwal, *supra* note 274.

283. At current prices, treating just 10 percent of inmates with HCV would cost $3.3 billion. At the nominal pricing discount, the cost would be $337.5 million. *Id.*

284. Schoenberg, *supra* note 130.

285. Chappell, *supra* note 121.

286. John Monk, *Multi-million dollar settlement in SC prison hepatitis C case gets initial approval*, THE STATE (Jan. 14, 2020, 6:34 PM), https://www.thestate.com/news/local/crime/article239271673.html [https://perma.cc/685P-T4DE].

In *Hoffer*, the court found that monitoring was required to ensure that the FDC was complying with the permanent injunction.[287] This required a monthly status report, which must include the total number of inmates who have been: screened for HCV, identified as having chronic HCV, staged for treatment, submitted to the medical review board, treated with DAAs, completed DAA treatment, eliminated the disease, failed to eliminate the disease, and deemed ineligible for DAA treatment along with the specific reasons for ineligibility.[288] Conversely, Tennessee was able to avoid any court-imposed monitoring by successfully defending itself against claims of deliberate indifference.

It may be that states will have an extra incentive to establish comprehensive HCV treatment protocols that comply with the Eight Amendment to avoid third party monitoring. However, if states continue to fail to provide constitutionally adequate HCV treatment, courts will likely impose monitoring over treatment programs to ensure compliance.

CONCLUSION

"The [Eighth] Amendment must draw its meaning from the evolving standards of decency that mark the progress of a maturing society."[289] The hepatitis C crisis in prisons presents the next challenge to those words. As drug enforcement policies continue to funnel drug users into incarceration, the medical problems of those individuals will continue to drive the cost of imprisonment. The treatment of inmates with HCV presents an opportunity to shape how our country responds to drug addiction.

States can provide adequate treatment under the Eighth Amendment if they provide systematic testing of inmates upon intake, establish medical review boards that make individual treatment determinations, prioritize treatment of individuals based on those determinations, allocate specific funding for the purchase of DAAs and other treatment costs, and allow for third party monitoring. These components create cost-effective standards that address the health needs of inmates and the burden that states face. Hopefully, adequate treatment of HCV in prisons will mirror the progress in the non-institutionalized population and lead to the eradication of such an insidious disease.

287. Hoffer v. Inch, 382 F. Supp. 3d 1288, 1312 (N.D. Fl. 2019).
288. *Id.* at 1312–13.
289. Trop v. Dulles, 356 U.S. 86, 101 (1958).