No. 20-60204

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

JERRY VANWAGNER,

Plaintiff-Appellant,

v.

C. FAULKS, M.S.P. MEDICAL DIRECTOR, et al.,

Defendants-Appellees.

On Appeal from the U.S. District Court for the Northern District of Mississippi, No. 4:18-cv-150-GHD-RP, Hon. Glen H. Davidson, Senior U.S. District Judge

BRIEF OF DRS. JOSEPH GOLDENSON, ROBERT B. GREIFINGER, HOMIE RAZAVI, MARC STERN, AND STACEY B. TROOSKIN, THE HEPATITIS EDUCATION PROJECT, THE INTERNATIONAL NETWORK ON HEPATITIS IN SUBSTANCE USERS – PRISONS NETWORK, AND THE NATIONAL VIRAL HEPATITIS ROUNDTABLE AS *AMICI CURIAE* IN SUPPORT OF APPELLANT

GREGORY F. LAUFER
ROBERT N. KRAVITZ
NICHOLAS A. CASELLI
NICHOLAS A. BUTTO
DAVID I. BERMAN
PAUL, WEISS, RIFKIND, WHARTON, & GARRISON LLP
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

SAMUEL WEISS
KELLY JO POPKIN
RIGHTS BEHIND BARS
416 Florida Ave. NW #26152
Washington, D.C. 20001
(202) 455-4399

KEVIN COSTELLO
CENTER FOR HEALTH LAW & POLICY INNOVATION
HARVARD LAW SCHOOL
1585 Massachusetts Ave.
Cambridge, MA 02138
(617) 495-3109

Counsel for Amici Curiae

SUPPLEMENTAL STATEMENT OF INTERESTED PARTIES

Pursuant to Fifth Circuit Rule 29.2, I hereby certify that I am aware of no persons or entities, in addition to those listed in the merits briefs, that have an interest in the outcome of this litigation other than the signatories to this brief and their counsel.

Dated: August 31, 2020

/s/ Gregory F. Laufer
Gregory F. Laufer

Counsel for Amici Curiae

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INTEREST OF *AMICI CURIAE* [1]

Dr. Joseph Goldenson, MD, served as Director of Jail Health Services for the San Francisco County Jail. He served as a member of the Board of Directors of the National Commission on Correctional Health Care and is a past President of the California chapter of the American Correctional Health Services Association. He has served as a court-appointed expert on correctional medical care in several cases, including *Brown* v. *Plata*, 563 U.S. 493 (2011); *Wilkinson* v. *Austin*, 545 U.S. 209 (2005); and *Madrid* v. *Gomez*, 889 F. Supp. 1146 (N.D. Cal. 1995).

Dr. Robert B. Greifinger, MD, was the Deputy Commissioner and Chief Medical Officer of the New York State Department of Correctional Services. He was the principal investigator for the *Report to Congress: The Health Status of Soon-to-Be Released Inmates*, and the *Report to Congress: Seizing Public Health Opportunities through Correctional Health Care*, both published in 2002. He edited the book *Public Health Behind Bars: From Prisons to Communities* (Springer, New York 2007) and served as co-editor of the *International Journal of Prisoner Health*.

Dr. Homie Razavi, PhD, MBA, is the Managing Director at the Center for Disease Analysis Foundation (CDAF), a non-profit dedicated to the global elimination of viral hepatitis. He is the co-author of over 70 peer-reviewed

[1] All parties have consented to the filing of this *amicus* brief. No party's counsel authored this brief. No party or party's counsel, or any other person, other than the *amici curiae* or their counsel, contributed money to fund this brief.

publications on the global elimination of hepatitis and is a frequent speaker on the subject. He is a fellow in the Society of Decision Professionals and a member of the American Association for the Study of the Liver and the European Association for the Study of the Liver. He is also a board member of the World Hepatitis Alliance and the CDA Foundation.

Dr. Marc Stern, MD, MPH, served as Assistant Secretary for Health Services for the Washington State Department of Corrections. He is an assistant professor of health services at the University of Washington. He serves as a court-appointed expert in the case of *Parsons* v. *Ryan*, 754 F.3d 657 (9th Cir. 2014).

Dr. Stacey B. Trooskin, MD, PhD, MPH, is the Director of Viral Hepatitis Programs at Philadelphia FIGHT Community Health Centers and Clinical Assistant Professor of Medicine at the Perelman School of Medicine at the University of Pennsylvania. Dr. Trooskin serves as the Chief Medical Advisor to the National Viral Hepatitis Roundtable and is a former member of the AASLD/IDSA HCV Guidelines Committee.

The Hepatitis Education Project is a non-profit organization that advocates for access to affordable, high-quality care to support all health needs and is committed to improving the health of underserved communities disproportionately impacted by viral hepatitis.

The International Network on Hepatitis in Substance Users – Prisons Network (INHSU Prisons), established in 2019, is a special interest group for INHSU members, with a focus on the prison setting. INHSU Prisons aims to connect healthcare providers, policy makers, health administrations, academics, and advocates from across the world to participate in scientific knowledge exchange and knowledge translation, and to advocate for health, including hepatitis C (HCV) prevention and care among people who use drugs and are incarcerated.

The National Viral Hepatitis Roundtable (NVHR) is a national coalition of organizations that work together with the goal of eliminating hepatitis B and C in the United States. NVHR is dedicated to reducing the incidence of infection, morbidity, and mortality from viral hepatitis.

BACKGROUND AND SUMMARY OF ARGUMENT

This appeal is one of the growing number of actions seeking to confirm that corrections facilities that deny life-saving treatment to prisoners with chronic hepatitis C violate the Eighth Amendment.[2] It is among the first to reach a court of appeals on the merits.

[2] *West* v. *Gobeille*, No. 2:19-cv-81, 2020 WL 1505677, at *1 (D. Vt. Mar. 30, 2020) (granting class certification and denying motion to dismiss in hepatitis C statewide inmate class-action where Vermont DOC allegedly refused to provide direct-acting antivirals (DAAs) because of cost); *Molina* v. *Fla. Dep't of Corr.*, No. 4:19-cv-157, ECF No. 92, 102 (N.D. Fla. Mar. 20, 2020) (denying motions to dismiss where inmate-plaintiffs alleged that Florida DOC denied them DAAs);

The increase in such cases is not a coincidence—it is the direct result of revolutionary advances in the treatment of the HCV. The discovery of easy-to-use and remarkably effective direct-acting antivirals (DAAs) with minimal side effects has led not only to positive changes in medical outcomes that were previously impossible to achieve, but also to downstream changes in treatment guidelines and the medical standard of care. Since DAAs were introduced, standard-of-care guidelines have shifted, Medicaid programs have updated their treatment coverage policies, prison systems have altered their practices, and foreign governments have

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Pfaller v. *Clarke*, No. 3:19-cv-00728, ECF No. 51 (E.D. Va. Mar. 11, 2020) (denying motions to dismiss where inmate-plaintiff alleged that Virginia DOC denied him DAAs); *Kruse* v. *Fisher*, No. 1:19-cv-00005, 16 (E.D. Cal. Aug. 28, 2019) (denying motion to dismiss inmate-plaintiff's Eighth Amendment claim that California Valley State Prison refused to provide him with DAAs); *Lovelace* v. *Clarke*, No. 2:19-cv-75, 2019 WL 3728265 (E.D. Va. Aug. 7, 2019) (denying motions to dismiss where inmate-plaintiff alleged that Virginia DOC denied him DAAs); *Barfield* v. *Cook*, No. 3:18-cv-1198, 2019 WL 3562021 (D. Conn. Aug. 6, 2019) (certifying class of inmates who alleged that Connecticut DOC denied them DAAs); *Hoffer* v. *Inch*, 382 F. Supp. 3d 1288, 1315 (N.D. Fla. 2019) (holding Florida DOC's failure to treat prisoners with chronic HCV unconstitutional and entering permanent injunction for administration of DAAs); *Stafford* v. *Carter*, No. 1:17-cv-00289, 2018 WL 4361639, at *1 (S.D. Ind. Sept. 13, 2018) (granting summary judgment for inmate-plaintiffs as to their Eighth Amendment claim that Indiana DOC withheld DAAs from HCV-infected inmates); *Chimenti* v. *Wetzel*, No. 15-cv-3333, 2018 WL 3388305, at *1 (E.D. Pa. July 12, 2018) (denying summary judgment in part on claim that Pennsylvania DOC withheld DAAs from HCV-infencted inmates); *Abu-Jamal* v. *Wetzel*, No. 3:16-cv-2000, 2017 WL 34700, at *1 (M.D. Pa. Jan. 3, 2017) (granting preliminary injunction for inmate-plaintiff with chronic HCV to be treated with DAAs).

instituted programs to cure the disease. But where, as here, an outmoded treatment policy persists despite these advances, parties have challenged that outdated policy through litigation.

Prior to 2011, the standard of care for treating HCV was based on using interferon, which mimicked a natural substance made by the body's white blood cells to aid the immune system.[3] However, interferon-based treatment had several problems, including variable responses in patients depending on a host of factors, an extended course of treatment, and, for many, severe side effects.[4]

In 2011, when the first DAAs were introduced, HCV treatment improved radically. Gone are the varied responses; the new regimen yields a Sustained Virologic Response (SVR) rate of higher than 90%.[5] No longer does treatment last

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[3] Eni Williams, *What Are Interferons and How Do They Work?*, MedicineNet, https://www.medicinenet.com/interferon/article.htm#what_are_interferons_and_how_do_they_work (last visited Aug. 31, 2020); Stephen Holt, *What Are the Long-Term Side Effects of Interferons for Hepatitis C?*, Hepatitis Central (Mar. 4, 2019), https://www.hepatitiscentral.com/news/what-are-the-long-term-side-effects-of-interferons-for-hepatitis-c/.

[4] Dr. Daniel Murell, *Interferons for Hepatitis C: Understanding the Long-term Side Effects*, Healthline (Feb. 1, 2019), https://www.healthline.com/health/hepatitis-c/interferons-long-term-effects.

[5] Jennifer L. Horsley-Silva & Hugo E. Vargas, *New Therapies for Hepatitis C Infection*, Gastroenterology & Hepatology (Jan. 2017), Millennium Med. Pub., https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5390323/. SVR refers to a test result indicating that the hepatitis C virus is no longer detectable in the body at least 12 weeks following treatment; it is "tantamount to a virologic cure."

48 weeks; the standard course is now for only 8 to 12 weeks.[6] Severe toxic side effects are absent; DAA treatment is well-tolerated. This sea-change in HCV treatment transformed the medical standard of care. However, some public agencies' HCV treatment policies, including, it appears, the Mississippi Department of Corrections' (MDOC), fail to reflect this standard, often out of cost concerns.[7] In deciding this appeal, the Court should consider Defendants' blatant disregard for the contemporary standards of care widely accepted by providers who treat individuals living with HCV.

Background on Hepatitis C. Hepatitis C is an easily transmitted liver disease resulting from HCV infection that has devastating effects on those who contract it. Estimates suggest that two to three million people in the United States are living

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AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), https://www.hcvguidelines.org/evaluate/when-whom.

[6] *See* AASLD/IDSA, HCV Guidance, *Recommendations for Testing, Managing and Treating Hepatitis C* (Dec. 10, 2019), https://www.hcvguidelines.org/treatment-naive/simplified-treatment.

[7] In fact, Centurion, the medical company that provides care at MDOC facilities, has recently announced that it will terminate its contract with Mississippi as the state was not providing the funding needed to "improve the effectiveness of [their] level of care." Alissa Zhu, *Mississippi Prisons' Health Care Proider Ends Multimillion-Dollar Contract with MDOC*, Mississippi Clarion Ledger (Jul. 30, 2020), https://www.clarionledger.com/story/news/2020/07/30/mississippi-prisons-health-care-provider-centurion-ends-contract/5550733002/.

with the chronic form of this disease.[8] For every 100 persons newly infected with HCV, more than half will develop chronic hepatitis C, a long-term illness that can lead to deadly liver problems.[9] For instance, of those same 100 people, 5 to 25 will eventually develop cirrhosis of the liver—scarring that severely damages the liver's function and can result in liver cancer and liver failure.[10]

HCV is spread when blood from a person infected with the virus enters the body of another, for instance, through contact with a needle previously used by an individual with HCV or, less commonly, by sharing personal care items, through sexual contact, or by getting a tattoo or body piercing in an unregulated setting.[11]

As it progresses, HCV causes severe liver damage, among the many effects that accompany a chronic inflammatory disease.[12] Liver inflammation is apparent when patients exhibit elevated levels of alanine aminotransferase (ALT) and

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[8] CDC, *Hepatitis C FAQs for Health Professionals*, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Aug. 31, 2020); U.S. Department of Health and Human Services, *Basic Hepatitis C Information*, https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-c-basics/index.html (last visited Aug. 31, 2020).

[9] CDC, *Hepatitis C FAQs for Health Professionals*, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Aug. 31, 2020).

[10] *Id.*

[11] *Id.*

[12] *Id.*

aspartate aminotransferase (AST).[13] Chronic liver injury eventually results in an increase in serum concentrations of aminotransferases.[14] Sustained inflammation over time leads to progressive damage in the form of scar tissue.[15] This progressive damage to the liver, called "fibrosis," is most commonly measured using ascending fibrosis scores of F0 (no scarring) to F4 (advanced scarring, or cirrhosis of the liver).[16] Even if fibrosis never reaches an advanced stage, HCV puts patients at risk for depression, fatigue, joint pain, sore muscles, arthritis, various cancers, nerve damage, and jaundice, and may increase the risk of heart attack and diabetes.[17]

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[13] Mariana Lazo, *Johns Hopkins Diabetes Guide: Liver Function*, Johns Hopkins Medicine, https://www.hopkinsguides.com/hopkins/view/Johns_Hopkins_Diabetes_Guide/547086/all/Liver_function (last visited Aug. 31, 2020).

[14] Edoardo G. Giannini, et al., *Liver Enzyme Alteration: A Guide for Clinicians*, 172 CMAJ 367–79 (Feb. 2005), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC545762/.

[15] American Liver Foundation, *The Progression of Liver Disease*, https://liverfoundation.org/for-patients/about-the-liver/the-progression-of-liver-disease/#1503432878616-a25d5b59-3a75 (last visited Aug. 31, 2020).

[16] *See, e.g.*, AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), https://www.hcvguidelines.org/evaluate/when-whom.

[17] *See* Francesco Negro & Gamal Esmat, *Extrahepatic Manifestations in Hepatitis C Virus Infection*, 8 J. of Advanced Res. 85–87 (Mar. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5272942/; Krystian Ślusarz, et al., *Infection with Hepatitis C Virus as a Cause of Nervous System Disorders*, 9 J. of Educ., Health & Sport 230–40 (2019), http://www.ojs.ukw.edu.pl/index.php/johs/article/download/7016/8741.

The Centers for Disease Control and Prevention (CDC) approximates that in 2016, HCV directly caused or contributed to at least 18,713 deaths in the United States.[18] Beginning in 2012, the number of Americans killed by HCV surpassed those killed by 60 other nationally significant infectious diseases, including HIV, tuberculosis, and pneumococcal disease, combined.[19] As early as 2012, the U.S. Surgeon General deemed viral hepatitis a "silent epidemic."[20]

Chronic hepatitis C disproportionately affects incarcerated individuals—by recent estimates, HCV is 17 to 23 times more prevalent among prisoners than in the general population.[21] Less than 1% of the U.S. population is incarcerated today, but roughly 30% of all Americans infected with HCV reside in prison.[22] HCV also

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[18] CDC, *supra* n.9. *See also* CDC, *Hepatitis C Prevalence Estimates 2013-2016* (Nov. 6, 2018), https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates.html.

[19] CDC, *Hepatitis C Mortality* (May 4, 2016), https://www.cdc.gov/nchhstp/newsroom/2016/hcv-mortality.html.

[20] CDC, *Surgeon General's Perspectives: Raising Awareness of Viral Hepatitis: National Hepatitis Testing Day, May 19*, https://www.cdc.gov/hepatitis/pdfs/surgeongeneral-phr_may-june2012.pdf (last visited Aug. 31, 2020).

[21] AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings* (Nov. 6, 2019), https://www.hcvguidelines.org/unique-populations/correctional.

[22] Aiden K. Varen, et al., *Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High But Declining*, Public Health Reports, at 187–95 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904899/; *see also* AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings* (Nov. 6, 2019), https://www.hcvguidelines.org/unique-populations/correctional.

disproportionately impacts African Americans, who comprise approximately 11% of the U.S. population, but 25% of those infected with chronic hepatitis C.[23]

Hepatitis C Epidemic in Mississippi. Mississippi has been hard-hit by the hepatitis C epidemic.[24] Mississippi does not appear to have a system for the collection of HCV-related data,[25] nor does it appear to consistently report data on infections to the CDC.[26] The state's HCV problem has undoubtedly been exacerbated by the opioid crisis: a recent Mississippi State Department of Health report estimated that HCV hospitalizations associated with intravenous drug use increased by 53.8% between 2014 and 2018.[27]

A 2020 publication by the Mississippi State Department of Health stressed that the "growing number of new [HCV] cases presents a public health concern

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[23] Francis Collins, *Hepatitis C Disparities among African Americans*, U.S. Department of Health & Human Services (Feb. 27, 2017), https://www.hhs.gov/hepatitis/blog/2017/02/27/hepatitis-c-disparities-among-african-americans.html.

[24] *Hepatitis C: Who is At Risk*, Mississippi State Department of health. https://www.hhs.gov/hepatitis/blog/2017/02/27/hepatitis-c-disparities-among-african-americans.html (last visited Aug. 31, 2020).

[25] *See* Mississippi State Dep't of Health, Hospitalizations for Hepatitis C in Mississippi: 2014-2018 1 (2020), http://www.msdh.state.ms.us/msdhsite/_static/resources/8670.pdf.

[26] *See* Ctr. for Disease Control and Prevention, Viral Hepatitis Surveillance 47 (2019), https://www.cdc.gov/hepatitis/statistics/2017surveillance/pdfs/2017HepSurveillanceRpt.pdf.

[27] Mississippi State Dep't of Health, *supra* note 26 at 1-2.

because hepatitis C is associated with substantial morbidity, including cirrhosis of the liver, liver cancer, liver failure, and increased demand for organ transplants."[28] The Department concluded that Mississippi "needs to invest in the diagnosis and early treatment of this curable infection to control the spread of hepatitis C, decrease the burden of severe liver disease, prevent premature deaths, and reduce hospitalization-related expenses."[29] In doing so, the department specifically endorsed the use of DAAs, stating that "[i]mmunization and treatment are key factors for decreasing the burden of infectious diseases" and that "[c]urrent direct-acting antiviral (DAA) treatment regimens for hepatitis C are highly effective, achieving [over] 95% cure rate," have "fewer side effects," and are "relatively more accessible due to recent price reductions."[30]

At the same time, however, the Mississippi Department of Corrections (MDOC) has apparently maintained arbitrary conditions on treatment, which have resulted in delays or outright denials, thereby risking irreversible damage and, in some cases, death. In prisons, the consequences of such restrictions are grave. One 2010 study conducted on patients of a Mississippi clinic found that, even in the absence of intravenous drug use, incarceration itself poses a significant, independent

[28] *Id.* at 1.

[29] *Id.*

[30] *Id.* at 8.

risk for hepatitis C infection.[31] Though MDOC's current HCV treatment protocol remains unknown, as recently as 2018, MDOC has cited to a 2005 policy—written almost a decade before DAAs were introduced to the U.S. market—as its prevailing policy on HCV testing and treatment.[32] This hepatitis management policy provides treatment to infected inmates only "when indicated," which suggests that eligibility criteria are obscured and the number of HCV-infected inmates who receive treatment is small.[33] In 2017, for example, MDOC provided treatment to only 7 of 702 prisoners they had diagnosed with HCV while the rest were merely "monitored."[34] This denominator is almost certainly a severe undercount as Mississippi's estimate of HCV is roughly one tenth that of the CDC's, meaning that

[31] Mary Jane Burton et al., *Incarceration as a Risk Factor for Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) Co-infection in Mississippi*, 21 J. Health Care for the Poor and Underserved 1194, 1198 (2010).

[32] Siraphob Thanthong-Knight, *State Prisons Fail To Offer Cure To 144,000 Inmates With Deadly Hepatitis C*, Kaiser Health News (Jul. 9, 2018), https://khn.org/news/state-prisons-fail-to-offer-cure-to-144000-inmates-with-deadly-hepatitis-c/.

[33] Anna Wolfe, *Inmate says MDOC denied him treatment, even as reported hepatitis C cases doubled*, Clarion Ledger (Feb. 14, 2018), https://www.clarionledger.com/story/news/politics/2018/02/14/inmate-says-mdoc-denied-him-treatment-even-reported-hepatitis-c-cases-doubled/1058250001/.

[34] *Id.*

the vast majority of prisoners with HCV in Mississippi received no treatment in 2017.[35]

These restrictions on treatment are particularly alarming given that Mississippi's correctional facilities, instead of using opt-out testing, appear to test only those inmates for whom a prison doctor deems it necessary, even though HCV infection can remain asymptomatic for years.[36] Given the churn of Mississippians into and out of the state's prisons, MDOC's failure to treat the disease in its prisons undercuts the state's efforts to eradicate it outside of them.

ARGUMENT

I. THE INTRODUCTION OF DIRECT-ACTING ANTIVIRALS REVOLUTIONIZED HCV TREATMENT

Prior to 2011, interferon-based treatment for HCV required a series of "grueling shots" and "pills that gave patients flu-like symptoms."[37] These side effects, coupled with a prolonged course of treatment and a cure rate of only 40% to

[35] *Id.*

[36] *Id.*

[37] Associated Press, *FDA Approves New Drug to Treat Hepatitis C*, CBS News (Aug. 4, 2017), https://www.cbsnews.com/news/fda-approves-mavyret-abbvie-drug-to-treat-hepatitis-c/.

50%, posed significant problems.[38] Indeed, whether to provide interferon treatment was a debated question of medical judgment.[39]

This all changed around 2011, when the U.S. Food & Drug Administration (FDA) began approving a series of DAAs.[40] In 2013, approval of sofosbuvir (brand name Sovaldi®) marked the "advent of interferon-free treatments for hepatitis C" and "a landmark shift" in the treatment of the disease.[41] Since December 2013, the FDA has approved additional DAAs to treat hepatitis C.[42] The FDA has called these

[38] FDA, *Hepatitis C Treatments Give Patients More Options* (Mar. 4, 2017), https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm.

[39] *See, e.g.*, *Howze* v. *Hickey*, No. 10-cv-094, 2011 WL 673750, at *10 (E.D. Ky. Feb. 17, 2011) ("[T]his case is simply a situation where there is a disagreement among medical professionals regarding the medical appropriateness of interferon therapy for plaintiff's Hepatitis C condition.").

[40] Ayman Geddawy, et al., *Direct Acting Anti-hepatitis C Virus Drugs: Clinical Pharmacology and Future Direction*, 5 J. of Transnat'l Int'l Med. 8, 8–9 (Mar. 2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490957/pdf/jtim-05-008.pdf.

[41] Richard Knox, *Treatments: FDA Expected To Approve New, Gentler Cure for Hepatitis C*, NPR (Dec. 5, 2013), https://www.npr.org/sections/health-shots/2013/12/05/248934833/fda-set-to-approve-hepatitis-drug.

[42] *See, e.g.*, James Myhre & Dennis Sifris, *FDA-Approved Hepatitis C Drugs*, Verywell Health, VeryWell Health (Jan. 13, 2020), https://www.verywellhealth.com/list-of-approved-hepatitis-c-drugs-3576465.

advances "transformative"[43] and "breakthrough therapies."[44] New DAAs "have double[d] the viral cure rates—90% to 100%—in just [ ] 12 weeks' time."[45] In fact, medical experts identified the development of DAAs used to treat HCV as one of the "biomedical breakthroughs" of the past decade, which "[f]rom a combined economic and public-health standpoint . . . may outstrip just about anything else" in the past 10 years.[46]

II. THE STANDARD OF CARE IS THAT NEARLY ALL CHRONIC HCV PATIENTS SHOULD BE TREATED

Because of the effectiveness of DAAs, the standard of care is that virtually all patients with chronic hepatitis C should be treated. This standard is articulated by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in published treatment guidelines. AASLD has over 5,000 members, including physicians, scientists, medical students, residents, and other healthcare professionals who work in hepatology and related

[43] FDA, *supra* n.34.

[44] FDA News Release, *FDA Approves Sovaldi for Chronic Hepatitis C*, U.S. Department of Health & Human Services (Dec. 9, 2013), https://www.hhs.gov/hepatitis/blog/2013/12/09/fda-approves-sovaldi-for-chronic-hepatitis-c.html.

[45] FDA, *supra* n.34.

[46] *See, e.g.*, Christina Farr, *These Biomedical Breakthroughs of the Decade Saved Lives and Reduced Suffering*, CNBC (Dec. 28, 2019), https://www.cnbc.com/2019/12/27/biomedical-breakthroughs-of-the-2010s-crispr-hep-c-treatment-prep.html.

fields.[47] IDSA comprises over 12,000 physicians, scientists, and health experts who specialize in infectious diseases.[48] The AASLD/IDSA guidelines are developed and maintained by a panel of HCV experts.[49] The CDC refers health professionals who treat chronic hepatitis C patients to the AASLD/IDSA guidelines and recognizes them as "evidence-based, expert-developed recommendations for hepatitis C management."[50] In March 2020, the U.S. Preventive Services Task Force, an independent panel of experts appointed by the U.S. Department of Health and Human Services, relied on the AASLD/IDSA guidelines in a report that recommended screening for HCV in all adults ages 18 to 79 to "enable more individuals to seek curative treatment sooner," because "more people can benefit . . . than ever before."[51] Inarguably, the guidelines are the most "credible source of

[47] *See* AASLD, *2017 Annual Report* at 1–3 (Jan. 2017), https://www.aasld.org/sites/default/files/2019-05/2018-AASLD-AnnualReport-Interactive.pdf.

[48] IDSA, *Mission & Values*, https://www.idsociety.org/about-idsa/mission-values/ (last visited Aug. 31, 2020).

[49] AASLD/IDSA, HCV Guidance, *Methods* (Nov. 6, 2019), https://www.hcvguidelines.org/contents/methods.

[50] CDC, *Hepatitis C FAQs for Health Professionals*, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Aug. 31, 2020).

[51] *See* U.S. Preventive Services Task Force, *U.S. Preventive Services Task Force Issues Final Recommendation Statement on Screening for Hepatitis C in Adolescents and Adults* (Mar. 2, 2020), https://www.hhs.gov/hepatitis/blog/2020/03/04/uspstf-issues-updated-hepatitis-c-screening-recommendation.html.

unbiased guidance on how best to treat [healthcare practitioners'] patients with HCV infection."[52]

The guidelines state: "Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure and, as such, is expected to benefit nearly all chronically infected persons."[53] They add that "from a medical standpoint, data continue to accumulate that demonstrate the many benefits, both intrahepatic [within the liver] and extrahepatic [outside of the liver], that accompany HCV eradication."[54] The guidelines therefore "recommend treatment for all patients with chronic HCV infection," except for the small subset with "a short life expectancy that cannot be remediated by HCV treatment, liver

[52] AASLD/IDSA, HCV Guidance, *About the Guidance*, https://www.hcv guidelines.org/about (last visited Aug. 31, 2020). The AASLD/IDSA guidelines are widely cited as authoritative. *See* U.S. Department of Veteran Affairs (Aug. 27, 2018), *Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations*, https://www.hepatitis.va.gov/pdf/treatment-considerations-2018-08-27.pdf (noting that the AASLD/IDSA guidelines constitute the "current best practices in the treatment of chronic HCV"); Kaiser Permanente, *Hepatitis C Screening Guideline* (Sept. 2016), https://wa.kaiserpermanente.org/static/pdf/public/guidelines/ hepatitis-c.pdf ("The [AASLD] and the [IDSA] have updated their published guidance to recommend HCV treatment for patients at all risk levels.").

[53] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), https://www.hcvguidelines.org/evaluate/when-whom (emphasis added).

[54] *Id.*

transplantation, or another directed therapy."[55] Accordingly, once it is confirmed that a patient is infected with hepatitis C, the recommended course of action in all but the most limited of circumstances is treatment with DAAs.

By contrast, institutional treatment guidelines recommending that doctors "monitor" HCV patients and delay treatment based on fibrosis scores (scarring levels) and liver enzymes are inconsistent with the guidelines. When a chronic illness has a known and available cure, passive "monitoring" does not constitute treatment, but the absence of it.[56] When providers choose to passively monitor patients in lieu of treating them, they force individuals to endure the painful side effects related to HCV. Worse still, higher fibrosis scores indicate tissue scarring that might be irreversible. Plaintiff and other individuals with high fibrosis scores are therefore at risk for reduced liver functionality even after delayed treatment.[57]

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[55] *Id.* (emphasis added).

[56] *See Postawko* v. *Mo. Dep't of Corr.*, No. 2:16-cv-04219, 2017 WL 1968317, at *7 (W.D. Mo. May 11, 2017), *aff'd*, 910 F.3d 1030 (8th Cir. 2018) ("[A]dopting a monitoring policy instead of treatment and waiting to see just how much the inmate's health may deteriorate is not permissible."); *B.E.* v. *Teeter*, No. c16-227, 2016 WL 3033500, at *3 (W.D. Wash. May 27, 2016) (crediting plaintiffs' argument that "mere 'monitoring' is not an equally effective treatment because 'waiting until a Medicaid enrollee's liver is damaged before providing treatment is harmful to his/her health and significantly increases the risk of both morbidity and mortality'").

[57] Connie M. Welch, *Hepatitis C and Cirrhosis; Stages of Liver Damage*, Hep (Jul. 20, 2020), https://www.hepmag.com/blog/hepatitis-c-cirrhosis-stages-liver-damage.

One study has shown that patients with fibrosis scores exceeding 1.45 experience a 127% increase in risk of death, and more than double the risk of adverse clinical events.[58]

Because the standard of care is that nearly all individuals with chronic hepatitis C should be treated, and because fibrosis estimates are not always sufficiently sensitive, it is not appropriate to use fibrosis scores to justify delaying treatment. The guidelines indicate that treating patients at early stages of the disease is particularly beneficial because"[i]nitiating therapy in patients with lower-stage fibrosis augments the benefits of SVR" and "[t]reatment delay may decrease the benefit of SVR."[59] Initiating treatment early is also important because "[f]ibrosis progression is variable across different patient populations as well as within the same individual over time."[60] Relatedly, "[m]any of the components that determine

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[58] Jeffrey McCombs, et al., *Using the Fib-4 Score to Monitor Morbidity and Mortality Risk in Chronic Hepatitis C Patients*, J. of Virology & Retrovirology, https://symbiosisonlinepublishing.com/virology-retrovirology/virology-retrovirology10.php.

[59] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6. 2019), https://www.hcvguidelines.org/evaluate/when-whom; *see also* American Society of Addiction Medicine, *Public Policy Statement on Hepatitis C Infection* (Apr. 5, 2017), https://www.asam.org/advocacy/find-a-policy-statement/view-policy-statement/public-policy-statements/2017/04/11/hepatitis-c.

[60] *Id.* *See also* Javier A. Cepeda, et al., *Increased Mortality Among Persons With Chronic Hepatitis C With Moderate or Severe Liver Disease: A Cohort Study*, 65 Clinical Infectious Diseases 235, 241 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5850450/ ("Withholding medical treatment based on disease

fibrosis progression and development of cirrhosis in an individual are unknown."[61] Further, individuals who have been cured of chronic hepatitis C can no longer transmit the virus to others.[62] As such, due to the lack of sensitivity for leading liver fibrosis estimates, there is no "safe stage" of hepatitis C during which treatment can be delayed while "monitoring" and attempting to guarantee that the patient suffers no adverse consequences or does not transmit it to others.[63] Courts across the country have recognized this standard of care.[64]

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stage implies that there is a 'safe' disease stage. Additionally, it is assumed that the 'safe' stage and transitions out of that stage can be accurately detected . . . [L]iver fibrosis estimates cannot differentiate mild from moderate fibrosis with sensitivity >80%. Likewise, progression of liver fibrosis was not predicted with sufficiently high diagnostic accuracy in most other studies.").

[61] *Id.*

[62] Behzad Hajarizadeh, et al., *Hepatitis C Treatment as Prevention: Evidence, Feasibility, and Challenges*, 1 Lancet Gastroenterology & Hepatology P317-27 (2016), https://www.thelancet.com/journals/langas/article/PIIS2468-1253(16)30075-9/fulltext.

[63] *See id.*

[64] *See, e.g.*, *Postawko* v. *Mo. Dep't of Corr.*, 910 F.3d 1030, 1034 (8th Cir. 2018) ("The medical standard of care put forward by organizations such as the Infectious Diseases Society of America and the American Association for the Study of Liver Diseases now recommends that almost all persons with chronic HCV receive DAA drug treatment."); *Stafford* v. *Carter*, No. 1:17-cv-00289, 2018 WL 4361639, at *9 (S.D. Ind. Sept. 13, 2018) ("The [AASLD/IDSA] gudiance is the national standard of care with respect to the treatment of patients with HCV."); *Hoffer* v. *Jones*, 290 F. Supp. 3d 1292, 1296 (N.D. Fla. 2017) ("[T]he present-day standard of care is to treat chronic-HCV patients with DAAs as long as there are no contraindications or exceptional circumstances. It is inappropriate to only treat those with advanced levels of fibrosis."); *Roberts* v. *Wilson*, No. 3:15-cv-1607, 2017 WL 8727155, at

Healthcare coverage, policies, and practices also reflect this shift in available medicines and recognize that nearly all chronic HCV patients should be treated with DAAs:

Medicaid. In 2015, the Centers for Medicare & Medicaid Services (CMS) issued a letter to state Medicaid coordinators characterizing DAAs for patients with HCV as "effective, clinically appropriate, and medically necessary" and rebuking states for "unreasonably restrict[ing] access" to DAAs by "limiting treatment" to beneficiaries with F3 or F4 fibrosis scores.[65]

In response, several state Medicaid programs removed barriers to treatment. Although the Mississippi Department of Medicaid does not appear to require a particular level of liver damage as a prerequisite for treatment,[66] as of 2019, it still had in place significant barriers to HCV treatment, including sobriety and prescriber

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*2 (M.D. Pa. Sept. 27, 2017) ("The use of DAADs for the treatment of Hepatitis C is the new standard of care in the medical community, and is currently recommended for treatment of all stages of Hepatitis C, except for those who are terminally ill."), *R. & R. adopted*, 2018 WL 1583543 (M.D. Pa. Mar. 30, 2018); *Abu-Jamal* v. *Wetzel*, No. 3:16-cv-2000, 2017 WL 34700, at *18 (M.D. Pa. Jan. 3, 2017).

[65] CMS, *Assuring Medicaid Beneficaries Access to Hepatitis (HCV) Drugs*, U.S. Department of Health & Human Services, Release No. 172 (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf. Even in 2015, there were no states limiting treatment to people with F3 fibrosis scores.

[66] *Id.*

restrictions.[67] Indeed, a 2019 report by the Center for Health Law and Policy Innovation at Harvard Law School and the National Viral Hepatitis Roundtable gave the Mississippi Division of Medicaid's HCV program a "D+" grade due to these discriminatory restrictions on access to treatment.[68]

Where state Medicaid programs did not voluntarily conform their policies to the standard of care, courts repeatedly condemned their inaction. For example, in May 2016, a federal district court in Washington ordered the state's Medicaid program to cover prescription medications for hepatitis C without regard to fibrosis score.[69] This decision ended Washington's policy of denying coverage to patients with mild liver scarring (fibrosis scores of F0 through F2) who were not diagnosed with any other diseases. In June 2016, in response to a formal litigation demand, Delaware's Division of Medicaid and Medical Assistance revoked categorical coverage exclusions that restricted treatment to those with significant liver damage or cirrhosis.[70] That same month, Florida expanded access to hepatitis C treatment

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[67] Hepatitis C: The State of Medicaid Access Report Card—Mississippi (2017), https://stateofhepc.org/wp-content/themes/infinite-child/reports/HCV_Report_Mississippi.pdf.

[68] *Id.*

[69] *See B.E.* v. *Teeter*, Case No. c16-227, 2016 WL 3033500, at *1, *6 (W.D. Wash. May 27, 2016).

[70] Center for Health Law & Policy Innovation at Harvard Law School, *In Face of Class Action Lawsuit, Delaware Medicaid Removes Unlawful Restrictions to the Cure for the Hepatitis C Virus* (June 8, 2016), https://www.chlpi.org/in-face-of-

by removing fibrosis score restrictions.[71] Under its previous policy, insurers were prohibited from reimbursing treatment costs unless the patient had advanced liver scarring (an F3 or F4 score).[72] In February 2019, Indiana reached an agreement approved in federal court for its Medicaid coverage policy to remove all restrictions based on the severity of the disease.[73] Similarly, in April 2019, the U.S. District Court for the District of Kansas approved a class settlement removing all fibrosis score restrictions from Kansas's Medicaid coverage policy.[74]

Taken as a whole, there is an unmistakable trend to remove coverage restrictions on DAA treatment in state Medicaid programs. The National Viral Hepatitis Roundtable study of this trend reveals that, in the past five years, such

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class-action-lawsuit-delaware-medicaid-removes-unlawful-restrictions-to-the-cure-for-the-hepatitis-c-virus/.

[71] Associated Press, *Florida Changes Hep C Drug Policy for Medicaid*, NBC Miami (June 1, 2016), https://www.nbcmiami.com/news/local/Florida-Changes-Hep-C-Drug-Policy-for-Medicaid-381573511.html.

[72] *Id.*

[73] Marilyn Odendahl, *Indiana Agrees to Provide Hepatitis C Drugs to More Medicaid Recipients*, The Indiana Lawyer (Feb. 19, 2019), https://www.theindianalawyer.com/articles/49505-indiana-agrees-to-provide-hepatitis-c-drugs-to-more-medicaid-recipients.

[74] *See* ACLU, *The ACLU of Kansas Settles Hep-C Lawsuit* (Apr. 30, 2019), https://www.shb.com/-/media/press-releases/2019/press-release-aclu-shook-hep-c.pdf?la=en (describing settlement in *Harper* v. *Andersen*, No. 18-4008-DDC-GEB (D. Kan. filed Feb. 15, 2018)).

restrictions have been removed in more than 30 states through voluntary cessation, policy reform, and litigation.[75]

International Standards. The World Health Organization (WHO) recommends treating all persons infected with chronic hepatitis C over the age of 12 with DAAs, "irrespective of disease stage."[76] WHO reasoned that "[e]xpanding treatment to the general population is cost-effective" and cited Egypt as an example.[77] Egypt, which has "one of the world's highest incidence rates of hepatitis C—about 7 percent of its 90m population," instituted an aggressive program to eliminate hepatitis C by using DAAs, and treated nearly one million hepatitis C patients in two years.[78] One study found that the use of DAAs in Egypt led to HCV elimination in nearly all treated patients,[79] and experts say that Egypt could serve as

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[75] *See* National Viral Hepatitis Roundtable & Center for Health Law & Policy Innovation, *Hepatitis C: The State of Medicaid Access*, https://www.chlpi.org/wp-content/uploads/2013/12/HCV_State-of-Medicaid-Access_November-2019-fix.pdf (last visited Aug. 31, 2020).

[76] WHO, *Guidelines for the Care and Treatment of Persons Diagnosed with Chronic Hepatitis C Virus Infection* at xiii (July 2018), https://apps.who.int/iris/bitstream/handle/10665/273174/9789241550345-eng.pdf?ua=1.

[77] *Id.* at 19.

[78] Heba Saleh, *Egypt Combats Hepatitis C Epidemic with State-run Scheme*, Financial Times (Jan. 22, 2017), https://www.ft.com/content/d1e18e96-d81b-11e6-944b-e7eb37a6aa8e.

[79] *See* Ahmed Nagaty, *Real-life Results of Sofosbuvir based Therapy in Chronic Hepatitis C -naïve and -experienced Patients in Egypt*, PLOS One (Oct. 5, 2017),

the model in this field for the rest of the world.[80] Further, the European Association for the Study of the Liver (EASL) recommends that all patients with HCV be treated with DAAs, and the Canadian Association for the Study of the Liver indicates that there is no medical justification for HCV treatment restrictions.[81]

Prisons. A similar trend has occurred across the United States as state corrections departments face judicial scrutiny from Eighth Amendment challenges over their HCV treatment policies. For example, the New York Department of Corrections increased its spending on prescription drugs from fiscal 2013 through 2015, which state officials attributed mostly to the purchases of new hepatitis C medications.[82] New York treated more than 600 inmates with DAAs as of 2016.[83] In May 2017, "[b]ecause of advances in medicine," Wisconsin treated more than 200

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http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0184654 (finding an overall sustained virologic response rate of 97.1%).

[80] Saleh, *supra* n.73.

[81] *See* EASL, *EASL Recommendations on Treatment of Hepatitis C 2018*, J. of Hepatology 1, 6 (2018), https://easl.eu/wp-content/uploads/2018/10/HepC-English-report.pdf; Hemant Shah, et al., *The Management of Chronic Hepatitis C: 2018 Guideline Update from the Canadian Association for the Study of the Liver*, 190 CMAJ E677, E679 (2018), https://www.cmaj.ca/content/190/22/E677.

[82] Pew Charitable Trusts, *Prison Health Care: Costs and Quality* at 16 (Oct. 2017), http://www.pewtrusts.org/~/media/assets/2017/10/sfh_prison_health_care_costs_and_quality_final.pdf.

[83] Beth Schwartzapfel, *Prisons Are Spending Millions on a Pricey New Drug*, Business Insider (Oct. 14, 2016), http://www.businessinsider.com/prisons-are-spending-millions-on-a-pricey-new-drug-2016-10.

inmates infected with chronic hepatitis C with DAAs in less than one year.[84] In California, the state's 2018 budget allotted $176 million to treat all of its inmates with hepatitis C over a three-year period.[85] And earlier this year, the governor of New Mexico proposed a budget calling for $30 million in funding for treatment of HCV, with the expectation that most inmates will be cured by 2024.[86]

The effectiveness of DAAs has led to a standard of care of near-universal treatment and has caused a variety of organizations to update their policies and practices. Once a distant dream, elimination of the disease in our prisons—and in society as a whole—is now an attainable reality.

III. EXPANDED TREATMENT YIELDS ENORMOUS BENEFITS

While state prison systems that deprive their HCV-infected inmates of DAAs primarily justify their actions based on cost concerns, the benefits of DAAs far outweigh the expense for society at large. As the AASLD/IDSA guidelines note,

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[84] Keegan Kyle, *Wisconsin Prisons Spend $10M Treating Hepatitis C*, Post Crescent (May 25, 2017), http://www.postcrescent.com/story/news/investigations/2017/05/25/wisconsin-prisons-spend-10m-treating-hepatitis-c/99007788/.

[85] Hannah Holzer, *Not All Californians Can Get Life-saving Hepatitis C Treatment. Governor's Budget Aims to Fix*, The Sacramento Bee (June 24, 2018), https://www.sacbee.com/news/local/health-and-medicine/article213702989.html.

[86] Ted Alcorn, *Major Milestone: Governor's Budget Targets Hepatitis C Epidemic In Prisons*, New Mexico In Depth (Jan. 16, 2020), http://nmindepth.com/2020/01/16/major-milestone-governors-budget-target-hepatitis-c-epidemic-in-prisons/.

"[t]reating inmates ultimately benefits public health because they can no longer transmit the virus to others."[87] Further, because a high concentration of HCV-infected Americans live in prisons, researchers have recognized the substantial public health opportunity these institutions present for eradicating the disease.[88]

In one significant meta-study, researchers synthesized the results of published cost-effectiveness studies regarding the DAA era.[89] The results were striking. Using a range of 2017 cost assumptions, the study provided evidence not just that the use of DAAs in both cirrhotic and pre-cirrhotic patients was cost-effective, but that it was even cost-saving. The difference is important. While "cost-effective" treatments produce enough benefit to merit investment at a given price threshold, "cost-saving" interventions are so effective in preventing downstream outcomes that they pay for themselves and yield a net fiscal benefit. As the study's authors note,

[87] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy* (Nov. 6, 2019), https://www.hcvguidelines.org/evaluate/when-whom.

[88] Josiah D. Rich, et al., *Responding to Hepatitis C through the Criminal Justice System*, 370 N. Engl. J. Med. 20, 1872–74 (May 15, 2014), http://www.natap.org/2014/HCV/nejmp1311941.pdf, (prisons "may be the best place to efficiently identify and cure the greatest number of HCV-infected people").

[89] *See* Jagpreet Chhatwal, et al., *Direct-acting Antiviral Agents for Patients with Hepatitis C Virus Genotype 1 Infection Are Cost-saving*, Clinical Gastroenterology & Hepatology, 827, 827–37 (2018), https://www.cghjournal.org/article/S1542-3565(16)30673-5/fulltext.

"not many treatments have been shown to be cost-saving in the history of medicine."[90]

Other research accords. A 2020 study modelled cost-effectiveness of DAA treatment in prisons using data from the Washington Department of Corrections and wholesale acquisition costs of medication.[91] The authors found that the only approaches to HCV treatment that were "an efficient use of limited resources" were those that "test all [and] treat all."[92] In contrast, risk-based testing, testing only at release, and restriction of treatment to patients with above F3 liver fibrosis staging were found to be inefficient resource allocations.[93] Thus, the authors concluded that targeted testing—as compared to universal or opt-out testing—is cost-ineffective, "misses too many cases," and simply "should not be employed."[94] The authors reasoned that while prioritizing individuals with more advanced disease progression was appropriate at the high DAA prices observed in 2013, "[a]t today's lower

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[90] *Id.*

[91] The specific regimen modelled were "8 weeks of glecaprevir/pibrentasvir for individuals without cirrhosis, and 12 weeks of sofosbuvir/velpatasvir for those with cirrhosis." Sabrina A. Assoumou 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, 1390 (2020).

[92] *See id.* at 1392.

[93] *Id.*

[94] *Id.* at 1393.

treatment costs, . . . systems treating only patients with advanced fibrosis could use their available funds to attain better population-level outcomes, without increase in total spending, by moving to a 'treat all' approach."[95]

A 2019 study observed that "[i]n terms of cost-effectiveness, treatment of HCV with highly effective DAAs improves disease burden and outcomes."[96] Along with healthcare costs, the study considered patient and caregiver time, lost earnings due to absenteeism, and lost productivity.[97] The study concluded that "DAAs were cost saving in both 10- and 20-year scenarios."[98]

A 2016 study found that expanded screening and treatment in prisons for ten years would prevent 12,700 new HCV infections over the next 30 years, 89% to 92% of which would have occurred in the outside community.[99] They would also prevent 4,200 to 11,700 liver-related deaths, 300 to 900 liver transplants, 3,000 to 8,600

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[95] *Id.* at 1392-93.

[96] T. Joseph Mattingly II et al., *Value in Hepatitis C Virus Treatment: A Patient-Centered Cost-Effectiveness Analysis*, 38 PharmacoEconomics 233, 240 (Dec. 2, 2019), https://link.springer.com/content/pdf/10.1007/s40273-019-00864-8.pdf.

[97] *Id*. at 235.

[98] *Id*. 238–39.

[99] Tianhua He, et al., *Prevention of Hepatitis C by Screening and Treatment in United States Prisons*, Annals Internal Med. at 4 (Jan. 19, 2016), http://www.natap.org/2015/HCV/AIME201601190-M150617.pdf.

cases of liver cancer, and 2,600 to 7,300 cases of cirrhosis over a 30-year span.[100] Notably, among liver-related deaths averted by DAA treatment in prisons, 80% would have occurred outside prisons.[101] Costs attributable to HCV would fall by $760 million over 30 years—with approximately 84% of the cost savings realized by the outside community—"an even better value for [society's] money."[102]

Moreover, the cost of DAAs has declined substantially since their introduction. The continued decline of DAA prices will only increase the cost-effectiveness of these treatment regimens. A 2019 study noted that "DAAs were initially more expensive than older treatment options; however, these costs have declined substantially over time with increased competition. . . . [L]ist prices for DAAs themselves have declined drastically, from nearly $100,000 per treatment course in 2014 to as low as $24,000 per treatment course [in 2019]."[103]

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[100] *Id.*

[101] *Id.*

[102] *Id.* at 5–6.

[103] M. Christopher Roebuck & Joshua N. Liberman, *Assessing the Burden of Illness of Chronic Hepatitis C and the Impact of Direct-acting Antiviral Use on Healthcare Costs in Medicaid*, Am. J. of Managed Care (June 18, 2019), https://www.ajmc.com/journals/supplement/2019/burden-chronic-hepatitis-c/assessing-burden-illness-chronic-hepatitis-impact-antiviral-healthcare-costs-medicaid?p=1.

Negotiated prices are even lower. For instance, in 2019, Louisiana agreed that Asegua Therapeutics, a Gilead Sciences's affiliate, would serve as the state's hepatitis C provider for its Medicaid and correctional populations for five years and would delink the price it charges for DAAs from the volume supplied.[104] Louisiana's goal is to treat 80% of its Medicaid and correctional populations that have hepatitis C by 2024, which would result in a cost per patient of less than $10,000.[105] This type of subscription model is gaining popularity among states and drug manufacturers alike: one month after the announcement of Louisiana's agreement, Washington State revealed a similar arrangement with AbbVie, another manufacturer of DAAs.[106]

In addition, federal programs can expand access to DAAs. One federal program, for example, allows eligible institutions to receive steep discounts on

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[104] Ted Alcorn, *Louisiana's Deal for Hepatitis C Drugs May Serve as Model*, The Wall Street Journal (Sept. 13, 2019), https://www.wsj.com/articles/louisianas-deal-for-hepatitis-c-drugs-may-serve-as-model-11568347621.

[105] *Id.* Another analysis estimated that, if Louisiana treats 31,000 patients between 2019 and 2024, the average cost per course of treatment could be as low as $5,645. Harry H. Liu et al., Subscription Models for Prescription Drugs 3 (2020), https://www.rand.org/content/dam/rand/pubs/perspectives/PEA200/PEA289-1/RAND_PEA289-1.pdf.

[106] Press Release, Wash. State Health Care Auth., HCA finalizes contract with AbbVie to eliminate HCV in Washington State (July 1, 2019), https://www.hca.wa.gov/about-hca/hca-finalizes-contract-abbvie-eliminate-hcv-washington-state.

hepatitis C and HIV medications, and some states have engaged in partnerships that would allow their correctional institutions to receive those favorable rates.[107]

Rather than alleviate the hepatitis C epidemic, Defendants' apparent failure to treat virtually all HCV-infected prisoners, even extreme cases like those with cirrhosis, ensures that, upon release, these individuals will be sicker and more likely to transmit the infection to others; more likely to develop end-stage liver disease, cirrhosis, or cancer; and more likely to rely on government programs for treatment. Were this Court to sanction delayed treatment and prolonged disease, it would risk significant constitutional harm inside prison walls and a sicker public outside of them, all for purported cost savings that in the long run will have the opposite of its intended effect.

[107] *See* Dave Boucher, *New Tennessee Prison Health Contract Could Top $473 Million, Points to Hepatitis C Plan*, Tennessean (Aug. 7, 2017), https://www.tennessean.com/story/news/2017/08/07/massive-new-tennessee-prison-health-contract-points-possible-hepatitis-c-partnership/546417001/ (Tennessee awarded a prison healthcare contract to provider who "approached Vanderbilt University Medical Center about a partnership that would allow [the state] to receive favorable rates [for DAAs under the federal program]").

CONCLUSION

The District Court's order granting summary judgment should be reversed.

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Respectfully submitted,

PAUL, WEISS, RIFKIND,
WHARTON & GARRISON LLP

By: /s/ Gregory F. Laufer
Gregory F. Laufer
Robert N. Kravitz
Nicholas A. Caselli
Nicholas A. Butto
David I. Berman
1285 Avenue of the Americas
New York, NY 10019
(212) 373-3000

RIGHTS BEHIND BARS
Samuel Weiss
416 Florida Ave. NW #26152
Washington, D.C. 20001
(202) 455-4399

Kelly Jo Popkin
276 Stratford Road
Brooklyn, NY 11218

CENTER FOR HEALTH LAW
& POLICY INNOVATION
HARVARD LAW SCHOOL
Kevin Costello
1585 Massachusetts Ave.
Cambridge, MA 02138
(617) 495-3109

Counsel for Amici Curiae

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This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5) because it contains 6,404 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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/s/ Gregory F. Laufer
Gregory F. Laufer

Counsel for Amici Curiae

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing *amici curiae* brief with the Clerk of the Court for the U.S. Court of Appeals for the Fifth Circuit by using the CM/ECF system on August 31, 2020. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ Gregory F. Laufer
Gregory F. Laufer

Counsel for Amici Curiae