No. 20-3101

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

LUTHER JOHNSON,

Plaintiff-Appellant,

v.

LISA PETERSON; OSCAR CATALDI, JR.; ROBERT YOCHUM,

Defendants-Appellees.

On Appeal from the United States District Court for the Northern District of Ohio, No. 3:18-cv-331, Hon. Jeffrey J. Helmick, 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 PLAINTIFF-APPELLANT AND IN SUPPORT OF REVERSAL

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Fed. R. App. P. 26.1, the Hepatitis Education Project, the International Network on Hepatitis in Substance Users – Prisons Network, and the National Viral Hepatitis Roundtable are not subsidiaries of any parent corporation, and no publicly held corporation owns 10 percent or more of the organizations' stock.

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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*.

[1] Pursuant to Fed. R. App. P. 29(a)(4), all parties have consented to the filing of this *amici* brief. No party's counsel authored this brief in whole or in part. No party or party's counsel, or any other person, other than the *amici curiae* or their counsel, contributed money that was intended to fund the preparation or submission of this brief.

Dr. Homie Razavi, PhD, MBA, is the Managing Director at the Center for Disease Analysis Foundation, a nonprofit dedicated to the global elimination of viral hepatitis. He is the co-author of over 70 peer-reviewed publications on the global elimination of hepatitis and frequently speaks 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 (NVHR) and is a former member of the AASLD/IDSA Hepatitis C Virus (HCV) Treatment Guidelines Committee.

The Hepatitis Education Project is a nonprofit 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 HCV prevention and care among people who use drugs and are incarcerated.

The 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 challenging policies at correctional facilities that delay or deny treatment to residents with chronic hepatitis C in violation of the Eighth Amendment's established right to adequate medical care in prison.[2]

[2] *See, e.g.*, *Ritchie* v. *Mo. Dep't of Corr.*, No. 2:19-cv-04216-BCW (W.D. Mo. filed Dec. 5, 2019); *Pfaller* v. *Clarke*, No. 3:19-cv-00728-REP (E.D. Va. filed Oct. 2, 2019); *West* v. *Gobeille*, No. 2:19-cv-00081-WKS (D. Vt. filed May 21, 2019); *Molina* v. *Fla. Dep't of Corr.*, No. 4:19-cv-00157-AW-CAS (N.D. Fla. filed Apr. 9,

The increase in such cases is not a coincidence—rather, it is the direct result of revolutionary advances in the treatment of HCV since 2011. 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, some prison systems have altered their practices, and foreign governments have instituted programs to cure the disease. But where, as here, an outmoded treatment policy persists despite long-recognized 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] Interferon-based treatment had several problems,

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2019); *Reese* v. *Bryan*, No. 2:19-cv-00512-RFB-BNW (D. Nev. filed Mar. 26, 2019); *Waltermeyer* v. *FCI Berlin*, No. 1:19-cv-00233-LM (D.N.H. filed Mar. 6, 2019); *Lovelace* v. *Clarke*, No. 2:19-cv-00075-DEM (E.D. Va. filed Feb. 15, 2019); *Kruse* v. *Fisher, Jr.*, No. 1:19-cv-00005-NONE-EPG (E.D. Cal. filed Jan. 2, 2019); *Baca* v. *Biter*, No. 1:15-cv-01916-DAD-JDP, 2019 WL 316815 (E.D. Cal. Jan. 24, 2019), *report and recommendation adopted*, No. 1:15-cv-01916-DAD-JDP, 2019 WL 1353707 (E.D. Cal. Mar. 26, 2019).

[3] MedicineNet, *What Are Interferons and How Do They Work?*, https://www.medicinenet.com/interferon/article.htm#what_are_interferons_and_

including variable responses in patients depending on a host of factors, an extended course of treatment, and, for many, severe side effects.[4]

Beginning in 2011 with the introduction of the first DAAs, HCV treatment improved radically. Gone were the varied responses; the new regimen yields Sustained Virologic Response (SVR) rates higher than 90%.[5] No longer does treatment take 48 weeks; the standard course is now 8 to 12 weeks.[6] Severe toxic side effects are not present; DAA treatment is well tolerated. This sea change in

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how_do_they_work (last visited Oct. 8, 2020); Stephen Holt, *What Are the Long-Term Side Effects of Interferons for Hepatitis C?*, Hepatitis Central, https://www.hepatitiscentral.com/news/what-are-the-long-term-side-effects-of-interferons-for-hepatitis-c/ (last visited Oct. 8, 2020).

[4] *See* Healthline, Interferons for Hepatitis C: Understanding the Long-term Side Effects, https://www.healthline.com/health/hepatitis-c/interferons-long-term-effects (last visited Oct. 8, 2020).

[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/; A. Majumdar, et al., *Systematic Review: Current Concepts and Challenges for the Direct-Acting Antiviral Era in Hepatitis C Cirrhosis*, 43 Alimentary Pharmacology & Therapeutics 1276, 1276–92 (Apr. 2016), https://doi.org/10.1111/apt.13633. SVR refers to a test result "tantamount to a virologic cure," indicating that HCV is no longer detectable in the body at least 12 weeks following treatment; AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, https://www.hcvguidelines.org/evaluate/when-whom (last visited Oct. 8, 2020).

[6] *See* AASLD/IDSA, HCV Guidance, *Recommendations for Testing, Managing and Treating Hepatitis C*, https://www.hcvguidelines.org/treatment-naive/ simplified-treatment (last visited Oct. 8, 2020); K.V. Kowdley, et al., *Ledipasvir and Sofosbuvir for 8 or 12 Weeks for Chronic HCV without Cirrhosis*, 370 N. Engl. J. Med. 1879, 1879–88 (May 2014).

HCV treatment transformed the medical standard of care. However, some public agencies' HCV treatment policies, including the Ohio Department of Rehabilitation and Corrections' (ODRC's), fail to reflect this standard. This Court should consider the evident disparity—between the established standard of care and the inflexible treatment policies at issue—in determining whether Mr. Johnson plausibly alleged that Defendants had demonstrated deliberate indifference towards his serious medical needs.

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 with the chronic form of this disease,[7] including nearly 85,000 *new* cases in Ohio reported between 2014 and 2018.[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] Of those same 100 people, 5 to 25 will eventually develop

[7] CDC, *Hepatitis C FAQs for Health Professionals*, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Oct. 8, 2020); U.S. Dep't of Health & Human Servs., *Basic Hepatitis C Information*, https://www.hhs.gov/hepatitis/learn-about-viral-hepatitis/hepatitis-c-basics/index.html (last visited Oct. 8, 2020).

[8] Ohio University, *Prevalence of Hepatitis C Rates in Ohio May Indicate Highest Areas of Opioid Misuse*, ScienceDaily (Nov. 7, 2019), https://www.sciencedaily.com/releases/2019/11/191107160559.htm.

[9] CDC, *Hepatitis C FAQs for Health Professionals*, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Oct. 8, 2020).

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 can result from this chronic inflammatory disease.[12] This progressive damage, called "fibrosis," can be measured using the aspartate aminotransferase to platelet ratio index (APRI), a noninvasive alternative to liver biopsy. Researchers have found that APRI scores above 1.5 predict significant fibrosis and cirrhosis (*i.e.*, advanced scarring) with a high degree of accuracy.[13] Even if fibrosis never reaches an advanced stage, HCV puts patients at risk for adverse mental changes, fatigue,

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[10] *Id.*

[11] *Id.*

[12] CDC, *Hepatitis C FAQs for the Public*, https://www.cdc.gov/hepatitis/hcv/cfaq.htm (last visited Oct. 8, 2020).

[13] CT Wai, et al., *A Simple Noninvasive Index Can Predict Both Significant Fibrosis and Cirrhosis in Patients with Chronic Hepatitis C*, 38 Hepatology 518, 522 (2003), https://aasldpubs.onlinelibrary.wiley.com/doi/pdf/10.1053/jhep.2003.50346.

joint pain, depression, sore muscles, arthritis, various cancers, nerve damage, and jaundice, and may increase the risk of heart attacks and diabetes.[14]

The Centers for Disease Control and Prevention (CDC) approximates that in 2016, HCV directly caused or contributed to at least 18,153 deaths in the United States.[15] 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.[16] As early as 2012, the U.S. Surgeon General deemed viral hepatitis a "silent epidemic."[17]

Chronic hepatitis C disproportionately affects incarcerated individuals—by recent estimates, HCV is 17 to 23 times more prevalent among prisoners than the

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[14] *See* Francesco Negro and Gamal Esmat, *Extrahepatic Manifestations in Hepatitis C Virus Infection*, 8 J. Advanced Res. 85, 85–86 (2017), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5272942/; Salvatore Monaco, et al., *Hepatitis C Virus-Associated Neurocognitive and Neuropsychiatric Disorders: Advances in 2015*, 21 World J. Gastroenterology 11974, 11974–83 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4641119.

[15] CDC, *Viral Hepatitis Surveillance*, at 27 (2016), https://www.cdc.gov/hepatitis/statistics/2016surveillance/pdfs/2016HepSurveillanceRpt.pdf.

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

[17] 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 Oct. 8, 2020).

general population.[18] Less than 1% of the United States population is incarcerated today, but roughly 30% of all Americans with HCV reside in prison.[19] HCV also disproportionately impacts African Americans, who comprise approximately 11% of the U.S. population but 25% of those infected with chronic hepatitis C.[20]

Hepatitis C Epidemic in Ohio. Ohio has been hard hit by the hepatitis C epidemic. According to a 2018 study, between 2013 and 2016, there were 89,600 cases of acute or chronic hepatitis C infection among Ohio's 8,938,500 adult residents.[21] The study singled out Ohio as one of nine states containing over half of all persons infected with HCV across the United States.[22] Moreover, in recent years,

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[18] AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings*, https://www.hcvguidelines.org/unique-populations/correctional (last visited Oct. 8, 2020); *see also* Brian R. Edlin, et al., *Toward a More Accurate Estimate of the Prevalence of Hepatitis C in the United States*, 62 Hepatology 1353, 1353–63 (2015), https://doi.org/10.1002/hep.27978.

[19] AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings*, https://www.hcvguidelines.org/unique-populations/correctional (last visited Oct. 8, 2020); Aiden K. Varan, et al., *Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High But Declining*, Public Health Reports, 187–95 (2014), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904899/.

[20] Francis Collins, *Hepatitis C Disparities among African Americans*, U.S. Dep't of Health & Human Servs. (Feb. 27, 2017), https://www.hhs.gov/hepatitis/blog/2017/02/27/hepatitis-c-disparities-among-african-americans.html.

[21] Eli S. Rosenberg et al., *Prevalence of Hepatitis C Virus Infection in US States and the District of Columbia, 2013 to 2016*, at 6, Jama Network Open (Dec. 21, 2018), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2719137.

[22] *Id.* at 7.

hepatitis C cases have surged in Ohio due to the opioid crisis, rising 38%—from 15,806 cases to 21,882—between 2014 and 2017.[23] This growing epidemic has a disproportionate effect on certain vulnerable populations; for example, between 2006 and 2015, the rate of maternal HCV infection in Ohio increased by 631%, from 1.6 to 11.7 cases per 1,000 live births.[24]

The hepatitis C problem in Ohio is similarly pronounced among incarcerated individuals. According to a 2017 meta-analysis, Ohio's prison population has one of the highest reported rates of HCV infection as measured by antibody prevalence, at a rate of 36% compared to the national average of 18%.[25] There is also a high risk of undetected infection, because Ohio does not employ "opt out" testing, which tests every incarcerated individual for hepatitis C unless the individual declines. Instead, under the ODRC's most recent "Infectious Diseases" policy, prisons simply screen incoming residents for risk factors associated with HCV exposure, testing only those

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[23] Ginger Christ, *Ohio Department of Medicaid to treat those with Hepatitis C earlier*, Cleveland (Oct. 31, 2018), https://www.cleveland.com/metro/2018/10/ohio-department-of-medicaid-to-treat-those-with-hepatitis-c-earlier.html.

[24] Robert M. Rossi & Carri R. Warshak, *Prevalence of Maternal Hepatitis C Virus Infection in Ohio*, 132 Obstetrics & Gynecology 708, 710–13 (Sept. 2018), https://journals.lww.com/greenjournal/Fulltext/2018/09000/Prevalence_of_Maternal_Hepatitis_C_Virus_Infection.24.aspx.

[25] Anne C. Spaulding, et al., *HIV and HCV in U.S. Prisons and Jails: The Correctional Facility as a Bellwether Over Time for the Community's Infections*, 19 AIDS Rev. 134, 134–41 (2017), https://www.aidsreviews.com/resumen.php?id=1398&indice=2017193&u=unp.

who "give information that strongly suggests that the inmate presently has, or has in the past been diagnosed with Hepatitis A, B or C."[26] This selective screening approach is likely ineffective. Empirical studies have revealed, for example, that between 15% and 25% of patients with HCV were born after 1965 and/or had no reported history of intravenous drug use—that is, they reported none of the most common risk factors for the disease.[27] As one analysis concluded, such patients would be "missed by even perfect implementation" of selective, risk factor-based screening.[28]

Ohio's approach to treatment is equally inadequate. One platform estimated that, in 2017, Ohio treated only approximately 20—or 0.14%—of its 14,087

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[26] Ohio Dep't of Rehabilitation & Correction, Infectious Diseases, No. 68-MED-04 § VI(B) (2018), https://www.drc.ohio.gov/Portals/0/Policies/DRC%20Policies/68-MED-04%20%28July%202018%29.pdf.

[27] *See* Yu-Hsiang Hsieh et al., *Evaluation of the Centers for Disease Control and Prevention Recommendations for Hepatitis C Virus Testing in an Urban Emergency Department*, 62 Clinical Infectious Diseases 1059, 1061–62 (2016), https://academic.oup.com/cid/article/62/9/1059/1745341; Michael S. Lyons et al., *Prevalence of Diagnosed and Undiagnosed Hepatitis C in a Midwestern Urban Emergency Department*, 62 Clinical Infectious Diseases 1066 (2016); Elissa M. Schecter-Perkins, et al., *Implementation and Preliminary Results of an Emergency Department Nontargeted, Opt-out Hepatitis C Virus Screening Program*, 25 Acad. Emergency Med. 1216, 1216–25 (2018), https://onlinelibrary.wiley.com/doi/epdf/10.1111/acem.13484.

[28] AASLD/IDSA, HCV Guidance, *Overview of Cost, Reimbursement, and Cost-Effectiveness Considerations for Hepatitis C Treatment Regimens*, https://www.hcvguidelines.org/evaluate/cost (last visited Oct. 14, 2020).

incarcerated treatment candidates.[29] Given the churn of Ohioans into and out of the state's prisons, ODRC's failure to treat the disease in its prisons also undercuts any efforts to eradicate HCV outside of them.

ARGUMENT

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

Prior to 2011, HCV treatment required a series of "grueling shots and pills that gave patients flu-like symptoms."[30] These side effects, coupled with a prolonged course of treatment and a cure rate of only 40% to 50%, were significant problems for interferon-based treatment.[31] Whether to provide interferon treatment was indeed a debated question of medical judgment.[32]

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[29] HepCorrections, http://www.hepcorrections.org/ (last visited Oct. 14, 2020).

[30] 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/.

[31] FDA, *Hepatitis C Treatments Give Patients More Options*, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm (last visited Oct. 8, 2020).

[32] *See*, *e.g.*, *Howze* v. *Hickey*, No. 10-cv-094-KKC, 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."); *Goforth* v. *Oderinde*, No. 5:02-cv-94-1(HL), 2008 WL 906421, at *3 (M.D. Ga. Mar. 31, 2008) ("[T]here is a school of thought that *delay* in treatment until it is absolutely necessary *may* be prudent, in hopes that new and improved treatment options can be found.") (emphasis added).

This all changed in 2011, when the U.S. Food and Drug Administration (FDA) began approving a series of DAAs.[33] In 2013, the FDA's 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.[34] Since December 2013, the FDA has approved additional drugs to treat hepatitis C.[35] The FDA has called these advances in HCV treatment "transformative"[36] and has formally identified several DAA treatments as "breakthrough therapies."[37] In March 2017, the FDA announced that DAAs available at the time "have double[d] the viral cure rates—90% to 100%—in just [ ] 12 weeks' time."[38] In fact, medical

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

[34] Richard Knox, *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.

[35] *See*, *e.g.*, James Myhre & Dennis Sifris, *FDA-Approved Hepatitis C Drugs*, VeryWell Health, https://www.verywellhealth.com/list-of-approved-hepatitis-c-drugs-3576465 (last visited Oct. 8, 2020).

[36] FDA, *Hepatitis C Treatments Give Patients More Options*, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm (last visited Oct. 8, 2020).

[37] FDA News Release, *FDA Approves Sovaldi for Chronic Hepatitis C*, U.S. Dep't of Health & Human Servs. (Dec. 9, 2013), https://www.hhs.gov/hepatitis/blog/2013/12/09/fda-approves-sovaldi-for-chronic-hepatitis-c.html.

[38] FDA, *Hepatitis C Treatments Give Patients More Options*, https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm (last visited Oct. 8, 2020).

experts have 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" from the past ten years.[39]

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 for HCV patients is that virtually all patients with chronic HCV infection 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 areas.[40] IDSA comprises over 12,000 physicians, scientists, and health experts who specialize in infectious diseases.[41] The

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[39] Max Nisen, *The 2010s Were a Decade of Drug Breakthroughs*, L.A. Times (Dec. 30, 2019), https://www.latimes.com/business/story/2019-12-30/drug-breakthroughs-of-the-2010s; Christine 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.

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

[41] IDSA, *Mission & Values*, https://www.idsociety.org/about-idsa/mission-values/ (last visited Oct. 8, 2020).

AASLD/IDSA guidelines are developed and maintained by a panel of HCV experts.[42] The CDC refers health professionals who treat chronic hepatitis C patients to the AASLD/IDSA guidelines and recognizes that the guidelines are "evidence-based, expert-developed recommendations for hepatitis C management."[43] Inarguably, the guidelines are the most "credible source of unbiased guidance on how best to treat [healthcare practitioners'] patients with HCV infection."[44]

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."[45] 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],

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[42] AASLD/IDSA, HCV Guidance, *Methods*, https://www.hcvguidelines.org/contents/methods (last visited Oct. 8, 2020).

[43] CDC, *Hepatitis C FAQs for Health Professionals*, https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm (last visited Oct. 8, 2020).

[44] AASLD/IDSA, HCV Guidance, *About the Guidance*, https://www.hcvguidelines.org/about (last visited Oct. 8, 2020). The AASLD/IDSA guidelines are widely cited as authoritative. *See*, *e.g.*, U.S. Dep't of Veteran Affairs *Chronic Hepatitis C Virus (HCV) Infection: Treatment Considerations* at 9 (Aug. 27, 2018), 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").

[45] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, https://www.hcvguidelines.org/evaluate/when-whom (last visited Oct. 8, 2020).

that accompany HCV eradication."[46] Therefore, the guidelines "recommend treatment for all patients with chronic HCV infection, except those with a short life expectancy that cannot be remediated by HCV treatment, liver transplantation, or another directed therapy."[47] 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, the institutional treatment guidelines at issue here base treatment decisions on fibrosis scores (scarring levels), which is inconsistent with the community standard of care articulated by AASLD/IDSA. 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 rely upon fibrosis scores to determine who should and should not be treated. The guidelines indicate that treating patients at early stages of the disease is 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."[48]

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[46] *Id.*

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

[48] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, https://www.hcvguidelines.org/evaluate/when-whom (last visited Oct. 8, 2020); *see also* American Society of Addiction Medicine, *Public Policy Statement on Hepatitis C Infection*, https://www.asam.org/advocacy/find-a-policy-statement/view-policy-

Initiating treatment early on is also important because "[f]ibrosis progression is variable across different patient populations as well as within the same individual over time."[49] Relatedly, "[m]any of the components that determine fibrosis progression and development of cirrhosis in an individual are unknown."[50] In addition, it is clear that individuals who have been cured of chronic hepatitis C can no longer transmit the virus to others.[51] Accordingly, due to the lack of sensitivity of leading liver fibrosis estimates, there is no "safe stage" of hepatitis C during which treatment can be delayed while guaranteeing that the patient suffers no adverse

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statement/public-policy-statements/2017/04/11/hepatitis-c (last visited Oct. 8, 2020).

[49] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, https://www.hcvguidelines.org/evaluate/when-whom (last visited Oct. 8, 2020); *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 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.").

[50] AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, https://www.hcvguidelines.org/evaluate/when-whom (last visited Oct. 8, 2020).

[51] Behzad Hajarizadeh, et al., *Hepatitis C Treatment as Prevention: Evidence, Feasibility, and Challenges*, 1 Lancet Gastroenterology & Hepatology 317, 317–27 (2016), https://www.thelancet.com/journals/langas/article/PIIS2468-1253(16)30075-9/fulltext.

consequences or does not transmit it to others.[52] Courts across the country have recognized this standard of care.[53]

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:

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[52] *See id.*

[53] *See*, *e.g.*, *Postawko* v. *Missouri 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-JMS-MJD, 2018 WL 4361639, at *9 (S.D. Ind. Sept. 13, 2018) ("The [AASLD/IDSA] guidance 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 *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) ("[T]he standard of care is to administer DAA medications regardless of the disease's stage."); *see also Allah* v. *Thomas*, 679 F. App'x 216 (3rd Cir. 2017) (reversing district court's dismissal of state inmate's Eighth Amendment claim for refusal to provide treatment with DAAs); *Henderson* v. *Tanner,* No. 15-804-SDD-EWD, 2017 WL 1015321 (M.D. La. Mar. 15, 2017), *adopting Report and Recommendation,* 2017 WL 1017927 (Feb. 16, 2017) (denying motion to dismiss state inmate's Eighth Amendment claim for refusal to treat with DAAs); *Chimenti* v. *Pennsylvania Dep't of Corr.*, 2017 WL 3394605 (E.D. Pa. Aug. 8, 2017) (denying motion to dismiss complaint that alleged prisoners with hepatitis C were denied or delayed treatment with DAAs because of cost).

Medicaid. In 2015, the Centers for Medicare & Medicaid Services (CMS) issued a letter to state Medicaid coordinators that characterized DAA drug treatment for patients with chronic HCV as "effective, clinically appropriate, and medically necessary" and rebuked states for "unreasonably restrict[ing] access" to DAAs by "limiting treatment" to beneficiaries with F3 or F4 fibrosis scores.[54]

Several state Medicaid programs removed barriers to treatment in the wake of this guidance. Significantly, the state whose very regulations are at issue has broadened Medicaid coverage for hepatitis C treatment. As of January 1, 2019, the Ohio Department of Medicaid began paying for the treatment of HCV at earlier stages of the disease, so that patients are treated as soon as they are found to have chronic hepatitis C, instead of waiting until their condition progresses further.[55]

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[54] CMS, *Assuring Medicaid Beneficaries Access to Hepatitis (HCV) Drugs*, U.S. Dep't of Health & Human Servs., Release No. 172, at 2–3 (Nov. 5, 2015), https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf.

[55] *See* Ginger Christ, *Ohio Department of Medicaid to Treat Those with Hepatitis C Earlier*, Cleveland.com (Nov. 1, 2018), https://www.cleveland.com/metro/2018/10/ohio-department-of-medicaid-to-treat-those-with-hepatitis-c-earlier.html; *see also* Kaitlin Schroeder, *Ohio Medicaid Lifts Restrictions on Costly Hep C Drugs*, Dayton Daily News (Nov. 2, 2018), https://www.daytondailynews.com/news/000-pill-ohio-medicaid-lifts-restrictions-costly-hep-drugs/4P0DZ4ACJ1ZxWIeb4SmqaK/; *Ohio Medicaid to Pay for Earlier Hepatitis C Treatment*, Health Policy Institute of Ohio (Nov. 2, 2018), https://www.healthpolicynews.org/daily_review/2018/11/ohio-medicaid-to-pay-for-earlier-hepatitis-c-treatment.html.

Where state Medicaid programs did not voluntarily agree to conform their coverage policies to the standard of care, courts have repeatedly condemned their decisions as illegal. For example, in May 2016, a federal district court in Washington ordered the state's Medicaid program to provide coverage for prescription medications to treat hepatitis C without regard to fibrosis score.[56] This decision ended Washington's previous Medicaid policy, which had denied coverage to patients with mild liver scarring (fibrosis scores of F0 through F2) who were not diagnosed with any disease other than hepatitis C.

In June 2016, in response to a formal litigation demand, Delaware's Division of Medicaid and Medical Assistance revoked categorical coverage exclusions of HCV cures (providing cures "only to those whose disease had progressed to the point of significant liver damage of cirrhosis").[57] That same month, Florida expanded access to hepatitis C treatment by removing the fibrosis score restrictions in its

[56] *See B.E.* v. *Teeter*, No. C16-227-JCC, 2016 WL 3033500, at *1, *6 (W.D. Wash. May 27, 2016).

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

Medicaid policy.[58] Under its previous policy, insurers were prohibited from reimbursing treatment costs unless the patient had advanced liver scarring (an F3 or F4 score).[59]

In January 2019, Iowa, known as one of the most restrictive states in terms of treating hepatitis C, expanded its Medicaid care to include patients with moderate scarring (a fibrosis score of F2)—a change from its previous policy of restricting care to those with advanced liver scarring (scores of F3 or above).[60] 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.[61] Similarly, in April 2019, the U.S. District Court for the District of Kansas

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[58] 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.

[59] *Id.*

[60] Kate Payne, *Iowa Medicaid Expands Care To Hepatitis C Patients, But Restrictions Remain*, Iowa Public Radio (Jan. 10, 2019), https://www.iowapublicradio.org/health/2019-01-10/iowa-medicaid-expands-care-to-hepatitis-c-patients-but-restrictions-remain.

[61] 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.

approved a class settlement removing all fibrosis score restrictions from Kansas's Medicaid coverage policy.[62]

Taken as a whole, there is an unmistakable trend in the removal of coverage restrictions on DAA treatment in state Medicaid programs. The NVHR study of this trend reveals that, in the past five years, such restrictions have been removed from more than 30 states through voluntary cessation, policy reform, and litigation.[63]

International Standards. The World Health Organization (WHO) recommends treating all persons with chronic HCV infection over the age of 12 with DAAs, "irrespective of disease stage."[64] WHO reported that "[e]xpanding treatment to the general population is cost-effective."[65] Further, the European Association for the Study of the Liver (EASL) has long recommended that all patients with HCV be

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[62] *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)).

[63] *See* NVHR and 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 Oct. 9, 2020).

[64] 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.

[65] *Id.* at 19.

treated, and the Canadian Association for the Study of Liver likewise has consistently indicated that there is no medical justification for restricting treatment.[66]

Prisons. A similar trend has occurred across the country as state corrections departments face judicial scrutiny under the Eighth Amendment 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.[67] New York has treated more than 600 inmates with DAAs.[68]

In May 2017, "[b]ecause of advances in medicine," Wisconsin treated "more than 200 inmates" with DAAs in less than a year.[69] Officials at Wisconsin's

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[66] *See* EASL, *Recommendations on Treatment of Hepatitis C 2016: Summary*, 66 J. Hepatology 153, 157 (2017), https://www.journal-of-hepatology.eu/article/s0168-8278(16)30489-5/fulltext; 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.

[67] 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.

[68] 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.

[69] 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/.

Department of Corrections indicated that the state increased the number of incarcerated individuals receiving treatment for HCV from 72 in 2016 to 249 through spring 2017 because "pills with higher success rates and fewer side effects landed on the market and medical professionals shifted their recommendations to promote earlier treatment."[70] In California, the state's 2018 budget allotted $176 million to treat all of its inmates with hepatitis C over a three-year period.[71] 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.[72]

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.

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[70] *Id.*

[71] 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.

[72] 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/.

III. EXPANDED TREATMENT YIELDS ENORMOUS BENEFITS

Although cost is the primary justification cited by prisons that deprive HCV-infected residents of DAAs, the benefits far outweigh the expense for society at large. As the AASLD/IDSA guidelines note, "treatment can ultimately reduce the risk of liver-related and extrahepatic complications, and has the potential to decrease HCV transmission in correctional facilities and the community after release."[73] Further, because of the high concentration of HCV-infected Americans living in prisons, several researchers have recognized the substantial public health opportunity these institutions present for eradicating the disease.[74]

In one significant meta-study, researchers synthesized the results of published cost-effectiveness studies of HCV treatment in the era of DAAs.[75] The results were striking. Using a range of 2017 cost assumptions, the study provided evidence that use of DAAs in both cirrhotic and pre-cirrhotic patients was not just cost-effective,

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[73] AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings*, https://www.hcvguidelines.org/unique-populations/correctional (last visited Oct. 8, 2020)

[74] Josiah Rich, et al., *Responding to Hepatitis C through the Criminal Justice System*, 370 N. Engl. J. Med. 1871, 1872 (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").

[75] *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.

but that it even was cost-saving. The difference is important. While treatments deemed "cost-effective" produce significant 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 to the system as a whole. As the study's authors note, "not many treatments have been shown to be cost-saving in the history of medicine."[76]

Other research accords. A 2020 study modeled the cost-effectiveness of DAA treatment in the prison context using data from the Washington Department of Corrections and wholesale acquisition costs of medication.[77] 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."[78] In contrast, risk-based testing, testing only at release, and restriction of treatment to patients with above F3 liver fibrosis scores were "inefficient allocation[s] of resources."[79] Thus, the authors concluded that targeted testing—as compared to universal or opt-out testing—is

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[76] *Id.* at 836.

[77] 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, 1388 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7318776/.

[78] *See id.* at 1392.

[79] *Id.*

cost-ineffective, "misses too many cases," and simply "should not be employed."[80] 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 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."[81]

A 2019 study similarly observed that "[i]n terms of cost-effectiveness, treatment of HCV with highly effective DAAs improves disease burden and outcomes."[82] Along with healthcare costs, the study considered patient and caregiver time, lost earnings due to absenteeism, and lost productivity.[83] The study concluded that "DAAs were cost saving in both 10- and 20-year scenarios."[84]

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[80] *Id.* at 1393.

[81] *Id.* at 1392–93.

[82] T. Joseph Mattingly II et. al., *Value in Hepatitis C Virus Treatment: A Patient-Centered Cost-Effectiveness Analysis*, 38 PharmacoEconomics 233, 240 (2020), https://link.springer.com/content/pdf/10.1007/s40273-019-00864-8.pdf.

[83] *Id*. at 235. One 2017 study similarly concluded that "treating all HCV-infected individuals is cost saving and net social benefits are over $500 billion greater compared with limiting treatment." Gigi A. Moreno, et al., *Value of Comprehensive HCV Treatment among Vulnerable, High-risk Populations*, 20 Elsevier 736, 736 (2017), https://www.sciencedirect.com/science/article/pii/S1098301517300852 ("Increased access to treatment . . . over the long-term reduces costs for payers, as the benefits accrued from long-term reduction in prevalent and incident cases, mortality, and medical costs outweigh the cost of treatment.").

[84] *Id*. at 234.

A study published in 2016 by researchers from Harvard Medical School and other prominent universities found that expanded screening and treatment in prisons for a 10-year period would prevent 12,700 new HCV infections over the next 30 years, 89% to 92% of which would have occurred in the outside community.[85] The study also found that expanded screening and treatment in prisons would reduce the costs attributable to HCV by $760 million over 30 years—with approximately 84% of the cost savings realized by the outside community—and would provide society with "an even better value for [its] money" than alternative approaches.[86]

What's more, the cost of DAAs has declined substantially since their introduction. A 2019 healthcare research 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."[87]

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[85] 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.

[86] *Id.* at 5–6.

[87] 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-

Negotiated prices are even lower. For instance, the state of Louisiana negotiated an agreement with Gilead Science's affiliate Asegua Therapeutics whereby Asegua would serve as the state's primary hepatitis C provider for its Medicaid and correctional populations for five years and would delink the price it charges for DAAs from the volume of drugs it supplied.[88] 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.[89]

In addition, federal programs and hospitals are working together to expand access to DAA drugs. A current federal program, for example, allows eligible institutions, like hospitals, to receive steep discounts on hepatitis C and HIV medications, and some states have engaged in partnerships that would allow their correctional institutions to receive those favorable rates.[90]

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c/assessing-burden-illness-chronic-hepatitis-impact-antiviral-healthcare-costs-medicaid?p=1.

[88] 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.

[89] *Id.*

[90] *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/ (stating that Tennessee awarded a prison healthcare contract to a medical provider who approached them with a partnership that would allow for favorable DAA drug rates).

Rather than alleviate the hepatitis C epidemic, Defendants' systemic, arbitrary delay and failure to treat HCV-infected incarcerated individuals ensures that, upon release, these individuals are 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. Delaying treatment risks permanent liver scarring and damage, which compromises liver function over time. Momentary shortsightedness should not divert society's long-term goals. 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, as well as higher overall medical costs.

CONCLUSION

For the foregoing reasons, the District Court's orders dismissing Plaintiffs' Complaint should be reversed.

Dated: October 16, 2020

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) and 29(a)(5) because it contains 6,079 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

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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 Sixth Circuit by using the CM/ECF system on October 16, 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.

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