

No. 20-15471

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**IN THE UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

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JOHN MELNIK,

Plaintiff-Appellant,

v.

ROMEO ARANAS,

Defendant-Appellee.

On Appeal from the United States District Court for the District of Nevada,  
No. 2:17-cv-02378-JCM-EJY, Hon. James C. Mahan, U.S. District Judge

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**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 ten percent or more of the organizations' stock.

## TABLE OF CONTENTS

	<u>Page</u>
CORPORATE DISCLOSURE STATEMENT .....	i
TABLE OF AUTHORITIES .....	iii
INTEREST OF <i>AMICI CURIAE</i> .....	1
BACKGROUND AND SUMMARY OF ARGUMENT .....	3
ARGUMENT .....	10
I. THE INTRODUCTION OF DIRECT-ACTING ANTIVIRALS REVOLUTIONIZED HCV TREATMENT.....	10
II. THE STANDARD OF CARE IN 2017 WAS THAT NEARLY ALL CHRONIC HCV PATIENTS SHOULD BE TREATED .....	12
III. EXPANDED TREATMENT YIELDS ENORMOUS BENEFITS.....	22
CONCLUSION.....	28

## TABLE OF AUTHORITIES

	<b>Page(s)</b>
<b>CASES</b>	
<i>Abu-Jamal v. Wetzel</i> , No. 3:16-CV-2000, 2017 WL 34700 (M.D. Pa. Jan. 3, 2017) .....	16
<i>Allah v. Thomas</i> , 679 F. App'x 216 (3rd Cir. 2017).....	16
<i>Ancata v. Prison Health Servs., Inc.</i> , 769 F.2d 700 (11th Cir. 1985) .....	6
<i>B.E. v. Teeter</i> , No. C16-227-JCC, 2016 WL 3033500 (W.D. Wash. May 27, 2016) .....	17
<i>Baca v. Biter</i> , No. 1:15-cv-01916-DAD-JDP, 2019 WL 316815 (E.D. Cal. Jan. 24, 2019), <i>report and recommendation adopted</i> , No. 1:15-cv- 01916-DAD-JDP, 2019 WL 1353707 (E.D. Cal. Mar. 26, 2019).....	4
<i>Brown v. Plata</i> , 563 U.S. 493 (2011).....	1
<i>Chimenti v. Pennsylvania Dep't of Corr.</i> , 2017 WL 3394605 (E.D. Pa. Aug. 8, 2017) .....	16
<i>Darrah v. Krisher</i> , 865 F.3d 361 (6th Cir. 2017) .....	6
<i>Egberto v. Nevada Dep't of Corr.</i> , 678 F. App'x 500 (9th Cir. 2017) .....	6
<i>Goforth v. Oderinde</i> , No. 5:02-cv-94-1(HL), 2008 WL 906421 (M.D. Ga. Mar. 31, 2008) .....	10
<i>In re HCV Prison Litig.</i> , No. 3:19-cv-00577-MMD-CLB, 2020 WL 806170 (D. Nev. Feb. 18, 2020) .....	22

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<i>Howze v. Hickey</i> , No. 10-cv-094-KKC, 2011 WL 673750 (E.D. Ky. Feb. 17, 2011).....	10
<i>Kruse v. Fisher, Jr.</i> , No. 1:19-cv-00005-NONE-EPG (E.D. Cal. filed Jan. 2, 2019) .....	4
<i>Lovelace v. Clarke</i> , No. 2:19-cv-00075-DEM (E.D. Va. filed Feb. 15, 2019) .....	4
<i>Madrid v. Gomez</i> , 889 F. Supp. 1146 (N.D. Cal. 1995).....	1
<i>Molina v. Fla. Dep't of Corr.</i> , No. 4:19-cv-00157-AW-CAS (N.D. Fla. filed Apr. 9, 2019) .....	3
<i>Monmouth Cty. Corr. Institutional Inmates v. Lanzaro</i> , 834 F.2d 326 (3d Cir. 1987) .....	6
<i>Parsons v. Ryan</i> , 754 F.3d 657 (9th Cir. 2014) .....	2
<i>Pfaller v. Clarke</i> , No. 3:19-cv-00728-REP (E.D. Va. filed Oct. 2, 2019) .....	3
<i>Postawko v. Missouri Dep't of Corr.</i> , 910 F.3d 1030 (8th Cir. 2018) .....	15
<i>Reese v. Bryan</i> , No. 2:19-cv-00512-RFB-BNW (D. Nev. filed Mar. 26, 2019).....	3
<i>Ritchie v. Mo. Dep't of Corr.</i> , No. 2:19-cv-04216-BCW (W.D. Mo. filed Dec. 5, 2019).....	3

<i>Roberts v. Wilson</i> , No. 3:15-cv-1607, 2017 WL 8727155 (M.D. Pa. Sept. 27, 2017), <i>R. &amp; R. adopted</i> , 2018 WL 1583543 (M.D. Pa. Mar. 30, 2018) .....	16
<i>Stafford v. Carter</i> , No. 1:17-cv-00289-JMS-MJD, 2018 WL 4361639 (S.D. Ind. Sept. 13, 2018) .....	16
<i>Waltermeyer v. FCI Berlin</i> , No. 1:19-cv-00233-LM (D.N.H. filed Mar. 6, 2019) .....	3
<i>West v. Gobeille</i> , No. 2:19-cv-00081-WKS (D. Vt. filed May 21, 2019) .....	3
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### **INTEREST OF *AMICI CURIAE*<sup>1</sup>**

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

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<sup>1</sup> Pursuant to Fed. R. App. P. 29(a)(4), all parties have consented to the filing of this *amicus* 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.

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 and is a former member of the AASLD/IDSA Hepatitis C Virus (HCV) Treatment 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 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 many 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.<sup>2</sup>

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<sup>2</sup> 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, 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,



The multitude of 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.<sup>3</sup> Interferon-based treatment had several problems,

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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).

<sup>3</sup> MedicineNet, *What Are Interferons and How Do They Work?*, [https://www.medicinenet.com/interferon/article.htm#what\\_are\\_interferons\\_and\\_how\\_do\\_they\\_work](https://www.medicinenet.com/interferon/article.htm#what_are_interferons_and_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,

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

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%.<sup>5</sup> No longer does treatment take 48 weeks; the standard course is now 8 to 12 weeks.<sup>6</sup> Severe toxic side effects are not present; DAA treatment is well-tolerated. This sea change in HCV treatment transformed the medical standard of care. However, some public

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<https://www.hepatitiscentral.com/news/what-are-the-long-term-side-effects-of-interferons-for-hepatitis-c/> (last visited Oct. 8, 2020).

<sup>4</sup> 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).

<sup>5</sup> 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).

<sup>6</sup> 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).

agencies' HCV treatment policies, including the Nevada Department of Corrections', failed (and continue to fail) to reflect contemporaneous standards of medical care, often out of cost concerns. Defendant has never argued, however, that a lack of resources was the basis for NDOCS' decision.<sup>7</sup> And, regardless, such considerations can increasingly be mitigated through negotiated pricing. This Court should consider the evident disparity—between the established standard of care as it stood in 2017 and the inflexible treatment policies at issue—in determining whether Mr. Melnik established a genuine issue of material fact regarding Defendant's deliberate indifference toward 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

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<sup>7</sup> Absent such evidence, making decisions on the basis of cost can constitute a constitutional violation on its own. *See Egberto v. Nevada Dep't of Corr.*, 678 F. App'x 500, 505 (9th Cir. 2017) (holding that a delay or denial of recommended treatment for “non-medical reasons” violated clearly established Eighth Amendment law); *accord Darrah v. Krisher*, 865 F.3d 361, 372 (6th Cir. 2017) *quoting Blackmore v. Kalamazoo Cty.*, 390 F.3d 890, 899 (6th Cir. 2004) (“When prison officials are aware of a prisoner’s obvious and serious need for medical treatment and delay medical treatment of that condition for non-medical reasons, their conduct in causing the delay creates a constitutional infirmity.”); *Ancata v. Prison Health Servs., Inc.*, 769 F.2d 700, 704 (11th Cir. 1985) (“[I]f necessary medical treatment has been delayed for non-medical reasons, a case of deliberate indifference has been made out.”); *Monmouth Cty. Corr. Institutional Inmates v. Lanzaro*, 834 F.2d 326, 346–47 (3d Cir. 1987) (same).

with the chronic form of this disease,<sup>8</sup> including over 21,000 Nevadans, as of 2016.<sup>9</sup> 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.<sup>10</sup> 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.<sup>11</sup>

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.<sup>12</sup>

As it progresses, HCV causes severe liver damage, among the many effects that result from this chronic inflammatory disease.<sup>13</sup> This progressive damage,

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

<sup>9</sup> HepVu, *Local Data: Nevada*, <https://hepvu.org/state/nevada> (last visited Oct. 8, 2020).

<sup>10</sup> CDC, *Hepatitis C FAQs for Health Professionals*, <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited Oct. 8, 2020).

<sup>11</sup> *Id.*

<sup>12</sup> *Id.*

<sup>13</sup> CDC, *Hepatitis C FAQs for the Public*, <https://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last visited Oct. 8, 2020).

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.<sup>14</sup> Even if fibrosis never reaches an advanced stage, HCV puts patients at risk for mental changes, fatigue, joint pain, depression, sore muscles, arthritis, various cancers, nerve damage, and jaundice, and may increase the risk of heart attacks and diabetes.<sup>15</sup>

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.<sup>16</sup> Beginning in 2012, the number of Americans killed by HCV surpassed those killed by 60 other nationally significant infectious diseases, including HIV,

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<sup>14</sup> 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>.

<sup>15</sup> 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>.

<sup>16</sup> CDC, *Viral Hepatitis Surveillance*, at 27 (2016), <https://www.cdc.gov/hepatitis/statistics/2016surveillance/pdfs/2016HepSurveillanceRpt.pdf>.

tuberculosis, and pneumococcal disease, combined.<sup>17</sup> As early as 2012, the U.S. Surgeon General deemed viral hepatitis a “silent epidemic.”<sup>18</sup>

Chronic hepatitis C disproportionately affects incarcerated individuals—by recent estimates, HCV is 17 to 23 times more prevalent among prisoners than the general population.<sup>19</sup> Less than 1% of the United States population is incarcerated today, but roughly 30% of all Americans with HCV reside in prison.<sup>20</sup> HCV also disproportionately impacts African Americans, who comprise approximately 11% of the U.S. population, but 25% of those infected with chronic hepatitis C.<sup>21</sup>

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<sup>17</sup> CDC, *Hepatitis C Mortality* (May 4, 2016), <https://www.cdc.gov/nchhstp/newsroom/2016/hcv-mortality.html>.

<sup>18</sup> 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](https://www.cdc.gov/hepatitis/pdfs/surgeongeneral-phr_may-june2012.pdf) (last visited Oct. 8, 2020).

<sup>19</sup> 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>.

<sup>20</sup> AASLD/IDSA, HCV Guidance, <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/>.

<sup>21</sup> 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>.

## 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.”<sup>22</sup> 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.<sup>23</sup> Whether to provide interferon treatment was indeed a debated question of medical judgment.<sup>24</sup>

This all changed in 2011, when the FDA began approving a series of DAAs.<sup>25</sup> 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

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<sup>22</sup> 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/>.

<sup>23</sup> FDA, *Hepatitis C Treatments Give Patients More Options*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm> (last visited Oct. 8, 2020).

<sup>24</sup> 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).

<sup>25</sup> 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>.

treatment of the disease.<sup>26</sup> Since December 2013, the FDA has approved additional drugs to treat hepatitis C.<sup>27</sup> The FDA has called these advances in HCV treatment “transformative”<sup>28</sup> and has formally identified several DAA treatments as “breakthrough therapies.”<sup>29</sup> 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.”<sup>30</sup> In fact, medical 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.<sup>31</sup>

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<sup>26</sup> 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>.

<sup>27</sup> 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).

<sup>28</sup> FDA, *Hepatitis C Treatments Give Patients More Options*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm> (last visited Oct. 8, 2020).

<sup>29</sup> 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>.

<sup>30</sup> FDA, *Hepatitis C Treatments Give Patients More Options*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm> (last visited Oct. 8, 2020).

<sup>31</sup> 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),



## **II. THE STANDARD OF CARE IN 2017 WAS 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, and it has been that way for at least the past five years. 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.<sup>32</sup> IDSA comprises over 12,000 physicians, scientists, and health experts who specialize in infectious diseases.<sup>33</sup> The AASLD/IDSA guidelines are developed and maintained by a panel of HCV experts.<sup>34</sup> 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

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<https://www.cnbc.com/2019/12/27/biomedical-breakthroughs-of-the-2010s-crispr-hep-c-treatment-prep.html>.

<sup>32</sup> See AASLD, *2017 Annual Report* at 1–3 (Jan. 2017), <https://www.aasld.org/sites/default/files/2019-05/2018-AASLD-AnnualReport-Interactive.pdf>.

<sup>33</sup> IDSA, *Mission & Values*, <https://www.idsociety.org/about-idsa/mission-values/> (last visited Oct. 8, 2020).

<sup>34</sup> AASLD/IDSA, HCV Guidance, *Methods*, <https://www.hcvguidelines.org/contents/methods> (last visited Oct. 8, 2020).

C management.”<sup>35</sup> Inarguably, the guidelines are the most “credible source of unbiased guidance on how best to treat [healthcare practitioners’] patients with HCV infection.”<sup>36</sup>

Since 2015, the AASLD/IDSA guidelines have stated: “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.”<sup>37</sup> 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.”<sup>38</sup> Therefore, the guidelines “recommend treatment for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by [liver] transplantation, or by other directed therapy.”<sup>39</sup> Accordingly, once it is

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<sup>35</sup> CDC, *Hepatitis C FAQs for Health Professionals*, <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited Oct. 8, 2020).

<sup>36</sup> AASLD/IDSA, HCV Guidance, *About the Guidance*, <https://www.hcvguidelines.org/about> (last visited Oct. 8, 2020).

<sup>37</sup> AASLD/IDSA, 2015 HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://web.archive.org/web/20151212105917/http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited Oct. 14, 2020) (emphasis added). Current guidelines AASLD/IDSA reflect the same language and treatment approaches.

<sup>38</sup> *Id.*

<sup>39</sup> *Id.* (emphasis added).

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 based 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 for some time has been 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. In 2015, the guidelines specifically stated 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.”<sup>40</sup> 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.”<sup>41</sup> Relatedly, “[m]any of the

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<sup>40</sup>AASLD/IDSA, 2015 HCV Guidance, *When and in Whom to Initiate HCV Therapy*,

<https://web.archive.org/web/20151212105917/http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited Oct. 14, 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-statement/public-policy-statements/2017/04/11/hepatitis-c> (last visited Oct. 8, 2020).

<sup>41</sup> AASLD/IDSA, 2015 HCV Guidance, *When and in Whom to Initiate HCV Therapy*,

components that determine fibrosis progression and development of cirrhosis in an individual are unknown.”<sup>42</sup> In addition, it is clear that individuals who have been cured of chronic hepatitis C infection can no longer transmit the virus to others.<sup>43</sup> 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 consequences or does not transmit it to others.<sup>44</sup> Courts across the country have recognized this standard of care.<sup>45</sup>

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<https://web.archive.org/web/20151212105917/http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited Oct. 14, 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.”).

<sup>42</sup> AASLD/IDSA, 2015 HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://web.archive.org/web/20151212105917/http://www.hcvguidelines.org/full-report/when-and-whom-initiate-hcv-therapy> (last visited Oct. 14, 2020).

<sup>43</sup> 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](https://www.thelancet.com/journals/langas/article/PIIS2468-1253(16)30075-9/fulltext).

<sup>44</sup> *See id.*

<sup>45</sup> *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

Well before 2017, healthcare coverage, policies, and practices reflected this shift in available medicines and recognized that nearly all chronic HCV patients should be treated:

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

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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 DAAs 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 a DAA because of cost).

necessary” and rebuked states for “unreasonably restrict[ing] access” to DAAs by “limiting treatment” to beneficiaries with F3 or F4 fibrosis scores.<sup>46</sup>

Several state Medicaid programs removed barriers to treatment in the wake of this guidance. Significantly, the state whose very regulations are at issue eliminated all restrictions on hepatitis C treatment coverage by 2017: the Nevada 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, without regard to fibrosis scores, instead of waiting until their condition progresses further.<sup>47</sup>

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.<sup>48</sup> This

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<sup>46</sup> CMS, *Assuring Medicaid Beneficiaries Access to Hepatitis (HCV) Drugs*, Dep’t of Health & Human Servs., Release No. 172, at 2–3 (Nov. 5, 2015), <https://www.medicare.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/rx-releases/state-releases/state-rel-172.pdf>.

<sup>47</sup> See National Viral Hepatitis Roundtable & Center for Health Law & Policy Innovation at Harvard Law School, *Hepatitis C: The State of Medicaid Access* (2017), [https://www.chlpi.org/wp-content/uploads/2013/12/State-of-HepC\\_2017\\_FINAL.pdf](https://www.chlpi.org/wp-content/uploads/2013/12/State-of-HepC_2017_FINAL.pdf).

<sup>48</sup> See *B.E. v. Teeter*, No. C16-227-JCC, 2016 WL 3033500, at \*1, \*6 (W.D. Wash. May 27, 2016).

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 or cirrhosis).<sup>49</sup> That same month, Florida expanded access to hepatitis C treatment by removing the fibrosis score restrictions in its Medicaid policy.<sup>50</sup> Under its previous policy, insurers were prohibited from reimbursing treatment costs unless the patient had advanced liver scarring (an F3 or F4 score).<sup>51</sup>

Taken as a whole, there is an unmistakable trend in the removal of coverage restrictions on DAA treatment in state Medicaid programs that was well underway in 2017 and has continued in the years since. The National Viral Hepatitis

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<sup>49</sup> 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-medicare-removes-unlawful-restrictions-to-the-cure-for-the-hepatitis-c-virus/>.

<sup>50</sup> 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>.

<sup>51</sup> *Id.*

Roundtable 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.<sup>52</sup>

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.”<sup>53</sup> WHO reported that “[e]xpanding treatment to the general population is cost-effective” and cited Egypt as an example.<sup>54</sup> Egypt, which has “one of the world’s highest incidence rates of hepatitis C—about 7 percent of its 90m population,” began an aggressive program to eliminate hepatitis C using DAAs and treated nearly 1 million hepatitis C patients in 2016 and 2017.<sup>55</sup> One 2017 study found that the use of DAAs in Egypt led to HCV viral suppression in nearly all treated patients,<sup>56</sup> and experts said that Egypt could be the model for the

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<sup>52</sup> 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](https://www.chlpi.org/wp-content/uploads/2013/12/HCV_State-of-Medicaid-Access_November-2019-fix.pdf) (last visited Oct. 9, 2020).

<sup>53</sup> 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>.

<sup>54</sup> *Id.* at 19.

<sup>55</sup> 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>.

<sup>56</sup> 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),



rest of the world.<sup>57</sup> Further, the European Association for the Study of the Liver (EASL) has long recommended that all patients with HCV be treated, and the Canadian Association for the Study of Liver likewise has consistently indicated that there is no medical justification for restricting treatment.<sup>58</sup>

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 purchases of new hepatitis C medications.<sup>59</sup> 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%).

<sup>57</sup> 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>.

<sup>58</sup> See EASL, *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](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>.

<sup>59</sup> 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](http://www.pewtrusts.org/~media/assets/2017/10/sfh_prison_health_care_costs_and_quality_final.pdf).

inmates” with DAAs in less than a year.<sup>60</sup> Officials at Wisconsin’s 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.”<sup>61</sup>

In Nevada, the State Board of Examiners recently approved \$1.59 million for the Nevada Department of Corrections (NDOC) to perform testing and treatment of incarcerated individuals with hepatitis C.<sup>62</sup> Thus far, testing has identified approximately 1,200 hepatitis C-positive incarcerated individuals in need of treatment.<sup>63</sup> Despite this budgetary increase, the NDOC refuses to comply with

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<sup>60</sup> 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/>.

<sup>61</sup> *Id.*

<sup>62</sup> Geoff Dornan, *\$1.6 Million Proposed to Treat Nevada Inmates with Hepatitis C*, Nevada Appeal (Apr. 15, 2020), <https://www.nevadaappeal.com/news/1-6-million-proposed-to-treat-nevada-inmates-with-hepatitis-c/>.

<sup>63</sup> State of Nevada Board of Examiners, *Meeting Minutes*, at 8 (Apr. 14, 2020) [http://budget.nv.gov/uploadedFiles/budgetnv.gov/content/Meetings/Board\\_of\\_Examiners/2020/05-12-2020\\_Agenda\\_Item\\_3\\_BOE\\_Meeting\\_04-14-2020-Minutes.pdf](http://budget.nv.gov/uploadedFiles/budgetnv.gov/content/Meetings/Board_of_Examiners/2020/05-12-2020_Agenda_Item_3_BOE_Meeting_04-14-2020-Minutes.pdf).

contemporary medical standards of care and continues to delay treatment entirely until its residents reach a more advanced stage of hepatic fibrosis.<sup>64</sup>

The effectiveness of DAAs led to a standard of care of near-universal treatment and caused a variety of organizations to update their policies and practices by 2017. Once a distant dream, elimination of the disease in our prisons—and in society as a whole—became an attainable reality.

### **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.”<sup>65</sup> Nevada Governor Steve Sisolak, upon approving funding for HCV testing and treatment in the state’s prison system, explained that inaction was not acceptable and would otherwise cause the disease to “spread widely through the prisons.”<sup>66</sup> Further,

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<sup>64</sup> *In re HCV Prison Litig.*, No. 3:19-cv-00577-MMD-CLB, 2020 WL 806170, at \*3 (D. Nev. Feb. 18, 2020).

<sup>65</sup> AASLD/IDSA, HCV Guidance, *HCV Testing and Treatment in Correctional Settings*, <https://www.hcvguidelines.org/unique-populations/correctional#:~:text=Prisons%20should%20implement%20opt%2Dout,surveillance%20for%20HCV%2Drelated%20complications> (last visited Oct. 12, 2020).

<sup>66</sup> State of Nevada Board of Examiners, *Meeting Minutes*, at 8 (Apr. 14, 2020) [http://budget.nv.gov/uploadedFiles/budgetnv.gov/content/Meetings/Board\\_of\\_Exa](http://budget.nv.gov/uploadedFiles/budgetnv.gov/content/Meetings/Board_of_Exa)

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.<sup>67</sup>

In one significant meta-study, researchers synthesized the results of published cost-effectiveness studies of HCV treatment in the era of DAAs.<sup>68</sup> 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, 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.”<sup>69</sup>

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miners/2020/05-12-2020\_Agenda\_Item\_3\_BOE\_Meeting\_04-14-2020-Minutes.pdf.

<sup>67</sup> Josiah D. 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”).

<sup>68</sup> 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](https://www.cghjournal.org/article/S1542-3565(16)30673-5/fulltext).

<sup>69</sup> *Id.* at 836.

Other research accords. One 2017 study concluded that “treating all HCV-infected individuals is cost saving and net social benefits are over \$500 billion greater compared with limiting treatment.”<sup>70</sup> “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.”<sup>71</sup> 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.<sup>72</sup> The study found that expanded screening and treatment in prisons would also 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.<sup>73</sup>

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<sup>70</sup> 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>.

<sup>71</sup> *Id.*

<sup>72</sup> 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>.

<sup>73</sup> *Id.* at 5–6.

According to a 2014 essay in the *New England Journal of Medicine* by researchers at Brown University, UC San Francisco, and UC Riverdale, expanded HCV treatment in prisons will allow society “to efficiently identify and cure the greatest number of HCV-infected people.”<sup>74</sup> Screening in prisons could prevent 4,200 to 11,700 liver-related deaths, 300 to 900 liver transplants, 3,000 to 8,600 cases of liver cancer, and 2,600 to 7,300 cases of cirrhosis in the next 30 years.<sup>75</sup> Notably, among liver-related deaths averted by treatment, “80% would have occurred in the outside community.”<sup>76</sup>

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.”<sup>77</sup>

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<sup>74</sup> 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>.

<sup>75</sup> Tianhua He, et al., *Prevention of Hepatitis C by Screening and Treatment in United States Prisons*, *Annals Internal Med.* at 7 (Jan. 19, 2016), <http://www.natap.org/2015/HCV/AIME201601190-M150617.pdf>.

<sup>76</sup> *Id.*

<sup>77</sup> M. Christopher Roebuck & Joshua Liberman, *Assessing the Burden of Illness of Chronic Hepatitis C and the Impact of Direct-acting Antiviral Use on Healthcare*

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.<sup>78</sup> 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.<sup>79</sup> 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 the favorable rates.<sup>80</sup>

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*Costs in Medicaid*, Am. J. 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-medicare?p=1>.

<sup>78</sup> 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>.

<sup>79</sup> *Id.*

<sup>80</sup> 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

Rather than alleviate the hepatitis C epidemic, Defendant's 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.

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approached them with a partnership that would allow for favorable DAA drug rates).



## CONCLUSION

For the foregoing reasons, the District Court's order granting Defendant's Motion for Summary Judgment should be reversed.

Dated: October 15, 2020

Respectfully submitted,

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