

No. 19-4060

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

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JEFFREY D. MANN, et al.,

Plaintiffs-Appellants,

v.

OHIO DEPARTMENT OF REHABILITATION & CORRECTIONS, et al.,

Defendants-Appellees.

On Appeal from the United States District Court for the Southern District of Ohio,  
No. 2:18-cv-01565, The Honorable George C. Smith, U.S. District Judge

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**BRIEF OF DRS. JOSEPH BICK, JOSEPH GOLDENSON, ROBERT B.  
GREIFINGER, 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 APPELLANTS**

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## **CORPORATE DISCLOSURE STATEMENT**

Pursuant to Fed. R. App. P. 26.1 and Circuit Rule 26.1(a), 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 other corporation, and no publicly held corporation owns ten percent or more of each organization's stock.

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<sup>1</sup> Pursuant to Fed. R. App. P. 29(a)(4), all parties have consented to this brief's filing. 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.

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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) was established in 2019 as a special interest group for INHSU members, with a focus on the prison setting. INHSU Prisons aims to

connect healthcare providers, policy makers, health administrations, academics, and advocates from across the world to participate in scientific knowledge exchange and knowledge translation, and to advocate for health, including hepatitis C (HCV) prevention and care among people who use drugs and are incarcerated.

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

### **BACKGROUND AND SUMMARY OF ARGUMENT**

This appeal is one of the growing number of actions to argue that categorical denial of treatment to prisoners with chronic hepatitis C on the basis of an institutional policy violates the Eighth Amendment.<sup>2</sup> It is one of the first to reach a court of appeals on the merits.

The increase in such cases is not a coincidence—rather, it is the direct result of revolutionary advances in the treatment of the hepatitis C virus (HCV). The

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<sup>2</sup> See *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, 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-LJO-EPG (E.D. Cal. filed Jan. 2, 2019).

discovery of easy-to-use and remarkably effective direct acting antiviral (DAA) drugs 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 DAA drugs 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. Where, as here, an outmoded treatment policy persists despite these advances, parties have challenged that outdated policy through litigation.

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

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<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 Jan. 27, 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 Jan. 27, 2020).

<sup>4</sup> Healthline, *Interferons for Hepatitis C: Understanding the Long-term Side Effects*, <https://www.healthline.com/health/hepatitis-c/interferons-long-term-effects> (last visited Jan. 27, 2020).



Beginning in 2011 with the introduction of the first DAA drugs, HCV treatment improved radically. Gone are the varied responses; the new regimen yields a Sustained Virologic Response (SVR) rate 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 agencies' HCV treatment policies fail to reflect this standard, often out of cost concerns. However, cost is an improper consideration in the Eighth Amendment context,<sup>7</sup> and it can be reduced through negotiated pricing. This Court should consider that dissymmetry—between the standard of care and the treatment

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<sup>5</sup> Jennifer L. Horsley-Silva & Hugo E. Vargas, *New Therapies for Hepatitis C Infection*, Gastroenterology & Hepatology, Millennium Med. Pub., <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5390323/> (last visited Jan. 27, 2020). SVR refers to a test result indicating that the Hepatitis C virus is no longer detectable in the body at least 12 weeks following treatment; it is “tantamount to a virologic cure.” AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom> (last visited Jan. 27, 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 Jan. 27, 2020).

<sup>7</sup> If proven, such a rationale can constitute a constitutional violation on its own. See *Darrah v. Krisher*, 865 F.3d 361, 372 (6th Cir. 2017) (“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.”) (quoting *Blackmore v. Kalamazoo Cty.*, 390 F.3d 890, 899 (6th Cir. 2004)).

policies at issue—in determining whether the *pro se* complaint plausibly alleged an impermissible failure to treat.

Background on hepatitis C. Hepatitis C is an easily transmitted liver disease resulting from HCV infection, which has devastating effects on those who contract it. Estimates suggest that 2 to 3 million people in the United States are living with this chronic disease, including nearly 85,000 *new* cases in Ohio reported between 2014 and 2018.<sup>8</sup> For every 100 persons newly infected with HCV, approximately 75 to 85 will develop chronic hepatitis C, a long-term illness that can lead to deadly liver problems.<sup>9</sup> For instance, of those same 100 people, 10 to 20 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>10</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>11</sup>

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

<sup>9</sup> CDC, *Hepatitis C FAQs for the Public*, <https://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last visited Jan. 27, 2020).

<sup>10</sup> *Id.*

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

As it progresses, HCV causes severe liver damage, among the many effects that accompany a chronic inflammatory disease.<sup>12</sup> This progressive damage, called “fibrosis,” is most commonly measured using ascending fibrosis scores of F0 (no scarring) to F4 (advanced scarring, or cirrhosis of the liver).<sup>13</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 attack and diabetes.<sup>14</sup>

The Centers for Disease Control and Prevention (CDC) approximates that in 2016, HCV directly caused or contributed to 18,153 deaths in the United States, but believes that number to be an underestimate.<sup>15</sup> In May 2016, the CDC compared hepatitis C to 60 other nationally significant infectious diseases,

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<sup>12</sup> CDC, *Hepatitis C FAQs for the Public*, <https://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last visited Jan. 27, 2020).

<sup>13</sup> See, e.g., AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom> (last visited Jan. 27, 2020).

<sup>14</sup> See Francesco Negro & Gamal Esmat, *Extrahepatic Manifestations in Hepatitis C Virus Infection*, 8 J. of Advanced Res. 85–87 (2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5272942/>; Krystian Ślusarz, et al., *Infection with Hepatitis C Virus as a Cause of Nervous System Disorders*, 9 J. of Educ., Health & Sport 230–40 (2019), <http://www.ojs.ukw.edu.pl/index.php/johs/article/download/7016/8741>.

<sup>15</sup> CDC, *Hepatitis C FAQs for the Public*, <https://www.cdc.gov/hepatitis/hcv/cfaq.htm> (last visited Jan. 27, 2020). See also CDC, *Hepatitis C Prevalence Estimates 2013-2016* (Nov. 6, 2018), <https://www.cdc.gov/nchhstp/newsroom/2018/hepatitis-c-prevalence-estimates.html>.

including HIV, tuberculosis, and pneumococcal disease, and found that HCV killed more Americans than the 60 others combined.<sup>16</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>17</sup> Less than 1% of the U.S. population is incarcerated today, but 30% of all people in the United States with HCV are in prison.<sup>18</sup> HCV also disproportionately impacts African Americans, who comprise approximately 11% of the U.S. population but 25% of those with chronic hepatitis C.<sup>19</sup> As early as 2012, the Surgeon General referred to viral hepatitis as a “silent epidemic.”<sup>20</sup>

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

<sup>17</sup> AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings*, <https://www.hcvguidelines.org/unique-populations/correctional> (last visited Jan. 27, 2020).

<sup>18</sup> Aiden K. Varen, et al., *Hepatitis C Seroprevalence Among Prison Inmates Since 2001: Still High But Declining*, Public Health Reports, at 187–95 (2014), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3904899/>. See also AASLD/IDSA, HCV Guidance, *Testing and Treatment in Correctional Settings*, <https://www.hcvguidelines.org/unique-populations/correctional> (last visited Jan. 27, 2020).

<sup>19</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>.

<sup>20</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 Jan. 27, 2020).

## ARGUMENT

### I. THE INTRODUCTION OF DAA DRUGS REVOLUTIONIZED HCV TREATMENT

Prior to 2011, interferon-based treatment for HCV required a series of “grueling shots” and “pills that gave patients flu-like symptoms.”<sup>21</sup> These side effects, coupled with a prolonged course of treatment and a cure rate of only 40% to 50%, posed significant problems.<sup>22</sup> Indeed, whether to provide interferon treatment was a debated question of medical judgment.<sup>23</sup>

This all changed around 2011, when the FDA began approving a series of DAA drugs.<sup>24</sup> Later, in 2013, the FDA’s approval of sofosbuvir (brand name Sovaldi®) marked the “advent of interferon-free treatments for hepatitis C” and “a

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<sup>21</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>22</sup> FDA, *Hepatitis C Treatments Give Patients More Options*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm> (last visited Jan. 27, 2020).

<sup>23</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) (“[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.”).

<sup>24</sup> Ayman Gedday, et al., *Direct Acting Anti-hepatitis C Virus Drugs: Clinical Pharmacology and Future Direction*, 5 J. of Transnat’l Int’l Med. 8, 8–9 (Mar. 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5490957/pdf/jtim-05-008.pdf>.

landmark shift” in the treatment of the disease.<sup>25</sup> Since December 2013, the FDA has approved additional DAA drugs to treat hepatitis C.<sup>26</sup> The FDA has called these advances in HCV treatment “transformative”<sup>27</sup> and “breakthrough therapies.”<sup>28</sup> New DAA drugs “have double the viral cure rates—90% to 100%—in just [ ] 12 weeks’ time.”<sup>29</sup> In fact, medical experts have identified the development of DAA drugs used to treat HCV as one of the “biomedical breakthroughs” of the past decade, which “[f]rom a combined economic and public-health standpoint . . . may outstrip just about anything else” in the past ten years.<sup>30</sup>

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<sup>25</sup> Richard Knox, *Treatments: FDA Expected To Approve New, Gentler Cure for Hepatitis C*, NPR (Dec. 5, 2013), <https://www.npr.org/sections/health-shots/2013/12/05/248934833/fda-set-to-approve-hepatitis-drug>.

<sup>26</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 Jan. 27, 2020).

<sup>27</sup> FDA, *Hepatitis C Treatments Give Patients More Options*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm> (last visited Jan. 27, 2020).

<sup>28</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>29</sup> FDA, *Hepatitis C Treatments Give Patients More Options*, <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm405642.htm> (last visited Jan. 27, 2020).

<sup>30</sup> See, e.g., 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 IS THAT NEARLY ALL CHRONIC HCV PATIENTS SHOULD BE TREATED

Because of the effectiveness of DAA drugs, the standard of care is that virtually all patients with chronic hepatitis C should be treated. This standard is articulated by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) in published treatment guidelines. AASLD has over 5,000 members, including physicians, scientists, medical students, residents, and other healthcare professionals who work in hepatology and related areas.<sup>31</sup> IDSA comprises over 12,000 physicians, scientists, and health experts who specialize in infectious diseases.<sup>32</sup> The AASLD/IDSA guidelines are developed and maintained by a panel of HCV experts.<sup>33</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,

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

<sup>31</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>32</sup> IDSA, *Mission & Values*, <https://www.idsociety.org/about-idsa/mission-values/> (last visited Jan. 27, 2020).

<sup>33</sup> AASLD/IDSA, HCV Guidance, *Methods*, <https://www.hcvguidelines.org/contents/methods> (last visited Jan. 27, 2020).

expert-developed recommendations for hepatitis C management.”<sup>34</sup> The guidelines are a “credible source of unbiased guidance on how best to treat [healthcare practitioners’] patients with HCV infection.”<sup>35</sup>

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.”<sup>36</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>37</sup> 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.”<sup>38</sup> With regard to testing for the presence of HCV

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<sup>34</sup> CDC, *Hepatitis C FAQs for Health Professionals*, <https://www.cdc.gov/hepatitis/hcv/hcvfaq.htm> (last visited Jan. 27, 2020).

<sup>35</sup> AASLD/IDSA, HCV Guidance, *About the Guidance*, <https://www.hcvguidelines.org/about> (last visited Jan. 27, 2020).

<sup>36</sup> AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom> (last visited Jan. 27, 2020) (emphasis added).

<sup>37</sup> *Id.*

<sup>38</sup> *Id.* (emphasis added).



infection, the AASLD/IDSA guidelines recommend periodic testing of “persons with ongoing risk factors for HCV exposure,” including incarceration.<sup>39</sup>

By contrast, institutional treatment guidelines, such as those at issue here, may 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 no longer appropriate to rely upon fibrosis scores to determine who should and should not be treated. In particular, the guidelines indicate that treating patients at early stages of the disease is beneficial, noting that “[i]nitiating therapy in patients with lower-stage fibrosis augments the benefits of SVR” and that “[t]reatment delay may decrease the benefit of SVR.”<sup>40</sup> Initiating treatment early is also important because “[f]ibrosis progression is variable across different patient

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<sup>39</sup> See AASLD/IDSA, HCV Guidance, *HCV Testing and Linkage to Care*, <https://www.hcvguidelines.org/evaluate/testing-and-linkage> (last visited Jan. 27, 2020).

<sup>40</sup> AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom> (last visited Jan. 27, 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 Jan. 27, 2020).

populations as well as within the same individual over time.”<sup>41</sup> Relatedly, “[m]any of the components that determine fibrosis progression and development of cirrhosis in an individual are unknown.”<sup>42</sup> And, it is clear that individuals who have been cured of chronic hepatitis C can no longer transmit the virus to others.<sup>43</sup> As such, 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.<sup>44</sup> Courts across the country have recognized this standard of care.<sup>45</sup>

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<sup>41</sup> AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom> (last visited Jan. 27, 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 . . . liver 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> *Id.*

<sup>43</sup> Behzad Hajarizadeh, et al., *Hepatitis C Treatment as Prevention: Evidence, Feasibility, and Challenges*, 1 *Lancet Gastroenterology & Hepatology* P317-27 (2016), [https://www.thelancet.com/journals/langas/article/PIIS2468-1253\(16\)30075-9/fulltext](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. Mo. Dep’t of Corr.*, 910 F.3d 1030, 1034 (8th Cir. 2018) (“The medical standard of care put forward by organizations such as the Infectious Diseases Society of America and the American Association for the Study of Liver

Healthcare coverage, policies, and practices also reflect this shift in available medicines and recognize 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 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.<sup>46</sup>

Several state Medicaid programs have removed barriers to treatment in the wake of this guidance. Significantly, the state whose very regulations are at issue

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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.”).

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

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.<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 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

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<sup>47</sup> 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](https://www.healthpolicynews.org/daily_review/2018/11/ohio-medicaid-to-pay-for-earlier-hepatitis-c-treatment.html).

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

Medical Assistance revoked categorical coverage exclusions, which restricted treatment 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> In January 2019, Iowa, known as one of the most restrictive states in terms of treating hepatitis C,<sup>52</sup> expanded its Medicaid care to include patients with moderate scarring (a fibrosis score of F2)—a change from its previous policy of restricting

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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-medicaid-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.*

<sup>52</sup> In a 2017 nationwide analysis conducted by the Center for Health Law and Policy Innovation at Harvard Law School and the National Viral Hepatitis Roundtable, Iowa received a grade of ‘D’ in its “State of Medicaid Hepatitis C Treatment Access.” The report noted that with Iowa’s “severe restrictions,” “very few people with hepatitis C have access to treatment.” *Hepatitis C: State of Medicaid Access Report Card* (2017), [https://stateofhepc.org/wp-content/themes/infinite-child/reports/HCV\\_Report\\_Iowa.pdf](https://stateofhepc.org/wp-content/themes/infinite-child/reports/HCV_Report_Iowa.pdf).

care to those with advanced liver scarring (scores of F3 or above).<sup>53</sup> In February 2019, Indiana Medicaid reached an agreement in federal court to remove all restrictions based on the severity of the disease so that patients could receive treatment or reimbursement for DAAs sooner.<sup>54</sup> Similarly, in April 2019, the U.S. District Court for the District of Kansas approved a class settlement removing all fibrosis score restrictions from the Kansas Medicaid coverage policy for HCV.<sup>55</sup>

Taken as a whole, there is an unmistakable trend in the removal of illegal coverage restrictions on DAA treatment in state Medicaid programs. The National Viral Hepatitis Roundtable study of this trend reveals that, in the past five years, such restrictions have been removed in more than 30 states through voluntary cessation, policy reform, and litigation.<sup>56</sup>

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<sup>53</sup> Iowa Dep't of Human Servs., *Informational Letter No. 966-MC-FFS* (Nov. 28, 2018), [https://dhs.iowa.gov/sites/default/files/1966-MC-FFS\\_IowaMedicaidPharmacyProgramChanges.pdf?122020190757](https://dhs.iowa.gov/sites/default/files/1966-MC-FFS_IowaMedicaidPharmacyProgramChanges.pdf?122020190757).

<sup>54</sup> 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>.

<sup>55</sup> 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)).

<sup>56</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 Jan. 27, 2020).

International Standards. The World Health Organization (WHO) recommends treating all persons with chronic hepatitis C over the age of 12 with DAAs, “irrespective of disease stage.”<sup>57</sup> WHO reported that “[e]xpanding treatment to the general population is cost-effective” and cited Egypt as an example.<sup>58</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 DAA drugs and treated nearly 1 million hepatitis C patients in two years.<sup>59</sup> One study found that the use of DAAs in Egypt led to HCV viral suppression in nearly all treated patients,<sup>60</sup> and experts say Egypt could serve as the model for the rest of the world.<sup>61</sup> Further, the European Association for the Study of the Liver (EASL) recommends that all patients with HCV be

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<sup>57</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>58</sup> *Id.* at 19.

<sup>59</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>60</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), <http://journals.plos.org/plosone/article?id=10.1371/journal.pone.0184654> (finding an overall sustained virologic response rate of 97.1%).

<sup>61</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>.

treated, and the Canadian Association for the Study of Liver likewise indicates that there is no medical justification to place restrictions on treatment.<sup>62</sup>

Prisons. A similar trend is occurring across the country as state corrections departments face judicial scrutiny under the Eighth Amendment over their HCV treatment policies.<sup>63</sup> 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>64</sup> New York has treated more than 600 inmates with DAAs.<sup>65</sup> In May 2017, “[b]ecause of advances in medicine,” Wisconsin treated “more than 200 inmates” with DAAs in less than a year.<sup>66</sup> Officials at Wisconsin’s Department of

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<sup>62</sup> See EASL, *EASL Recommendations on Treatment of Hepatitis C 2018*, J. of Hepatology 1, 6 (2018), <https://easl.eu/wp-content/uploads/2018/10/HepC-English-report.pdf>; Hemant Shah, et al., *The Management of Chronic Hepatitis C: 2018 Guideline Update from the Canadian Association for the Study of the Liver*, 190 CMAJ E677, E679 (2018), <https://www.cmaj.ca/content/190/22/E677>.

<sup>63</sup> Many of these decisions are cited in the Appellants’ brief for the purpose of identifying holdings on particular questions of law. See, e.g., Appellants’ Br. at 24.

<sup>64</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).

<sup>65</sup> 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>.

<sup>66</sup> Keegan Kyle, *Wisconsin Prisons Spend \$10M Treating Hepatitis C*, Post Crescent (May 25, 2017), <http://www.postcrescent.com/story/news/>



Corrections indicated that the state increased the number of inmates 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>67</sup> And in California, the state’s 2018 budget allotted \$176 million to treat all of its inmates with hepatitis C over a three-year period.<sup>68</sup>

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

### **III. EXPANDED TREATMENT YIELDS ENORMOUS BENEFITS**

Although cost is the primary justification cited by prisons that deprive their HCV-infected inmates of DAA drugs, the benefits far outweigh the expense for society at large. As the AASLD/IDSA guidelines note, “[t]reating inmates ultimately benefits public health because they can no longer transmit the virus to

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investigations/2017/05/25/wisconsin-prisons-spend-10m-treating-hepatitis-c/99007788/.

<sup>67</sup> *Id.*

<sup>68</sup> 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>.

others.”<sup>69</sup> Further, because of the high concentration of HCV-infected Americans living in prisons, researchers have recognized the substantial public health opportunity these institutions present for eradicating the disease.<sup>70</sup>

In one significant meta-study, researchers synthesized the results of published cost-effectiveness studies of HCV treatment in the era of DAAs.<sup>71</sup> The results were striking. Using a range of 2017 cost assumptions, the study provided evidence not just that use of DAAs in both cirrhotic and pre-cirrhotic patients was 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>72</sup>

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<sup>69</sup> AASLD/IDSA, HCV Guidance, *When and in Whom to Initiate HCV Therapy*, <https://www.hcvguidelines.org/evaluate/when-whom> (last visited Jan. 27, 2020).

<sup>70</sup> Josiah D. Rich, et al., *Responding to Hepatitis C through the Criminal Justice System*, 370 N. Engl. J. Med. 20, 1872–74 (May 15, 2014), <http://www.natap.org/2014/HCV/nejmp1311941.pdf>, (stating that prisons “may be the best place to efficiently identify and cure the greatest number of HCV-infected people”).

<sup>71</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>72</sup> *Id.*

Other research accords. A 2017 study found that “treating all HCV-infected individuals is cost saving and net social benefits are over \$500 billion greater compared with limiting treatment.”<sup>73</sup> “Increased access to treatment . . . 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>74</sup>

A 2016 study by researchers from Harvard Medical School, the University of Pittsburgh, Emory University, and Georgia Tech found that expanded screening and treatment in prisons for 10 years would prevent 12,700 new HCV infections over the next 30 years, 89% to 92% of which would have occurred in the outside community.<sup>75</sup> It would also 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 over 30 years.<sup>76</sup> Notably, among liver-related deaths averted by treatment, 80% would have occurred outside prisons.<sup>77</sup> Expanded screening and treatment in prisons would also reduce the costs attributable to HCV by \$760

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<sup>73</sup> Gigi A. Moreno, et al., *Value of Comprehensive HCV Treatment among Vulnerable, High-risk Populations*, 20 Elsevier 736, 738 (2017), <https://www.sciencedirect.com/science/article/pii/S1098301517300852>.

<sup>74</sup> *Id.*

<sup>75</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>76</sup> *Id.*

<sup>77</sup> *Id.*

million over 30 years—with approximately 84% of the cost savings realized by the outside community— “an even better value for [society’s] money.”<sup>78</sup>

What’s more, the cost of DAAs has declined substantially since their introduction. A 2019 healthcare study noted that “DAAs were initially more expensive than older treatment options; however, these costs have declined substantially over time with increased competition. . . . [L]ist prices for DAAs themselves have declined drastically, from nearly \$100,000 per treatment course in 2014 to as low as \$24,000 per treatment course [in 2019].”<sup>79</sup>

Negotiated prices are even lower. For instance, in 2019, the state of Louisiana negotiated an agreement with Gilead Sciences’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 supplied.<sup>80</sup> Louisiana’s goal is to treat 80% of its Medicaid and correctional populations that have hepatitis C

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<sup>78</sup> *Id.* at 5–6.

<sup>79</sup> M. Christopher Roebuck & Joshua N. Liberman, *Assessing the Burden of Illness of Chronic Hepatitis C and the Impact of Direct-acting Antiviral Use on Healthcare Costs in Medicaid*, *Am. J. of Managed Care* (June 18, 2019), <https://www.ajmc.com/journals/supplement/2019/burden-chronic-hepatitis-c/assessing-burden-illness-chronic-hepatitis-impact-antiviral-healthcare-costs-medicaid?p=1>.

<sup>80</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>.

by 2024, which would result in a cost per patient of less than \$10,000.<sup>81</sup> In addition, federal programs may help to expand access to DAA drugs. A current federal program, for example, allows eligible institutions 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>82</sup>

Rather than alleviate the hepatitis C epidemic, Appellees' systemic, arbitrary failure to treat HCV-infected inmates 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. 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 poorer, sicker public outside of them.

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<sup>81</sup> *Id.*

<sup>82</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 provider who “approached Vanderbilt University Medical Center about a partnership that would allow [the state] to receive favorable rates [for DAAs under the federal program]”).

## CONCLUSION

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

Dated: January 29, 2020

Respectfully submitted,

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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 5,265 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 January 29, 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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