March 4, 2016

The Hon. Ron Wyden
The Hon. Charles Grassley
Committee on Finance
United States Senate
219 Dirksen Senate Office Building
Washington, DC 20510-6200

Dear Senators Wyden and Grassley:

The National Health Law Program ("NHeLP") is a public interest law firm working to advance access to quality health care and protect the legal rights of low-income and underserved people. NHeLP protects and advances the health rights of low income and underserved individuals. The oldest non-profit of its kind, NHeLP advocates, educates and litigates at the federal and state level. In this role, NHeLP provides technical support to direct legal services programs, community-based organizations, the private bar, providers and individuals who work to ensure access to health care services for low-income people. In this role, we are working with consumer advocates in over 20 states who are assisting Medicaid beneficiaries infected with hepatitis C to access the new breakthrough treatments for the disease. In almost all states, the very high costs of these treatments result in Medicaid beneficiaries not getting the treatment they need to cure their hepatitis C. A study released last month found that at least 30% of Medicaid beneficiaries with hepatitis C who request a new breakthrough drug are denied access to treatment.[1]

We appreciate your leadership and the exemplary work of your staff in the 18 month investigation into Gilead and the pricing of breakthrough treatments for hepatitis C, including Sovaldi and Harvoni. This letter responds to your January 21, 2016 request for public comment on policy issues including the financial impact of high prices of breakthrough drugs, data on prescription drug costs, and ensuring patient access, particularly for low income and vulnerable populations.

[1] *See* Zobair M. Younossi *et al., Disparate Access to Treatment Regimens in Chronic Hepatitis C Patients*, 10 J. VIRAL HEPATITIS 12506 (2016).

(1) Drug company marketing of breakthrough drugs limits access for low-income people because of the drugs' high costs.

First and foremost, when new, breakthrough drugs become available, they create a potential to improve health outcomes for thousands of people. Unfortunately, as your report documents, this potential is entirely illusory when new drugs are priced so high that low-income Americans do not have real access to them. A June 2015 survey by the Kaiser Family Foundation found that 25% of those surveyed had declined to fill a prescription due to costs, and 18% of those surveyed had skipped doses or cut pills in half.[2] This country's recent experiences with Solvaldi and other breakthrough treatments for hepatitis C clearly illustrate that high drug prices are creating dangerous barriers to curative treatments for those who rely on Medicaid for their health coverage. As you are aware, the Centers for Medicare & Medicaid Services (CMS) issued guidance in November 2015, instructing states to lift draconian restrictions on access to the new direct-acting antiretroviral (DAA) treatments for hepatitis C.[3] However, state Medicaid programs persist in using unlawful restrictions to limit access to these breakthrough medications for *only because the cost of treatment is so high*.

Because of the high cost of the new drugs for hepatitis C, few Medicaid beneficiaries—who are by definition low-income—have the means to pay out-of-pocket for medications when their state Medicaid program will not cover treatment. Instead they are forced to live with a serious chronic and potentially deadly disease. Hepatitis C in all cases causes inflammation to the liver and other internal organs. In the early stages of the disease, individuals infected with hepatitis C may experience no symptoms or may experience generalized symptoms fatigue, nausea, suppressed appetite, or muscle and joint pain.[4] As the disease progresses, however, the symptoms become more serious and can include secondary infections, organ damage, brain damage, liver cancer, and death.[5] In addition, hepatitis C can cause infected individuals to contract other diseases, including cryoglobulinemia (a condition that causes damage to the blood vessels), autoimmune diseases, central nervous system disorders, other cancers, and cardiomyopathy.[6] Moreover, since hepatitis C is a communicable disease, limiting

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[2] BIANCA DIJULIO *ET AL.,* KAISER HEALTH TRACKING POLL at fig. 5 (2015), http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-june-2015/.

[3] CMS, DSMDL No. 172 (2015), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

[4] *See, e.g.,* WORLD HEALTH ORGANIZATION, HEPATITIS C (2015), http://www.who.int/mediacentre/factsheets/fs164/en.

[5] Fasiha Kanwal & Bruce R. Bacon, *Does Treatment Alter the Natural History of HCV? in* CHRONIC HEPATITIS C VIRUS ADVANCES IN TREATMENT, PROMISE FOR THE FUTURE 103, 103 (Mitchell L. Shiffman, ed., 2011).

[6] Franco Dammacco & Domenico Sansonno, Review Article: Therapy for Hepatitis C Virus–Related Cryoglobulinemic Vasculitis, 365 NEW ENGLAND J. MED. 1035 (2013) (cryoglobulinemia), http://www.nejm.org/doi/full/10.1056/NEJMra1208642; Jian-Hua Xu *et al., Hepatitis B or C Viral Infection and Risk of Pancreatic Cancer: A Meta-Analysis of Observational Studies*, 19 WORLD J. GASTROENTEROLOGY 4234 (2013) (pancreatic cancer), http://www.wjgnet.com/1007-9327/full/v19/i26/4234.htm; Salvatore Monaco *et al., HCV-Related*

treatment has the effect of exacerbating and prolonging a public health crisis, as those who are denied treatment may pass on the infection to others.

Consider Sarah Jackson, an Indiana Medicaid beneficiary who has been denied treatment by the Medicaid program. Treatment is being denied because her hepatitis C has not yet progressed to an advanced stage, and she is neither co-infected with HIV or post-liver transplant.[7] Nevertheless, Ms. Jackson requires treatment to prevent her hepatitis C infection from progressing and causing her serious pain, liver damage, and other life threatening consequences.[8] In addition, as a recently postpartum mother, Ms. Jackson requires treatment to ensure that she does not pass hepatitis C on to her child via breastfeeding.[9] Because Indiana Medicaid restricts access to treatment for hepatitis C to Ms. Jackson and thousands of others, solely due to the high cost of these treatments, Indiana Medicaid beneficiaries are deprived of desperately needed curative treatment for their hepatitis C.

In Pennsylvania, Dara Dundon was diagnosed with hepatitis C in 2005.[10] In her case, the infection was traced back to a tattoo she received years ago.[11] She has lived with the symptoms of the infection for years, including fatigue and flu-like symptoms.[12] She was eager to have a chance at a cure when the new breakthrough medications were approved in late 2013.[13] But though her doctor has requested treatment for her hepatitis C from Medicaid four times, the request is denied each time because Dara's hepatitis C has not yet progressed to stage 3.[14] Pennsylvania Medicaid will require Dara to continue living with debilitating symptoms—perhaps for years—before it will provide her with curative treatment.

In Delaware, Adam Suib is a 24-year-old Medicaid beneficiary who stopped using drugs in 2014, after using for over ten years.[15] He was diagnosed with hepatitis C in 2011,

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Nervous System Disorders, 2012 CLINICAL & DEVELOPMENTAL IMMUNOLOGY 236148 (2012) (autoimmune diseases), http://www.hindawi.com/journals/jir/2012/236148; Huaibin M. Ko *et al., Morphologic features of Extrahepatic Manifestations of Hepatitis C Virus Infection*, 2012 CLINICAL & DEVELOPMENTAL IMMUNOLOGY 740138 (2012) (multiple), http://www.hindawi.com/journals/jir/2012/740138.

[7] C*omplaint* at ¶ 29*,* Jackson v. Secretary, No. 1:15-cv-01874 (S.D. Ind. Nov. 25, 2015).

[8] See *id.* at ¶ 30.

[9] See *id.* at ¶ 31.

[10] Ryan Loughlin & Joie Chen, *For many Medicaid Patients, Hepatitis C wonder Drugs are Out of Reach*, ALJEEZERA AMERICA, Dec. 10, 2015, http://america.aljazeera.com/watch/shows/america-tonight/articles/2015/12/10/for-many-medicaid-patients-hepatitis-c-wonder-drugs-are-out-of-reach.html.

[11] *Id.*

[12] *Id.*

[13] *Id.*

[14] *Id.*

[15] Jen Rini, *Hepatitis C: Delaware's Hidden Epidemic*, NEWS JOURNAL, Aug. 21, 2015, http://www.delawareonline.com/story/news/health/2015/08/21/delawares-hidden-epidemic/32147655/.

which he contracted by sharing needles while he was using heroin.[16] While Adam is very motivated to seek treatment for his hepatitis C, as his liver is already quite damaged from the disease, he has reason to be worried that Medicaid will refuse to cover his treatment. Delaware only treats beneficiaries who are at the most advanced hepatitis C—stage 4.[17] Adam may have to wait until his liver decompensates to the point of cirrhosis before Delaware Medicaid will provide him with curative treatment.

These stories are only illustrative of those coming into the National Health Law Program. All around the country, Medicaid beneficiaries are suffering the symptoms associated with hepatitis C and are being denied access to a cure only because the treatments available to rid them of the infection are expensive. At the same time that states have restricted access to treatment in their Medicaid programs, Gilead—which manufacturers the two most popular hepatitis C treatments, Solvaldi and Harvoni—has eliminated access to its patient assistance programs for individuals with Medicaid coverage.[18] While states and drug companies jockey over costs, it is the patients who left to sink to the bottom, unable to access life-saving, curative treatment for a serious and communicable disease.

(2) & (3) Drug companies need to be more accountable to patients and payers.

Your report clearly details that Gilead failed to appropriately account for the impact of the high price it charges for Solvaldi and Harvoni—especially on low-income patients.[19] Gilead instead engaged in a sophisticated marketing campaign to convince doctors and patients that its drugs represented value for price.[20] Unfortunately, Gilead's actions are not unique—nor are they limited to new, breakthrough medications. Other drug companies, too, have recently taken action to use life-saving drugs as way to maximize profits for their companies, without regard for the impact on patients and payers.[21] One

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[16] *Id.*
[17] *See id.*
[18] *See* Ed Silverman, Gilead Limits Enrollment in its Hep C Patient Program to Pressure Insurers, WALL STREET J. PHARMALOT BLOG, Jul. 16, 2015, http://blogs.wsj.com/pharmalot/2015/07/16/gilead-limits-enrollment-in-its-hep-c-patient-program-to-pressure-insurers/.
[19] PETER T. GARTRELL *ET AL.*, SENATE FINANCE COMMITTEE, THE PRICE OF SOVALDI AND ITS IMPACT ON THE U.S. HEALTH CARE SYSTEM 99-100 (2015), http://www.finance.senate.gov/ranking-members-news/wyden-grassley-sovaldi-investigation-finds-revenue-driven-pricing-strategy-behind-84-000-hepatitis-drug.
[20] *Id.* at 69-76.
[21] *See, e.g.,* Memorandum from Democratic Comm. Staff, U.S. House Reps. Comm. Oversight & Govt. Reform, to Democratic Members. Of the Full Comm. (Feb. 2, 1016) [hereinafter Turing memo] (detailing tactics used by Turing Pharmaceutics to inflate drug prices), http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Turing%20Documents.pdf; Memorandum from Democratic Comm. Staff, U.S. House Reps. Comm. Oversight & Govt. Reform, to Democratic Members. Of the Full Comm. (Feb. 2, 1016) [hereinafter Valeant memo] (detailing tactics used by Valeant Pharmaceutics to inflate drug prices), http://democrats.oversight.house.gov/sites/democrats.oversight.house.gov/files/documents/Memo%20on%20Valeant%20Documents0.pdf.

recent study found that, in 2015, drug prices for 60 of the most common drugs doubled, and prices quadrupled for 20 of those drugs.[22] Another study noted that "U.S. prescription drug spending increased 13.1% in 2014 – the largest annual increase since 2003 – and this was largely driven by an unprecedented 30.9% increase in spending on specialty medications."[23] While a significant proportion of the cost increase in 2014 can be attributed to the approval of new treatments for hepatitis C, high prices associated with other specialty drugs also caused this enormous increase in spending.[24]

Yet as drug prices soar, patients and payers have few tools at their disposal to evaluate whether the cost of drugs is appropriate. Moreover, the patent system that grants pharmaceutical companies a monopoly on new drugs for years at a time means that, especially with respect to new drugs, patients and payers have little power to negotiate on price, and drug companies face little competition that would provide an incentive to price their drugs based on their value.[25] The data state Medicaid programs provided to your staff confirm that Medicaid programs are spending millions on the new treatments for hepatitis C.[26] But at the same time, in other countries, Gilead has sold Solvaldi and Harvoni at a fraction of the price charged to U.S. Medicaid programs; the price of a course of treatment in Egypt is just over 10% of the cost in the U.S.[27]

While problems with transparency are by far most egregious where drug companies are concerned, state Medicaid programs could do better. NHeLP urges the committee to request additional data from states showing the hepatitis C rates among enrollees by Medicaid eligibility category. Such data would be useful in revealing the actual financial impact on the expenditure of state dollars for hepatitis C treatments. The Affordable Care Act created a new eligibility category for low income adults, with 100% of the costs of services paid for by the federal government through the end of 2016, and gradually reducing to 90% by 2020.[28] To date, 32 states and District of Columbia that have thus

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[22] Robert Langreth & Rebecca Spalding, *Shkreli Was Right: Everyone's Hiking Drug Prices*, BLOOMBERGBUSINESS, Feb. 2, 2016, http://www.bloomberg.com/news/articles/2016-02-02/shkreli-not-alone-in-drug-price-spikes-as-skin-gel-soars-1-860.

[23] EXPRESS SCRIPTS, THE 2014 DRUG TREND REPORT EXECUTIVE SUMMARY 2 (2015), http://lab.express-scripts.com/lab/drug-trend-report.

[24] *Id.*

[25] *See, e.g.,* CONSUMERS UNION, RX COSTS: A PRIMER FOR HEALTH CARE ADVOCATES 5 (2015) ("Average profits for brand-name pharmaceutical companies is 18.4 percent compared to 5.6 percent for generics.") (citations omitted), http://www.healthcarevaluehub.org/files/2214/3508/0516/Research_Report_No._5_-_Drug_Cost_Primer.pdf; Turing memo, *supra* note 21; Valeant memo, *supra* note 21.

[26] *See generally* OFF. CHUCK GRASSLEY, DATA BEHIND THE SOVALDI REPORT: WYDEN-GRASSLEY INVESTIGATION LOOKS AT DRUG COSTS IN EVERY STATE MEDICAID PROGRAM (2015), http://www.grassley.senate.gov/news/news-releases/data-behind-sovaldi-report-wyden-grassley-investigation-looks-drug-costs-every.

[27] GARTRELL *ET AL.*, *supra* note 19, at 58-60.

[28] 42 U.S.C. § 1396d(y)(1); *see also* CMS, MEDICAID AND CHIP FAQS: NEWLY ELIGIBLE AND EXPANSION STATE FMAP (2013), https://www.medicaid.gov/State-Resource-Center/FAQ-Medicaid-and-CHIP-Affordable-Care-Act-Implementation/Downloads/FAQs-by-Topic-Expansion-State-FMAP-2013.pdf.

far implemented the ACA Medicaid expansion.[29] For those states that have expanded Medicaid, data on the infection rate by eligibility category may be particularly useful in determining whether a state's overly restrictive utilization criteria prevented newly eligible adults at earlier stages of hepatitis C infection from obtaining curative treatment. These persons may be required to delay treatment until later stages of disease progression when they qualify for Medicaid under a traditional disability category, which does not receive the enhanced federal match.

(4) Congress should consider strategies to lower the cost of hepatitis C prescription drugs and improve value transparency.

Congress should address the fiscal and health care crisis created by runaway prescription drug prices. Manufacturers of brand-name prescription drugs will receive more than $1.1 trillion in revenues from the sale of outpatient drugs to federal healthcare programs, including Medicare and Medicaid.[30] Drug companies also receive billions of additional dollars in federal funding through the research and development (R&D) tax credit.[31]

While there is no simple remedy for high cost prescription drugs, there are a number of policies and strategies to reduce the cost of prescription drugs that Congress should consider:

Federal prescription drug pricing for Medicaid

The District of Columbia is authorized to procure drugs through the Federal Supply Schedule (FSS), a pricing program enacted to enable federal purchasers to "obtain or beat the lowest prices negotiated for brand-name drugs between manufacturers and their most-favored commercial customers under comparable terms and conditions." The Department of Veterans Affairs (VA) negotiates FSS drug-related contracts. As of the mid-2000s, FSS prices for single-source brand-name drugs were on average 53% of the average wholesale price.[32] Extending FSS pricing to all state Medicaid programs could lower state and federal expenditures significantly.

Increasing Medicaid drug rebates and equity

The Medicaid Drug Rebate Program was established by Congress to require drug manufacturers to enter a national rebate agreement with the Secretary of Health and

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[29] *See* KAISER FAMILY FOUND., STATUS OF STATE ACTION ON THE MEDICAID EXPANSION DECISION, http://kff.org/health-reform/state-indicator/state-activity-around-expanding-medicaid-under-the-affordable-care-act/ (last visited Mar. 3, 2016).
[30] AVALERE HEALTH, FEDERAL SPENDING ON BRAND PHARMACEUTICALS (2015).
[31] NAT'L SCIENCE FOUND., FEDERAL RESEARCH AND EXPERIMENTATION TAX CREDIT CLAIMS, BY NAICS INDUSTRY: 1998–2008 (2012), http://www.nsf.gov/statistics/seind12/append/c4/at04-36.pdf.
[32] CONG. BUD. OFF., PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS, TABLE 1 AT 4 (2005), http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/64xx/doc6481/06-16-prescriptdrug.pdf.

Human Services in order to sell their drugs in state Medicaid programs.[33] Medicaid drug rebates totaled $16.7 billion in 2012.[34] Moreover, in addition to the federal rebate requirements, as of 2012 44 states and D.C. have also negotiated supplemental rebate agreements with certain drug manufacturers, so that they can receive further discounts on drug costs.[35] Currently, the amount of federal rebates is set by statute, and the amount of supplemental rebates is based entirely on what a state is able to negotiate with a given manufacturer. In neither case is the amount of the rebate connected to the value a drug provides to states or their Medicaid beneficiaries. Congress should amend the rebate provisions of the Medicaid Act to ensure that rebates reflect value—that is, when a drug manufacturer can demonstrate value for price, the amount of the rebate would be less, and where the manufacturer makes no such demonstration, the amount of the rebate would be more. Under this scenario, rebates for high-cost hepatitis C drugs should increase because, as your study suggests, while the drugs are highly effective at curing the disease, the cost may outpace the value the drug provides.[36]

There is also something inherently unfair about the heterogeneous rebate process from state-to-state and within states, among Medicaid managed care plans. Differences in negotiated contracts mean that Medicaid beneficiaries have widely disparate access to high cost drugs, including hepatits C treatment, depending on the state where they live and the health plan where they are enrolled (in many instances auto-enrolled into by the state). The pathway to curing a communicable disease should not depend on the luck of the state residency or health plan draw.

Using federal "march in" rights

Under 28 U.S.C. § 1498, the federal government may use or manufacture patented products without threat of injunction so long as it provides "reasonable and entire compensation to the patent holder."[37]

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[33] 42 U.S.C. § 1396r-8(a)(1).

[34] U.S. DEP'T HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GENERAL, MEDICAID REBATES FOR BRAND-NAME DRUGS EXCEEDED PART D REBATES BY A SUBSTANTIAL MARGIN 6 (2015), http://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf.

[35] U.S. DEP'T HEALTH & HUMAN SERVS. OFFICE OF INSPECTOR GENERAL, STATES' COLLECTION OF OFFSET AND SUPPLEMENTAL MEDICAID REBATES 8 (2014), http://oig.hhs.gov/oei/reports/oei-03-12-00520.pdf.

[36] *See* GARTRELL *ET AL.*, *supra* note 19, at 101; *see also, e.g.,* Harinder S. Chahal *et al., Cost-effectiveness of Early Treatment of Hepatitis C Virus Genotype 1 by Stage of Liver Fibrosis in a US Treatment-Naive Population*, 76 JAMA INTERN. MED. 65, 65 (2016) ("In this simulated model, treating HCV infection at early stages of fibrosis appeared to improve health outcomes and to be cost-effective but incurred substantial aggregate costs."); Benjamin P. Linas *et al.*, *The Cost-Effectiveness of Sofosbuvir-Based Regimens for Treatment of Hepatitis C Virus Genotype 2 or 3 Infection,* 162 ANN. INTERN MED. 619 (2015) (find Solvaldi cost-effective for some patients, but not others); Jagpreet Chhatwal *et al., Cost-Effectiveness and Budget Impact of Hepatitis C Virus Treatment With Sofosbuvir and Ledipasvir in the United States*, 162 ANN. INTERN MED. 397 (2015) ("Treatment of HCV is cost-effective in most patients, but additional resources and value-based patient prioritization are needed to manage patients with HCV.").

[37] 28 U.S.C. § 1498(a).

On several occasions, policymakers have raised the possibility of using § 1498 in the face of a public health crisis.[38] During the anthrax scare in 2001, the suggestion of using § 1498 helped secure 50% price reduction for Cipro®.[39]

Section 1498 requires that the federal government provide "reasonable and entire compensation." Courts have used three methods to determine the required compensation levels under § 1498: 1) reasonable royalty; 2) percentage of government cost savings; or 3) lost profits.[40] To calculate the level of royalties due, courts use a fifteen-factor analysis established in *Georgia-Pacific Corp. v. U.S. Plywood Corp*.[41] Even if a generous royalty rate were established—such as 50% of generic producer profits, a rate recently upheld in a drug patent infringement case—the overall cost to the government, and ultimately taxpayers, would still be relatively low compared to current prices for brand name drugs.[42]

Section 1498 could be utilized here to make curative treatment available to individuals with this progressive and communicable condition.

Increase R&D transparency

Pharmaceutical companies spend significantly more on marketing than on research and development.[43] Legislative proposals in several states require certain drug makers to report costs related to development, production, distribution and administrative costs for the prescription drugs.[44] These R&D transparency proposals generally seek annual reporting by pharmaceutical companies on the costs related to research, clinical trials, and the actual production costs for prescription drugs priced above $10,000 for a course of treatment.

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[38] *See, e.g.*, Aaron S. Kesselheim & Jerry Avorn, *Biomedical Patents and the Public's Health Is There a Role for Eminent Domain?*, 295 J. AM. MED. ASS'N 434, 435 (2006) (describing how the federal government considered using §1498 to import generic versions of CIPRO® in response to the anthrax scare in 2001); *Assessing the National Pandemic Flu Preparedness Plan: Hearing Before the H. Comm. on Energy and Commerce*, 109th Cong. 39 (2005) (statement of Michael Leavitt, Secretary, U.S. Department of Health and Human Services) (the Secretary answered that he would "do everything necessary" to acquire Tamiflu).

[39] Keith Bradshur, *Bayer Halves Price for Cipro, but Rivals Offer Drugs Free*, NY TIMES, Oct. 26, 2001, http://www.nytimes.com/2001/10/26/business/26CIPR.html?pagewanted=all.

[40] See *Decca Ltd. v. United States*, 640 F.2d 1156, 1167 (Ct. Cl. 1980); *Leesona Corp. v. United States*, 599 F.2d 958, 971 (Ct. Cl. 1979).

[41] 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified* 446 F.2d 295 (2d Cir. 1971); *see also Tektronix, Inc. v. United States*, 552 F.2d 343, 349 (Ct. Cl. 1977) *opinion modified on denial of reh'g*, 557 F.2d 265 (Ct. Cl. 1977).

[42] *AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1337 (Fed. Cir. 2015).

[43] CENTER FOR AMERICAN PROGRESS, ENOUGH IS ENOUGH – THE TIME HAS COME TO ADDRESS SKY-HIGH DRUG PRICES 22 (2015) (citing Richard Anderson, *Pharmaceutical Industry Gets High on Fat Profits*, BBC NEWS, Nov. 6, 2014, http://www.bbc.com/news/business-28212223).

[44] *See* e.g., AB 463, 2015 Reg. Sess. (Cal. 2015-16); S 1048, 189th Sess. (Mass. 2016); HB 839, 2015-2016 Reg. Sess. (N.C. 2015); HB 3486, 78th Leg. Assem. (OR 2015); HB 1042, 2015 Sess., (PA 2015).

While state legislative efforts to increase drug pricing transparency and accountability are important, they do not supplant the need for federal action to address skyrocketing drug prices.

(5) Congress should work with CMS to ensure that state Medicaid programs are providing appropriate access to high cost drugs.

All 50 states and the District of Columbia have opted to cover outpatient prescription drugs as part of their Medicaid benefit packages.[45] Under traditional fee-for-service (FFS) Medicaid, enrollees obtain medications from retail pharmacies, which then request reimbursement from the state for their acquisition and dispensing costs. States then seek quarterly rebates from manufacturers for an agreed upon percentage of the acquisition costs.[46]

Some state Medicaid programs refuse to meet minimum federal statutory requirements when providing outpatient prescription drug benefits and fail to comply with recent CMS guidance clarifying states' obligation under federal law. In November 2015, CMS released guidance to the states on Medicaid coverage of Solvaldi and other DAA treatments for hepatitis C.[47] CMS made clear that state policies that overly restrict access to these medications violate the Medicaid Act by imposing limitations on the amount, duration, and scope of treatment, inconsistent with clinical standards of care and by limiting treatment for hepatitis C more severely than treatments for other medical conditions.[48] Since releasing this guidance, however, we are not aware that CMS has taken any further action to review state Medicaid coverage policies for hepatitis C treatments or taken any enforcement action against a state whose coverage policy is out-of-compliance. Meanwhile, Medicaid beneficiaries with hepatitis C in Indiana and Washington have challenged their state Medicaid programs' policies.[49]

The committee found that at least 25 states limit treatment to beneficiaries whose hepatitis C has progressed to advanced stages.[50] As a result, beneficiaries must live with their hepatitis C and suffer increasingly poor health for months—if not years—before they can be cured. Medicaid programs that limit treatment to beneficiaries with advanced liver disease effectively force beneficiaries to endure pain and suffering and risk their health and life expectancy while waiting for an available cure.

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[45] 42 U.S.C. § 1396d(a)(12); CTRS. FOR MEDICARE & MEDICAID SERVS., PRESCRIPTION DRUGS, http://medicaid.gov/medicaid-chip-program-information/by-topics/benefits/prescription-drugs/prescription-drugs.html (last visited Feb. 25, 2016).

[46] CONG. BUDGET OFF., PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS 10 (2005), https://www.cbo.gov/sites/default/files/06-16-prescriptdrug.pdf.

[47] CMS, DSMDL No. 172 (2015), https://www.medicaid.gov/Medicaid-CHIP-Program-Information/By-Topics/Benefits/Prescription-Drugs/Downloads/Rx-Releases/State-Releases/state-rel-172.pdf.

[48] *See id.* at 3-4.

[49] *See* Complaint, Jackson v. Secretary, No. 1:15-cv-01874 (S.D. Ind. Nov. 25, 2015); Complaint, B.E. & A.R., No. 2:16-cv-227 (W.D. Wa. Feb. 16, 2016).

[50] GARTRELL *ET AL.*, *supra* note 19, at Appx. B Tables 1a, 2a.

At least 22 states will not provide treatment to beneficiaries who are using drugs or alcohol.[51] There is no evidence that substance use during DAA treatment impacts the efficacy of treatment.[52] Substance use can sometimes interfere with adherence to the treatment regimen but is not a per se contraindication to treatment. Indeed, since hepatitis C in the United States is primarily spread through needle-sharing among intravenous drug users, treating these individuals is particularly important to stopping the spread of hepatitis C.[53]

At least 17 states limit treatment to once per lifetime (some states limit the benefit by drug, others only permit beneficiaries to access one DAA treatment for hepatitis C per lifetime).[54] These limits mean that, in the small number of cases that do not respond to treatment, or where a person must stop treatment before completing the full course (due to a medical emergency or unplanned pregnancy, for example), or where a person becomes re-infected with hepatitis C after undergoing successful treatment, Medicaid beneficiaries are absolutely barred from receiving treatment that can cure their disease, alleviate pain and illness, and prevent the spread of the infection to others.

At least 10 states require beneficiaries to document treatment effectiveness to continue receiving treatment.[55] While most beneficiaries will show response to treatment within 4 to 12 weeks, there is no clinical evidence suggesting that treatment is ineffective if a patient does not show a reduction of hepatitis C in the bloodstream during that period.[56] On the contrary, the evidence suggests that in a many cases, the response to treatment may be delayed, but treatment is nevertheless effective and curative when completed.[57] Policies that force beneficiaries to abandon treatment midway deprive beneficiaries of potentially curative treatment for no good reason. These policies are particularly harsh when they are combined with policies that limit treatment to once per lifetime.

Lack of access to potentially life-saving treatments harms low-income people who rely on Medicaid. The harms are primarily borne by highly vulnerable populations and exacerbate health care disparities.[58] Medicaid enrollees include populations

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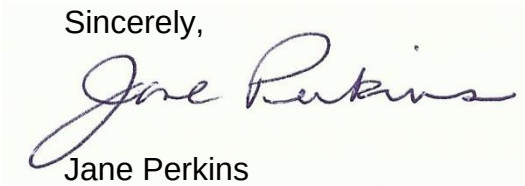
[51] *Id.*
[52] *See, e.g.,* Geert Robaeys *et al., Recommendations for the Management of Hepatitis C Virus Infection Among People Who Inject Drugs,* 57 CLINICAL INFECTIOUS DISEASES S129 (2013), http://cid.oxfordjournals.org/content/57/suppl_2/S129.short.
[53] *see, e.g.,* Paul Nelson *et al., Global Epidemiology of Hepatitis B and Hepatitis C in People Who Inject Drugs: Results of Systematic Reviews*, 378 LANCET 571 (2011), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3285467/.
[54] GARTRELL *ET AL.*, *supra* note 19, at Appx. B Tables 1a, 2a.
[55] *Id.*
[56] *See* Evguenia S. Svarovskaia *et al., Infrequent Development of Resistance in Genotype 1–6 Hepatitis C Virus–Infected Subjects Treated With Sofosbuvir,* 10 CLINICAL INFECTIOUS DISEASES 11 (2014), http://cid.oxfordjournals.org/content/early/2014/10/13/cid.ciu697.short.
[57] *Id.*
[58] *See* HHS OFFICE OF MINORITY HEALTH, HHS ACTION PLAN TO REDUCE RACIAL AND ETHNIC HEALTH DISPARITIES (2015), http://minorityhealth.hhs.gov/assets/pdf/FINAL_HHS_Action_Plan_Progress_Report_11_2_2015.pdf.

disproportionately impacted by the hepatitis C virus, including low-income people, formerly incarcerated persons, and racial and ethnic minorities. As such, the limits on treatment state Medicaid programs are using as a result of high prescription drug prices place effective treatments out of reach for many. NHeLP looks forward to working with the committee and other officials to curb excessive drug pricing and ensure prescription drug access regardless of ability to pay.

If you have any questions or need any further information, please contact Wayne Turner (turner@healthlaw.org; 202-289-7661 ext. 307), Staff Attorney, at the National Health Law Program.

Sincerely,



Jane Perkins
Legal Director