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July 16, 2018

VIA ELECTRONIC SUBMISSION

Office of the Secretary
U.S. Department of Health and Human Services
200 Independent Avenue, SW
Room 600E
Washington, DC 20201

Re: HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

RIN 0991-ZA49

Dear Secretary Azar:

The National Health Law Program (NHeLP) is a public interest organization working to advance access to quality health care and protect the legal rights of low-income and underserved people. We appreciate the opportunity to comment on the Department of Health and Human Services (HHS) [*Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*](#) published as a Request for Information in the Federal Register (83 Fed. Reg. 22692 (May 16, 2018)), as well as the report posted to the HHS website, [*American Patients First The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs*](#) (hereinafter referred to collectively as the HHS Blueprint unless otherwise noted).

Our comments focus on three key areas that the HHS Blueprint addresses only in part or overlooks completely: pricing and access to outpatient prescription drugs in the Medicaid program; proposals to reduce consumer cost sharing in the private insurance market; and strategies to reduce drug prices.

1. Medicaid

a. Closed formularies hurt low income enrollees

Medicaid coverage of outpatient prescription drugs serves as a vital lifeline for enrollees, particularly those with serious or chronic conditions. Congress recognized that Medicaid enrollees live in poverty and have no other means to obtain potentially life-saving medication. Accordingly, Congress requires states that provide Medicaid coverage for outpatient prescription drugs to cover most medications approved by the Food and Drug Administration (FDA) for medically accepted indications, in exchange for substantial rebates from pharmaceutical manufacturers.¹

NHeLP welcomes HHS' acknowledgement that it lacks authority under Social Security Act § 1115 to allow states to severely limit patient access through so-called "closed formularies."² (We note that states have authority to exclude certain outpatient prescription drugs from state Medicaid formularies under 42 U.S.C. § 1396r-8(d)(4)(D).)

Closed formularies, such as those proposed in Massachusetts' recently denied § 1115 waiver application and in the Administration's proposal for demonstration authority to allow closed formularies in up to five states, would not address the high cost of outpatient prescription drugs. Moreover, a closed formulary means that some people will not get the medical treatment they need. The burden of cost savings for outpatient prescription drugs should not fall on those with serious, debilitating, and chronic medical conditions who have no other way to obtain needed care.

Federal law already provides state Medicaid programs with significant cost savings for outpatient prescription drugs. In addition to the hefty rebates that pharmaceutical companies must provide, states can achieve additional savings by negotiating supplemental rebates and through utilization controls that steer beneficiaries toward preferred drugs and limit access to more expensive drugs. For example, while the original list price for hepatitis C drugs could be as high as \$85,000 for a full treatment regimen, the actual price paid by Medicaid programs is much lower (but still unknown due to confidentiality agreements between states and drug companies).

Limiting access to outpatient prescription drugs does not lower health care costs. In fact, research shows that closed formularies have the opposite effect. A recent Tufts study found that at least 20% of closed formularies actually resulted in increased costs.³ At the same time, there is ample evidence to suggest that a closed formulary would result in low-income people not getting medical treatment that they need. The same Tufts study found that patients in at least 25% of closed formularies experienced worse health outcomes.⁴

¹ 42 U.S.C. §1396r-8.

² U.S. Dept. of Health and Human Srvs., *American Patients First The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs* (May, 2018) at 13.

³ Laura Joszt, Do Formulary Drug Exclusions Save Money as Promised?, *AMERICAN JOURNAL OF MANAGED CARE* (Aug. 26, 2016), <https://www.ajmc.com/newsroom/infographic-do-formulary-drug-exclusions-save-money-as-promised>.

⁴ *Id.*

HHS should encourage states to pursue other strategies to reduce spending on outpatient patient prescription drugs, such as preferred drug lists (PDLs), negotiating supplemental rebates, and participating in multi-state purchasing pools, while protecting access for Medicaid enrollees.⁵

b. Medicaid Drug Rebate Program is highly effective and should be strengthened

Under the Medicaid Drug Rebate Program (MDRP), drug manufacturers must provide rebates to the federal government and states as a condition of having their drugs covered by Medicaid. In the case of brand-name drugs, manufacturers must pay rebates equal to 23.1% of the Average Manufacturer Price (AMP) or the AMP minus the “best price” provided to most other purchasers, whichever is greater.⁶ (The AMP is generally the average price paid by wholesalers for drugs distributed to retail community pharmacies.) For generic drugs, rebates equal 13% of the AMP.⁷ Manufacturers must also pay additional rebates for both brand-name and generic drugs if their prices rise faster than general inflation. Nearly all states also directly negotiate with manufacturers (or negotiate together as part of a multi-state purchasing pool) for voluntary supplemental rebates on top of these federally required rebates.

The MDRP ensures that state Medicaid programs obtain substantial rebates, which significantly reduce their prescription drug costs. For example, in fiscal year 2016, according to the Medicaid and CHIP Payment and Access Commission (MACPAC), nationwide, drug manufacturers paid \$31.2 billion in rebates to the federal government and the states, lowering Medicaid prescription drug costs by 51.3%.⁸ In contrast, data from the 2018 Medicare Trustees report shows that the rebates negotiated between private insurers and drug manufacturers lowered Medicare Part D costs by only 19.9% in 2016.⁹ Other analyses from the HHS Office of Inspector General, Altarum and the Congressional Budget Office (CBO) have similarly found that the drug rebates manufacturers pay in Medicaid are far larger than what Medicare Part D plans receive.¹⁰

⁵ See e.g., Katherine Young and Rachel Garfield, KAISER FAMILY FOUNDATION, Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control (Feb.21, 2018), <https://www.kff.org/medicaid/issue-brief/snapshots-of-recent-state-initiatives-in-medicaid-prescription-drug-cost-control/>.

⁶ 42 U.S.C. §1396r-8(c)(1)(B)(i)(VI).

⁷ 42 U.S.C. §1396r-8(c)(3)(B)(iii).

⁸ MACPAC, MACStats: Exhibit 28 Medicaid Gross Spending and Rebates for Drugs by Delivery System, FY 2016,(Dec. 2017), <https://www.macpac.gov/publication/medicaid-gross-spending-and-rebates-for-drugs-by-delivery-system/>.

⁹ 2018 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, June 2018 (see Table IV.B8), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf>

¹⁰ U.S. Dept. of Health and Human Svcs., Office of Inspector General, Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin (April 2015) <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>; Charles Roehring, “The Impact of Prescription Drug Rebates on Health Plans and Consumers,” Altarum (April 2018),

While rebates sharply lower states' Medicaid prescription drug costs, Medicaid includes beneficiary protections that ensure that enrollees have affordable access to the prescription drugs they need. For example, except for a very limited set of drug classes, state Medicaid programs cannot outright deny coverage of drugs produced by manufacturers participating in the drug rebate program.

The MDRP is already highly effective and must be sustained. While we recognize that state Medicaid programs need additional tools and assistance in addressing the twin drug pricing problems of high launch prices and excessive annual price increases, HHS should only consider Medicaid policy proposals that build on, improve, and strengthen the MDRP.

HHS should reject any policy proposals that would have the effect of weakening or undermining MDRP, which would result in higher state Medicaid drug costs. These include proposals to allow states to opt out of MDRP, repeal Medicaid drug rebate improvements included in the Affordable Care Act (ACA), and eliminate or weaken the MDRP's "best price" requirement.

As MACPAC recently stated, policymakers must not only consider how to rein in Medicaid drug spending but "must also consider how such efforts would affect Medicaid beneficiaries' access to therapies that extend lives and improve health and functional status."¹¹

To strengthen the existing MDRP, we urge the Administration to support the following:

- *Legislation that would require increases in minimum Medicaid drug rebates for new drugs with excessive launch prices.* To help state Medicaid programs address the cost of new brand-name drugs with high launch prices, the minimum percentage for the Medicaid base rebate should be increased above 23.1%. The percentage increase should escalate as the launch prices exceed certain tiered thresholds. This would not only allow states to better afford the cost of new brand-name drugs with high launch prices, but also help deter manufacturers from setting such high initial prices in the first place.
- *Increase inflation-related rebates to discourage excessive price increases.* To further deter the increasingly common tactic of manufacturers substantially hiking the price of existing drugs, the Medicaid inflation-related rebates for both brand-name and generic drugs should be further increased if annual price increases exceed certain thresholds. Manufacturers would be subject to an add-on inflation-

<https://altorum.org/publications/the-impact-of-prescription-drug-rebates-on-health-plans-and-consumers>; Anna Anderson-Cook, Jared Maeda and Lyle Nelson, "Prices for and Spending on Specialty Drugs in Medicare Part D and Medicaid," Congressional Budget Office (June 11, 2018) <https://www.cbo.gov/system/files/115th-congress-2017-2018/presentation/53929presentation.pdf> .

¹¹ MACPAC, Report to Congress, Chpt. 2: Improving Operations of the Medicaid Drug Rebate Program (June 2018), <https://www.macpac.gov/wp-content/uploads/2018/06/Improving-Operations-of-the-Medicaid-Drug-Rebate-Program.pdf>.

related rebate (that is, the inflation-related rebate they would otherwise owe would be increased by certain percentages and such increases would be set on a tiered basis so that the amount of the add-on would rise with the size of the annual percentage price increase).

- *Include all pharmacy benefit manager rebates in calculation of “best price.”* Some rebates negotiated by pharmacy benefit managers (PBMs) in the private insurance market are excluded from best price under federal regulations. (Rebates that are passed on to the retail or provider level are included in best price.) We believe that HHS should reconsider this exclusion and amend the best price regulations to include PBM rebates in the determination of best price. Because private insurers in both the employer-based and individual markets increasingly rely on PBMs to negotiate rebates and discounts on their behalf, it is appropriate that such rebates be included in best price. That would have the effect of increasing base Medicaid rebates for certain drugs and thus lowering overall federal and state Medicaid prescription drug costs.
- *Conduct periodic audits on drug manufacturers to ensure better rebate compliance.* Currently, the Centers for Medicare & Medicaid Services (CMS) has no systematic review process to ensure the accuracy of the information reported by manufacturers under the MDRP. CMS should conduct periodic audits of manufacturers participating in the MDRP. Each manufacturer would be subject to an audit on a rolling basis in order to verify the accuracy of the pricing information submitted as well as of the methods, assumptions and underlying data manufacturers used. This would ensure better compliance with the requirements of the MDRP and that manufacturers are fully paying the rebates they owe to state Medicaid programs.
- *Give states full access to Medicaid pricing data on a confidential basis.* Average Manufacturer Price and best price information for each drug reported by manufacturers is confidential and not shared by CMS with the states. Sharing such pricing information with states would facilitate state efforts to help the federal government ensure manufacturer compliance with the MDRP as well as help them negotiate larger supplemental rebates, among other purposes.
- *Bar manufacturer gaming using “authorized generics” to lower rebate amounts.* Manufacturers that make their own generic version of their drugs (known as “authorized generics”) can artificially lower the Medicaid rebates they pay. Drug companies sometime sell the authorized generic version of their brand-name drug to another manufacturer so that it can be distributed. But, if that second company has a corporate relationship with the brand-name drug company (for example, they have the same parent company), the brand-name company may intentionally charge a much lower “transfer” price than it would charge a non-affiliated manufacturer or wholesaler. This has the effect of lowering the Medicaid rebates the manufacturer pays for its brand-name drug because the formula used to determine rebate amounts takes into account the price of authorized generics. In other words, manufacturers can game the rebate program through this approach and reduce the rebates they otherwise would owe to state Medicaid programs. MACPAC

recommends eliminating these types of authorized generic transactions from the calculation of rebates.¹²

- *Give HHS better enforcement tools to prevent manufacturers from misclassifying drugs to lower their rebate amounts.* Some manufacturers have inappropriately and inaccurately classified some of their brand-name drugs as generics in order to reduce how much they pay in rebates, as generic drugs are subject to a lower minimum rebate percentage and are not subject to the “best price” requirement, unlike brand-name drugs. To address the problem of misclassification, the Secretary should seek the explicit authority to impose civil monetary penalties on manufacturers for misclassification and to directly change the classification of a drug.

2. Strategies to limit consumers’ out-of-pocket costs

The HHS Blueprint focuses on out-of-pocket expenses for Medicare beneficiaries, but does not address out-of-pocket expenses for private plans. The Administration should support and implement solutions to lower cost-sharing expenses for private plan enrollees. These include supporting legislation to lower the ACA cap on annual cost sharing or placing a cap on “specialty” drug cost sharing, eliminating or placing restrictions on the use of coinsurance, and reinstating the cost-sharing subsidy payments that the Administration stopped paying in October 2017.¹³

a. Cost sharing harms families and causes people to postpone care

Cost sharing is based on the premise that consumers should have some “skin in the game,” – i.e., they should be responsible for some of their health care costs, so that they are more cost-conscious when it comes to their use of health care services.¹⁴

Unfortunately, when consumers must pay high copays, coinsurance, or deductibles in order to access needed health care services and benefits like prescription drugs, those drugs and other benefits often become completely inaccessible, or cause individuals and families to make difficult choices between financial stability, quality of life, and the care they need.¹⁵ For this reason, Congress prohibited cost sharing for Medicaid outpatient prescription drugs for certain populations, and limited cost sharing to nominal amounts for low income enrollees.¹⁶

¹² *Id.* at 28.

¹³ Note – there is no statutory, regulatory, or industry standard defining “specialty” drugs outside of Medicare. The term is generally used to describe more expensive or newer medications.

¹⁴ See *Even With ‘Skin in the Game,’ Health Care Shoppers are Not More Savvy*, KAISER FAMILY FOUND. (Jan. 19, 2016), <https://khn.org/news/even-with-skin-in-the-game-health-care-shoppers-are-not-more-savvy/>.

¹⁵ See e.g., *New Kaiser/New York Times Survey Finds One in Five Working-Age Americans with Health Insurance Report Problems Paying Medical Bills*, KAISER FAMILY FOUND. (Jan. 5, 2016) <https://www.kff.org/health-costs/press-release/new-kaisernew-york-times-survey-finds-one-in-five-working-age-americans-with-health-insurance-report-problems-paying-medical-bills/> [hereinafter *New Kaiser/New York Times Survey*].

¹⁶ See 42 U.S.C. §§ 1396o, 1396o-1; 42 C.F.R. § 447.53.

A 2017 survey by Kaiser Family Foundation (KFF) found that 29% of those surveyed reported having problems paying medical bills. A significant percentage of survey respondents (31%) reported having a difficult time affording copays for doctor visits and prescription drugs.¹⁷ According to another KFF survey, among respondents with medical bill problems, 75% of respondents with insurance said that the amount they had to pay for their insurance copays, deductibles, or coinsurance was more than they could afford.¹⁸

Not only do high out-of-pocket expenses contribute to financial instability; they often lead people to delay treatment. Numerous studies have found that people defer care due to high out-of-pocket expenses, including one recent study by the Commonwealth Fund which found that 45% of respondents with high cost-sharing expenses put off medical care.¹⁹

Prescription drugs, which account for much of consumer out-of-pocket spending, are no exception. While insured patients often pay less for generic prescriptions, they can be billed tens of thousands of dollars for certain specialty drugs.²⁰ A 2016 survey found that 14% of insured respondents reported that they did not fill a prescription or skipped doses because of the cost, and that 24% of low-income adult respondents reported not taking a prescribed drug because of the cost.²¹ The numbers are even higher for insured Americans facing medical bill problems: the aforementioned 2016 KFF study found that 41% of respondents reported not filling a prescription.²²

b. Support legislation to lower the ACA cap on out-of-pocket expenses

The ACA places an annual limit on cost sharing which is calculated annually by HHS.²³ Using the formula established by the ACA, HHS determined that the 2018 annual limitation on cost sharing for self-only coverage is \$7,350, and \$14,300 for other than self-only coverage.²⁴

HHS lacks the authority to alter the cap on out-of-pocket expenses beyond the statutory limits. Therefore, the Administration should ask Congress to reduce the annual limit. While

¹⁷ Data Note: Americans' Challenges with Health Care Costs, KAISER FAMILY FOUND. (Mar. 2, 2017), <https://www.kff.org/health-costs/poll-finding/data-note-americans-challenges-with-health-care-costs/>.

¹⁸ *New Kaiser/New York Times Survey supra* note 15.

¹⁹ Sara R. Collins et al., *How Well Does Insurance Coverage Protect Consumers from Health Care Costs?*, COMMONWEALTH FUND 1 (Oct. 2017), https://www.commonwealthfund.org/sites/default/files/documents/media_files_publications_issue_brief_2017_oct_collins_underinsured_biennial_ib.pdf.

²⁰ Dana O. Sarnak et al., *Paying for Prescription Drugs Around the World: Why is the U.S. an Outlier?*, COMMONWEALTH FUND 1, 6 (Oct. 2017),

<http://www.commonwealthfund.org/publications/issue-briefs/2017/oct/prescription-drug-costs-us-outlier>.

²¹ *Id.*

²² *New Kaiser/New York Times Survey, supra* note 15.

²³ See 42 U.S.C. § 18022(c).

²⁴ See *Maximum Annual Limitation on Cost Sharing for Calendar Year 2018*, 81 Fed. Reg. 94140, (Dec. 22, 2016), <https://www.gpo.gov/fdsys/pkg/FR-2016-12-22/pdf/2016-30433.pdf>.

such a change would save money for plan enrollees with significant prescription drug costs (or other medical costs), it would likely result in shifting costs to other consumers in the form of premium increases.²⁵ However, research shows that such increases would be modest, as they would be spread across all plan enrollees.²⁶ A number of states have taken such an approach to lowering cost-sharing charges for consumers.²⁷ Most insurers in the various states that implemented caps on cost sharing for specialty drugs estimated rate increases of only 1-2%.²⁸

c. *Eliminate or restrict the use of coinsurance*

The use of coinsurance, whereby insurers charge consumers a percentage of the drug's cost instead of a flat co-pay, has increased significantly in recent years, particularly for specialty drugs. From 2016 to 2017, the percentage of silver plans charging coinsurance for specialty drugs increased 10%, up to 84%.²⁹ Further, the percentage of the cost that consumers are responsible has increased – in 2016, the average coinsurance rate for specialty drugs was 34%; in 2017, it was 37%. Additionally, half of all silver plans charge over 30% coinsurance for specialty drugs, a substantial increase from 36% of plans in 2016. Finally, silver plans generally use copays for generics and coinsurance for specialty drugs, a practice that unfairly burdens those in need of drugs for which there often are no alternatives.³⁰

Coinsurance disproportionately affects persons with serious or chronic medical conditions who may need multiple medications, including more expensive drugs. Coinsurance allows insurers to shift the financial burden of needed care onto consumers. Moreover, consumers have no information on the actual cost of their medication at the time of plan selection. Although NHeLP and other advocacy groups including The AIDS Institute, the National Alliance for Mental Illness, and the Epilepsy Foundation have urged HHS to require greater transparency on actual costs charged to consumers through coinsurance, the agency has to date failed to take any action.³¹

²⁵ See Sandy Ahn & Sabrina Corlette, *State Efforts to Lower Consumer Cost-Sharing for High-Cost Prescription Drugs*, URBAN INST. 1 (Aug. 2017),

<https://www.urban.org/sites/default/files/publication/93071/2001491-state-efforts-lower-rx-cost-sharing.pdf>; Stacie Dusetzina et al., *Improving the Affordability of Specialty Drugs by Addressing Patients' Out-of-Pocket Spending*, HEALTH AFFAIRS 1, 4 (Mar. 15, 2018), https://www.healthaffairs.org/doi/10.1377/hpb20180116.800715/full/HPP_2018_CMWF_01_W.pdf.

²⁶ See e.g., Gabriela Dieguez, Bruce Pyenson, and Rebecca Johnshon, *Specialty Tiers: Benefit Design Considerations for Medicare Part D*, MILLIMAN REPORT PREPARED FOR PFIZER, INC. (June 25, 2013).

²⁷ See Ahn & Corlette, *supra* note 25.

²⁸ *Id.* at 6.

²⁹ Caroline F. Pearson et al., *Consumer Costs Continue to Increase in 2017 Exchanges*, AVALERE HEALTH (Jan. 18, 2017), <http://avalere.com/expertise/life-sciences/insights/consumer-costs-continue-to-increase-in-2017-exchanges>.

³⁰ *Id.*

³¹ National Health Law Program, Comments - Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2016 (Dec. 22, 2014), <http://www.regulations.gov/#!documentDetail;D=CMS-2014-0152-0276>. See also I Am Essential, Re: Comments on Notice of Benefit and Payment Parameters for 2016 Proposed Rule (Dec. 19,

HHS, which sets requirements for Qualified Health Plans (QHPs) participating in the ACA marketplaces, as well as standards for plans offering Essential Health Benefits (EHBs), should issue regulations barring the use of coinsurance. Copayments improve patients' access to treatment by providing more predictability for out-of-pocket expenses.³² Several states have already take the initiative to implement such policies. In 2015, the insurance commissioners of Colorado and Montana issued guidance to insurers participating in the ACA exchanges requiring them to offer a minimum number of plans with fixed dollar prescription drug copays and no prescription drug deductible or coinsurance requirements, beginning in 2016.³³

A July 2017 report commissioned by Pfizer compared the availability, premium levels, and benefit design features of plans in Colorado and Montana before and after the guidance went into effect.³⁴ The report found that the number of plans with first-dollar coverage and fixed copays for prescription drugs increased significantly in Colorado (such plans were already available in Montana prior to the release of the guidance, thus the guidance did not have as significant an effect there). Moreover, while medical deductibles, maximum out-of-pocket maximums, and other cost-sharing mechanisms were somewhat higher, the differences were modest and diffused.³⁵ Further, the decreases in the number of Silver and Bronze exchange plans offered and premium increases experienced by both states mirrored plan and premium changes nationwide, suggesting that the coinsurance regulations may not have had very much effect on these variables.³⁶

d. Reinstate cost sharing reduction payments

The Administration should also restore the payments to insurers for cost sharing subsidies. Their nonpayment leads to market instability and increases in premium rates.³⁷ CBO projected last August that stopping cost-sharing reduction (CSR) payments would drive up federal marketplace subsidy costs, raise premiums, cause more insurers to withdraw from the marketplaces, and increase the number of uninsured.³⁸ Many of these predictions have come to pass. Research shows that 3.2 million more people were uninsured at the end of

2014) available at https://www.iamessential.org/wp-content/uploads/2016/11/2014-Dec_NBPP-IASE-NBPP-Letter-Final_12-19-14.pdf.

³² Dusetzina et al., *supra* note 25, at 3.

³³ Tia G. Sawhney et al., *Impact of Prescription Drug Copay Regulatory Action on ACA Exchange Plans in Colorado and Montana*, MILLIMAN, INC. 3 (July 2017), <http://us.milliman.com/uploadedFiles/insight/2017/Impact-Prescription-Drug-Copay-Guidance-CO-MT.pdf>.

³⁴ *Id.*

³⁵ *Id.* at 3-4.

³⁶ *Id.* at 4.

³⁷ See Sabrina Corlette et al., *States Step Up to Protect Consumers in Wake of Cuts to ACA Cost-Sharing Reductions Payments*, COMMONWEALTH FUND (Oct. 27, 2017), <http://www.commonwealthfund.org/publications/blog/2017/oct/states-protect-consumers-in-wake-of-aca-cost-sharing-payment-cuts>.

³⁸ *The Effects of Terminating Payments for Cost-Sharing Reductions*, CONG. BUDGET OFF. 1,2 (Aug. 2017), <https://www.cbo.gov/system/files/115th-congress-2017-2018/reports/53009-costsharingreductions.pdf>.

2017 than at the end of 2016, before this policy went into effect.³⁹ Further, the uninsured rate among working-age adults is up significantly since 2016 – from 12.7% to 15.5%.⁴⁰ Although most insurers opted to remain in the exchanges, some chose to leave as a result of the elimination of CSR funding.⁴¹ While remaining insurers responded to the end of CSR payments in a variety of ways, the majority chose to increase premiums.⁴² This leads to further market instability, as healthy individuals earning too much to be eligible for the ACA’s tax credits decide to drop out of the market entirely.⁴³

HHS has ample authority to make CSR payments under current law.⁴⁴ To maintain market stability, keep consumer cost sharing down, and comply with federal law, the Administration should restore the cost sharing reduction payments to insurers.

3. The Administration should take substantive steps to address the high cost of prescription drugs

The proposals described in the HHS Blueprint do not fully address the root of the problem of high cost prescription drugs: pharmaceutical company profiteering on the backs of consumers and taxpayers. With their drug monopolies, and without price controls, pharmaceutical companies are free to charge any price they think the market can bear. As described below, viable strategies exist that would lower the prices of prescription drugs. These include increasing competition, incentivizing companies to set lower prices, exposing the true costs of developing a drug, and using existing authority to lower drug prices.

a. Increased transparency in pharmaceutical R&D

Pharmaceutical companies often justify their high prices by arguing that their research and development (R&D) costs are enormous.⁴⁵ Admittedly, many drugs under development do not make it to market, and only about 30% of drugs launched are profitable.⁴⁶ However,

³⁹ Zac Auter, *U.S. Uninsured Rate Steady at 12.2% in Fourth Quarter of 2017*, GALLUP (Jan. 16, 2018).

⁴⁰ Sara R. Collins et al., *First Look at Health Insurance Coverage in 2018 Finds ACA Gains Beginning to Reverse: Findings from the Commonwealth Fund Affordable Care Act Tracking Survey, Feb.-Mar. 2018*, COMMONWEALTH FUND (May 1, 2018), <https://www.commonwealthfund.org/blog/2018/first-look-health-insurance-coverage-2018-finds-aca-gains-beginning-reverse>.

⁴¹ See e.g., Louise Norris, *Maine Health Insurance Marketplace: History and News of the State’s Exchange*, HEALTH INS.ORG., (June 18, 2018), <https://www.healthinsurance.org/maine-state-health-insurance-exchange/#Anthem>; Paul Demko, *GOP Uncertainty Over Obamacare Drives Out Insurers*, POLITICO (June 8, 2017), <https://www.politico.com/story/2017/06/08/gop-uncertainty-over-obamacare-drives-out-insurers-239281>.

⁴² See Rabal Kamal et al., *How the Loss of Cost-Sharing Subsidy Payments is Affecting 2018 Premiums*, KAISER FAMILY FOUND. Table 1, (Oct. 2017), <https://www.kff.org/health-reform/issue-brief/how-the-loss-of-cost-sharing-subsidy-payments-is-affecting-2018-premiums/>.

⁴³ See *Eliminating Cost-Sharing Reductions*, COMMONWEALTH FUND 1 (Apr. 2017), <http://www.commonwealthfund.org/publications/explainers/2017/apr/cost-sharing-reductions>.

⁴⁴ 42 U.S.C. § 18071(c)(3)(A).

⁴⁵ Richard Anderson, *Pharmaceutical industry gets high on fat profits*, BBC NEWS, Nov. 6, 2014, <https://www.bbc.com/news/business-28212223>.

⁴⁶ *Id.*

drug companies continue to make enormous profits year after year, making the pharmaceutical industry the most profitable one in the country.⁴⁷ Further, evidence shows that high drug prices are not linked to the actual costs of research and development, making the pharmaceutical companies' main justification for their high prices patently false.⁴⁸ Over half of all R&D costs come from the taxpayers through government funding for drug development.⁴⁹ Government reports show that drug companies spend only around 1.3% of revenues on basic research to discover new molecules,⁵⁰ as more than 80% of all funds for research to discover new drugs come from public sources.⁵¹

Due to the enormous lobbying influence of pharmaceutical companies at the federal level, there has been no serious federal action to curb drug prices. Without widely available public information about the true costs of research and development, there is little to spur enough public outrage to hold drug manufacturers accountable for their prices.

Because of the dearth of federal legislation to address high drug prices, states across the country have drafted their own drug price transparency bills in an attempt to identify the costs that contribute to the high prices.⁵² As 86% of Americans "favor requiring drug companies to release information to the public on how they set drug prices," more transparency legislation is likely to be proposed at the state level.⁵³

The HHS Blueprint mentions price transparency in general but does not propose any regulations outside of the Medicare program. HHS should learn from the states that have already passed transparency legislation despite massive pharmaceutical lobbying efforts. For example, Vermont's Act 165, passed in 2016, was the nation's first state drug price transparency law, requiring the state to identify "drugs on which the state spends significant health dollars and for which the wholesale acquisition price has increased by 50 percent or

⁴⁷ *Id.*

⁴⁸ Aaron S. Kesselheim et al., *The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform*, 316 J AMERICAN MEDICAL ASSOCIATION 858, 863 (2016), <https://jamanetwork.com/journals/jama/article-abstract/2545691>.

⁴⁹ Henry Waxman et al., THE COMMONWEALTH FUND, GETTING TO THE ROOT OF HIGH PRESCRIPTION DRUG PRICES: DRIVERS AND POTENTIAL SOLUTIONS 12 (2017), https://www.commonwealthfund.org/sites/default/files/documents/media_files_publications_fund_report_2017_jul_waxman_high_drug_prices_drivers_solutions_report.pdf.

⁵⁰ Donald Light & Hoel Lexchin, Pharmaceutical R&D: What do we get for all that money?, 345 British Medical Journal 22, 23 (2012), <https://www.bmj.com/bmj/section-pdf/187604?path=/bmj/345/7869/Analysis.full.pdf>.

⁵¹ *Id.*

⁵² Comparison of State Transparency Laws: What They Require and What Enforcement Action States Can – or Can't – Take, NATIONAL ACADEMY FOR STATE HEALTH POLICY, <https://nashp.org/wp-content/uploads/2018/04/Transparency-Law-Comparison-Chart-final.pdf>.

⁵³ Aaron Berman et al., GLOBAL HEALTH JUSTICE PARTNERSHIP OF THE YALE LAW SCHOOL AND THE YALE SCHOOL OF PUBLIC HEALTH, CURBING UNFAIR DRUG PRICES: A PRIMER FOR STATES 4, 7 (2017), https://law.yale.edu/system/files/area/center/ghjp/documents/curbing_unfair_drug_prices-policy_paper-080717.pdf.

more over the past five years or by 15 percent or more over the past 12 months.”⁵⁴ After identifying the drugs, the Vermont Attorney General may require manufacturers to submit information to justify the price.⁵⁵ Following in Vermont’s footsteps, Maine, Connecticut, Nevada, Oregon, California, and Maryland have also passed similar price transparency legislation.⁵⁶

Optimally, HHS would go beyond the state legislation to mandate price transparency even in the absence of significant price increases. However, increasing prescription drug price transparency on its own will not solve the problem of high drug prices. Public disclosure of R&D costs and related profits would help create the foundation and impetus for further reform.

b. Increase competition through generics and limiting drug monopolies

A study published in the Journal of the American Medical Association found that “the most important factor that allows manufacturers to set high drug prices is market exclusivity, protected by monopoly rights awarded upon FDA approval and by patents.”⁵⁷ Today, the patent protections available for new pharmaceutical development vary by drug type and include:

- the underlying 20-year patent on the drug product, its use, or the process for manufacturing the product;
- market-exclusivity periods of seven years for orphan drugs, five years for all new small-molecule drugs, three years for new clinical uses of small-molecule drugs, and twelve years for new biologic drugs;
- extensions of patents on approved small-molecule drugs for up to five years, with a maximum of fourteen years;
- extensions of six months to existing patents and market-exclusivity periods for conducting pediatric studies;
- the right to delay FDA approval of competing generic drugs by claiming patent infringement; and
- the right to acquire the exclusive rights to drugs discovered through government-funded research and to set prices without restriction.⁵⁸

Once new drugs are approved by the FDA, their patents create monopolies that allow manufacturers to choose any price that they wish. Patents do expire, leading to competition from generics, but there are even generic monopolies that prevent lowered prices.

Brand name prescription drug companies and generic firms often enter into patent settlements, called “pay for delay,” in which the brand name companies will pay generic

⁵⁴ Lowering Drug Costs: Transparency Legislation Sets Off Flurry of New State Approaches, NATIONAL ACADEMY FOR STATE HEALTH POLICY, <https://nashp.org/lowering-drug-costs-transparency-legislation-sets-off-flurry-of-new-state-approaches/>.

⁵⁵ *Id.*

⁵⁶ Comparison of State Transparency Laws, *supra* note 52.

⁵⁷ Kesselheim et al., *supra* note 48, at 861.

⁵⁸ Waxman et al., *supra* note 49, at 7.

firms not to bring generic versions of the brand name drugs for a period of time.⁵⁹ Further, certain pharmaceutical companies abuse the risk evaluation and mitigation strategy (REMS) requirements by denying manufacturers of generics and biosimilars access to the product samples they need for FDA approval and market entry.⁶⁰ These methods delay the entry of generics into the market and stifle drug competition, preserving companies' drug monopolies and price-setting power.

Recognizing the potential that increased competition has on lowering drug prices, the FDA has already been setting records for the number and speed of its generic drug approvals. However, a recent report from PricewaterhouseCoopers has said that more generic competition would not, by itself, solve the problem of high drug prices.⁶¹ According to the report, generic competition *would not affect* 46% of the estimated sales revenue of the top 100 drugs through 2023. Nevertheless, assuming this is true, increasing generic competition *would affect* the revenue of 54% of the top 100 drugs, making it a strategy worth considering to lower drug prices.

The HHS Blueprint mentions increased competition as a strategy to lower drug prices. For example, HHS is considering issuing FDA guidance "to address some of the ways in which manufacturers may seek to use shared system REMS to delay or block competition from generic products entering the market."⁶² However, these vague statements have done nothing to scare drug companies about the possibility of lowered profits. Further, the HHS Blueprint fails to mention any new regulations on pay-for-delay agreements. The Administration should support legislation addressing pay-for-delay and REMS to prevent anticompetitive behavior.

c. Support state efforts to obtain lower cost drugs

The U.S. has the highest per capita drug spending in the world, largely due to strong patent protections and the limited negotiating power of payors.⁶³ In Canada and other countries with a national health insurance system, government agencies or independent organizations have more power to negotiate down drug prices, causing their brand-name medications to cost a fraction of their prices in the United States. Importing medications from Canada or other countries may help lower the costs of prescription drugs by increasing competition in the U.S. drug market. A 2017 Kaiser poll found that 72% of Americans supported drug importation, yet legislative efforts to authorize importation have never gained traction at the state or federal level until recently.⁶⁴

⁵⁹ *Id.* at 27.

⁶⁰ *Id.* at 22.

⁶¹ Health Research Institute, *The FDA is approving more generic drugs than ever before, faster than ever before. Is it enough to lower drug costs?*, PRICEWATERHOUSECOOPERS, <https://www.pwc.com/us/en/health-industries/health-research-institute/pdf/pwc-health-research-institute-generic-drug-pricing-june-2018.pdf>.

⁶² 83 Fed. Reg. 22694.

⁶³ Peter Olson & Louise Sheiner, *The Hutchins Center Explains: Prescription drug spending*, BROOKINGS, Apr. 26, 2017, <https://www.brookings.edu/blog/up-front/2017/04/26/the-hutchins-center-explains-prescription-drug-spending/>.

⁶⁴ *Poll: Majority of Democrats, Republicans and Independents Support Actions to Lower Drug Costs, Including Allowing Americans to Buy Drugs from Canada*, KAISER FAMILY FOUNDATION, May

On May 16, 2018, Vermont enacted SB 175, which authorizes a program to import prescription drugs from Canada to Vermont.⁶⁵ The law directs the Vermont Agency of Human Services to design a wholesale prescription drug importation program that complies with 21 U.S.C. §384, including requirements for safety and cost savings. Maine passed its own drug importation act in 2013, which would have facilitated the personal importation of prescription drugs from international mail order prescription pharmacies.⁶⁶ However, a 2015 court ruling held that the act was unconstitutional because it was preempted by “clear Congressional intent to occupy the field of pharmaceutical importation.”⁶⁷

Secretary Azar has spoken strongly against importation, calling it a “gimmick” that would not meaningfully lower drug prices.⁶⁸ Yet, the costs of many brand-name drugs in Canada fall well below their U.S. prices. States can potentially design programs where pharmacies and other dispensers will sell drugs at the Canadian price without any mark-up.

Secretary Azar also questions the safety of imported drugs. This claim, however, is implausible, as many Canadian and American drugs are made and approved under similar standards. And, in cases of past drug shortages and public health emergencies, the United States has imported drugs. Further, according to former FDA Commissioner Margaret Hamburg, 80% of active ingredients used to manufacture drugs in the U.S. are imported, and 40% of prescription drugs sold in the US are produced abroad.⁶⁹

Secretary Azar has stated that “improved competition” is one of the strategies for reform set out in the HHS Blueprint. The Administration should support state initiatives such as the Vermont proposal to import drugs from Canada to improve competition and force companies to lower their drug prices in the U.S.

d. Anti-price gouging legislation

Pharmaceutical companies have enormous leeway to set whatever prices they choose for prescription drugs. Cases of price-gouging have frequently appeared in the news, often occurring after a company acquires a new drug and wants to profit. In 2015, Martin Shrekli infamously increased the price of Daraprim, a drug that treats a life-threatening parasitic

1, 2017, <https://www.kff.org/health-costs/press-release/poll-majorities-of-democrats-republicans-and-independents-support-actions-to-lower-drug-costs-including-allowing-americans-to-buy-drugs-from-canada/>.

⁶⁵ S. 175 (Vt. 2018), <https://legislature.vermont.gov/bill/status/2018/S.175>.

⁶⁶ “An Act To Facilitate the Personal Importation of Prescription Drugs from International Mail Order Prescription Pharmacies.” 2013 Me. Legis. Serv. ch. 373 (S.P. 60) (L.D. 171) (effective Oct. 9, 2013).

⁶⁷ *Ouellette v. Mills*, 91 F. Supp. 3d 1, 12 (D. Me. 2015).

⁶⁸ Alex M. Azar II, Remarks on Drug Pricing Blueprint (May 14, 2018), <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>.

⁶⁹ *Is It Safe and Cost-Effective to Import Drugs from Canada?*, NATIONAL ACADEMY FOR STATE HEALTH POLICY, <https://nashp.org/is-it-safe-and-cost-effective-to-import-drugs-from-canada/>.

infection, from \$13.50 to \$750 per tablet.⁷⁰ This overnight change meant that the total cost of treatment for some patients would cost hundreds of thousands of dollars.

Unfortunately, Shrekli's price increase is not an isolated example. In the health care system, where access to prescription drugs can determine whether a patient lives or dies, pharmaceutical companies hold far more negotiating power than insurers, providers, and patients because of their patent rights. This is particularly true for drugs that treat life-threatening diseases. Daraprim is one of these drugs, as it mainly treats toxoplasmosis, a parasitic infection that can cause life-threatening problems for babies born to women infected during pregnancy, as well as people with compromised immunity.⁷¹ Cycloserine, a drug that treats multi-resistant tuberculosis, increased in price to \$10,800 for 30 pills from \$500 after its acquisition by Rodelis Therapeutics.⁷² Doxycycline, an antibiotic, went from \$20 a bottle to \$1,849 in less than 6 months.⁷³

Many states have introduced legislation to fight against price gouging. Maryland's new law, which focuses on generic and off-patent drugs, empowers the state Attorney General to identify drugs with prices that climb 50% or more in a year and require companies to justify the hike.⁷⁴ If the attorney general finds the increase unwarranted, he or she can file suit in state court, and manufacturers could face a fine of up to \$10,000 for price gouging.⁷⁵ Other states have also introduced bills to enable states to take legal action and impose financial penalties on manufacturers for price gouging, including Washington, Colorado, Minnesota, Wisconsin, Illinois, Louisiana, Mississippi, Virginia, Maryland, New Jersey, Rhode Island, and New Hampshire.⁷⁶

The HHS Blueprint makes no mention of these or other measures that could address pharmaceutical price gouging, like taxes on unjustified price increases, or requiring disclosure of justifications for prices increases. The Administration should consider proposals, like the legislation mentioned above, that penalize price gouging in order to deter such actions and lower prescription drug prices.

e. Use 28 U.S.C. § 1498 to lower prices

The Administration should exercise its authority under 28 U.S.C. § 1498, which permits the federal government to use patents, including drug patents, without permission of the patent

⁷⁰ Andrew Pollack, *Drug Goes From \$13.50 a Tablet to \$740, Overnight*, THE NEW YORK TIMES, Sept. 20, 2015, <https://www.nytimes.com/2015/09/21/business/a-huge-overnight-increase-in-a-drugs-price-raises-protests.html>.

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ Shefali Luthra, *Absent Federal Action, States Take The Lead On Curbing Drug Costs*, KAISER HEALTH NEWS, Sep. 29, 2017, https://khn.org/news/absent-federal-action-states-take-the-lead-on-curbing-drug-costs/?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=health-care.

⁷⁵ *Id.*

⁷⁶ State Legislative Action on Pharmaceutical Prices, NATIONAL ACADEMY FOR STATE HEALTH POLICY (updated June 22, 2018), <https://nashp.org/state-legislative-action-on-pharmaceutical-prices/>.

holder, as long as it provides reasonable compensation.⁷⁷ Courts have used three methods to determine the required compensation under § 1498: 1) reasonable royalty, 2) percentage of government cost savings, and 3) lost profits.⁷⁸ To calculate the level of royalties due, courts use a fifteen-factor analysis established in *Georgia-Pacific Corp. v. U.S. Plywood Corp.*⁷⁹

This authority receives little attention, even though the government routinely relies on § 1498 for a variety of inventions. Over the past decade, government agencies including the Department of Treasury, U.S. Army Corps of Engineers, National Institutes of Health, National Gallery of Art, the National Park Services, and the General Services Administration have all used § 1498.⁸⁰ This power has been used only once for medicines in recent years: during the 2001 anthrax scare, the government threatened to use § 1498 to buy an antibiotic and quickly cut a deal with the manufacturer for greatly reduced prices.⁸¹

In most cases, use of § 1498 authority should be confined to situations where a patent holder hinders the availability of generics and where there is an overriding public interest to make a medication less expensive and more accessible. One such example is Truvada, a medication used in the treatment of HIV, which is the only drug approved for pre-exposure prophylaxis (PrEP) to prevent HIV infection.⁸²

According to the Centers for Disease Control and Prevention (CDC), PrEP can reduce the risk of HIV infection in people who are at high risk by up to 92%.⁸³ Yet, despite the fact that it has been more than six years since the FDA approved Truvada for use as PrEP, and more than four years since CDC recommended PrEP as a proven HIV prevention strategy,

⁷⁷ Hannah Brennan et al., *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE JOURNAL OF LAW AND TECHNOLOGY 275, 280 (2016), <http://digitalcommons.law.yale.edu/cgi/viewcontent.cgi?article=1124&context=yjolt>.

⁷⁸ 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).

⁷⁹ 318 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).

⁸⁰ *Id.* at 302.

⁸¹ *Id.* at 280.

⁸² Press Release, FDA Approves First Drug for Reducing the Risk of Sexually Acquired HIV Infection, FOOD & DRUG ADMIN. (July 16, 2012), <https://wayback.archive-it.org/7993/20170112032741/http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm312210.htm>. *Pre-exposure Prophylaxis (PrEP) for HIV Prevention*, CENTERS FOR DISEASE CONTROL AND PREVENTION 1 (May 2014), https://www.cdc.gov/hiv/pdf/PrEP_fact_sheet_final.pdf; *PrEP*, CENTERS FOR DISEASE CONTROL AND PREVENTION (March 23, 2018), <https://www.cdc.gov/hiv/basics/prep.html>. While a generic version of Truvada was approved by the FDA in 2017, it appears likely that it will not become commercially available until 2021, when Gilead's patent on emtricitabine (one of the two HIV antiretroviral drugs Truvada is composed of) expires. See *The FDA Has Approved Generic PrEP – but Access May Remain Difficult*, PROJECT INFORM (June 16, 2017), <https://www.projectinform.org/hiv-news/the-fda-has-approved-generic-prep-but-access-may-remain-difficult/>.

⁸³ *Pre-Exposure Prophylaxis (PrEP)*, CENTERS FOR DISEASE CONTROL AND PREVENTION (May 15, 2018), <https://www.cdc.gov/hiv/risk/prep/index.html>.

few people can access this potentially life-saving treatment. In February 2016, the drug's manufacturer, Gilead Sciences, estimated that only 98,732 U.S. residents had started Truvada for PrEP since 2012, which accounts for less than 10% of the 1.2 million people for whom the CDC estimates PrEP is indicated.⁸⁴

One of the main reasons for this underuse is cost. For the uninsured, the cost for PrEP can be as high as \$1,250 per month or \$15,000 per year.⁸⁵ For those with insurance, PrEP can still be prohibitively expensive, with out-of-pocket costs estimated at \$6,000 annually.⁸⁶ Although Gilead provides a Copay Assistance Program (CAP), its maximum allowance is only \$4,800 per year.⁸⁷

Research shows that for those most at-risk for HIV infection, the cost associated with PrEP is one of the most significant barriers to PrEP utilization. One study conducted among high-risk gay men having sex with men (MSM) found that 80% of respondents would be likely to use PrEP if it were provided without cost sharing.⁸⁸ Another study found that the most commonly reported barrier to PrEP use among study participants who did not take PrEP after completion of the study's project was cost or lack of health insurance.⁸⁹ Yet another study found that higher income was significantly associated with PrEP usage.⁹⁰

⁸⁴ Robertino M. Giler et al., *Changes in Truvada for Hiv pre-exposure prophylaxis utilization in the USA: 2012-2016*, 9th International AIDS Society Conference on HIV Science (July 2017), <http://programme.ias2017.org/Abstract/Abstract/1614>; *Vital Signs: Estimated Percentages and Numbers of Adults with Indications for Pre-exposure Prophylaxis to Prevent HIV Acquisition – United States, 2015*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Nov. 27, 2015), https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6446a4.htm?s_cid=mm6446a4_w.

⁸⁵ Jason Ervin & Carolyn McAllaster, *We Have the Tools to End HIV: Benefits, Barriers, and Solutions to Expanded Utilization of Pre-Exposure Prophylaxis (PrEP) in the US Deep South*, SOUTHERN HIV/AIDS STRATEGY INITIATIVE 1, 9 (June 2016); *Are You PrEP Skeptical?*, PREP FACTS, <http://men.prepfacts.org/the-questions/> (last visited June 26, 2018); Kimberly A. Koester et al., *Financial Assistance for PrEP: Best Practices & Recommendations for the California State Office of AIDS' PrEP Assistance Program*, FACTS CAL. HIV/AIDS POLICY RESEARCH CENTERS 1 (2017), http://www.chprc.org/wp-content/uploads/2017/09/PrEP-Benefits-Report_September_2017_FINAL.pdf

⁸⁶ *Id.*

⁸⁷ HOW CAN YOU GET HELP PAYING FOR TRUVADA FOR PREP?, <https://www.truvada.com/how-to-get-truvada-for-prep/truvada-cost> (last visited June 26, 2018); See e.g. Jason Ervin & Carolyn McAllaster, *We Have the Tools to End HIV: Benefits, Barriers, and Solutions to Expanded Utilization of Pre-Exposure Prophylaxis (PrEP) in the US Deep South*, SOUTHERN HIV/AIDS STRATEGY INITIATIVE at 2 (June 2016).

⁸⁸ Jason Ervin & Carolyn McAllaster, *We Have the Tools to End HIV: Benefits, Barriers, and Solutions to Expanded Utilization of Pre-Exposure Prophylaxis (PrEP) in the US Deep South*, SOUTHERN HIV/AIDS STRATEGY INITIATIVE at 9-10 (June 2016).

⁸⁹ Susan Doblecki-Lewis et al., *Healthcare Access and PrEP Continuation in San Francisco and Miami after the US PrEP Demo Project*, JOURNAL OF ACQUIRED IMMUNE DEFICIENCY SYNDROME 531, 534 (Apr. 15, 2017).

⁹⁰ Ian Holloway et al., *PrEP Uptake, Adherence, and Discontinuation among California YMSM Using Geosocial Networking Applications* 1, 5 (Jan. 1, 2018).

Low-income communities and communities of color disproportionately bear the burden of HIV and are at the highest risk of infection.⁹¹ A recent analysis by the CDC found that, while two-thirds of people who could potentially benefit from PrEP are black or Latino, they account for the smallest percentage of prescriptions to date.⁹²

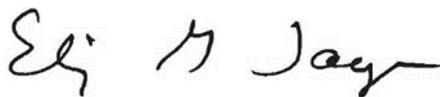
HHS should take immediate action to cut the price of PrEP and make this vital HIV prevention tool more accessible. Advocates estimate it costs less than \$6 to make a 30-day supply of the Truvada, yet Gilead charges more than \$1,600 for the same amount.⁹³ This is a price inflation of more than 25,000%.⁹⁴

Given the private and public health costs for treating persons living with HIV and AIDS, the urgency of making this proven prevention strategy more widely available could not be greater. Moreover, using § 1498 authority to reduce Truvada pricing would send a strong message to the pharmaceutical industry and help deter price gouging.

Conclusion

We urge HHS to take concrete steps to reduce the cost of prescription drugs without limiting access for consumers. We also urge the Administration to support efforts to lower out-of-pocket expenditures for health services and benefits, including prescription drugs, and to cease action which destabilize the private insurance market and drive up health care premiums. If you have further questions, please contact NHeLP Senior Attorney Wayne Turner at turner@healthlaw.org.

Yours truly,



Elizabeth G. Taylor
Executive Director

⁹¹ *HIV Prevention Pill Not Reaching Most Americans Who Could Benefit*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Mar. 6, 2018), <https://www.cdc.gov/nchhstp/newsroom/2018/croi-2018-PrEP-press-release.html>.

⁹² *Id.*

⁹³ #Breakthepatent, <https://breakthepatent.org/>.

⁹⁴ *Id.*