



July 16, 2018

The Honorable Alex Azar
Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Re: RIN 0991-ZA49 HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs

Dear Secretary Azar:

Treatment Action Group (TAG), NASTAD (National Alliance of State and Territorial AIDS Directors), and the HIV Medicine Association (HIVMA) appreciate the opportunity to submit these comments in response to the proposed HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (RIN 0991-ZA49).

TAG is an independent, activist and community-based research and policy think tank fighting for better treatment, prevention, a vaccine, and a cure for HIV, tuberculosis (TB), and hepatitis C virus (HCV).

NASTAD is a leading non-partisan, non-profit association that represents public health officials who administer HIV and hepatitis programs in the U.S. and around the world.

HIVMA represents nearly 5,000 physicians, scientists and other health care professionals working on the frontlines of the HIV epidemic.

We appreciate the importance of a multi-faceted approach to high medicine pricing and actual costs to public payors, commercial insurers, and U.S. patients. Though the HHS Blueprint includes many more exploratory questions than it does actual policy recommendations, we acknowledge that high medicine prices and unsustainable spending on pharmaceuticals and biologics are rooted in problems at virtually all points in the complex U.S. pharmaceutical market, in part due to existing federal laws and regulations that have either never been applied or haven't kept pace with largely successful pharmaceutical industry efforts to game existing controls.

Largely missing from the HHS Blueprint are exploratory questions and policy recommendations related to pricing practices by the pharmaceutical industry itself,

including: 1) unjustified launch prices, particularly those beyond what the market can reasonably bear, resulting in inequitable access to lifesaving therapies; 2) net and list price increases that are out of lockstep with rates of inflation; 3) monopolization of critical generic drug products, notably those for serious but low-prevalence diseases that do not constitute large market shares; and 4) anti-competitive tactics among brand-name drug and biologic manufacturers to prevent timely generic competition, including patent thickets, evergreening, and REMS abuses.

In this response, we focus on aspects of the HHS Blueprint that are most crucial to drug and biologics pricing and access in HIV, HCV, and TB. We welcome any opportunity to more fully engage with the Department of Health and Human Services regarding any of the recommendations contained herein.

Curtail “Global Freeloading” Rhetoric and Related Policy Threats

We reject the assertion that pharmaceutical purchasers and payors in high-income countries – notably those with centralized price control policies – are engaged in “global freeloading.” Not only is there a paucity of validated data supporting the idea that lower prescription drug prices in other high-income countries are a barrier to research and development, there is evidence to the contrary.

Pharmaceuticals remain one of the most profitable industries in the world, with 2015 net sales of \$775 billion and net profit margins of 17.5% among 500 companies included in a 2017 U.S. Government Accountability Office (GAO) analysis.¹ Among the largest 25 companies—12 of which headquartered in other high-income countries²—the profit margin was 20.1 percent in 2015. For comparison, GAO estimates the annual average profit among the 500 largest non-pharmaceutical industries fluctuates between 4 and 9 percent.

Pharmaceutical and biotech companies in other high-income countries often succeed in maintaining revenues that exceed R&D costs, based on domestic sales at prices that are substantially lower than those in the U.S. According to the 2016 annual report produced by the Canadian Patented Medicine Prices Review Board, companies that are members of the Innovative Medicines Canada consortium reported domestic sales revenues of \$15.6 billion – approximately 20 times greater than research and development costs (\$769.9 million, or 4.9% R&D-to-sales ratio).³

¹ U.S. Government Accountability Office. Profits, Research and Development Spending, and Merger and Acquisition Deals. 2017 Nov. <https://www.gao.gov/assets/690/688472.pdf>

² GLobalData. Global Top 25 Pharma Companies by Market Cap – January 2018. <http://client.globaldata.com/static/PR1298.jpg>

³ Patented Medicine Prices Review Board (Canada). Annual Report 2016. <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1334>

We are aware of analyses suggesting that price controls implemented by other high-income countries are associated with reduced investments in R&D and that similar measures in the U.S. will potentially diminish pharmaceutical and biotech investments.^{4,5} However, these analyses are fully dependent on R&D expenditure reporting by manufacturers, which have consistently evaded public and Congressional requests for transparency. In fact, there is considerable debate regarding the cost associated with bringing a new drug to market.

One of the most widely cited estimates of R&D costs associated with developing a new drug is \$2.55 billion, which comes from an analysis conducted by the pharmaceutical industry-supported Tufts Center for the Study of Drug Development.⁶ Neither the drugs included in the analysis, nor an adjudication of how the ten participating manufacturers assigned costs to R&D, were reported. The validity of the average out-of-pocket R&D costs (\$1.39 billion), in the absence of R&D expenditure transparency, must therefore be questioned.

Additionally, the capitalization of drug discovery costs in the Tufts analysis – estimates of how much profit would have been made if R&D expenditures had instead been invested in an index fund – and the inclusion of basic research expenditures⁷ has been heavily criticized,⁸ with one group estimating total R&D costs associated with bringing a new drug to market to be closer to \$110 to \$115 million.⁹

Of additional consideration are the significant contributions from the public purse toward the development of new drugs. According to an analysis conducted by the National Academy of Sciences, National Institutes of Health funding contributed to published research associated with every one of the 210 new drugs approved by the FDA from

⁴ U.S. Dept of Commerce, International Trade Administration. Pharmaceutical Price Controls in OECD Countries – Implications for U.S. Consumers, Pricing, Research and Development, and Innovation. 2004 December. <https://2016.trade.gov/td/health/DrugPricingStudy.pdf>

⁵ Information Technology & Innovation Foundation. The Impact of Regulation on Innovation in the United States: A Cross-Industry Literature Review. 2010 June. <http://www.iom.edu/~media/Files/Report%20Files/2011/Health-IT/Commissioned-paper-Impact-of-Regulation-on-Innovation.pdf>

⁶ DiMasi JA, Grabowski HG, Hansen RW. Innovation in the pharmaceutical industry: New estimates of R&D costs. *J Health Econ.* 2016 May;47:20–33. <https://www.sciencedirect.com/science/article/abs/pii/S0167629616000291>.

⁷ U.S. Government Accountability Office, 2017. Data from the pharmaceutical industry, the National Science Foundation, and government indicate international public investments in basic research far exceed industry investments, with the National Institutes of Health alone investing \$13.6 billion (54% of its budget) in drug research in 2014, which is more than twice the basic science investments made by pharmaceutical companies.

⁸ Knowledge Ecology International. KEI comment on the new Tufts Study on Drug Development Costs. 2014 November. <https://www.keionline.org/22646>.

⁹ Maxmen M. Busting the billion-dollar myth: how to slash the cost of drug development. *Nature.* 2016 August;536:388–390. <https://www.nature.com/news/busting-the-billion-dollar-myth-how-to-slash-the-cost-of-drug-development-1.20469>.

2010–2016. Collectively, this research involved more than 200,000 years of grant funding totaling more than \$100 billion.¹⁰

Moreover, the relationship between R&D and drug prices is subject to debate. As argued by the Office of the Assistant Secretary for Planning and Evaluation in its December 2016 report to Congress:¹¹

The prices charged for drugs are unrelated to their development costs. Drug manufacturers set prices to maximize profits. At the time of marketing, R&D costs have already occurred and do not affect the calculation of a profit-maximizing price.

Lower drug development costs, however, do help to spur innovation in drug development. When drug manufacturers consider prospectively whether to invest in developing a new drug, they weigh the costs of development against future returns. Shorter development times and lower R&D costs make investing in developing new drugs more attractive by increasing expected net returns.

Even with the high-end median estimate of \$1.096 billion¹² in overall research and development costs to bring a single drug to market, these costs are generally recovered within the first few years of commercial availability. Consider Gilead Science's Sovaldi (sofosbuvir) and Harvoni (sofosbuvir and ledipasvir), the first highly curative direct acting antivirals approved for chronic hepatitis C virus (HCV) infection. Following successful preclinical, Phase I, and Phase II evaluations by Pharmasset, Inc. (the original developer of sofosbuvir), Gilead purchased the company and its assets for \$11.2 billion in January 2012. Gilead also reported that its additional R&D costs for sofosbuvir-based regimens was estimated to be \$880.3 million between 2012 and 2014.¹³ In its first year on the market (2014), global annual sales for Sovaldi and Harvoni were \$12.4 billion; in 2015, \$19.1 billion; in 2016, \$10.8 billion; and in 2017, \$7.8 billion – more than \$50 billion in sales through the end of last year alone.

¹⁰ Galkina Cleary E, Beierlein JM, Khanuja NS, McNamee LM, Ledley FD. Contribution of NIH funding to new drug approvals 2010-2016. Proc Natl Acad Sci U S A. 2018 Mar 6;115(10):2329-2334. <http://www.pnas.org/content/early/2018/02/06/1715368115>.

¹¹ Office of the Assistant Secretary for Planning and Evaluation. Prescription Drugs: Innovation, Spending, and Patient Access. Report to Congress. 2016 December 7. <https://delauero.house.gov/sites/delauro.house.gov/files/Prescription-Drugs-Innovation-Spending-and-Patient-Access-12-07-16.pdf>

¹² DiMasi JA, 2003. \$802 million in 2018 dollars.

¹³ Wyden R, Grassley CE. The price of Sovaldi and its impact on the U.S. health care system. Report to the Committee on Finance, United States Senate. 2015 December. <https://www.finance.senate.gov/download/the-price-of-sovaldi-and-its-impact-on-the-us-health-care-system-full-report>

Additionally, if we do accept that price controls, either foreign or domestic, potentially impact pharmaceutical company investments in R&D, there is no evidence to suggest that reductions in R&D would either halt or slow the development of drugs and biologics with true clinical value, after adjusting for inefficient, wasteful, and superfluous research that serves to expand patent thickets and evergreen products to stave off generic competition, and the development of low-value, high-profit drug products without clear safety or efficacy improvements over existing drugs or biologics.

We also urge both the White House administration and Congress to resist any challenges to Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities, notably the right of World Trade Organization member states to include in their patent legislation a provision for use without authorization of the patent holder. These flexibilities are critical to low- and middle-income countries, particularly those with high incidence and prevalence rates of HIV, HCV, and TB and unable to secure voluntary licensing or affordable access to life-saving drugs by patent holders.

Lastly, and critically, we note the lack of evidence that U.S. efforts to de-control drug prices abroad will actually result in lower domestic list prices; cost savings that accrue to purchasers, payors, and patients; and won't simply further inflate pharmaceutical industry profit margins.

Recalibrate FDA Regulations to Maximize Competition and Ensure Stringency

TAG, NASTAD, and HIVMA support HHS efforts to hasten and maximize competition among manufacturers to help ensure the lowest possible costs of multi-source (generic) drugs to payors and patients. A 2016 Government Accountability Office report supports this need. Of 1,441 established generic drugs included in the analysis of Medicare Part D prices, 300 (21%) had at least one extraordinary price increase of 100 percent or more between the first quarter of 2010 and first quarter of 2015, moderating the overall decline in generic drug prices.¹⁴

Reducing the median approval times for ANDAs – currently 47 months – as allowed under the Hatch-Waxman Amendments should remain a priority under the Generic Drugs User Fee Amendments (GDUFA) II.¹⁵ We appreciate that many generics are not approved in the first cycle of ANDA review because they do not meet FDA stringency standards in place to ensure bioequivalence and good manufacturing practices. Our recommendations therefore focus on other potential regulatory steps to strengthen competition and the approval of multi-source drug products for populations who need them the most.

¹⁴ Government Accountability Office. Part D generic drug prices declined overall, but some had extraordinary price increases. 2016 August. <http://gao.gov/assets/680/679022.pdf>

¹⁵ Regulatory Affairs Professional Society. GDUFA II: FDA looks to speed up generic drug approval process. 2016 September 26. <http://www.raps.org/Regulatory-Focus/News/2016/09/26/25898/GDUFA-II-FDA-Looks-to-Speed-Up-Generic-Drug-Approval-Process/>

We support regulations and legislation aiming to correct abuses by manufacturers refusing to sell samples of drugs requiring Risk Evaluation and Mitigation Strategies (REMS) to multi-source competitors. HHS should recommend Congressional action to prohibit the use of REMS in anticompetitive behavior and to fully empower the FDA to compel innovator product manufacturers to cooperate and develop alternative bioequivalence study mechanisms – such as the use of samples of drugs approved by foreign stringent regulatory agencies – to ensure competition.

HHS should commit to a comprehensive analysis, with recommendations for reform, pertaining to the usefulness, anticompetitive risks, and cost effectiveness of citizen petitions. Noting that manufacturers of innovator drug and biologics products submit 92 percent of all citizen petitions,¹⁶ we are alarmed at the misuse of section 505 petitions, which can potentially block the commercialization of multi-source versions of innovator drug products that are both safe and effective.

Additionally, FDA currently lacks the power to resolve questions on patent coverage, remanding all patent disputes to litigation that is both time-consuming and costly, likely driving up costs for both single-source (brand-name) and multi-source drug products. HHS should conduct analyses and public hearings on the quality of patents to be included in the Orange Book. At present, the Orange Book freely allows for patent evergreening, whereby additional patents on newer features (e.g., isomers, polymorphs, metabolites, and process patents) of older drugs – with potentially negligible effects on the overall clinical value and cost effectiveness – can be filed by the original New Drug Application (NDA) holder, often in a staggered manner to block multi-source competition. For each patent, separate paragraph IV certifications are required, resulting in additional 30-month stays and litigation. While the Medicare Modernization Act¹⁷ does permit innovator and non-innovator multi-source manufacturers to certify only those patents listed in the Orange Book at the time of the initial ANDA filing – thereby preventing original NDA holders from filing additional patents requiring paragraph IV certification – patent thickets and evergreening through reformulations and line extensions remain a pervasive threat to generic drug competition.

Strengthen Public Payor Discount and Rebate Formula Determinations

Adjustments to public payor discount and rebate formulas are essential. Manufacturers are circumventing the formulas used to regulate prices for Medicare, Medicaid, and other federal purchasers. These formulas were originally designed to leverage the

¹⁶ Califf RM. Eighth annual report on delays in approvals of applications related to citizen petitions and petitions for stay of agency action for fiscal year 2015. Report to Congress. 2016 July 29. <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM517279.pdf>

¹⁷ Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108–173. 2003 December 8. <http://www.gpo.gov/fdsys/pkg/PLAW-108publ173/pdf/PLAW-108publ173.pdf>

power of private industry negotiations for government purchasers, but privately negotiated discounts are now excluded from these averages. Consider the Average Manufacturer Price (AMP), which sets prices for state Medicaid and 340B programs. As amended under Section 2503 of the Affordable Care Act (ACA), the formula only considers “the average price paid to the manufacturer for the drug in the United States by (i) wholesalers for drugs distributed to retail community pharmacies; and (ii) retail community pharmacies that purchase drugs directly from the manufacturer, specifically excluding “rebates or discounts provided to pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers,” and others.¹⁸

Therefore, instead of offering discounts to wholesalers and pharmacies, which would result in lower AMPs (and, by extension, lower Medicaid and 340B ceiling prices), manufacturers provide back-end rebates and incentive payments to insurers and revenue-seeking pharmacy benefit managers (PBMs), which are not reflected in government price reporting calculations.

This is how we know manufacturers are not including these discounts in government price reporting calculations: pharmacy invoice prices are only 1 percent greater than the AMP for brand name drugs, consistent with the requirement that manufacturers only include pharmacy sales prices in the AMP calculation.¹⁹ Yet in 2016, “discounts, rebates, and other price concessions” on brand name drugs amounted to 28 percent of invoice drug costs. If these had been included in AMP, then AMP would be 28 percent lower than the pharmacy invoice price, not 1 percent lower.²⁰ This implies that governments could be paying more for drugs than the private market – while Medicaid receives 23.1 percent off the calculated market price, overall manufacturers offer discounts of 28 percent.

The Medicaid rebate amount begins with the AMP, and therefore the AMP should reflect true market prices. Medicaid rebates have an additional safeguard – “Best Price”²¹ – intended to ensure that Medicaid realizes the benefit of all commercial discounts. The Medicaid rebate can be greater than 23.1 percent of AMP if the manufacturer offers a

¹⁸ Section 2503 of the Patient Protection and Affordable Care Act. The change from “retail pharmacy class of trade” to “retail community pharmacies” excluded many discounted sales to certain specialty and mail order pharmacies from inclusion in AMP, reducing manufacturers’ rebate liability.

¹⁹ Office of Inspector General. Review of Drug Costs to Medicaid Pharmacies and Their Relation to Benchmark Prices. 2011 October. <https://oig.hhs.gov/oas/reports/region6/61100002.pdf>

²⁰ IQVIA Institute. Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021. 2017 May. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicines-use-and-spending-in-the-us.pdf>.

Centers for Medicare & Medicaid Services: National Health Expenditure Accounts 2014. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html>

²¹ 42 CFR § 447.505

discount to certain purchasers greater than 23.1 percent of AMP, establishing a “Best Price” that Medicaid is entitled to receive. However, the most important discounts—PBM rebates—are excluded from Best Price. Best Price only considers prices, net of all discounts, to “any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity,” explicitly excluding prices paid by most Federal agencies, manufacturer co-pay assistance programs, and prices negotiated by private Medicare Part D plans. In regulatory guidance, CMS clarifies that Best Price specifically excludes pharmacy benefit manager “rebates, discounts, or other financial transactions except their mail order pharmacy's purchases or where such rebates, discounts, or other financial transactions are designed to adjust prices at the retail or provider level.” While the pharmaceutical market has shifted from offering discounts to pharmacies to offering discounts to PBMs, Medicaid is prohibited from realizing those discounts through either a reduced AMP or through establishing a Best Price.

Back-end price reductions also keep pharmacy prices artificially high, increasing out-of-pocket costs to both uninsured patients and insured patients subject to high co-insurance rates.²² Discouraging back-end rebates and discounts could lead to normalized prices across the entire drug delivery system, passing discounts onto patients rather than to PBMs and private insurers.

In the accompanying white paper developed by the Fair Pricing Coalition (FPC) – of which TAG, NASTAD, and HIVMA are members – submitted to the incoming White House administration in December 2016, we make three recommendations regarding rebate determination formulations.²³ In addition to the formula fixes required to ensure that all back-end discounts and rebates are included in AMP and Best Price, strengthened legislation to modernize “Big Four” – the Department of Veterans Affairs, the Department of Defense, Public Health Service/Indian Health Service, and the Coast Guard—non-Federal average manufacturer price (non-FAMP) calculations is also needed.

We also note that HHS has the authority to incorporate back-end discounting and rebates into the Average Sales Price calculation required for Medicare Part B coverage as a condition of manufacturers’ Medicaid agreement. In fact, the Government Accountability Office has called for strengthen the ASP formula, noting that the inclusion of additional discounts in ASP in 2016 would have resulted in at least \$69 million in annual savings.²⁴

²² Langreth R. Secret Rebates: Why Patients Pay \$600 for Drugs That Cost \$300. Bloomberg. 2016 October 5. <http://www.bloomberg.com/news/articles/2016-10-05/patients-lose-out-on-big-pharma-s-secret-rebate-merry-go-round>.

²³ Dickson S, Horn T. Tackling Drug Costs: A 100-Day Roadmap. 2016 December. <https://fairpricingcoalition.org/wp-content/uploads/2016/12/Tackling-Drug-Costs-A-100-Day-Roadmap-FINAL.pdf>

²⁴ Government Accountability Office, Medicare Part B: Data on Coupon Discounts Needed to Evaluate Methodology for Setting Drug Payment Rates. 2016 July. <http://www.gao.gov/assets/680/678690.pdf>.

Modernize Inflationary Rebate Limits

The Administration is right to assess inflationary rebate limits, which have failed to halt runaway drug prices. We focus here on the Medicaid “additional rebate,” or Consumer Price Index (CPI) penalty, which is levied if the current quarter’s AMP is greater than the drug’s initial AMP adjusted for inflation to the present.

The cap on the total Medicaid rebate encourages manufacturers to take excessive price increases. Manufacturers are clearly willing to allow Medicaid sales at \$0 in exchange for massive price increases to other payers. Because of the Additional Rebate, Medicaid rebates on brand name drugs are, on average, three times higher than the privately-negotiated rebates paid to Medicare Part D plans.²⁵ Medicaid drug expenditures before rebates, however, are only 9% of the market – and manufacturers are clearly willing to forgo profits on Medicaid to extort profits from the rest of the market.²⁶ Consider the 5,000% price increase for Daraprim, which established a net \$0 price for Medicaid. Yet Vyera Pharmaceuticals (née Turing), which has not adjusted its list price despite considerable public scrutiny, continues to find it profitable to give away two-thirds of its sales for free because of the revenue from the remaining third, highlighting the perverse incentives under the current penalty.

The Additional Rebate must be heightened for Medicaid’s 9 percent% market power to shape prices in the rest of the market. This can be achieved by adding a multiplier to the Additional Rebate for large price increases and eliminating the rebate cap when the total rebate exceeds the quarterly AMP. For price increases 5% greater than the rate of inflation, we advocate that the Additional Rebate should be doubled; for increases more than 25% greater than the rate of inflation, tripled. Manufacturers should then be required to pay Medicaid the total rebate for the drug, even if it would result in a loss.

In the FPC paper we also advocate for conforming changes to the Federal Ceiling Price inflation penalty for the Big Four.

Enhancing the existing inflation penalty leverages long-standing policy and systems infrastructure and does not require government price-setting or controls on the private market; rather, manufacturers will have to rationally price drugs in the private market to ensure full reimbursement by government payers. Moreover, by fixing the formulas and including back-end rebates and discounts in the calculation of AMP, current AMPs

²⁵ HHS Office of Inspector General. Medicaid Rebates for Brand-Name Drugs Exceeded Part D Rebates by a Substantial Margin. 2015 April. <https://oig.hhs.gov/oei/reports/oei-03-13-00650.pdf>.

²⁶ CMS, National Health Expenditure Accounts 2014. Medicare accounted for 29% of prescription drug spending, while patient out-of-pocket costs were 15% of prescription drug spending – more than all of Medicaid spending.

should drop, lessening the immediate impact of the inflation penalty while still holding future price increases closer to the rate of inflation.

Evaluate and Implement Drug Pricing Transparency

Sub-wholesale acquisition cost (WAC) pricing is complex and opaque, with only surveyed retail pharmacy prices, multi-source product reimbursement maximums, Average Sales Price (Part B), and Federal Supply Schedule/Big 4 purchase prices made public. The pharmaceutical industry has adeptly hidden the true price of drugs, skirting the intent of federal price reporting regulations by offering complex back-end discounts to insurers and PBMs. And because these back-end discounts are not included in federal price reporting metrics, existing transparency tools fail to show true market prices.

In the FPC paper we make four drug pricing transparency recommendations:

- Strengthen existing transparency tools by modernizing price reporting formulas through existing authority and legislation (as above).
- Require manufacturer disclosure of detailed drug development costs, marketing costs, and executive compensation for egregious price increases through legislation.
- Study whether additional transparency, such as public and private payor discount and rebate amounts, will reduce costs or, instead, lead to anti-competitive price fixing.
- Study the relationship between drug development costs and prices, including an assessment of the role of federal, state, and non-profit funding and other incentives (such as tax abatements or other local corporate incentives)

Deter Cost Sharing under Part D and other Commercial Plans

Out-of-pocket costs create barriers to maintaining consistent access to the medications necessary for people living with HIV, HCV and others with chronic conditions to stay healthy and prevent disease progression or illness.^{27,28} We support policy actions that will deter the practice of commercial and Medicare Part D plans employing cost sharing and formulary tier placement to manage drug utilization and drug expenditures and to

²⁷ Artiga, S, Ubri, P, Zur, J. Effects of Premiums and Cost Sharing on Low-Income Populations: Updated Review of Research Findings. Kaiser Family Foundation. June 2017.

²⁸ Kostova D¹, Fox J. Chronic Health Outcomes and Prescription Drug Copayments in Medicaid Med Care 2017 May;55(5):520-527.

adversely select enrollees by deterring individuals with higher drug needs and costs from enrolling in their health or drug plan.²⁹

Effective utilization management must be grounded in clinical evidence and recommendations developed to promote appropriate care and treatment and to improve outcomes. The use of cost sharing to manage drug utilization is a blunt instrument discouraging drug utilization even when a medication may be the most effective or only treatment option for the patient.

- **Transparency & Disclosure:** We support greater disclosure of drug price increases that result in out-of-pocket cost increases to patients but also feel strongly that decisions regarding treatment changes must be left to the provider and the patient. We recommend requiring plans to notify enrollees prior to an increase in cost sharing taking effect to provide patients with the opportunity to discuss other treatment options with their HIV providers. We also urge that healthcare providers have improved access to drug costs and associated out-of-pocket costs incurred by patients.
- **Drug Rebates:** While passing along drug rebates negotiated by health plans and PBMs to patients may lower out-of-pocket costs for some enrollees, we are concerned that the costs will be born elsewhere in the system, such as through higher premiums. Ultimately, the most effective strategy for lowering out-of-pocket costs is lowering the list price of prescription drugs and to keep subsequent increases to the medical inflation rate or lower.
- **Part D Gag Clauses:** We concur with the Centers for Medicare & Medicaid Services that any form of “gag clauses” are unacceptable.³⁰ Such clauses prevent pharmacies from informing patients if their insurance copay is more than the cash cost of their prescription drugs. We also agree with CMS in that Part D health plans must disclose cost differentials between Part D brand-name drugs and biologics and therapeutically equivalent generic drugs and biosimilars. The Administration should not only ensure that these gag clauses are effectively banned, it should support legislation extending the ban to commercial plans.
- **Co-Pay Cards/Assistance:** We recognize the paradox of supporting the use of copay cards and coupons to defray exorbitant cost-sharing amounts while also raising concerns regarding increasing prices for HIV medications and others. In reality, without co-pay assistance many people with HIV and others with chronic

²⁹Jacobs, DB, Sommers, BD. Using Drugs to Discriminate — Adverse Selection in the Insurance. *N Engl J Med* 2015; 372:399-402.*Engl J Med* 2015; 372:399-402.

³⁰Centers for Medicare & Medicaid Services. Unacceptable Pharmacy Gag Clauses. Memorandum to all Part D plan sponsors. 2018 May. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/Other-Content-Types/2018-05-17.pdf>.

conditions would be unable to access their medications without assistance due to the high cost of the medications. Without meaningful drug price reform and protections to limit out-of-pocket costs for patients, any restrictions on co-pay cards will result in patients losing access to necessary treatment.

Protect AIDS Drug Assistance Programs Under 340B

The 340B Drug Pricing Program is critical; it enables eligible covered entities “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services” and to expand care to clients and to support the underlying public health infrastructure that ultimately prevents new HIV infections. The Ryan White HIV/AIDS Program and STD and TB programs have the expertise, services and delivery models to successfully enroll people in care and keep them healthy. Underfunding these systems with destabilization of the 340B Drug Pricing Program will exacerbate existing structural inequities in HIV, STD, and TB care, particularly for communities of color and other disproportionately impacted populations.

Spending and discounts associated with the 340B Drug Pricing Program account for only a small share of net U.S. drug spending (\$457 billion in 2015).³¹ Total 340B Drug Pricing Program spending in 2015 was \$12 billion (2.6 percent of net U.S. prescription drug spending) and total 340B Drug Pricing Program discount in 2015 was \$6.1 billion (1.3 percent of net spending). Approximately \$1.9 billion of the overall discount offered in 2015 was due to CPI penalties – triggered when manufacturers take price increases on outpatient prescription drugs that exceed standard inflation metrics – or because manufacturers voluntarily offered a lower price, which translates into \$4.2 billion baseline 340B discount (0.9 percent of net drug spending). 340B Drug Pricing Program discounts are 3.6 percent of total industry discounts and rebates, while negotiated health plan and PBM rebates and fees of \$57.7 billion in 2015, accounting for 33.9 percent of all rebates.

The current 340B patient definition recognizes the unique relationship that AIDS Drug Assistance Programs (ADAPs) have with their clients. We appreciate the Health Resources and Services Administration’s explicit recognition of the unique methods by which ADAPs participate in the 340B program and the categorical inclusion of ADAP clients under the patient definition. Participation in the 340B program is necessary for ADAPs to meet the needs of low-income persons living with HIV/AIDS. Otherwise, ADAPs would be forced to severely limit client enrollment – thereby jeopardizing national HIV/AIDS treatment targets to ensure individual and public health – if required to pay full price for client’s necessary medications. Any regulatory efforts to change the 340B definition must recognize the unique and differing relationships 340B-eligible

³¹ Dobson A, Murray K, DaVanzo JE. Assessing the Financial Impact of the 340B Drug Pricing Program on Drug Manufacturers. 2017 July. http://www.340bhealth.org/files/340B_Financial_Impact_7_17.pdf.

entities have with patients and the underlying legislation that governs each type of entity.

We are aware of the U.S. Government Accountability Office's review and recommendations of contract pharmacy compliance under the 340B Drug Pricing Program.³² Contract pharmacies are a critical component of assisting 340B-covered entities in meeting the needs of their patients by providing a variety of distribution methods. The requirements for subgrantee monitoring with the Ryan White HIV/AIDS Program is sufficient and we strongly discourage the implementation of any recommendations to Health and Human Services that would increase the burden on existing compliance requirements.

While the 340B Drug Pricing Program, more generally, could be strengthened to ensure hospitals are reinvesting 340B savings in care and services for those in need, safety-net hospitals play a critical role providing services that prevent and treat infectious diseases including HIV and HCV in their communities and are more commonly on the frontlines of the opioid epidemic. Therefore, we strongly caution against any administrative or legislative efforts to significantly alter the 340B Drug Pricing Program without careful consideration of the financial resources required by 340B entities to deliver high-quality, evidence-based disease services to those living with or vulnerable to HIV, HCV, and TB.

Centralize Purchasing and Price Negotiations

Federal purchasers have enormous power to negotiate prices, and the Veterans Administration and some state Medicaid programs have achieved substantial discounts. However, these negotiations are uncoordinated across the multiple drug purchasing programs, which results in disparate access to care. HHS should assess what authority exists for coordinated negotiations and what legislation may be needed to allow federal agencies to formally coordinate negotiations, strengthening existing Medicaid models and multi-agency negotiations.

While state Medicaid programs have long been able to negotiate supplemental rebates, not all states access rebates at the same level. Four states – Hawaii, New Jersey, New Mexico, and South Dakota – do not have any supplemental rebate agreements; 47 states and the District of Columbia participate in single-state (30) and/or multi-state (30) supplemental rebate agreements.³³ Further limiting the effectiveness of supplemental rebates, only 18 states have supplemental rebate agreements for drugs dispensed under Medicaid managed care organizations (MCOs). These uncoordinated

³² Government Accountability Office. Federal Oversight of Compliance at 340B Contract Pharmacies Needs Improvement. 2018 June 21. <https://www.gao.gov/assets/700/692697.pdf>.

³³ Centers for Medicare and Medicaid Services. Medicaid Pharmacy Supplemental Rebate Agreements. 2018 March. <https://www.medicaid.gov/medicaid-chip-program-information/by-topics/prescription-drugs/downloads/xxsupplemental-rebates-chart-current-qtr.pdf>.

negotiations lead to disparities in the costs of medications from state to state, ultimately resulting in disparate access to care as states limit who can access the most expensive drugs.

Federally coordinated negotiations would create baseline supplemental rebates for all states, while still allowing states to pursue additional negotiations on their own or in smaller groups. Federally-coordinated supplemental rebate negotiations for high-cost drugs would result in \$5.8 billion in savings over 10 years;³⁴ this proposal should be extended to allow for negotiations on all drugs.

Additionally, mechanisms to centralize procurement of important medicines can dually address cost and chronic stock-outs, particularly to address diseases of public health significance, including TB. For example, backbone drugs such as isoniazid (INH) have been withdrawn from the market by manufacturers because of inconsistent market concerns, leaving U.S. patients without access to drugs that are otherwise available globally.³⁵

Conversely, the Global Drug Facility (GDF), a program within the Stop TB Partnership and funded by the U.S. Agency for International Development (USAID), centralizes procurement of rigorously assessed, quality-assured TB drugs for the global market. The GDF provides substantial market stability and critical access to low-cost TB medications that are often in short supply and prone to price spikes in the U.S. The U.S. must consider methods through the expertise and leadership of the FDA to harmonize with the global supply, not only to ensure access to medicines critical to address public health threats, but also to diversify our public health arsenal with drugs that are unavailable to U.S. patients.

Recognize and Invoke Eminent Domain/March-in Rights

The patchwork of public and private systems intended to minimize the impact of high drug prices on patients and to ensure Americans have access to prevention, treatment, and curative modalities – particularly for diseases of public health significance – can fail. For example, the high prices of HCV direct acting antivirals have been prohibitive for state Medicaid programs and uninsured/underinsured patients, resulting in rationing and unethical treatment qualification requirements.³⁶ Truvada as pre-exposure prophylaxis

³⁴ President's Budget for Fiscal Year 2017, HHS FY 2017 Budget in Brief.

³⁵ Food and Drug Administration. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: Isoniazid tablets. 2018 May. https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Isoniazid+Oral+Tablets+&st=d&tab=tabs-2

³⁶ Tribble SJ. Louisiana proposes tapping a century-old patent law to cut hepatitis C drug prices. Washington Post. 2017 May 2. https://www.washingtonpost.com/national/health-science/louisiana-proposes-tapping-a-century-old-patent-law-to-cut-hepatitis-c-drug-prices/2017/05/02/fc611990-2f76-11e7-9534-00e4656c22aa_story.html?utm_term=.d0b3d057ddd0.

(PrEP), one of the most effective biomedical modalities for HIV primary prevention, remains prohibitively expensive, particularly among low-income individuals and those without health insurance.³⁷

Similarly, bedaquiline (Sirturo), the first new drug approved in 40 years for the treatment of drug-resistant tuberculosis – a disease that primarily affects uninsured or underinsured people in the U.S. – is priced out of reach for city and state public health programs (including those with access to 340B pricing) expected to absorb the costs of medicines and care for TB patients who often require extended hospitalization and treatment for up to two years to achieve cure.³⁸ As a result, TB patients are receiving treatment with more toxic and less effective medicines.

The U.S. government has statutorily defined mechanisms at its disposal to remedy access barriers to essential drugs and biologics, particularly when the market patchwork fails U.S. residents in need. One such example is compulsory licensing through 28 U.S.C. §1498, which allows the federal government the right to use patented inventions without permission, while paying the patent holder reasonable and entire compensation.³⁹

While the U.S. government has not exercised its rights under 28 U.S.C. §1498, at least not for a pharmaceutical drug or biologic, threats to invoke the statute have resulted in significant price reductions to achieve affordability and access requirements determined by the Department of Health and Human Services. In response to the 2001 anthrax threat and Bayer's reluctance to discount the price of ciprofloxacin for U.S. government stockpiles, Health and Human Services Secretary Tommy Thompson threatened to invoke 28 U.S.C. §1498, which prompted a 50 percent price reduction by Bayer.⁴⁰

There is also the government's march-in right, a provision of the Patent and Trademark Law Amendments Act (Bayh-Dole Act). The provision allows a funding government agency, either on its own or at the request of a third party, to ignore monopolistic patents and grant additional licenses to reasonable applicants.⁴¹ No federal agency has ever exercised its power to march in and license patent rights to others. In particular, the National Institutes of Health (NIH) has received six march-in petitions – including

³⁷ California HIV/AIDS Research Program. Addressing PrEP Disparities Among Young Gay and Bisexual Men in California. 2016 September. https://aplahealth.org/wp-content/uploads/2016/09/APLA_PrEP_FullReport_WEB.pdf.

³⁸ DeLuca AN, Madoori S, Kanouse J, et al. Barriers to bedaquiline use in tuberculosis programs in the United States. 22nd Annual Conference of the Union-North America Region. Chicago, Illinois; 28 February–3 March, 2018.

³⁹ Kapczynski A, Kesselheim A. Government Patent Use¹: A Legal Approach To Reducing Drug Spending. *Health Affairs*. 35(5791): 791–797. <https://www.healthaffairs.org/doi/10.1377/hlthaff.2015.1120>.

⁴⁰ *Ibid*.

⁴¹ 35 U.S. Code § 203 - March-in rights.

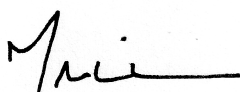
one to address a 400 percent price hike taken by Abbott Laboratories on the HIV protease inhibitor Norvir (ritonavir)⁴² – and has denied each one. Yet it remains an essential, albeit unused, safety net for combatting particularly egregious prices set for drugs, biologics, and devices.

TAG, NASTAD, and HIVMA acknowledge that both rights are contentious, yet both provide the U.S. government with considerable leverage in controlling the costs of essential medicines that remain unaffordable to Americans needing them most. HHS is duty-bound to invoke these statutes, particularly when called upon to do so by the public, where there is evidence of drug pricing as a structural barrier to critical medicines and existing market-based remedies have been exhausted.

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We conclude with appreciation for the opportunity to submit these comments and trust you will be in touch with any questions. You may do so by contacting Tim Horn by phone at 917-407-8256 or via e-mail at tim.horn@treatmentactiongroup.org.

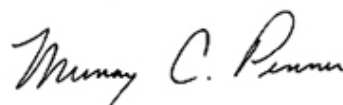
Sincerely,



Tim Horn
Deputy Executive Director
HIV & HCV Programs
Treatment Action Group
90 Broad Street, Suite 2503
New York, NY 10004



Melanie Thompson, MD
Chair
HIV Medicine Association
1300 Wilson Boulevard,
Suite 300
Arlington, VA 22209



Murray C. Penner
Executive Director
NASTAD
444 North Capitol Street,
NW, Suite 339
Washington, DC 20001

⁴² Harrison C. NIH denies march-in rights on Norvir patent. Nature Reviews. 2013 November 29. <https://www.nature.com/articles/nrd4198>