



VIA ELECTRONIC SUBMISSION

July 16, 2018

Office of the Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW, Room 600E
Washington D.C. 20101

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

Community Catalyst is a national non-profit advocacy organization dedicated to quality affordable health care for all. Since 1997, Community Catalyst has been working to build the consumer and community leadership required to transform the American health system. With the belief that this transformation will happen when consumers are fully engaged and have an organized voice, Community Catalyst works in partnership with national, state and local consumer organizations, policymakers, and foundations, providing leadership and support to change the health care system so it serves everyone – especially vulnerable members of society.

Community Catalyst respectfully submits the following comments in response to the HHS Blueprint to Lower Drug Prices and reduce Out-Of-Pocket Costs.

High drug prices are a growing concern for many Americans: One in four of those taking a prescription drug reported skipping doses or cutting pills in half due to costs. Millions of Americans with chronic conditions (such as cancer, digestive disease or mental illness) spent an additional \$1,000 or more in 2014 despite having insurance coverage.¹ One-third of Medicare patients with leukemia failed to fill prescriptions within six months of diagnosis when the cost of the life-saving drug, Gleevec, went up to \$146,000 a year.² The effects of burdensomely high drug costs are not limited to the health of individual patients. When patients abandon their prescriptions, it leads to increased costs to the health care system in the form of unnecessary

¹ Cynthia Cox, Anthony Damico, Gary Claxton and Larry Levitt. Examining High Prescription Drug Spending For People With Employer Sponsored Health Insurance. Henry J Kaiser Family Foundation. October 2016. <https://www.healthsystemtracker.org/brief/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/#item-start>

² Liz Szabo. As Drug Costs Soar, People Delay Or Skip Cancer Treatments. NPR Shots. March 15, 2017. <http://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments>

hospitalizations, emergency services, and physician visits. Escalating drug prices also strain state budgets. Between 2013 and 2014, Medicaid prescription drug spending rose more than 24 %.³ This large increase in spending creates a challenge for policymakers; with few tools available for addressing spending growth, a number of states have taken harmful measures such as cutting prescription drug benefits, imposing prescription drug copays and curtailing the use of new medicines that many people depend on.⁴

In addition, pharmaceutical manufacturers are heavily using manipulative marketing tactics to lure providers and consumers toward high-cost medications. Drug manufacturers are spending far more on marketing than research. According to a 2012 study published on BMJ, for every dollar on “basic research,” pharmaceutical companies invested \$19 toward marketing and promoting new drugs to health care professionals to influence their prescribing practices.⁵ In 2015, nearly two thirds of the top 100 pharmaceutical manufacturers by sales spent twice as much on marketing and sales than on research and development.⁶

We believe that curbing out-of-control prescription drug prices requires bold actions at the federal level. Given the control that the federal government has over both the granting of patents and the flow of research dollars, and its role as a purchaser of prescription drugs, the federal government has multiple tools that it can currently use or strengthen to prevent drug corporations from launching new drugs at extortionately high price points or increasing the price of older drugs year after year far in excess of any increase in the cost of production.

We concur with HHS that there are multiple dimensions to the prescription drug cost challenge, but while there are a number of useful proposals in the Blueprint, we believe that it errs in its description of the problem in some important respects. Additionally, we believe it bypasses effective actions in favor of policies that are unlikely to have much impact or worse, to cause harm to consumers.

With respect to problem definition, the Blueprint identifies a number of challenges—specifically high list prices, lack of negotiation tools for Medicare/ Medicaid, high and rising out-of-pocket costs and foreign government “free-riding.” In our view, several of these challenges stem from the same underlying cause which is largely neglected in the Blueprint— *the excessive monopoly power over drug pricing held by pharmaceutical companies*. This is the fundamental cause of unconscionably high drug prices in the United States. In addition, we believe that the focus in the Blueprint on the actions of other countries is misguided. There is no reason to believe that higher prices in other countries will result in lower prices in the U.S. Instead, the most likely effect of U.S. actions to force drug prices up in other countries would be windfall profits for the drug

³ Medicaid and CHIP Payment and Access Commission (MACPAC). Medicaid Spending for Prescription Drugs. MACPAC. January 2016. <https://www.macpac.gov/wp-content/uploads/2016/01/MedicaidSpending-for-Prescription-Drugs.pdf>

⁴ The Kaiser Family Foundation. State Health Facts: Medicaid Benefits: Prescription Drugs. 2012. <https://www.kff.org/medicaid/state-indicator/prescription-drugs/>

⁵ Donald W Light, professor 1, Joel R Lexchin. Pharmaceutical Research And Development: What Do We Get For All That Money? BMJ 2012; 345:e4348. <https://doi.org/10.1136/bmj.e4348>

⁶ Institute for Health and Socio-Economic Policy. The R&D Smokescreen: The Prioritization of Marketing & Sales in the Pharmaceutical Industry. October 2016. http://nurses.3cdn.net/e74ab9a3e937fe5646_afm6bh0u9.pdf

industry. Our problem is not that other countries bargain aggressively over drug prices; it is our own failure to curb or counterbalance the monopoly power of pharmaceutical manufacturers with a strong coordinated purchasing strategy.

Below we lay out a set of interventions that we believe are most likely to be effective with respect to high drug costs. These recommendations are discussed in greater detail in our recent paper “[Addressing Out of Control Prescription Drug Prices: Federal and State Strategies.](#)”

We strongly urge HHS to work with Congress on solutions that:

- (1) Curtail the monopoly power of drug corporations;**
- (2) End the manipulative practices of the drug industry that discourage and delay competition; and**
- (3) Prevent misleading marketing to consumers and providers and include measures to provide unbiased information to physicians to help them prescribe safely and cost-effectively.**

Additionally, we urge HHS to strengthen, not undermine the Medicaid Drug Rebate Programs (MDRP)—which is proven to be successful in significantly reducing state Medicaid prescription drug costs while ensuring access to needed prescription drugs for low-income individuals and family.

To that end, we would like to draw attention to the following measures:

To reduce pharmaceutical monopoly power over drug pricing HHS should take the following steps:

- *Leverage existing federal authorities under ‘March-In Rights’ ([35 U.S.C. §203](#)) and ‘Patent & Copyright’ ([28 U.S.C. §1498](#)) that allow HHS to force down prescription drug prices.* For instance, in case of supply shortage or exorbitant price hikes, HHS has the right under [35 U.S.C. §203](#) to force patent manufacturers that used taxpayers’ dollars to develop their innovations to allow drugs to enter the market at cheaper prices. HHS can also invoke the government use of patented interventions under [28 U.S.C. §1498](#) to license generic version of high-cost medications at low prices.⁷ This approach was used in the 1950s and 1960s to procure cheaper drugs.⁸
- *Work with Congress to enact legislation to shorten patent and market exclusivity periods and eliminate patent extensions.* Various federal patent laws, including the Drug Price Competition and Patent Term Restoration Act (commonly known as the Hatch-Waxman Act), the Orphan Drug Act, the Biologics Price Competition and Innovation Act, and the

⁷ Hannah Brennan, Amy Kapczynski, Christine H. Monahan, and Zain Rizvi. A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health. Yale J.L. & Tech 2016; 275(18): 275- 354. https://www.yjolt.org/sites/default/files/kapczynski_18yjolt275_gk_0_0.pdf

⁸ Katherine Young and Rachel Garfield. Snapshots of Recent State Initiatives in Medicaid Prescription Drug Cost Control. Henry J Kaiser Family Foundation. February 2018. <http://files.kff.org/attachment/Issue-Brief-Snapshots-of-Recent-State-Initiatives-in-Medicaid-Prescription-Drug-Cost-Control>

Generating Antibiotic Incentives Now Act give pharmaceutical manufacturers patents and market exclusivity rights as incentives for research and development of innovative products. Depending on the drug type, market exclusivity periods vary between five to 20 years. During the period of multiyear market protection, manufacturers of patented drugs are free to set market entry prices often at high levels and annually increase drug prices, which discourage the development of generic versions at cheaper prices.⁹ To rebalance innovation incentives and competitions, experts suggest, for instance, to grant brand-name drug manufacturers only up to seven years of market exclusivity for biologics.¹⁰ In addition, any drugs that have no demonstrated added values compared to those already on the market should have their patent rights and market exclusivity terminated.

- *Work with Congress to amend March-In Rights' (35 U.S.C. §203) to set limits on introductory prices for new innovative drugs and annual price increases for existing drugs that receive federal funding for research and development. This measure would allow the federal government to prospectively review the launch price of a drug developed with federal support.*
- *Work with Congress to eliminate the 'noninterference' clause in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 to allow Medicare to directly negotiate drug price with drug manufacturers and use reference pricing to set a benchmark price for clinically comparable drugs in Medicare. According to a 2007 analysis conducted by the Congressional Budget Office, savings for Medicare could occur if the HHS Secretary has the authority to negotiate lower prices for a broad set of drugs or drug types (including many of today's high-priced specialty drugs and biologics) on behalf of Medicare beneficiaries.¹¹ It is puzzling that this proposal is omitted from the Blueprint given the emphasis it places on the issue of public sector price negotiation and given that the idea was prominently advocated by the president during his campaign.*

To end the manipulative practices of the drug industry that discourage and delay competition, we urge HHS to take the following actions:

- *Work with Congress to enact legislation that prohibits anti-competitive practices (such as pay-for-delay, product-hopping, and authorized generics) pharmaceutical companies engage in to limit the effect of generic competitions. These anticompetitive practices cause substantial harm to consumers as they prevent affordable medications from entering the market.*

⁹ Naren P. Tallapragada. Off-Patent Drugs At Brand-Name Prices: A Puzzle For Policymakers. *Journal of Law and the Biosciences*. 2016; 3(1):238-247. doi:10.1093/jlb/lsw008

¹⁰ Aaron S. Kesselheim, MD, JD, MPH; Michael S. Sinha, MD, JD, MPH; Jerry Avorn, MD. Determinants of Market Exclusivity for Prescription Drugs in the United States. *JAMA Intern Med*. 2017;177(11):1658- 1664. doi:10.1001/jamainternmed.2017.4329

¹¹ Juliette Cubanski and Tricia Neuman. Searching for Savings in Medicare Drug Price Negotiations. Henry J Kaiser Family Foundation. April 2018. <http://files.kff.org/attachment/issue-brief-searching-for-savings-in-medicare-drug-price-negotiations>

According to the most recent available data released by the Federal Trade Commission (FTC), Americans pay \$3.5 billion more for prescription drugs each year because of pay-for-delay deals between brand-name drug manufacturers and patent challengers.¹² The FDA should be empowered to terminate market exclusivity on any product found to engage in anti-competitive practices that increase the price of drugs. HHS should:

- *Require all patent claims (including biologics) to be disclosed in the Orange Book at the time of originator drug registration—not years later when the originator is trying to block the generic manufacturers from market entry.*
- *Work with Congress to increase FTC resources to monitor, oversee and investigate drug manufacturers engaging in anticompetitive practices.*

To prevent misleading marketing to consumers and providers, HHS should work with Congress to:

- *Enact legislation that bans direct-to-consumer advertising (DTCA) or eliminates the tax deduction for DTCA. It is irresponsible to promote potentially harmful drugs or unnecessarily expensive to consumers who don't have medical knowledge to make smart decisions. The American Medical Association has called for a ban on advertising prescription drugs and medical devices directly to consumers.¹³ The U.S. and New Zealand are the only countries in which drug manufacturers can advertise prescription drugs directly to consumers. Common DTCA tactics include: providing financial assistance (e.g. copay coupons) to patients, and promoting prescription products on television, radio, print (magazines, newspapers), the Internet, and other forms of mass media (billboards and direct mailings). Research shows that providing copay coupons effectively steers patients away from lower-cost generic alternatives.¹⁴ In addition, patients are more likely to speak to their doctors about a brand-name drug if it has been promoted on television.¹⁵ HHS should work with Congress to amend the Internal Revenue Code of 1986 to eliminate the tax breaks that drug makers can take to offset their spending on ad campaigns. Savings generated from the elimination of these tax breaks should be used to fund academic detailing programs and educate consumers about how to review prescription drug ads.*

¹² Federal Trade Commission. Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions. 2010. <https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-costconsumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>

¹³ American Medical Association. AMA Calls for Ban on DTC Ads of Prescription Drugs and Medical Devices. Statement released on November 17 2015. <https://www.ama-assn.org/content/ama-calls-ban-directconsumer-advertising-prescription-drugs-and-medical-devices>

¹⁴ Leemore Dafny, Christopher Ody, Matt Schmitt. When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization. UCLA Anderson School of Management, October 4, 2016. http://www.hbs.edu/faculty/Publication%20Files/DafnyOdySchmitt_CopayCoupons_32601e45-849b-4280-9992-2c3e03bc8cc4.pdf

¹⁵ John Henning Schumann. Those TV Drug Ads Distract Us From The Medical Care We Need. NPR Shots, April 29, 2017. <https://www.npr.org/sections/health-shots/2017/04/29/525877472/those-tv-drug-adsdistract-us-from-the-medical-care-we-need>

- *Implement measures that limit or ban physician gifts from pharmaceutical companies.* A study published in JAMA in May 2018 found that doctors who received free meals and other kinds of payments from pharmaceutical companies tended to prescribe more opioid painkillers to their patients over the course of a year than those who did not get such freebies.¹⁶ The Physician Payment Sunshine provisions under the ACA require drug and medical device manufacturers to publicly report gifts and payments made to physicians and teaching hospitals. However, the law does not limit financial relationships between these entities. *We urge HHS to work with Congress to put in place policies that prohibit manufacturers from offering gifts, including “any payment, food, entertainment, travel, subscription, advance or service,” to health care professionals and other providers.*

Finally, **we strongly urge HHS to build on, improve and strengthen the existing Medicaid Drug Rebate Program (MDRP), rather than weaken it.** We are highly skeptical of claims that the MDRP increases prices for other payers and are concerned that allowing states to opt out of the MDRP would result in either higher costs or severely impede beneficiary access to needed medicines.

In our view, the Medicaid Drug Rebate Program (MDRP) has generally worked well for states, beneficiaries and manufacturers. A number of measures could improve the program while maintaining beneficiary access to needed prescription drugs.

One change that would address the largest current weakness of the MDRP would be to require an increase in the Medicaid drug rebate for new drugs with excessive launch prices. While for the most part, the MDRP works well, it does not do enough to help states afford the new and extremely expensive medicines that have recently been or will soon be introduced. Increasing the rebate percentage would not only allow states to better afford the cost of new brand-name drugs with launch prices of tens of thousands or hundreds of thousands of dollars but also help deter manufacturers from setting such high initial prices. The broader measures we recommend to reduce excessive monopoly power over pricing would of course also benefit the Medicaid program.

Additional measures that could strengthen the MDRP include:

- *Uncap total Medicaid drug rebate amounts;*
- *Increase inflation-related rebates to discourage excessive price increases;*
- *Give states full access to Medicaid pricing data on a confidential basis.* (Sharing such pricing information with states would facilitate state efforts to help the federal government ensure manufacturer compliance with the Medicaid Drug Rebate Program as well as help them negotiate larger supplemental rebates).

¹⁶ Scott E. Hadland, MD, MPH, MS; Magdalena Cerdá, DrPH, MPH; Yu Li, MD, PhD; et al Maxwell S. Krieger, BS; Brandon D. L. Marshall, PhD. Association of Pharmaceutical Industry Marketing of Opioid Products to Physicians With Subsequent Opioid Prescribing. JAMA. May 2018. doi:10.1001/jamainternmed.2018.1999

In addition, we urge the extension of the MDRP *to other federal health programs like the Children's Health Insurance Program (CHIP) and Medicare Part D*. Medicaid is doing a far better job in lowering drug costs than Medicare Part D because it is obtaining rebates that are much larger than those negotiated by private Part D insurers. The elimination of the mandatory rebate under Part D for low-income Medicare beneficiaries represented a windfall for drug manufacturers. The Congressional Budget Office estimates that imposing Medicaid-level rebates for low-income beneficiaries in Medicare Part D would produce federal savings of \$145 billion over ten years.¹⁷ The rebate program could also be extended to separate state CHIP programs, which would lower federal and state costs.

Thank you again for the opportunity to provide input on this important topic. Please do not hesitate to contact us at qnguyen@communitycatalyst.org should you have any questions or if you would like additional information.

Respectfully submitted,



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¹⁷ Congressional Budget Office, "Options for Reducing the Deficit: 2017 to 2026," December 2016, <https://www.cbo.gov/publication/52142>.