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December 16, 2019

The Honorable Diana DeGette
Chair
Oversight and Investigations Subcommittee
Committee on Energy and Commerce
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
Member
Committee on Energy and Commerce
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Dear Representatives DeGette and Upton:

Public Citizen, a consumer advocacy organization with more than 500,000 members and supporters nationwide, is writing in response to your solicitation of proposals for health care-related reforms to be considered for inclusion in potential future Cures 2.0 legislation. We urge you to include in any such legislation the following proposals to improve patient safety and expand access to medicines by lowering prescription drug prices. Furthermore, it is imperative that any such legislation exclude expanded monopoly protections that keep prices higher for longer and inhibit access to medicines.

Faster safety updates for generic drug product labeling

Since 1985, generic drug sales have grown dramatically. Approximately 90% of prescriptions now are filled with generic versions, and many drugs are sold only as generics. New safety issues commonly arise after generic versions have entered the market, underscoring the imperative of maintaining incentives for robust manufacturer surveillance of safety concerns throughout the life of a drug product.

The Food and Drug Administration (FDA) currently does not allow generic drug manufacturers to initiate safety updates to product labeling when they become aware of new risks, although brand-name manufacturers have long had that ability and responsibility. Although the FDA in 2013 proposed a new rule to correct this safety gap,¹ the rule was not finalized and was later withdrawn by the current administration.

Public Citizen urges you to include in any Cures 2.0 legislation a provision requiring the FDA to re-propose, not later than three months after the date of enactment of the legislation, and promptly finalize, not later than 12 months after the date of enactment of the legislation, a rule allowing generic drug manufacturers to update product labeling promptly to reflect certain types of newly acquired information related to drug safety, irrespective of whether the revised labeling differs from that of the reference listed drug, in advance of the FDA's review of the changes through a "changes being effected" (CBE-0) supplement.

¹ 78 FR 67985.

Restore the right of patients to sue for injuries caused by defective high-risk medical devices

A Supreme Court decision in 2008, *Riegel v. Medtronic*, held that the existing law preempts the right of a patient to bring damages claims against medical device manufacturers for injuries caused by high-risk medical devices marketed pursuant to a premarket approval application. This decision ended over 30 years in which federal and state laws had worked hand in hand to strengthen device safety. Several bills have been introduced to override the *Riegel* ruling, including the Medical Device Safety Act of 2009 (S. 3398, H.R. 1346) championed by Sen. Ted Kennedy, Sen. Patrick Leahy and Rep. Frank Pallone. More recently, injuries linked to the Essure female sterilization device prompted Rep. Mike Fitzpatrick to introduce a bill with identical language in 2016, this time titled Ariel Grace's Law (HR 5403).

Public Citizen urges you to include in any Cures 2.0 legislation a provision restoring the ability of patients injured by high-risk medical devices to bring state-law damages actions against device manufacturers. (See Appendix A for suggested statutory text.)

Provide mandatory drug recall authority

The FDA can require manufacturers to recall medical devices, biological products, tobacco, infant formula, and food. Yet shockingly, when it comes to drugs, the FDA can only ask a drug producer to issue a recall voluntarily. A provision granting the FDA mandatory drug recall authority was introduced in the Drug Safety and Accountability Act of 2010 (S.3690) but did not pass. Since that time, in several cases, the FDA has requested that sterile drug producers voluntarily recall their products after inspections revealed substandard manufacturing conditions that could lead to contamination, but the companies involved refused to issue recalls. These drug producers included traditional compounding pharmacies, outsourcing facilities engaged in the production of sterile compounded drugs, and manufacturers of homeopathic drug products.

Public Citizen urges you to include in any Cures 2.0 legislation a provision closing this dangerous loophole and giving the FDA authority to order recalls of drugs, such as the Recall Unsafe Drugs Act of 2017 (H.R. 1108), which was introduced by Rep. Rosa DeLauro.

End the FDA's dangerous use of enforcement discretion for pharmacy compounding by outsourcing facilities

Section 503B of the Federal Food, Drug, and Cosmetic Act (FDCA), which was enacted under the Drug Quality and Security Act (DQSA) in 2013, stipulates the conditions that must be satisfied for human drug products compounded by an outsourcing facility to be exempt from the FDCA requirements concerning (a) the approval of drugs under new drug applications or abbreviated new drug applications, (b) the labeling of drugs with adequate directions for use, and (c) drug supply chain security.

One of the conditions that must be met for a drug product compounded by an outsourcing facility to qualify for exemptions under section 503B is that the outsourcing facility may not compound a drug using a bulk drug substance unless (a) the bulk drug substance appears on a list established by the Secretary of Health and Human Services identifying bulk drug substances

for which there is a clinical need (hereafter, the 503B Bulks List) or (b) the drug compounded from such bulk drug substances appears on the drug shortage list in effect under section 506E of the FDCA at the time of compounding, distribution, and dispensing.

Disturbingly, more than six years after the DQSA was enacted, the FDA has not yet placed any bulk drug substance on the 503B Bulks List. Instead, the agency in January 2017 issued a guidance document, entitled “Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act.”² Under this guidance, outsourcing facilities are permitted to compound drugs using bulk drug substances that have been nominated for inclusion on the 503B Bulks List with *sufficient information* for the FDA to evaluate them but have not yet been evaluated by the agency. The list of such nominated bulk drug substances currently includes approximately 260 drugs. Importantly, for many of the nominated bulk drug substances, there are FDA-approved versions of the drugs on the market.

Moreover, the list of nominated bulk drug substances with sufficient information for the FDA to evaluate is likely to grow, given that several hundred additional bulk drug substances were nominated with information deemed by the FDA to be *insufficient* for evaluation, but the agency has invited nominators to resubmit additional information.

On August 28, 2018, the FDA published a notice in the *Federal Register* proposing *not* to include bumetanide, nicardipine hydrochloride, and vasopressin on the 503B Bulks List.³ The agency noted that each of these nominated bulk drug substances is a component of one or more FDA-approved drug products and that the nominators failed to demonstrate that there was a clinical need for outsourcing facilities to compound drug products using these bulk drug substances. On March 1, 2019, the FDA issued a 503B Bulks List document stating that the agency had not placed any bulk drug substance on the 503B Bulks List and that it had evaluated the nominations for nicardipine hydrochloride and vasopressin and decided not to include them on the list.⁴ Action on bumetanide is pending.

On September 3, 2019, the FDA published a notice in the *Federal Register* proposing *not* to include dipyrindamole, ephedrine sulfate, famotidine, hydralazine hydrochloride, methacholine chloride, sodium bicarbonate, sodium tetradecyl sulfate, trypan blue, and vecuronium bromide on the 503B Bulks List.⁵ The FDA noted that each of these nine nominated bulk drug substances is a component of one or more FDA-approved drug products. The agency also determined that in each case, the nominators failed to identify an attribute of the corresponding FDA-approved drug(s) that makes them unsuitable to treat certain patients and that the proposed compounded drug products are intended to address. FDA action on these nine bulk drug substances is pending.

The FDA repeatedly has noted that compounded drugs pose a higher risk to patients than FDA-approved drugs. The agency reaffirmed that position in its September 3, 2019, notice by emphasizing that compounded drugs produced by outsourcing facilities have not undergone

² <https://www.fda.gov/media/94402/download>.

³ 83 FR 43877.

⁴ <https://www.fda.gov/media/120692/download>

⁵ 84 FR 46014.

FDA premarket review for safety, effectiveness, and quality. In addition, these drugs have not been determined to be safe or effective for conditions of use reflected in drug product labeling and lack a premarket inspection for ensuring manufacturing quality. We agree with the FDA that because compounded drug products are subject to a lower regulatory standard than FDA-approved drug products, they should be used only by patients whose medical needs cannot be met by an FDA-approved drug product.

It is readily apparent that the basis for nominating many bulk drug substances for inclusion on the 503B Bulks List was not to ensure that unmet clinical needs are satisfied but rather to meet the commercial goals of the nominators.

There is no dispute that (a) compounded drugs pose a higher risk to patients than FDA-approved drugs; (b) the FDA has evaluated only a small fraction of the bulk drug substances nominated for inclusion on the 503B Bulks List and taken action on only two; and (c) for every nominated bulk drug substance that the agency has evaluated so far, the agency concluded that the bulk drug substance should not be placed on the 503B Bulks List. Thus, maintaining the FDA's January 2017 Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act is indefensible, reckless, and a threat to public health. It is unacceptable for the FDA to allow outsourcing facilities to continue compounding drugs using the approximately 260 bulk drug substances that were nominated with sufficient information for the FDA to evaluate them but have not yet either been included on or excluded from the 503B Bulks List.

Public Citizen urges you to include in any Cures 2.0 legislation a provision requiring the FDA, not later than six months after the date of the enactment of the legislation, to rescind the agency's January 2017 interim policy, begin enforcing all requirements of 503B, and not allow outsourcing facilities to produce drugs from bulk drug substances unless those substances appear on either the 503B Bulks List or the agency's drug shortage list.

Require FDA development and implementation of a new opioid-specific regulatory framework

In March 2016, to better understand the ongoing opioid crisis and to determine whether specific new actions by the agency were required to protect the public health, the FDA, headed by then-FDA Commissioner Robert Califf, commissioned the National Academies of Sciences, Engineering, and Medicine (the National Academies) to convene an ad hoc committee of experts to, among other things, review the current status of FDA opioid regulation and to suggest improvements in it. Among the areas of focus in the FDA's charge to the committee, which was named the Committee on Pain Management and Regulatory Strategies to Address Prescription Opioid Abuse, was input on "How to **formally** incorporate the broader public health impact of opioid abuse in future FDA approval decisions regarding opioids" [emphasis in original] and the "public health consequences of any actions [the FDA] take(s) or could take with regard to opioid misuse, abuse, overdose, and death."⁶

⁶<http://www.nationalacademies.org/hmd/~media/Files/Activity%20Files/PublicHealth/PainResearch/FDA%20slides%207-6-2016.pdf>. Slide 21

A comprehensive effort was undertaken by the National Academies, including engagement with many outside experts in the fields of public health, pharmacology, law, pharmacoepidemiology, and addiction medicine. This effort resulted in a report issued 29 months ago (July 2017) by the National Academies, with the major finding explicitly being that the FDA had failed to adequately “incorporate public health considerations into opioid-related regulatory decisions.” The National Academies therefore recommended many specific changes, compatible with the agency’s existing statutory authority, to be incorporated into a new FDA framework for opioid regulation that would address the agency’s long-standing deficiencies in this process.

To date, the only tangible action taken by the FDA in response to the National Academies’ recommendations was issuing on June 21, 2019, a draft guidance for industry entitled “Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework.”⁷ The draft guidance overall was woefully inadequate because its cursory content is far more focused on the nonspecific, generalized factors that the FDA itself will consider when reviewing a new drug application (NDA) for an opioid, rather than providing industry with guidance as to what specific benefit and risk information needed to be sought out and included in future NDAs for opioids.

Had the FDA acted with the urgency demanded by the ongoing opioid crisis and begun the important public process of developing a desperately needed improved opioid regulatory framework soon after it received the detailed, carefully considered National Academies’ recommendations more than two years ago, it is likely that the process of creating this framework would have been completed by now, rather than just beginning.

Public Citizen urges you to include in any Cures 2.0 legislation a provision requiring the FDA, not later than six months after the date of the enactment of the legislation, to implement a new framework for opioid regulation based on the National Academies’ 2017 recommendations.

Improve the utility of the National Practitioner Data Bank to better protect patients from dangerous doctors, dentists, and other health care practitioners

The National Practitioner Data Bank (NPDB) was authorized by the Health Care Quality Improvement Act of 1986 and began operation on September 1, 1990, after publication of implementing regulations and creation of the NPDB’s computer system. The NPDB plays a central role in ensuring patient safety by providing the most comprehensive, reliable information concerning the malpractice payment and disciplinary history of physicians, dentists, and other health care practitioners to licensing boards, credentialing authorities, peer reviewers, and other users. The purpose of the NPDB is to reduce the likelihood that doctors and other health care practitioners disciplined by state licensing boards, hospitals, or other health care organizations might continue to injure patients by relocating to another state or hospital where their reputations and track records are unknown.

We have two suggestions for important improvements to the NPDB.

⁷ <https://www.regulations.gov/document?D=FDA-2019-D-1536-0002>.

First, state licensing boards can query the NPDB for the doctors and dentists to whom they have granted licensure or who are applying for licensure. Currently the cost of performing a one-time query for each query submitted is \$2.00. Similarly, the cost of a one-year “Continuous Query” per practitioner is \$2.00. Enrollment in Continuous Query allows a state licensing board to be notified by email within 24 hours of any new report received by the NPDB regarding a licensed practitioner.

However, because of the query cost, most state medical boards do not routinely query the NPDB either on an ad hoc basis or by enrollment in Continuous Query. According to a *USA Today/Milwaukee Journal Sentinel* investigation, 30 of the nation’s state medical boards each checked the NPDB fewer than 100 times in 2017.⁸ Furthermore, the report noted that more than 500 physicians who had had problems in one jurisdiction were allowed to practice in another.

Making NPDB Continuous Query free for all state licensing boards and requiring all states to participate in this service would result in state licensing boards always having the most up-to-date information that is needed to protect the public from dangerous or miscreant practitioners.

The NPDB also would benefit by being able to compile a single unified list of all practitioners and where they are licensed to practice based on the Continuous Query registration information received from the states.

Public Citizen urges you to include in any Cures 2.0 legislation a provision eliminating all fees for state licensing board enrollment in NPDB Continuous Query and requiring such enrollment.

Second, among the events that must be reported to the NPDB are malpractice payments made on behalf of individual practitioners. But the current NPDB regulations allow for what is commonly referred to as the “corporate shield” loophole. Use of this loophole involves a practice where a medical malpractice victim agrees to dismiss a defendant health care practitioner from a malpractice lawsuit or claim — usually as part of settlement negotiations — thereby leaving or substituting a hospital or other corporate entity as a defendant. Such dismissals often occur in response to a request from attorneys of a self-insured hospital or other corporate entity that employs the defendant health care practitioner. The loophole is used, at least in part, for the purpose of allowing the practitioner to avoid having a report of a malpractice payment made on his or her behalf submitted to the NPDB.

The Health Resources and Services Administration (HRSA) — the agency that operates the NPDB — itself noted in a December 24, 1998, proposed rule intended to close the corporate shield loophole that the loophole “makes it possible for practitioners whose negligent or substandard care has resulted in compensable injury to patients to evade having that fact appear in the [NPDB].” That proposed rule was subsequently withdrawn a year later.

Evidence suggests that the corporate shield loophole is used more frequently today than it was in 1998 when HRSA first sought to close the loophole. Since then, the percentage of physicians who are employed by hospitals and other corporate entities (as opposed to those who are in

⁸ <https://www.jsonline.com/story/news/investigations/2018/03/07/theres-tool-help-states-find-problem-doctors-why-do-so-few-use/400723002/>.

private practice) has increased markedly.⁹ Therefore, the number of doctors who are potentially shielded from reporting by the loophole has increased. Meanwhile, the number of malpractice payments made on behalf of physicians reported to the NPDB has steadily fallen for the past decade. Although tort reform has played a role in this decline, use of the corporate shield loophole also has contributed to this trend. The result has been a reduction in the comprehensiveness of malpractice payment data reported to the NPDB and therefore in the usefulness of the NPDB.

Public Citizen urges you to include in any Cures 2.0 legislation a provision eliminating the “corporate shield” loophole in the requirement for reporting of medical malpractice payments made on behalf of practitioners to the NPDB. This could be accomplished most effectively by requiring the revisions to the Department of Health and Human Services regulations at 45 C.F.R. § 60.7. (See Appendix B for suggested statutory text.)

Expand access to medicines by lowering prescription drug prices

The unfettered monopoly power and greed of the pharmaceutical industry has brought about an affordable medicines crisis in the U.S. Nearly three-in-ten adults in the U.S. report not taking a medicine as prescribed because of the cost, including by not filling a prescription, taking an inappropriate alternative treatment, cutting pills in half, or skipping doses.¹⁰

Ever-increasing launch prices of new drugs and routine price hikes on existing medicines are the key drivers of the pharmaceutical industry’s price gouging. Drug companies have increased the launch prices of new cancer medications by more than 10% annually,¹¹ with the average price of new cancer medicines now at a staggering \$149,000.¹² Hiking prices on existing drugs has become a standard feature of pharmaceutical corporations’ business model.¹³ For the 45 top-selling drugs, more than half of all sales growth in the past three years was due to price increases.¹⁴ Industry analysts project that by 2024 Americans will spend \$38.3 billion on just five drugs alone.¹⁵

It is imperative that Congress pass a bold set of legislative solutions to provide relief that people around the country need.

Public Citizen therefore urges you to include in any Cures 2.0 legislation a comprehensive set of policy solutions to expand access to affordable medicines by lowering prescription drug prices.

⁹ <http://www.amednews.com/article/20121119/business/311199971/2/>.

¹⁰ A. Kirzinger, L. Lopes, B. Wu, M. Brodie. (March 1, 2019). KFF Health Tracking Poll – February 2019: Prescription Drugs. The Henry J. Kaiser Family Foundation. <https://tinyurl.com/y289gncj>.

¹¹ D.H. Howard, P.B. Bach, E.R. Berndt, R.M. Conti. (January 2015). Pricing in the Market for Anticancer Drugs. National Bureau of Economic Research. <https://tinyurl.com/y6esh77a>.

¹² IQVIA. (May 30, 2019). Global Oncology Trends. <https://tinyurl.com/y5wy5rw3>.

¹³ L.A. Johnson, N. Forster. (September 24, 2018) AP Investigation: Drug prices going up despite Trump promise. Associated Press. <https://tinyurl.com/y2mkzyxq>.

¹⁴ Between 2014 and 2017, U.S. sales for 45 leading products increased by about \$23 billion. \$14 billion of that increase was attributable to price increases. See: Price increases on top drugs drove majority of recent growth, analysis finds, BioPharma Dive (2018), <https://tinyurl.com/y2tyos5o>.

¹⁵ EvaluatePharma. (June 2019). World Preview 2019, Outlook to 2024. <https://tinyurl.com/y2lh2e7q>.

Taken together, comprehensive drug pricing reform must increase government negotiating power, stop price hikes, and curb monopoly abuses.¹⁶ Please see Appendix C for more detailed proposals.

Exclude any measures providing for new monopoly protections that keep prescription drug prices higher for longer and impede access to medicines

Government-granted monopolies, in the form of patent protections provided by the Patent and Trademark Office and data and marketing exclusivity protections provided by the FDA, enable prescription drug corporations to charge exorbitant and often unaffordable prices for medicines that people need. Expansion of monopoly protections would further exacerbate our medicines affordability crisis.

The initial version of the 21st Century Cures Act, as introduced, included language that would have provided an additional six months of marketing exclusivity for all uses of a drug when that drug receives FDA approval for a new orphan indication. That provision, also introduced in 2017 as standalone legislation as the OPEN Act, would have been ripe for abuse, and if enacted, would have cost consumers and taxpayers billions of dollars.¹⁷

More recently, policymakers have proposed the REVAMP Act, which would provide a transferable exclusivity voucher as a new incentive for antibiotic drug development. A prescription drug corporation would be able to use such a voucher to extend the monopoly period for one of their products for as much as a year. A single voucher, if used to extend a monopoly on a blockbuster medicine, could cost taxpayers and consumers several billion dollars.

Public Citizen therefore urges you to exclude from any Cures 2.0 legislation measures that would further exacerbate our access to medicines crisis by expanding monopoly privileges granted by the government to prescription drug corporations.

Thank you for the opportunity to offer these health care-related reform proposals and concerns for consideration during the drafting of any future Cures 2.0 legislation.

Sincerely,



Michael Carome, M.D.
Director
Public Citizen's Health Research Group



Steven Knievel
Advocate
Public Citizen's Access to Medicines Program

¹⁶ For more information on the industry model, see Public Citizen (Aug. 7 2019). Pharma 101: A Primer. <https://tinyurl.com/y3hs8hgw>.

¹⁷ <https://www.citizen.org/wp-content/uploads/2289.pdf>

Appendix A

The Medical Device Safety Act of 2017

A BILL

To amend the Federal Food, Drug, and Cosmetic Act with respect to liability under State and local requirements respecting devices.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SEC. 1. SHORT TITLE.

This Act may be cited as the “The Medical Device Safety Act of 2017.”

SEC. 2. LIABILITY UNDER STATE AND LOCAL REQUIREMENTS RESPECTING DEVICES.

(a) AMENDMENT.—Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) is amended by adding at the end the following:

“(c) NO EFFECT ON LIABILITY UNDER STATE LAW.—Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.”.

(b) EFFECTIVE DATE; APPLICABILITY.—The amendment made by subsection (a) shall—

(1) take effect as if included in the enactment of the Medical Device Amendments of 1976 (Public Law 94–295); and

(2) apply to any civil action pending or filed on or after the date of enactment of this Act.

Appendix B

Proposed Revisions to Department of Health and Human Services regulations at 45 C.F.R. § 60.7 that Would Close the “Corporate Shield” Loophole¹⁸

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a physician, dentist or other health care practitioner in settlement (or partial settlement) of, or in satisfaction ~~in whole or in part~~ of a claim or a judgment against such physician, dentist, or other health care practitioner for in, a medical malpractice, ~~must~~ action or claim shall report information respecting the payment and circumstances thereof, as set forth in paragraph (b) of this section, to the Data Bank and to the appropriate State licensing board(s) in the State in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a “payment” and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information:

(1) With respect to the physician, dentist, or other health care practitioner for whose benefit the payment is made, including each practitioner whose acts or omissions were the basis of the action or claim— ...

¹⁸ Proposed additions are underlined and proposed deletions are in strikeout.

Appendix C

Proposed Legislative Solutions to Expand Access to Medicines by Lowering Prescription Drug Prices

1) Stop Pharmaceutical Companies from Setting Prices as High as They Want

Prescription drug prices are higher in the U.S. than other wealthy countries because, unlike nearly every other country, the U.S. allows drug companies to set prices.¹⁹ Conversely, other countries regulate prices through negotiations or decide what companies may charge through other means, such as international reference pricing. Key features of a U.S. drug pricing system should include making government negotiations or pricing determinations available for all branded drugs, and for such prices to be enforced through a strong backstop authority when pharma refuses to offer fair prices. A well-designed backstop will ensure patient access, strongly deter noncompliance, and be impervious to pharma tricks.

- Require the Department of Health and Human Services to negotiate directly with pharmaceutical companies to obtain fair prices or administratively determine fair prices.
- Assess whether a fair price has been obtained based on—
 - therapeutic benefit, including whether the product provides a significant improvement in health outcomes over existing therapies;
 - prices paid in other large, wealthy countries;
 - research and development costs associated with bringing the drug to market;
 - public support of research and development, including grants and tax credits;
 - the impacts of the price on health program spending and budgets;
 - the impacts of the price on patients' access and finances; and
 - the extent to which the manufacturer has obtained or is expected to obtain a reasonable return on its investment through global sales of the drug.
- If a company refuses to sell the drug at a fair price, issue open licenses on patent and clinical data to allow competition.
- Claw back revenues derived from excessive pricing prior to the establishment of the fair price.
- (option) In addition to the fair pricing assessment above, consider the price of a drug in excess of the price paid by other large, wealthy countries to be *de facto* unfair.
- (option) Begin with Medicare Part D, under which the government is currently forbidden from engaging in direct price negotiations or administrative pricing determinations, before expanding the system to the entire U.S. prescription drug market.

Many of the reform proposals listed above are included in The Medicare Negotiation and Competitive Licensing Act (H.R. 1046, S. 377), sponsored by Rep. Lloyd Doggett and Sen.

¹⁹ Aaron Kesselheim et al. (2016). The High Cost of Prescription Drugs in the United States, 316 JAMA 858. <https://tinyurl.com/yx9gmcaak>.

Sherrod Brown; The Prescription Drug Price Relief Act (H.R. 465, S. 102), sponsored by Rep. Ro Khanna and Sen. Bernie Sanders; and The Prescription Drug Affordability and Access Act, sponsored by Sen. Cory Booker.

2) Penalize Prescription Drug Price Spikes

Drug companies routinely spike prices on old medicines without providing any meaningful therapeutic improvement, simply because they can. Unless strict limitations are placed on price increases that prevent drug companies from profiting off this behavior, they will continue to price gouge consumers.

- Impose a 100 percent excise tax equivalent to the amount by which the price of a prescription drug is increased beyond the rate of general inflation multiplied by all U.S. sales of the drug.
- Assess the tax based on price increases over annual and multi-year periods so companies cannot benefit in future years from price spikes in prior years.
- (option) The tax could begin at 50% for smaller price spikes and increase to 100% for price spikes above a higher threshold.

The proposals outlined above are included in the Stop Price Gouging Act (H.R. 1093, S. 378), sponsored by Rep. Mark Pocan and Sen. Brown.

3) Curb Monopoly Power and Gaming

Pharmaceutical companies' ability to price gouge consumers is derived from government-granted patent and other monopoly privileges, which they often abuse to charge U.S. consumers higher prices than those in other high-income countries that better regulate price. Facilitating competition by putting in place safeguards to limit the exploitation of government-granted monopolies, better structuring rules so companies cannot inappropriately extend monopoly privileges, and curbing their abuse are core components of reform.

- Require a fair return on public investment by establishing statutory requirements for government agencies to license generic competition through exercising march-in rights when drug companies charge U.S. consumers more than those in other large, wealthy countries.
- Reduce the biologic marketing exclusivity term to five years to help spur earlier biosimilar competition. This proposal has been offered by Rep. Jan Schakowsky in the PRICED Act (H.R. 3379).
- Raise the bar on granting patents so only truly new biopharmaceutical inventions qualify and drug companies can no longer "evergreen" their patent exclusivity terms, extending monopoly terms without providing corresponding improvements in therapeutic value.
- Define the creation of patent thickets through filing excessive and redundant patent applications to prevent competition as anticompetitive and provide the Federal Trade Commission (FTC) sufficient resources for aggressive enforcement.

- Define product hopping, wherein a company introduces a follow-on product with no significant therapeutic benefit over its predecessor in order to stymie competition, as anticompetitive and provide the FTC sufficient resources for aggressive enforcement. This proposal is included in the Affordable Prescriptions for Patients Act (S. 1416), sponsored by Sen. John Cornyn, and the Affordable Prescriptions for Patients Through Promoting Competition Act (H.R. 5133), sponsored by Rep. David Cicilline.
- Establish a private right of action for generic and biosimilar firms to sue branded drug companies when they refuse to provide samples necessary for bioequivalency and biosimilarity studies necessary for a potential competitor to receive marketing approval. This proposal is included in the CREATES Act (S. 340, H.R. 965), sponsored by Sen. Patrick Leahy and Rep. Cicilline.
- Make pay-for-delay patent settlement deals that delay generic and biosimilar competition presumptively anticompetitive and provide the FTC sufficient resources for aggressive enforcement. This proposal is included in the Preserve Access to Affordable Generics and Biosimilars Act (S. 64, H.R. 2375), sponsored by Sen. Amy Klobuchar and Rep. Jerry Nadler.