Public Citizen Written Comments RE: FDA Public Meeting: “Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access”

Public Citizen is a national consumer advocacy organization with more than 400,000 members and supporters. We advocate in an array of issue areas to advance the public interest, including ensuring prescription drugs meet high safety and efficacy standards and are made more affordable both in the U.S. and abroad.

When Congress passed Hatch-Waxman into law in 1984, it attempted to strike a balance between providing incentive for biomedical innovation and ensuring that patients have access to the medicines they need. Today, our country lacks that balance. The Department of Health and Human Services (HHS) projected that in 2017 we will spend $500 billion on prescription drugs, approaching 17% of all personal health care spending.\(^1\) Drug spending represents 19% of health spending in employer health insurance plans, not much less than the 23% employers spend on inpatient hospital care (which itself includes spending on prescription drugs administered in hospital inpatient settings).\(^2\) Per capita spending on prescription drugs exceeds that in every other country in the world, including after accounting for rebates and discounts.\(^3\) High U.S. spending on prescription drugs is largely driven by drug companies raising prices on brand-name drugs.\(^4\)

High prices charged by prescription drug companies not only drive up the spending of our health programs, but also place heavy financial burdens on consumers and result in detrimental health outcomes. For example, drug companies now regularly price cancer drugs at more than $10,000 per month.\(^5\) High costs of cancer treatments result in cancer patients being 2.65 times more likely to go

\(^4\) Ibid.
bankrupt than people without cancer.⁶ Beyond the direct financial impacts of such hardship, a subsequent study found that cancer patients who file for bankruptcy are at 1.79 times higher risk of mortality than cancer patients that do not file for bankruptcy.⁷

In a recent cross-sectional analysis of a survey in 11 developed countries, the United States ranked worst on cost-related non-adherence (CRNA) – when patients report either not filling a prescription or skipping doses because of out-of-pocket costs.⁸ The study placed CRNA at 16.8% in the U.S.; for Americans with below-average income, CRNA reached 24.9%; for Americans in the 55-64 age group, CRNA reached 22.2%.⁹

These data points and countless others show that our country is in desperate need of strong action to lower prescription drug prices and expand access to medicines. While there are remedies under existing law that agencies can take to lower prescription drug prices and expand access to medicine, the nature of the problem requires robust legislative reform. In our view, the root problem of high U.S. drug prices is the monopoly power of the pharmaceutical industry. Government-granted monopolies provide incentive for prescription drug corporations to engage in a range of abusive behaviors, from fraudulent reimbursement schemes and price gouging, to efforts to inappropriately extend monopolies through evergreening, Risk Evaluation and Mitigation Strategy (REMS) abuse and pay-for-delay deals. Restoring balance demands addressing these problems and going further, through instituting other systemic reforms to make medicines affordable and accessible.

These comments will explore a range of the issues included by the FDA in its request for comments¹⁰, including: the effects of exclusivity periods and patents, marketplace dynamics relating to drug shortages, REMS abuse, and other elements of the prescription drug market impacting innovation and access to medicines.

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⁹ Ibid.
Policymakers Should Oppose Measures that Lengthen and Strengthen Prescription Drug Monopolies

Because our nation’s medicine affordability crisis derives from the pharmaceutical industry’s monopoly power, the first step is for policymakers to stop expanding monopoly powers. For instance, the OPEN Act (S.1509, H.R.1223), which would provide a new six-month exclusivity period for all indications of a prescription drug when that drug is granted a new orphan designation, should be rejected. A 2015 Public Citizen report estimated that such an expansion of prescription drug monopolies could cost U.S. taxpayers and patients up to $11.6 billion over ten years.

In efforts to extend monopolies on high-revenue products, under such a system proposed by the OPEN Act, companies likely would focus their efforts on their most lucrative products, leading to a rush to develop orphan indications for blockbuster drugs. This has been the experience with pediatric exclusivity, which similarly provides a six-month extension of exclusivity for all indications in exchange for a study of the drug in pediatric patients. A 2013 McKinsey & Co. report found that the benefits of pediatric exclusivity have “skewed heavily toward blockbuster treatments,” with the top 10 drugs accruing 75% of incremental revenue from pediatric exclusivity.

This proposal comes at a time when by all metrics tracked by FDA Law Blog, not only is there not a shortage in orphan drug development, but it is booming. In 2016, FDA experienced another record year in orphan drug designation requests, with each of the past four years being the highest on record. While there was a slight dip from 2015 to 2016, the number of orphan drug designations in each of the past four years is greater than at any other time, and the same goes for the number of orphan drug product approvals in each year from 2013 to 2016.

Moreover, existing law on orphan drug development already results in the approval of too many non-innovative, poorly tested drugs. A 2010 Institute of Medicine review found that, of the 101 orphan drugs approved from 2000 to 2009, only about a third were new molecular entities. The OPEN Act would exacerbate this trend. Public Citizen’s report on the OPEN Act highlighted that even for orphan diseases with patient populations near the 200,000-patient threshold, clinical trials have been extremely small and studies supporting orphan drug approvals are often not randomized controlled trials.

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14 Ibid.
We do not have a scarcity of orphan drug development, and the new monopoly period would increase prices and provide incentive for abuse. We are encouraged by the planned GAO study into the Orphan Drug Act. We hope that it helps to shed light on ways drug companies abuse the system to earn higher revenues at the expense of consumers without being truly innovative or developing drugs proven through rigorous safety and efficacy tests.

The 2011 America Invents Act\(^\text{15}\) resulted in some progress to address monopoly abuses by providing the public a low-cost remedy\(^\text{16}\) to overly broad patents through post-grant challenges at the U.S. Patent and Trademark Office. However, the proposed STRONGER Patents Act (S.1390)\(^\text{17}\) would reverse much of its progress. The STRONGER Patents Act would enhance the ability of prescription drug corporations to file overly broad patents, unduly limit who is allowed to challenge patents, and restrict the grounds upon which parties could challenge those patents.\(^\text{18}\) These measures would allow for longer monopolies, delay competition, keep prices higher for longer and have a chilling effect on innovation.

**Existing Tools to Remedy Monopoly Abuses and Increase Competition**

When drug corporations abuse their government-granted monopolies by price gouging consumers and taxpayer-funded government health programs, the U.S. government should exercise its existing authorities to remedy the abuse. This is especially the case when it comes to U.S. government-funded biomedical inventions. 35 U.S.C. § 203 provides federal agencies with the authority to ‘march-in’ on U.S. government-funded inventions to allow for generic competition when a patent holder fails to make a product available on reasonable terms. When U.S. taxpayers are paying more than other wealthy countries for an invention developed through taxpayer dollars, it is inherently unreasonable. When that is the case, the National Institutes of Health (NIH), the Department of Defense (DOD) and other agencies should exercise their march-in authority.

Sen. King (I-Maine) recently introduced language into the Senate Armed Services Committee report to accompany the National Defense Authorization Act for Fiscal Year 2018 (S.1519), which was approved unanimously by the full Senate Armed Services Committee:

**Licensing of federally owned medical inventions**

*The committee directs the Department of Defense (DOD) to exercise its rights under sections 209(d)(1) or 203 of title 35, United States Code, to authorize third parties to use inventions that*

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benefited from DOD funding whenever the price of a drug, vaccine, or other medical technology is higher in the United States than the median price charged in the seven largest economies that have a per capita income at least half the per capita income of the United States.

The report language directs the DOD to exercise its Bayh-Dole rights 1) to practice or have practiced on its behalf the subject invention throughout the world without the payment of royalty, or 2) to force a rights holder to license an invention that is not being made available on reasonable terms when it passes the pricing threshold defined in the directive. Public Citizen concurs with Knowledge Ecology International that by defining that threshold through large economy prices, it will be more difficult to game the system, and by limiting the reference countries to ones with per capita incomes at least half that of the United States, it will not deter efforts to lower prices in countries with lower incomes, where lower prices than those in the United States are justified.¹⁹

Public Citizen applauds Sen. King for leading this initiative as well as his colleagues on the Senate Armed Services Committee for unanimously approving this common-sense measure. But such a reasonable pricing trigger for government agencies to exercise Bayh-Dole rights should not be limited to inventions funded by the DOD. We encourage legislators to advance analogous language for other agencies that fund biomedical inventions, especially the NIH and HHS, but agencies do not need to wait and should not wait for such directives before exercising their existing authorities.

In cases of drug industry price gouging of government health programs, we urge the government to exercise its authority under 28 U.S.C. § 1498, also known as ‘government use’. Section 1498 permits the government to use a patented invention without permission of the patent holder, so long as it provides reasonable compensation.²⁰

A recent article in the Yale Journal of Law and Technology showed that the government routinely relies on exercising its authority under § 1498 to procure a wide array of patented inventions from non-patent holders, ranging from electronic passports to genetically mutated mice and fraud detection software to waste removal methods.²¹ In the 1960s, the DOD used § 1498 on numerous occasions to procure generic drugs at steep discounts.²² While the authority has not been exercised to procure medicines in recent years, in 2001, then Secretary of HHS Tommy Thompson raised the prospect of using § 1498 to procure generic ciprofloxacin; in response, Bayer cut its price of the brand-name drug in half.²³,²⁴

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²¹ Ibid.
²² Ibid.
²³ Ibid.
Earlier this year, Louisiana Secretary of Health and Human Services Rebecca Gee wrote experts to explore the viability of utilizing § 1498 to expand access to treatment for people with hepatitis C.\textsuperscript{25} Public Citizen submitted joint comments in support of that approach.\textsuperscript{26} As a result of high prescription drug prices and budget constraints, patients in Louisiana and other states are facing treatment rationing, such as requirements to get sicker before they’ll be granted access to treatment.\textsuperscript{27} From a public health perspective, this is irrational. From a moral perspective, this is unconscionable. When drug industry profiteering prevents access to lifesaving medicines, the government should use § 1498 and allow generic competition.

While the primary problems with high drug prices are rooted in the brand-name drug industry, increases in prices of generic drugs have increasingly become a problem in recent years.\textsuperscript{28} Generic industry consolidation impedes competition, increasing potential for off-patent, no-exclusivity products to face no competition, allowing for sharp price spikes. A recent paper and corresponding chart (see below) in \textit{Globalization and Health} showed that there has been a dramatic increase in mergers and acquisition deals in the generic drug industry in recent years.\textsuperscript{29}

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The authors stated, “studies analyzing increasing prices of generics and drug shortages have observed that mergers and acquisitions were often a factor associated with significant price increases, drug shortages, supply disruption, and a reduced number of competing manufacturers.”30 Relatedly, the study states, “[g]enerics with a duopoly, near-monopoly, and monopoly were associated with price increases of 29%, 59% and 116% respectively between 2008 and 2013 as compared to drugs with the highest level of competition.”31 One important finding of a working paper from the National Bureau of Economic Research on “The Landscape of US Generic Drug Markets, 2004-2016” found that for most therapeutic classes of generic drugs, market concentration among manufacturers is “very high and above Department of Justice horizontal merger guideline thresholds.”32 These findings suggest that the Federal Trade Commission (FTC) should work aggressively to prevent mergers and acquisitions in the generic industry to ensure the robust competition necessary for a well-functioning generic drug marketplace.

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30 Ibid.
31 Ibid.
Policy Proposals to Curb Monopoly Abuses, Increase Competition and Spur Innovation

Rather than expanding the monopoly power of the pharmaceutical industry through bills like the OPEN Act, legislators should seek to curb monopolistic abuses to lower medicine prices for consumers, taxpayers and government health programs while providing incentive for innovation.

**Pay-for-Delay**

Brand-name prescription drug corporations and generic firms sometimes enter into patent settlements wherein brand-name companies pay generic firms not to bring low-cost generic versions of their brand-name prescription drug product on the market for a certain period of time, also known as “pay-for-delay”. The FTC estimates that this practice costs U.S. consumers $3.5 billion in higher drug costs each year. While in recent years the FTC has been stepping up actions to stop these anticompetitive deals, the commission rightly supports legislation to end these deals. The FTC should continue to aggressively prosecute pay-for-delay deals and legislators should pass the Preserve Access to Affordable Drugs Act (S.124), introduced by Sens. Klobuchar (D-Minn.) and Grassley (R-Iowa), to help curb this anticompetitive behavior.

**REMS Abuse**

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA), which included new requirements to provide additional safeguards for use of certain high-risk prescription drugs through REMS programs. Brand-name companies at times abuse REMS programs to prevent potential competitors from attaining FDA approval for generic and biosimilar products that, once approved, would compete with the originator’s drug.

These abuses from brand-name drug companies take three forms: 1) invoking the existence of a REMS program as a rationale for denying a generic company access to a sample they require to pursue an abbreviated new drug application (ANDA), 2) attaining method patents on a REMS program itself to prevent generic firms from making use of the same REMS program as required under the FDAAA, and 3) refusing to negotiate a shared REMS with a generic firm to prevent launch of a competing generic product that is otherwise ready for FDA approval. Industry abuses of REMS inappropriately extend

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34 Ibid.

35 Ibid.


monopolies and delay competition, costing consumers and taxpayers $5.4 billion annually. Legislators should stop these abuses through bipartisan reforms like the CREATEs Act (S.974, H.R.2212) and the FAST Generics Act (H.R.2051).

**Biologic Exclusivities**

IMS Health’s recent study of biosimilars in Europe found that biosimilar competition lowers prices and increases patient access to the whole product class – even beyond the biosimilar and its reference product. Legislators should reduce the period of biologics exclusivity from 12 to seven years to help lower biologic medicine prices and improve patient access. Such legislation has been estimated by the Department of Health and Human Services to save the federal government nearly $7 billion dollars over a ten-year period, and it is reasonable to anticipate that accrual of such savings would increase in later years as more biosimilars enter the market.

To ensure a well-functioning biosimilar marketplace, in addition to reducing regulatory exclusivity periods, Congress must act to limit aggressive strategies by brand-name companies to build patent thickets which delay competition long beyond the intentions of law. A recent article in Bloomberg reads:

_In a presentation by AbbVie in October 2015, a slide titled “Broad U.S. Humira Patent Estate” detailed its strategy: patents covering every aspect of the drug’s life, from its origins to the diseases it’s approved for. The company listed 22 patents for various diseases or methods of treatment, 14 on the drug’s formulation, 24 on its manufacturing practices, and 15 “other” patents. The latest expiration date is 2034—providing more than double the protection span a drug such as Humira might normally expect. “Congress had extensive discussion about how_

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long should biologics get exclusivity before they get competition,” says Jeff Francer, general counsel at the Association for Accessible Medicines, the lobbying group formerly known as the Generic Pharmaceutical Association. “They settled at 12 years, and if you take 12 years from when Humira was approved, that brings you to 2014, so they’re now trying to get that extended to 2034.”

Fraudulent behavior
A Public Citizen analysis found that from 1991-2015, the pharmaceutical industry paid more than $35 billion dollars in civil and criminal penalties to states and the federal government. Illegal marketing, such as off-label promotion, resulted in the largest amount of penalties, while fraudulently overcharging Medicaid and other government health programs was the most common violation resulting in such payments. However, such fines and payments have not been enough to curtail the abuse. When drug corporations abuse consumers and taxpayers through fraudulent and other criminal behavior with relation to a drug, the government should stop providing the corporation with monopoly market protections for that drug. Public Citizen supports Section 304 in the Improving Access to Affordable Prescription Drugs Act (S.771, H.R.1776) which would do just that. Holding prescription drug corporation CEOs accountable for criminal behavior under their watch would also help to curb such practices.

Direct-to-Consumer Advertising
The U.S. is one of two developed countries to allow prescription drug corporations to advertise their products directly to consumers on television and other media, with industry spending more than four billion dollars on such advertisements annually. Even further, the U.S. government provides corporations with tax deductions for these advertisements. One negative consequence of Direct-to-Consumer (DTC) advertisements is the resulting higher costs paid by patients and taxpayers as drug corporations steer consumers to more expensive treatment options. Public Citizen supports Section 405 in the Improving Access to Affordable Prescription Drugs Act that would remove special tax incentives for DTC advertisements, helping to make treatment decisions more rational and provide savings to consumers and taxpayers.

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Antibiotic Prize Fund

Beyond the aforementioned proposals and other remedies to curtail monopoly abuses of the drug industry, policymakers should also pursue alternative measures to promote innovation. This is particularly the case where medical needs are unmet by current innovation incentives, such as in developing new medicines to combat the ever-increasing number of strains of bacteria resistant to current antibiotics. The Antibiotic Resistance Coalition, an international collection of civil society groups, in its declaration states, “Antibiotic resistance threatens to undermine the effectiveness of modern medicine [...] lack of effective antibiotics is a global concern with the potential to affect all humans and domesticated animals,” and “the policy frameworks for research and development are further fueling resistance without advancing innovation.”

Providing a prize fund that rewards developers of a new antibiotic, such as that proposed in Section 301 of the Improving Access to Affordable Prescription Drugs Act, provides an effective alternative to the monopoly-based framework that has failed to provide the world with “a truly new class of antibiotics for decades.” The prize fund is a market-based approach that has been endorsed by experts and lauded by proponents of delinking the costs of research and development from the prices of medicines, including most recently by the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria.

Policymakers Should Avoid False Fixes

Finally, as policymakers seek solutions, they should watch out for reforms that would have no or negligible impact, especially when they may have negative, unintended consequences. Generic drug priority review voucher (PRV) proposals represent a fundamental misunderstanding between the different ways the brand name drug market and generic drug market operate. A generic PRV program

53 Ibid.
56 Ibid.
would provide little to no incentive to induce competition for sole-source, off-patent, small-market
drugs, and would not prevent Shkreli-style price gouging or lower prices.\textsuperscript{60}

The recently-passed FDA Reauthorization Act of 2017\textsuperscript{61} includes in Sec. 808 a new 180-day exclusivity
period for so-called ‘first generics’. Such a mechanism is unlikely to achieve the stated goal of increasing
competition for otherwise uncompetitive generic markets.\textsuperscript{62} Further, the FDA has shown that dramatic
price reductions only occur when there are two or more generic competitors on the market.\textsuperscript{63}

Conclusion

These comments are by no means exhaustive in describing the nature of the problems of high
prescription drug prices in the United States or their solutions, but they include several important
elements of both. Fundamentally, Congress and the Executive Branch must work together to reduce
rather than expand drug industry monopoly power, and implement existing and proposed remedies to
monopoly abuses. We look forward to engaging further on these and other issues relating to lowering
drug prices; as well as working towards our shared goal of ensuring Americans have affordable access to
the medicines they need to lead healthy and productive lives. Thank you for the opportunity to
comment.