February 6, 2018

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, DC 20510

The Honorable Charles Schumer
Democratic Leader
United States Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Democratic Leader
U.S. House of Representatives
Washington, DC 20510

Dear Majority Leader McConnell, Leader Schumer, Speaker Ryan, and Leader Pelosi:

The undersigned organizations write to voice our strong support for the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (S. 974/H.R. 2212) and encourage Congress to pass this important, bipartisan legislation as soon as possible.

President Trump remarked in his State of the Union address that the "injustice of high drug prices [is] one of our top priorities." It is also a top priority for voters across the country, and Congress has a golden opportunity to make a real impact on prescription drug prices by passing the CREATES Act.

Each of our organizations is committed to ensuring that Americans have access to the life-enhancing and life-saving medications that they need at an affordable price. It is undisputed that the key driver of affordability in prescription drugs is competition from generics once the market exclusivity has expired on a brand-name medication. Unfortunately, manufacturers of brand name drugs often go to great lengths to stave off competition from generics in order to keep prices high.

In particular, certain companies abuse the Food and Drug Administration's (FDA) regulatory rules that allows them to use a tool designed to protect patient safety as a pretext to deny generic manufacturers the ability to purchase the samples they need to bring more affordable FDA-approved drugs to market. These actions contradict Congressional intent. Through this anti-competitive abuse, brand companies extend their monopoly pricing power, costing patients and the healthcare system an additional $5.4 billion annually.

The CREATES Act is a narrowly targeted, bipartisan, pro-competition, and market-based solution to these abuses that cost patients, job-creators, and taxpayers billions of dollars each year. The CREATES Act is a step towards restoring the balance that Congress attempted to strike in Hatch-Waxman, between providing incentive for innovation through exclusivity while providing for affordability through generic competition.

We thank the bipartisan, bicameral sponsors of this important legislation for the work that they have done to, in the words of FDA Commissioner Scott Gottlieb, "end the shenanigans" by certain brand companies, and we strongly encourage Congress to pass the CREATES Act without delay.

Sincerely,

AARP
Academy of Managed Care Pharmacy
Alliance of Community Health Plans
America's Health Insurance Plans
American College of Physicians
American Consumer Institute
American Hospital Association
American Society of Health-System Pharmacists
Anthem
Ascension
Association for Accessible Medicines
Autistic Self Advocacy Network
Blue Cross Blue Shield Association
Blue Cross Blue Shield of Arizona
Blue Cross Blue Shield of Michigan
Blue Shield of California
Campaign for Sustainable Rx Pricing
Coalition to Reduce Federal Spending
Colorado Consumer Health Initiative
CVS Health
Consumers Union
Doctors for America
Express Scripts
Families USA
Federation of American Hospitals
FreedomWorks
Greater New York Hospital Association
Healthcare Supply Chain Association
I-MAK (Initiative for Medicines, Access & Knowledge)
Kaiser Permanente
Knowledge Ecology International
National Coalition on Health Care
National Committee to Preserve Social Security and Medicare
Patients For Affordable Drugs
Pharmaceutical Care Management Association
People's Action Institute
People of Faith for Access to Medicines
Premier Healthcare Alliance

Prime Therapeutics
Public Citizen
Social Security Works
Union for Affordable Cancer Treatment
Universal Health Care Foundation of Connecticut
Vizient

ConsumersUnion®

POLICY & ACTION FROM CONSUMER REPORTS

February 7, 2018

The Honorable Paul Ryan, Speaker
The Honorable Nancy Pelosi, Minority Leader
The Honorable Greg Walden, Chairman, Committee on Energy and Commerce
The Honorable Frank Pallone, Ranking Member, Committee on Energy and Commerce
The Honorable Bob Goodlatte, Chairman, Committee on the Judiciary
The Honorable Jerrold Nadler, Ranking Member, Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

Dear Mr. Speaker, Madam Leader, Chairmen, and Ranking Members:

Consumers Union, the policy division of Consumer Reports, urges your favorable consideration, as part of the pending budget agreement, of legislation that would improve the availability of affordable generic alternatives for prescription drugs. This bipartisan legislation, the Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act, is now pending in the House as H.R. 2212. It would remove two anticompetitive roadblocks imposed by brand name drug manufacturers – one blocks access to samples that generics need for testing, and the other blocks participation by generics in FDA-required protocols for safe distribution and use.

We have long supported constructive efforts to bring down the high prices consumers pay for prescription drugs – in our advocacy work, as well as in our publications, such as our August 2016 article, "Is There a Cure for High Drug Prices?"[1] That article reported on the results of a nationally representative telephone poll, conducted by our Best Buy Drugs program, of more than 2,000 consumers who take prescription medications. Disturbingly, we found recent price hikes on a range of medications, from longtime generics used to treat common conditions such as diabetes, high blood pressure, and high cholesterol, to new treatments for diseases such as hepatitis C.

Consumers benefit significantly when more affordable generic alternatives are available for the prescription medications they need. We have long supported government efforts, including the Hatch-Waxman Act, to expedite the ability of generic alternatives to make it to market, after appropriate testing to ensure their safety and efficacy as the generic equivalents for FDA-approved drugs. And we have long been concerned by anti-competitive tactics on the part of brand-name drug makers that keep generics from making it to market as a choice for cost-conscious consumers.

[1] http://www.consumerreports.org/drugs/cure-for-high-drug-prices/.

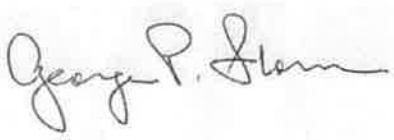
We have supported the CREATES Act since its introduction in June 2016.[2] It addresses two clearly anti-competitive tactics, both of which take unfair advantage of FDA requirements designed to ensure that medications given to American consumers are safe and effective. One tactic is to refuse to sell samples to a generic company for FDA-required testing to show that the generic product is bioequivalent to the brand-name product. The other tactic is to block participation by the generic company in FDA-required protocols for safe distribution and use, known as a Risk Evaluation Mitigation Strategy, or REMS. In both instances, a legitimate FDA safety requirement is being exploited by the brand-name drug maker to block competition, and to thereby artificially prolong its monopoly profits at the expense of consumers.

These tactics were reportedly behind Turing's astronomical post-acquisition price hike of Daraprim in 2015, for example – from $13.50 per tablet to $750. Daraprim is the best treatment for toxoplasmosis, a deadly infection to which people with compromised immune systems are particularly susceptible. For decades, this drug has been off-patent, and until recently it was widely available on ordinary distribution channels to wholesalers and retail pharmacies. But two months before the acquisition, reportedly as a condition of the deal, Daraprim was restricted to a closed pharmacy system, and obtaining samples became exceedingly difficult.

The CREATES Act gives generic drug companies a clear path to keep these competition-blocking tactics from succeeding – by giving generics a clear legal right to obtain the samples they need, and by allowing generics to establish their own safe distribution protocols.

The Congressional Budget Office has estimated that enacting the CREATES Act would save the Treasury between $3.6 and $3.8 billion over 10 years. The savings to taxpayers – and consumers – is clear. We urge you to take this opportunity to enact the CREATES Act into law – to bring greater competition into the prescription drugs marketplace, and its benefits to consumer pocketbooks.

Sincerely,



George P. Slover
Senior Policy Counsel
Consumers Union

cc: Members, Committee on Energy and Commerce
Members, Committee on the Judiciary

[2] https://www.judiciary.senate.gov/imo/media/doc/06-21-16%20Slover%20Testimony.pdf.

April 27, 2017

The Honorable Chuck Grassley
Chairman
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable Tom Marino
Judiciary Committee
United States House of Representatives
Washington, D.C. 20515

The Honorable Patrick Leahy
Committee on the Judiciary
United States Senate
Washington, D.C. 20510

The Honorable David Cicilline
Judiciary Committee
United States House of Representatives
Washington, D.C. 20515

Dear Senators Grassley and Leahy, and Representatives Marino and Cicilline:

As stakeholders firmly committed to fostering patient access to affordable medicines and pharmaceutical competition, we would like to thank you for introducing the bicameral and bipartisan Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act. The bill would provide a clear solution to abusive, anticompetitive business practices that increase costs to the American health care system by impeding patient access to generic and biosimilar medicines.

Since it was created in 2007, the Food & Drug Administration's (FDA's) Risk Evaluation and Mitigation Strategies (REMS) program has been an important tool for patient safety by ensuring that the benefits of a drug or biological product outweigh its safety risk. FDA-mandated REMS programs can, and do, serve a compelling public good by providing additional information to patients and providers. Yet some have been exploiting a loophole in the law and abusing the REMS Elements to Assure Safe Use (ETASU) requirements to prevent competition for products with and without required REMS programs.

Specifically, certain companies are employing restricted distribution networks to deny manufacturers of generics and biosimilars access to product samples they need to obtain FDA approval and market entry. Many of these restricted distribution setups are implemented completely independently from FDA mandates, and exist solely to exert control of who purchases the product. These abuses are growing and the resulting delay in generic and biosimilars competition is costing patients, the federal government, and the health care system billions of dollars annually. A July 2014 analysis by Matrix Global Advisors[1] found that abusing these restricted access programs to prevent generic competition costs the health care system $5.4 billion annually, including $1.8 billion to the federal government. Equally alarming, as companies expand this practice to biosimilars, it could result in approximately $140 million in lost savings for every $1 billion in biologics sales.

Abusers of this practice have not denied the existence of the financial incentive for this obstruction. When asked about potentially approving a sale to a generic manufacturer one executive responded:

> *Most likely I would block that purchase. We spent a lot of money for this drug. We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make*

[1] *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry*

generics], no matter what. But I'm certainly not going to make it easier for them.[2]

Without access to these samples, generic and biosimilars approvals are blocked and patients are left without access to more affordable medicines. The CREATES Act would give generic and biosimilar manufacturers a clear and efficient pathway to combat these bad actors. The bill targets two forms of anticompetitive behavior used by certain brand manufacturers to stifle generic and biosimilar entry: refusal to provide adequate samples to gain approval, and denying generic and biosimilar access into to an FDA approved single-shared REMS program. Additionally, courts would be empowered to award damages that would provide sufficient incentives to encourage good-faith dealing by brand manufacturers from the outset. The CREATES Act would ensure patient safety by requiring that only appropriate manufacturers receive these samples through an affirmative authorization from FDA that satisfies any relevant safety concerns.

Over 30 years ago, the Hatch-Waxman Act opened up the pharmaceutical marketplace to competition by creating a balance between patient access and brand innovation. Competition from generic drugs has saved the health care system $1.46 trillion over the past decade and $227 billion in 2015 alone. Companies that exploit restricted access programs – whether under the pretext of an FDA-mandate or on their own accord - delay generic competition and undermine the intent of Hatch-Waxman at the expense of America's patients. The CREATES Act is a common sense solution that will prevent such abuses, and further patient access to safe, effective, and affordable medications. We thank you again for your incredible efforts in introducing this bill.

Sincerely,

AARP
Academy of Managed Care Pharmacy
America's Health Insurance Plans (AHIP)
American College of Physicians
American Society of Health System Pharmacists
Association for Accessible Medicines and The Biosimilars Council
BlueCross BlueShield Association
Campaign for Sustainable Rx Pricing
Coalition to Reduce Spending
CVS Health
Express Scripts
Frontiers of Freedom
Healthcare Supply Chain Association
Pharmaceutical Care Management Association (PCMA)
Premier healthcare alliance
Prime Therapeutics
Public Citizen
Public Sector HealthCare Roundtable

CC:
Hon. Mike Lee, Hon. Amy Klobuchar, Hon. Tom Cotton, Hon. Sheldon Whitehouse, Hon. John McCain, Hon. Richard Blumenthal, Hon. Susan Collins, Hon. Claire McCaskill, Hon. Dick Durbin, Hon. Diane Feinstein

[2] "How Martin Shkreli prevents generic versions of his pricey pill." *Pharmalot*. October 2015.

April 27, 2017

Re: Pass the *Creating and Restoring Equal Access to Equivalent Samples Act of 2017*

Dear Leader McConnell, Minority Leader Schumer, Speaker Ryan, Minority Leader Pelosi, Chairman Grassley, Ranking Member Feinstein, Chairman Goodlatte, Ranking Member Conyers and members of the Senate and House Judiciary Committees:

The undersigned organizations representing healthcare providers, clinical researchers, public health experts, and consumer and taxpayer advocates are committed to advancing public health and promoting access to affordable medicines. We are writing to express our support for and urge you to pass the *Creating and Restoring Equal Access to Equivalent Samples Act of 2017* (CREATES Act), a bipartisan, bicameral reform to bring down drug prices.

Generic competition has been proven to be an effective method to bring down prescription drug prices and is an integral component of limiting costs in our healthcare system. Lawmakers strived to strike a balance between innovation and access through the *Drug Price Competition and Patent Term Restoration Act*, commonly known as the Hatch-Waxman Act, but too often brand-name prescription drug companies abuse regulatory and other systems to prevent generic competition and preserve monopolies. Those tactics allow them to charge exorbitant prices, leading to increased healthcare costs, higher premiums and out-of-pocket expenses for consumers and, at times, putting medicines out of reach of the people who need them to lead healthy and productive lives.

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 Risk Evaluation and Mitigation Strategy (REMS) programs. While REMS programs can help ensure safety with certain drugs, 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[1,2]: 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.

While the CREATES Act could be strengthened to address anticompetitive patenting of REMS, the measures of the bill provide strong remedies to the other two forms of REMS abuse. By curbing REMS abuses, the CREATES Act is estimated to save taxpayers more than three billion dollars over the next decade. In the context of annual national prescription drug spending projected to reach $610-640 billion

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[1] Sarpatwari A, Avorn J, Kesselheim AS. Using a drug-safety tool to prevent competition. *N Engl J Med.* 2014;370(16):1476-1478. Accessed at: http://www.nejm.org/doi/pdf/10.1056/NEJMp1400488.

[2] Testimony of Bruce A. Leicher, Senior Vice President and General Counsel, Momenta Pharmaceuticals, before the U.S. House of Representatives' Committee on Oversight and Government Reform's Subcommittee on Health Care, Benefits, and Administrative Rules. March 22, 2017. Accessed at: https://oversight.house.gov/wp-content/uploads/2017/03/Leicher-Testimony-House-OGR-Hearing-3.22.17.pdf.

in 2018[3], this is only a modest step, yet it is an important bipartisan remedy to one form of anticompetitive and monopolistic abuse that the drug industry uses to price gouge consumers. Please pass the CREATES Act without delay.

Sincerely,

ACT UP/ NY
AFL-CIO
American College of Physicians (ACP)
Center for Medicare Advocacy
Doctors for America
Families USA
Health Global Access Project (Health GAP)
Knowledge Ecology International (KEI)
National Physicians Alliance (NPA)
National Center for Health Research (NCHR)
National Committee to Preserve Social Security & Medicare (NCPSSM)
Public Citizen
Social Security Works (SSW)
Taxpayers for Common Sense
Treatment Action Group (TAG)
Universities Allied for Essential Medicines (UAEM)

[3] IMS Institute for Healthcare Informatics. Medicines Use and Spending in the U.S.: A Review of 2015 and Outlook to 2020. April 2016. Accessed at: https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf

WEST-WARD
A HIKMA COMPANY

West-Ward Pharmaceuticals
International Limited
1 New Burlington Place
London
W1S 2HR
United Kingdom
Tel: + 44 20 7399 2760
Fax: + 44 20 7399 2761

July 12, 2107

Hon. Tom Marino
Chair, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Hon. David Cicilline
Ranking Member, Regulatory Reform,
Commercial & Antitrust Law Subcommittee
House Judiciary Committee
U.S. House of Representatives
2138 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Marino and Ranking Member Cicilline:

On behalf of West-Ward Pharmaceuticals, a Hikma company, and our over 2500 US-based employees, I am asking you today to support the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act (H.R. 2212), bipartisan legislation to increase competition and patient access to safe and affordable generic medicines. While you are to be commended for holding a hearing on this important bill. I urge the Committee to mark-up the bill and move it to the House floor promptly.

Certain brand pharmaceutical companies are currently preventing competition by blocking generic drug manufacturers' ability to purchase samples, which are used to conduct the bioequivalent testing necessary to bring safe and affordable generic medicines to market at the earliest possible date. The Food and Drug Administration (FDA) has stated that this anti-competitive practice – known as Risk Evaluation and Mitigation Strategy (REMS) and non-REMS restricted access abuse – is "a problem" that "delays the availability of generics."[1]

More than 150 complaints have been sent to the FDA and a significant majority of these brand drug products are quite expensive, costing patients thousands of dollars per month. Recent research estimates the potential scope of the current brand revenue of the products affected by this loophole at $22 billion.[2] This problem is accelerating and delaying patient access to safe and affordable generic medication.

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[1] Food & Drug Administration (FDA), Dr. Janet Woodcock, Congressional Testimony before House Committee on Oversight & Investigations, March 22, 2017.

[2] Matrix Global Advisors, Alex Brill, "REMS and Restricted Distribution Programs: An Estimate of the Market," June 2017.

WEST-WARD
A HIKMA COMPANY

Unfortunately, the FDA does not have the authority to prevent the abuse of REMS and restricted access programs. REMS put in place important safety protocols, but are explicitly prohibited from being used to delay or prevent generic competition. It should be noted that generic drug developers are required to adhere to safe handling and other structures that protect patient safety, and this is done every time brand companies permit the sale of samples for generic drug development.

To ensure that generic drug developers are not prevented, by a small handful of brand companies, from obtaining samples necessary to bring new accessible generic drugs to patients and payors, Congressional action is necessary. The bipartisan CREATES Act (H.R. 2212) would provide a safe, efficient and targeted pathway to end these abusive, anti-competitive tactics. The FDA is well-known for its "gold standard" in protecting the safety of patients and in the Agency's review of the CREATES Act has stated that current FDA guidance on the provision of samples protects patients.

With nearly nine out of ten Americans (87%) in favor of "making it easier for generic drugs to come to marker in order to increase competition and reduce costs"[3] and over 18 health care stakeholders calling for Congressional action to provide "generic manufacturers a clear and efficient pathway to combat these bad actors," support for the bipartisan CREATES Act (H.R. 2212) is broad and well-founded. Thank you for holding this important hearing and I look forward to watching the bill's progress in your Committee.

I appreciate you considering my company's view. Please do not hesitate to contact myself at 732.740.9251 or mraya@west-ward.com. Joe Simonetta with PSI will follow-up with your staff and can be reached at 609.273.3257 or jsimonetta@njpsi.com.

Sincerely,

Michael Raya

Michael Raya, CEO
West-Ward Pharmaceuticals Corp., a Hikma company

[3] Kaiser Family Foundation, "Poll: Majorities of Democrats, Republicans and Independents Support Actions to Lower Drug Costs," May 2017.

the campaign for
SUSTAINABLE Rx PRICING
Transparency. Competition. Value.

July 19, 2017

The Honorable Tom Marino
Chairman
Subcommittee on Regulatory, Reform,
Commercial and Anti-Trust Law
House Judiciary Committee
U.S. House of Representative
Washington, DC 20510

The Honorable David Cicilline
Ranking Member
Subcommittee on Regulatory, Reform,
Commercial and Anti-Trust Law
House Judiciary Committee
U.S. House of Representatives
Washington, DC 20510

Dear Chairman Marino and Ranking Member Cicilline:

The Campaign for Sustainable Rx Pricing (CSRxP) is a broad-based coalition of leaders, comprising physicians, nurses, hospitals, consumers, health plans, PBMs, pharmacists, and businesses, that promotes bipartisan, market-based solutions to lower drug prices in America.

We write today to voice the strong support of our coalition and its members for the Creating and Restoring Equal Access to Equivalent Samples ("CREATES") Act. This bipartisan legislation would help to end a longstanding pattern of anticompetitive behavior by branded pharmaceutical companies that distorts markets by thwarting generic competition and results in higher prescription drug prices for consumers, job creators, and taxpayers.

CSRxP is committed to increasing transparency, competition, and value in the prescription drug market. We applaud your commitment to combating anticompetitive behavior that blocks access to affordable generic drugs. Currently, drug companies can use a loophole in U.S. laws to deny samples of their branded drugs to generic manufacturers in order to keep generic companies from pursuing the necessary research to comply with FDA regulations and bring alternate products to market. This practice restricts competition in the market and often leaves patients with fewer choices for their medications. As a result, patients may be at the mercy of a single drug company for the medication they need to stay healthy, and that company is free to set the price for the medication indiscriminately. Such practices put a financial strain on patients and drive up health care expenses for everyone

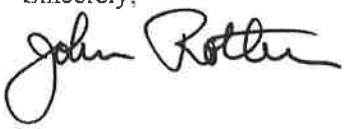
We represent a wide swath of healthcare stakeholders and patient safety is our foremost concern. As such, we fully support the goals of the Federal Drug Administration's Risk Evaluation and Mitigation Strategies program as a tool for patient safety. These REMS are important components of the overall patient safety regime that work to ensure that the benefits of a given medication subject to FDA-mandated REMS outweigh the potential deleterious effects.

Because of the important contribution that REMS make to patient safety, it is all-the-more disappointing that certain branded pharmaceutical companies have cynically abused this program to deny potential generic and biosimilar competitors the requisite samples needed to conduct equivalency testing, gain FDA approval, and compete in the marketplace.

Generic competition is demonstrably beneficial for consumers, job creators, and taxpayers. A recent study (funded by none other than the Pharmaceutical Research and Manufacturers of America (PhRMA)), found that "oral generics cost 80% less than the brands they replace within five years." Because generic or biosimilar entry into the market precipitates significant price reductions, the anticompetitive abuses that the CREATES Act addresses result in enormous unnecessary costs that burden the entire healthcare system. A 2014 study by Matrix Global Advisors found that abuse of the REMS program to stifle generic and biosimilar competition costs the healthcare system $5.4 billion annually, including $1.8 billion in extraneous government spending.

The CREATES Act is a targeted, procompetitive, and market-based solution to this problem that has plagued the healthcare system for far too long. We thank the bipartisan, bicameral sponsors for their work to promote competition and lower drug prices for consumers, job creators, and taxpayers alike, and hope that the Judiciary Committee will consider this legislation this year.

Sincerely,



John Rother,
Executive Director
Campaign for Sustainable Rx Pricing (CSRxP)

September 19, 2017

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
Washington, D.C. 20510

The Honorable Nancy Pelosi
Democratic Leader
U.S. House of Representatives
Washington, D.C. 20510

Dear Speaker Ryan and Democratic Leader Pelosi:

As the House returns to work this Fall, the undersigned organizations encourage the House to consider the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. Our organizations represent a broad-based and diverse cross-section of stakeholders – including providers and payers, physicians and consumers, corporations and unions – all of whom have come together in strong support of the CREATES Act.

For too long, brand-name pharmaceutical manufacturers have exploited patient safety tools in order to stifle generic competition and attendant lower prescription drug prices. The Food and Drug Administration (FDA) Commissioner Scott Gottlieb recently testified on this topic at a hearing in front of the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law:

> *For example, we know that sometimes statutory and regulatory requirements, established to ensure the safety and quality of drugs approved by FDA, may also be leveraged – or "gamed" – in an effort to delay generic drug approvals beyond the timeframe the law has intended. This can serve to thwart expected competition.*

This "gaming" by brand-name pharmaceutical companies denies generic manufacturers access to the samples that they require in order to conduct necessary equivalence testing to ensure the quality, efficacy, and safety of a generic drug. As a result of this pattern of anticompetitive practices, brand-name manufacturers are able to stifle generic competition, inflating prescription drug prices by artificially extending their monopoly pricing power far beyond the exclusivity period intended by Congress.

This anticompetitive conduct harms not only the patients who depend on these drugs, but results in an enormous and unnecessary burden on the healthcare system as a whole. A 2014 study by Matrix Global Advisors found that this type of anticompetitive conduct costs the healthcare system $5.4 billion annually, including $1.8 billion in government spending and nearly $1 billion in out-of-pocket costs for patients.

The CREATES Act is a targeted, market-based, bipartisan solution to this longstanding problem that affects both access to and affordability of prescription medications. We thank the bipartisan, bicameral Congressional sponsors of this legislation, as well as the Food and Drug Administration and the Federal Trade Commission which recently testified favorably about this bill.

We strongly encourage Congress to act on this important bill this fall, and we stand ready to work with Members towards our common goal of promoting competition and lowering drug prices for all Americans.

Sincerely,

AARP
AFL-CIO
American College of Physicians
Anthem
Alliance of Community Health Plans
American Hospital Association
American Society of Health System Pharmacists
America's Health Insurance Plans
Ascension
Blue Cross Blue Shield Association
Blue Cross Blue Shield of Arizona
Blue Cross Blue Shield of Michigan
Blue Shield of California
Campaign for Sustainable Rx Pricing
Center for Medicare Advocacy
Coalition for Affordable Prescription Drugs
Coalition to Reduce Spending
CVS Health
Doctors for America
Families USA
Federation of American Hospitals
Freedom Works
Greater New York Hospital Association
Healthcare Supply Chain Association
Kaiser Permanente
Knowledge Ecology International
National Center for Health Research
National Committee to Preserve Social Security and Medicare
National Physicians Alliance
Patients for Affordable Drugs
Pharmaceutical Care Management Association
Prime Therapeutics
Public Citizen
Social Security Works
Treatment Action Group
Vizient
Walmart

Cc: Chairman Robert W. Goodlatte
Cc: Ranking Member John Conyers

Cc: Representative Tom Marino
Cc: Representative David Cicilline

The Proposed CREATES Act: How to Fix Legislative Barriers to Competition at the FDA

Written Statement of

Geoffrey A. Manne

Founder and Executive Director,
International Center for Law & Economics

on

"Antitrust Concerns and the FDA Approval Process"

U.S. House of Representatives
Committee on the Judiciary,
Subcommittee on Regulatory Reform, Commercial, and Antitrust Law

July 27, 2017

ICLE | 3333 NE Sandy Blvd., #207 | Portland, OR 97232 | 503.770.0650 | icle@laweconcenter.org |
@laweconcenter | www.laweconcenter.org

The Proposed CREATES Act: How to Fix Legislative Barriers to Competition at the FDA

*Written Statement of Geoffrey A. Manne**

Introduction

Poorly drafted regulations, especially in heavily regulated industries, can create opportunities for anticompetitive abuse. Established companies know how to navigate regulatory mazes, and the complexities of such regimes create innumerable opportunities for nominal compliance at the expense of competition, innovation, and new entry.

The legislative and regulatory impulse when faced with deeply entrenched regulations and their competitive manipulations is often to pile on, either with even more-complex regulatory amendments or else antitrust enforcement that side-steps the root problem, focusing on "fixing" allegedly anticompetitive conduct rather than reforming the underlying laws that facilitate it.

But the government has a questionable track record in promoting competition, not infrequently adopting policies seemingly tailor-made to perpetuate, rather than constrain, harmful conduct.

The FDA Act and the regulations promulgated under it by the agency stand as Exhibit A in this regard. Last year's controversy over Mylan Pharmaceuticals' price hike on the EpiPen, for example, is symptomatic of the problem. The market for pharmaceuticals is complicated, but one thing seems clear in the pricing controversy: the FDA has been an effective ally for Mylan in keeping out competitive producers of generic epinephrine auto-injectors. Drug safety is important, of course, but since 1962 the FDA has also reviewed drugs for "efficacy," which introduced massive delay and uncertainty, arguably without concomitant benefit. And the FDA's approval and oversight processes for generics and biosimilars, although improved since 1962,

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* Geoffrey A. Manne is founder and Executive Director of the International Center for Law & Economics (ICLE), a research center dedicated to building the intellectual foundation for rigorous, economically grounded policymaking. The author's full bio is attached to the end of this statement.

continue to impede effective entry. Thus, with the field clear of competitors, it is no surprise that Mylan was able to raise prices. Only following the angry public outcry did the FDA finally accelerate its review process and approve a competing product last month.

But efficacy review is not the FDA's only regulatory *cul de sac* through which pharmaceutical manufacturers can employ regulatory policies to keep unwanted competitors off the block. In particular, one aspect of the FDA's drug safety oversight regime has emerged as a device for some manufacturers to delay generic entry: the Risk Evaluation and Mitigation Strategies, or "REMS," program.

What I will refer to collectively as the FDA Act's REMS program comprises two elements that are relevant here: First, it requires branded drug manufacturers to make samples of their drugs available to would-be generic entrants so that they can use them in the lengthy safety and efficacy testing process required to secure FDA approval. Second, it requires brand drug companies to adopt a concerted set of practices and policies aimed at mitigating the risks inherent in the use of most drugs, and additional, more restrictive practices to ensure the safe use of particularly dangerous or addictive drugs – the so-called "REMS with ETASU" ("Elements to Assure Safe Use"). The program also requires that brand manufacturers allow generic entrants to share in these enhanced mitigation processes in order, presumably, to streamline the process and economize on compliance costs.

By forcing collaboration between competitors, the REMS program is practically tailor-made for problems. Although the FDA Act specifically prohibits the use of these regulatory elements to block lower-cost, generic alternatives from entering the market (of course),[1] almost immediately following the law's enactment, a small handful of branded pharmaceutical companies began using REMS for just that purpose (also, of course).

Some (now-former) FTC commissioners, among others, have raised concerns that brand drug manufacturers can (and do) take advantage of these provisions by adopting tough negotiating positions that, they allege, amount to anticompetitive

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[1] 21 U.S.C. § 355-1(f)(8).

exclusion requiring agency enforcement.[2] I believe that that would be decidedly the wrong approach to dealing with the issue. *These are not properly antitrust problems; they are problems of poor regulatory design.*

But it is also true that the program itself exists to implement an underlying policy that may be even worse, and it is likely that reforming a few key elements of the program would help prevent such abuses – but Congress should adopt more fundamental policy changes, as well.

The first part – sharing samples – cannot easily be fixed by removing the required collaboration, at least not without completely revamping (or removing) the FDA's drug safety and efficacy oversight function (however desirable reform of these functions would be). But the second – sharing REMS programs – can be.

Enter the CREATES Act...

Thus it is heartening that Senate Antitrust, Competition Policy, and Consumer Rights Subcommittee Chairman, Mike Lee, and several of his Judiciary Committee colleagues (Sens. Leahy, Grassley, Klobuchar, Feinstein, McCaskill, Collins, McCain, Blumenthal, Whitehouse, Cotton, and Durbin), along with House Regulatory Reform, Commercial, and Antitrust Law Subcommittee Chairman, Tom Marino, and his colleague, Rep. Cicilline, have introduced a bill – the CREATES Act of 2017[3] – that would seem to offer the right kind of relief, aimed at fixing defective statutory language and regulatory policies, while explicitly eschewing expanded antitrust enforcement.

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[2] *See, e.g.*, FTC Chairman Edith Ramirez, *Prepared Statement of the Federal Trade Commission*, Before the U.S. House of Representatives Committee on the Judiciary, Subcommittee on Regulatory Reform, Commercial and Antitrust Law, Hearing on "Oversight of the Enforcement of the Antitrust Laws" (Nov. 13, 2015), *available at* https://www.ftc.gov/sites/default/files/documents/public_statements/prepared-statement-federal-trade-commission-oversight-enforcement-antitrust-laws-presented/131115antitrustlawtestimony.pdf.

[3] The Creating and Restoring Equal Access to Equivalent Samples Act of 2017, S.974 (CREATES Act of 2017), *available at* https://www.congress.gov/bill/115th-congress/senate-bill/974; H.R.2212 (CREATES Act of 2017), *available at* https://www.congress.gov/bill/115thcongress/house-bill/2212 (the "CREATES Act").

The proposed legislation would both ameliorate the bad incentives created by the first part of the law, and remove the faulty, underlying policy that creates the problem in the second.

And it would do so without resorting to an inappropriately invigorated antitrust regime. As the bill notes:

> While the antitrust laws may address actions by license holders who impede the prompt negotiation and development on commercially reasonable terms of a single, shared system of elements to assure safe use, ***a more tailored legal pathway would help ensure that license holders negotiate such agreements in good faith and in a timely manner***, facilitating competition in the marketplace for drugs and biological products.[4]

The legislative solution put forward in the CREATES Act targets the right culprit: the poor regulatory drafting that permits possibly anticompetitive conduct to take place. Moreover, the bill refrains from creating a *per se* rule, instead implementing several features that should still enable brand manufacturers to legitimately restrict access to drug samples when appropriate.

In essence, the proposed CREATES Act introduces a third party (in this case, the Secretary of Health and Human Services (presumably acting through the Commissioner of Food and Drugs) who is capable of determining whether an eligible generic manufacturer is able to comply with REMS restrictions – thus bypassing any bias on the part of the brand manufacturer who would otherwise be tasked with making that determination under the FDA Act. Where the Secretary determines that a generic firm meets the REMS requirements (and is thus eligible to receive samples), the bill also creates a narrow cause of action (for this narrow class of plaintiffs) against certain brand manufacturers who nevertheless misuse the process to delay competitive entry.

With respect to shared REMS, the proposed bill adopts an even more direct approach, altering the language introduced into the FDA Act by the 2007 FDA

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[4] *Id.* at § 2(9) (emphasis added).

Amendments Act ("FDAAA")[5] to remove the regulatory dynamic that creates the possibility of anticompetitive conduct in the first place.

... And exit antitrust

In order to understand the real value of the CREATES Act, it is important to recognize that antitrust law has historically had an uneasy relationship with other regulatory schemes. Not least because of the Supreme Court's *Trinko*[6] and *Credit Suisse*[7] decisions, it is a tough case to make that brand manufacturers are violating antitrust laws when they rely upon legal obligations under a regulatory regime that is essentially *designed* to limit generic entry on safety grounds. The issue is all the more properly removed from the realm of antitrust enforcement given that the problem is actually one of *regulatory* failure, not market failure.

Further, antitrust law doesn't impose a duty to deal with rivals except in very limited circumstances.[8] In *Trinko*, for example, the Court rejected the invitation to extend a duty to deal to situations where an existing, voluntary economic relationship was not terminated. By definition this is unlikely to be the case here where the alleged refusal to deal is what prevents the generic from entering the market in the first place. The logic behind *Trinko* (and a host of other cases that have limited competitors' obligations to assist their rivals) was to restrict duty to deal cases to those rare circumstances where refusals to deal reliably lead to long-term competitive harm — not where they amount to perfectly legitimate efforts to compete without giving rivals a leg-up.

But antitrust is such a powerful tool, and such a flexible "catch-all" regulation, that enforcers and regulatory advocates perpetually seek to thwart reasonable judicial limits on its use. As I have written about at length in the past,[9] for example, former

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[5] Public Law 110–85, 121 STAT. 823 (Sep. 27, 2007), *available at* https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf.

[6] Verizon Communications, Inc., v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398 (2004).

[7] Credit Suisse Securities (USA) LLC v. Billing, 551 U.S. 264, 282 (2007).

[8] *See, e.g.*, Thomas A. Lambert & Alden F. Abbott, *Recognizing the Limits of Antitrust: The Roberts Court Versus the Enforcement Agencies*, 11 J. COMP. L. & ECON. 791 (2015).

[9] *See, e.g.*, Geoffrey A. Manne, *The FTC's Misguided Rationale for the Use of Section 5 in Sherman Act Cases*, 2 CPI ANTITRUST J. (February 2010), *available at* https://ssrn.com/abstract=1562489;

FTC Commissioner, Tom Rosch, and former FTC Chairman, Jon Leibowitz, were vocal proponents of using Section 5 of the FTC Act to circumvent sensible judicial limits on making out and winning antitrust claims, arguing that the limits were meant only for *private* plaintiffs — not (implicitly infallible) government enforcers. Although no one at the FTC has yet (publicly) suggested bringing a REMS action as a standalone Section 5 case, such an action would be consistent with the sorts of theories that animated past standalone Section 5 cases.

Again, such an approach would serve as an end-run around the reasonable judicial constraints that evolved as a result of judges actually examining the facts of individual cases over time, and is a misguided way of dealing with what is, after all, fundamentally a regulatory design problem.

Finally, it is important to note that the proposed bill completely avoids the question of whether antitrust laws are applicable, leaving that possibility open to determination by courts; it does not *preclude* the possibility of antitrust enforcement — as is appropriate. At the same time, however, by establishing even more clearly the comprehensive regulatory regime governing potential generic entrants' access to dangerous drugs, the bill would, given the holding in *Trinko*, probably make application of antitrust laws here considerably less *likely* — which is *also* appropriate.

The problem of withholding drug samples

To enter into pharmaceutical markets that no longer have any underlying IP protections, generic drug manufacturers must submit to the FDA an Abbreviated New Drug Application (ANDA) for a generic, or an Abbreviated Biologic License Application (ABLA) for a biosimilar, of the brand drug. The purpose is to prove to the FDA that the competing product is as safe and effective as the branded reference product. In order to perform the testing sufficient to prove efficacy and safety, generic and biosimilar drug manufacturers must acquire a sample (many samples, in fact) of the reference product they are trying to replicate.

Geoffrey Manne, *Debunking the "pro-business" rationale for Section 5 enforcement*, TRUTH ON THE MARKET (Feb. 4, 2010), https://truthonthemarket.com/2010/02/04/debunking-the-pro-business-rationale-for-section-5-enforcement/; Geoffrey Manne, *The folly of the FTC's Section 5 case against Google*, TRUTH ON THE MARKET (May 7, 2012), https://truthonthemarket.com/2012/05/07/the-folly-of-the-ftcs-section-five-case-against-google/.

Drugs subject to a REMS with ETASU are often difficult to obtain through market channels and are not otherwise readily available, even for would-be generic manufacturers; safety protocols under a brand drug company's REMS with ETASU typically require the brand manufacturer to restrict distribution of these drugs that present safety or abuse risks. For this narrow class of dangerous or frequently abused drugs, generic manufacturers are forced to comply with any REMS restrictions placed upon the brand manufacturer — even when the terms require the brand manufacturer to tightly control the distribution of its product.

But the drug-sample provision process allows brands considerable leeway to determine whether generic manufacturers are compliant. And given this discretion, it is no surprise that brand manufacturers may be tempted to block competition by citing "safety concerns."

And therein lies the problem. Because the brand manufacturer controls access to its products, it can refuse to provide the needed samples, using its REMS protocols as an convenient cover story.

It is surely true in certain cases that a brand manufacturer is justified in refusing to distribute samples, of course; *some* would-be generic manufacturers certainly do not meet the requisite standards for safety and security. But a REMS program can also create an opportunity for the branded drug manufacturer to take advantage of imprecise regulatory requirements to inappropriately limit access by generic manufacturers, thus delaying or thwarting their ability to enter the market.

It turns out that, in practice, most of the (publicly known) examples of brands refusing to provide samples happen across the board — they preclude essentially *all* generic competition, not just the few firms that might have insufficient safeguards. It is difficult to justify such refusals on the basis of a generic manufacturer's suitability when *all* would-be generic competitors are denied access, including well-established, high-quality manufacturers.

But, for a small number of brand manufacturers, at least, that seems to be how the REMS program is implemented. Thus, for example, one pharmaceutical executive referred to the practice of denying generics samples this way:

> We would like to do our best to avoid generic competition. It's inevitable. They seem to figure out a way [to make generics], no matter what. But I'm certainly not going to make it easier for them.[10]

As currently drafted, the REMS program gives branded manufacturers the ability to limit competition by stringing along negotiations for product samples for months, if not years.

The CREATES Act solution

The CREATES Act, on the other hand, aims to solve the problem by improving the existing regulatory mechanism and by adding a limited judicial remedy to incentivize compliance under its amended regulatory scheme. In summary:

- The bill creates a cause of action for a refusal to provide samples only where a plaintiff can prove, by a preponderance of the evidence, that certain well-defined conditions are met.
- If a drug is not covered by a REMS, or if the generic manufacturer is specifically authorized, then it can sue the brand manufacturer if it does not receive sufficient quantities of samples on commercially reasonable terms.
- This is not a *per se* offense subject to outsized antitrust damages. Instead, the remedy is a limited injunction ensuring the sale of samples on commercially reasonable terms, enforced through the threat of reasonable attorneys' fees and a monetary fine.
- The bill also gives a brand manufacturer an affirmative defense if it can prove by a preponderance of the evidence that, regardless of its own refusal to supply them, samples were nevertheless available elsewhere on commercially reasonable terms, or where the brand manufacturer is unable to supply the samples because it does not actually produce or market the drug.

The primary remedy is thus limited, injunctive relief to mitigate the risk of improper delay.

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[10] Jon Haas, director of patient access at Turing Pharmaceutical, *quoted in* Ed Silverman, *How Martin Shkreli prevents generic versions of his pricey pill*, STAT PHARMALOT (Oct. 5, 2015), http://pharmalot.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/.

But the bill does not simply mandate compliance by branded manufacturers without acknowledging that, in many cases, a brand's refusal to supply samples may be perfectly appropriate. Instead, the bill removes the primary justifications for such delay and also holds the branded manufacturer harmless if the generic competitor turns out to create the sort of safety problems the program was intended to prevent by a) outsourcing a generic's eligibility determination to a third party; b) creating a safe harbor from claims that providing samples in accordance with the bill violates a brand's REMS obligations; and c) adopting a blanket limitation of liability:

> A [brand manufacturer] shall not be liable for any claim arising out of the failure of an eligible [generic manufacturer]to follow adequate safeguards to assure safe use of the [samples] during development or testing activities described in this section, including transportation, handling, use, or disposal of the [samples] by the [generic manufacturer].[11]

The bill also protects brands with an affirmative defense under which they need only show that the product is available for purchase on reasonable terms elsewhere. And damages are available only if a court finds that the brand manufacturer lacked a legitimate business justification for its conduct (which, under the drug safety regime, means essentially a reasonable belief that its own REMS plan would be violated by dealing with the generic entrant). And monetary damages do not include punitive damages.

A note of caution: The devil is in the details

It is true that, in order to make the injunction effective, the CREATES Act would impose a penalty for noncompliance that is not simply commensurate with the harm imposed by delaying generic entry (not least because the bill would allow generic entrants to receive samples in certain circumstances even if withholding them would not, *in fact*, delay entry (for a number of statutory reasons)). There are sound reasons for this, although some caution is warranted.

In order for an injunction to be effective it must impose a penalty for *non*compliance large enough to ensure compliance: The point is *not* compensatory damages, but rather enforcement of the injunction. For that reason, however, and the fact that the

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[11] CREATES Act, *supra* note 3, at § 3(c).

penalty is paid to the generic manufacturer, the significant size of the potential award risks incentivizing generic entrants *themselves* to game the system in order to receive a payout from unmeritorious litigation under the bill.

The relevant question is, as always, the error-cost tradeoff inherent in any policy choice. The CREATES Act imposes an injunction and assigns a penalty that shifts relative bargaining power in the FDA regulatory environment toward generic entrants and away from brand manufacturers by some amount. Whether the specific penalty contemplated ("not [] greater than the revenue that the [brand manufacturer] earned on the covered product during the period")[12] and the other specific terms of enforcement shift the relative bargaining power the *optimal* amount is not clear. As far as I know the penalty amount and other terms were arrived at without careful consideration of the relevant data, and are more of an educated guess than a careful calibration.

While I believe that imposing a penalty large enough to deter bad conduct is appropriate (and it is certainly possible that the current bill gets it right), I do not know (and I doubt anyone knows) if *this* penalty is appropriately calibrated to reflect the current risk of harm *as well as* the risk of harm from possible abuse by generic entrants of their new bargaining power under the bill. In order to ensure that the legislation does more good than harm it is important to know this, and I urge members of both subcommittees to collect and assess the relevant information. I do believe that the overall structure of the CREATES Act offers a sound, and limited, solution to a structural problem of the regulatory environment. But that does not mean that it is necessarily perfect in every detail.

The shared REMS problem

The REMS program itself was introduced as part of the FDAAA in 2007.[13] Following the withdrawal of the arthritis pain reliever, Vioxx, from the market because of a post-approval linkage of the drug with increased heart attack risk, the FDA was under

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[12] *Id.* at § 3(b)(4)(B).

[13] The REMS program is codified in the FDA Act at 21 U.S.C. § 355-1.

considerable fire,[14] and there was a serious risk that fewer and fewer net beneficial drugs would be approved. The REMS program was introduced by Congress as a mechanism to ensure that society could continue to reap the benefits from risky drugs and biologics – rather than the FDA preventing them from entering the market at all.[15] It accomplishes this by requiring (among other things) that brands and generics adopt appropriate safety protocols for distribution and use of drugs, particularly when a drug has the potential to cause serious side effects, or has an unusually high abuse profile.

That is all well and good. But the Act also requires that brand manufacturers *share* their own REMS processes with generic entrants on commercially reasonable terms. The *shared* REMS requirement may have been included by Congress in order to economize on compliance costs, or on the theory that established brand manufacturers were more likely to adopt effective programs (and forced sharing would confer that enhanced effectiveness on generics, as well). In any case, the law effectively makes collaboration with brand manufacturers a prerequisite for generic entrants.

This is particularly true as it has been implemented by the FDA, which virtually never grants waivers for generics to operate their own REMS. The reasons for the FDA's reluctance to grant such waivers are unclear, but it seems likely it has something to do with the agency's continued concern for its own reputation. Certainly, one would think, granting a waiver in the event of a negotiating impasse (or even, when it occurs, intentional intransigence by brand manufacturers) would regularly meet the statute's requirement that the FDA "permit the applicant to use a different, comparable aspect of the elements to assure safe use if... the burden of creating a single, shared system outweighs the benefit of a single, [shared] system...."[16] In any case, as noted, such waivers are essentially never granted, even where both parties would prefer operating

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[14] *See* John E. Calfee, *Reform without Reason: What's Wrong with the FDA Amendments Act of 2007*, AEI Health Policy Outlook No. 12 (Sep. 2007), *available at* https://www.aei.org/wp-content/uploads/2011/10/20070927_HPOcorrected_3.pdf.

[15] *See* Stacey L. Worthy, *Don't sell out safety: a call to preserve risk evaluation and mitigation strategies to reduce harm to patients and the public in the U.S.*, 9(2) J. PHARM. POL'Y & PRACT. 1 (Dec. 2016), *available at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4721201/.

[16] 21 U.S.C. § 355-1(h)(8)(i)(1).

under separate programs to protracted, contentious, and possibly strategic negotiations.

The result is that the law and the pattern of enforcement by the FDA combine to create an opportunity for brand manufacturers to further delay entry, because they impose on generics a duty to enter into sharing arrangements without perfectly specified terms, and without waiver, thus giving brands an opportunity to string out negotiations or impose unreasonable terms. As important, the situation also imposes significant – and seemingly unnecessary – costs on brands.

But the *fundamental* problem is created by the shared requirement in the first place – which effectively imposes on the parties a duty to deal – and the FDA's unwillingness to allow generics to go it alone when mutually agreeable terms of a deal prove difficult to reach.

While a generic's ability to piggyback on a brand manufacturer's program surely does reduce costs for the generic (and arguably increases the likelihood of entry, at the margin), that mode of cost-cutting is as improper as it would be if the law simply mandated that generic entrants be allowed to occupy a brand manufacturer's offices rent free, conscript its researchers, or co-opt its marketing.

Moreover, there is no evidence that shared REMS programs are more or less effective than separate ones. The problem here is the statutory shared REMS requirement, and the practical limitations on the FDA's incentives to grant waivers from it.[17]

For all of these reasons, the appropriate fix is revision or removal of the offending language that requires brand manufacturers and generic entrants to enter into shared REMS programs.

And, indeed, rather than doubling down on the statute's quixotic effort to force competitors to negotiate and collaborate in order to economize on costs, the CREATES Act simply explicitly permits generics to use a separate REMS system without a waiver, provided it meets the statute's safety requirements to the FDA's satisfaction. This removes a brand manufacturer's ability to withhold agreement on

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[17] *Id.*

terms – *and* it mitigates the unnecessary costs imposed on brand manufacturers of complying with the FDAAA's forced sharing provisions. As the proposed bill notes:

> ***Clearer regulatory authority to approve different systems that meet the statutory requirements to ensure patient safety, however, would limit the effectiveness of bad faith negotiations*** over single, shared systems to delay generic approval. At the same time, clearer regulatory authority would ensure all systems protect patient safety.[18]

It is worth noting that, in this way, the CREATES Act mitigates the risk of holdup by branded incumbents without trading it for the risk of hold*out* by generic entrants – unlike the bill's solution to the drug samples problem, which does necessitate weighing this tradeoff.

Conclusion

Ultimately the proposed bill would effect a well-thought-out and targeted fix to an imperfect regulation that facilitates arguably anticompetitive conduct by a few bad actors. It accomplishes this without trampling on the courts' well-established antitrust jurisprudence, and seemingly (subject to analysis of the data) without imposing excessive cost or risk on the majority of brand manufacturers that behave perfectly appropriately under the law.

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[18] CREATES Act, *supra* note 3, at § 2(10) (emphasis added).

Author Bio

Geoffrey A. Manne | Executive Director, International Center for Law & Economics

Geoffrey A. Manne is the founder and executive director of the International Center for Law and Economics (ICLE), a nonprofit, nonpartisan research center based in Portland, Oregon. He is also a distinguished fellow at Northwestern Law School's Searle Center on Law, Regulation, & Economic Growth. In April 2017 he was appointed by FCC Chairman Ajit Pai to the FCC's Broadband Deployment Advisory Committee, and he recently served for two years on the FCC's Consumer Advisory Committee.

Mr. Manne earned his JD and AB degrees from the University of Chicago and is an expert in the economic analysis of law, specializing in competition, telecommunications, consumer protection, intellectual property, and technology policy.

Prior to founding ICLE, Manne was a law professor at Lewis & Clark Law School. From 2006-2009, he took a leave from teaching to develop Microsoft's law and economics academic outreach program. Manne has also served as a lecturer in law at the University of Chicago Law School and the University of Virginia School of Law. He practiced antitrust law and appellate litigation at Latham & Watkins, clerked for Hon. Morris S. Arnold on the 8th Circuit Court of Appeals, and worked as a research assistant for Judge Richard Posner. He was also once (very briefly) employed by the FTC.

Mr. Manne's publications have appeared in numerous journals including the Journal of Competition Law and Economics, the Harvard Journal of Law and technology, the Supreme Court Economic Review, and the Arizona Law Review, among others. With former FTC Commissioner, Joshua Wright, Manne is the editor of a volume from Cambridge University Press entitled, COMPETITION POLICY AND INTELLECTUAL PROPERTY LAW UNDER UNCERTAINTY: REGULATING INNOVATION. Manne has also testified on several occasions before Congress and at the FCC and FTC, and he regularly files written comments and amicus briefs on key antitrust, IP, and telecommunications issues. His analysis is frequently published in popular print and broadcasting outlets such as the Wall Street Journal, Wired, Foreign Affairs, NPR, and Bloomberg, among others.

Manne is a member of the American Law and Economics Association, the Canadian Law and Economics Association, and the Society for Institutional & Organizational Economics. He blogs at Truth on the Market (www.truthonthemarket.com) (of which he is also the co-founder), is a contributor at WIRED, and tweets at @geoffmanne. His scholarly publications are available at http://ssrn.com/author=175541.