



# WHAT THEY ARE SAYING – BLOCKING ACCESS TO SAMPLES

-- STAKEHOLDERS --

## **David Mitchell, Patients for Affordable Drugs**

[Testimony](#), House Oversight Committee, March 22, 2017

“Of course, during this same period, Celgene was doing its best to delay generic versions of the drug by hiding behind its restricted distribution system and REMS—refusing to give samples to generic drug makers. Here’s what that meant for me: My out-of-pocket cost for Revlimid went from \$42 a month in 2011 to \$250 a month by the time I had to stop taking it last year because of side effects. As you can see from the attached bill, the retail price for one four-week cycle of Revlimid is \$10,691—more than \$500 per capsule.”

“It’s clear to me that Celgene is gaming our system. It is using the bogus pretext of Risk Evaluation and Mitigation to unlawfully deny samples to generic manufacturers in order to prevent them from developing a cheaper alternative. It is ripping off patients and taxpayers while blocking market competition.”

## **Bruce Leicher, SVP and General Counsel, Momenta Pharmaceuticals**

[Testimony](#), House Oversight Committee, March 22, 2017

“This refusal to sell samples may be direct, or may take the form of the brand restricting the supplier from selling the product for research purposes or through unreasonable contract terms. In any case, it has nothing to do with safety and they are rarely designed to manage costs or prevent a shortage. These samples are used solely for FDA-required testing, following FDA’s review and approval of the competitor’s safety protocols. Ultimately, the brand’s actions to keep generic and biosimilar firms from receiving samples makes it impossible for prospective competitors even to submit an application for FDA approval – indefinitely preventing patients from accessing affordable treatment options.”



**Dr. Gerard Anderson, Professor, Johns Hopkins Bloomberg School of Public Health**

[Testimony](#), House Oversight Committee, March 22, 2017

“The problem is that some drug companies have used the REMS concept for their own benefit when they created limited distribution networks. The objective was not safety but profit.”

**Alden Abbott, Deputy Director and Senior Legal Fellow, Heritage Foundation**

[Testimony](#), Senate Judiciary Committee, June 21, 2016

“In short, I believe that the current version of the CREATES Act would, if enacted by Congress, enhance competition and consumer welfare ... The Act also would not impose undue burdens on the manufacturers of brand name drugs and biologics. The Act would further its objectives in two ways. First, it would help prevent prospective generic and biosimilar entrants from unreasonably being denied access to the drug samples that are needed for regulatory testing to enter the market, without challenging the validity of the established firms’ intellectual property protections. Second, it would afford prospective generic and biosimilar competitors access to safety-based regulatory protocols required to compete in the market.”

**Robin Feldman, Director of the Institute for Innovation Law, University of California Hastings College of the Law**

[Testimony](#), Subcommittee Hearing, June 21, 2016

“The temptation to avoid the impact of Hatch-Waxman can be overpowering when even a few months of additional monopoly profits can be worth hundreds of millions of dollars or more. This encourages companies to expend tremendous energy blocking generic entry by any means possible, with some companies using ever more clever and complicated strategies. As a result, many pharmaceutical firms may no longer compete solely on the basis of innovation, but rather on their ability to manipulate policy mechanisms and pathways to extend monopoly and duopoly terms.”

**Beth Zelnick Kaufman, Assistant General Counsel, Amneal Pharmaceuticals**

[Testimony](#), Subcommittee Hearing, June 21, 2016

“For example, in December 2013 Amneal initially requested samples of one product subject to a REMS in order to conduct the required bioequivalence testing to bring a lower-cost competitor to market. Though it took nearly three years, a supply agreement was finally signed in February 2016. However, four months later, my company still does not have product samples because the brand’s



staff won't export to our location. Without these samples, Amneal cannot begin developing a competitor, and patients are denied access, while the brand maintains monopolistic pricing power, despite the fact that all intellectual property and exclusivity protections have expired."

**Blair Childs, Senior Vice President, Public Affairs, Premier Inc.**

[Statement](#), Introduction of FAST Generics Act, April 6, 2017

"This legislation is critical to ongoing efforts to prevent anti-competitive behavior in the marketplace and stop some branded drug makers from blocking the introduction of generic and biosimilar medications. Specifically, the bill would expressly prohibit branded manufacturers from exploiting FDA's Risk Evaluation and Mitigation Strategies (REMS) program by establishing closed distribution networks that bar potential generic and biosimilar competitors from accessing the samples they need to conduct equivalence studies necessary for FDA approval of new drug applications. In closing this loophole, the legislation will give generic drug makers a clear pathway for market entry and unleash competitive forces that could help save \$5.4 billion a year in reduced drug costs."

**Mytheos Holt, Senior Fellow, Institute for Liberty**

[Op-ed](#), "How 'Big Pharma' stifles pharmaceutical innovation," The Hill, March 24, 2017

"Simply put, a pharmaceutical company abused a process meant to facilitate fair competition for a drug over which it no longer had any intellectual property rights, effectively quintupling the price of that medicine for patients. Celgene was rewarded with nearly \$2 billion in profits for the effort. And the lengths some brands will go to prop up their profits, keeping taxpayers, patients and other purchasers paying the monopolistic prices, appears to be unending. Manipulating markets and laws is not enough. Some of the biggest abusers are leveraging their political clout to prevent competition."

**Jonathan Bydlak, Founder and President, Coalition to Reduce Spending**

[Op-ed](#), "Opinion: Stifling Competition Reduces Access to Affordable Prescriptions," Roll Call, April 19, 2017

"What's going on, though, is actually pretty straightforward: Brand-name producers regularly take advantage of systems designed to protect consumers to instead protect their bottom lines and crush out competition from their generic competitors. One common way by which anti-competitive behavior occurs is by preventing access to the materials needed to test generic or biosimilar alternatives. In other words, pharmaceutical companies refuse to let competitors prove their safety, and then enjoy the monopoly that results when theirs are the only drugs proven to be safe."



**Geoffrey Manne, Executive Director, International Center for Law and Economics**

[Statement](#), June 14, 2016

The CREATES Act “would mitigate the competitive leverage that brand manufacturers are currently able to exercise under the Food and Drug Administration Amendments Act’s imperfectly drafted REMS provisions.”

-- PUBLIC SECTOR --

**Edith Ramirez, Chairwoman, FTC**

[Testimony](#), Subcommittee Hearing, March 9, 2016

“The concern is that branded firms may use FDA-mandated REMS distribution restrictions or other closed distribution systems to deny generic drug makers the samples they need to conduct bioequivalence tests, which they must do before they can enter the market. As we urged in two amicus briefs in separate private actions, this conduct undermines the careful balance created by the Hatch-Waxman Act to encourage generic entry, and may violate the antitrust laws.”

**Dr. Janet Woodcock, Center for Drug Evaluation & Research, FDA**

[Testimony](#), Subcommittee Hearing, March 22, 2017

“Nevertheless, sponsors do continue to withhold products. We’ve had around 150 inquiries from generic firms about difficulties that they have had obtaining product for bioequivalence testing.”

[Q&A](#), E&C Committee Hearing, March 2, 2017

“This is a problem we struggle with a lot. It has delayed availability of generics.”

**Rep. Jim Jordan (R-OH), Chairman, House Oversight Committee**

[Opening Statement](#), Subcommittee Hearing, March 22, 2017

“But then enter bad actors. Turing thwarted generic competition by blocking generic companies’ access to sample of Turing’s pricey product inhibiting generic manufacturers from conducting the



bioequivalence testing for the generic application. Indeed, Turing testified -- Turing testified admitting to this blocking strategy to try and block generic competitors for at least three years. Companies should not be able to abuse the system to block generic competition. Such abuse is leading to debilitating drug costs.”

**Rep. Raja Krishnamoorthi (D-IL), Ranking Member, House Oversight Committee**

[Opening Statement](#), Subcommittee Hearing, March 22, 2017

“We want drug companies to be able to earn a fair profit that allows them to recoup their research and development cost and invest in the next cure. But no company should be able to misuse public safety regulations to stifle competition and secure a monopoly advantage.”

[Q&A](#), Subcommittee Hearing, March 22, 2017

“In fact, the FTC warned in a 2014 amicus brief filed in a lawsuit against Celgene, quote, ‘If a brand firm can effectively block generic firms from accessing brand product for bioequivalence testing, it may be able to continue to prevent generic competition even after its patents on these products expire.’ So this – we’re really talking about a -- a time period after the patent has expired. The FTC also warned that this practice could quote, ‘Undermine the core principle of the patent system that patents have a limited duration.’”

**Rep. Frank Pallone (D-NJ), Ranking Member, House Energy & Commerce Committee**

[Q&A](#), Committee Hearing, March 2, 2017

“I believe with many of my colleagues on the committee that we should encourage and support robust generic competition in the marketplace, however, if we are to achieve this goal we must ensure that we are limiting barriers to generic entry wherever possible. Unfortunately, there is evidence that some brand drug manufacturers are using REMS programs to delay competition by preventing generic and biosimilar manufacturers access to samples of branded drug products and these samples are needed by generic and biosimilar manufacturers to conduct the bioequivalence studies needed for FDA approval.”

**Sen. Chuck Grassley (R-IA), Chairman, Judiciary Committee**

[Opening Statement](#), Subcommittee Hearing, June 21, 2016



“So I was concerned when we heard of other tactics that appeared to frustrate the intent of the Hatch-Waxman Act – a law enacted to streamline and expedite the approval process for generic drugs. We heard that certain brand drug companies were misusing their Risk Evaluation and Mitigation Strategies, known as REMS, to withhold access to drug samples for bioequivalence testing and generic drug development in violation of FDA regulations and the Hatch Waxman Act. We also heard that certain brand companies were misusing REMS to deny access to the REMS single shared system requirements under FDA regulations.”

**Sen. Patrick Leahy (D-VT), Ranking Member, Judiciary Committee**

[Opening Statement](#), Subcommittee Hearing, June 21, 2016

“Unfortunately, some brand-name companies are refusing to provide samples of their product to generic companies for them to make the necessary comparison. This simple delay tactic uses regulatory safeguards as a weapon to block competition.”

**Sen. Mike Lee (R-UT), Member, Judiciary Committee**

[Opening Statement](#), Subcommittee Hearing, June 21, 2016

“Some companies realized they could take advantage of this situation. When they have a drug subject to a REMS with restricted distribution, they can use it as an excuse to deny samples of the drug to potential generic competitors--samples that are necessary for the generic to conduct the testing required by the FDA under the Hatch-Waxman Act, the Act whose entire purpose was to increase generic entry.”

-- PRESS COVERAGE --

**Anna Rose Welch, Editor, Biosimilar Development**

[Article](#), “Biosimilar Makers to Congress: Time to Act on REMS Legislation,” March 27, 2017

“And here we see the problem taking shape for biosimilar companies. In order to carry out advanced analytical testing and large Phase 3 clinical trials, biosimilar companies require large quantities — and multiple batches — of the reference drug. But certain innovators, claiming concerns about patient safety, hide behind REMS or a voluntary restricted-distribution program. Their actions ultimately bar biosimilar and generics makers from gathering what they need to secure approval and introduce competition.”



**Glenn Manishin, Attorney**

[Op-ed](#), “How to CREATE generic pharma competition,” The Hill, March 16, 2017

“Unfortunately for consumers, brand-name drug manufacturers are using strategies to extend their profits and deny would-be generic competitors the tools and resources required to meet FDA safety rules to manufacture generic versions of expensive drugs after their patents have expired.”

**David Olson, Associate Professor, Boston College Law School**

[Op-ed](#), “Real conservatives should fight anticompetitive abuse of FDA regulations,” The Hill, September 14, 2016

“The problem is that while the law’s requirements are clear, there is no effective penalty for refusing to comply, and thus a growing number of drug companies have been effectively blocking generic entry by not sharing samples or allowing REMS participation.”

**Ed Silverman, Pharmalot (Stat)**

[Article](#), “How Martin Shkreli prevents generic versions of his pricey pill,” October 5, 2015

“Turing is using a so-called controlled distribution system that prevents generic drug makers from purchasing Daraprim. And without sufficient supplies, a generic drug maker is unlikely to have enough medicine to run clinical tests needed for FDA approval.”