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**FOR ACCESSIBLE MEDICINES**  
**SUBCOMMITTEE ON HEALTH CARE, BENEFITS, AND ADMINISTRATIVE RULES**  
**OF THE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM**  
**HOUSE OF REPRESENTATIVES**

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Good morning Chairman Chaffetz, Chairman Jordan, Ranking Member Cummings, Ranking Member Krishnamoorthi and Members of the Subcommittee. Thank you for the opportunity to participate in this timely and important hearing.

I am Bruce Leicher, Senior Vice President and General Counsel at Momenta Pharmaceuticals, and Chair of the Biosimilars Council Board of Directors. The Council is a division of the Association for Accessible Medicines (AAM), formerly GPhA.

AAM and the Biosimilars Council commend you for holding today's hearing to discuss a problem that limits patient access to affordable medicines: certain brand pharmaceutical manufacturers' use of restricted distribution programs, including Food and Drug Administration (FDA)-mandated Risk Evaluation and Mitigation Strategies (REMS), to limit market access and generic development of their product.

Having worked in the biotechnology industry for over 25 years and in the biosimilars industry since its inception, I've seen firsthand how these strategies prevent or delay competition. Congress has encouraged generic and biosimilar competition through a delicate balance between innovation and competition established by The Drug Price Competition and Patent Term Restoration Act (P.L. 98-417; 21 U.S.C. §355,) commonly referred to as Hatch-Waxman, and the Biologics Price Competition and Innovation Act (BPCIA) (P.L. 114-38, 42 U.S.C. § 262). Alarming, anticompetitive practices threaten to undermine the success achieved through generic competition and to strangle an emerging biosimilars market.

For over 30 years, generic companies have safely and effectively purchased branded drugs on the free market so that they could conduct the testing necessary to file applications for marketing approval at the FDA. But in recent years, certain brand pharmaceuticals have used restricted distribution schemes, including REMS, to block such purchase and testing. If brand products cannot be purchased, then generic drugs and biosimilars cannot be developed. Without such development, the competition envisioned by Hatch-Waxman and the BPCIA will not occur and patients will not have access to safe, effective and more affordable life-saving medicines.

Momenta, and the larger generic and biosimilar industry, are committed to ensuring that all Americans have access to safe, effective and affordable drugs. We have supported the proper use of FDA REMS programs since their inception nearly a decade ago. These programs allow for the safe distribution and use of certain pharmaceuticals that have a higher risk profile. This industry does not support any policies that would endanger patients. Nor do we want to contribute to drug shortages or add unnecessary overhead costs to already low-margin products. Our members comply with the same rules and regulations administered by the FDA for testing of medicine. Any discussion or insinuation to the contrary is simply an effort to distract from the real issue at hand: addressing the use of REMS or other non-FDA mandated restrictions on drug supply to block or delay lower cost generics and biosimilars from coming to market.

## **I. COMPETITION WORKS**

Hatch-Waxman is the foundation on which the nation's generic drug industry was built. For more than 32 years, it has proven to be a tremendous success. Generic medicines are almost 90% of the prescriptions dispensed in this country, yet account for less than 30% of drug spending<sup>1</sup>. On average, generics are 80-85% less expensive than brand drugs<sup>2</sup>. By bringing drugs to the market at a lower price point, generics help drive down costs to patients, as well as the greater U.S. healthcare system, including private health insurance plans and public programs. Generic drug savings provide the healthcare system with the ability to invest in new medications and save hundreds of billions of dollars annually. In fact, generic competition has expanded patient choice and lowered healthcare costs, saving \$1.46 trillion in the last decade alone<sup>3</sup>. To underscore the success of our sector, consider that while generic drug utilization continues to

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<sup>1</sup> *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 <http://www.gphaonline.org/media/generic-drug-savings-2016/index.html>

<sup>2</sup> *Understanding Recent Trends in Generic Drug Prices*. HHS Office of the Assistant Secretary for Planning and Evaluation. January 2016. <https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices>

<sup>3</sup> *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 <http://www.gphaonline.org/media/generic-drug-savings-2016/index.html>

increase, the share of pharmaceutical spending attributed to generics is decreasing<sup>4</sup>. More prescription drugs are being dispensed to patients, while the cost of generic medicines declines.

Looking forward, biosimilars present the same opportunity – competition for high-cost specialty biologic medicines. To contextualize the promise of biosimilars, consider that branded specialty medicines are only 1% of all prescriptions, but account for more than 30% of total pharmaceutical spending<sup>5</sup>. Utilization of these costly drugs is only expected to increase in the coming years. Experts anticipate that specialty products will account for nearly half of all pharmaceutical costs in the next three to five years<sup>6</sup>. As more conditions are treated with these more effective but higher cost biologics instead of traditional small molecule drugs, total spending is expected to increase. This is why the competition promised by biosimilars is so important to patients and taxpayers.

Thanks to the bipartisan work of Congress to enact the BPCIA, opportunities for greater access to lower-cost and high-quality biosimilar medicines are on the horizon. Today we have a growing and thriving biosimilars industry – creating good jobs and leading the world with our innovative science – particularly in the science of more fully understanding our biologic products. In fact, the FDA reported that over 64 biosimilar programs were under review for development of 23 different biologic products.<sup>7</sup> Momenta alone has seven biosimilar development programs which has required us to more than double the size of our workforce. These are American jobs, paying good wages that enhance the economic and innovative dynamism of the U.S economy. Various economic impact studies estimate projected savings for American taxpayers and patients between \$42 billion<sup>8</sup> to as much as \$250 billion<sup>9</sup> over the first 10 years of biosimilar market formation. But if we are not able to access comparator brand product to conduct development in a timely and routine manner, this will not happen.

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<sup>4</sup> *Understanding Recent Trends in Generic Drug Prices*. HHS Office of the Assistant Secretary for Planning and Evaluation. January 2016. <https://aspe.hhs.gov/pdf-report/understanding-recent-trends-generic-drug-prices>

<sup>5</sup> *Generic Drug Savings and Access in the United States* report. Generic Pharmaceutical Association. October 2016 <http://www.gphaonline.org/media/generic-drug-savings-2016/index.html>

<sup>6</sup> 2015 ExpressScripts Drug Trend Report, available at <https://lab.express-scripts.com/lab/~media/e2c9d19240e94fcf893b706e13068750.ashx>

<sup>7</sup> Testimony of Dr. Janet Woodcock Testimony “Examining FDA’s Generic Drug and Biosimilar User Fee Programs.” House Energy and Commerce Committee. March 2, 2017. <https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs>

<sup>8</sup> “*The Cost Savings Potential of Biosimilar Drugs in the United States*” RAND Corporation. 2014. [https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND\\_PE127.pdf](https://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf)

<sup>9</sup> “*The \$250 Billion Potential of Biosimilars*” Express Scripts. April 2013. [http://lab.express-scripts.com/lab/insights/industry-updates/the-\\$250-billion-potential-of-biosimilars](http://lab.express-scripts.com/lab/insights/industry-updates/the-$250-billion-potential-of-biosimilars)

Generics, and the patient access and savings they produce, are an American success story. A robust biosimilar market is becoming more of a reality every day. However, we are leaving savings on the table. We need to boost competition and reduce regulatory burdens to ensure this dynamic thrives. One of the surest ways to accomplish that goal is to address restricted distribution schemes and abuses of FDA REMS programs that limit generic and biosimilar development and competition.

## **II. RESTRICTED DISTRIBUTION ABUSES BLOCK GENERIC DRUG ENTRY**

Our efforts to lower costs and improve access to medicines are often frustrated by brand tactics designed to block or delay the generic and biosimilar drug development process. These tactics take the form of novel self-imposed restricted distribution schemes with wholesalers or specialty pharmacies that mimic FDA REMS programs, or hide behind the veneer of patient safety and FDA mandates.

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.

For instance, in the past few years, when we have sought to purchase brand products from customary wholesalers in the supply chain, we are now asked if we are conducting generic or biosimilar studies. On multiple occasions, they inform us that their contract prohibits them from selling the brand product for that purpose. No REMS program was involved; it was simply a self-justified refusal to sell to a generic or biosimilar competitor.

On another occasion, we were told we could not purchase a product because it was subject to a REMS program that restricted distribution to patients only on a named basis. We looked up the product and it was not subject to a REMS. We then informed the wholesaler, who then informed us they could not sell the product to us for biosimilar development.

Ironically, when we attempt to purchase the same product for use in comparative novel development programs that are not designed to develop competitive products, we do not encounter these refusals. It is clear that this dichotomy has nothing to do with safety but everything to do with preventing lower-cost generic or biosimilar competition.

As a result, we are now forced to consider how difficult it will be to obtain the brand product when selecting generic or biosimilar development programs. In cases where access is restricted, we have not initiated some programs. Uncertain litigation is often the only option to gain access, and that is too costly and time-consuming for companies like Momenta. Some of the larger companies that have the resources to sustain such litigation have been suing over access to individual products for years.

Other AAM members report similar experiences: a REMS or self-imposed restricted distribution program limits sale of a drug and acts to preclude timely development of follow-on products. The bottom line is simple: a generic or biosimilar manufacturer is prevented from obtaining the brand drug, is unable to perform the testing required for FDA review and approval, and patients miss out on the savings that would be available through generic competition. These barriers need to be removed and customary access restored.

### **III. FEDERAL REGULATORS HAVE RECOGNIZED THESE ABUSES**

These abuses have real costs: a 2014 study concluded the abuse of REMS and REMS-like limited distribution strategies cost the U.S. healthcare system \$5.4 billion annually - \$1.8 billion to the federal government<sup>10</sup>. But these abuses affect more than just payers – they have a direct impact on the costs borne by patients. The Federal Trade Commission (FTC) has weighed in on cases currently pending in federal court. In one, the FTC noted “a troubling phenomenon: the possibility that procedures intended to ensure the safe distribution of certain prescription drugs may be exploited by brand drug companies to thwart generic competition.”<sup>11</sup>

In a 2010 presentation to ACI’s REMS Conference, a prominent Washington, D.C. law firm highlighted how REMS programs could be used as a “tool for profitability.”<sup>12</sup> They went on to make a nod to Stanley Kubrick’s 1964 film *Dr. Strangelove*, subheading the title of their presentation, “How to learn to stop worrying and love REMS” because of the potential the program had to forestall competition<sup>13</sup>.

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<sup>10</sup> Brill, Alex, Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry, Matrix Global Advisors, July, 2014.

<sup>11</sup> Brief for the Federal Trade Commission as Amici Curiae, Mylan Pharmaceuticals, Inc. v. Celgene Corporation, (No. 2:14-CV-2094-ES-MAH) Available: <https://www.ftc.gov/policy/advocacy/amicus-briefs/2014/06/mylan-pharmaceuticals-inc-v-celgene-corporation>

<sup>12</sup> Powerpoint Presentation contained in Congressional Record of Senate Judiciary Subcommittee on Antitrust, Competition Policy and Consumer Rights hearing titled, “The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition” <https://www.judiciary.senate.gov/meetings/the-creates-act-ending-regulatory-abuse-protecting-consumers-and-ensuring-drug-price-competition>

<sup>13</sup> *Id.*

In addition to the FTC's activity, senior officials at the FDA have repeatedly spoken of the challenge. Dr. John Jenkins, M.D., then Director of the FDA's Office of New Drugs previously stated that, "the problem is the use of REMS blocking generic competition."<sup>14</sup> He went on to say that "innovators have really become very aggressive in using that strategy [and] hiring the best lawyers to back up that strategy."<sup>15</sup> The Director of the FDA Center of Drug Evaluation and Research, Janet Woodcock, M.D., testified only a few weeks ago that these abuses are "a problem we struggle with a lot"<sup>16</sup> and went on to note that they have "delayed [the] availability of generics."<sup>17</sup>

But access to the brand drug is only part of the problem. Another common ploy is to use the law's shared-REMS requirement to prevent launch of a filed and otherwise ready to be approved generic competitor. This involves the statutory requirement that, unless waived, the brand and follow-on products must enter into a single, shared safety protocol<sup>18</sup>. It has become yet another opportunity for brands to game the system.

For example, a product to treat irritable bowel syndrome was able to continue to repeatedly increase prices through abuse of the FDA administered shared REMS system since 2008<sup>19</sup>. While a generic competitor ultimately entered the market, this occurred only after prolonged refusal by the brand to negotiate a shared-REMS which FDA noted took more than three years to conclude. The Agency characterized the brand's repeated delays as "pre-textual appeals to safety as a means to delay that competition."<sup>20</sup> Unfortunately, FDA has only limited authority to allow generic manufacturers to implement their own REMS programs, even when the agency has confirmed the generic company's ability to satisfactorily implement the necessary precautions.

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<sup>14</sup> Gingery, Derrick. REMS That Block Generics Are 'Major' Problem For FDA, Jenkins Says. "The Pink Sheet" Daily. January 8, 2015.

<sup>15</sup> *Id.*

<sup>16</sup> Testimony of Dr. Janet Woodcock Testimony "Examining FDA's Generic Drug and Biosimilar User Fee Programs." House Energy and Commerce Committee. March 2, 2017. <https://energycommerce.house.gov/hearings-and-votes/hearings/examining-fda-s-generic-drug-and-biosimilar-user-fee-programs>

<sup>17</sup> *Id.*

<sup>18</sup> Federal Food, Drug and Cosmetic Act § 505-1(i)(1)(B), 21 U.S.C. 355-1 (i)(1)(B)

<sup>19</sup> AAM Analysis of AWP Data from Truven Health Analytics, Micromedex Solutions. RED BOOK Online. Alosetron. Oral. 0.5 mg. 30s ea.

<sup>20</sup> Brief of Defendant Sylvia Matthews Burwell, et al. on Plaintiff's motion for a Temporary Restraining Order, Prometheus Laboratories, Inc. v. Sylvia Matthews Burwell, et al. (2015) (No. 1:15-CV-00742 (JEB)). Available at: <http://www.fdalawblog.net/LOTRONEX%20-%20Roxane%20TRO-PI%20Opp.pdf>

Even after FDA provided a waiver for the generic manufacturers to operate an equivalent REMS program, the brand sued the Agency in an attempt to force the generics back into the stalled negotiations. In the time period between expiration of the brand exclusivity and the FDA waiver, the brand raised its price over 50%, much more rapidly than it had prior to the threat of generic competition<sup>21</sup>.

These abuses keep important products off the market indefinitely, even after the FDA has determined that the company's follow-on product is just as safe and just as effective as the brand product, and even when the brand product's patent protection has expired. The FDA needs more explicit authority to authorize generic and biosimilar companies to implement safe REMS programs of their own under FDA regulation.

#### **IV. THESE ABUSES ARE NOT NEW AND SHOW NO SIGNS OF SLOWING**

This is not a new problem. Almost five years ago, the Senate passed legislation that included language – at FDA's request – to address it. In 2012, the Senate passed that language as part of the prescription drug user fee reauthorization<sup>22</sup>. Unfortunately, the language fell out when the bill went to conference with the House of Representatives. Since then, FDA has frequently called for legislation to address REMS abuse. Dr. Woodcock has repeatedly addressed the point head-on in testimony to Congress, calling for a legislative fix. Last year, when asked why brand companies are abusing the REMS program she stated, “innovator companies feel it is their duty to their stockholders to delay completion as long as possible.”<sup>23</sup> These products bring in billions of dollars in revenue to the brand so, as Dr. Woodcock noted, market manipulations are viewed merely as a cost of doing business.

There were further legislative discussions last year, as legislation was introduced in the House and Senate, and as part of the 21<sup>st</sup> Century Cures process. We are encouraged by the continued attention, and hope that Congress will complete work on a solution to this issue this year.

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<sup>21</sup> AAM Analysis of AWP Data from Truven Health Analytics, Micromedex Solutions. RED BOOK Online. Alosetron. Oral. 0.5 mg. 30s ea.

<sup>22</sup> Food and Drug Administration Safety and Innovation Act, S. 3187, 112<sup>th</sup> Congress (As passed by Senate May 24, 2012)

<sup>23</sup> *Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs. Before S. Comm. on Health, Education, Labor and Pensions, 114<sup>th</sup> Congress (2016)* (Comments by Janet Woodcock, MD, Director of Center for Drug Evaluation and Research at FDA). Available at: <http://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs>

The potential for abuses is only growing. Increasingly, new FDA approvals are subject to REMS, and the percentage of REMS programs that require distribution restrictions referred to as Elements to Assure Safe Use (ETASU) has increased dramatically in the last several years. In 2009, roughly 75% of REMS programs only required medication guides – but now over 50% of REMS programs include limits on distribution<sup>24</sup>. Some manufacturers have even requested FDA to impose these restrictions despite FDA’s conclusion that they are not necessary to protect patient safety<sup>25</sup>. In the context of biologic products – drugs that tend to have extremely high list prices – 34% of all biologics approved are subject to a REMS program<sup>26</sup>. As more biologics lose underlying patents and market exclusivities, the profit incentives for brand manufacturers to delay biosimilar development will become even more pronounced than they already are.

## **V. RESTRICTED DISTRIBUTION ABUSES ARE NOT LIMITED TO PRODUCTS WITH REMS**

There is also growing use of self-imposed restricted distribution programs. While most attention has focused on high-profile examples, these are by no means outliers. AAM has surveyed their membership about products they have encountered where restricted distribution agreements prevent a generic or biosimilar drug developer from purchasing samples. There are dozens of products on that list in addition to the 78 FDA REMS programs. Many self-imposed restricted-distribution programs are designed – often explicitly – to block generic entry.

For example, in an investor presentation, the pharmaceutical manufacturer Retrophin discussed how limiting distribution of the drugs Thiola® and Chenodal® to a single specialty pharmacy would block a lower-cost alternative from coming to market and serve to protect their product from competition<sup>27</sup>. I’ll also note this Committee’s previous investigation of Turing Pharmaceuticals’ pricing practices around the drug Daraprim®. Turing used a closed distribution system as an effective block on generic competition. John Hass, the company’s director of patient access, said so explicitly, noting that generics wishing to buy samples of the drug would not be welcome. Hass said:

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<sup>24</sup> Individual REMS programs listed at: <https://www.accessdata.fda.gov/scripts/cder/remis/>

<sup>25</sup> Letter from FDA to Jennifer Ekelund at pg 3. February 2015. [http://www.accessdata.fda.gov/drugsatfda\\_docs/appletter/2015/021196Orig1s015ltr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/appletter/2015/021196Orig1s015ltr.pdf)

<sup>26</sup> Individual REMS programs listed at: <https://www.accessdata.fda.gov/scripts/cder/remis/>

<sup>27</sup> Retrophin: Manchester Pharmaceuticals Acquisition February 13, 2014. Available at: <https://web.archive.org/web/20150226002409/http://www.retrophin.com/pdf/ManchesterAcquisitionAgreementConferenceCall.pdf>



*“Most likely I would block [a generic 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 manufacture a generic alternative] no matter what. But I’m certainly not going to make it easier for them”<sup>28</sup>.*”

These programs do not stand on any FDA safety requirements. Rather, the manufacturers choose to adopt REMS-like protocols because they know how effective a tool they can be in blocking lower-cost alternatives from coming to market.

Your colleagues on the Senate Aging Committee have also examined market restrictions absent any FDA-mandate. Summarizing their investigations of abuses by drug companies like Turing, Retrophin, and Valeant, they noted that:

*“In the cases of Turing and Retrophin, placing the drug into restricted distribution was a way for the companies to control who could buy their drugs. Mr. Shkreli blocked any purchase that looked like an attempt by a potential generic entrant to obtain the [brand product]. To the extent that drugs travelled through less-typical channels (such as 340B institutional distribution), the same rules applied—sales via that channel were carefully regulated and quantity limited to ensure that drugs were not sold to a potential generic entrant.”<sup>29</sup>*”

The Committee also noted testimony from Dr. Woodcock on the challenge posed by non-FDA-mandated restricted distribution schemes. She explained:

*“[T]he companies on their own behalf have restricted programs that we do not really understand, but they are not related to REMS. We have had over 100 inquiries from generic companies who cannot get a hold of the innovator drug to compare their drug to. We have done everything we can to—we have written a letter saying, you know, that REMS does not require this, you can give it out for this purpose, and so forth, and we also refer these to [the Federal Trade Commission], okay? But we still continue to get*

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<sup>28</sup> Ed Silverman, *How Martin Shkreli prevents generic versions of his pricey pill*, Pharmedica, October 5, 2015. Available: <http://pharmedica.com/how-martin-shkreli-prevents-generic-versions-of-his-pricey-pill/>

<sup>29</sup> Special Committee on Aging United States Senate, *Sudden Price Spikes in Off-Patent Prescription Drugs:*

*The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System.* December 2016.

*complaints from generic companies that they cannot get a hold of the drug to make the comparison they need to do.*<sup>30</sup>”

So while many opponents of reform have argued that there are only a small number of products that are subject to REMS with ETASU, they ignore two very important facts: first, more and more products approved are subject to a REMS requirement, just setting the system up for further abuse; second, there is no public record of what companies are already using restricted distribution networks to restrict access to specific drug samples. Most troubling, the FDA cannot prevent those contractual arrangements and the FTC has yet to bring an enforcement action against one.

## **VI. RESTRICTED DISTRIBUTION ABUSES POSE A PARTICULARLY GRAVE THREAT TO THE DEVELOPMENT OF BIOSIMILARS**

I have made clear the harm that these abuses are already causing today. But the danger is even more pronounced as we look to the future. As the biosimilars market develops, the high price of many new biologics will only incentivize further abuse of these types of arrangements, and create incredibly excessive spending for the healthcare system through the loss of potential savings.

As we increasingly shift from use of small-molecule drugs to biologic products, the development of biosimilar medicines will be critical to reducing the cost of prescription drugs. But such products are much more complex and difficult to develop. The foundation of biosimilar development is demonstrating that a biosimilar is highly similar to the brand product. This requires thorough characterization of multiple lots of the brand product over time. If access to brand lot variability is blocked by restricted access to brand product, then biosimilar development will be blocked.

In addition, unlike most small molecule generic drugs, the development of biosimilars is more likely to involve clinical trials and require far greater quantities of samples of the original product. For instance, clinical studies blind the medicine from the physician to avoid bias and ensure the validity of the data. This requires the purchase and re-labeling of the product to conduct the study. Moreover, the quantities are large and require purchases over a longer period

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<sup>30</sup> Testimony of Dr. Janet Woodcock, “Generic Drug User Fee Amendments: Accelerating Patient Access to Generic Drugs” January 28, 2016 HELP Hearing, Trans. at 51:4–14 <https://www.help.senate.gov/hearings/generic-drug-user-fee-amendments-accelerating-patient-access-to-generic-drugs>

of time than generic development. Restricted access at any point in the development cycle could cause a study to fail, thereby slowing or preventing the entry of lower-cost biosimilar medicines.

Perhaps what is most interesting is a review of ClinicalTrials.gov – the website listing clinical studies in the United States – showing over 90 comparative clinical trials underway by brand companies that use comparative or combined use of brand products that appear to be freely purchased without any of these restrictions<sup>31</sup>. This makes clear that the motivation of the restrictions is to protect profits, not patients.

To be clear, the use of restricted distribution schemes, whether tied to a REMS or self-imposed, poses a severe threat to the billions in savings expected in the next ten years through biosimilar competition.

Some may tell you that this is “too small” of a problem to address legislatively. But the numbers say otherwise. The Congressional Budget Office has estimated various reform proposals as saving billions of dollars for taxpayers. Experts at the FDA and FTC have called for fixes to these abuses. Anything less merely continues the opportunity for further abuse.

I would be happy to address any questions from the Subcommittee.

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<sup>31</sup> Individual studies available at <https://clinicaltrials.gov/>.