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LEGISLATIVE TESTIMONY

The CREATES Act: Ending Regulatory Abuse, Protecting Consumers, and Ensuring Drug Price Competition of 2016

Testimony before the Subcommittee on Antitrust, Competition Policy, and Consumer Rights
Committee on the Judiciary
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Chairman Lee, Ranking Member Klobuchar, and distinguished Members of the Subcommittee:

I. Overview

Thank you for the opportunity to speak to you today about the "Creating and Restoring Equal Access to Equivalent Samples Act" (CREATES Act) of 2016, and, more particularly, that draft legislation's implications for competition and consumer welfare. I applaud you for convening this hearing.

My name is Alden Abbott. I am the Deputy Director and the John, Barbara, and Victoria Rumpel Senior Legal Fellow in the Edwin Meese III Center for Legal and Judicial Studies at The Heritage Foundation.[1] The views I express in this testimony are my own, and should not be construed as representing any official position of the Heritage Foundation.

I have considerable experience in competition policy and in the interaction among antitrust law, intellectual property law, and pharmaceutical regulation. I bring to you the perspective of someone who has addressed these issues as a U.S. Federal Trade Commission (FTC) official during the George W. Bush Administration, as a Heritage Foundation scholar, as an adjunct professor at the George Mason University School of Law, and as a lecturer and published author.

In short, I believe that the current version of the CREATES Act would, if enacted by Congress, enhance competition and consumer welfare. Specifically, the Act would promote welfare-enhancing competition in the market for brand name pharmaceuticals and biological products (biologics), and their lower-priced generic and biosimilar substitutes, without inappropriately undermining the intellectual property rights of individuals who bring forth new innovative medical treatments that greatly improve the quality of American health care. 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.

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For purposes of convenience, I will employ the term "generic" in referring both to generic substitutes for patented branded pharmaceuticals, and to biosimilar substitutes for biologic drugs. I will also use the term "branded" or "brand name" drugs in referring both to innovative branded pharmaceuticals and branded biologics, originally protected by patent and (in the case of biologics) marketing and data exclusivity periods.[2] Brand name and branded drugs are also sometimes referred to as "innovator drugs."

II. Regulatory Manipulation to Deter Generic Drug Entry

Concerns have been raised for several years that brand name pharmaceutical companies may be manipulating U.S. Food and Drug Administration (FDA) regulations to deter and delay entry into the marketplace of generic competition to branded drugs that no longer are under patent.[3] Under the 1984 Hatch-Waxman Act,[4] enacted to encourage generic pharmaceutical competition, the manufacturer of a generic drug must file an abbreviated new drug application (ANDA) with the FDA to demonstrate that its generic formulation is bioequivalent to the brand drug with which it intends to compete.[5] The ANDA mandate requires the generic producer to obtain a sample of the established brand drug in order to carry out bioequivalence testing. The Biologics Price Competition and Innovation Act of 2009[6] and subsequent FDA guidance established a "stepwise" abbreviated licensure pathway to facilitate market entry of biological products that are demonstrated to be "biosimilar" to or "interchangeable" with an FDA-licensed biological product.[7]

The 2007 Food and Drug Administration Amendments Act (FDAAA)[8] "represents a very significant addition to FDA authority."[9] Among other things, the FDAAA authorizes the FDA to require that manufacturers of pharmaceuticals and biologics carry out plans that use risk minimization strategies beyond professional labeling ("risk evaluation and mitigation strategies," or REMS) to ensure that certain very high risk prescription drugs are used only in circumstances where their benefits outweigh their risks.[10] The FDA decides what drugs are sufficiently risky to merit REMS coverage, and may impose tight distribution restrictions (for example, allowing

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[2] *See, e.g.*, Erwin A. Blackstone & P. Fuhr Joseph, Jr., *The Economics of Biosimilars*, 6 AMERICAN HEALTH & DRUG BENEFITS No. 8, at 469-478 (Sep.-Oct. 2013), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4031732/.

[3] *See, e.g.*, Alex Brill, Matrix Global Advisors, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry* (July 2014), *available at* http://www.gphaonline.org/media/cms/REMS_Studyfinal_July2014.pdf.

[4] Drug Price Competition and Patent Term Restoration Act , P.L. 98-417, 98 Stat. 1585 (1984).

[5] *See* 21 U.S.C. § 355(j).

[6] Sections 701-703 of the Patient Protection and Affordable Care Act, P.L. 111-148, 124 Stat. 119 (2010).

[7] *See* FDA, Information on Biosimilars (May 10, 2016), *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/.

[8] P.L. 110-85, 121 Stat. 823 (2007).

[9] FDA, Food and Drug Administration Amendments Act (FDAAA) of 2007 (last updated Dec. 2, 2011), *available at* http://www.fda.gov/RegulatoryInformation/Legislation/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm.

[10] FDA's authority to impose REMS requirements is set forth in 21 U.S. Code § 355–1. See generally FDA, FDA Basics Webinar: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS), *available at* http://www.fda.gov/aboutfda/transparency/basics/ucm325201.htm (accessed June 8, 2016).

sales only to hospitals) on particularly sensitive REMS drugs. Nevertheless, the FDAAA makes it clear that drug producers may not invoke REMS restrictions to undermine generic competition.[11]

In December 2014, the FDA issued draft guidance allowing generic producers to obtain an FDA opinion letter stating that testing protocols comply with specific REMS programs.[12] As one commentator has explained, however, such guidance may do little to encourage brand name companies to cooperate in facilitating entry by generic competitors:

> Many of the brand pharmaceutical industry's justifications for using REMS distribution restrictions may not be mooted by such an FDA opinion letter. Brand companies have argued that, even if generic companies possess detailed safety protocols associated with ANDA testing, a brand need not simply take the word of others that these protocols are adequate to protect against harm to consumers or the risk of brand liability. Brand manufacturers may be liable under state law for harm caused during generic bioequivalency testing; they may also suffer reputational harm or regulatory censure as a result of adverse events that occur during the generic study. This debate is complicated where the generic's safety protocol has been blessed by the FDA, but it is by no means ended. Nor does the guidance affect the legal debate regarding the [antitrust] duty of a competitor to deal with its rivals[ ].[13]

FTC Chairwoman Edith Ramirez highlighted the problem of regulatory evasion by brand pharmaceutical companies to undermine generic competition, in March 2016 testimony before this Subcommittee:

> The [Federal Trade] Commission . . . continues to review . . . strategies adopted by pharmaceutical companies that may have the effect of delaying or preventing generic entry. For example, we continue to be concerned about potential abuses by branded pharmaceutical companies of Food and Drug Administration (FDA) safety protocols known as REMS—risk evaluation and mitigation strategies—to impede generic competition. REMS programs are implemented by a drug's manufacturer to provide safety measures for handling and distributing high-risk medicines. 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.[14]

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[11] *See* 21 U.S.C. § 355-1(f)(8) (specifying that no REMS "element to assure safe use" of an established drug may be used to "block or delay approval of" a generic drug application).

[12] *See* FDA, How to Obtain a Letter from FDA Stating that Bioequivalence Study Protocols Contain Safety Protections Comparable to Applicable REMS for RLD: Guidance for Industry (Dec. 2014*), available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM425662.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery.

[13] Anna M. Fabish, *Why REMS Abuse Doesn't Belong in Antitrust Litigation*, LAW 360, Apr. 23, 2015, at 4, *available at* http://www.law360.com/articles/645875/why-rems-abuse-doesn-t-belong-in-antitrust-litigation.

[14] *Oversight of the Enforcement of the Antitrust Laws: Hearing before the Subcomm. on Antitrust, Competition Policy and Consumer Rights of the S. Comm. on the Judiciary*, 114th Cong. (2016), at 10 (statement of Edith Ramirez, Chairwoman, FTC) (footnote reference deleted), *available at* https://www.ftc.gov/system/files/documents/public_statements/934563/160309enforcementantitrustlawstest.pdf.

Even assuming that the concern about anticompetitive regulatory manipulation by branded drug companies is well-founded, I do not believe that antitrust enforcement is the best means to combat it, for three reasons.

First, the primary goal of promoting generic competition is to expedite entry of generic drugs that compete with established branded products and drive down prices.[15] The shorter the regulatory delay associated with generic entry, the greater the aggregate benefit to consumers and to the competitive process. Antitrust litigation, however, is inherently slow, and years of costly discovery may go by before a complaint is resolved. Several antitrust complaints brought in recent years by generic firms against alleged anticompetitive manipulation of REMS requirements by brand name companies, while still active, have yet to bear fruit.[16]

Second, the need to show antitrust-related harm presents obstacles to a successful antitrust lawsuit against a brand name company for allegedly restricting access to its products by generics. Private plaintiffs face problems in showing causation and harm to their business interests, and the FTC could have difficulty in demonstrating likely harm to consumers, as one commentator cogently explains:

> Antitrust actions and FTC enforcement are comparatively inefficient means of addressing alleged REMS abuse. This is largely the result of the proximate cause and consumer-harm requirements involved. For example, in a typical REMS distribution restriction fact pattern, the generic is trying to obtain brand samples to perform bioequivalence testing for its ANDA. Thus, at the time the claim arises, the ANDA for the generic drug has not even been completed, let alone approved. For a consumer or a generic to prove he or she was harmed by the brand's alleged abuse of its REMS program restrictions, the consumer or generic would need to establish that had the generic received the requisite samples from the brand: (1) the bioequivalence testing using the brand's sample would have been successful, (2) the ANDA would have been approved, and (3) the generic would have ultimately been manufactured and successfully brought to market. The FTC would encounter these issues in establishing likely harm to consumers. In private actions, estimating the timing in such a but-for world would likewise complicate both proof of injury and damages.[17]

Third, U.S. antitrust law has a general presumption against requiring a firm to assist a competitor, as the Supreme Court emphasized in *Verizon v. Trinko*,[18] in holding unanimously that a monopoly telecommunications company's violation of its *regulatory* duty (under federal communications law) to make its facilities available to a rival did not constitute an *antitrust*

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[15] It is well established in the economic literature that the entry of generic products substantially enhances competition and reduces drug prices. *See, e.g.*, *Generic Pharmaceuticals*, Contribution of the United States, OECD Competition Committee, Oct. 14, 2009, *available at* https://www.ftc.gov/sites/default/files/attachments/us-submissions-oecd-and-other-international-competition-fora/genericpharma.pdf.

[16] For a summary of current REMS antitrust litigation, *see*, *e.g.*, Seth C. Silber, Jeff Bank, Courtney Armour, Kellie Kemp, Brendan Coffman, & Ryan Maddock, *Pharmaceutical Antitrust Litigation in 2015—Settlements, Product Hopping, and REMS*, COMPETITION POLICY INTERNATIONAL (Dec. 2015(1)), at 9-12, *available at* https://www.wsgr.com/publications/PDFSearch/CPI-1215.pdf.

[17] Fabish, *supra* note 13, at 5. The FTC and private plaintiffs might counter that inherently inefficient delaying tactics should be presumed to be "exclusionary" and thus anticompetitive (that is, likely to harm consumers) even in the absence of final FDA review, but such a position would face challenges, given the existence of possible good faith explanations for brand name producers' conduct, *see supra* note 13 and accompanying text.

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

violation (specifically, illegal monopolization under Section 2 of the Sherman Antitrust Act[19]). In light of *Trinko*, a branded drug producer could argue persuasively that its failure to cooperate fully by not providing drug samples to a potential generic competitor (or by not working jointly with the generic competitor to develop risk mitigation strategies acceptable to the FDA) would comport with the antitrust laws, *even if* it violated a federal *regulatory* duty (which it arguably does not).[20] Reinforcing this conclusion, a branded pharmaceutical company could also plausibly maintain that its failure to cooperate with a generic producer reflected not anticompetitive intent, but rather legitimate good faith public health concerns. In that regard, the branded firm could cite possible reputational damages and legal liability it might face, should the generic recipient of samples impose harm on consumers.[21]

Assuming, then, that antitrust law is a poor vehicle to promote generic competition with respect to REMS-covered products when the branded firm fails to provide drug samples to potential generic entrants, what is the best solution? One possibility, of course, would be statutory language that authorized the FDA to impose regulatory enforcement mechanisms, coupled with specific sanctions for violations, to "put teeth" in the existing statutory supply obligations placed on brand name companies.[22] I take no position on this legislative option. I note, nonetheless, that new regulatory norms inevitably risk misapplication, and may inadvertently impose excessive costs even on companies that are legitimately cooperating in supplying samples – for example, by imposing uniform "one-size-fits-all" standards that do not take into account differences in business settings.[23] I would respectfully recommend that Congress keep those concerns in mind if it contemplates such a statutory amendment.

III. The CREATES Act

A second possibility, the one embodied in the CREATES Act (the Act), is to authorize potential generic entrants to sue branded producers directly: (1) for failure to provide them with samples needed to undertake testing and obtain FDA approval; and (2) for failure to jointly negotiate REMS-related regulatory protocols required for generic drug approval. After briefly describing important CREATES Act provisions, I will assess their effectiveness in advancing the procompetitive goal of generic competition.

Section 2 of the Act sets forth key legislative findings, concluding that generic competition has been harmed (to the tune of billions of dollars in losses to consumers and taxpayers) due to delays in generic entry attributable to insufficient access to branded drug samples. Section 2 also sets forth the finding that certain branded producers of pharmaceuticals and biologics have impeded negotiations with generic companies on the development of a shared system of safety-related "elements," needed to ensure the safe use of drugs and FDA approval of

[19] 15 U.S.C. § 2.

[20] In its June 17, 2016 *amicus curiae* brief in a private REMS antitrust case, the FTC argued that a branded producer's failure to sell to a generic rival may constitute exclusionary conduct, while conceding "Congress's failure to create an explicit duty to sell [branded drug] samples". Federal Trade Commission Brief as *Amicus Curiae* (June 17, 2016), Mylan Pharms Inc. v Celgene Corp, No. 2:14-cv-02094-ES-MAH (DNJ filed 3 April 2014).

[21] *See supra* note 13 and accompanying text.

[22] *See* 21 U.S.C. § 355-1(f)(8), *supra* note 11.

[23] There is also a risk that prospective generic entrants may mischaracterize their dealings with established brand producers, in the hope of generating regulatory investigations of the latter firms so as to raise their costs and attenuate their competitive vigor.

generic substitutes. Section 2 concludes that "a more tailored legal pathway" than antitrust would facilitate generic competition.

Section 3(b) of the Act authorizes a potential generic entrant to file a civil action in federal district court against a brand producer for (1) failing to provide sufficient quantities of the branded drug on commercially-reasonable, market-based terms; and (2) failing to facilitate access to safety-based regulatory protocols for REMS-covered drugs. This section requires that, in order to bring suit in the case of a REMS-covered drug, the generic firm must have taken the necessary preliminary steps to obtain eventual regulatory drug approval, specifically by obtaining a "covered product authorization" from FDA, which has also been presented to the brand name company.

With respect to civil actions based on failure to provide drugs, section 3(b) requires the generic entrant to prove, by a preponderance of the evidence, that: (1) the brand name company has not complied, by a statutorily-specified date, with the generic firm's request to purchase "sufficient quantities" needed for regulatory testing of the branded drug in question; and (2) the generic entrant has not otherwise received sufficient quantities of the drug on commercially reasonable, market-based terms. (The calculation of the date differs somewhat for REMS-covered and non-REMS-covered branded products.) The brand name firm may interpose the affirmative defense that it no longer sells the drug in question, or that the drug can be purchased in sufficient quantities on commercially reasonable, market-based terms from the brand name firm's agents, distributors, or wholesalers. Remedies for a prevailing generic firm include receipt from the branded company of (1) sufficient quantities of the required drug on commercially reasonable terms, (2) reasonable attorney fees and litigation costs, and (3) additional monetary damages sufficient to deter the branded company from failing to provide other generic producers with sufficient quantities of the required drug, without a legitimate business justification. Monetary damages may be up to the amount the defendant earned on the branded product during the period of unjustifiable delay.

With regard to civil actions based on failure to negotiate, section 3(b) requires the generic entrant to prove, by a preponderance of the evidence, that the brand name firm: (1) failed to reach agreement on a single set of regulatory protocols ("shared system of elements") to assure safe use of the drug in question under REMS; or (2) precluded the generic producer from entering into a preexisting REMS safety-based regulatory system. Remedies for a prevailing generic firm include (1) authorization to employ the regulatory protocols required for production of the REMS-covered drug in question, (2) reasonable attorney fees and litigation costs, and (3) additional monetary damages sufficient to deter the branded company from blocking other generic producers from entering into required regulatory protocols. Monetary damages may be up to the amount the defendant earned on the branded product during the period it unjustifiably delayed the generic company's adoption of the regulatory system required for production of the REMS-covered drug at issue.

Finally, section 3(c) of the Act provides a shield for brand companies that are required to cooperate with generic firms by stating that the brand company "shall not be liable for any claim arising out of the failure of" an aspiring generic entrant "to follow adequate safeguards to assure safe use of the . . . product" in question. While helpful, this provision might provide brand name producers even greater protection from the costs of unwarranted litigation by specifically preempting *all state and federal law causes of action* arising out of any harm attributable to the Act's drug supply and regulatory cooperation mandates.

The CREATES Act takes a pragmatic, measured, well-tailored approach to promoting generic drug entry. It efficiently disincentivizes brand name drug companies from manipulating FDA regulation by exposing them to the loss of revenues associated with unwarranted delay tactics (plus the costs of suit), while precluding exemplary damage awards that would incentivize inefficient "bounty hunting" lawsuits by generic firms. By narrowly defining the scope of causes of action for regulatory evasion, and providing an affirmative defense for failure to supply, the Act encourages suits by only those generic producers that truly have been harmed, thereby constraining the overall costs of litigation. The Act is in every sense a superior vehicle to antitrust suits, which are costly, cumbersome, wide-ranging, and ill-designed to provide effective relief in this area. Furthermore, the Act avoids authorizing potentially overbroad FDA regulations that would raise costs to non-culpable firms and bad actors alike. Finally, the Act does nothing to limit the exercise of legitimate intellectual property rights by brand name firms (it establishes no new grounds for challenging their patents or other intellectual property), nor does it impose inappropriate new regulatory burdens on those companies. To the contrary, the Act *reduces* net regulatory costs by discouraging incumbent brand name producers from manipulating the drug regulatory system to artificially disadvantage prospective generic entrants.[24]

In closing, two notes of caution are in order. First, as noted previously, the Act's welfare benefits could be further enhanced by the addition of language shielding brand drug producers from unwarranted state and federal lawsuits generated by the Act's requirements. Second, the Act deals with only one among several sources of drug-related competitive problems. In weighing possible legislative and regulatory reforms in this area, Congress may wish to explore other sources of drug market imperfection as well.[25]

IV. Conclusion

In sum, I conclude that the CREATES Act, as currently drafted, is a reasonable measure that, if enacted, would likely promote (albeit it in an inherently limited fashion) competition and consumer welfare in markets for pharmaceuticals and biologics. This Act, as well as other measures designed to promote generic entry and competition in drug markets, merit serious congressional consideration.

I thank you for inviting me here to testify today, and I look forward to answering any questions you might have.

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[24] Although the creation of new causes of action against brand producers implicitly is a source of potential regulatory costs to them, those costs are not associated with a reduction in economic efficiency. Instead, the CREATES Act tends to raise economic efficiency by deterring the imposition of regulatory entry barrier costs on potential generic drug competitors. In other words, the Act is designed on net to lower regulatory costs. Moreover, while no litigation scheme (including this one) is error free, the causes of action allowed by the Act are sufficiently narrowly drawn so as to rein in error costs. That fact reinforces the conclusion that the Act overall is a social cost-reducing measure.

[25] *See, e.g.*, *Hearing before the H. Comm. on Oversight and Government Reform*, 114th Cong. (2016) (statement of Devon M. Herrick, Ph.D.), *available at* http://www.ncpa.org/pdfs/16-0204%20NCPA%20Testimony-%20Herrick-%20Generic%20Drug%20Prices.pdf.