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**Strategies that Delay Timely Entry of Generic Drugs and Potential Policy Solutions:
The CREATES Act and Beyond**

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Subcommittee on Regulatory Reform, Commercial and Antitrust Law
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Summary

- Generic competition helps lower drug prices, which leads to improved patient adherence and outcomes, but manufacturers of brand-name drugs often use “life-cycle management” business strategies to delay the availability of generic versions.
- Strategies commonly used by brand-name manufacturers include patenting aspects of a drug apart from the active ingredient or slight modifications of the drug that do not add clinical value (“secondary patents”), settling lawsuits with generic challengers over the validity of their patents, denying generic manufacturers access to drug samples necessary for bioequivalence testing, misusing risk evaluation and mitigation strategies (REMS), and filing questionable citizen petitions with the FDA
- To combat such tactics, the CREATES Act offers a number of important changes that this Committee should support
- Additional legislative interventions could promote administrative challenges to ensure that patents are only granted or upheld for true innovations, discourage anticompetitive settlements of litigation, and adopt the presumption that certain potentially frivolous citizen petitions be summarily rejected
- Ensuring the timely introduction of generic drugs through these interventions could improve patient outcomes by decreasing the costs of medical care and encourage investment in the next generation of therapeutic products

Chairman Goodlatte, Ranking Member Conyers, and other members of the committee: My name is Aaron Kesselheim. I am an internal medicine physician, lawyer, and health policy researcher in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital in Boston and an Associate Professor of Medicine at Harvard Medical School. I lead the Program On Regulation, Therapeutics, And Law (PORTAL), an interdisciplinary research core that studies the intersections between laws and regulations and the development, utilization, and affordability of drugs. We are the largest, academic-based, independent group conducting empirical research in this area in the country. Thank you for this opportunity to provide some comments on antitrust abuses and the timely availability of generic drugs, and the role of the CREATES Act in addressing these practices.

There are two distinct phases in the US drug marketplace.¹ The first phase occurs after initial Food and Drug Administration (FDA) approval of a new prescription drug or biologic, and it is characterized by market exclusivity for that product. Patents, as well as other government-authorized protections earned based on FDA approval, ensure that manufacturers face no direct competition during this time and that the brand-name drug is the only available formulation that patients can receive. Manufacturers charge high prices based on whatever prices the market will bear to compensate for investments in research and development and earn substantial profits.² Our review of top-selling drugs found that this period lasts on average 12.5 years, and 14.5 years for the most innovative, first-in-class products.³

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1. Some of my comments today will be published in a forthcoming article I have co-authored: Vokinger KM, Kesselheim AS, Avorn J, Sarpatwari A. Strategies that Delay Market Entry of Generic Drugs. *JAMA Internal Medicine* 2017 [in press]
 2. Kesselheim AS, Avorn J, Sarpatwari A. The high cost of prescription drugs in the United States: origins and prospects for reform. *JAMA* 2016;316(8):858-871.
 3. Grabowski H, Long G, Mortimer R. Recent trends in brand-name and generic drug competition. *Journal of Medical Economics* 2014;17(3):207-214.

Today’s hearing focuses on the point of transition between the end of this period and the beginning of the second phase: when other FDA-approved versions of the original product made by different manufacturers—generic drugs and biosimilar—can be sold. Most generic small-molecule drugs are clinically interchangeable with their brand-name counterparts, which means that they can be automatically substituted at the pharmacy and provide similar patient outcomes. The automatic interchange of these products leads the price of the drug to fall by 80% or more, approaching the cost of production.⁴ Availability of lower-priced generic drugs improves patient adherence and outcomes,⁵ and has been estimated to lead to a trillion dollars in health care system savings over the last decade.⁶ Biosimilar versions of biologic drugs are now being approved as well, although none yet exist that have been deemed interchangeable by FDA. There is also hope that availability of biosimilar drugs will reduce biologic drug prices, albeit to a lesser extent.⁷

Despite the public health importance of timely availability of generic drugs, manufacturers of brand-name drugs work to extend the market exclusivity of their products via a number of different strategies called “life-cycle management,” or more pejoratively, “evergreening.” Many of these strategies invoke antitrust concerns, and some of them are addressed by the CREATES Act. These strategies include secondary patenting leading to product hopping, reverse payment settlements of patent challenges, failure to provide samples needed for product testing or to collaborate on Risk Evaluation and Mitigation Strategies (REMS), and inappropriate use of Citizen

4. Generic competition and drug prices. Food and Drug Administration.

<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>. Updated May 13, 2015.

5. Shrank WH, Hoang T, Ettner SL, Glassman PA, Nair K, DeLapp D, Dirstine J, Avorn J, Asch SM. The implications of choice: prescribing generic or preferred pharmaceuticals improves medication adherence for chronic conditions. *Archives of Internal Medicine* 2006;166(3):332-337.

6. Drug pricing: research on savings from generic drugs use. Government Accountability Office.

<http://www.gao.gov/assets/590/588064.pdf>. Published January 31, 2012.

7. Lee SY. A cheaper version of a blockbuster drug just launched at a 35% discount — and it could save the US billions. Reuters. July 24, 2017.

Petitions. I will review these strategies and discuss potential legislative fixes like the CREATES Act that can help address these problematic practices and better ensure appropriate availability of generic or biosimilar drugs for the benefit of patients and the health care system.

Strategies that Delay Timely Generic Entry

Secondary Patenting and Product Hopping

Patents last for 20 years, and are supposed to be granted by the US Patent and Trademark Office (USPTO) only for products that are “novel” and “non-obvious” over what has already been discovered. The original patents on the underlying active ingredient of a prescription drug are usually sought near the time of its discovery, which can be many years before its FDA approval. However, much of this time can be recovered through “Patent Term Restoration,” a process created by the Hatch-Waxman Act in which manufacturers add years to the end of their key drug patents to account for the clinical trials and FDA review periods.

Apart from this key original patent, manufacturers of FDA-approved drugs often seek and obtain multiple additional patents covering modified aspects of the drug or its use. These “secondary” patents may cover such features as a drug’s coating, salt moiety, formulation, or method of administration. Many of them may not be truly novel and non-obvious, due to lax interpretation of standards and insufficient resources for close reviews at the USPTO. But since each patent lasts 20 years and has a presumption of validity once issued, later-issued secondary patents can delay entry of generic drugs if generic manufacturers’ products infringe those subsequent patents. One classic example was the anti-ulcer medication omeprazole (Prilosec), which was protected by a patent covering its coating that lasted until 2007, as compared to the patent on the underlying active ingredient, which expired in 2001 (litigation over this patent

ultimately provided for generic entry in 2003).⁸ In a study I helped lead on the HIV drugs ritonavir and lopinavir, we found patents on the drug covering related chemical structures and compositions or formulations (N=81), manufacturing methods and processes (N=68), methods of disease treatment (N=31), and other more general patents (N=28), threatening to extend market exclusivity on the drug for 12 years after expiration on the patents on the underlying active ingredient.⁹ From 1998 to 2005, the average number of patents associated with each new FDA-approved drug increased from 2 to 10.¹⁰

Another way that secondary patents delay or undercut generic entry is by providing the opportunity for manufacturers to engage in “product hopping” to a new product covered by the later-expiring patent. For example, in an attempt to extend market exclusivity for the transformative chronic myelogenous leukemia treatment imatinib (Gleevec), Novartis replaced its original product with a new version featuring a different crystal of the active ingredient covered by secondary patents.¹¹ There was no evidence that the modified version offered any improvements in effectiveness or safety over the original version.¹² Another classic example also related to omeprazole, a racemic mixture of inactive r- and active s-enantiomers, and its purified s-enantiomer formulation, esomeprazole (Nexium), which was introduced as generic competition for omeprazole was on the horizon.¹³ Esomeprazole went on to become one of the top-selling

8 Kesselheim AS, Fischer MA, Avorn J. Extensions of Intellectual Property Rights and Delayed Adoption of Generic Drugs: Effects on Medicaid Spending. *Health Affairs* 2006;25(6):1637-1647

9 Amin T, Kesselheim AS. Secondary patenting of branded pharmaceuticals: a case study of how patents on two HIV drugs could be extended for decades. *Health Affairs* 2012;31:2286-2294.

10. Kapczynski A, Park C, Sampat B. Polymorphs and prodrugs and salts (oh my!): an empirical analysis of “secondary” pharmaceutical patents. *PLoS One*. 2012;7(12): e49470.

11 Chen CT, Kesselheim AS. The journey of generic imatinib: a case study in oncology drug pricing. *Journal of Oncology Practice* 2017;13(6):352-355.

12. *Novartis AG v. Union of India*, (2013) (6) S.C.C. 1-112.

13. *In re Nexium consumer/payor advertising litigation: consolidated class action complaint*. Community Catalyst. http://www.communitycatalyst.org/pal-docs/Nexium_DE.pdf. Published May 27, 2005.

products in the world, despite demonstrating no clear clinical superiority to omeprazole at equivalent doses.

Product hopping is especially problematic when the manufacturer removes the original drug from the market shortly before its patent term expires to channel physicians, consumers, and payors towards its new product. One such case involved Forest Laboratories, which sold memantine (Namenda), an immediate-release, twice-daily treatment for Alzheimer's disease. Before a generic was released, Forest received separate FDA approval for a patented, extended-release, once-daily version of the drug—memantine XR—while also announcing its intention to remove the original product from the market.¹⁴ This action would have forced physicians to switch patients from memantine to memantine XR, undercutting subsequent automatic substitution of a generic for brand-name memantine.¹⁵ In other similar cases, Teva accused Abbott in 2006 of serial product hops of fenofibrate (Tricor), a drug that treats high levels of triglycerides and cholesterol, by slightly changing the dose and formulation of the drug,¹⁶ Reckitt in 2014 moved opioid-dependence-treating buprenorphine/naloxone (Suboxone) from tablets to sublingual film,¹⁷ and Mylan accused Warner Chilcott in 2015 of product hopping its antibiotic doxycycline (Doryx) through three successive insignificant reformulations of the drug.¹⁸ The manufacturer's conduct in these cases typically makes sense only by harming the generic.¹⁹

14. Capati VC, Kesselheim AS. Drug product life-cycle management as anticompetitive behavior: the case of memantine. *Journal of Managed Care & Specialty Pharmacy* 2016;22(4):339-344

15. *New York v. Actavis*, No. 14 Civ. 7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014).

16. Wang SS. TriCor case may illuminate patent limits. *Wall Street Journal*. June 2, 2008.

17. Sarpatwari A, Sinha MS, Kesselheim AS. The opioid epidemic: fixing a broken pharmaceutical market. *Harvard Law and Policy Review* 2017;464(11):463-484.

18. Federal Trade Commission's Brief as *Amicus Curiae* in *Mylan Pharmaceuticals v. Warner Chilcott*, Civ Action 12-3824, November 21, 2012. Available on-line at: <https://www.ftc.gov/news-events/press-releases/2012/11/ftc-files-amicus-brief-explaining-pharmaceutical-product-hopping>.

19. Carrier M, Shadowen S. Product hopping: a new framework. *Notre Dame Law Review* 2016;92:167-230.

Reverse Payment Settlements

There is a well-known pathway—called the Paragraph IV process—by which generic drug manufacturers can challenge brand-name manufacturers’ patents and litigation then determines whether the patents are valid or should be overturned. It was initially created by the Hatch-Waxman Act, which also provided for a 180-day generic exclusivity period at the end of the brand-name market exclusivity period to be awarded to the generic manufacturer that first brought a challenge. An analysis in *Science* revealed that in cases litigated to completion, brand-name manufacturers won 92% of such challenges when they involved a patent on the active ingredient and only about 32% of challenges to “secondary” patents.²⁰

However, in the last decade, brand-name drug manufacturers have frequently settled these cases with generic manufacturers.²¹ The most controversial kind of settlement involve agreements in which generic manufacturers receive substantial compensation and agree to market their products later than might have been anticipated if their litigation was successful. These are called “reverse payment” deals (or, more pejoratively “pay for delay” settlements), since payments in patent litigation cases usually move from the patent challenger to the patent holder. The Federal Trade Commission (FTC) estimated in 2010 that reverse payment settlements would cost American consumers \$3.5 billion annually in forgone savings over the next decade.²⁰ In the 2013 case *FTC vs. Actavis*, the Supreme Court ruled that reverse payment settlements based around large monetary transfers were subject to antitrust review.²² However, since the Supreme Court

20 Hemphill CS and Sampat B. Drug patents at the Supreme Court. *Science* 2013;339:1386-1387.

21. FTC. Pay-for-delay: how drug company pay-offs cost consumers billions.

<https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf>. Published January 2010.

22. *FTC v. Actavis, Inc.*, 133 S. Ct. 2223 (2013).

case, reverse payment settlements have persisted and have shifted to more complex co-marketing agreements “meant to obscure the fact the generic firm is still receiving large consideration in return for delay.”²³

Restrictions on Drug Distribution

Another strategy brand-name manufacturers use to delay generic entry is to restrict access to the brand-name drugs themselves, since comparative testing between the generic and brand is generally required for FDA approval. For example, some manufacturers have instituted systems in which drug distribution occurs only through particular specialty pharmacies. For example, there has been substantial controversy related to the antiparasitic medication pyrimethamine (Daraprim), a treatment for a rare complication of AIDS, and its massive price hike. What is less known about that episode was a change in the distribution system for the drug occurred before the price hike, in which prescriptions or supplies of the product could be obtained only from a single specialty pharmacy, with the goal of sustaining the price hike from subsequent generic entrants for this decades-old, off-patent drug.²⁴ Comments from Turing executives suggest that a primary goal of the system was to make it impossible for anyone other than registered clients to obtain the drug, including generic manufacturers wishing to obtain samples for use in testing for FDA approval.²⁵ The FDA has received about 150 inquiries from generic manufacturers regarding their inability to secure sufficient samples.²⁶

23. Feldman R, Frondorf E. Drug wars: a new generation of generic pharmaceutical delay. *Harvard Journal of Legislation* 2016;53:499-561.

24 Pollack A, Creswell J. The Mercurial Man Behind the Drug Price Increase that Went Viral. *NY Times*, September 23, 2015, at B1.

25 Carrier MA, Levidow NL, Kesselheim AS. Using antitrust law to challenge Turing’s Daraprim price increase. *Berkeley Technology Law Journal* 2016;31(2):1379-1408.

26. Dabrowska A. FDA risk evaluation and mitigation strategies (REMS): description and effect on generic drug development. Congressional Research Service. <https://fas.org/sgp/crs/misc/R44810.pdf>. Published April 11, 2017.

Misuse of Risk Evaluation and Mitigation Strategies

A Risk Evaluation and Mitigation Strategy (REMS) is a program that the FDA can require of manufacturers of drugs with safety issues. REMS might involve enhanced prescribing restrictions, such as special informed consent or enrollment in a patient registry. However, there have been numerous occasions in which REMS have been used to delay entry of generic drugs. First, after a brand-name manufacturer loses its market exclusivity, the generic manufacturer is supposed to enter using the same REMS system. Shared REMS make sense for physicians and patients, because they increase efficiency in prescribing these drugs—why should otherwise clinically interchangeable drugs be forced to use separately administered REMS? They also make sense from a drug safety point of view by facilitating consistency in side effect collection and potentially allowing more effective epidemiological analysis of them. However, on several occasions, brand-name manufacturers have refused to engage in or intentionally delayed discussions over the framework for such shared systems.²⁶ In the case of buprenorphine/naloxone (Suboxone), the FDA reported that the manufacturer “feigned cooperation with the shared REMS development process and used deceptive tactics for months to hide its true intent, which was to delay the generic industry from obtaining” approvals.²⁷

REMS have also been the subject of patents, serving as another type of secondary patent to block generic entry.²⁸ Celgene, for example, obtained multiple patents on its REMS for its cancer treatment (and well-known teratogen) thalidomide (Thalomid), and used these REMS in efforts to block generic entrants by arguing that these patents would be infringed.

27. FDA/CDER to Reckitt Benckiser Pharmaceuticals, Inc. – denial. Regulations.gov.

<https://www.regulations.gov/document?D=FDA-2012-P-1028-0011>. Published February 22, 2013.

28. Sarpatwari A, Avorn J, Kesselheim AS. Using a drug-safety tool to prevent competition. *New England Journal of Medicine* 2014;370(16):1476-8.

Citizen Petitions

Citizen Petitions are used to request that the FDA take or refrain from taking an administration action. Brand-name drug manufacturer have used this strategy to delay generic drug entry.²⁹ Between 2011 and 2015, the FDA received 124 citizen petitions pertaining to pending generic applications; 108 (87%) were filed by manufacturers of brand-name drugs.³⁰ In particular, brand-name manufacturers frequently file Citizen Petitions for generic drugs that are complex to copy—including special dermatologic formulations or medications that act locally in the gastrointestinal tract (instead of being absorbed into the bloodstream)—to claim that the normal bioequivalence testing process was insufficient and that the FDA should require additional testing before approval.³¹ In one case, a brand-name manufacturer filed 24 different citizen petitions to the FDA between 2006 and 2012 to delay FDA approval of a generic version of oral vancomycin (Vancocin), commonly used in *Clostridium difficile*-associated diarrhea.³² One review found that between 2011 and 2015, 92% of such Citizen Petitions were ultimately denied, and almost all (98%) of the Citizen Petitions filed close to the date of generic drug entry were ultimately denied.³³ Of note, we conducted a systematic review of 6 drugs that were the subject of multiple Citizen Petitions, like oral vancomycin, and found no evidence of differences for any of them between the clinical effect of the brand-name and generic versions.³⁴

29. Feldman R, Wang C. A citizen's pathway gone astray – delaying competition from generic drugs. *New England Journal of Medicine* 2016;376(16):1499-1501.

30. Carrier M, Minniti C. Citizen petitions: long, late-filed, and at-last denied. *American University Law Review* 2017;66(2):305-52.

31. Kesselheim AS, Gagne JJ. Product-specific regulatory pathways to approve generic drugs: the need for follow-up studies to ensure safety and effectiveness. *Drug Safety* 2015;38(10):849-53.

32. Federal Trade Commission. FTC charges that Shire ViroPharma Inc. abused government Processes through serial, sham petitioning to delay generics and maintain its monopoly over Vancocin HCl capsules. <https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes>. Published February 7, 2017.

33. Carrier MA, Minniti CJ. Citizen Petitions: Long, Late-Filed, and At-Last Denied. *American University Law Review* 2016;66:305-352.

34. Kesselheim AS, Polinski JP, Fulchino LA, Isaman DL, Gagne JJ. Modified regulatory pathways to approve generic drugs in the US and a systematic review of their outcomes. *Drugs* 2015;75(6):633-650.

The CREATES Act and Other Policy Reforms

One of the main legal strategies to curb some of these problematic business practices is application of antitrust law, usually by the FTC. While the FTC does excellent work, there are numerous limitations to using antitrust law as a corrective. First, it is inherently uncertain how courts will view some of these behaviors, and courts have in some cases resisted finding that these problematic life-cycle management strategies violated antitrust law.³⁵ For example, in product-hopping cases, courts have sometimes defined the market very broadly in assessing whether substitutes could be available for a product that was being discontinued. In REMS refusal cases, courts may accept the arguments that brand-name manufacturers do not have a duty to deal with rivals, perhaps invoking product safety as a justification.³⁶ Second, antitrust cases take a very long time to litigate, and the FTC's resources are limited. The *Actavis* case, for example, was initiated back in 2006 and due to a number of appeals and remands, there has still has not yet been a trial. In addition, when the remedy sought does not sufficiently penalize manufacturers for illegal strategies, the case can be thought of as a mere cost of doing business.

Therefore, we need legislative solutions that can prevent these strategies in the first place, without resorting to antitrust litigation. As my colleague Ameet Sarpatwari and I have written,³⁷ the CREATES Act helps block some of the delaying strategies. If a brand-name drug maker were to withhold samples needed for bioequivalence testing, the generic manufacturer would be able to petition a court to require their sale. To ensure patient safety, generic manufacturers seeking

35. Carrier MA. Sharing, Samples, and Generics: An Antitrust Framework. Cornell Law Review [in press 2017]. Available on-line at: https://papers.ssrn.com/sol3/Papers.cfm?abstract_id=2979565.

36 Carrier MA. Statement to the Subcommittee on Regulatory Reform, Commercial and Antitrust Law U.S. House Committee on the Judiciary on "Antitrust Concerns and the FDA Approval Process." July 24, 2017.

37. Sarpatwari A, Kesselheim AS. Get generics to market faster. Bloomberg View. June 20, 2017. Available on-line at: <https://www.bloomberg.com/view/articles/2017-06-20/get-generic-drugs-to-market-faster>.

samples of REMS-covered drugs would have to subject their testing protocol to FDA review. The Congressional Budget Office has estimated that the CREATES Act would help save the federal government more than \$3 billion in drug costs.

In addition to the CREATES Act, the Committee should consider other potential reforms. First is strategies that prevent the issuance of weakly innovative secondary patents or their use in blocking or undermining generic entry. One possible mechanism for addressing these patents is the Patent Trial and Appeals Board (PTAB), which was created by the 2011 America Invents Act. The PTAB is an administrative body of experts intended to be more familiar with complex scientific and patenting issues than judges in federal district court, and its resolution of patent cases is faster—a maximum of 18 months—and thus less expensive than litigation. Between September 2012 and March 2016, 18% (790 of 4,288) petitions for review had a final written decision with 73% leading to patent invalidation.³⁸

A potential opportunity for PTAB administrative review of patents could occur after a pharmaceutical patent is first listed with the FDA. In that situation, the pharmaceutical manufacturer would have to defend the secondary patent against a lawyer appointed by the government, perhaps from a public interest legal organization (or a generic manufacturer seeking to be the first generic manufacturer to market could step in), to justify the FDA's listing of it.³⁹ Such a system of routinely subjecting secondary patents to PTAB review could have additional effects, such as reducing the number of weak secondary patents that the USPTO issues, which could in turn promote the timely availability of generic drugs. If effectively organized (and perhaps associated with a small award for a successful challenger), an administrative process

38. Grewal M, Hill J, Zalewski J. Trends in inter partes review of life sciences patents, *BNA Patent Trademark Copyright Journal* 2016;92:1-4.

39. Treasure CL, Kesselheim AS. How patent troll legislation can increase timely access to generic drugs. *JAMA Internal Medicine* 2016;176(6):729-30.

could resolve patent issues before generic manufacturers would typically file Paragraph IV challenges.⁴⁰

Second, the Committee should consider additional mechanisms to help prevent problematic settlements of Paragraph IV patent cases. Potential solutions include preventing all transfers of value for delayed entry over the cost of the litigation as part of any brand-name/generic settlement agreement, increasing the penalties imposed for settlements found by the FTC to be anticompetitive (such as full disgorgement of profits or treble damages), and shifting the burden of proof more fully onto the settling parties to justify their settlement.⁴¹ Another lever might be to adjust the awarding of the 180-day exclusivity to allow the generic manufacturer that wins at litigation to claim this exclusivity prize.⁴² Congress also needs to ensure that settlements of PTAB cases and settlements as part of biosimilar challenges to innovator biologic drugs are reported to the FTC for official review akin to the current process for Paragraph IV settlements.

Third, additional legislation can help prevent misuse of REMS systems beyond the protections provided in the CREATES Act. For example, REMS should not be allowed to include proprietary information; rather, all terms of the REMS should be public. To prevent REMS patents from blocking generic entry, a royalty-free license for such patents could be made available for the government to provide to generic manufacturers. Other solutions to REMS patents include ensuring that REMS patents cannot be listed with the FDA.⁴³

To address the misuse of Citizen Petitions, the FDA can be encouraged to provide guidance about the types of tests needed to determine bioequivalence for complex generic products well in

40 Kesselheim AS, Murtagh L, Mello MM. "Pay-for-delay" settlements of disputes over pharmaceutical patents. *New England Journal of Medicine* 2011;365(15):1439-1445.

41. Carrier MA. Solving the Drug Settlement Problem: The Legislative Approach. *Rutgers Law Journal* 2009;41:81-101.

42 Hemphill CS and Lemley MA. Earning Exclusivity: Generic Drug Incentives and the Hatch-Waxman Act *Antitrust Law Journal* 2011; 77: 947-989.

43. Carrier MA, Minniti CJ, Sooy B. Five solutions to the REMS patent problem. *Boston University Law Review* Vol 97 [in press 2017]. Available on-line at: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2995827

advance of when the primary patent expires. The Committee could also expand the opportunities for the FDA to summarily reject certain Citizens Petitions without requiring in-depth review. For example, legislation could require additional procedural hurdles for petitions filed by brand-name manufacturers either a year before the anticipated launch date of the generic or more than one year after the safety or efficacy issue identified in the petition was uncovered,⁴⁴ such as requiring the FDA to make a preliminary finding that the petitions will likely be granted before proceeding to a full review. Data on Citizen Petition filing and disposition should be collected by the FDA and published each year to promote transparency about the Citizen Petition process.⁴⁵

Finally, I think it is important to point out that the current naming conventions for biosimilar drugs, in which suffixes are added to the biosimilar (but not the original innovator), may help reduce evidence-based use of approved biosimilars and could diminish cost reductions particularly when interchangeable biosimilars are eventually FDA-approved. I recommend that the Committee examine how a more consistent and user-friendly naming system can be adopted for biosimilar drugs that can promote uptake of these products.

Conclusion

Manufacturers of brand-name drugs use many strategies to delay generic entry. The CREATES Act is a laudable first step in helping address some of these strategies, but other policy reforms to address weak secondary patents, reverse payment settlements, and the misuse of REMS, among other issues, will be needed as well. I appreciate the Committee's commitment to solving these issues and would be happy to continue to be involved in the deliberative process.

44. Carrier MA. Statement to the Subcommittee on Regulatory Reform, Commercial and Antitrust Law U.S. House Committee on the Judiciary on "Antitrust Concerns and the FDA Approval Process." July 24, 2017.

45. Carrier MA. Statement to the Subcommittee on Regulatory Reform, Commercial and Antitrust Law U.S. House Committee on the Judiciary on "Antitrust Concerns and the FDA Approval Process." July 24, 2017.