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## **Generic Priority Review Vouchers Are Not the Answer to Price Gouging**

In the wake of egregious price spikes from individuals and corporations that have become infamous symbols of pharma greed, such as Martin Shkreli, formerly of Turing, and Heather Bresch, CEO of Mylan; policymakers have been seeking solutions to curtail pharma price gouging, particularly relating to corporations that steeply raise prices on off-patent, small-market prescription drugs. One proposal that has gained some attention is creating a generic priority review voucher (PRV) as an attempt to provide incentive for generic competition. This paper will examine the potential impact of creating a generic PRV program through analysis of recent legislative proposals that include generic PRVs as a component.

The Increasing Competition in Pharmaceuticals Act (S. 297) and the Lower Drug Costs through Competition Act (H.R. 749) express a laudable goal of lowering prescription drug costs through competition; however, their provisions would have a minimal impact on lowering drug prices, and may forestall meaningful reform.

**Section 101** of the bills would provide for a priority review of abbreviated new drug applications (ANDAs or generic drug applications) 1) for a drug that is not facing competition or for which the only competition is from one or two drugs that have been granted tentative approval, as well as for 2) drugs on the drug shortage list. Yet the Food and Drug Administration (FDA) already prioritizes the review of ANDAs of ‘first generics’ (most recently expanding this policy to include products that have fewer than three competitors on the market) and drugs on the drug shortages list.<sup>1</sup> Section 101 of S. 297 and H.R. 749 would only enshrine in law the prioritization of first generics, which falls short of current FDA policy, and the existing FDA practice of prioritizing applications for medicines on the drug shortage list.

**Section 201** of the bills would provide for the award of a generic priority review voucher (PRV) to a company that receives approval and sustains a market presence for a drug that is the first generic in its class. While the FDA awards a variety of PRVs, this would be the first priority review voucher award relating to ANDAs for generic drugs.<sup>2</sup> While there are significant problems with brand-name PRV programs in need of remedy,<sup>3</sup> they include substantial financial incentives towards developing and

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<sup>1</sup> In the Manual of Policy and Procedures (MAPP) document outlining the prioritization of review of ANDAs at the time of the introduction of these bills (MAPP 5240.3 Rev 2), the first consideration listed was whether the ANDA is for a potential first generic competitor to a product for which there are no blocking patent or other exclusivities or stays. The next consideration list was whether the ANDA submission “could help mitigate or resolve a drug shortage and prevent future shortages” That MAPP document was updated on June 27, 2017 to include prioritization of generic drug applications for products that have fewer than three competitors, rather than only ‘first generics’. MAPP 5240.3 Rev 3 is available at:

<http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ManualofPoliciesProcedures/UCM407849.pdf>

<sup>2</sup> The FDA awards PRVs to companies that gain new drug approval (NDA or brand-name approval) for treatments or vaccines for rare and neglected tropical diseases, new pediatric medicines, and most recently for medical countermeasures.

<sup>3</sup> For information on the shortfalls and loopholes of the neglected disease priority review voucher program, see the letter from Médecins Sans Frontières, Drugs for Neglected Diseases Initiative, et. al. titled “Open Letter to the

bringing to market vaccines and treatments.<sup>4</sup> Conversely, the value of a generic PRV provided under S. 297 and H.R. 479 would be unlikely to provide sufficient incentive to introduce a first generic for a variety of reasons.

First, a generic PRV would only be useful for an application that the FDA would not otherwise prioritize. However, existing FDA policy prioritizes the review of ANDAs for products that have fewer than three competitors, and Sec. 101 would codify prioritization of first generics. In turn, the generic PRV would only be used for a drug that is for a product that already has at least three competitors – limiting the potential of the product to earn substantial revenues, since the profits for subsequent generics would be more limited. Second, due in part to a mandate within the Generic Drug User Fee Amendments of 2012, FDA review of new generic applications is already relatively fast.<sup>5</sup> A generic PRV would be likely to expedite FDA action by a short period of time, diminishing its value. Third, FDA frequently sends generic drug applicants ‘complete response letters’ (CRLs) to communicate that the application will not be approved in its current form. Some FDA observers believe that FDA is regularly making use of CRLs to buy more time to conduct its reviews when pressed against response deadlines.<sup>6,7</sup> It is plausible that some FDA officials may respond to an accelerated review timeline driven by the use of a generic PRV by issuing a CRL when they otherwise may have worked with the manufacturer to resolve issues and approve the application. In such cases, the generic manufacturer will have to re-submit its application and the process of getting the drug to market will take longer than it would have under more a flexible review timeline.

**Section 301** of the bills would require a study on Risk Evaluation and Mitigation Strategies (REMS), but unfortunately this may distract attention and support from proposals to prevent brand-name drug corporations from abusing the REMS system to deter competition and preserve monopolies, such as the CREATES and FAST Generics acts.<sup>8</sup>

For these reasons, generic PRVs provide little hope for increasing competition, and S. 297 and H.R. 749 would be ineffective in addressing high drug prices.

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U.S. Senate HELP Committee Leadership: Suggestions to Fix the FDA PRV for Neglected Disease” available at: [https://www.doctorswithoutborders.org/sites/usa/files/joint\\_open\\_prv\\_letter\\_to\\_help\\_committee\\_web.pdf](https://www.doctorswithoutborders.org/sites/usa/files/joint_open_prv_letter_to_help_committee_web.pdf)

<sup>4</sup> The incentives towards developing and bringing to market certain kinds of vaccines and treatments of the various brand-name PRV programs derive from the value of gaining an additional six-months of market exclusivity on a product that will earn much higher revenues (e.g. a blockbuster drug) than the product qualifying the company for a PRV.

<sup>5</sup> In the Generic Drug User Fee Amendments of 2012 (GDUFA I), the FDA put in place a variety of goal dates, including the goal of taking action on 90% of original generic applications within 10 months. See: <http://www.fda.gov/downloads/ForIndustry/UserFees/GenericDrugUserFees/UCM282505.pdf>

Dr. Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research, testified last September that “FDA has met or exceeded all performance goals under GDUFA I with respect to ANDA’s submitted after GDUFA had commenced.” See: <http://www.fda.gov/NewsEvents/Testimony/ucm522119.htm>

<sup>6</sup> See “FDA Complete Response Letters: The design v. reality of FDA’s responses to drug applications” available at: <http://www.healthcarelawinsights.com/2015/01/fda-complete-response-letters-the-design-v-reality-of-fdas-responses-to-drug-applications/>

<sup>7</sup> In FY2016, FDA approved 651 ANDA applications and sent 1,725 CRLs in response to ANDA applications. See: <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm528997.htm>

<sup>8</sup> The text of the CREATES Act introduced in the 115th Congress is available here: <https://www.congress.gov/bill/115th-congress/senate-bill/974/text>. The text of the FAST Generics Act introduced in the 114th Congress is available here: <https://www.congress.gov/bill/114th-congress/house-bill/2841/text>