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Submitted electronically via Regulations.gov

Food and Drug Administration
Department of Health and Human Services
Attention: FDA-2017-N-3615
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: FDA-2017-N-3615; The Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting

Dear Sir or Madam:

The Pew Charitable Trusts (Pew) is pleased to offer comments on the Hatch-Waxman Amendments Public Meeting. Pew is an independent, nonpartisan research and public policy organization dedicated to serving the American public. Our drug spending research initiative is focused on identifying policies that would allow public programs to better manage spending on pharmaceuticals while ensuring that patients have access to the drugs that they need.

The Drug Price Competition and Patent Term Restoration Act of 1984 has largely been a success, giving manufacturers incentives to develop new drugs while facilitating competition and access to medications. The law has driven innovation and created a robust generic drugs market. The savings from this competition is estimated in the hundreds of billions of dollars per year. However, there are areas where the law may not be working as intended, and some practices can

inhibit the availability of lower cost generics and undermine competition. Additional efforts to remedy these challenges may be warranted. Some barriers to competition lay outside the scope of FDA's current authority and efforts to address them would require Congressional action.

Risk Evaluation and Mitigation Strategies

A mounting concern is the use of Risk Evaluation and Mitigation Strategies, or REMS, to delay generic entry. Many REMS include elements to assure safe use (ETASU), which can limit distribution of a drug. For example, they may include a requirement that pharmacies, practitioners, or health care settings dispensing a high-risk drug be specially certified to handle the product. While REMS are intended to reduce specific serious risks listed in the labeling of the drug, generic developers may have difficulty acquiring samples of innovator drugs subject to ETASU REMS, as the statute contains no provision to explicitly require makers of these drugs to sell product samples to generic developers. This can inhibit generic developers' ability to conduct bioequivalence testing required to bring a product to market.

In addition to the necessity for a generic manufacturer to obtain product samples for testing, a generic version of a drug with an ETASU REMS requirement is subject to the same safeguards as the original product. Innovator and generic developers of drugs with ETASU REMS are required to participate in a single, shared REMS protocol, unless FDA waives the requirement. However, some innovator manufacturers may make it difficult for generics to participate in a joint REMS protocol.

Current law prohibits drugmakers from using ETASU REMS to block or delay the approval of a generic drug application or to prevent a generic developer from participating in a shared ETASU REMS program with the innovator company.[1] The law also provides FDA the authority to deem a drug misbranded or levy fines on brand drug developers in violation.[2] While FDA has not taken enforcement action against any manufacturer for violating these requirements, we encourage FDA to exercise its existing authorities in cases where an innovator company is using a REMS, directly or indirectly, to delay the development or approval of a generic application.

In addition, FDA has signaled that it may use its authority to waive the shared REMS requirement more often in order to limit delays in generic approvals. Negotiations on a shared REMS can be complex and require agreement on several topics, including the design of the shared REMS, coordination of reporting, creation of standards for data collection, protocol for shared decision-making, and resolution of legal issues involving intellectual property. These negotiations often involve multiple generic developers seeking to join a single, shared REMS with an innovator drug developers. However, waiving the shared REMS requirement has the potential to create inefficiencies. For example, participating pharmacies and prescribers may need to spend additional time enrolling in or training in multiple REMS systems. We urge FDA to exercise this authority judiciously. When waiving the shared REMS requirement, we suggest the agency do so in a way that creates parallel systems and minimizes any potential for discrimination between uptake of brand and generic products.

Citizen Petition Process

Another issue of concern is abuse of the citizen petition process. Citizen petitions can be useful when they contain legitimate recommendations or raise valid scientific concerns for FDA consideration. The citizen petition process has often been used to request that FDA take action related to a pending application for generic drug approval. However, citizen petitions have the potential to delay generic approval and reduce competition. The majority of citizen petitions related to generic applications are ultimately denied, suggesting that many are meritless. Although FDA has met statutory deadlines for reviewing petitions related to generic applications, its 2015 report notes that the agency has had to redirect resources from other work in order to do so.[3] That same year FDA reported that two generic applications were delayed due to citizen petitions. In one case brought by the Federal Trade Commission (FTC) in 2017, the Commission alleged that abuse of the citizen petition process to delay access to generics of just one drug resulted in hundreds of millions of dollars in additional costs.[4]

We recognize FDA's recently implemented changes, as directed by Congress, to ensure that citizen petitions are not improperly used to delay approval of generics. We recommend FDA continue to monitor potential abuses of the program, including establishing procedures to

identify and make publicly available information on manufacturers or their proxies that frequently submit petitions that lack valid concerns and are routinely denied. In addition, the FDA could develop procedures to minimize agency resources spent evaluating and rejecting petitions from manufacturers that routinely submit meritless petitions.

Unapproved Drugs Initiative

FDA's Unapproved Drugs Initiative has an important goal, but it has the potential to drive up costs by granting exclusivity to already widely prescribed medications. The grant of exclusivity should be commensurate with the cost to the sponsor of conducting new research and submitting an application. We encourage FDA to conduct and publish an analysis on the scope of new clinical research on drugs for which exclusivity has been granted under this initiative, as well as evaluate how the prices for these drugs changed after receiving exclusivity. We encourage the agency to take additional steps to ensure that when it approves a New Drug Application for a previously marketed unapproved drug, consumers and payers are not subjected to significant price increases and product shortages that may limit patient access to the drug.

Public Access to Market Information

As a baseline for understanding the pharmaceutical market, FDA must have reliable data on the status of approved products. The FDA Reauthorization Act of 2017 requires that sponsors inform FDA whether approved drugs are currently marketed. We encourage FDA to require this information be provided to the agency in a standard format so it is easily usable and can be made public.

Safety and Quality

FDA should not emphasize changing its safety or quality standards to speed access to generics. These approaches may pose risks to patients and have other unintended consequences. Current law requires FDA to determine that each drug is safe and effective before it can be marketed in the U.S., approving not just the drug itself, but also the manufacturing location, source of active

ingredients, processing methods, and many other factors that may affect the product's safety or effectiveness.[5] Because the importation of drugs from foreign sources would bypass current FDA review processes, by creating a separate certification process, it could increase safety risks. It is also unclear how imported drugs could comply with established measures to ensure that counterfeit and diverted drugs do not enter the pharmaceutical supply chain. The Drug Supply Chain Security Act (Title II of the Drug Quality and Security Act of 2013) requires that pharmaceutical manufacturers and repackagers put a unique product identifier on most prescription drug packages and outlines steps to build an electronic, interoperable system for identifying and tracing prescription drugs as they are distributed in the United States.

We appreciate the opportunity to comment on the Hatch-Waxman Amendments Public Meeting. Should you have any further questions, please contact me by phone at 202-540-6512 or via email at ireynolds@pewtrusts.org.

Sincerely,

Ian Reynolds
Associate Manager, Drug Spending Research Initiative
The Pew Charitable Trusts

[1] Food Drug and Cosmetic Act § 505-1(f)(8).
[2] Food Drug and Cosmetic Act § 502(y); §303(f)(4).
[3] Food and Drug Administration, "Report to Congress – Eight Annual Report on Delays in Approvals of Applications Related to Citizen Petitions and Petitions for Stay of Agency Action for Fiscal Year 2015" (July 29, 2016), https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ReportsBudgets/UCM517279.pdf.
[4] 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," (Feb. 7, 2017), https://www.ftc.gov/news-events/press-releases/2017/02/ftc-charges-shire-viropharma-inc-abused-government-processes.
[5] Congressional Research Service, "Prescription Drug Importation: A Legal Overview" (Dec. 1, 2008), https://www.everycrsreport.com/reports/RL32191.html.