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Comments of the National Consumers League

Docket No: FDA-2017-N-3615
Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access

September 15, 2017

The National Consumers League (NCL) appreciates the opportunity to submit these comments in response to the July 18, 2017 public meeting on "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access." Since our founding in 1899, NCL has long been concerned with ensuring the safety of foods and drugs. Among NCL's top priorities are ensuring the safety, effectiveness, and appropriate use of both prescription and over-the-counter (OTC) drugs, and medication adherence, which we have helped to advance through our *Script Your Future* Campaign. In addition to being a champion for safe and effective medicines, NCL is committed to ensuring that patients and consumers have access to quality medicines that are also affordable. It is in that spirit that we express our strong support for the Hatch-Waxman Amendments, as they have been critical in encouraging innovation and helping to control drug costs for American consumers.

According to the Association for Accessible Medicines (AAM), generics account for 89 percent of all prescriptions, but only 26 percent of total prescription drug costs. These savings enable our health system to invest in new technologies and medicines that will undoubtedly improve the quality of life for patients and consumers. The Hatch-Waxman Amendments have been integral in achieving a delicate balance between incentivizing new drug innovation and bolstering generic drug competition. Unfortunately, branded companies have at times disrupted this balance by obstructing generic competition. These actions are not in the best interest of American consumers.

The entry of generics into the market has broadened patient access to drugs, and ultimately has helped them to realize better health outcomes. When patients have access to affordable medications, their ability to take their medicines as directed is improved. Medication non-adherence is responsible for approximately 125,000 deaths each year in the United States and costs the healthcare system $290 billion annually. Efforts to stifle generic development pose a threat to the well-being of consumers and to the U.S. economy. While NCL recognizes that FDA does not have the capacity to police every anti-competitive behavior, FDA can take steps to improve competition and ensure the intent of the Hatch-Waxman Amendments is not undermined.

Pay-for-Delay Deals

"Pay-for-delay" is a tactic branded drug companies may employ to stifle competition by paying generic companies to NOT bring an affordable generic alternative to market. The Federal Trade Commission (FTC) estimates that such "pay-for-delay" deals cost consumers and taxpayers $3.5 billion annually. NCL encourages FDA to maintain a collaborative working relationship with the FTC and report any information that would aid FTC in overseeing bad actors and rooting out this abuse.

Product Hopping

While policies that promote innovation and product improvement are fundamental to the success of the pharmaceutical industry, the intricacy of FDA rules and regulations sometimes means that branded companies can take advantage of loopholes to their financial benefit. One example is product hopping, which refers to the practice of a company making inconsequential changes to a drug, typically towards the end of its patent life, in order to extend exclusivity. While some drug product changes might be beneficial to patients, inconsequential changes threaten the pro-competition climate the Hatch-Waxman Amendments intend to establish. Since the capacity for antitrust enforcement is limited, NCL supports the exploration of potential regulatory remedies, such as whether FDA might change the standard for product reformulations.

Citizen Petition Process

At the July 18, 2017 FDA public meeting, several commenters expressed concern about the filing of Citizen Petitions in order to delay FDA approval of a generic drug application. NCL encourages FDA to consider ways in which the agency can deter the filing of petitions that are frivolous and filed without merit.

REMS and Restricted Distribution Networks

NCL acknowledges the importance of FDA-mandated Risk Evaluation and Mitigation Strategies that include Elements to Assure Safe Use (REMS ETASU) for drugs that may carry some risk and supports its appropriate application in protecting consumers. Nearly 40 percent of new FDA drug approvals are subject to REMS, which may include restrictions on product distribution. However, the misuse of these programs to block generic manufacturers' access to brand product samples for necessary bioequivalence testing is cause for concern. Without samples of the branded product, generic companies cannot bring lower cost alternatives to the market. This results in lost savings not only for consumers, but also for government healthcare programs and thus taxpayers. In fact, the Association for Accessible Medicines estimates that misuse of REMS to delay generic competition costs the U.S. healthcare system over $5 billion every year. NCL opposes the abuse of statutory requirements established through REMS as a means to thwart generic competition.

NCL supports FDA's proposal to make public its letters to branded companies stating that the generic drug manufacturer's proposed study protocols contain sufficient protections such that sale of the medicine to the generic drug applicant by the branded manufacturer for the purpose of bioequivalence testing would not be considered by FDA to be a violation of the branded drug's REMS. FDA Commissioner Gottlieb noted that publicizing instances in which generic drug manufacturers might be having difficulty securing product samples could be "one step to help ensure that unnecessary hurdles to generic drug development are removed."

In addition, NCL believes that Harvard's Dr. Ameet Sarpatwari's proposal for FDA to require the submission of sample deposits sufficient for bioequivalence testing

by three generic manufacturers as a condition of drug approval is worthy of consideration – assuming that safe sample collection and storage would be feasible and not unduly burdensome.

Generic Drug Backlog

NCL supports a drug market with ample choice and competition, affordable drug prices, and incentives for innovative drug development. Although FDA does not have jurisdiction over drug pricing, the agency can leverage its authority to spur generic competition. NCL strongly supports equipping the FDA with adequate resources to address the generic drug backlog currently pending at the agency. We applaud the recent progress FDA has made in increasing the speed by which generic drugs are approved -- much of which can be attributed to the Generic Drug User Fee Amendments of 2012 (GDUFA). We look forward to the implementation of GDUFA II, as this legislation will facilitate further improvements in the efficiency of the FDA's generic drug review program. We welcome FDA's intent to issue a "Good ANDA Assessment Practices" MAPP, which will outline the measures being taken to streamline the FDA's internal ANDA review process. Simplifying these protocols will ideally accelerate the availability of generic drugs to the public.

NCL also supports FDA's prioritizing the review of ANDAs for off-patent, off-exclusivity drugs that do not currently have an approved ANDA.

Conclusion

NCL strongly supports FDA's role in administering the Hatch-Waxman Amendments and encourages the FDA to continue its critical work to bring safe, effective, and affordable generic medications to market. We look forward to continuing to work collaboratively with the FDA, the advocacy community, and industry stakeholders to ensure that consumers and patients have access to the treatments they need to maintain their health and enjoy a positive quality of life.