July 18, 2017

Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2017-N-3615 for “Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access; Public Meeting; Request for Comments.”

Dear Commissioner Gottlieb:

The National Business Group on Health (the “Business Group”) appreciates the opportunity to comment on the administration of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act (FD&C Act) to ensure the appropriate balance between encouraging innovation in drug development and accelerating the availability of lower cost alternatives to innovator drugs.

The National Business Group on Health represents 413 primarily large employers, including 73 of the Fortune 100, who voluntarily provide group health and other employee benefits to over 55 million American employees, retirees, and their families. Being mostly self-funded, our employer members as well as many other employers have a vested interest in more effective, efficient health care and promote health plan designs that encourage delivery of the right care at the right time and in the right place; an emphasis on promoting health in primary and preventive care; improving value while reducing the cost of care; and, delivering services to the highest level of customer satisfaction.

First and foremost, we commend the FDA for its work on the implementation of a successful pathway by which generic pharmaceuticals are brought to market and recognize the Agency’s initiative through Generic Drug User Fee Amendments of 2012 (GDUFA I) to modernize the Abbreviated New Drug Application (ANDA) review program, which resulted in record high approvals for generic products in 2016. We further commend the Agency on the proposed GDUFA II, which will continue enhancements to the ANDA review program.

We agree with the position that the life cycle of a pharmaceutical product, as contemplated by the Hatch-Waxman Amendments, includes a patent for a branded product, followed by the expiry of said patent, followed by the entrance of one or
multiple generic versions of that product to market, thereby increasing competition and introducing downward pricing pressure on pharmaceutical marketplace. We are very pleased that the Agency has taken up this important issue and within the context of the notice in the Federal Registrar, our comments will focus on question number one: How has the balance struck in the Hatch-Waxman Amendments been affected by practices and trends related to the following:

- Exclusivity periods
- Patents (including patent listing procedures)
- Post-approval changes to innovator drug products, e.g., reformulations

**Current permissive patent and exclusivity period protocols may unduly delay market entry of lower cost alternatives to brand medications**

After a generic or biosimilar is approved by the FDA, in many cases, it may still take years for less expensive versions to come to market. Often the delay is due to litigation by the manufacturer of the original drug over outstanding legal questions about whether patent protection can be extended through various secondary approvals for the original drug.

Employers and other members of the public have trouble understanding why this happens – meaning, how can this claim of “protection” extend well beyond the original intent of the underlying patent? There can be multiple patents for one product, covering different indications, delivery methods, and/or combinations of the product. Determining when a patent term expires often requires specialized legal expertise. In fact, a publication by the Center for Drug Evaluation and Research (CDER), part of the FDA, states that “patent” and “exclusivity” are two of the most commonly searched terms on the FDA website,¹ which underscores both the complexity and value of these product protections to drug manufacturers, as well as the level of interest from outside stakeholders.

Beyond statutory extensions due to delays by the Patent and Trade Office (PTO) or the FDA, the life of a drug’s overall patent protection can be extended by applying for secondary patents through new formulations of the drug, new routes of administration, new indications, or uses of the drug in combination with another drug (“patent estates”)

**The Business Group agrees that an appropriate period of protection is essential to promoting investment in innovation and the discovery of new medicines, but we also believe a balance must be struck between both the right to enjoy the benefits as a creator of intellectual property and society’s interest in affordable medications.**

As mentioned, patents and exclusivity periods afforded to drug manufacturers by the PTO and the FDA are intended to reward innovators for their contributions. The expiration of patents theoretically yields the introduction into the market of generics

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¹ Lal R. Patents and Exclusivity. CDER Small Business Chronicles.2015.
and biosimilars, which increases competition and benefits consumers. Unfortunately, what we sometimes see is repeated and dubious use of the patent system to extend periods of market exclusivity, which adds to the growing unaffordability and unsustainability of pricing and spending in the prescription drug market.

The costs of extended monopolies in the pharmaceutical market are more than just financial; they reduce patient access to needed medications and can serve to threaten further innovation. Therefore, policies that extend patent protection terms or exclusivity periods should be revisited by policy makers and regulators.

In the attached addendum to our comments, specific patent abuses and other anticompetitive practices are explained in more detail. While these practices do not in effect extend original patents, they do create patent estates, which increase the probability of litigation between brand and generic manufacturers. Additionally, building patent estates tends to run in congruence with applications for additional market exclusivity from the FDA.

**Recommendations for Policy Makers**

- Eliminate or limit additive patent extensions and exclusivity periods that serve only to extend monopoly power, especially where there is limited or no additional company investment or patient value produced.
- Develop sound policy that would discourage patent abuses such as “evergreening” and “product hopping.” These policies may include financial penalties, loss of exclusivity periods and/or reduced patent terms for other products.
- Eliminate pay-for-delay deals and/or implement penalty provisions for companies that engage in pay-for-delay deals.
- Reduce the market exclusivity for biologics from 12 years to 7 years.

Again, we thank the Agency for holding this important public meeting, and look forward to future dialog on assuring access to affordable prescription medicines – an issue that has taken center stage for both public and private payers, as well as consumers of all types across the nation. Please contact me or Steven Wojcik, the National Business Group on Health’s Vice President of Public Policy, at (202) 558-3012, if you want to discuss our comments in further detail.

Sincerely,

Brian Marcotte
President and CEO
Pharmaceutical Patent Abuses

“Evergreening” or “Product Hopping”
This term describes a practice in which a brand manufacturer makes minor or modest formulation changes that provide little to no therapeutic advantage to a brand medication’s formulation for the purpose of extending the life of both patent protection and FDA exclusivity. Companies have been known to introduce a nearly identical version of a brand-name drug before patent expiration and allow the original drug’s patent to expire, promoting the “new” drug as an improvement over the previous brand-name drug. The Federal Trade Commission (FTC) and other government officials have flagged this practice as anti-competitive, but it remains legal. In addition to using this method for piling up patents, FDA approval for a new use or a new formulation also triggers an additional three years of marketing exclusivity.

Label Patents
Refers to any patent that covers a method or product mentioned in the FDA-approved label. Label patents typically target a new patient population or a new indication, or include a new dosage form, dosing regimen or route of administration. The patent term for such new patents is 20 years from date of filing, which can significantly extend the period of exclusivity for the repurposed drug. Examples of label patents include:

- Administering a different dose to the elderly;
- Titration of dosage over a certain number of days;
- Titration pack with escalation dosages;
- Administering a drug without food;
- Administering a dosage form that achieves plasma level of X, measured Y hours after dosing;
- Administering with an anticonvulsant in patients at risk of seizure;
- Informing the caregiver or patient to avoid taking the approved drug with another drug;
- Offering a drug in combination with unique packaging;
- Offering a drug in combination with a delivery device, such as an; and
- Providing a unit dosage of a drug with particular dissolution values or resulting pK values.

30-Month-Stay

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4 Ibid.
Refers to the burden placed on the generic drug manufacturer when bringing a potential generic entrant to market while operating under the assumption that a patent on the branded product is invalid; under those conditions, the generic manufacturer must file its application with a “paragraph IV certification,” stating the reasons the patent is invalid. At this juncture, an automatic 30-month-stay is initiated, preventing the generic from coming to market to allow for the resolution of litigation between the brand and generic manufacturers. Improper patent listings by branded manufacturers trigger frivolous 30-month-stays; this practice has been flagged by the FTC and litigated extensively. Essentially, when this is done, branded manufacturers list new patents after an application for a generic is filed, which grants the brand-named company additional 30-month stays of FDA approval of the generic’s application.⁵

Other Anticompetitive Practices

Pay for Delay
There are two main types of pay for delay deals: 1) those involving cash payments from brand manufacturers to generic manufacturers to delay generic market entry; 2) pay-for-delay scenarios that occur when a generic company agrees to delay introduction of a generic version of a brand-name drug in return for the brand-drug-maker’s agreement to refrain from marketing an authorized generic (a “no AG agreement”) version of the branded product during the “first filer” 180-day exclusivity period, a practice that the FTC does not condone.⁶

Patent Trolling
Because of the sizable amount of money involved in certain patents, some investment firms acquire many patents and then assert rights against brand manufacturers, sometimes in a frivolous manner. This practice is referred to as “patent trolling.” The goal of many patent trolls is to extract cash settlements from manufacturers that want to avoid the expense of patent litigation.