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Hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

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Good morning Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee on Health. My name is Kurt R. Karst. I am a Director at Hyman, Phelps & McNamara, P.C, where I specialize in food and drug law, and, in particular, the Drug Price Competition and Patent Term Restoration Act of 1984 (or "Hatch-Waxman Amendments"), and the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA" or "Biosimilars Act"). I am also a co-author of the legal treatise *Generic and Innovator Drugs: A Guide to FDA Approval Requirements*, and a co-founder of the popular FDA Law Blog (www.fdalawblog.net). I am honored to participate in today's hearing. I would like to make clear at the outset that I am testifying today in my personal capacity and that the views I express are solely my own and not my law firm's or any company or client of my law firm.

The Subcommittee has asked for my views regarding several bills that are intended to lower the cost of prescription drugs and biologics. The information and perspectives I provide today are based on nearly twenty years of experience helping drug and biologic manufacturers—both brand-name and generic drug manufacturers—obtain FDA approval for life-saving therapies and high quality, low-cost generic versions of drug and biological products.

"First, do no harm"—or "primum non nocere" in Latin—is a maxim as old as medicine itself. It is one of the principal precepts of medicine and bioethics. And I believe it applies to the law just as much as it does to medicine.

As an attorney who studies and cares deeply for the Hatch-Waxman Amendments—and some might say obsessively so, particularly when it comes to FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations*, or the "Orange Book", which I carry with me as I travel the world—I always am concerned about what good or what harm proposals to amend these laws might cause—or if they are needed at all. In my experience, amending and tinkering with the Hatch-Waxman Amendments is akin to performing brain surgery: one wrong move can have dire consequences. So it is

through the "first, do no harm" lens that I approach the package of bills at issue in today's hearing.

We obviously do not have time to cover the details of each of the seven bills on today's agenda, but I do have particular comments on some of the bills. To help simplify things, these bills can be roughly sorted into three "buckets": (1) those addressing drug and biological product information transparency; (2) those involving 180-day generic drug exclusivity and patent settlement agreements; and (3) those seeking to facilitate generic manufacturers' access to the brand-name samples needed to participate in the Hatch-Waxman and biosimilar processes.

Drug and Biologic Information Transparency

- ***H.R. 1503 – "Orange Book Transparency Act of 2019"***

H.R. 1503, the "Orange Book Transparency Act of 2019," seeks to clean up—and to some extent, modernize—the Orange Book, a publication of approved prescription and over-the-counter drug products, including patent and regulatory exclusivity information, that has been around for nearly 40 years. The Orange Book is the linchpin of the Hatch-Waxman Amendments and the generic drug approval process. Generic drug manufacturers depend on it to list accurate patent and exclusivity information as they consider what generic drugs to develop. And including—or excluding—patent information in the Orange Book can have a significant effect on the timing of generic drug approval.

H.R. 1503 authorizes FDA to remove from the Orange Book information on patents determined to be invalid, to allow the listing of unspecified "additional patent information," and to prohibit the listing of information on drug-delivery devices. These changes could dramatically impact the timing of generic market entry. To cite just one example, the Hatch-Waxman Amendments typically prevent FDA from approving a generic version of a previously approved drug for 30 months if the innovator files a patent infringement lawsuit on a patent that's listed in the Orange Book. Broadening or narrowing the scope of information on patents that can be included in the Orange Book can therefore affect the timing of generic drug approval.

H.R. 1503 also would give FDA the authority to "choose to include [in the Orange Book] additional patent information respecting the drug." It is unclear, however, what is meant by "additional patent information." To the extent that information on patents other than drug substance, drug product, and method-of-use patents could be included in the Orange Book, the Orange Book patent thicket could become all that thicker for generic drug manufacturers to go through. But to the extent such "additional patent information" means greater information on listed patents purported to cover an approved drug

substance, drug product, or method-of-use, such information could be helpful to generic drug manufacturers. Additional clarity is needed on this point.

- ***H.R. 1520 – "Purple Book Continuity Act of 2019"***

If the Hatch-Waxman Amendments are the marriage between food and drug law and patent law, then the Biosimilar Act is the divorce between them. With more than 25 years of experience with Hatch-Waxman under its belt, Congress decided with the passage of the Biosimilars Act to separate biosimilar licensure from patent infringement proceedings. Whether or not this was a good decision is an issue up for debate.

While the Orange Book is the linchpin to the Hatch-Waxman Amendments, the *Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*—otherwise known as the "Purple Book"—is merely ancillary to the Biosimilars Act and is not currently mandated by statute. H.R. 1520 would change that by requiring FDA to publish the Purple Book and to update it each month.

H.R. 1520 would also require FDA to include in the Purple Book certain patent information on brand-name reference products. But this information would only be added after initiation of the so-called "patent dance" provisions of the statute instead of immediately after licensure of the brand-name product. While the proposed patent information provision of H.R. 1520 is, in my opinion, a good first step to facilitating biosimilar availability, Congress should consider whether a more enhanced patent notice feature should be added to the law.

180-Day Generic Drug Exclusivity and Patent Settlement Agreements

- ***H.R. 938 – "Bringing Low-cost Options and Competition while Keeping Incentives for New Generics Act of 2019" or the "BLOCKING Act of 2019"***

The 180-day marketing exclusivity period for the first generic drug manufacturer that risks patent infringement litigation incentivizes companies to clear the patent thicket. Today, in a highly competitive generic drug market where only a handful of manufacturers may be able to successfully commercialize a drug, 180-day exclusivity is the brass ring. Legislative measures that dilute or obscure that prize could jeopardize the generic drug industry. The BLOCKING Act would do just that.

The bill seeks to prevent exclusivity-eligible applicants from "parking" their 180-day exclusivity when alleged deficiencies prevent FDA from granting final ANDA approval when subsequent ANDA applicants otherwise are ready for approval. Whatever merit that proposal has, the BLOCKING Act would address it by imposing an immensely and unnecessarily complex framework to trigger 180-day exclusivity—and the analysis

under that framework becomes more complex with the addition of each variable (e.g., multiple first applicants).

As a food and drug lawyer, this proposal will keep me in business for a generation. Few others will benefit from the costly and time-consuming litigation these changes will spur. The generic industry certainly won't: This bill will make 180-day exclusivity eligibility far more unpredictable for ANDA applicants, reducing the incentives generics have to challenge brand manufacturers' patents. And it would be difficult to apply in practice: Information on some of the factors that can lead to the triggering of exclusivity under the BLOCKING Act is not readily available (or is not immediately available) to the public, such as the time of a subsequent applicant's tentative approval and the date of submission of an ANDA.

In my opinion, the BLOCKING Act is not necessary. Indeed, FDA already has the statutory and regulatory authority to determine that eligibility for 180-day exclusivity is forfeited or that exclusivity should not be granted because a first applicant has not diligently pursued ANDA approval.

- ***H.R. 1506 – "Fair and Immediate Release of Generic Drugs Act" or the "FAIR Generics Act of 2019"; and H.R. 1499 – "Protecting Consumer Access to Generic Drugs Act of 2019"***

Both H.R. 1506 and H.R. 1499 address patent settlement agreements—or so-called "pay-for-delay" agreements—peppered with a dash of 180-day exclusivity. Although I am not a patent attorney, from my standpoint as a Hatch-Waxman attorney, legislation that bans or severely restricts patent settlement agreements can delay generic competition and lead unnecessarily to time-consuming and costly patent infringement litigation. That is, from my standpoint, patent settlement agreements are generally pro-competitive and represent a fair balancing of the parties' relative risks from inherently uncertain litigation. Legislation that also brings 180-day exclusivity into the mix is doubly concerning as it dilutes the value of and brings greater uncertainty to that statutory incentive.

Reference Product Access

- ***H.R. 965 – "Creating and Restoring Equal Access to Equivalent Samples Act of 2019" or the "CREATES Act of 2019"; and H.R. 985 – "Fair Access for Safe and Timely Generics Act of 2019" or the "FAST Generics Act of 2019"; and***

H.R. 965 and H.R. 985 both address the availability of reference product sample needed for comparative testing and the eventual submission of a marketing application for a generic drug or biosimilar biological product. This topic has received increased attention in recent years. Indeed, last May, FDA Commissioner Scott Gottlieb announced that the Agency started publishing a list of reference product access inquiries

to provide transparency to the general public about this potential impediment to competition.

Both H.R. 965 and H.R. 985 would address the sample access concern, as well as other Risk Evaluation and Mitigation Strategies issues, to establish a system that more effectively facilitates generic competition. The bills would go a long way to address legitimate concerns about reference product access.

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Again, I would like to thank the Subcommittee for inviting me to testify on this set of legislative proposals. I look forward to working with you and your staff and welcome any questions you may have.

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