DIFFERENT RISK, DIFFERENT NAME?: THE DEBATE OVER ASSIGNMENT OF NONPROPRIETARY NAMES FOR BIOSIMILAR BIOLOGICS

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In the wake of the Supreme Court's highly-anticipated decision in National Federation of Independent Business v. Sebelius, the implementation of the Patient Protection and Affordable Care Act (ACA) is now underway by the federal government, states, employers, and insurers. While the debate over the ACA focused chiefly on the Constitutionality of the individual mandate and the severability of a Medicaid expansion provision, the ACA also introduced a challenging new paradigm for regulation of biologics by the Food and Drug Administration (FDA).

Nestled within the expansive ACA, the Biologics Price Competition and Innovation Act (BPCIA) spanned only three sections of the legislation, yet vastly altered the face of the Food, Drug and Cosmetic Act (FDCA) by setting forth an abbreviated pathway to market for "biosimilar" and "interchangeable" biological products. Fueled by both the failures and successes of the Drug Price Competition and Patent Term Restoration Act of 1984 (also known as the Hatch-Waxman Act) which created the generic drug approval process and incentives, the BPCIA unveils a panoply of regulatory tasks for the FDA. Along with these tasks, Congress delivers a mere skeletal vision of how the outcomes are to be achieved by the FDA.

As industry and the FDA knock heads over the details, one aspect of the BPCIA is proving to be a particular sticking point: how the resulting biosimilar and interchangeable biologics are to be named. Following the Hatch-Waxman Act, generics are assigned an international nonproprietary name (INN) and identical U.S. adopted name (USAN) which reflect the idea that the active ingredient of the generic is an exact copy of the active ingredient of the reference brand drug. The INN and USAN are then used in pharmacopeia listings, product labeling, advertising and promotional material, scientific and medical literature, as a basis for generic names, and to assist in pharmacovigilence. However, given the characteristics of biologics as complex macromolecules that are much more susceptible to variation in the

biological activity of the final product given manufacturing procedures; temperature, media, and storage conditions; and interaction of the final product with the human body, many resist the use of an INN and USAN for biosimilars due to the potential for a biosimilar to have a much different risk profile than that of the reference biologic.

This article aims to examine the current debate surrounding the use of nonproprietary names for biologics as tied to considerations of risk. Part I of the article will provide a brief overview of the BPCIA, including the foundational definitions and basic application requirements. Part II will address the current debate regarding nomenclature of biosimilars and interchangeable products, particularly addressing concepts of risk. Part III will examine challenges for the FDA, including effect of naming on product labeling requirements, pharmacist substitution, adverse event reporting and pharmacovigilence, and perceptions of patients and the general public. Part IV will examine the related implications for manufacturers, physicians, patients, and insurers. Part V will conclude with recommendations for implementation of a responsible and responsive naming system for biologics and interchangeable products.