Editorial

The Ongoing Challenges of Implementing Generic Drugs in the Global Market

Jill L. Maron, MD, MPH

Policy decision-making over the use of or government mandate for generic drug substitutes remains at the forefront of health care.[1] High prescription drug prices are a major contributor to the exponentially rising costs of health care worldwide and are a target of politicians, policy makers, pharmaceutical companies, and consumers. The issue is complex. Theoretically, providing reduced-cost bioequivalent drug substitutes seems highly desirable, yet numerous barriers exist that continue to make implementation challenging across multiple sectors of the health care system. Governmental and pharmaceutical finances and patent protection laws, as well as consumer and prescriber perceptions of the efficacy of generic drugs, all contribute to availability and acceptance of bioequivalents in the market. Surprisingly, dividing lines on the issue are not always clearly delineated, and stakeholder allegiance is not always apparent.

As with any hotly debated issue, there are two sides to this story. It is estimated that a pharmaceutical company may spend in excess of US $1 billion and require 10 to 15 years of rigorous research and clinical trials before achieving US Food and Drug Administration approval for a novel therapeutic drug.[2] These figures may not fully consider years of preclinical research required to bring the drug to clinical testing, further increasing the financial burden on pharma. To both recoup costs and drive a competitive market, initial pricing for a newly approved drug protected under patent exclusivity is not surprisingly, if not necessarily, pricey. In turn, revenue made under patent protection funds ongoing drug discovery and innovation,[1] which has resulted in life-saving and life-prolonging discoveries. However, exorbitant market prices come with a high cost for patients who often have to choose between paying for their medicine and paying rent. As a result, multiple government policies and strategies to reduce drug pricing and combat the rising costs of pharmaceuticals have been implemented globally.

Nearly 4 decades ago the United States passed the Drug Price Competition and Patent Term Restoration Act of 1984 (frequently referred to as the Hatch-Waxman Act) aimed at providing a shortened pathway for bioequivalents to come to market.[2] Under the Act, drug developers who could reverse-engineer an innovator drug are not required to repeat safety and effectiveness studies, bypassing both the time and costs to develop a new drug, as well as the time it takes to bring a drug to market. These benefits result in a substantial savings to the drug manufacturers. Since inception of the Act, generic drugs have gone from constituting only 19% of the US market in 1984 up to 89% of all drugs available in the United States today. However, generic drugs make up only approximately 25% of the pricing market, which is dominated by their brand-named predecessors.[2] Thus, despite obvious successes in availability of generic alternatives, clear challenges remain in reducing overall drug costs that are seemingly not easy to solve.

Five years ago, Canada initiated its own drug reform legislation. Centered at its drug price agency, the Patented Medicine Prices Review, several modifications to the nation's current pricing system were proposed, including making Canada one of the first countries worldwide to require proof that drug prices were worth their value.[3] However, in May 2022, after constitutional challenges to the drug reform led by the nation's drug lobby, combined with ground forces led by patient groups declaring that "millions of lives were at stake," fearing that new reform measures would limit access to lifesaving drugs, efforts ceased.[3] These efforts once again highlight the numerous challenges associated with drug reform, inclusive of consumers' voices on both sides of the aisle.

Clinical Therapeutics reports on both novel drug discoveries and their economic impact on the health care system. Beyond the pharmacoeconomics, we consider that value added for the consumer implies not simply getting one's money worth in terms of safety and efficacy but also incorporates quality of life-added years. This month we feature a report by Fisher et al,[4] who examined the impact of government-mandated prescribing of biosimilar insulin glargine in British Columbia, Canada. Compared with a recent retrospective cohort prior to policy implementation,

the authors report marginal changes in health service utilization without a negative health impact on patients by switching to the generic formulation. These types of comparative reports are highly encouraged at the Journal, as we aim to highlight innovation, safety, and practicality of drug therapies.

Fueled by competing interests on a multitude of fronts, the ongoing global challenges associated with drug pricing and health care costs will undoubtedly continue. Along with other stakeholders, health care journals share in the responsibility of balancing the reporting of drug discovery with drug accessibility. Treatments only work when they reach the patient for whom they are intended. That goal should serve as an important compass as we continue to navigate these challenges.

Jill L. Maron, MD, MPH
Department of Pediatrics, Division of Newborn Medicine, Women and Infants Hospital of Rhode Island, Providence, Rhode Island

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