



Statement for the Record

Energy and Commerce Subcommittee on Health

U.S. House of Representatives

Hearing on “Examining the Role of Incentives in Advancing Treatments and Cures for Patients”

June 11, 2014

Submitted by the Generic Pharmaceutical Association

The Generic Pharmaceutical Association (GPhA) appreciates the opportunity to submit this statement for the record. GPhA represents the manufacturers and distributors of finished generic pharmaceuticals, manufacturers and distributors of bulk pharmaceutical chemicals, and suppliers of other goods and services to the generic industry.

The United States is fortunate to have the most competitive and innovative prescription drug market in the world. The pharmaceutical industry can trace much of its current success back thirty years to the passage of the Hatch-Waxman Act. With this law, Congress created a precise balance between access to lower cost generic medicines and incentives to innovate new and better medicines. This balance has now been in place for three decades and has delivered public health and economic benefits far greater than could have ever been imagined when President Reagan signed the bill into law. As a result of Hatch-Waxman, the U.S. is now home to the world’s most robust generic market with the highest rate of generic utilization, has the largest brand drug market, and the highest amount of pharmaceutical research and development spending.

Access to Affordable Medicines

Prior to the passage of Hatch-Waxman, patients had very limited access to generic alternatives. In the first year after Hatch-Waxman, however, FDA received 1,050 ANDAs (generic drug applications). By the end of the second year, generic drugs accounted for about 22 percent of all prescriptions. By 1990, generic substitution had reached 30 percent, and annual savings were approximately \$5 billion. By the end of first decade, generic substitution had reached 42 percent and annual savings were \$30 billion. After 20 years of Hatch-Waxman, generics were accounting for half of all prescriptions dispensed in the United States, and annual savings generated by generic drugs use reached \$69 billion. Today, generics account for 84% of all prescriptions in the United States, and annual savings have reached \$217 billion.¹

¹ Annual generic utilization and savings data compiled from IMS Health, the Generic Pharmaceutical Association, and the Congressional Budget Office.

The use of lower cost, FDA-approved generics will continue to be critical to the sustainability of our healthcare system in the coming decade. IMS Health estimates that as access to healthcare expands and the demand for medicines increases, annual spending for prescription drugs will rise to between \$420 billion and \$460 billion by 2017, up from the current annual spending level of about \$330 billion.² Without the savings generated by the use of generic medicines, which on average cost up to 70 percent less than their brand name counterparts, drug spending in 2017 (assuming the same level of drug use) would exceed \$1 trillion.

Competition Drives Innovation

The enactment of Hatch-Waxman and the resulting introduction of robust generic competition has been a catalyst for investments in research and development by brand pharmaceutical manufacturers. The competition in the pharmaceutical marketplace currently provided by generic drugs – and the competition that biosimilars will soon provide – is vital in both assuring patient access to life-saving cures and in spurring innovation and research into new cures. The Congressional Budget Office (CBO) has noted that since the law’s enactment in 1984, private sector spending on research and development increased from \$8 billion to \$50 billion in 2008, with annual increases of approximately 9% per year.³ PhRMA reports that, “In the last ten years, more than 300 new medicines have been approved by the FDA, helping patients live longer, healthier lives.”⁴ The 2009 Medco Drug Trend Report reported that “about one-third to one-half of the products in Phase III development are new molecular entities (NMEs), new therapeutic biologics, or new vaccines/blood products; the remainder involve new indications for existing drugs, new combination products, new dosage forms, or new routes of administration.”⁵

Another example of competition driving innovation is the Biologics Price Competition and Innovation Act (BPCIA), which the President signed into law in 2010. Currently, the FDA is implementing the BPCIA, which establishes the new pathway for generic versions of biologic drugs, known as biosimilars. The intent of the BPCIA is to bring competition to the biologics market in the same way that Hatch-Waxman brought competition to the small molecule drug market. Biologics are the future of medicine and are often the only lifesaving treatments for the most severe diseases, but their high price tag can keep them out of reach for many patients. Capturing the opportunity to make lifesaving biologic medicines available to millions of patients at lower cost is a priority objective for our industry, and generic manufacturers are working actively in this field.

Looking Ahead

GPhA has member companies that manufacture both brand and generic products, so we

² IMS Institute for Healthcare Informatics. “The Global Use of Medicines: Outlook through 2017,” p. 13. (November 2013)

³ Congressional Budget Office, Economic and Budget Issue Brief. “Pharmaceutical R&D and the Evolving Market for Prescription Drugs.” (October 26, 2009)

⁴ Pharmaceutical Research and Manufacturers of America. “Explore the Latest Progress on Medicines in Development.” (2014)

⁵ Medco. “Drug Trend Report.” (2009)

understand the importance of a balanced approach that fosters both innovation and competition. When looking at economic and other types of incentives to spur drug development, it is important to take a holistic approach and focus on the specific reasons why companies are not investing in certain drug treatment areas. Is it because the cost to conduct clinical trials continues to grow? Are there regulatory barriers? Are there reimbursement issues? Is additional federal funding for basic research needed? Pinpointing the reasons for lack of investment can help identify the appropriate incentive.

Legislative proposals intended to incentivize investment in biomedical research and the development of new drugs should avoid unnecessary intellectual property or exclusivity incentives that could act as barriers to generic competition, which has proven to be a driver of new drug innovation, and thereby create an incentive for inefficient and non-innovative research and development. The goal should be for companies to direct funding to the innovative discovery of new cures rather than rewarding the development of non-innovative, “me too” products. As Dr. Fred Ledley of Bentley University noted in his testimony for this hearing, “Extended exclusivity for existing drugs or biologics can create incentives for incremental innovation, making companies less likely to discover and develop new medicines; less likely to enter into alliances with entrepreneurial biotechnology companies; and less likely to make acquisitions of such companies.”⁶

GPhA and its members understand that the generic and biosimilar industry is dependent upon the development of new therapies, which is why a measured approach should be taken to determine the appropriate incentives to spur innovation.

Innovative does not have to mean more expensive, and ensuring that patients have affordable access to innovative treatments is vital. Even the best of medicines are of no value if their high cost puts them out of reach for patients who need them.

We look forward to continuing to work with the Committee on the 21st Century Cures initiative and ensuring that patients have affordable access to life saving medicines.

⁶ Testimony of Fred David Ledley, MD, Director, Center for Integration of Science and Industry. Hearing on “21st Century Cures: Examining the Role of Incentives in Advancing Treatments and Cures for Patients.” (June 11, 2014)