Timeline of Significant Events in the U.S. Generic Pharmaceutical Industry

1938 — Congress passes the Federal Food, Drug, and Cosmetic Act (FDCA) in response to the deadly elixir sulfanilamide incident. This law designates drugs introduced after 1938 as “new drugs” requiring studies to show safety.

1951 — Durham-Humphrey Amendment establishes two categories of approved drugs: prescription-only (Rx-Only) and over-the-counter (OTC).

1951 — American Pharmaceutical Association begins a nationwide campaign to enact state anti-substitution legislation.

1962 — Thalidomide issue spurs Kefauver-Harris drug efficacy amendment to FDCA requiring new drug manufacturers to prove *efficacy* as well as safety; for drugs approved prior to 1962, the amendment allows for approval of generic versions of brand name drugs via a “paper” New Drug Application (NDA).

1962 — Kefauver-Harris amendment produces the Drug Efficacy Study Implementation (DESI) program, which begins a process of classifying all pre-1962 drugs as either effective, ineffective, or needing further study.

1962 — 3,443 products evaluated under the DESI program; 2,225 were found to be effective, 1,051 were found not effective, the remaining were found to need further study.

1965-1967 — Enactment of the Medicaid and Medicare programs pushes generic drugs into the forefront as key factors in providing economic sustainability to federal health programs.

1980 — Despite the “paper” NDA process for generic approvals, of the 150 drugs that were off-patent, only 15 had approved generic alternatives.

1984 — The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman) was signed into law by President Reagan on September 24, amending the FDCA to create a generic drug approval pathway via an abbreviated new drug application (ANDA).

1985 — In the first year following enactment of Hatch-Waxman ANDA approval pathway, FDA received approximately 1,050 applications for new generics; the projected annual savings at the time was $1 billion.

1986 — By the end of year two of Hatch-Waxman, the substitution rate for FDA-approved generic drugs jumped from 12 percent to 22 percent.

1992 — Generic Drug Enforcement Act imposes penalties for illegal acts related to ANDAs; requires generic drug manufacturers to include more scientific data concerning quality and bioequivalence in their ANDAs.
1994 — Ten years after Hatch-Waxman the generic substitution rate reaches 42 percent and the estimated annual savings are approximately $30 billion.

1997 — Food and Drug Administration Modernization Act (FDAMA) amends the FDCA to recognize changes in the way FDA would be operating in the 21st Century; a primary goal is to reduce approval times for NDAs through reauthorization of prescription drugs user fees under PDUFA II.

1998 — Congressional Budget Office study of brand company investment in new drug development before and after Hatch-Waxman finds that R&D spending during the decade following Hatch-Waxman increased 20 percent and brand sales nearly tripled. CBO concludes: “The changes that have occurred since 1984 appear to be favoring investment in drug development.”

2001 — The Generic Pharmaceutical Association (GPhA) is founded by the merger of the Generic Pharmaceutical Industry Association (GPIA) and the National Association of Pharmaceutical Manufacturers (NAPM). The National Pharmaceutical Alliance (NPA) soon becomes part of the newly formed GPhA.

2003 — The Medicare Prescription Drug, Improvement, and Modernization Act (also called the Medicare Modernization Act or MMA) is enacted, producing the largest overhaul of Medicare in its 38-year history and introducing prescription drug coverage (Part D) for Medicare beneficiaries. It also eliminates multiple 30-month stays of FDA approval of an ANDA, improving access to generic drugs.

2004 — Twenty years after Hatch-Waxman the generic substitution rate reaches 50 percent and the estimated annual savings are $74 billion.

2007 — The Food and Drug Administration Amendments Act (FDAAA) is enacted expanding and reauthorizing several existing pieces of legislation regulating the FDA, including rules for pediatric drugs and user fees for NDAs (PDUFA IV).

2009 — Twenty-five years after Hatch-Waxman nearly two-thirds of the prescriptions written in the United States are dispensed using generic drugs, generating $139 billion in health care savings.

2010 — Biologics Price Competition and Innovation Act (BPCIA) of 2009 is enacted as part of the Patient Protection and Affordable Care Act (ACA); FDA is authorized to create a regulatory approval pathway for biosimilar products.

2012 — The Generic Drug User Fee Amendments (GDUFA) are enacted as part of the Food and Drug Administration Safety and Innovation Act (FDASIA) with the goal of speeding access to safe and effective generic drugs by requiring generic companies to pay application and facility fees.

2012 — FDASIA also incorporates the Biosimilar User Fee Act of 2012 (BSUFA), authorizing FDA to require that manufacturers pay fees when submitting biosimilar applications.

2013 — Department of Health and Human Services approves the reorganization of FDA’s Office of Generic Drugs (OGD) into a “super office” putting it on the level of the Office of New Drugs.

2014 — First biosimilars filing accepted for review by FDA, 30th Anniversary of Hatch-Waxman; the generic substitution rate reaches 86 percent and the annual healthcare savings from the use of generic drugs tops $230 billion.