the pharmaceuticals industry with this goal in mind. The law required demonstration of both efficacy and safety of potential new drug candidates prior to granting marketing approval, effectively abolishing the automatic approval clause of the 1938 Food, Drug, and Cosmetic Act. The law also required that all drugs launched between 1938 and 1962 had to be proven effective in order to maintain their place in the pharmacy. The National Academy of Sciences and the FDA collaboratively studied this set of drugs, and discovered that nearly 40% were not effective. They were subsequently removed from the list of approved drugs.

Clinical trials, manufacturing processes, and even advertising of prescription drugs were also placed within the jurisdiction of the FDA. Clinical trial design had to be approved by the FDA, informed consent of study participants was required, and known side effects had to be disclosed to the public under the new law. Good manufacturing practices (GMP) and FDA access to company control and production records were also required in order to promote quality assurance. Finally, advertising for prescription drugs was placed under strict regulation. Marketing of generic drugs as new breakthrough medications was barred, and accurate disclosures of efficacy and side effects associated with drug treatment were required in all advertisements for prescription medications. In summary, the Kefauver-Harris Amendment of 1962 gave the FDA virtually complete authority over drug approval and marketing.

Hatch–Waxman Act of 1984[131]

Although the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch–Waxman Act, did not have a direct impact on the drug discovery process itself, it did fundamentally alter the pharmaceutical landscape. Unlike the previously discussed laws which were focused on safety issues, the Hatch–Waxman Act was designed to encourage the growth of the generic drug industry, thereby decreasing the costs of prescription medication. Prior to the enactment of this legislation, generic drugs represented approximately 10% of the prescription market, despite the fact that many major medicines were no longer under patent protection. By 2008, the market share held by generic drugs had risen to nearly 70% of the market, providing a clear indication that the Hatch–Waxman Act was successfully increasing competition in the prescription drug market. The positive impact on health care costs in the form of cheaper, generic prescription drugs was also viewed as a positive sign to those interested in containing the rising cost of health care.

The success of the Hatch–Waxman Act was driven by a few key changes in the drug approval process and patent laws that simplified market entry for generic drugs. First, the approval process itself was simplified through