A Brief History of Early Drug Regulation in the United States

The U.S. Food and Drug Administration is the oldest federal agency dedicated to consumer protection, originating as a single chemist appointed to the U.S. Department of Agriculture in 1862. FDA in 2006 employed more than 10,000 toxicologists, chemists, pharmacologists, physicians, microbiologists, pharmacists, veterinarians, lawyers, and others. This poster, excerpted from materials produced by the FDA’s History Office (On-line information at www.fda.gov/oc/history) highlights the fascinating early origins of the regulation of medicines and accompanies several objects generously loaned by the University of Arizona’s Museum of Pharmacy.

Rising Popularity of Patent Medicines or “Nostrums” in the 19th Century

Throughout the 1800’s, in an era of limited physician tools for treating illness that had been scrutinized and supported by empirical evidence and the scientific method, an increasingly urban population in the United States developed an appetite for medical elixirs. Marketed through exoticism, mystery, and grandiloquence claims of efficacy, these medicines claimed to cure everything from cancer, venereal disease, female troubles, stomach aches, and epilepsy. One product sold widely in the late 1800’s and early 20th century, William Radam’s Microbe Killer, boldly declared on the label “Cures all diseases,” while Dr. Sibley advertised that his Solar Tincture was even able to “restore life in the event of sudden death.” In fact, these products often simply relied upon opiates, cocaine, or alcohol to make imbibers feel better or “cured”; however, in many cases, they contained toxic ingredients such as acetanilide or cresyl phosphate (an organophosphate causing nerve paralysis).

The Great American Fraud and the Pure Food and Drugs Act of 1906

In the early 1900’s, while famed muckraking journalist Upton Sinclair’s publications detailed the horrific conditions of the meat-packing industry, some of his colleagues exposed the false claims, harmful ingredients, and market manipulation of nostrums and their producers. The most famous of these investigations was published in Collier’s magazine by Samuel Hopkins Adams in a series entitled “The Great American Fraud,” concluding in February, 1906, the same month Sinclair’s Jungle was published. Four months later, the first Federal Pure Food and Drug Act was published, prohibiting interstate commerce of adulterated and misbranded food and drugs. Although this led many patent medicines to remove narcotics instead of label them, it was less successful in corralling exaggerated claims or preventing many dangerous substances from reaching consumers.

The Sulfanilamide Disaster and the Federal Food, Drug, and Cosmetic Act of 1938

Between 1906 and 1938, legal proceedings over many problems with dangerous drugs demonstrated that the Pure Food and Drugs Act did not go far enough to protect public safety. In 1937, Massengill distributed an Elixir Sulfanilamide indicated for “all conditions in which the hemolytic streptococci appear.” It contained diethylene glycol, a chemical analogue of antifreeze, leading to the documented deaths of 107 people, including many children. This disaster became the urgent impetus for the passing of the Federal Food, Drug, and Cosmetic Act. Among the Act’s provisions were notably that all drugs be tested for safety prior to marketing, and the results submitted to the FDA in a new drug application (NDA). It additionally authorized factory inspections, and required the establishment of safe tolerances for unavoidable poisonous substances.

Furthermore, FDA promulgates the policy in August that sulfanilamide and selected other dangerous drugs must be administered under the direction of a qualified expert, thus launching the requirement for prescription only (non-narcotic) drugs.