

required the FDA to obtain evidence of the drug's efficacy as well as its safety, granted the FDA powers to determine clinical testing of proposed drugs for safety and efficacy (13,14).

c. Drug Amendments Act of 1962

The Drug Amendments Act of 1962, also known as Public Law 87-781, and also known as the Kefauver-Harris Amendments, became effective on October 10, 1962. The text of Public Law 87-781 (15) can be found on the HeinOnline database (16).

This law changed the pre-existing definition of a new drug by adding the words "and effectiveness" and the words "and effective" to the existing definition. Therefore from 1938 to 1962 an "old drug" was one generally recognized by qualified experts as safe for its intended uses. There was no requirement that an old drug generally be regarded as effective (17). Today, it might seem self-evident that the FDA should review the efficacy of proposed drugs before granting approval. However, this was not at all self-evident prior to passage of Drug Amendments Act of 1962. After the passage of this law, the FDA reacted as follows, at least in the words of one commentator (18) "[t]he FDA has wavered, procrastinated, and quaked with indecision on rulings which often they are unqualified to make, owing to the multifaceted areas of medical science and medical practice involved. In addition, the volume of work has become so enormous that the staff has become inundated by its size and complexity...the FDA staff has made a monumental effort to cope with its additional responsibilities."

d. Food and Drug Administration Modernization Act of 1997 and Phase IV clinical trials

Later developments in FDA law included the option to impose a requirement for Phase IV clinical trials. Phase IV clinical trials involve capturing data on safety and efficacy after FDA approval of a drug. In Phase IV trials, data is captured from experiences of ordinary consumers (not from subjects enrolled in clinical trials). As reviewed by Steenburg (19) the first FDA-regulated Phase IV clinical trial occurred in 1970. This Phase IV trial involved levodopa, used for treating Parkinson's disease. At this

¹³ Nelson RJ. Regulation of investigational new drugs: "giant step for the sick and dying"? *Georgetown Law J.* 1988;77:463.

¹⁴ Stepp DL. The history of FDA regulation of biotechnology in the twentieth century. *Food and Drug Law.* 1999;46:1-116.

¹⁵ HeinOnline 76 Stat. 780-796 (1962) (17 pages).

¹⁶ William S. Hein and Co., Inc. & HeinOnline, 1285 Main Street, Buffalo, NY 14209. At HeinOnline statutes can be accessed at the bulletpoint, "U.S. Statutes at Large."

¹⁷ United States v. An Article of Drug "Bentex Ulcerine." 469 F.2d 875; 1972 U.S. App. LEXIS 6476.

¹⁸ Krantz JC. New drugs and the Kefauver-Harris Amendment. *J Clin Pharmacol.* 1966;6:77-79.

¹⁹ Steenburg C. The Food and Drug Administration's Use of Postmarketing (Phase IV) Study Requirements: Exception to the Rule? *Food and Drug Law J.* 2006;61:295-400.