beyond the scope of this text to describe the historical context and impact of all of the laws governing the drug industry (The FDA as it exists in 2013, for example, is the result of over 200 laws passed since 1906), there are some key milestones that should be examined.

## Durham–Humphrey Amendment of 1951[129]

As discussed earlier, the Pure Food and Drug Act of 1906 and the Food, Drug, and Cosmetic Act of 1938 established the authority of the FDA to act in the interest of consumers and protect the populace from dangerous drugs. In fact, the FDA used the authority granted to it in 1906 and 1938 to declare that some drugs were not safe for use in the absence of individualized medical supervision. By 1941, more than 20 drugs and drug classes, including sulfa antibiotics, barbiturates, and amphetamines, required a prescription from either a physician or dentist. Neither of these two laws, however, provided clear definitions for prescription versus nonprescription drugs, and there was no specification as to who was responsible for labeling drugs as belonging to one class or the other. In addition, there were no clear guidelines regarding refilling of prescriptions. This lack of clarity led to a number of legal battles between the FDA, the drug industry, and professional pharmacy organizations over the distribution of prescription drugs.

The Durham–Humphrey Amendment of 1951 addressed this hole in the law by firmly establishing two classes of drugs, those that required a prescription, legend drugs, and those that did not, over-the-counter (OTC) drugs. In short, under this amendment, drugs that have been proven to be safe, effective, and require little, if any, medical oversight in their use (e.g., aspirin) could be sold as OTC products. On the other hand, drugs with addictive properties (e.g., morphine) or that required medical monitoring to ensure safety (such as monitoring of liver functions required with the use of statin cholesterol-lowering drugs) could only be distributed with the consent or under the direction of a physician via prescription. The new law also codified the role of the pharmacist in ensuring that prescription drugs were provided only with a properly documented prescription and the conditions under which refills would be available.

## Kefauver–Harris Amendment of 1962[130]

The tragic events that unfolded around the failure of Thalidomide led to substantial public outrage and pressure to enact stricter laws and regulations designed to ensure that public safety and well-being were at the forefront of the drug discovery process. The Kefauver–Harris Amendment of 1962 significantly broadened the FDA's regulatory authority over