

Troubling Marketplace

Wallace Janssen writes about how bad conditions were in the U.S. food and drug industries a century ago. The use of chemical preservatives, primitive sanitation, the lack of refrigeration capabilities beyond the use of ice, the lack of bacteriology discoveries, and other factors combined for very poor and dangerous conditions. Medicines containing such drugs as opium, morphine, heroin, and cocaine were sold without restriction. Labeling gave no hint of their presence.³

We need to be thankful to live in the United States. I have been to third world countries, and to an extent, some of these conditions still exist today. We have to look no further than Central and South America to find countries where clean drinking water is scarce and refrigeration is at a premium outside the major cities. The same holds true in India, China, and Southeast Asia. This is why we need to be vigilant on imports, especially in terms of food and pharmaceutical drugs.

The 1906 Pure Food and Drug Act (The Wiley Act)

It took 27 years to pass the 1906 Pure Food and Drug Act, commonly referred to as the Wiley Act. Dr. Harvey Washington Wiley is credited as being the main crusader for the passage of this act. Wiley believed, among other things, that the burden of proving food and drug safety should fall on the producer, and that no chemicals should be used without informing the consumer on the label—basic principles of today’s law and regulations. Ingredients in the drugs were also of high concern. For the first time, ingredients such as alcohol, morphine, opium, and cannabis had to be listed on labels.⁴ He worked hard with other chemists to pursue passage of this important act (Figure 8.1). (See Chapter 10 for more information on Dr. Wiley.)

The Wiley Act of 1906 was signed by President Theodore Roosevelt, becoming the first federal law regulating foods and drugs. The effective date of the act, June 30, 1906, is considered the founding date for the FDA.⁵ This law also defined *misbranding* and *adulteration* for the first time. It also prescribed penalties for each offense. The law recognized the U.S. Pharmacopeia and the National Formulary as standards authorities for drugs.⁶

Enforcing the Wiley Act

Administration of the new law was assigned to the Bureau of Chemistry. Through reorganization, the Food, Drug, and Insecticide Administration