U.S. Food and Drug Administration

Several of the compounding pharmacy owners I interviewed complained about selected FDA inspectors. When I questioned why, there were three reasons for these complaints. The first reason was not the inspector, but a lack of structured audit criteria that produced a standard audit template. We discussed a private sector alternative to this in Chapter 3. The second reason was a distaste for the added regulations. Again, this is not an inspector issue. From what I can tell at this point, the FDA inspectors are focused on defining compounding pharmacies that compound to specific patient prescriptions, and then assume all other compounding pharmacies are compound manufacturers (and subject to current good manufacturing practices (cGMP), etc.). I do know of one FDA inspector that found one example "in the gray area" and deferred the determination of the compounding pharmacy to the state board of pharmacy. However, this appears to be an exception rather than the rule. The third reason was the auditor himself or herself. I will attribute this to the 1% we have been discussing since my introduction. There are jerks and bad people in every profession. However, what I have found during my book research is that the FDA has outstanding professionals trying to do their best given their task to protect the public from unsafe pharmaceutical drugs. The following is a history of the FDA, dedicated to the 99% of these FDA professionals.

The FDA* has a long and proud history. Despite all the wrongdoing or alleged wrongdoing in the Internal Revenue Service (IRS) and other government agencies, we should be thankful that we have a strong FDA and dedicated workers who make up the agency. I have traveled all around the world and lived in South America, and from my perspective, we have the best consumer protection as it relates to food, drugs, cosmetics, and other products.

Officially, the FDA as a law enforcement agency dates back to 1906 and the 1906 Food and Drug Act. However, as an institution, scientific activity in food and other agricultural substances to protect consumers dates back to 1862. Federal concern for drugs started with the establishment of U.S. Customs laboratories to administer the Import Drugs Act of 1848. This act was established to counteract counterfeit, contaminated, diluted, and decomposed drug materials (sound familiar?).[2]

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* The following was largely excerpted from an article on the FDA website titled "The Story of the Laws behind the Labels" by Wallace F. Janssen, FDA historian. It is provided with approval from the FDA.