JOURNAL OF CLINICAL RESEARCH BEST PRACTICES

Vol. 1, No. 8, August 2005 "Can You Handle the Truth?"

"Protecting America's Health: The FDA, Business, and One Hundred Years of Regulation"

Philip J. Hilts, 2003, 394 pages, Alfred A. Knopf, $26.95 hardcover, $19.95 softcover

Review by Norman M. Goldfarb

"Protecting America's Health" answers three of the most puzzling questions in clinical research: Who are those people at the FDA, what do they do all day, and why won't they just leave me alone?

This book has been selected for
The First Clinical Research Bookshelf
Essential reading for clinical research professionals

The reality of regulation of clinical research, and the medical products industry as a whole, is that the FDA's staff doesn't sit around all day dreaming up ways to throw sand in our gears. Every FDA regulation, even the most excessive, was created in response to blatant mischief by the industry. There would be no "D" in "FDA" if the industry behaved itself.

The book describes the morbidly fascinating historical incidents that drove the creation of today's regulatory environment. For example, in 1937, the Massengill Company was selling a drug called sulfanilamide. It was an excellent antibiotic for adults, but the huge market for treating childhood infections such as strep throat demanded a palatable liquid formulation. Harold C. Watkins, Massengill's chief chemist, discovered that the drug dissolved readily in diethylene glycol, a sweetish but largely tasteless liquid. Problem solved!

Massengill manufactured 240 gallons of the drug and shipped it off in 4-ounce bottles under the trade name "Elixer Sulfanilamide". 107 people, mostly children, quickly died from kidney failure. Fortunately, 234 gallons were recovered, meaning that the 107 deaths were caused by, at most, 192 bottles of the elixir. As it turns out, diethylene glycol is a co-product in the manufacture of ethylene glycol, the principle ingredient in automobile antifreeze, popular among suicidal cats and dogs.

So why didn't the FDA prevent this health disaster? Under the Pure Food and Drug Act of 1906, it had the authority to prosecute Massengill for errors in manufacturing and mislabeling of the drug, but it did not have the authority to approve the drug before shipment. Furthermore, the drug was "pure", i.e., manufactured properly, and the labels did not claim it was safe. In fact, few of the sick children subsequently complained of sore throats. The FDA's hands were tied.

In 1939, President Roosevelt signed the Food, Drug and Cosmetic Act and the clinical research industry was born.

Current safety standards are orders of magnitude stricter. AstraZeneca's hypercholesterolemia drug Crestor, for example, is under attack for serious side effects in less than 0.003% of patients. Randomized clinical trials cannot identify this frequency of side effects, so reform is likely for our highly ineffective post-marketing safety reporting system. Stay tuned.

The book is available at online bookstores.

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