

"FDA: A Century of Consumer Protection"

Wayne L. Pines, editor, 2006, 286 pages, Food and Drug Law Institute, \$79.00

Review by Norman M. Goldfarb

Reading "FDA: A Century of Consumer Protection" is like visiting with a dear old friend. He may have a few foibles, but he has a good heart and lots of great stories from a life well-lived. Wayne L. Pines, the editor, has gathered together 43 other friends of the FDA to tell its story. Dozens of vignettes, many first-hand, and photographs help illuminate the FDA's personality on the occasion of its 100th birthday. The authors' admiration of the FDA does not prevent them from telling its story fairly, even the embarrassing bits.

This book has been selected for
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Essential reading for clinical research professionals

The FDA was created by the 1906 Pure Food and Drugs Act, but did not come into its own until passage of the Food, Drug, and Cosmetics Act in 1938 gave it some enforcement teeth. When the Drug Amendments of 1962 required manufacturers to prove the efficacy of their products before marketing them, the golden age of clinical research was born. The FDA's headcount grew from about 1,700 in 1960 to 10,000 in 2000.

The FDA has always walked a tightrope, with public health on one side, industry on the other, and public opinion often jiggling the rope. For example, in 1976, the FDA issued a list of products containing Red Dye No. 2, explaining that scientific testing had been unable to prove or disprove its safety. A public outcry led to its banning later that year. In 1977, based on scientific evidence (later disproved) that the sweetener saccharin may cause cancer, the FDA banned the product. A public outcry led to an act of Congress reversing the ban.

The book has 11 chapters:

- The Struggle for the 1906 Act
- The Mission and the Institution: Ever Changing Yet Eternally the Same
- FDA Comes of Age: A Century of Change
- FDA in the World Community
- Keeping America's Food Supply Safe
- FDA's Role in the Pathway to Safe and Effective Drugs
- FDA's Role in Regulating Biologics
- The Regulation of Foods and Drugs for "Animals Other Than Man": Distorted Mirror or Mineshaft Canary?
- Dietary Supplements: Populism and Pirandello
- "The Least of FDA's Problems"
- FDA Adapts to a New Industry

The book is available at <http://www.fdpi.org>

Reviewer

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