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Vol. 1, No. 12, December 2005 "Can You Handle the Truth?"

"Inside the FDA: The Business and Politics Behind the Drugs We Take and the Food We Eat"

Fran Hawthorne, John Wiley & Sons, 2005, 338 pages, $27.95

Review by Norman M. Goldfarb

"Inside the FDA: The Business and Politics behind the Drugs We Take and the Food We Eat" focuses on issues related to FDA regulation of drug research and marketing. As a healthcare reporter, Ms. Hawthorne has essentially written a fine book-length magazine series.

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

Ms. Hawthorne effectively uses interviews and case studies to animate differing perspectives on the regulatory process and surrounding political environment. She thoroughly and objectively presents both (or more) sides to each issue, only rarely making judgments. (Her judgments may be correct, but given her reportorial background and the anecdotal quality of her research, they should be taken with a grain of salt.)

A comparison of the personalities of three FDA divisions is very interesting:

- The "businessman" Center for Drug Evaluation and Research (CDER) is efficient and careful to follow the rules and meet deadlines.
- The "academic" Center for Biologics Evaluation and Research (CBER) is staffed with reviewers who also conduct their own scientific research.
- The "cowboy" Center for Devices and Radiological Health (CDRH) has the most lenient approval requirements, smallest trials, and fastest reviews.

The book starts with a brief history of the FDA and ends with a grab-bag of topics such as:

- Over-the-counter drug advertising
- Me-too and trivial drugs
- Drug patents (The U.S. patent office recently issued a patent to a drug company on the swallowing method of taking its drug.)
- Generic drugs
- Drug reimportation
- Off-label drug prescribing
- Safety surveillance
- Clinical trial registries

Material related to "the food we eat" is minimal.

The book is available at bookstores.

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