

Recent Publications

Regulating change

The United States Food and Drug Administration has recently celebrated the fiftieth anniversary of the Federal Food, Drug and Cosmetic Act of 1938 which effectively launched it into the modern era. The occasion was used as an opportunity to look at the challenges of the future rather than the achievements of the past. Representatives drawn from industry, academia, the legal community and consumer organizations were invited to participate in a series of round-table discussions covering various key aspects of the FDA's mandate, and the edited proceedings of these meetings have now been published.

The basic issue that predictably permeates the book is the need to accommodate society's desire for the progress that is promised by technological change yet, at the same time, to assure its protection from the inevitable hazards of innovation. This was undoubtedly as true 50 years ago as it is today. What is new is that demand for protection has to be satisfied, particularly in the USA, in the face of growing consumer pressure for earlier and freer access to regulated products.

Society is also impatient for new drugs that will give hope to the many patients for whom effective therapies still remain elusive. For the Food and Drug Administration, commitment to this expectation represents far more than an obligation to accord priority to innovative marketing applications. Through the Orphan Drug Act, in particular, the Agency has acquired influence actively to promote the development of needed drugs that would otherwise never emerge because of lack of commer-

cial incentive. The results have been impressive and it is heartening that the FDA Commissioner, in his foreword to this book, is bold enough to set as his first objective for the immediate future "to find, test, and approve drugs for the desperately ill". In no other country could the regulatory authority claim to exert a direct and positive influence on the drug development process.

He is equally positive in his view that collaboration with academia and industry must be active and supportive if full advantage is to be gained in the short term from the advent of biotechnology, and he sees closer cooperation between practising doctors, pharmaceutical companies and regulators as the key to more effective surveillance of drugs subsequent to their registration. At a time of diminishing resources, he underscores the need "to focus on real, not imagined, threats to public health".

He appreciates, however, that a collaborative relationship between the industry and regulators — no matter how strong may be its justification in terms of social benefit — can only be countenanced by society with equanimity when the regulatory authority has both the resolve and the resources to take vigorous and even-handed enforcement action whenever occasion demands. At all costs, he recognizes, public trust must be preserved. Its erosion would inevitably and profoundly set back the evolutionary process of therapeutic innovation which still, for so many, holds out the prospect for improved quality of life.

Reference: *Regulating Change: the regulation of foods, drugs, medical devices and cosmetics in the 1990's*. Eds. Peck, J.C., Rabin, K.H. Institute for Alternative Futures; Hill and Knowlton, Washington DC, 1989. LCCN 89 82416