FDA—75 Years Later

A memorable year in the history of the Food and Drug Administration is about to end—the 75th year of the first Federal Food and Drugs Act, signed by Theodore Roosevelt on June 30, 1906.

During 1981 we have been looking at the past, present, and future of food and drug regulation in the United States, not to mention the other areas now subject to FDA's jurisdiction—cosmetics, biological products, medical devices, and radiation safety.

Significantly, this major consumer protection agency began as a scientific institution long before it had any law enforcement responsibilities. Eventually, the research findings of the Bureau of Chemistry (now FDA) would back the goals of the Pure Food Movement—a trade phenomenon starting in the 1870s. Indeed, the first advocates of a Federal law to stop food adulteration were trade leaders who feared the competition of ersatz products and the already intolerable variations in State laws. And it was Harvey W. Wiley, who came to head the Bureau of Chemistry in 1883, who forged the coalition of producer and consumer interests that finally secured the legislation.

Today's generation has no memory and little knowledge of those faraway days before and after the turn of the century. Published elsewhere in this issue is a collection of pictures, culled from FDA's family album, which remind us of some of the differences—and similarities—between those times and ours. Imagine a day when the term "pasteurized" was unknown, and when it had just been discovered that cholera was transmitted by contaminated water or food. Imagine a day when anyone could put anything into a bottle and label it a cure for any or all diseases, without being held responsible for either truth or safety. And then, after a quarter century of struggle, a law was enacted which, viewed from now, was incredibly inadequate.

The 1906 law prohibited interstate distribution of adulterated or misbranded foods and drugs and gave the Government authority to seize such products and to prosecute, fine, or imprison their shippers. There were few specific requirements to guide compliance. Misbranding included labeling that was "false or misleading in any particular," but the law did not even require the declaration of net content. Products containing "any poisonous or deleterious substance" were adulterated, but the Government had first to discover what a product contained and then be able to prove in court that it was harmful or fraudulent.

Yet the same Congress which passed the 1906 Food and Drugs Act also passed a meat inspection law requiring Government surveillance of every animal and pound of meat before interstate distribution. And an earlier Congress, in 1902, had licensed the production of biologics, another strong system of premarketing control. Nor was it long after 1906 that the makers of coal tar colors asked the Bureau to designate the colors safe to use in foods and drugs and to test and certify them before shipment.

Today the principle of premarket regulation is applied systematically to a wide range of chemicals, drugs, and devices, a major change from the days when compliance was obtained only by fear of punishment. Extensive regulations, mandated by the Federal Food, Drug, and Cosmetic Act of 1938 and its numerous amendments, are needed to spell out the procedures and requirements for premarket approvals. In effect, industry and Government are required to work at the same job—consumer protection.

Now that we are in the 1980s, I believe that we are being asked by society to digest, if you will, this incredible series of controls and regulations, to eliminate the excesses, to root out duplication, to be sure that our social goals are achieved efficiently and reasonably. In the months and years ahead FDA will be undertaking a major reevaluation to determine whether the regulatory activities in which we have engaged are indeed serving our social goals. For example, we cannot afford, in the name of regulation, to inhibit creativity in scientific development.

We need to revise our food safety laws to make them more consistent with the information that science provides us. Another item on my agenda is food labeling, particularly for sodium. I have a personal interest in this project as the former Director of the Hypertension Clinic at the Hershey Medical Center. We are seeking to encourage the food industry to reduce the amounts of sodium added to processed foods and to provide better information as to sodium content on food labels.

In the drug area, we need to make our review systems more efficient. We must not only see that unnecessary barriers are removed, but also that the system helps expedite the marketing of useful products, while still protecting the public.

I believe strongly in the need for regulation. People cannot decide for themselves which drugs or devices or food additives are safe and effective. The chemistry is too sophisticated, the marketing system too complex. People cannot be expected to visit manufacturing plants to see that products are made under sanitary conditions or that they are not short-weighted.

Our need, our mandate in the 1980s, is to draw a balance between regulations that are needed and those that are not, between those that make a contribution and those that are inhibitory, between those that cost us more than we ought to be paying and those that are necessary to protect the public health.

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