Book Reviews

A Question of Intent: A Great American Battle with a Deadly Industry

David Kessler
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512 pages; $27.50 hardcover.

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Despite all the rhetoric to the contrary, our society makes it exceedingly difficult to enact fundamental changes to protect the public's health. Numerous obstacles, from bureaucratic inertia to industry's lobbying efforts, hinder initiatives to regulate hazardous products other than drugs. It doesn't have to be this way; Congress has decided on our behalf that the right to manufacture and sell products that are, or may be, toxic is more important than our right to be protected from such hazards.

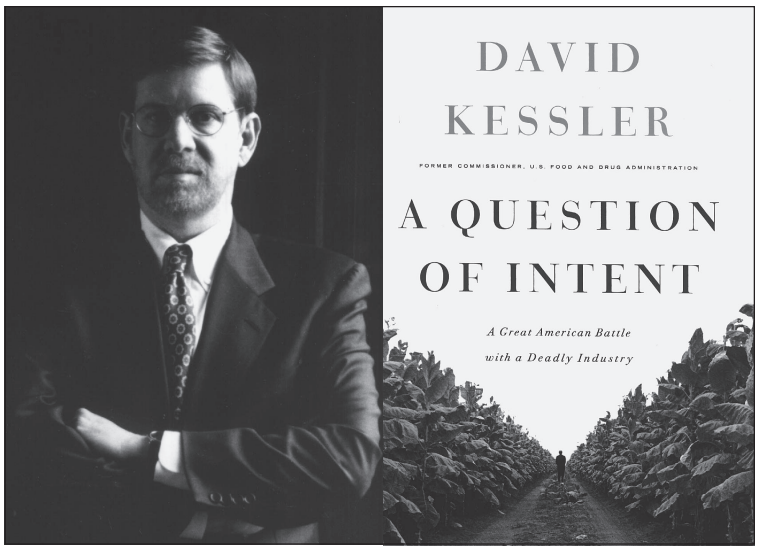
David Kessler recognized this and articulated his role by quoting Harvey Wiley, the founding commissioner of the US Food and Drug Administration: "I began my public career without any idea of being quarrelsome and belligerent. But from my entry into the public life I became a belligerent in, I think, the best sense of the term. I fought with all my power for what I considered to be right."

With David Kessler as the commissioner of the FDA from 1990 to 1997, the FDA took on two major public health initiatives: food labeling and regulation of cigarettes as a drug delivery device. *A Question of Intent* focuses on the latter. Although numerous books have been written about the tobacco wars, this book fills an important void by describing the FDA's attempt to "enforce the law" and regulate the sale of cigarettes to children and adolescents.

Scientific evidence had implicated cigarettes as a major cause of cancer by 1964, but focusing regulatory efforts on this point proved to be ineffective against the tobacco industry's well-funded lobbying efforts. The success of the FDA's new strategy was summarized in the opening discussion with a high-level tobacco industry informant: "You hit the bull's eye three times. You were right to focus on nicotine as an addictive drug. You were right to elevate the discourse to the levels of public health. You were right to focus on the addiction of children."

David Kessler, who was trained in both medicine (pediatrics) and law, describes the investigation and discovery of evidence implicating the tobacco industry in one of the most disturbing crimes against public health. Tobacco is the number one cause of death in the United States, leading to more than 400,000 deaths each year. Revelations that the tobacco industry concealed and distorted data to further its own interests were disturbing, but they were not surprising. The failure or impotence of the federal agencies to protect the public from this public health hazard was more troubling.

A Question of Intent is gripping reading. Indeed, I read it through while two novels (one by Ken Follett) lay untouched on my bedside table. The investigation unfolds in a clear and objective style, capturing and holding the reader's attention. Kessler's early interests in health policy are evident. After his poignant introduction centered on a discussion with an informant from the tobacco industry, Kessler quotes two of his mentors at Amherst University. Oscar Schotté, a developmental biologist, helped Kessler to understand that "meticulous attention to detail and patience are as important to problem solving as a grand vision." Henry Steele Commager, a historian, cautioned Kessler to "examine carefully the long-term consequences of actions intended to remedy the immediate problems of the world" and "that important things are never achieved quickly."



This book accurately portrays the complexity of the FDA's undertaking. Kessler played a central role in the investigation, but he is quick to recognize the efforts of other FDA investigators. He is also quick to confess his hesitancy to tackle tobacco and his uncertainty about their efforts and chances of succeeding. Finally, he describes the interactions and political wrangling of the White House and various agencies involved in policy making. Thus, this book serves as a guide for scientists, advocates, and policy makers for other public health initiatives.

Kessler describes how the FDA verified, in painstaking detail and by following creative avenues of investigation, that the industry intentionally manipulated nicotine content to maximize the addictive properties of cigarettes. This was done by mixing tobacco leaf containing various levels of nicotine and using ammonia to "liberate free nicotine from the blend that is associated with increased impact and satisfaction." The FDA uncovered documents written by William Dunn, a psychologist at the R.J. Reynolds Tobacco Company, describing the industry's efforts to ensure "that total nicotine in the system remains at or near the nicotine need threshold." In the early 1970's, RJR executive Claude Teague confessed, "Thus a tobacco product is, in essence, a vehicle for the delivery of nicotine, designed to deliver the nicotine in a generally acceptable and attractive form." "Happily for the tobacco industry, nicotine is both habituating and unique in its variety of physiological actions, hence no other active material or combination of materials provides equivalent 'satisfaction.'" All of this material was intentionally concealed to prevent the FDA from regulating tobacco as a drug.

Kessler realized that "children and adolescents were essential to the economic health of the tobacco industry." He describes how the industry studied children and adolescents to take advantage of their "fragile, developing self-image." Perhaps earlier than anyone else—with the exception of the tobacco industry—Kessler recognized that "nicotine addiction begins as a pediatric disease." Imperial Tobacco, a Canadian tobacco company, wrote in its marketing strategy, "If the last ten years has taught us anything, it is that the industry is dominated by the companies who respond most effectively to the needs of younger smokers."

How did the tobacco industry quash efforts to regulate tobacco over the past four decades? As described by Kessler, the industry developed strategies to deal with scientific critics, including "smearing and belittling them" and "overwhelm[ing] them with mass publication of the opposed viewpoints of other specialties." It created the Special Projects initiative in 1964. "The Special Projects grants created a network of consultants, 'rented white coats,' who were friendly witnesses whose interpretation of scientific studies always managed to be favorable to the industry." Numerous researchers at prestigious institutions accepted money, including Sloan Kettering, where Kessler had worked during college. The medical community also colluded with the tobacco industry. On February 12, 1964, the American Medical Association accepted more than $10 million from the tobacco industry to "fund research on smoking and health." Two weeks later, "Francis Blasingame, AMA's Executive Vice President, sent a letter to the Federal Trade Commission, a strong advocate of warning labels. 'With respect to cigarettes, cautionary labels cannot be anticipated to serve the public interest with any particular degree of success.'" Most important, the tobacco industry made huge contributions to members of Congress. There are no better examples of the need for campaign finance reform than the tobacco industry's successful lobbying efforts to control congressional actions.

I have only one minor criticism of the book. In his quest to describe the events objectively, Dr. Kessler minimizes the wrenching decisions he faced. He was ready to resign over two decisions: food labeling and tackling the tobacco industry. Kessler must have been under extreme pressure from his staff for the loss of congressional support to replace the Parklawn Building, described by Kessler as "[a] gray behemoth . . . , with mazes of offices branching off a confusing network of corridors." Congress had been gradually putting funds aside to replace the Parklawn Building with a new building that would house the "8,000 employees scattered across the Washington metropolitan area." Kessler makes it clear that Congressional support for the building, described by his opponents as "Kessler's Castle," was withdrawn to punish the FDA for its crusade against the tobacco industry.

Unfortunately, the FDA's attempts at regulation were, in the short term, unsuccessful. The US Supreme Court ruled five to four that the FDA lacked the authority to regulate tobacco. "They beat us," a colleague at the Justice Department admitted to Kessler. But she continued, "Ultimately, they will lose because of what you did. It's not over." Indeed, the FDA was instrumental in unleashing effective litigation against the tobacco industry.

It is clear from this book that David Kessler was, in the best sense of the term, an effective and belligerent commissioner. This book would provide valuable insight and captivating reading for anyone with an

interest in public health, but especially for public health practitioners, scientist-advocates, and policy makers.

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Making Better Environmental Decisions
Mary O'Brien
Cambridge: MIT Press, 2000.
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Ellen Silbergeld, PhD

We are all precautionary now, to paraphrase the famous comment about Keynesian economics. As a consequence, it may be that the precautionary principle is in danger of death by overacceptance. After a first wave of reaction characterized by suspicion and dismay, all sides in the deeply divided national discourse on environmental policy have vigorously professed allegiance to precaution. One reason for this remarkable unanimity of purpose is that no one really knows what the precautionary principle means in practice. Despite a spate of books and articles over the past five years, invocations of its successful applications in European policy, and its inclusion by reference in several international agreements, an operational definition of the precautionary principle remains elusive. As stated, the precautionary principle appears to embody a simple notion of prudence or foresight: "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically."[1] What this actually means is less easy to put into practice.

On the evidence of Mary O'Brien's book, *Making Better Environmental Decisions,* and last year's important set of essays collected by Raffensperger and Tichner,[1] the precautionary principle may in fact have two different meanings. In the context of regulating toxic chemicals, where it takes action to overcome an entrenched assumption of safety, precaution has been invoked to encourage an incentive or even an obligation to act in the absence of scientific certainty. In the context of siting a controversial new facility or operation, where a new action is proposed, precaution is invoked to justify opposing actions that have the potential to cause unwanted ecological or health impacts. Thus, in one context, precaution is associated with activism, and in the other context with resistance to action. In the former context, uncertainty is not a bar to action to reduce or ban an unacceptable pesticide or chemical process; in the latter context, uncertainty is a disadvantage as regards siting a new facility or licensing a new product.

Clearly, the second meaning of precaution is easier to understand, and closer to the common sense statement of precaution: look before you leap. This is the main thrust of O'Brien's book. O'Brien has a distinguished record as an environmental advocate working with local, regional, and national nongovernmental organizations. She brings to her book the passion of experience and a deep respect for the values and rights of ordinary citizens working as individuals or in small groups around the local, but not so ordinary, matters of community life: Who will clean up the local dumpsite? Where will the hazardous waste facility be? How will regional ecosystems be protected? Her determination to challenge the hegemony of risk assessment arises from the same commitment to democratic empowerment expressed nearly 20 years ago by William Ruckelshaus. In an important essay, Ruckelshaus warned that the increasing reliance upon risk assessment, which he recognized as a technically complex and data-driven policy method, carried dangers not only to the process of transparent environmental policy-making but also to the Jeffersonian ideal of participatory democracy and enlightened self-government.[2] O'Brien adds to his political critique of risk assessment her objection to its narrowness of focus upon the scientifically quantifiable, "using certain bits of information in such a way as to exclude feeling and to artificially sever connections of parts to a whole." As does Sandra Steingraber in her more personal reflections on environmental policy (*Living Downstream*),[3] she calls for reducing the preeminence given to technical/scientific/economic analyses of options to a scale commensurate with the cultural, social, religious, and emotional contexts of people's lives.

The passion of O'Brien's writing is persuasive, and her examples of environmental policymaking make a strong case for reintroducing human perspectives into agencies seemingly staffed by anomic robots. She characterizes with particular accuracy the insensitivity of much of the risk assessment related to hazardous waste site cleanups. I, too, have been present at meetings