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

by David Kessler

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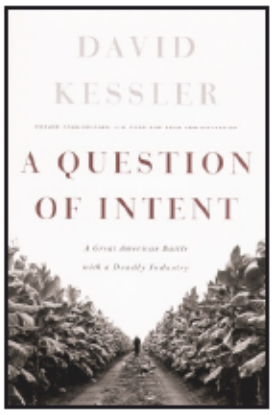
Until the American Civil War, an excuse often used to justify the continuation of slavery was, simply, that it was legal. The 14th Amendment finally made the peculiar institution illegal.

Tobacco-product manufacturers also take refuge in the fact that tobacco products are legal. Legal though they may be, they are as yet unregulated. Despite their deadliness and addictiveness, tobacco products are not subject to the regulatory oversight that has long been expected of other drugs, foods, cosmetics and medical devices. The manufacturers are not accountable to anyone to make their products less harmful despite the fact that their products cause more than one in five deaths in the United States.



David Kessler has come closer than anyone else to making the peculiar industry of tobacco accountable. As Commissioner of Food and Drugs, he led an effort to assert jurisdiction over cigarettes and smokeless tobacco products. *A Question of Intent* is a fast-paced recount of this effort. The book successfully intertwines the story of how the agency's investigation unfolded with the bare facts of the case the FDA built. It is written at a level accessible to non-specialists but captures the interest and attention of people long familiar with the field. There are ample references and bibliographic suggestions permitting the interested reader to delve into the technical and policy aspects of the matter.

The book's title refers to a key element in one of the definitions of drugs and medical devices under which FDA operates. Products are drugs and/or devices to the extent that a manufacturer 'intends' that they affect the structure or function of the body. For instance, water may be sold for a wide variety of purposes, such as for drinking, use in steam irons and as a diluent for injectible medicines. FDA regulates only the last use under its drug regulations.

FDA began its investigation of tobacco in early 1994. Eighteen months later, it published its proposed rule, and a year later, it published a final rule asserting jurisdiction over cigarettes and smokeless tobacco products.

One of the major contributions FDA made to tobacco control in the final rule was its analysis of the manufacturers' intentions for their products. Using multiple lines of evidence, including persuasive internal company documents, the agency showed that tobacco product makers intend that their products have pharmacologic effects in the bodies of their customers. Specifically, the agency showed that the companies intend that their products addict their customers to nicotine.

The industry's challenge to the FDA's rule was finally decided in March 2000. Five Supreme Court justices—the ones whose decision gave George W. Bush the presidency—sided with the industry. This majority said that Congress had never given FDA authority to regulate tobacco products. The minority agreed with the agency that the industry intended addiction and that it should be under the agency's purview.

The issue is presently before Congress. Philip Morris and R.J. Reynolds are both talking about wanting narrowly circumscribed FDA regulatory oversight. Their view of FDA authority would not give the government authority to actually regulate the product or to prevent the sort of consumer fraud that the industry has perpetuated with its so-called 'light' cigarettes. Instead, their version of regulation would largely pave the way for them to make health claims for the next generation of filtered and low-tar cigarettes—products like Eclipse and Accord. Although the public health will benefit from a good regulatory structure, a bad one such as this will cause harm.

Besides being a good read and providing a context for a key policy debate on Capitol Hill, the book offers a strikingly good suggestion about the ultimate direction we should take in regulating the tobacco industry. Since tobacco products are inherently poisonous and addictive, and since they should not be made illegal, their manufacturers should not do anything more than to merely make them available, in plain wrappers. Specifically, nothing should be done to promote these products or their makers. Kessler comments,

> As a society, we have allowed the tobacco companies to shape public perceptions of cigarettes for far too long. Even now, with all that the FDA uncovered about nicotine manipulation and industry deception, it is too easy to be swayed by the argument that tobacco is a legal product and should be treated like any other. But a product that kills people—when used as intended—is different. No one should be allowed to make a profit from that.

Kessler envisions what would amount to nationalizing this industry so that its purpose would be merely to provide tobacco products to addicted smokers rather than to maximize a return on investment for stockholders. Such a change would remove the adversarial gulf that presently divides tobacco product makers from the public health and medical communities. Such a change would dissolve opposition to expanded protections from environmental tobacco smoke and would make it far easier to put in place proven approaches to treatment and prevention.

Ice Bound: A Doctor's Incredible Battle for Survival at the South Pole

by Dr. Jerri Nielsen with Maryanne Vollers

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Ice Bound: A Doctor's Incredible Battle for Survival at the South Pole is the memoir of Dr. Jerri Nielsen, the emergency-room–trained 47-year-old physician who, because she could not be evacuated during the South Pole winter, had to biopsy and then treat her own breast