President Obama signed the Family Smoking Prevention and Tobacco Control Act (FSPTCA) in June. As the FDA begins to implement the law, it seems a good time to revisit David Kessler’s book, *A Question of Intent*, published in 2001. Last night I finished reading it for the first time.

To begin with, it is a riveting read, a detective tale and conspiracy mystery worthy of a screenplay. (Some of the events in the books were the subject of a screenplay, but not based on Kessler’s book. The 1999 film *The Insider*, written by Marie Kessler, Eric Roth and director Michael Mann, starring Russel Crowe and Al Pacino, focused on a small part of the story of Big Tobacco’s efforts to keep secret its strategy to hook lifelong users of its products. The real-life character depicted in the movie is Jeffrey Wigand, whose website is worth a visit: www.jeffreywigand.com.) The book came out in the first year of George W. Bush’s administration, which helps us understand the last two sentences: “Whatever the challenges, the industry cannot be left to peacefully reap billions of dollars in profits, totally unrepentant, and without thought to the pain caused in the process. For that remains its intent.”

FSPTCA is a collection of baby steps, the most serious of which might be more prominent labels and more oversight of the chemistry of cigarettes—each lie several years down the road. Kessler’s book will make readers grateful for even these small steps.

Readers should remember that the US Surgeon General published a report in 1964 linking cigarettes to all kinds of health problems. I had started smoking that year, and my little circle of friends were calling them “coffin nails” before the release of the report. But Kessler describes a strategy by tobacco companies to construct a script to counter the science of tobacco related death and illness, to pound on a “thin wedge of doubt... (that) smoking had not been proved to cause cancer.” For 45 years almost no tobacco company leaders departed from the script.

Kessler was appointed to lead the FDA in 1990, an organization that emerged from the Reagan years severely underfunded, under constant pressure from the OMB to deregulate, and by most accounts demoralized by the anti-government climate. He is frank about his steep learning curve as the new boss, including a good retelling of the Tylenol tampering scare. The upshot is that the FDA has very little control over its agenda and public face—events are in the saddle. A new commissioner is immediately in the spotlight if he or she acts, and so the public face of action has to be carefully managed.
Kessler learned this the hard way. He is brutally honest about his public relations failures, including an absurd first appearance on national television. (Readers contemplating a media invitation may want to read pp. 45-6 before you accept.) The book is told in roughly chronological order, and with a nod to Henry Adams I offer a subtitle: The Education of David Kessler.

FDA relationships with Congress are a vital part of its work. When Kessler arrived, John Dingell of Michigan invited him in for a talk, and let him know that, above all, it is the mission of FDA that counts. Yet Dingell seemed more concerned with the problems of bureaucracy than with the power of interest groups. Even friends are frightening for the agency.

Career officials in FDA were of at least two minds on tobacco. Some wanted vigorous regulation—it was so obvious. Yet others argued against it, chiefly because regulation would cost it the support of Democrats from tobacco states, and because it would “burn too many resources.” Part of the Reagan era deregulation strategy was to starve the law enforcers to the point of inaction. A central feature of getting around the impasse was to focus on the tobacco industry’s intent. Did tobacco companies treat cigarettes like a drug? Did they intend to do so? One informant told them directly that the question was the key to understanding the industry and its public strategy. He was wondering when FDA would figure it out.

The FDA sits within HHS, and its budget, rulemaking and enforcement are closely scrutinized by the OMB, whose very political people are not scientists. Kessler reports on an OMB attempt to script his remarks to a congressional committee. Powerful interest groups had access to the White House, and OMB was the instrument they were able to move. For example, food label estimates of the proportion of sugars and fat are reported as a percentage of a normal daily diet. The USDA, which is heavily influenced by meat producers, wanted a normal diet defined as 2,350 calories per day. Kessler prevailed, and the current reference number for the labels is 2,000. He did it, in part, by testifying to Congress in such a bland manner that they asked for clarifying questions, which Kessler handed off to the experts he had brought to the hearing. It did help convince Vice President Gore that McDonald’s used the 2,000 figure on its own labeling. Every agency needs some champions, in Congress and in the executive branch. At a couple of key places the support of Al Gore made a difference.

The center of the book’s action is the unraveling of the tobacco maze. They figured it out in part because of a simple idea: nicotine was highly variable in tobacco plants, yet constant in cigarettes. Did this not mean tobacco companies were regulating it? One informant, dubbed “Deep Cough,”
provided many stories of nicotine manipulation. As FDA officials looked into it, the tobacco companies seemed to behave remarkably like pharmaceutical companies. And, they lied about it. When Kessler and his people figured out what they needed to ask the companies, they were never responded to with honesty. They lied about their research into the components of tobacco and the chemistry of nicotine absorption into the human body, they lied about whether they developed and used tobacco with three to four times the nicotine as regular plants, they lied about their work on the design of cigarettes to deliver a calculated dose of nicotine, they hid their research that led them to put higher nicotine tobacco into filter cigarettes, they hid their research into how to make a cigarette with nearly all the carcinogens removed (!), and were particularly secretive about research into manipulating nicotine absorption in human lungs. They moved a research laboratory to Germany, in large part to hide it. The many pieces of this puzzle make for a good detection story. The detection had to pierce a conspiracy (what else should we call a script all the companies followed for nearly a half century?) that actively silenced critics. The companies even considered suing Gary Trudeau, whose comic strip sometimes featured “Mr. Butts”--

The maze was solved, in bits and pieces, over time. Some informants and documents did reveal that the tobacco companies explicitly did the research to produce a drug delivery device, they did study how to appeal to young people.

Remember the old adage, people who like sausages and laws should not watch either being made. Some members of Congress come across as despicable figures, not because of Kessler’s words but because they behaved despiciably. Prior to committee hearings, some members sent Kessler requests about his evidence, in effect asking for full disclosure of everything he had. These were clearly fishing expeditions to identify, among other things, who was informing on the tobacco companies. Some were direct mouthpieces for tobacco companies, reading their questions and remarks prepared by the company attorneys. They launched a coordinated attach on Kessler’s
character, fronted by Newt Gingrich—who delivered one anti-FDA speech after stepping off a tobacco company jet. A former FDA commissioner charged that Kessler failed to safeguard public health and follow the agency mission. That same person had earned $125,000 from tobacco companies plus promises of research support. Tobacco earns big money, and Congress listens to it. John Boehner handed out checks from tobacco interests on the floor of the House. The money also bought three attorneys who had been FDA chief counsels to defend the companies against regulation, all the way to the Supreme Court.

The FDA did attempt to regulate nicotine, and the Supreme Court, in a conservative block victory, stopped it. Justices Rhenquist and Scalia were derisive in their comments, ironically saying “everyone knows cigarettes are dangerous” as a reason to not regulate them.

The book offers a broad lesson about human nature. You simply can not trust a person who has a strong monetary interest in cheating and lying. Kessler does not call them liars, he simply reports what happened. His nuanced reading makes it clear that deception and self-deception usually go together. Tobacco officials report, for example, that it would be terrible for them to make all of this money off of a product that kills so many people—every year, significantly more than all of US combat deaths in WWII. The company men (and they appear to have been all men) don’t just deny the harms to the public. They deny them to themselves. The attorneys who worked for Big Tobacco failed to follow their professional code of ethics, and because co-conspirators in the deception and cover-up (see pp. 370-2 for a discussion of ethics). This picture of fallible human nature is not just about tobacco. Conservatives love to criticize government bureaucracies by reference to the dangers of giving power to fallible people. It is perhaps the strongest argument to regulate or even dismantle large economically powerful interests. The tradeoff between money and public health is clear and compelling.

Tobacco is still big business, Congress still depends on big contributions, and the FDA is still underfunded. We should not expect the passage of FSPTCA to change the world very soon. Kessler’s book is an important account of the political atmosphere that will affect FDA’s efforts to follow its mission: “The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation’s food supply, cosmetics, and products that emit radiation.” I hope someone is keeping track of the public health consequences of moving so slowly in that direction.