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## REPORT

### FDA Commissioner David Kessler Resigns

By John Hamell

On Monday, Nov. 25, 1996, David Kessler, Commissioner of the U.S. Food & Drug Administration (FDA) announced his resignation. According to the Washington Times (Nov. 26), the Clinton administration had asked Dr. Kessler to stay in office for the president's second term, but the 45-year-old pediatrician and lawyer said that he preferred to return to private life. Kessler said he would stay on the job through the early part of 1997, when his successor is expected to be chosen.

There was considerable speculation in the media about why Kessler resigned after fighting so hard to stay in office after Clinton wanted to replace him four years ago. John Hammell, LEF's Political Coordinator has gathered inside information about why Kessler may have resigned, but first we'd like to comment about Kessler's resignation.

#### OUR POSITION REGARDING KESSLER'S RESIGNATION FROM THE FDA

The Life Extension Foundation has been quite critical of David Kessler throughout his 6-year reign as FDA Commissioner, but the primary focus of our criticism has been the agency itself, especially the FDA's abuse of its law enforcement powers. We have been unrelenting in our criticism and protest of illegal and unconstitutional attacks by the FDA against organizations such as The Foundation which are providing Americans with valuable information and access to alternative therapies for life-threatening diseases and aging.



While Kessler supported these illegal actions, there is no evidence that he was especially zealous in his pursuit of forward-thinking organizations like The Foundation. Kessler was not in office when the FDA raided The Foundation in 1987—the event that started our 9-year war with the agency—which culminated in the FDA dropping all charges against us in 1996. Kessler did not speak out much against dietary supplements, and seemed to lose his zeal to persecute the industry after widespread public support for dietary supplements became apparent.

In our opinion, David Kessler was primarily a political persona who sought greater power for himself and for the FDA, but was realistic enough to back off when it was clear that he didn't have support for his initiatives in congress or among the American people regarding the agency's ability to police the dietary supplement industry.

During Kessler's 6-year reign, there was an unprecedented explosion of scientific evidence supporting the use of dietary supplements for the prevention and treatment of many diseases and conditions, along with information on these advances in newspapers, magazine, books and on radio and TV, and greatly expanded interest in alternative approaches to healthcare and medicine. There was also immense protest against attempts by the FDA to curtail freedom of choice in healthcare in the United States. The FDA under Kessler resisted the expansion of freedom of choice in healthcare, and acted illegally and unconstitutionally on many occasions but, in our opinion, this was more institutional resistance than the result of specific direction from Kessler. The FDA has been biased against dietary supplements and alternative therapies for its entire existence, under every one of its commissioners. It has, and continues to act, primarily on behalf of mainstream medicine, and is an advocate and protector of the large pharmaceutical companies. The fact is that today, near the end Kessler's regime, there is more freedom of choice in healthcare in the United States than ever before. It remains to be seen whether this freedom will grow or decline under the regime of Kessler's successor.

David Kessler's resignation caught many observers off guard. Most had expected him to stay at his post through President Clinton's second term of office, or until he completed his regulatory agenda, especially against the tobacco companies. Washington insiders generally agree that Kessler was not driven out of office because of his campaign against the tobacco companies. In fact, this was Kessler's most well-received initiative. It had the support of Clinton, a good degree of bipartisan support in Congress, generally good reviews in the media, and large-scale support among the public.

After conversations with a number of insiders in Washington, I've uncovered what I believe to be three likely reasons for Kessler's

decision to resign:

1. It is common knowledge among insiders that Kessler lied before Congress when he testified under oath at the FDA Oversight hearings last year. There has been talk about the possibility of subcommittee members asking the Justice Department to prosecute him for perjury. Shortly after one of these hearings, I overheard a conversation in the hall between two congressmen, who were discussing Kessler's lies before Congress.
2. Kessler got caught cheating on travel vouchers. He overcharged for dozens of cab rides, illegally used his government credit card to get a discount plane ticket for his wife, and committed other similar transgressions. This was widely reported in the media. Kessler was quite likely concerned that his might get fired or prosecuted for these acts.
3. Kessler's wife wanted him to quit. She was tired of seeing him trashed in the media, and was upset about all the pressure he was under. What may have pushed her over the edge was the fact that, in 1996, Kessler's home address was leaked by two of his opponents, which led to some very critical letters sent to his home.

Now speculation is focused on who will replace Kessler as head of the agency that regulates nearly one fourth of the U.S. economy.

Mark Smith in Senator Connie Mack's office, along with other Republican staff, told me that Senate confirmation of his replacement may be driven by the nominee's position on overhauling the agency. Smith felt that Deputy Commissioner Carl Peck, M.D. might be chosen as Kessler's successor due to his "stellar credentials", diplomatic nature, and the fact that he has assisted Congress in FDA reform efforts.

When asked about Peck, the CEO of a Capital Hill think tank that specializes in monitoring the FDA (who prefers to remain anonymous) said that he doubts if any current FDA employee will be selected due to political pressure from industry to insert their favorite people, however he could see why Congress might want Peck.

He also told me that he considers Peck to be a good person for the supplement industry to back because he is "a lackluster, do nothing, keep your head down kind of guy who wouldn't give you, or anyone any trouble." He said that he doubted Peck would get in because groups like The Center for Science in the Public Interest (CSPI), the AARP and the AMA would push for a more aggressive Commissioner like Kessler.



When reached for comment, CSPI would not say who they were backing, but a logical choice would be FDA Deputy Commissioner Bill Schultz, because he is a long time opponent of the dietary supplement industry who pushed hard for the Nutrition Labeling and Education Act, and actively opposed the Dietary Supplement Health and Education Act, working closely with Waxman to weaken the bill.

### **OTHER CANDIDATES FOR FDA COMMISSIONER**

Along with Peck and Schultz, other candidates within the FDA include FDA Deputy Commissioners Mary Pendergast and Michael Friedman. Another candidate is former FDA official Michael Taylor, who now heads the food safety program at the Department of Agriculture. Taylor is a long time opponent of the dietary supplement industry. He came to the FDA from the Monsanto Chemical Company, where he became embroiled in the scandal involving the Monsanto's bovine growth hormone, which he was instrumental in approving.

The BGH scandal, along with the fact that Taylor is an attorney, not an M.D., may work against him. The FDA has never had a commissioner who was not an M.D. (on the other hand, Monsanto has political power, and Taylor is also Vice President Al Gore's cousin).

There are currently about 50 different names kicking around on Capital Hill as possible replacements for Kessler. LEF will be monitoring the selection process closely and we will keep you informed about what happens.

### **COMMENTS ABOUT KESSLER KESSLER'S SUPPORTERS**

Rep. Henry Waxman of California, senior Democrat on the Commerce Committee's health subcommittee praised Kessler as "the finest commissioner the agency has ever had."

"He is the single most important FDA commissioner, a public health giant," said Matthew Myers, the executive director of the National Center for Tobacco Free Kids.

"Overall, David Kessler is probably the best FDA commissioner ever," said Dr. Michael Jacobson, executive director of the Center for Science in the Public Interest.

Dr. Sidney Wolfe, director of Public Citizens Health Research Group, said Kessler "mainly gets high marks," but because the agency has spent so much time speeding up the drug approval process, it has paid little attention to petitions to take certain drugs off the market and to put warning labels on others.

The U.S. Court of Appeals for the District of Columbia has upheld a district court order directing Kessler to appear for a deposition in connection with the Washington Legal Foundation's First Amendment litigation against the FDA. This decision was a major victory for WLF which has been battling for months to obtain testimony from Kessler over the issue of FDA suppression of information pertaining to off label uses of drugs.

If WLF wins, it could also help supplement manufacturers who have been blocked from making truthful health claims for dietary supplements. Kessler now has three options:

1. He can seek review of the December 3 decision before all 10 judges on the D.C. circuit;
2. He can simply refuse to appear for a deposition, and then appeal a decision holding him in contempt of court; or
3. He can agree to be deposed. Lawyers for the government have not yet announced which of these options they intend to pursue.

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