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Probe of 3 FDA Officials Sought

Industry Ties Before Approval of Bovine Growth Hormone Are at Issue

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Three members of Congress have called for a federal investigation into possible conflicts of interest involving three officials of the Food and Drug Administration, which approved a controversial genetically engineered Monsanto Corp. drug last year. All three agency officials had some ties to Monsanto before coming to the FDA, but an agency spokesman denied there was any misconduct.

In a letter Friday to the General Accounting Office, Reps. George E. Brown Jr. (D-Calif.), David R. Obey (D-Wis.) and Bernard Sanders (I-Vt.) asked the watchdog agency to conduct a 30-day review of the FDA's approval of recombinant bovine somatotropin (bST), a substance that increases milk yields in cows.

"A troubling pattern of unanswered questions is emerging that suggests an altogether too cozy relationship between some FDA officials central to this food safety decision and their close dealings with the Monsanto Company," Sanders said in a statement.

The letter—which cites an anonymous March 16 complaint ostensibly written by members of the FDA's Center for Veterinary Medicine (CVM)—asks the GAO to probe the roles of three "key" FDA officials in the approval of the Monsanto drug.

The highest ranking is Michael R. Taylor, deputy commissioner for policy, a past FDA employee who rejoined the agency in 1991 from the Washington law firm of King and Spalding, which represents Monsanto. Also named was Margaret A. Miller, deputy director of the agency's office of new animal drugs. The letter characterized her as "a former Monsanto company employee" who wrote the FDA's opinion on why milk from bST-treated cows should not require special labeling.

A third staff member, Susan Sechen, was described as a data reviewer at FDA who had worked as a graduate student for a Cornell University professor who conducted Monsanto-sponsored research on bST.

Anti-biotechnology activist Jeremy Rifkin first made the charges about Taylor in February, when he petitioned the FDA to rescind the approval of bST and investigate the three staff members' role in the agency's policy.

On March 15, FDA Commissioner David A. Kessler sent Rifkin a four-page letter stating that "none of the activities of Mr. Taylor cited in your petition were in violation of any applicable law or regulation, or were otherwise inappropriate. . . . I believe that Mr. Taylor's behavior adhered to all applicable ethical standards."

Kessler said that Taylor had not been "intimately" involved in Monsanto's efforts to obtain approval, as Rifkin charged, and that he was involved in the FDA's bST policy only in the final stages of review.

Kessler attached a nine-page memo by FDA ethics official Jack M. Kress supporting that position. Upon arriving at the FDA in the summer of 1991, Taylor recused himself for one year from taking part in any agency action dealing directly with Monsanto or any other King and Spalding clients.

Some longtime agency critics found the charges against Taylor misplaced. Sidney Wolfe, a physician who heads the Public Citizen Health Research Group here, has filed complaints with the FDA about revolving-door ethics issues concerning other officials. But he said yesterday that "It's barking up a silly kind of tree to be going up against Mike Taylor."

Wolfe said that "as far as we're concerned, he's done a perfectly good job." Wolfe compared Rifkin's charges to saying that anyone who worked for a drug company and began working for the FDA should not be allowed to say anything about drugs in general—a stance that Wolfe characterized as "preposterous."

As for the two other FDA employees named in the House members' letter, agency spokesman Jim O'Hara said there was no impropriety. "As we have learned of these allegations, we have looked at them. The appropriate safeguards against conflict of interest have been taken," O'Hara said.

Miller was not involved in the decision to approve bST, and Sechen's involvement with the bST review was approved at the outset by the FDA's ethics and program integrity division, which "determined that there was not a conflict of interest based on the information they were provided," O'Hara said.

Although reluctant to comment in the face of a possible investigation, Taylor said yesterday that "I would welcome any scrutiny of my actions."

Much of the material used in the lawmakers' letter, including the anonymous CVM letter alleging Miller's conflict of interest, came from Rifkin, a long-standing opponent of bST. Bill Goold, a spokesman for Sanders, said the search of scientific literature relied upon by Sanders's staff in drafting the letter came from Rifkin's organization.

Rifkin has fought against the approval of bST for more than seven years as part of an all-fronts assault against biotechnology. He called his ethical charges "a significant scandal" that he said showed moral weakness at the top of the organization. "We want Kessler's resignation," Rifkin said yesterday. He said that the nine-page ethics memo by FDA's Kress was "people in government trying to protect their own."

Sanders and Obey have previously taken stands against the approval of bST and its use without consumer labels that identify the milk as coming from cows treated with the drug.

But many Capitol Hill staff members were surprised to see Brown—who chairs the Science, Space and Technology Committee—as a signer of the letter.

Sources familiar with the process said key committee staff members felt they had been end-run by activists. One congressional aide said staff members who normally would be informed of such an action were unaware that Brown had signed the letter.

"George's issue is with the process of approval. He wants to make sure people are squeaky-clean," the aide said. Brown did not see the FDA response to the Rifkin petition before signing the Sanders letter, an aide said. Obey said yesterday that he had seen the FDA response, and "I'm frankly not impressed."

Some acquaintances of Taylor were incredulous that the official would be the object of ethical scrutiny. "There's no more ethical person in this town than Mike Taylor," said Wayne Pines, a former FDA official who now consults with companies on FDA matters. "Mike would never get involved in a situation in which there's a conflict—that's a no-brainer."

Dairy-state Reps. Bernard Sanders, left, David R. Obey, center, and George E. Brown Jr. signed letter to the General Accounting Office regarding FDA approval of recombinant bovine somatotropin (bST), which raises cows' milk yields.