Kessler Gives FDA a Facelift

A little more than a year after David Kessler took charge at the Food and Drug Administration (FDA), the 40-year-old physician-attorney has slimmed down and donned hip, horn-rimmed glasses. But Kessler isn't the only one undergoing a makeover. He's also trying to give his embattled agency a new look. The new look doesn't have to do with lapel widths but with institutional arrangements—including an attempt to speed up approval of biotech products, appointment of a high-powered science advisor, and the creation of a cabinet that can act for Kessler on a wide range of internal matters.

At the heart of those changes are plans to strengthen and streamline the FDA's handling of biotech. Speaking in Boston at a meeting of the Massachusetts Biotechnology Council last week, Kessler announced reorganization of the center that reviews most biotech products, the Center for Biologics Evaluation and Research (CBER). CBER has been criticized by industry, AIDS activists, and academic analysts as an obstacle to the rapid approval of genetically engineered products, and Kessler is apparently aware of the flak the center has taken. Promising that the "FDA will not be a bottleneck in the development of these products," the commissioner announced he was promoting FDA biochemist Kathryn Zoon to be director of CBER. And that's not all; Zoon's unit will be beefed up by the hiring of 50 scientists whose sole job will be to review and research biotech products.

Industry leaders give Kessler high marks for both moves. "Dr. Zoon is an outstanding choice," says Genentech president G. Kirk Raab, whose views are shared by the Pharmaceutical Manufacturers' Association, the Industrial Biotechnology Association, and the Association of Biotechnology Companies. Zoon also has the backing of FDA staff, who formed a standing-room only crowd in a large auditorium at the National Institutes of Health last week to applaud her appointment. She has strong credentials as a scientist, having worked for 5 years at NIH on the genetic engineering of interferon, and as a manager; she was the first director of the CBER division of cytokine biology, which has a good track record in reviewing and licensing AIDS-related cytokine products.

Even with her new staff, however, Zoon has her work cut out. Although FDA won't release information about drugs under review, by industry's count 21 biotech drugs have already completed clinical trials and are awaiting final approval, while another 111 are being tested in humans. To make matters worse, CBER, which reviews most of those biotech products, has had an acting director for only the past 18 months.

This situation galled both the White House's Council on Competitiveness, which has lately become a champion of the biotech industry, and a blue-ribbon panel of outside experts known as the Edwards Commission, which completed a major review of the FDA last year. Both groups recommended new staff for the overburdened CBER, and so it is not surprising that Kessler gave priority to hiring more scientists there and appointing a fast-track director.

Those weren't the only changes Kessler unveiled at the Massachusetts meeting. At the same gathering, he announced that he had appointed an eminent new science advisor—Harvard Medical School professor emeritus Elkan Blout, a National Medal of Science recipient whose mission is to forge better links between the FDA and researchers in industry and academia. This appointment completes Kessler's new team of advisors, whose aggressive, hands-on management style is a far cry from the team in place under former commissioner Frank Young. "It will not be business as usual," promises Kessler.

And, in a change that wasn't announced at the recent meeting, but which portends some important alterations in how the FDA conducts its internal business, Kessler has appointed a half-dozen new deputy and assistant commissioners with impressive credentials. This group is serving as a kind of internal cabinet to act for the commissioner on a wide range of issues. The move has caused grumbling at the agency from people who now have less direct access to the commissioner, but others argue that it is the only way Kessler will be able to get anything done. "It's good," says Washington D.C. attorney William Vodra, former FDA counsel. "Now Kessler can be in six places at the same time." In fact, he will need to be in at least six places at once to make sure his facelift goes more than skin deep on an agency that has been worn down by scandal, new responsibilities, an increasing volume of new product applications, and poor management. ■ ANN GIBBONS

Technology Initiative Initiated

Throughout much of the past 3 years, the Bush Administration has been divided over how deeply the federal government should be involved in supporting industrial technology. Now, it seems, those arguing for a more activist role have gained the upper hand. Last week, D. Allan Bromley, the president's science adviser, summoned a group of reporters to his office to announce that the Administration is about to launch a major new "initiative" to see what the federal government can do to help U.S. industry develop and apply computer-based manufacturing technologies. Mass manufacturing of the kind pioneered by Henry Ford has almost run its course in the United States, said Bromley. Rather than churning out a huge quantity of identical widgets, manufacturers should now focus on churning out a huge variety of high-quality ones.

Like other science and technology initiatives, this one will report to the interagency committee that Bromley uses to shape policy, the Federal Coordinating Council for Science Engineering and Technology (FCCSET). The reason for using this cumbersome outfit, Bromley explained, is that it guarantees that the top political appointees who sit on the panel actually endorse FCCSET decisions and see that they get carried out by the bureaucracy. In this case, the review will be run by a task force headed by Robert White, undersecretary of Commerce. Eugene Wong, a professor of engineering from the University of California at Berkeley, serving as Bromley's assistant on computers and technology, will staff the operation.

"Over the next few months we hope to define exactly what we mean by 'manufacturing,' " said White. Once that's done, "we will take an inventory" of all federal programs that support R&D on manufacturing technology. A preliminary check last year, according to White, revealed that the government spends about $1.2 billion a year in this area. By summer, White expects his White House group will be ready to get together with another group of experts attacking the same subject for the Defense Science Board and combine their insights.

If this initiative follows the pattern of the five that have come before, it will catch the president's attention and get favorable treatment in the next budget. Bromley noted that funding has increased for all the areas previously reviewed: global change research, biotechnology, high-performance computing, advanced materials and processing, and math and science education. There's just one thing unusual about this one (which happens to come in an election year): the White House is publicizing it even before launching it. ■ ELIOT MARSHALL