

Kennedy Leaves as FDA Commissioner

Stanford biologist brought new approach to agency

"Balik başdan kokar," goes the old Turkish proverb—"A fish rots from the head down." It may be that resurrections, when they occur, proceed the same way. The Food and Drug Administration, a long despised bureaucracy in good odor with almost no one, has recently undergone a most surprising transformation, and the reason seems to lie in the brief but enlivening reign of its now departing commissioner, Donald Kennedy.

It was not that Kennedy made sweeping changes in the agency—his 2-year tenure of office did not allow time for that; nor did he succeed in his major legislative initiative of a drug regulatory reform bill. But his style produced an intangible change of great moment. He raised the esteem in which the agency was held by outsiders, and in doing so he transformed morale within.

"Public confidence is a very fragile and important thing, and he has worked on that very effectively. That is the most important thing he has done in the FDA," says the agency's former general counsel Peter Hutt.

Somehow or other, Kennedy managed to gain the respect of all the FDA's constituencies, a group whose members do not invariably see eye to eye with each other. "He has been a very good commissioner, I am saddened to see him go," observes Sidney Wolfe of the consumer oriented Health Research Group. "He brought an élan and brilliance to that organization which it needed. He turned a phrase as well as anyone I have ever heard in my life," remarks John Adams, scientific director of the Pharmaceutical Manufacturers Association.

Kennedy also enjoyed an unusually cordial relationship with Congress, a body accustomed to batting the FDA commissioner about like a shuttlecock. Unlike Energy Secretary James Schlesinger, whose approach to hostile questions is to intellectually demolish the questioner, and thus lose the battle, Kennedy's style was to disarm his interrogators with charm and a direct but tactful answer. Academic politics, he had found, was the best possible rehearsal for thinking on one's feet at a congressional hearing.

Kennedy arrived at the FDA in April

1977 from Stanford University, to which he is now returning as vice president for academic affairs. A neurobiologist and member of the National Academy of Sciences, he is the kind of scientist one expects to see around the National Institutes of Health or the President's science adviser. It was precisely this convention that Kennedy hoped to break. His goal in becoming commissioner of the FDA, he said in an exit interview, had been to make the process work, and to command the respect of the scientific community and most of the public in doing so. "But I had something secondary to prove. I am convinced that the better scientists in academic life have not had as great a respect for the regulatory process as they should. Academic scientists have preferred to fly in to Washington to give some advice to government through the Academy and then fly out again. My argument is that more significant science policy is made every day at the working interface between the regulatory agencies and Congress, and that that too is worth the interest of academic scientists."

One seasoned FDA watcher suggests that although Kennedy's aim was to bring more and better science into decision-making, he may have been appalled to find how little science, and how much politics, is involved in major decisions. Kennedy concedes that "I think I probably had the idea when I came in here that the ratio of science to policy was higher than I have in fact experienced it." But his ideas about the nature of regulation do not seem to have changed much during his tenure: asked if he found the commissioner's job much as he expected, Kennedy says that "I have learned a lot, without being able to write down for you what it is. I have a sense of the roles of all the different actors—the White House, the Congress, the policy leadership as opposed to the career bureaucracy. I guess a lot of the things I thought were comparatively simple I have learned to respect the complexity of." As for decision-making, Kennedy has no magic formula: "I can't distill out a rule. You just have to look at every one and dig into the merits and consult widely. Academic scientists are often telling me, 'How can you decide a matter like

that when the data are not clear?' But often you have to decide when the data are not as good as you would like."

Kennedy has been surprised by how uncoupled the public impact of a decision and the difficulty of making it can be. Saccharin was one of the most troublesome issues that crossed his desk, but "only because of the political problems and public credibility problems—I never thought saccharin was one of the difficult problems to decide on the merits. The science was clear. I have not changed my view on that." Kennedy inherited and supported a decision to remove saccharin from the market, but Congress delayed the ban for 18 months.

Articulacy, charm, what one colleague calls his "fantastic ease at communicating with quite different audiences"—these have been Kennedy's weapons in dealing with Congress. He managed to make allies, even friends, out of natural critics of the FDA's regulatory policies, such as the congressmen who represent agricultural interests. He toured the poultry industry in North Carolina with Charles Rose, chairman of the House subcommittee on dairy and poultry. He went to a fundraiser for Fred Richmond, chairman of the domestic marketing and nutrition subcommittee.

Yet Congress on several occasions thwarted Kennedy's actions, often for reasons that seemed more obviously in sectional interests than the public's. It intervened in the FDA's attempts to control saccharin, nitrates, and antibiotics in animal feeds. Rose and Richmond used the political clout of the farm lobby in Congress to sandbag the FDA on its new ice-cream regulations, an issue which on its merits the FDA should have won hands down. The agency proposed to let ice-cream makers use casein, the principal protein of milk, in their mixes. The dairy interests fought the measure on the grounds that it would reduce the nutritional quality of ice cream, although the real motive of their opposition was that it would have added to the politically already high cost of the federal milk support program (*Science*, 26 August 1977). "I think that the whole staging of the ice-cream brouhaha, claiming to be in the interest of the consumers and in fact being in the interest of the dairy industry, was

one of the more amazing examples of cynicism I have seen in this town," Kennedy says. In the view of some observers, he backed down from the ice-cream fight because he recognized the political reality: some of the most powerful members of Congress opposed him and there was no point going down fighting for principle on a relatively minor issue. Kennedy replies that the FDA didn't have a watertight case: "If we had, I would have pressed it further even though we would have been beaten anyway."

He is philosophical about his defeats.

He came from the land that is mellow,
This bookish, biologist fellow,
With glasses-horn-rimmed,
But with vision un-dimmed,
He separated red dye from yellow.

He pondered on foods artificial,
And risks versus effects beneficial,
He decreed that a label
Be truth and not fable
And additives not just superficial.

An idea that caused consternation
Was the case of ice cream
caseination.
It all comes from a cow
So who'd care anyhow?
Charlie Rose and the Milk Federation!

Now his glasses are not horned,
but wired,
And of D.C. he's grown a bit tired,
Enough of our town,
It's back to the gown
Before Joe can say, "Don, you're
fired!"

(Assistant Secretary of Agriculture Carol
Foreman's farewell poem to Kennedy)

"A lot of people in agencies feel that any struggle of this kind is a victory you have to win. Many have said, 'Don't you feel awful about saccharin?' I don't see it that way. To the extent that saccharin has been a good national education on toxicology problems, I think it may have been beneficial, and similarly with the ice-cream confusion, if it had been able to play out a little longer on the real grounds of discussion."

If Congress was one constraint on Kennedy's freedom of actions, another, in many people's perception, was the dominating personality of Secretary of Health, Education, and Welfare Joseph Califano. Califano is said to put enormous heat on his key people and,

say some observers, has intervened in areas of his department where no Secretary of HEW has gone before or should go again. Kennedy, however, seasons his praise of Califano with only the most delicate criticism: "He has done one or two things which I have disagreed with, and several things which have given me a momentary pang. What I have always said about Califano is that he is going to give you a pang every now and then. His values are terrific, as are his abilities and interests. We would never have gotten the whole question of drug regulatory reform to anything like the level of public and congressional interest that we have, without Joe's support. It just means enormously more when the Secretary is behind you. Given a choice between a Secretary who will let us alone and a Secretary who will just occasionally give us a little more help than we thought we needed, I wouldn't hesitate which to choose."

Kennedy declines to cite the two issues on which he disagreed with Califano. With two issues on which outsiders believe he was overruled—the banning of phenformin and the National Immunization Policy—he says he agreed completely with his Secretary.

Kennedy reports that he has "never had the slightest interference" in his freedom of action from either the White House or the Office of Management and Budget. He met Carter on only two occasions, both ceremonial.

Under his tenure the FDA may perhaps have moved to greater openness from a situation in which consumers tended to be heard less equally than other interests. Kennedy disagrees with the proposition that, as a protector of the consumer's interest, the agency should position itself nearer to the consumer than the industry: "I think the FDA should be open to all its constituencies on an even-handed basis." It did not look that way from the drug industry's lobbying arm, the Pharmaceutical Manufacturers Association. "He was falling over backwards to accommodate the consumer advocates," says the PMA's John Adams. "Wolfe [of the Health Research Group] seemed to have the hex on him. Kennedy's justification was that the FDA exists to protect the consumer. He bent over backwards to accommodate them at the expense of other groups such as doctors and industry."

"It's just not correct," says Kennedy, "that Sid Wolfe and I had any kind of private relationship. I made a number of decisions which he vigorously disapproved of, just as I made some decisions which the PMA vigorously disapproved

of. I honestly thought I dealt pretty even handedly with these groups and called the issues as I saw them."

Kennedy's major clash with the PMA came in an area into which the FDA has not ventured before, because it has no statutory authority there—the economics of the drug industry. Kennedy favored giving consumers more information about generic drugs, about the fact that the same chemical, under different brand names, may sell at very different prices. "That's none of his damned business," snaps Adams. The PMA recently lost this contention in court, Kennedy notes; in any case, "We were almost invited in by the PMA member firms because of their claim that there is a difference between brand names and generic drugs," Kennedy replies. He also differed with the PMA on his bill for drug regulatory reform, which aimed to encourage innovation in the drug industry and in return to exercise more control over drugs after they reached the marketplace. "The PMA may think we are stubborn and wrong-headed at looking at the economics of this industry. But I think industry has to get over its sense that the world is a conspiracy between the public interest movement and the regulators," Kennedy suggests.

Two years is a short time in which to reshape an agency with 7500 people and an annual budget of \$300 million. Kennedy had hoped to stay a full 4-year term, but the Stanford job couldn't wait. A consequence of his leaving so quickly is that the changes he has made may not stick, a problem of which he is well aware: "The question of whether I have been successful here will depend on whether or not some things I think I have had a little effect on get made permanent." He lists among these some senior appointments he had made, and his healing of some old wounds created when a group of FDA employees found reason to protest that management was overruling their decisions. "I have tried to be a strong public advocate of the agency and I think that this has taken. If some of that holds, and if the people here believe in themselves, which they really deserve to, then that will be the most important thing I have done here."

"New leadership in Government, I have learned, affects the public perception of organizations much more than it does their inherent worth," he wrote in a statement announcing his resignation. Kennedy's is a hard act to follow, and if it is too hard, his legacy may be short-lived. But he will at least have shown what a touch of style can do.

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