FDA Centennial

THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) IS TURNING 100. ITS LONGEVITY IS IN MANY ways a political miracle. Originally a chemistry unit in the Department of Agriculture, it was founded soon after Upton Sinclair’s scary portrait of turn-of-the-century meat production in The Jungle. Several metamorphoses followed over the next half-century: drugs were added; food laws were amended; and the agency moved to the Department of Health, Education and Welfare after World War II. It still bears remnants of that history: the FDA gets its appropriation from Agriculture committees in Congress and its oversight from Health and Commerce committees. What that meant, as I discovered when I became FDA commissioner in 1977, was that you go to rural conservatives for your money and to consumer-friendly urbanites for punishment or occasional praise.

Somehow the FDA has managed to retain a fairly respectable image with U.S. citizens while holding some regulatory responsibility for about 25 cents out of every dollar they spend. Food safety is a serious public concern, and most people like the fact that the FDA protects them from things such as bad seafood and aflatoxin in corn. The approval process for drugs and medical devices is trickier. Industry argues that FDA regulation keeps valuable therapies away from us, whereas consumers claim that it approves too many drugs with harmful side effects. Yet most Americans think the agency is staffed by seasoned professionals who have the public interest at heart and do their jobs with professional skill.

What I’d tell the few old friends left at the FDA is that you deserve better than you’re getting. Many of the current problems aren’t your fault, beginning with the alarming fact that in the past 6 years, the agency has had a confirmed commissioner for less than 20 months. That’s a clear signal that the FDA doesn’t matter much to the folks in the White House, and it won’t elevate agency morale. Acting FDA Commissioner Andrew von Eschenbach, also Director of the National Cancer Institute (NCI), has now been nominated for the top job, but the Senate may ask why he’s been allowed to develop drugs at NCI and then approve them at the FDA. After he explains that, his next challenge will be to deal with the Plan B contraceptive, which remains unavailable despite an advisory committee recommendation and is now hung up pending a long public comment period to evaluate whether it should available over the counter to women over the age of 17.

Those imposed burdens accompany other issues falling into the FDA’s responsibilities. Drug safety questions arose over the use of antidepressants by adolescents. Then came Vioxx and other COX-2 inhibitors and concerns about cardiovascular side effects. In the medical devices area, problems surfaced regarding the initial approval and postmarketing safety surveillance of certain pacemakers produced by the Guidant Corporation. Finally, there is the ethical controversy about patient protection in the clinical trial for a blood substitute called PolyHeme. Northfield Laboratories seeks approval for its use in treating hemorrhagic blood loss after trauma. In the trial, one group of patients will get PolyHeme while a control group gets saline along with blood transfusions. How do you get informed consent from a trauma victim? You waive the requirement for it! The Office of Human Research Protections objected vainly to that for over 2 years, and the FDA has been dressed down by a furious Senator Charles Grassley over its prolonged unresponsiveness. The plan is that the trial sites will deliver “community briefings” to help citizens decide whether to be subjects. To opt out, you call the company, request a blue hospital-style bracelet, and then wear it to warn paramedics that you’re not part of the experiment! If this is an adequate proxy for informed consent, I am a coloratura soprano.

Back in defense of the FDA, it’s not their fault that they have been chronically underfunded. Despite the recent requirement that pediatric drugs be approved and the need to monitor increasingly international drug production, appropriations have not accompanied the new mandates, and earmarks have cut the budget further. The White House seems to have forgotten who’s in charge there, and Congress is considering a new statute that lets patients who have run out of treatment options get new drugs that have not been fully tested (remember Laetrile?). It’s really too bad that we can’t find a few friends in high places for the FDA. After all, it’s their birthday; how about a little love? Or maybe money?

– Donald Kennedy