POLICY FORUM: PUBLIC HEALTH

Strengthening the FDA

Michael A. Friedman

To the practicing physician in the United States, there is probably no more important federal agency than the Food and Drug Administration (FDA). FDA oversight of approval and manufacture of products affects the care of every patient. To the biomedical researcher or research sponsor, the FDA is the essential vehicle for transforming basic science into products of clinical utility. To everyone else in the country, the FDA merely oversees about one-fourth of all our gross domestic products, as it safeguards much of our food, medicines, medical devices, blood, vaccines, and veterinary products.

This central role of FDA creates high public expectations. Despite the efforts of a generally hard-working and talented staff, FDA often falls short of what the public and its representatives think it should accomplish (*1*, *2*). More serious still, FDA policies and regulations are highly debated: Is it costing society more in foregone innovation than it gains for society by preventing the adverse effects of prematurely approving technology? (*3*, *4*).

Some of the obstacles that thwart FDA from delivering fully and functioning effectively include insufficient resources, inconsistent leadership, unclear mandates, and ambiguous and overly ambitious priorities. There are four simple, pragmatic steps toward a more effective FDA that should be pursued now.

1. Move the FDA budget appropriations process from the purview of the agriculture committees to the health committees. Currently, an FDA budget is proposed by the president of the United States with the direct input of the Department of Health and Human Services (HHS) and the Office of Management and Budget. It is then reviewed by the agriculture subcommittees in both the Senate and the House of Representatives (*5*). For decades, the committee members and their staffs have been responsible for determining the FDA budget requirements, and although their efforts have been thoughtful and serious, the process is fundamentally flawed. There is almost a two-log difference in the magnitude of the budget between Department of Agriculture (more than $100 billion) and FDA ($1 to 2 billion). Second, there is a limited reservoir of science and health expertise in the agriculture subcommittees. Furthermore, there is no formal linkage with other relevant government science and health functions. Other organizations, such as the National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) are dealt with differently by the two appropriations subcommittees on Labor, Health and Human Services, and Education. Once the budget is authorized, integration must occur at the departmental (HHS) level. Quite apart from getting lost in the agriculture committees, FDA has historically been whipsawed by opposite political agendas. Its appropriations come from a largely rural and conservative subcommittee. Authorization and oversight come from largely urban, liberal subcommittees.

The lack of coordination invites needless gaps, inefficiencies, redundancies, and waste. Underfunded mandates like ones for "food safety" or comprehensive inspection of foreign bulk drug manufacturing facilities are two examples. Others might include the inadequacies of postmarket safety surveillance for all regulated products and the lack of a coherent risk-benefit framework for dietary supplements.

2. Simplify the selection process for the commissioner. Before 1989, the responsibility for appointing the FDA commissioner rested solely with the U.S. president (in a manner identical to the selection of the director of the NIH or CDC). Currently, the FDA commissioner's appointment requires Senate confirmation and, although this change was meant to elevate the profile of the office, it probably has materially contributed to the delays in filling the post. Not only has the commissioner's selection become the arena for ideological contests, it only takes an objection from one senator to paralyze the selection process. Over the past 5 years, a permanent, confirmed commissioner has been in charge only about one-third of the time. Consistent agency leadership cannot exist in such a fractured environment. The fact that many good, positive actions were taken during that period in no way makes up for the other opportunities lost. Worst, at least from the viewpoint of regulated industry, is that authority percolates downward in the absence of leadership, leaving more of the daily implementation to the less consistent and less predictable management of regional offices. Neither congressional oversight nor Executive Office expectations would be diminished by returning the commissioner's job to a high visibility presidential appointment.

3. Initiate a formal comprehensive process to review FDA priorities implemented by the HHS Secretary. Because of discontinuities of leadership, a more deliberative, rigorous review exercise would be valuable. Priority setting could be as extensive and costly as thought necessary by the secretary but should be transparent, not unnecessarily protracted, and should provide an opportunity for input from relevant interests (certainly patients and consumers, but also academics, health professionals, and business, etc.). This kind of input occurs today, but not in a sufficiently disciplined and critical manner.

4. Obtain a substantially larger budget that would permit achievement of identified priorities. On the basis of the priorities identified by the Secretary of HHS — balancing all competing legal and public health expectations—the budget proposal should be nearly self-justifying. Of course, current budget exercises try to capture this process, but do so incompletely. A clear "to do" list of activities could be funded and the successes (or failures) judged.

Today, less than 3% of all imported food products is inspected either abroad or at the point of importation to the United States. If greater inspection of imported food is a priority, sufficient funds should be allocated. If a more comprehensive scientific scheme for evaluating xenotransplantation, reproductive technologies, or gene therapy is a priority, appropriate investments are needed. It is myopic to fund a minimal FDA when we have doubled the NIH budget roughly every 10 years for the past 40 years (proposed to be $27.3 billion in 2003) or when the pharmaceutical industry annually invests more than $30 billion in research and development (*6*). Because regulatory review is the final common pathway for all translational medicine, this lack of resources is rate-limiting. I cannot predict everything that our citizens demand from FDA, but I am sure they are not currently getting it. The issue is not what the FDA "needs"; it is rather what the American public deserves.

The author is with the Pharmacia Corporation, Peapack, NJ 07977, USA, and is a former Acting Commissioner of the FDA. E-mail: Michael.a.friedman@pharmacia.com

References and Notes

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7. My thanks to former FDA Commissioner Donald Kennedy for his review and comments.