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Commentary

The FDA, Politics, and the Public

SINCE it was begun in 1907, the Food and Drug Administration (FDA) has often been the center of controversy. Recent scandals in the executive branch of the government have reminded us that public officials are not above either the law or the public they are supposed to serve. It is therefore appropriate that the FDA be responsive to public concerns, and be held accountable when criticism erupts, be it from consumerists, the medical profession, the drug industry, or the Congress. Still, it is also crucial that a regulatory agency not become so embroiled in defensive maneuvers that it loses its ability to serve the public properly.

During the last decade, the FDA has been accused both of overregulation and underregulation. Such a situation is not as paradoxical as it might seem. On the one hand, the FDA might be considered culpable if it fails to police drug manufacturers and allows inferior brands of digoxin on the market, and on the other hand, it might be held to account if it demands so much evidence on new drugs that valuable medicaments are withheld from the American patient.

Of late, the FDA has been severely chastized for actions that are not only eminently defensible but reflect a welcome change in agency policy. At hearings in the House chaired by Mr. Fountain and in the Senate chaired by Mr. Kennedy, FDA officials have been reprimanded for being "soft" on industry and too ready to approve new drugs. At the August Senate hearings, a parade of disgruntled FDA employees and advisors were solicitiously listened to as they voiced criticisms of the top administrative echelons in the FDA for going against their negative advice, and then, Commissioner Schmidt was lectured by Senator Kennedy and warned not to take punitive action against his malcontent employees.

Any Truth to Charges?

Is there any truth to these charges? Has the FDA in fact adopted dangerously low standards for approving new drugs? If so, this would certainly mean an about-face from the public postures of a succession of agency leaders. From the statements and speeches while in office of such FDA personalities as James Goddard, Herbert Ley, Charles Edwards, Henry Simmons, Richard Crout, and Alexander Schmidt, it would be difficult to sense a desire to compromise with the legal and scientific requirements of the Kefauver-Harris Amendments of 1962. The last 12 years have seen the evolution by our FDA of the most rigorous standards in the world in regard to the marketing of new medicaments. Wardell,[1] among others, has in fact presented evidence that US patients have often suffered long delays in access to important new drugs, rather than being deluged by a flood of prematurely approved medicaments. Only in the last two years has the policy begun to be more in touch with medical reality.[2]

Nevertheless, we now hear that the agency is too lax toward new drugs. What examples are given? Propranolol was a cause célèbre at both sets of hearings just referred to. Here the question facing the FDA was whether the drug should have officially listed, as an indication for its use, the relief of angina pectoris. For many years, propranolol has had wide usage the world over not only as an antiarrhythmic (for which it was approved some time ago by the FDA) but as an antianginal and antihypertensive drug. Distinguished cardiologists in the United States, as in almost every other country, have for years prior to FDA action on the antianginal labeling, hailed propranolol as a major step in the management of severe angina. Surveys indicate that most of the use of propranolol in the United States had to do with angina pectoris. Some cardiologists came to consider a recommendation for coronary artery surgery without a trial of propranolol a form of malpractice. The FDA's action, therefore, was accepted by most knowledgeable people as a tardy admission of an unquestioned indication, and perhaps an augur that the antihypertensive effect would eventually be accepted by the FDA.

But what does one hear in the halls of Congress from the witnesses offering testimony on the FDA? Primarily criticism of this belated forward step—not of the unconscionable delay in taking it. Where were the cardiologists to rebut these criticisms? Where are the public pronouncements in support of the FDA in its action on propranolol?

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Will the profession only criticize the FDA for wrongdoing, and not aid it when allies are needed in a righteous struggle? One can only read the transcript of the Fountain and Kennedy Hearings with chagrin, dismay, and sympathy for Drs. Schmidt and Crout, and Peter Hutt, three of the ablest FDA personnel, as they tried to explain and justify the agency's judgments on propranolol.

Assessing In-House Procedures

Unfortunately, it is difficult for outsiders to assess accurately past in-house procedures in the FDA. It is widely known that the cardiopulmonary-physician reviewers in the FDA, from whose ranks much of the present criticism emerges, had acquired a reputation over a decade or more exemplified by Marshal Pétain's World War I motto: "They shall not pass." These employees, suspicious of industry and secure in commendation for their past stands against drug toxicity, allegedly rejected almost every drug that came within their purview. (It is noteworthy that several of the witnesses were originally in the cardiopulmonary-renal division, notorious for its tough attitude. In view of this fact, their testimony that drug approvals by them were never criticized has a hollow ring.) In order to break the logjam, presumably, and to modify the veto power of FDA monitors, it was necessary to shift some of these persons to other jobs within the agency. (Civil Service prevents their dismissal, even when there is no job appropriate for them.)

Were these men hounded by an industry-oriented FDA leadership? It seems unlikely. One suspects, rather, that the change in their status was a last-resort measure to remedy the frustration felt by people both within and outside the FDA of not having available for the public important and badly needed new medicines.

For the shifted FDA employees, the primary worry was safety, with a secondary concern about the data on efficacy. For physicians, the primary concern was to have developed and approved better drugs for patients desperately in need of treatment for crippling, killing diseases like hypertension. To doctors, the inability of the FDA to approve drugs that they were certain could help the sick was a manifestation of bureaucratic nit-picking. (It is all very well to say that hypertension's ravages can be diminished with drugs, but the practitioner knows all too well how many patients will fail to follow prescribed regimens so long as the effective drugs on the market carry a high risk of such unpleasant side effects as postural giddiness and impotence.)

Is there any merit in the posture of disgruntled FDA physicians? To be sure. Some of them have served the public well by their concern about drug toxicity. However, the question is really a bigger one: how *best* to serve the public *overall*? All of therapeutics is based on a cost-benefit analysis, and in the opinion of many, the FDA has far too long been constrained by the idea that the public is best protected if one worries primarily about drug toxicity. The ultimate application of that principle is to eliminate all drugs—no drugs, ergo no drug toxicity. It seems more rational to help the public by optimizing their therapy. Every benefit carries a risk in this world, and for big benefits, one may be willing to assume big risks. John Locke, centuries ago, pointed out that the physician at the bedside cannot practice agnosticism. Every clinical decision is an active one, including the decision not to treat. Therein lies a fundamental problem: The bureaucrat can engage in the luxury of abstract speculation, the practicing physician cannot. It is natural and reasonable that the practitioner should resent a limitation of therapeutic options for himself and for his patients by regulatory employees whose sights are too limited.

What Is the Solution?

What, then, needs to be done? To stifle FDA critics? Not at all. Anyone who cannot take criticism had best avoid government employ. Let the critics be heard, because no one can tell where the truth may lie. However, let there also be a *balanced* presentation of evidence. Congressional hearings on drugs often lack this balance. Some of the most knowledgeable drug experts and practitioners have been prominent by their absence. Surely the physician who wishes only the best for his patients is least suspect as to his motivations. Consumerists may be reveling in the exercise of newly found power, demoted employees may be seeking revenge, politicians may be hungry for headlines, and the drug industry can always be accused of an infatuation with the almighty dollar. But what of the sick patient? Who speaks for him? Certainly not the "consumerists," who often have only a narrow interest and are obsessed by a pathologic hatred of the drug industry. If the sick themselves cannot testify, their physicians must testify for them.

It is an extraordinary perversion of justice to accuse present FDA leadership of pro-industry bias. They are at least as tough-minded and public-spirited as any of their critics. Their probity is beyond reproach. The legislation that they seek to enforce needs no repeal; what the public needs is confidence that the law will be fairly and intelligently applied. The actions of people like Commissioner Schmidt, Mr. Hutt, and Dr. Crout will at times be in error and deserve criticism, but they should not be accused of crimes that they have not committed.

Our profession must rouse itself and take public positions in support of the actions of these men when, as is happening now, such actions are in the best interest of the sick. Let us bestir ourselves. If balance is to be achieved in the testimony given in the halls of Congress and reported in the media, we cannot afford to sit back and let someone else do it. Without some spirited support from the medical profession for the welcome recent trends in FDA policy, American patients will be faced with a new "dark age" of therapeutics before they have fully recovered from the previous one of the 1960s.

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References

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2. Wardell WM: Developments since 1971 in the patterns of introduction of new therapeutic drugs in the United States and Britain. Read before the Conference on Drug Development and Marketing at the American Enterprise Institute for Public Policy Research, Washington, DC, July 1974.