LETTERS

Drug Regulation

Louis Lasagna (26 May, p. 871) presents his usual brisk and thorough defense of the pharmaceutical industry position on new drug development. I have only two quarrels with it; one minor, the other more significant. At one point, Lasagna accuses me of having indicated my "intention to hold a series of hearings in various cities to 'demythologize' the medical profession," an assignment that he finds strange for the head of a regulatory agency. I have, in at least one speech, suggested that it would be a good idea to take some of the myth out of medicine; and I have held hearings, and intend to hold more, on such subjects as food standards and labeling, the use of antibiotics in animal feeds, and a variety of other regulatory issues. I do not know how these two matters relate to one another, but I want to assure Lasagna that I have no intention of holding hearings to "demythologize" the medical profession.

On the more serious issue, the most striking thing about Lasagna's article is that it takes so little account of current events. Nearly 10 months ago, two important things happened. First, an influential panel that advised the Secretary of Health, Education, and Welfare on new drug evaluation released the results (*1*) of the most extensive external investigation of the Food and Drug Administration (FDA) yet made. Second, partly in response to that undertaking, we announced that the Administration would work with Congress to provide the drug regulatory enterprise in this country with the statutory base that the Secretary's panel said it so badly needed. There followed a series of public hearings at FDA late in 1977 and various announcements of the general shape of the new legislation. Draft copies of the developing bill were widely circulated for comment and have been publicly available since the introduction of the Drug Regulation Reform Act of 1978 in early April. In the course of these discussions almost every one of the issues touched on in Lasagna's article has been analyzed, debated, and refined well beyond the level at which he treats them. Perhaps the timing of *Science*'s publication is at fault, or perhaps Lasagna was not quite as agile as he would like FDA to be. Whatever the reason his article is an anachronism. Readers of *Science* who are seriously interested in the public policy issue surrounding the new drug approval process in the United States should try to follow the developing debate on S. 2755 (H. 11611), and examine the Executive Summary of the Secretary's panel report.

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Reference

1. Review Panel on New Drug Regulation, *Final Report* (Department of Health, Education, and Welfare, Washington, D.C., 1977).

Kennedy's letter starts with unseemly innuendo and ends with the reddest of herrings. He misrepresents my personal critique of the present sorry state of drug innovation as a " . . . defense of the pharmaceutical industry position. . . ." If *Science* had wanted the latter, a more knowledgeable and appropriate protagonist could easily have been recruited from the ranks of industry. It is depressing to see the Commissioner of the Food and Drug Administration (FDA) politicizing so readily, in an apparent attempt to brush aside a concern which an ever increasing number of academic clinical pharmacologists have.

In several speeches, Kennedy has referred to the need to "demystify" science and medicine and to "demystify the relationship between the physician and the patient" (*1*). In a speech (*2*) on 19 January 1978 before the Consumer Federation of America, he coupled his perceived need for "a concerted effort to 'demystify medicine' " with his announcement of a national project on consumer access, to be "launched simultaneously in seven cities." I am delighted to hear that no anti-physician hearings are scheduled.

Now let me comment on Kennedy's "more serious issue." The Commissioner implies that everything I discussed has changed so drastically in the last 6 months that my article is an "anachronism." What has brought about this miracle? Answer: The Dorsen Panel report, the proposed Drug Reform Act of 1978 (which was introduced in the Congress *after* my article was sent to *Science*), and the discussions concerning these documents. If Kennedy in fact believes that these events have "refined" out of existence the long list of troubles identified in my article, the FDA is in worse shape than I imagined in my blackest moments.

On 11 July 1978, some of the country's most knowledgeable experts from government and academia convened in Washington, D.C., to discuss the proposed drug reform legislation. The group included two former FDA commis-

sioners (a third phoned in his comments) and two former general counsels for the FDA. There was unanimous agreement among these former public servants that the major problems besetting the FDA have little or nothing to do with drug legislation and cannot be corrected by statute.

Even Kennedy's own staff overwhelmingly indicated, at a 23 May Senate hearing on S. 2755 held at FDA's Parklawn Building, that the bill will actually slow down drug approval, despite the fact that the correction of delays is a prime goal of the legislation. Indeed, most knowledgeable drug experts predict that the unbelievably complex legal instrument proposed in March would only aggravate most of the problems I enumerated.

No one wishes more fervently than I for the rapid obsolescence of my critique. I see no hope for this, however, unless current FDA leadership is willing to learn from the lessons acquired so painfully by previous top FDA officials. The public will not be well served by mere rhetoric, no matter how clever. The squid's inky cloud is splendid for purposes of obfuscation, but who wants to more forever backward?

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References

1. D. Kennedy, "Stamping out sin and moving health to the consumer," *Pharm. Salesman* (September 1977), pp. 6–8.
2. ———, "Turtles and other chronic hazards," paper presented before the Consumer Federation of America, Washington, D.C., 19 January 1978.

Smallpox Eradication

In the article "Biological warfare fears may impede last goal of smallpox eradicators" by Nicholas Wade (News and Comment, 28 July, p. 329), the implication that the Walter Reed Army Institute of Research–U.S. Army Institute of Infectious Diseases is retaining variola viruses for other than archival purposes is both unfortunate and a misrepresentation of the facts. It is neither my personal view nor that of the Center for Disease Control that U.S. military researchers are engaged in offensive biological warfare activities.

The Center for Disease Control is presently completing an initial and voluntary national control effort to further limit the number of facilities retaining or working with variola viruses. More stringent controls will be necessary when global eradication is certified as being achieved. Until then, the two facilities currently retaining variola viruses for archival purposes will continue to do so.

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Pluto's Neighbor

The skepticism attributed to me in Richard A. Kerr's article (Research News, 11 Aug., p. 516) about the apparent discovery of a satellite of the semimajor planet Pluto correctly reflects the opinion that I held at the time of my conversation with him, but it must be remembered that this was only shortly after the U.S. Naval Observatory (USNO) press conference, and I had very little information. Over the course of several years, however, the Outer Planet Satellite Project, of which I am director, has accumulated a small number of observations of Pluto. Frankly, we were not interested in Pluto, and the observations were taken primarily because they represented very little additional effort, and could eventually be useful to someone, somewhere, sometime. One of the splendid advantages of the photographic plate is its capacity for storing enormous amounts of information for essentially indefinite periods of time, an advantage that has been greatly highlighted by the story surrounding the discovery of minor planet Chiron. Since talking with Kerr, I have examined the few Pluto plates that we have, but most are of inadequate quality to detect such a small deformation of the image as is required by Harrington's proposed orbit of the double system. Three of those plates, however, did seem to be of sufficient quality to merit further examination, one from December 1976 and two from May 1977, all taken by P. J. Shelus. According to Harrington's predictions, two of those plates should show stellar-like images, and the other should show an elongation in the declination direction. This is exactly what we found. This apparent support for the USNO finding causes me to withdraw my name from the ranks of the unconvinced. I retain some reservations about the semantic situation, but not about the physical reality of the second body.

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