Letters

FDA Reform: Unintended Outcome?

The political storms raging over the U.S. Food and Drug Administration (FDA), and the destructive financial consequences that follow inevitably in their wake, could not have been more sharply illustrated than in the the two recent letters juxtaposed under the heading "FDA 'reform'?" (9 Jan., p. 157). One, from five laboratory chiefs in the Division of Viral Products of the Center for Biologics Evaluation and Research (CBER), decried the massive reduction in scientific research capacity that CBER faces as a consequence of negotiations surrounding and provisions contained in the recently enacted FDA reform bill, while the other, from a former FDA official, scorched the bill for not going far enough to change the agency's regulatory processes and habits.

Last June, I wrote an editorial (13 June, p. 1627) about the report of the FDA Science Board Subcommittee on Research, which I chaired. While critical of much about current research management and practices, the report strongly endorsed the principle that a robust intramural program of well-organized, intelligently managed, rigorously evaluated, mission-focused, top-grade research was essential in support of the FDA's mission. At a time of remarkably rapid advances in the foundational disciplines of biomedicine, information technology, materials science, microelectronics, and other fields, and of an unprecedented rapidity of translation of those advances into entirely new classes of drugs and devices, the need for nimble, responsive, up-to-date intramural science to inform and maintain the currentness and quality of the agency's review processes has never been greater. This principle should be well understood by the agency, the public it serves, and the regulated industry itself.

The subcommittee was not charged to review the FDA's regulatory processes and took no position on them. It did highlight, however, the chronic inadequacy of advocacy for FDA science within the agency and the Department of Health and Human Services and warned that the congressional practice of coupling a progressively increasing regulatory workload with insufficient appropriations would inevitably erode, if not cripple, the agency's research base. The minutely negotiated, politically distracted FDA reform bill clearly has satisfied neither the FDA's most vocal critics nor protected the agency's ability to sustain the focus of intramural research that has been the hallmark of the U.S. system of medical, cosmetic, and food products oversight for nearly a century. Worse, it has contributed to the impending collapse of the scientific capacity of CBER and of the scientific research base of the agency.

Sadly, an immediate, albeit unintended, outcome of the laborious legislative "FDA reform" process may well be to compromise the ability of the agency to expedite the movement of the newest, most promising technologies from laboratory to marketplace, and ultimately to promote and protect the health of the American public.

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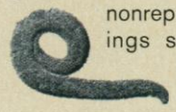
Vertebrates and Invertebrates

Reform at the Food and Drug Administration continues to be analyzed. Self-supporting women scientists, particularly Libbie H. Hyman, who wrote a six-volume definitive text on invertebrates (below, left, *Caenorhabditis elegans*), are given recognition. Acupuncture is compared with anesthesiology. The Cretaceous-Tertiary boundary is explored. Quality monitoring of the Human Genome Project is discussed. And a group of French researchers reports nonreplication of earlier findings showing a possible gene for Parkinson's disease.



On Their Own

Jon Cohen's most interesting article about scientists who fund their own research (Special News Report, 9 Jan., p. 178) does not point out that this has long been the practice of women scientists, especially in earlier eras when academic doors were firmly shut. One example suffices: famed invertebrate biologist Libbie H. Hyman funded her own position at the American Museum of Natural History in New York, using the royalties she earned from sales of her laboratory teaching manuals for vertebrate anatomy. Initially, the museum gave her a symbolically tiny research fund, but when they learned that she was contribut-