

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 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 hall-

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.



mark 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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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-

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ing it to the museum library, they stopped even that small resource.

More personally, I have for some years taken a certain ironic pleasure in using funds earned from speaking engagements where I talk about my work on gender and science to fund a small but fundamental project in basic biology. The time and emotional energy saved by not applying for grants has enabled me to develop a second field of scholarly expertise (feminist science studies). Not only that, I think it is a terrific example for my students, in this high-tech day and age, to see that the most essential tools of science are the brain, a little ingenuity, and a high level of devotion.

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One Man's "Torment..."

Arthur Taub (Letters, 9 Jan., p. 159) refers to acupuncture as "torment" and later describes it as "20-minute, painful needling." In the same manner, one might describe Taub's own practice of anesthesiology as a

systematic drugging of the patient that infrequently results in death.

Little if any pain is associated with acupuncture. If acupuncture truly were experienced as "torment" or a "20-minute, painful needling," it wouldn't have the widespread use and interest that prompted the National Institutes of Health to study it in the first place.

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"Gaps" in the K-T Record

In their letter "Ancient sharks and rays," (9 Jan., p. 161), J. Mark Erickson *et al.* state that, where they work in North Dakota, "the K-T [Cretaceous-Tertiary] boundary section is not complete because units of terrestrial Hell Creek and Ludlow Formations intervene...." They then state, in the next paragraph, that they sampled "nearshore marine facies on each side of the K-T boundary" and later say that "[s]ignificant species-level change in cartilaginous fish faunas occurred across the K-T boundary in the Williston Basin, and apparently globally...."

These remarks appear to be contradictory. Because one has Upper Cretaceous and Paleocene rocks superposed, one does not necessarily also have a K-T boundary section. The tick of the geological clock that we call the K-T boundary occurred whether or not we have rocks and fossils preserving the event. Probably no sections actually record the event, but several come close (tens of thousands of years) on one or both sides. The section studied by Erickson *et al.* is not one of those.

Data from a variety of sources [see references in (1)] suggest that the gap they study in the section through the K-T interval covers at least 1 million years—an extremely long time if one is attempting to examine species-level turnover.

Given this gap, I conclude that their data cannot be used to support the statement that "significant species-level change in cartilaginous fish faunas occurred across the K-T boundary in the Williston Basin, and apparently globally." As I have noted (1), because of this well-documented gap, it is not clear "whether the disappearances from the Western Interior [of elasmobranchs] are actually extinctions at the K/T boundary or whether the species survived elsewhere in marine environments into the earliest Paleocene." This also extends to statements

Them.