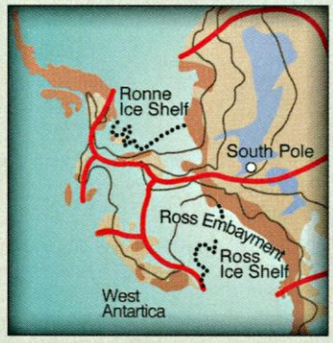
LETTERS

Going with the floe

"Rapid product approval" is said to be a goal of a new policy at the U.S. Food and Drug Administration. Nobel laureates are said to be "a little ungracious" if they complain about taxes. The probability of collapse of West Antarctic ice sheets (right) is discussed. Light is shed on the genetics of multiple sclerosis. Suggestions are made for improving the prospects of "young doctoral scientists preparing for careers." And Linus Pauling's curriculum vitae would not have included the word "biochemist."



Review Staff at FDA

Ira Berkower's letter (11 Apr., p. 183) about proposed cuts in the Center for Biologics Evaluation and Research (CBER) of the U.S. Food and Drug Administration (FDA) misstates the negotiated agreement for the reauthorization of the Prescription Drug User Fee Act (PDUFA). As the principal negotiator for the biotechnology industry, I can state unequivocally that under the terms of the agreement we are not requesting that any employees be "fired." A series of performance enhancements have been agreed on by FDA and industry that will improve drug development. It was our intent during the discussions to improve FDA resources. The results include increased funding (more than 20% greater relative to the user fees paid during the current fiscal year) for an information system that will permit electronic submissions as well as more review staff. Collectively, we believe that the improvements will shorten the development time for new drugs and therapies anywhere from 10 to 16 months.

Under the PDUFA agreement, the $10 million per year of user fee funds that goes into research will be phased out over 5 years. At the same time, there will be a phase-in of an additional $32 million per year to support increased review staff. Thus, we do not anticipate a net loss of FDA employees working on new drug reviews, but an increase. CBER will continue to have approximately 150 full-time research positions paid for out of appropriated funds.

The biotechnology industry is committed to an appropriately funded FDA with an augmentation of review activities by prescription drug user fees. The public has been well served by this program, and the enhancements will continue toward the goal of rapid product approval and a shortening of the development process.

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Nobelists' Taxes

Given that Nobel Prizes in the sciences are generally given for scientific discoveries rather than the scientist's inherent characteristics or selfless acts, and given that the research that made these discoveries possible was often funded by the government, or by tax-exempt institutions, it seems a little ungracious that Nobel laureates should complain if they are asked to support the very institutions that made it possible for them to receive the award in the first place (E. Stokstad, News & Comment, 11 Apr., p. 192). Or perhaps I am confused about their motivations. It would be interesting to know how much Nobel Prize money is donated to charitable causes.

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Arguably, the Nobel Prize winnings should be applied in its entirety to the national debt, as most of the winners have done their research at public expense.

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