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**Internet addresses:** science_editors@aaas.org (for general editorial queries); science_letters@aaas.org (for letters to the editor); science_reviews@aaas.org (for returning manuscript reviews)

# LETTERS

## Minnesota Drug Sales

Christopher Anderson's article "Scandal scars Minnesota medical school" (News & Comment, 17 Dec., p. 1812) reports that some do not understand why the Food and Drug Administration (FDA) put a clinical hold on the investigational drug Minnesota antilymphocyte globulin (MALG). The FDA acted because of the sponsor's failure to obtain informed consent, to properly monitor clinical trials, and to report adverse reactions (including deaths). These are serious violations of the Food, Drug, and Cosmetic Act.

Contrary to observations in the article, the FDA has successfully licensed 12 university facilities—five of them before the introduction of MALG in 1971—for the production of biological products and vaccines. In addition, two state health departments have been licensed for production of vaccines and other biological products.

Despite repeated requests to the MALG investigators, data establishing the drug's safety and efficacy have not been submitted to the FDA. Alternative therapies that have been shown to be safe and effective were available to patients at the time the FDA took action.

***Kathryn C. Zoon***
*Director, Center for Biologics Evaluation and Research, Food and Drug Administration, Rockville, MD 20857*

I am writing to add my perspective to the 17 December article about the University of Minnesota Medical School and the antilymphocyte globulin (ALG) program in its Department of Surgery.

First, it should be pointed out that it was *not* the university's General Counsel who temporarily withdrew a National Institutes of Health (NIH) grant renewal application from the ALG program that is under federal investigation. That action was taken by the appropriate university officer, the vice president for research and dean of the graduate school.

From my perspective, I am also concerned about the characterization that "after reviewing the grant with the researchers, university administrators resubmitted the application with only minor changes." As president, I find it difficult to characterize any information that federal agency regulations require as "minor." The regulations have the force of law. It's that simple.

By law and by contract, principal investigators and their staff members are obligated to know and comply with regulations, regardless of their opinions of the regulations and regardless of the sponsoring agency's oversight and enforcement behavior. As Minnesota's recent problems should be reminding researchers and administrators alike, persistent noncompliance with federal regulations is wrong, and it is trouble.

By common sense and institutional policy, researchers should be obliged to inform departmental, collegiate, and central administrators of problems with sponsoring agencies and steps being taken to solve them. Looking back, early and forthright notification of the appropriate medical school and central administrators could have—would have—avoided this entire controversy.

Looking back, we found what we regard to be compelling evidence of persistent noncompliance, research misconduct, and malfeasance in the ALG program, and we have taken appropriate action within the university's academic misconduct and tenure code provisions. We have also determined that there was inadequate oversight, including institutional policies that were not up to today's more demanding standards. With strong leadership from medical school faculty, we have strengthened the policies and developed a new management-oversight and administrative support structure that will meet modern standards, enhance competitiveness in the health care marketplace, and allow our highly talented medical faculty to concentrate on their teaching, research, and clinical contributions that continue to earn international respect. Those contributions are made every day, and it is a terrible price we pay when much less prevalent, but far better publicized problems divert public attention from that good work. But the price will go higher yet if the public loses confidence that institutions will own up to mistakes and correct them.

***Nils Hasselmo***
*President, University of Minnesota, Minneapolis, MN 55455–0110*

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## Heavy Ion Drivers

I write to add a footnote to Gary Taubes' interesting article about laser fusion of 3 December (News & Comment, p. 1504).