Animal Models in Research

Constance Holden (News & Comment 11 April, p. 147) points to the negative impact on biomedical research from compliance with the new amendments to the Animal Welfare Act and continuing pressure from the animal welfare movement. Animal care committees, extensive record-keeping and reporting requirements, frequent laboratory inspections, and modified animal facilities will clearly translate into higher administrative costs for biomedical research and higher costs for health care. Legislators have apparently found this acceptable. The adverse consequences to our society may, however, be more profound than most scientists and policy-makers realize.

The most important and inadequately addressed public policy issue is the impact the new law will have on narrowing the U.S. lead in biomedicine. The law will certainly slow down the whole process of biomedical research and direct it away from practical end points. These are ominous signs for the United States, which has been the world's premier generator of biomedical knowledge and useful medical products for the benefit of humans and animals.

In government and university laboratories, the shift of funds from direct research to indirect administrative costs will predictably slow the generation of new knowledge. This occurs at a time when the fiscal year 1987 budget of the National Institutes of Health represents a cut in funding, Gramm-Rudman-Hollings will result in further cuts, and the Office of Management and Budget is acting to cap the percent of indirect costs of research that universities can charge to government grants. Furthermore, the balance between in vivo and in vitro experiments will not be determined by their perceived usefulness in providing essential insights into biology, but will be driven increasingly by extraneous factors such as regulation. Fewer academic research programs will use animals, and fewer students will be trained in animal studies than may be optimum for advancing biomedicine. In her 18 April article (Research News, p. 309), Deborah Barnes describes some valuable animal models whose continuing availability to science has already been threatened.

For society to benefit from biomedical research, a strong health-care industry is essential. In addition to generating basic information, it performs the pivotal function of translating knowledge into products. The viability of the industry is only possible if its technology is protected by patents that allow the recovery of the huge investments necessary for innovation. If procedural burdens imposed upon research result in a delay of weeks or even 1 day in obtaining results and submitting a patent application, a loss of patent rights to a competitor is incurred. Being second simply translates into a wasted R&D investment. When a foreign competitor receives the patent, the U.S. work cannot be rewarded, and our nation becomes a loser in the worldwide competitiveness arena.

Policy-makers should now consider how much of the U.S. lead in biomedicine they

are willing to give up. Regulatory restraints clearly inhibit innovation, research, and commercialization (*1*). The degree to which the above effects are manifest now depends on the final regulations being drafted in the Department of Agriculture. Writing good regulations will require a high level of understanding of the biomedical research process and its needs as well as the interplay between academic research, industrial R&D, patents, and international competitiveness. In addition to having concern for the welfare of animals, one hopes the Animal and Plant Health Inspection Service will be cognizant of these matters and implement regulations that keep cost and paper work down to an absolute minimum and, more important, do not delay the process of research. U.S. leadership in biomedicine in the 21st century may well depend on the regulations implemented later this year.

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1. President's Commission on Industrial Competitiveness, *Global Competition: The New Reality* (Government Printing Office, Washington, DC, 1985), vol. 1, p. 18; vol. 2, pp. 277–299.

Holden's article "A pivotal year for lab animal welfare," although well done, contains several errors that need correction.

Holden states: "[T]here is a growing wing of the movement, made up of old-line antivivisectionists and new 'animal rights' groups, who see recent developments as only a step toward the real goal: total elimination of laboratory animals in research. These are the people who have staged laboratory break-ins."

I assume that the National Anti-Vivisection Society (NAVS) founded in 1929, which I represent, qualifies as one of the "old-line antivivisectionist" organizations referred to. The NAVS and other organizations with "Anti-Vivisection" in their logo do not underwrite unlawful activity. Nor does the NAVS maintain contact of any sort with the Animal Liberation Front, the only avowed instigator of many break-ins, including the one that eventually precipitated the shutdown of Thomas Gennarelli's head injury laboratory at the University of Pennsylvania Medical School.

Holden also writes: "These activists want to eliminate all research that impinges on any animal's quality of life. They do not perceive that any trade-offs are necessary because they maintain that animal research has not made any contribution of consequence to human health."

Again, these statements generalize from the rhetoric of a few. Worse, they inadvertently disguise the real concerns of the animal advocate community about the scientist's apparent disregard for the quality of independent animal lives and an apparent inability to translate concern for human life into a compassion for all intelligent and sensate life forms. Holden's conclusions are broadly generalized from testimonies given at the 1986 National Academy of Sciences hearing (*1*), where speakers stated that there had been no progress in the reduction of cancer or mental illness despite extensive animal research. The veracity of this statement in these two areas of traditional animal research has been well documented.

The only qualitative or substantive changes dictating the way animal research will be conducted must be codified in institutional guidelines and state and federal laws. Thus, the process of lawful change requires input from and the cooperation of both the animal advocate and the biomedical communities with the legislative arm.

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1. Committee on the Use of Laboratory Animals in Biomedical and Behavioral Research, Commission on Life Sciences, National Research Council–National Academy of Sciences, public hearing, 11 February 1986.

Biotechnology Center

I would like to comment on several matters discussed in Marjorie Sun's briefing "UN biotechnology center mired in politics" (News & Comment, 28 Feb., p. 915).

1) To the best of UNIDO's (the U.N. Industrial Development Organization's) knowledge there is no basis for the statement that the Indian government will not finance facilities in New Delhi until a scientific director is named.

2) Burke Zimmerman was appointed as project leader for a fixed term of 6 months with an extension of 2 months. He served his full term as planned and then returned to the United States.

3) The panel of scientific advisers and the scientists who have participated in the two workshops have provided valuable input to the planning for the International Centre for Genetic Engineering and Biotechnology (ICGEB). Their recommendations are being implemented.

4) In accordance with the policy of international organizations, only member governments are allowed to nominate candidates for the position of director. This does not mean that the director must be a citizen of one of the countries. The director should be nominated on the basis of the highest scientific and managerial qualifications and experience. In addition, because the goal of ICGEB is to help developing countries utilize biotechnology, it is important for the director to be attuned to and knowledgeable about the needs and desires of developing countries. The nomination of Fotis Kafatos was never brought to a vote because he withdrew his candidacy before complete information could be obtained from him.

5) To date, the governments of Italy and India have committed more than $42 million (U.S.) to ICGEB. Other member countries will be making contributions as well.

The first step toward the establishment of ICGEB as an international organization was taken in 1981. During the past 5 years funds have been mobilized, and facilities have begun to be developed. A director is to be appointed soon. When one takes into consideration the fact that creation of an international R&D center is a complex task, the pace at which ICGEB is being established is quite rapid.

The member countries and UNIDO are convinced that biotechnology will have a significant impact on developing countries. We are committed to the establishment and successful operation of ICGEB.

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Response: Although Italy and India have pledged millions of dollars to support the biotechnology center, they have actually spent far less than that, roughly about $200,000 according to Zimmerman. He and members of the science advisory board say that one of the main reasons the biotechnology program has not gotten off the ground is the lack of money up front.

—MARJORIE SUN

Erratum: In the briefing "House science committee chairman leaving Congress" by Colin Norman (News & Comment, 4 Apr., p. 18), the statement that Representative George E. Brown, Jr. (D–CA), "left Congress for a couple of years in the early 1970's to make an unsuccessful run for the governorship of California" was incorrect. Brown ran for the Democratic nomination for the U.S. Senate in 1970.

Erratum: In Gina Kolata's article "Obese children: A growing problem" (Research News, 4 Apr., p. 20), a statement in the second paragraph of the third column on page 20 referring to a "boy's basal metabolic rate [dropping] by 200 calories an hour while he watched cartoons" on television was incorrect. An extrapolation of the drop in the boy's metabolic rate to a 24-hour period would result in a drop of 200 calories a day.