

# Appendixes

# The Regulatory Environment for Science

## Regulatory Forces on Specific Fields—Two Case Studies

These case studies illustrate the regulatory forces at work on two different research areas—agricultural research and research on acquired immunodeficiency syndrome (AIDS). The first area, agricultural research, is highly organized and highly controlled. Regional needs largely determine the substance and agenda of research, even though the actors who set the agenda may be part of centralized government or in a multinational corporation. Recently, two well-publicized legal actions have had a dramatic influence on the research process in agriculture, attempting to prohibit research from progressing on certain topics or in a certain manner. The second area, research on AIDS, offers an interesting contrast in the types of forces regulating a “hot” research field. Here, the methodological traditions of science and some significant liability and privacy issues may be colliding with the push by advocacy groups for acceleration of the research.

## Regulatory Forces on Agricultural Research<sup>1</sup>

In April 1863, the U.S. Department of Agriculture (USDA) was given authority to use about 40 acres of land at the west end of the Capitol Mall in Washington, DC, as an experimental farm. Since then, food and agricultural research in the United States has expanded and now includes three major performers: the USDA; the State agricultural experimental stations (SAES), and private industry, all of which do both mission-oriented research and basic research.

For its research activities, USDA maintains three separate operating agencies—Agricultural Research, Cooperative Research, and Extension Service—and an Office of Science and Education, which sets broad agricultural research policies. The Agricultural Research Agency is responsible for most of USDA’s in-house agricultural research and is accountable and responsive to Congress and the executive branch for broad regional, national, and international concerns. The Cooperative Research Agency administers Federal funds that go to States for agricultural research. The Extension Service disseminates research results through, for example, publications, public meetings,

and demonstrations. The four SAES geographical regions are each headed by a deputy administrator and typically include a central station located often on the campus of a State’s land-grant university, and a number of branch stations throughout the State. Major private performers in agricultural research include such companies as General Foods Corp., Ralston Purina Co., and Campbell Soup Co..

In general, public sector agricultural research focuses on biological technologies, while the private sector sponsors research on mechanical and chemical technologies. In 1978, total Federal expenditures for all research and development (R&D) were \$26.2 billion. USDA’s expenditures were \$381 million, or only 1.5 percent of the total U.S. R&D budget. The total private sector agricultural R&D budget is about three-fourths of the total USDA contribution.

A multiplicity of actors—consumers, producers, investors, in-house scientists, scientific societies, the regulatory agencies, the executive branch and Congress—thus determine research priority setting in agricultural research. Within the SAES system, for example, line item administrators and scientists set specific project priorities according to their assumptions about what is the greatest need in their field and what would be of greatest value to the State. Traditionally, federally sponsored research has been managed through a classification system based on geography, type of research (i.e., basic or applied), the problem area, and program structure. A less direct, but no less influential determinant of research direction has been Federal environmental and safety regulations, such as regulations on chemical residues or additives in food.

Recently, two separate legal actions have introduced controversy into what has usually been a quiet region of the scientific community. In 1979, attorneys filed a lawsuit, on behalf of 17 farm workers and the California Agrarian Action Project, which charged the University of California with unlawfully spending public funds on mechanization research that displaced farm workers. That suit is still in litigation.

Mechanization research includes the development of machinery, crop varieties, chemical herbicides, growth regulators, and laborsaving methods of handling, transporting, and processing crops. Lawyers for the farm workers allege that such research displaces farm workers, eliminates small farms, harms consumers, impairs the quality of rural life, and impedes collective bargaining, thereby failing to satisfy the government’s obligation to consider the needs of small and family farmers, as specified in various Land-Grant

<sup>1</sup>This section summarizes material in U.S. Congress, Office of Technology Assessment, *United States Food and Agricultural Research System* (Washington, DC: U.S. Government Printing Office, December 1981).

Acts and the Hatch Act of 1877, which authorizes Agricultural Experiment Stations.

The plaintiffs are demanding that all mechanization research at the University of California be halted until a fund is created to be used to assist and retrain farm workers. "Their supporters feel that Federal funding for research on laborsaving devices is an improper use of Federal money; it is best supported by the marketplace because agribusiness is the primary group that stands to gain most from the benefits of such research. Opponents see it as a battle between consumerism and good science at best, and the imposition of Federal controls on research and a violation of academic freedom at worst. They cite many cases where mechanization research has resulted in lower prices for the consumer and more humane working conditions for the farm worker. The case, as yet unresolved, raises issues about: 1) the social costs of innovation through agricultural research, and 2) the legal and social responsibilities of those who conduct research that might adversely affect certain populations. In the legal sense, the case raises questions about the propriety of Federal expenditures for research activities that might primarily benefit private interests.

The other legal action and public protest, launched by activist Jeremy Rifkin and the Council on Economic Trends, has attempted to halt the deliberate release of genetically engineered products into the environment, a technology of potential use to the agricultural industry as a means of increasing and improving crop production. A Federal appeals court has ruled that experiments involving the release of genetically altered organisms into the environment can proceed, provided that their potential ecological effects have been properly evaluated. Rifkin's group has also filed suit along with the Humane Societies of the United States and the Minor Breeds Conservancy against the Department of Agriculture on the issue of transferring genes between species, such as injecting genes for human growth hormone into livestock to promote more rapid and exaggerated growth. As of September 1985, a hearing date had not been scheduled.

These actions demonstrate that even the most highly controlled of research fields may be disrupted by new regulatory forces.

## Research on AIDS<sup>3</sup>

Much of what we know about the biology of acquired immunodeficiency syndrome (AIDS) is also a

result of federally sponsored research activities; for example, Public Health Service (PHS) grantees "discovered" AIDS as a syndrome, PHS has conducted surveillance of AIDS, and PHS investigators and others have made significant scientific advances, including the discovery of the probable etiologic agent for AIDS. Furthermore, PHS investigators are extensively involved in collaborations with non-Federal researchers, both nationally and internationally. Thus, the environment in which AIDS research is funded, conducted, and reported is influenced not only by the politics of the disease (i. e., the special populations which it affects), but also by the traditional funding mechanisms, the grants review process, and the way in which commercial interest turns basic research results into vaccines. In the case of AIDS, these forces appear to have both contributed to and impeded the research.

Although AIDS funding increased substantially in fiscal years 1984 and 1985, the history of specific funding for AIDS has been marked by tension among the individual PHS agencies, Department of Health and Human Services (DHHS), and Congress. Through the Assistant Secretary for Health, individual PHS agencies have consistently asked DHHS to request specific sums from Congress; DHHS has submitted requests for amounts smaller than those suggested by the agencies; and Congress typically has appropriated amounts greater than those requested by the Department, except when prodded by Congress, DHHS has maintained that PHS agencies should be able to conduct AIDS research without extra funds. However, threatened cuts in overall funding and personnel levels have restricted the ability of affected agencies to redirect resources.

An additional indirect influence on the research has been the uncertainty of project staff levels. At critical times in the planning stages, the number of personnel needed to conduct and support the research has actually been reduced in several of the PHS agencies. As a result, the PHS agencies have been unable to plan their activities adequately because they have not known how much funding and staff will be available to them. Now that an etiologic agent for AIDS has been discovered and the research could move into areas where several agencies have overlapping expertise, the jurisdictional uncertainty—because of the uncertainty in resource allocation—has intensified competition.

The question of whether AIDS funds should come out of existing PHS agency budgets, or whether such funds should augment agency budgets, also reflects concern about the perceived appropriateness of PHS funding of AIDS-related research and the perceived magnitude and importance of the AIDS epidemic. Some scientists have expressed concern that 'research on other diseases will suffer because funds are being

<sup>3</sup>*California Agrarian Action Project (CAAP) et al v The Regents of the University of California*, Case 516427-5, Superior Court of the State of California, Oakland (filed Sept. 4, 1979)

<sup>4</sup>This section summarizes material in U.S. Congress, Office of Technology Assessment, *Review of the Public Health Service's Response to AIDS* (Washington, DC: U.S. Government Printing Office, February 1985)

transferred from these areas to AIDS-related research; other observers believe that AIDS-related research may be delayed because of wrangling over such transfers.

In AIDS research, some sharing of information has taken place through the informal networks that exist among PHS agencies and among their researchers, but tensions also surround formal communication. Since the National Cancer Institute's work on HTLV-III was announced in April 1984, formal information-sharing on a management level has increased substantially, and centralized coordination of activities is also on the increase. Members of the PHS Epidemiology and Prevention Task Force have agreed to distribute articles prior to publication, and to discuss studies at the planning stage in order to avoid unnecessary redundancies and to ensure that all the necessary areas are being covered. Many of these sharing and coordinating activities would have taken place regardless of any directive from PHS central management, but in other instances, earlier PHS guidance might have led to better coordination —e.g., PHS might have directed the National Cancer Institute (NCI) to share AIDS virus culture with the Centers for Disease Control, an action which was not taken.

Another factor that may have impeded the generation and dissemination of information is the Federal grants application and approval process for extramural research. National Institutes of Health (NIH) research grants take about 16 months from conceptualization to awards; contracts, about 14 months. The first round of extramural grants awarded by NIH for AIDS research took 14 months to be processed, in part because of negotiations with the Office of Management and Budget over the specific language used in the agreements. Since that time, some steps have been taken to speed up the process, such as mail balloting instead of face-to-face meetings by reviewers. Shortening the process, however, may only increase concerns about the quality of the research activities funded.

Federal regulations covering commercial development of drugs, biologics, and devices have also impeded open communication. In the United States, Federal policy tends to leave commercial development of technologies, including technologies derived from Federal biomedical research, to the private sector. Once under commercial sponsorship, R&D activities are considered proprietary and will not be made public unless voluntarily released. The Food and Drug Administration (FDA), therefore, cannot even divulge the protocols being used by the five companies under license from NCI to develop AIDS screening tests to

Federal researchers who are not directly involved in these activities. Yet the Federal researchers will generally share their research, including their research materials; their primary concerns are the qualifications of the private researchers and the quality control processes they have established. In the case of AIDS, the sharing of information developed by commercial firms was enhanced in small part because PHS selected the companies that would get the HTLV-III culture developed by the NCI laboratory. Other laboratories, however, have now cultured the virus and sold or given it to companies other than those selected by PHS, and the status of those companies' activities is formally unknown to any Federal researcher at FDA.

Finally, AIDS has been described as a "legal emergency" as well as a medical crisis. Much of the concern centers on social discrimination experienced by members of the groups at risk to contract the disease, especially homosexual men and intravenous drug users. Two sections of the Public Health Service Act, therefore, have been used to protect confidentiality in federally sponsored research. Section 242a authorizes the Secretary of DHHS to protect the privacy of individuals participating in research on mental health, including research on the use and effect of alcohol and other psychoactive drugs, by: 1) withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals; and 2) prohibiting persons authorized to protect the privacy of such individuals from being compelled to identify them in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings. Section 242m(d) provides that information may not be used for any purpose other than the purpose for which it was supplied unless consent has been given.

As more is known about the relationship between HTLV-III and AIDS, or as other diagnostic tests are developed, confidentiality safeguards will have to be implemented without sacrificing the surveillance needs of public health officials or data sharing among researchers. Informed consent will be an especially difficult issue, for example, because the first test to be applied will detect exposure to HTLV-III only through the presence or absence of antibodies and persons who test positive may actually be carriers of HTLV-III, may develop AIDS, or may remain well. Regulatory decisions, therefore, will have to balance the public health concerns surrounding the transmissibility of AIDS with the social stigma or employment discrimination that may accompany identification as a potential carrier or potential victim.