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ABSTRACT

This working paper of the Association of American Medical Colleges addresses four issues: the propriety of conducting industry-sponsored research in schools of medicine; necessary institutional safeguards; individual responsibilities of academic scientists; and the implementation and monitoring of the recommendations made herein. The paper was developed after consultation with other professional associations, and was submitted to the House Subcommittee on Health and the Environment. (MSE)

INDUSTRY-SPONSORED RESEARCH AND CONSULTATION: RESPONSIBILITIES OF THE INSTITUTION AND THE INDIVIDUAL

In late 1977, Representative Paul G. Rogers asked Dr. John A. D. Cooper of the Association of American Medical Colleges for his personal comments and thoughts on a series of questions about industry-sponsored research in medical schools. Dr. Cooper felt that the AAMC should respond as an organization to the questions asked by Mr. Rogers. In preparing its response the AAMC surveyed schools of medicine and academic societies asking them to review their existing policies and to submit their views on the questions posed dealing with the issues of propriety, institutional safeguards, and individual reponsibilities. Since industry-sponsored research and consultation to industry are often linked, as was the case in the public hearing on pesticides cited by Mr. Rogers, both activities are addressed by this response.

Propriety

Is it proper for public or publicly funded universities, health professions' schools and research centers to conduct directed research funded by private, profit-making manufacturers who have a direct economic interest in the research outcome?

Analysis

In general, universities may appropriately undertake research sponsored by industry provided that such activities further the essential purpose of the university which is to preserve and enlarge man's store of knowledge and to impart

it to students. Indeed, collaborative research involving private industry and universities provides a portion of the broad scientific information base that often serves the public interest as well as the private interest of the sponsoring industry. Most medical schools are guided by administrative policies which recognize the ethical and legal responsibilities to be observed in the approval of research proposals and are careful to distinguish between routine testing of commercial products and research projects that further the essential purpose of the university. It should be noted, however, that schools of medicine generally do not view classified research, whether sponsored by government or industry, as being compatible with the essential purpose of the university in that free discussion and open publication may be prohibited.

The research competence found in schools of medicine is a unique national resource for which no alternative exists and which has a responsibility to serve society as a whole. Workers, public interest groups, Federal, state and local government, and the general public are often indirect beneficiaries of collaborative research between medical schools and industry. Further, a national research enterprise with a broad base of support from all sectors--voluntary health organizations, private foundations, Federal agencies and private industry--may provide the most reliable guarantee to the nation that the research required by different segments

of society is impartial and objective. Attainment of these ideals, however, will usually depend on effective institutional safeguards, and this is true even if the school accepts no industry-sponsored research.

Recommendation

It is appropriate for universities, health professions' schools and research centers to conduct industry-sponsored research, provided that such research serves the public interest and is compatible with the goals, objectives and traditions of the institutions.

Institutional Safeguards

What safeguards exist or could be instituted to assure expeditious disclosure of research findings indicating potentially serious adverse effects on public health? What are the ethical responsibilities of research scientists and how should institutional safeguards be monitored?

Analysis

Universities and schools of medicine have established systems of institutional safeguards which contribute to scientific excellence, protect human subjects and meet other administrative requirements of the university. Administrative policies generally insure the right of the investigator to publish research findings in the scientific literature but have not addressed a number of other potential problems linked to research sponsored by parties having a direct interest in health and safety regulation.

During the past few years, major changes have occurred in

legislation and regulations designed to protect public health and to minimize safety hazards. University research, whether sponsored by government or industry, plays an important role in these regulatory decisions which affect the health, the quality of life and the economy of the nation. Several aspects of recent regulatory developments which seem highly relevant include: reporting requirements and their effect on publication; patents and proprietary rights; and previously unpublished research data.

Reporting Requirements. In the DBCP hearings it was alleged that all research reports showing adverse effects were not included in a manufacturer's submission to a regulatory agency. Results of the research conducted in an academic institution were reported in the open scientific literature several years after the study was completed. This delay in reporting and publication would be less likely to occur in the future. Under regulations awaiting final promulgation, new evidence of significant health hazards attributable to a chemical covered by the Toxic Substances Control Act must be reported to the Environmental Protection Agency not later than fifteen working days after the industry becomes aware of the new evidence. Further, industry will have 60 days after final rule making to report any existing but previously unreported evidence which indicates an unrecognized health hazard.

Existing or proposed Federal regulations published by

agencies dealing with consumer products, drugs, pesticides and toxic substances clearly place on the sponsoring industry the primary responsibility for expeditious disclosure to the appropriate regulatory agency of research findings indicating a previously unrecognized health or safety risk./1 The right of individuals to report health and safety risks is also recognized and protected by these agencies. Problems could arise if a company failed to meet its responsibilties or if disagreement arose between an investigator and the sponsoring company on the presence or the significance of a health or safety risk.

The proposed regulations will create at least one new problem for the scientific community. Under them, it is almost inevitable that reporting to Federal agencies will precede publication in the open scientific literature by at least several months because of the irreducible time period required by journals for review and publication. Since scientific journals are sometimes reluctant to publish research findings previously announced by the government and reported in the press, some accommodation should be negotiated to assure that prompt reporting to Federal agencies does not inadvertently jeopardize the invaluable process of peer

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/1 Consumer Product Safety Commission (16CFR 1115,1116) Substantial Product Hazards, Proposed Reporting Requirements for Manufacturers, Importers, Distributors, and Retailers of Products; Environmental Protection Agency (40CFR Part 162) Pesticides Programs Guidelines for Registering Pesticides in the United States; Environmental Protection Agency, Toxic Substances Control Act Notification of Substantial Risk Under Section 8(e) statement of interpretation and enforcement policy.

review associated with scientific publication in refereed journals.

Patents and Proprietary Rights. Government and industry are currently in the process of working out procedures that will protect the proprietary rights of industry while meeting the timely reporting requirements of health and safety regulatory agencies. With timely reporting to regulatory agencies assured, the policies of some universities permit agreements that allow a delay in open publication of research results for a short period while patent applications are being filed by industry. Such delays should be left to the discretion and judgment of the investigator and the university. They should not be automatically viewed as the withholding of information.

Previously Unpublished Data. The lack of an easily accessible, comprehensive corpus of information about health and safety hazards of chemicals is a longstanding problem which has become more important with the passage of the Toxic Substance Control Act. Old unpublished research on any particular chemical entity is likely to have been fragmented and to have involved a number of different investigators, located in more than one institution and sponsored by more than one company or by both government and industry. Some of these studies involved quick evaluations abruptly terminated when compounds proved too toxic for further development. Many others yielded negative results that were deemed of little interest to sci-

entific journals. Collecting, abstracting, collating, evaluating and reporting this scattered information is clearly a huge task that could not be undertaken by any individual investigator or university. Academic investigators could however cooperate with industrial or governmental efforts to gather all available information of this character on important substances and to establish an information system for currently unpublished research data. A careful study of the potential costs as well as the possible benefits of developing such a system should be undertaken before any decision to proceed is made.

Recommendations

1. The administration and faculty of each school of medicine should re-examine their policies and procedures for review, approval and monitoring of research sponsored by industry. Where these are not documented, formal and offical statements should be developed and published for the guidance of faculty members.

2. Research agreements with industry should incorporate these administrative principles:

- An industry sponsor should provide available information on the composition, structure, properties, toxicity and potential safety hazards of the substance to be investigated.
- An industry sponsor should agree to comply with the reporting requirements of governmental agencies and

and to take other steps which may be necessary to protect the health of workers and the general public. Responsibility for notification and counseling of those whose health might be adversely affected should be explicitly assumed by the industry sponsor.

- An industry sponsor should endorse the right of the academic investigator to publish research findings in the scientific literature.
- Payments to faculty members for research should be made exclusively through the administrative mechanisms established by the school.

3. Two specific actions might strengthen the internal university system for monitoring research and further assure expeditious disclosure of research findings indicating previously unsuspected health risks.

- The sponsor should be required to return to the investigator a certified copy of the investigator's research report to the company. This certification should reaffirm that the sponsor will comply with reporting, notification, and counseling requirements of the original research agreement.
- Investigators should consult with their department, their institutional review board and, if necessary, appropriate specialty groups if the sponsor is known or suspected of not complying with reporting, notification and counseling requirements. If those

consulted agree that the sponsor has not lived up to his agreement, appropriate governmental agencies should be notified.

4. Federal information systems developed in implementing the Toxic Substance Control Act or the National Library of Medicine toxicology information system should routinely include an adequate description of university research projects sponsored by industry.

Individual Responsibilities

What are the ethical responsibilities of academic researchers?

Analysis

All academic investigators have an ethical responsibility to contribute new information to mankind's common storehouse of knowledge. In the realm of new information about health hazards, this responsibility falls perhaps more heavily on physicians, because they are more likely to be involved with research involving human subjects and because their medical education and clinical experience may provide them better insight into potential health risks. The responsibility of research scientists, including physicians, should be discharged through the formal process established by society to protect and enhance public health. Academic scientists cannot and should not be expected to assume the ethical responsibilities of industry, government workers and public interest groups, all of whom have legal and ethical responsibilities of their own. The system will work well only to the extent that each segment meets its responsibilities. The professional integrity of the faculties of the medical schools

is probably the strongest ethical force in the system.

Policies which deal in a general way with outside consultations and with conflicts of interest have been adopted by many universities. However, little specific attention has been focused on the somewhat special problem of consultation to industry and apparent conflicts of interest that may arise in such situations with respect to regulatory matters involving health and safety. If a scientist employed by government, industry, a union or a public interest group offers an opinion in a regulatory matter, that individual's "interest" status is clear. On the other hand, academic consultants may participate in such matters without it being apparent to all parties concerned that the academician has received or is receiving support or consultation income from a party to a dispute. Any real or apparent lack of openness on the part of the individual consultant could at the least be misleading and might at worse reflect adversely on the individual and the university. Responsible companies, unions and agencies should not object to academic consultants revealing their relationship. Academic consultants to industry should completely disclose such relationships in regulatory or legislative hearings. The hearing authority deserves to know of any potential basis for bias or conflict of interest in a scientist's testimony and should under no circumstances be led to believe that a witness is an academician completely uninvolved with the issues in question or the parties affected by the hearings.

Academic consultants perform a wide variety of services

for industries affected by health and safety regulation; several of these merit individual comment.

- A consultant may be a participant in a dispersed research project contributing special skills as, for example, a pathologist or a biostatistician, or serving as one of a group of collaborative investigators. In this relationship the consultant has an ethical and professional responsibility to understand the larger project and to remind the principal investigator of collective institutional responsibilities.
- Consultants to industry may also be asked to plan research programs, review research proposals and comment on scientific studies. These are straightforward activities which should present no problem unless the academic researcher fails to disclose such relationships appropriately in public forums.
- Consultants often undertake clinical evaluations for purposes of worker compensation, according to agreed upon procedures established by the individual states that protect the rights of all concerned parties.
- Consultants may be asked to help identify potential hazards or appraise their significance. In this case the industry has the responsibility of notifying and counseling its workers about any potential hazards. If a significant new health risk attributable to chemical exposures is encountered, the legal responsibility of industry to report to government

is clear. The consultant and the practicing physician might encounter problems in two similar situations. The first would occur if the relationship between exposure and disease is not clearly causal, and there was a legitimate difference of professional opinion. What should the consultant do if the industry believes there is no problem and the consultant is convinced that there may be a significant health risk? The second is one in which the relationship between exposure and disease is well established but, since the hazard is not new, reporting to a governmental agency may not be required. Concerns about compensation or liability litigation may make the company reluctant to confront the problem and take necessary remedial measures. What is the ethical responsibility of the consultant in this case? With few exceptions, neither the states or the Federal Government have established effective systems for reporting cases of recognized occupational or environmental diseases.

Academic consultants occasionally relate to intermediary organizations that in turn contract with industry, labor or government.. In such cases the full disclosure requirement would not be met unless the consultant were to identify not only the intermediary firm but also the group contracting with that firm.

Recommendations

1. The administration and faculty of each school of medicine should re-examine their policies and procedures for consultancies relating to health and safety regulations.

2. Consultancy agreements should be augmented where necessary to incorporate these ethical and administrative principles:

- An industry seeking consultation should agree to comply with the reporting requirements of governmental agencies and to take other steps which may be necessary to protect the health of workers and the general public.
- If an intermediary consulting firm is involved that firm should require that an industry seeking consultation comply with the reporting requirements of governmental agencies.
- The consultant should take additional steps if he or she suspects that an industry or company is not appropriately responding to governmental reporting requirements or refuses to inform and counsel persons exposed to a significant health risk. In such cases consultants should confer with their department, their institutional review board and, if necessary, appropriate specialty groups. If there is agreement that a significant health risk is being hidden, appropriate governmental agencies should be notified.
- Payments to faculty members for consultation should be made through administrative mechanisms established by the school.

3. The Public Health Service, working with the Association of State and Territorial Health Officers and appropriate specialty societies such as the American Occupational Medical

Association, should develop model legislation on the reporting of cases of environmental and occupational diseases which have already been described in the scientific literature.

4. Academic scientists should fully disclose their participation in industry-sponsored research projects and their sources of consultant income when involved in any phase of the regulatory process. An acceptable mechanism would be for individuals to list such activities on their curriculum vitae. The information included should identify the specific company or industry requesting consultant services not just list an intermediary consulting firm.

Implementation and Monitoring

What if any, ethical or legal codes should be established and how might these be implemented and monitored to assure expeditious disclosure of research findings indicating endangerment to public health?

Analysis

The basic and best safeguard for assuring expeditious disclosure of significant risks to the health or workers or the public is the personal and scientific integrity of the nation's health professionals. Many scientific disagreements about health risks are to be expected and the expression of informed scientific opinions should be encouraged. Academic scientists should be more involved in this process through working with industry, labor, public interest groups and government. Broader participation in the scientific aspects of regulatory policy has been inhibited to some extent by attacks on the personal integrity of participating scientists. Heated criticism during

public policy debates is inevitable and academic scientists should be careful to separate personal values from objective scientific findings.

The administrative principles already articulated provide sound guidance for academic investigators and consultants. The collective wisdom and integrity of academic scientists will assist individual investigators or consultants who encounter problems or disagreements involving reporting to governmental agencies, expeditious disclosure to workers or the general public, and publication in the open scientific literature. These disagreements will at times involve legitimate differences of scientific opinion about complex technical issues. A sound administrative approach and collective scientific judgment is likely to be more useful and more effective than formal legal or ethical codes.

Recommendations

1. Medical schools and academic research societies should consider identifying panels of academic scientists willing to serve as consultants for all societal groups interested in health and safety regulation. Foundation support, governmental support, or joint labor-management support could help establish such panels.

2. The Executive Council of the Association of American Medical Colleges recommends that this report be utilized as a discussion document for consideration by the faculties of constituent medical schools. Implementation and monitoring of

an effective system of safeguards for expeditious disclosure should be the responsibility of each educational institution.

3. The AAMC would be pleased to review periodically the subject of industry sponsored research and consultation and to report to the Congress.