

Secrecy in Medical Research

The conduct of medical research is in increasing jeopardy. Scarce funds for research have been strained by the emergence of new problems requiring intensive work. But a more insidious problem is compromising the ability to make progress in medical research. Secrecy about methods and results has become a common and accepted practice. The complex legal arrangements that are often required before reagents are shared impedes scientists from acquiring the materials needed to perform their work. These impediments to research appear to be arising more frequently. The following four situations, which I encountered in the past several months, illustrate many of the problems.

Episode 1: In recent studies in animals, my colleagues and I uncovered what appeared to be a promising use for a new reagent as a component of a cancer vaccine we were developing for clinical trials. The company that developed the reagent had just completed studies to determine a safe dose in humans and agreed to supply the reagent to us for our trial. The company refused to reveal the dosage information, however, and would not provide data on the toxic effects in patients with cancer in their trial unless we agreed to keep the information confidential so that a competing company would not gain access to it. Our refusal to keep this information confidential resulted in a stalemate.

Episode 2: At a meeting of clinicians and scientists at the National Institutes of Health convened to discuss experimental cancer vaccines, one of the organizers prefaced the discussion with a request that all new information presented at the meeting be kept confidential so that we could have a "free and open exchange of information."

Episode 3: At a meeting of clinicians and scientists, a senior investigator described a new molecule he had identified that he claimed might have value in a cancer vaccine. During the question-and-answer period, the investigator refused to reveal the identity of the molecule, claiming that the paper he had written about this work had not yet been accepted for publication.

Episode 4: When I requested a reagent from a commercial company, the company insisted that I sign an agreement containing the following statement:

For a period of 10 years from the date of the termination of this agreement or any extensions thereof as set forth above [I] shall retain in confidence and not disclose to others and shall not use, except for the purposes of the studies, the materials, [company name] information and all results and data developed by [me] resulting from the studies.

I refused to agree to keep the information confidential and thus could not obtain the reagent.

These examples raise the moral issue of whether any physician or scientist should agree to keep secret information that may be of value in the treatment of a patient or in the development of a treatment for an illness. Perhaps the most egregious example of this

phenomenon in medicine involved the Chamberlen brothers in Europe in the 17th century. The brothers developed a device, the obstetrical forceps, that they boasted "could, even in the most difficult case, promptly effect the delivery of the child."¹ The device was kept secret by the family for three generations. Throughout Europe, women and children died in childbirth while the Chamberlens became rich as their fame in obstetrics spread. They finally offered to sell their secret, which was ultimately purchased and made public.

In the first episode I have described, researchers were asked to keep information confidential that might prevent patients with cancer from receiving ineffective or even harmful doses of a new agent. In fact, implicit in the company's insistence that the information be kept confidential was the desire that its competitors would indeed use the wrong dosage in patients, which would delay their progress in developing the agent for commercial use.

The second and third episodes are variations on a common theme: the increasing reluctance of scientists to share information in order to maintain their competitive edge over other workers in the field or to protect future patent rights. The request to maintain the confidentiality of information learned at a scientific conference is a veiled way of saying, "We are assembled to exchange information freely, but some of this information may be so new and important that unless you are here at the meeting, you do not have the right to know about it." Refusing to answer questions from scientists concerning details of information presented at a meeting (or in private discussion) is in effect admitting, "I possess new information that may help your research, but until I am sure that I will be the one who gains the greatest advantage from it or gets credit for it first, I will not provide you with important details about it."

In the fourth episode an investigator accepting a reagent under restrictions of confidentiality could make observations of value to other scientists or perhaps to patients with an incurable disease but be unable to publish them without the permission of the supplier (the Chamberlen brothers all over again).

The forces that influence scientists to agree to secrecy and exclusivity in the use of reagents are both internal and external and are often not directly confronted. Competition and a desire for recognition are common and are often important factors in the success of high achievers. Withholding research data or refusing to share useful reagents with other scientists can indeed provide a competitive edge. External pressures on scientists, such as evaluations for academic promotion and the need to secure funding, increase the tendency to view competition as against other scientists rather than against the disease. As public funds to support research diminish, these pressures increase.

It is ironic that an unwillingness to share information or reagents in order to augment one's personal accomplishments or reputation often has the opposite effect. Early disclosure of research findings leads to rapid use and expansion of the information and is more likely to reflect positively on those who performed the initial research than is delayed disclosure. Open discussion among scientists, even about the preliminary results

of ongoing experiments, if the preliminary nature of the data is made clear, can play an important part in advancing research.

The increasing involvement of for-profit biotechnology companies in medical research has provided new sources of funding, but with this involvement has come an emphasis on the ethical and operational rules of business rather than on those of science. Concealing information to protect future patent rights or to prevent competing companies from obtaining information is often considered essential to preserve the financial holdings of the company's investors. Blumenthal and colleagues provide interesting data on the subject elsewhere in this issue of the *Journal*.² These internal and external forces help explain the secretive behavior of some scientists. The impact of this behavior can be profound.

The goals of medical research are clear: to prevent human suffering and premature death from disease. Just as a physician has a moral responsibility to do no harm, so does a scientist engaged in medical research. Deliberately withholding useful information or reagents is a violation of this principle. If secrecy slows progress, then human suffering may be prolonged and unnecessary deaths may occur. Although these harms are not the intention of scientists who withhold information, they are a logical consequence of such secrecy.

Secrecy in science is understandable, but it is not justifiable. We need to find ways to satisfy the forces that encourage secrecy while maintaining the openness of scientific interchange.

The reluctance to disclose preliminary findings to other scientists for fear of misleading them is quite different from the deliberate withholding of information that would be useful to other investigators. Difficulty in distinguishing clearly between these two situations is often used to cloud issues. Too often, the unwillingness to share reliable information is couched in such terms as "It's not published yet," "I'm not sure it's correct," or "I have to check with a colleague," and the unwillingness to share reagents is justified by such statements as "It may not be pure" or "There are a few things I want to do with it first." The parties involved are often too embarrassed to articulate the real issues. A frank discussion of the problems of secrecy in science is needed. It may be embarrassing to discuss these problems openly, but the issues are too important to be skirted by platitudes or euphemisms. Sharing information and materials should be encouraged because it is right, and less altruistic behavior needs to be analyzed and discouraged.

Discussion of these issues in undergraduate and graduate science programs will increase awareness of the problem. It should be an important part of the mentoring of young scientists, who often enter graduate training as idealists and can later be confused and profoundly influenced by laboratory policies that restrict the sharing of information. Open discussion of the ethical conduct of science can keep the emphasis on the progress of science rather than the progress of scientists.

The support of medical research by biotechnology and pharmaceutical companies has introduced new pressures in the communication of scientific information. Scientists are pulled in opposite directions by the desire to share research findings and the need to protect the investors who have supported the research. The viability of some companies may depend in part on their ability to conceal information and develop products first. The intricacies of patent laws are unfamiliar to scientists, who are often frustrated by the restrictions the laws impose. In virtually all European countries, the disclosure of findings at an open meeting prevents the patenting of those findings. Ideally, patent legislation should allow for the sharing of information while protecting the commercial rights of the researchers and companies that first developed the information, regardless of its disclosure. Current patent law does not achieve this goal, although the June 1995 decision by the U.S. Patent and Trademark Office to accept simple and inexpensive provisional patent applications, which can be prepared and filed rapidly and provide disclosure protection, is a step in the right direction. More attention to this medicolegal issue is needed.

Studies of secrecy in science have not been conducted, and quantitative data on the prevalence and impact of the problem are therefore not available. My own experience, however, suggests that the problem has escalated dramatically in the past decade and is impeding the progress of medical research.

What can be done? Studies of the problem of secrecy can clarify many of the issues involved. Discussion and education about the problem can heighten awareness and perhaps lead to more open scientific interchange. Institutions that fund research and journals that publish the results of research should address this problem, since the withholding of information and reagents is at odds with their long-term goals. Legislation that protects intellectual-property rights while allowing for the free exchange of information and reagents is also needed.

This important problem requires attention on the part of all scientists. There would be immediate improvement if scientists refused to keep information confidential and refused to sign any agreements for the transfer of information or reagents that included a requirement of confidentiality.

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References

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