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Senator Tom Harkin (D-IA), shown here with GEN publisher Mary Ann Liebert, recently announced he is a candidate for the 1992 presidential race.

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NIH's Cooperative Research & Development Agreements Program Needs Some Repair Work

point of view

By Bruce F. Mackler, Ph.D., J.D., and Gary E. Gamerman

When the U.S. Congress passed the Federal Technology Transfer Act (FTTA) in 1986, the Cooperative Research and Development Agreement (CRADA) program was born. The goal was to promote R&D collaborations between the National Institutes of Health (NIH) and private industry to accelerate technology transfer.

CRADAs, however, have failed to multiply at NIH because the administrative structure at each Institute frequently delays, discourages and often blocked by the Technology Development Coordinators (TDCs) at their Institutes.

Many TDCs, the administrators charged with encouraging and facilitating technology transfer, misinterpret their roles, and build internal empires by controlling the progress of agreements. They are neither trained nor experienced negotiators, yet they routinely try to negotiate highly complex CRADAs that have broad scientific and commercial implications.



National Cancer Institute

Lifesaving discoveries at NIH would translate into clinical applications sooner if NIH scientists and industry could quickly establish collaborative agreements. Many believe the answer is to let the Office of Technology Transfer handle the complex legal and commercial facets of CRADAs, thus overcoming unnecessary red tape and bureaucratic delays. Such a restructuring would streamline the CRADA process, provide greater consistency, effectiveness and oversight, and achieve Congress' legislative intent for CRADAs.

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The problem is that NIH has dispersed authority over sensitive legal and commercial decisions regarding CRADAs to administrators at each NIH Institute, many of whom lack the qualifications or experience to be effective. This dispersal of authority causes delay and inconsistency in CRADA negotiations, and prevents oversight and intervention.

Many believe the cure is to use the expert staff at NIH's Office of Technology Transfer (OTT) to handle the complex legal and commercial facets of CRADAs, while allowing Institute administrators to perform the jobs at which they excel—supervision, training and resource management. Such a restructuring would

Well-Meaning Dilettantes

A few TDCs understand their jobs as intermediaries and enthusiastically try to bring scientists, lawyers and businessmen together rapidly, and facilitate agreements without excessive administrative delay. Yet, there are TDCs who, at best, are well-meaning dilettantes who believe they should engage in on-the-job legal training. Or, at worst, they are either short-sighted administrators who believe Congress is wrong to share scientific discoveries with industry, or egotistical technocrats.

there remains a huge lack of trust and productivity concerning the CRADA process.

Fragmented Authority

The fragmentation and scattering of NIH CRADA authority among 24 TDCs is good reason for that lack of trust and productivity. CRADA industry partners never know when a TDC will destroy their commercial investment in a CRADA, as happened when one TDC arbitrarily decided that publishing research results did not affect worldwide patent rights—and was wrong. In this situation, the TDC failed to adequately use the internal resources of the OTT. In another case, negotiations dragged on for almost a year, diminishing the value of the CRADA to the industry partner.

At the NIH-PMA conference, the new NIH Director, Dr. Bernadine P. Healy, listed technology transfer as a top goal. She highlighted the fact that the collaboration of NIH scientists with industry directly benefits patients, and she stressed the need for NIH to develop an agency-wide strategy for technology transfer.

A GAO report has found that major provisions of the FTTA "still have not been fully implemented." The report described "burdensome and time-consuming procedures" as big problems hampering CRADA activities. In the words of the respondents in the GAO study, the 1986 amendment to the FTTA "spawned a bureaucracy with no added value . . . ," and the CRADA process needs to be streamlined. Quantitatively, GAO found that 30% of the failed attempts to engage in technology transfer through a CRADA was a direct result of administrative incompetence—everything gets caught in a "bureaucratic maze."

For the CRADA program to reach its full potential, Dr. Healy must remove the bureaucratic barriers built by certain NIH Institutes and then implement a coordinated structure to bring CRADA and licensing together under OTT's authority.

Business Community

The other side to the story is the frustration felt by the business community, which genuinely wants to conduct joint research with the government. They find that each CRADA often necessitates dealing with a different TDC, whose understanding of the law and attitude toward technology transfer is unpredictable or even conflicting. Also CRADAs at some Institutes can tak

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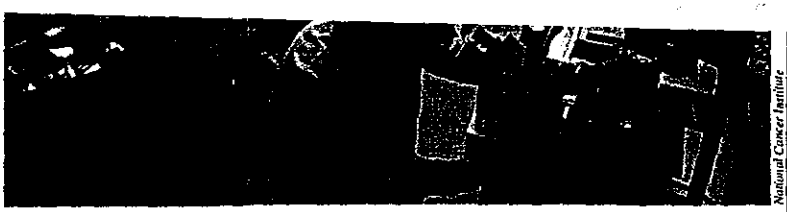

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Red Tape

Lifesaving discoveries at NIH could be brought to market more rapidly if NIH scientists and industry could quickly establish collaborative agreements. Meanwhile, red tape and bureaucratic delays cause promising discoveries to languish in some NIH labs for want of CRADAs. Japanese and European governments, on the other hand, have been collaborating closely with their domestic companies to help commercialize research developed in government labs, as well as to acquire foreign technology. Other countries are diligently removing governmental impediments to collaboration with their industries, rather than building bureaucratic mazes to delay them.

Under the CRADA program, engineering and science professionals have been eager to commercialize the technologies they have developed. OTT's equally skilled lawyers and negotiators have worked effectively to see that the government's intellectual property is commercialized. However, eager researchers and their industry counterparts are pret their roles, and build internal empires by controlling the progress of agreements. They are neither trained nor experienced negotiators, yet they routinely try to negotiate highly complex CRADAs that have broad scientific and commercial implications.

Well-Meaning Dilettantes

A few TDCs understand their jobs as intermediaries and enthusiastically try to bring scientists, lawyers and businessmen together rapidly, and facilitate agreements without excessive administrative delay. Yet, there are TDCs who, at best, are well-meaning dilettantes who believe they should engage in on-the-job legal training. Or, at worst, they are either short-sighted administrators who believe Congress is wrong to share scientific discoveries with industry, or egotistical technocrats.

According to one industry representative, who has negotiated many CRADAs over the past several years, "There are quite a few TDCs who are interested in getting technology on the market, but they are far outnumbered by the many petty empire-building despots who see their role as restraining the commercialization of science rather than transferring lifesaving discoveries from laboratory to patient."

For example, there are currently several potentially useful cancer treatments that are not being commercialized because of the slowness of CRADA negotiations, unnecessary bureaucratic delay and the reluctance of TDCs to resolve issues expeditiously. One NIH insider said there is "a blunting of the FTTA by Institute administrators who actively distrust collaboration," thus delaying the CRADA process because they lack adequate understanding of the concepts of technology transfer and oversight.

Dr. D. Allan Bromley, the Director of the Office of Science and Technology Policy (OSTP), has commented on the severity of the situation. At the NIH-PMA conference last April, he asserted that although most of the legal barriers to technology transfer have been removed, NIH to develop an agency-wide strategy for technology transfer.

A GAO report has found that major provisions of the FTTA "still have not been fully implemented." The report described "burdensome and time-consuming procedures" as big problems hampering CRADA activities. In the words of the respondents in the GAO study, the 1986 amendment to the FTTA "spawned a bureaucracy with no added value . . . ," and the CRADA process needs to be streamlined. Quantitatively, GAO found that 30% of the failed attempts to engage in technology transfer through a CRADA was a direct result of administrative incompetence—everything gets caught in a "bureaucratic maze."

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The other side to the story is the frustration felt by the business community, which genuinely wants to conduct joint research with the government. They find that each CRADA often necessitates dealing with a different TDC, whose understanding of the law and attitude toward technology transfer is unpredictable or even conflicting. Also, CRADAs at some Institutes can take 9-14 months to complete, which is unacceptable to companies and has caused deal-killing delays in several instances.

The most important asset that government technology transfer (through a CRADA) offers companies is access to advanced technology. However, this advantage is frittered away by the multitude of hands through which an agreement must pass. By the time many CRADAs get approved, the technology already has moved on.

Delays are often fatal when there are unplanned personnel changes, as recently happened at NCI. All uncompleted agreements go into limbo until the new people make their reviews. This manifold layer of review is perhaps the most important reason to consolidate the negotiation and approval process. The situation at NCI became so entrenched that several researchers there assert "they will never do another CRADA." Instead, out of frustration, they plan to use informal research activities with outside groups.

A number of companies that have dealt with NCI have expressed similar views, along with a reluctance to work with the Institute. One CEO, whose company has CRADAs with

everal NIH Institutes, including ICI, said that getting an NCI CRADA approved took the longest. o long, in fact, that he is discouraged from working with NCI again.

No Proactive Monitoring

Another serious drawback to the urrent process is that the dispersal of uthority to each Institute makes versight and consistency impossible. OTT has no way of proactively nonitoring how effectively TDCs re protecting the government's inellectual property—they only find ut when there is a problem. One ndividual at NIH put it bluntly: 'Oversight of CRADAs is ineffective. Because TDC management of he CRADA is not centralized and niform, it generally exists as crisis nanagement, not proactive prgram-wide strategy."

Inconsistency in the management of CRADAs is best exemplified by he different ways in which the Institutes fund patent prosecution. Each nstitute's ability to exercise individual control over patenting decisions as frustrated OTT's efforts to mount n effective licensing program. As a esult, OTT's success in obtaining a patent worth licensing depends upon luck, not planning.

Lack of funding for patent prosecution, and the use of different funding mechanisms by each NIH Institute, are additional roadblocks to technology transfer. Some examples will serve to illustrate the problem.

The Institute of Allergy and Infectious Disease and the National Institute of Mental Health are two very productive Institutes. Funding from a central budget spread across the entire Institute permits decisions based on the overall portfolio of patentable technologies, and allows the establishment of uniform policies on such matters.

Other Institutes and Centers, like NCI, pay for patent prosecution directly from the lab budgets of individual investigators. This effectively shuts out smaller labs because they often lack the money to afford the upfront costs associated with the patent process. In addition, any valuable research they may be carrying out will be left unprotected. The situation is extremely discouraging to scientists. One cancer researcher said, "It is not worth doing the work since I keep finding that my lab budget gets siphoned off to pay for prosecution."

Thus, at NCI, the lack of coordination in patent prosecution diminishes lab productivity and the attractiveness of its research to industry. NIH should set up a central patent prosecution fund under OTT's control, much like the system at most universities.

Commercial Opportunities

Helping NIH scientists find commercial opportunities for joint research with industry should be another key goal for TDCs. But the case of a TDC at one of the largest Institutes appears to be the rule rather than the exception. She is so busy attempting to get agreements going that she "has no time to work with the investigators, or check up on them." Regarding oversight, another TDC, who works with many researchers and industry representatives, said she has to "trust them to do the right thing since [she] spends her time putting these agreements together, not policing collaborators and scientists."

Thus, the government is susceptible to the predations of sophisticated industry collaborators who look for advantages to benefit their companies, as they are trained to do. NIH, therefore, should use OTT personnel with similar commercial and legal training to balance such negotiations.

Solving the Problems

The solution to most of the problems is not to eliminate TDCs, but to utilize them in the role for which they were trained—scientific administration. Freed from managing the legal and commercial details of negotiating CRADAs, TDCs would have the time to supervise Institute researchers as well as to encourage collaborations. They could be highly effective in spotting potentially useful technologies, and advising OTT on the negotiating details of CRADAs. TDCs could initiate proactive management of the collaborators and the commercialization of their work by helping them get the resources they need and by working out problems.

Freeing the TDCs would require shifting the bulk of the responsibility for managing legal and commercial details to the OTT's staff which has the necessary training and expertise. OTT's staff would coordinate and manage actual filing and protection of patents. Funding for patent prosecution based on commercial potential would be centralized in the OTT budget, and decisions regarding the methods and strategies for patent protection could then be made with responsible, experienced legal and commercial insights.

Centralization of legal and commercial authority in the OTT would allow the development and implementation of the coordinated NIH-wide technology transfer and long-term planning that Dr. Healy has articulated. Industry could be assured that legal and commercial relations with NIH would be consistent and competent without compromising the interests of NIH and the public. Scientists could feel confident that their attempts to commercialize their work would not be thwarted by uninterested or unskilled TDCs who have their own bureaucratic agendas. And the public could be certain that their tax dollars will generate cures and treatments of disease, as Congress intended through the FTTA.

Bruce F. Mackler, Ph.D., J.D., is a partner with the law firm Baker & Hostetler (Washington, DC) and general counsel to the Association of Biotechnology Companies. Gary E. Gamerman, a former law clerk with Baker & Hostetler, attends the National Law Center at George Washington University.

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