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The Director of the National Institutes of Health (NIH), Harold Varmus, M.D., today announced removal of the "reasonable pricing "clause from the Public Health service (PHS) model Cooperation Research and Development Agreement (CRADA) and the PHS model Exclusive License Agreement.*

"An extensive review of this matter over the past year indicated that the pricing clause has driven industry away from potentially beneficial scientific collaborations with PHS scientists without providing an offsetting benefit to the public," said Dr. Varmus. "Eliminating the clause will promote research that can enhance the health of the American people," he said.

Over the past year, NIH analyzed its CRADA activities including the scope of scientific research under CRADAs, the resources brought to the collaborations by NIH scientist and industry, intellectual property arising from the CRADAs, and the effect of the "reasonable pricing: clause on products developed under CRADAs. NIH also sought advice from scientist, patient advocacy groups, and representatives of academic institutions and industry on how the clause has affected research and development collaborations and the advancement of scientific discoveries.

*NIH is the lead technology transfer office on behalf of PHS.

NIH found that CRADAs, although they represent only a small fraction of NIH intramural research activities, significantly advance biomedical research by allowing the exchange and use of experimental compounds, proprietary research materials, reagents, scientific advice, and private financial resources between government and industry scientist. The "reasonable pricing" clause, however, discourages the execution of exclusive licenses and CRADAs and inhibits the ability of PHS scientist to obtain access to research materials and scientific expertise from their private sector counterparts, even outside the context of a license or a CRADA.

NIH also determined that very few CRADAs have directly resulted thus far in a new intellectual property or products. The six products developed under NIH CRADAs since 1987 either are non-exclusively licensed to one or more companies or had no patent protection and did not require licensure for development. Thus, to date, no CRADA product has been developed under an exclusive license, although several CRADA technologies have been exclusively licensed and may result in future products. The vast majority of CRADAs result in new scientific knowledge, not new products.

NIH also found that research on several technologies had resulted in CRADAs and exclusive licenses with different companies for the development of similar products that would compete with one another. Thus, even where a product results from an exclusively licensed technology, the commercial licensee is not assured a monopoly position in the marketplace. NIH believes that competition should be fostered by removing barriers to CRADAs and ensuring, where possible, that competing products are developed from the same area of technology.

No law or regulation requires or expressly authorizes the inclusion of the "reasonable pricing" clause. No other Federal agency except for the Bureau of Mines includes a reasonable pricing clause in

their CRADA or license agreements with the private sector. Licensees of PHS and other Federal agencies routinely pay fees and royalties to fairly compensate the Government for using intellectual property developed through taxpayer-supported research.

"The clause attempts to address the rare breakthrough product at the expense of a more open research environment and more vigorous scientific collaborations," said Dr. Varmus. "One has to have a product to price before one can worry about how to price it, and this clause is a restraint on the new product development that the public identified as an important return on their research investment."

NIH shares the voices by participants at the public meetings about potential inaccessibility of such products due to cost. However, NIH agrees with the consensus of the advisory panels that enforcement of a pricing clauses would divert NIH from its primary research mission and conflict with its statutory mission to transfer promising technologies to the private sector for commercialization. "NIH's primary programmatic mission, legislative mandate, and expertise is in biomedical research, not in product pricing" said Dr. Varmus.

Backgrounder

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- To encourage commercialization of Government conducted research, the Federal Technology Transfer Act of 1986 (FTTA) authorizes Federal laboratories to enter into CRADAs with numerous entities, including private business. Under a CRADA, companies may provide funds, personnel, services, and equipment in support of collaborative research with Public Health Service (PHS) scientist, most of whom are at the National Institutes of Health (NIH). Federal laboratories may provide all of these resources except funds, and the Government may also grant to their collaborators, in advance, exclusive license options to intellectual property rights on any invention made by a Federal employee under the terms of the agreement. In addition, under separate authority, Federal agencies are authorized to enter into exclusive licenses with companies for the commercialization of new technologies developed solely within the intramural research programs of Federal laboratories. Often the CRADA and exclusive licensing mechanisms are used together to further develop, through collaborative research, a new technology first discovered within a Federal laboratory.

- In fiscal years 1987 through 1994, the NIH executed a total of 237 CRADAs, most of them with industrial partners. These agreements covered a broad range of research, from the initial application of basic discoveries to advanced clinical trials. In the vast majority of cases, because of the nature of the research or the intellectual property position of either NIH or the collaborator at the inception of the CRADA, no new inventions (and hence no new intellectual property) were expected and none resulted. Frequently in these situations, NIH had extensive intellectual property protection on a technology that was licensed by a CRADA collaborator and further developed under a CRADA. Other times, the industrial partner had extensive intellectual property coverage and entered into the CRADA primarily to allow NIH access to the proprietary technology for the purposes of further basic research. In a small minority of cases, new intellectual property was developed during the CRADA. In no case has a product been brought to market based upon technology developed under a CRADA and exclusively licenses to the collaborator, although future products may be anticipated to arise out of exclusively licenses CRADA technologies currently in development.

- In 1989 the PHS, acting through the NIH patent Policy Board, adopted a policy statement and three model provisions addressing the pricing of products licensed by PHS research agencies on an exclusive basis to industry or jointly developed with industry through CRADAs. The most critical factor in adoption of the pricing provisions by the PHS was the substantial Congressional and public concern over the $8,000-$10,000 per patient per year launce price of AZ in 1987. The involvement of National Cancer Institute (NCI) scientist in development of this compound created a public expectation that this medication would reach the public at a more accessible price. Although there was no CRADA or exclusive license executed between the NCI and the drug company to govern the commercialization of AZT, in response to the issue, the NIH Patent Policy Board, in consultation with the Deputy Assistant Secretary for Health, PHS, decided to require pricing clauses in model CRADAs and exclusive license agreements.

- On the matter or pricing, the PHS CRADA Policy Statement provides:

  > "DHHS has responsibility for funding basic biomedical research, for funding medical treatment through programs such as Medicare and Medicaid, for providing direct medical care, and, more generally, for protecting the health and safety of the public. Because of these responsibilities as the public investment in research that contributes to a product licenses under a CRADA, DHHS has a concern that there be a reasonable relationship between pricing of a licensed product, the public investment in that product, and the health and safety needs of the public. Accordingly, exclusive commercialization licenses granted for the NIH/ADAMHA intellectual property rights may require that this relationship be supported by reasonable evidence."

  The model PHS CRADA and exclusive licenses each include similar provisions. The model PHS exclusive license states as well that the agreement "…shall not restrict the right of the Licenses to price a Licensed Product or Licensed process so as to obtain reasonable profit" and "…does not permit PHS or any other government agency to set or dictate prices…"

  The DHHA is the only federal agency to include the "reasonable pricing" clause in its CRADAs and exclusive licenses, other than the Bureau of Mines.

- The current pricing clauses apply in two circumstances: first, when new intellectual property arises out of a CRADA and then is licensed exclusively to the collaborator by the PHS; and second, when NIH develops through its intramural research new intellectual property that is then exclusively licensed to the private sector for commercialization.

- NIH held two public meeting on the subject of the "reasonable pricing" clauses: one on July 21, 1994 and one on September 8, 1994. These meetings included representatives from patient advocacy groups, industry, academia, and the scientific community. Attendees generally supported the public access purpose of the clause, but few believed the clause currently functions as intended. Many registered the view that the clause was driving industry away from potentially beneficial scientific collaborations without providing a compensating benefit to the public. Both of the two most relevant trade organizations, Pharmaceutical Research and Manufactures of America (PhRMA), representing traditional research and development bases pharmaceutical firms, and the Biotechnology Industry Organization (BIO), representing over 500 biotechnology firms, are on record as strongly opposing the model PHS pricing clauses. In addition, numerous PHS intramural research scientist have reported difficulty in entering into CRADAs due to the reluctance on the part of potential CRADA collaborators to accept the

"reasonable pricing" clauses. Several scientist reported difficulty in obtaining research materials and interacting with industry scientist even outside the context of a CRADA, due to the reluctance of some companies to become involved with NIH. (A report of the two public meetings is available by calling the NIH Office of Communications at (301) 496-5787.)

- NIH also obtained advice from the NIH Directors' Advisory Committee, The PHS Technology Transfer Policy Board, and the PHS Technology Transfer Policy Board, and the NIH Technology Transfer Advisory Committee. All three of these groups concluded that the clauses should not be permitted to impair NIH's ability to do collaborative research to improve public health. Further, these committees found that the NIH lacked the requisite legislative mandate or expertise to regulate prices and that such a role would conflict with its technology transfer mission.

- Six products have been developed under CRADAs since 1986. None of these products are exclusively licenses. The products fall in the following categories: therapeutics (Taxol, pilocarpine), vaccines (Hepatitis A vaccine), and research tools (D2 Short Dopamine Receptor, Patient Activity Monitor), and research services (cDNA megabase sequencing).

- NIH CRADA and licensing strategy has resulted in several CRADAs and licenses aimed at developing products which will eventually compete with each other. Examples include:

  1) AIDS: Two AIDS therapeutics, dideoxycytidine (DDC) and dideoxyinosine (DDT), were co-developed by NIH and compete with AZT in the marketplace.

  2) Cancer: Taxotere, an analog of taxol, is being developed by the NCI and will compete with taxol as a cancer therapeutic.

  3) Gaucher's Disease: Two CRADAs are underway to develop two different forms of recombinant glucocerebrosidase for the treatment of Gaucher's disease. In addition, a CRADA for gene therapy to permanently treat Gaucher's disease is ongoing.

  4) Chlamydia infections: Three CRADAs are underway using the same NIH technology to develop a Chlamydia vaccine. The three collaborators have brought their own proprietary delivery systems to the CRADAs and will obtain exclusive rights to the NIH technology only for use in conjunction with specific delivery systems.