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**TECHNOLOGIES FOR THE MARKETPLACE FROM
THE CENTERS FOR DISEASE CONTROL**

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ABSTRACT

The Centers for Disease Control, a Public Health Service agency, is responsible for the prevention and control of disease and injury. Programs range from surveillance and prevention of chronic and infectious diseases to occupational health and injury control. These programs have produced technologies in a variety of fields, including vaccine development, new methods of disease diagnosis, and new tools to ensure a safer work environment.

Development of a vaccine against hepatitis A, a common viral illness in day-care centers, is now possible due to techniques that produce large quantities of the viral agent. A recombinant rabies vaccine may assist in eradicating wildlife rabies. This vaccine is generated by inserting the rabies gene that elicits protective antibodies into a mammalian virus that does not produce disease in human beings. Similar technology has also produced the protein critical to the laboratory diagnosis of rabies, eliminating the current need for using infectious virus. *Legionella* species-specific monoclonal antibodies for the detection of legionellae in environmental samples and clinical specimens have been developed. A rapid method to diagnose human cysticercosis, a disease caused by consuming contaminated pork, is also available for commercial application. Finally, concern over worker safety has stimulated development of devices such as one that controls waste anesthetic gases in veterinary surgical units.

Consistent with the objectives of the Federal Technology Transfer Act, CDC is committed to transfer these and other technological innovations from the laboratory to the marketplace, so new products can be available to augment the control and prevention of disease and injury.

INTRODUCTION

The Centers for Disease Control (CDC) is one of seven Public Health Service agencies. Established in 1946, the Communicable Disease Center, as it was known then, grew out of the Office of Malaria Control in War Areas (MCWA) headquartered in Atlanta, Georgia. From its early work with state and local health officials to fight infectious diseases, CDC has grown into five centers/institutes. CDC has become a leader in:

1. prevention of disease, disability, and premature death caused by infectious and chronic diseases;
2. injury or disease associated with environmental, home, and workplace hazards; and
3. controllable risk factors such as poor nutrition, smoking, lack of exercise, high blood pressure, stress, and drug misuse.

As you know, in 1986, Congress passed the Federal Technology Transfer Act of 1986 (FTTA-86) to improve the link between the Federal laboratories' technology base and U.S. businesses. This law and related legislation authorized Federal laboratories to patent and exclusively license inventions to, and collaborate with, businesses on research and development. Until 1986, the principal methods used by CDC to transfer technology outside the Government were training, education, and information dissemination; CDC scientists presented information about technological developments in papers and at professional meetings and trained other scientists in new technologies.

In 1988 CDC established the Technology Transfer Office (TTO). TTO staff are responsible for the patenting and licensing of CDC inventions and, with CDC's Office of General Counsel (OGC), negotiating the language and licenses of the Center's Cooperative Research and Development Agreements (CRADAs), Biological Materials Licensing Agreements (BMLAs), and Materials Transfer Agreements (MTAs). Additionally, the TTO staff develop technology transfer training material, and conduct and sponsor seminars to educate and update CDC's scientific community on technology transfer issues. We also actively participate in the local biomedical/biotechnical community through our membership in the Clifton Corridor Council (CCC). The CCC, a Georgia-based non-profit organization, was founded in 1989 to promote Georgia's biomedical research institutions and to attract biotech companies to our state. Some of CCC's 34 institutional members are the American Cancer Society, Emory University School of Medicine, Georgia Institute of Technology, Morehouse School of Medicine, and the Medical College of Georgia. In addition, the CCC has more than 100 corporate and numerous individual members.

CDC's TTO staff have developed a technology licensing document highlighting our patented and patent-pending licensable technologies. This document is updated frequently and includes a statement on CDC's CRADA policy, as well as a model BMLA. Additionally, the CCC has put together a licensable technologies document, featuring available technologies from its member institutions. Both documents are available at our exhibit booth.

The Office of Technology Transfer (OTT), National Institutes of Health (NIH), coordinates the technology transfer activity for the PHS agencies, including NIH; the Alcohol, Drug, and Mental Health Administration (ADAMHA); the Food and Drug Administration (FDA); and CDC. As a part of their PHS-wide effort to offer "one-stop-shopping," OTT packages related groups of patented and patent-pending inventions from PHS laboratories, thus allowing licensing of complementary or interrelated technologies. OTT's profiles database is a mechanism whereby companies desiring to be contacted about new PHS inventions as they become available can share information about their corporate interests. Additionally, PHS-OTTO (Office of Technology Transfer On-Line) is a computer database providing modem access to data that can be copied into the user's own computer files. This electronic bulletin board includes

descriptions of patents and patent applications available for licensing and brief descriptions of existing CRADAs. Names and telephone numbers of PHS scientists interested in CRADAs and their individual areas of expertise are highlighted. Also included are directories of PHS resource people, forum and conference announcements, model technology transfer agreements, and technology transfer guidelines. Standardization of documents used by PHS agencies has further contributed to the one-stop-shopping concept. By easing the transfer of technology into the marketplace, OTT's efforts benefit not only public health, but the U.S. economy as well.

From implementation of FTTA-86 through September 1991, CDC has processed more than 100 employee invention disclosures resulting in 44 filed patent applications and 3 issued patents. CDC currently has 27 active CRADAs and has negotiated 24 BMLAs. Combined income from these activities has been significant.

A sample of the technologies developed by CDC and available for licensing follow; they span the realm of infectious disease diagnostics and vaccine candidates to worker health and safety devices. Many other technologies are available or are in development; these eight examples have been selected to show the range and variety available from CDC.

1. A number of promising technologies associated with hepatitis A (HAV) vaccine development and diagnosis have been generated at CDC. Among other qualities, efficient yields of large quantities of hepatitis A virus are needed for the commercial development of vaccines and diagnostic tests for the disease. A vaccine candidate HAV strain can now be collected in appropriately large volumes.
2. An hepatitis A virus found in cynomolgus monkeys appears to be nonpathogenic for humans. Studies with this strain indicate that low-level infections characterized by minimal virus shedding may occur. Thus, this virus could be used for an "infection permissive" vaccine, resulting in the induction of lifelong immunity, no clinical illness, and very little shedding of virus into the environment.
3. A new, rapid, and sensitive diagnostic test to detect hepatitis A is now available. The test uses specific primers and the polymerase chain reaction (PCR) to detect hepatitis A in serum, food, or environmental samples.
4. An oral rabies recombinant vaccine has been developed using raccoon poxvirus as the expression vector. The vaccine confers protection against rabies to a number of wild and domestic animals. Because humans are not a natural host for raccoon poxvirus, other veterinary vaccines have been produced using this expression vector system.
5. Recombinant rabies N protein produced by the baculovirus expression vector system offers a safe substitute for infectious rabies virus now used in the direct immunofluorescent test to diagnose rabies. The protein can be used as an immunogen to produce antisera and as adsorbent material for a specificity control reagent. It may also have value in the development of rabies vaccines.
6. A set of three monoclonal antibodies has been developed that, alone or in combination, react specifically with a protein found in all *Legionella*. These antibodies do not react with bacteria from other genera and can be used as reagents to detect *Legionella* in environmental samples and clinical specimens.
7. Antibodies to *Taenia solium* directed against one of seven diagnostic larval antigens can be detected in serum or cerebrospinal fluid by an immunoblot assay. This test is useful in the diagnosis of active cases of neurological disease caused by the organism.
8. An example of a device available for licensing is one that enables removal of 95% of the waste anesthetic gases associated with small veterinary surgical units. These harmful substances are

removed by a relatively compact cartridge containing activated charcoal connected to a conventional anesthetic administration system. Gases of vaporized anesthetic substances are selectively directed through the activated charcoal without the need for motors, blowers, or other powered devices.

SUMMARY

CDC has made substantial, rapid progress in implementing provisions of the technology transfer legislation. CDC's achievement in this regard is significant, both because of what has been accomplished, and because of the opportunities offered by future activity. Three of CDC's five centers/institutes are active participants in technology transfer. Continuing education of CDC investigators in the technology transfer process, combined with their desire to control and prevent disease and injury offer fertile ground for additional collaborative research and the development of patentable technologies. NIH experts in the areas of patent and license execution have made CDC's task easier with a staff of patent and licensing portfolio managers who coordinate like technologies from participating PHS laboratories for licensing purposes. Electronic bulletin boards, computerized databases, licensing documents, and conferences, both at CDC and OTT, are additional tools being used to expedite the transfer of technology.

The technologies presented today represent a growing commitment by CDC to put into practical use those inventions developed by its scientific and engineering staff to help ensure a better quality of life through more accessible health care products and processes.