EXPANDING THE TECHNOLOGY TRANSFER ACTIVITIES OF THE HEALTH PROTECTION BRANCH OF HEALTH CANADA FOR PUBLIC HEALTH ADVANTAGE: CAN IT BE DONE?

May, 1999

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Health Canada

Mission: *To help the people of Canada maintain and improve their health.*

Operating Principle: *We are committed to excellence in an environment characterized by teamwork, innovation, trust and co-operation, where we treat each other with fairness, dignity and respect.*

BACKGROUND

The mandate of the Health Protection Branch (HPB) of Health Canada is to protect Canadians against current and emerging risks in consumer and industrial products; conduct disease surveillance, prevention and control; and promote safe living and working environments. To fulfil this mandate, HPB regulates the use of new health-related products, food additives, drugs, medical and radiation emitting devices, and new commercial substances that may be released into the environment. HPB accomplishes this role with a staff of approximately 650 research and regulatory scientists and technical support staff. HPB's current total budget is $234 million of which $34 million supports the HPB laboratory function (HPB, March, 1999). Technology transfer of intellectual property developed by HPB personnel for the purposes of business development or commercialization is not, at the moment, a major activity or concern.

Technology transfer, however, is a valid element of Health Canada's overall mandate because it is an important concern of the federal government. As part of their general mandate, all science-based government departments and agencies have to improve the management of S&T activities within the federal government. This includes better management and commercial exploitation of intellectual property developed within government departments and agencies. Specifically the Government of Canada report entitled, ***Science and Technology for the New Century: Summary***, pp. 10-11, March, 1996 states the following "Commitments to Action":

5. The transfer of knowledge and technology is an explicit objective of federal S&T, and departments and agencies will be closely evaluated on their efforts in meeting it.

6. All science-based departments and agencies will develop strategies for promoting partnerships and collaborative S&T arrangements with industry, the provinces, universities, and other stake holders.

Thus Canadian government laboratories, including those of Health Canada, are being directed to increase their interactions or collaborations with external organizations, including the private sector.

In addition to the above mentioned "Commitments to Action", budgetary pressures resulting from Program Review that have reduced government funding of internal departmental research and development (R&D) have forced government laboratories to seek external sources of funding to offset the reductions. Ways in which Canadian government departments have engaged in technology transfer activities to attract or generate external funds include:

- conducting R&D on a fee-for-service basis (with or without matching government funds) (e.g., Agriculture and Agri-Food Canada's Matching Investment Initiative);

- "collaborative R&D projects" in which the partner provides money as their part of the collaborative agreement rather than, or in addition to, comparable scientific or other in-kind resources (e.g., HPB's work with the U.S. Health Effects Institute or Fisheries and Oceans work with the Woods Hole oceanographic research facility);

- licensing government developed intellectual property (IP);

- sale of information products produced by the department (e.g., Environment Canada's specialized weather data sets or Fisheries and Oceans' hydrographic maps);

- leasing unique facilities together with technical support staff (e.g., N.R.C.'s wind tunnel, Atomic Energy of Canada's reactor facilities);

- provision of scientific or technical advice on a consulting basis (e.g., Natural Resources Canada); and

- provision of specialized training (e.g., students doing their graduate thesis work in government laboratories).

Although the transfer to, and ultimate commercialization of HPB technology by the private sector has not been a major activity to date, testing and research conducted in the Health Canada laboratories in support of its mandate have resulted in the development of new technologies and techniques that have the potential for widespread use and application within the health care system. Examples of recent transfers are mould allergens IP to OMEGA and monoclonal antibodies IP to Bio Chem Vaccines.

This report provides officials in the Health Protection Branch with information that will assist them in determining whether there is potential within the Branch for increased technology transfer activities. It also identifies the concerns that HPB personnel have if the Branch expands its technology transfer activities. Recommendations are made on the supporting infrastructure that should be put in place to facilitate any expansion, if such expansion is deemed to be in the best interests of the Canadian public.

Although there are many technology transfer mechanisms, this report focuses on the licensing of HPB developed technology or knowhow, and collaborative R&D alliances with external partners.

Information contained in this report was gathered through a series of interviews with personnel in the Health Protection Branch, the R.C.M.P., the Canadian Food Inspection Agency, Environment Canada, the National Research Council, the U.S. Food and Drug Administration (FDA), the Medicines Control Agency and the Medical Devices Agency in the U.K., and the Center for Disease Control and Prevention (CDC) in the U.S. University technology transfer officials and representatives of Canadian medical/pharmaceutical associations were also contacted. In addition, an extensive review of the literature on technology transfer from government laboratories to industry was undertaken. Web-sites of pertinent organizations such as the FDA (www.fda.gov), CDC (www.cdc.gov), the National Institutes of Health (www.nih.gov), and the Medical Research Council (www.mrc.gc.ca) were also visited.

Definitions

The following definitions are used in this report:

Technology transfer is the managed process of transferring knowledge, expertise or hardware from an originator to an adopter in an organization that can maximize its value to the ultimate end-user. (Clarke, 1999)

"Commercialization" (of technology) is that subset of technology transfer activities that result in the development of new products, processes or services that are sold in the market place. (Keith Belinko, N.R.C.)

Conflict of interest is a set of conditions in which professional judgement concerning a primary consideration is unduly influenced by a secondary consideration. (Thomson, 1993)

REVIEW OF TECHNOLOGY TRANSFER LITERATURE

"*We must make every effort to improve our ability to transfer new knowledge from the (laboratory) bench and bedside to the community and market place*" - Henry Friesen, President of the Medical Research Council of Canada, 1995

Information in this section was gathered through a review of Canadian and U.S. government to industry technology transfer/commercialization literature, technology transfer literature associated with the health/medical field and Internet searches of key government sites.

Types of Government Technology Transfer Programs

Government technology transfer programs can be divided into two broad categories depending on the mission or mandate of the department or agency: Technology Spin-off Programs, and Technology Utilization Programs (Mock, et al, 1993).

Technology Spin-Off Program

A "technology spin-off" type technology transfer program tends to be associated with government laboratories involved in health, environmental or defence type research where the primary results of the research activities are targeted at fulfilling the department's own regulatory or policy mandate, or the needs of an internal customer. Only some of the technology, know-how or expertise developed in the laboratory may be appropriate for transfer to the private sector for commercialization. If it is, it may be used for purposes other than that for which it was originally created.

Government departments with a "spin-off" approach to technology transfer should have in place a system by which they can quickly identify "dual use" technology or research results that will support not only their internal mandate or client but also the requirements of an external adopter.

The primary mission of the department or agency can be met even if technology transfer efforts are ineffective or sporadic.

Technology Utilization Program

In sharp contrast, a "technology utilization" type technology transfer program is associated with a government department or agency whose primary mission is to develop or improve technology that is to be used in the private or non-government sector. The principal mission of the laboratory can only be achieved if technology transfer takes place successfully. Examples of government laboratories that fall into this category are those conducting R&D in agriculture, aquaculture, natural resource management, energy conservation and manufacturing processes. Atomic Energy of Canada, the Canada Centre for Remote Sensing of Natural Resources Canada, the National Research Council and most of Agriculture and Agri-Food Canada are in this category.

Government departments with this technology transfer orientation must have considerable industrial or other external client input into setting their R&D agendas if the results of their work are to be compatible with the needs of industry or their external clients.

Health Protection Branch's R&D clearly falls into the spin-off category of technology transfer activities as their primary mandate and reason for conducting R&D is to protect the health and safety of Canadians, not to develop technology for transfer to the private sector.

This does not, however, in anyway exempt HPB from conducting whatever technology transfer activities they do engage in, in an effective and efficient manner to the benefit of the Canadian public.

Fit with Mandate

In earlier studies of technology transfer from Canadian and foreign government laboratories, managers emphasized that any technology transfer activities undertaken should fit or support, directly or indirectly, the mandate of their government department or agency. The contract work they do for outsiders or the collaborative alliances in which they become involved had to support their operational mandate, otherwise they would not take on the outside activity (Clarke, 1996b).

For example, additional revenues for the laboratory were not generally considered to be sufficient reason to engage in collaborative alliances. Environment Canada managers said they are always on the alert for "mission drift" (i.e., projects pursued only for financial reasons).

Government business development activities also have to fit or support the departmental mandate. In his review of business development activities in government laboratories in England and Holland, Clarke (1997) found that this was a common theme. Support could include projects that on the surface had nothing to do with the departmental mandate, but that enhanced the basic skills of personnel in performing duties that were directly associated with the mandate. For example one military laboratory was working with the financial community on improved encryption processes for transmitting financial information/data between banks. This work was considered to add to the skill base of their people when working on military encryption problems.

Value of Technology Transfer Activities

The value or impact of technology transfer activities can be determined from two different perspectives; value of technology transfer activities in support of "Public Good" objectives; and the more commercial/financial impact of technology transfer activities to the government originator, and the private sector adopter. For completeness, the value from all perspectives are described below.

The following is drawn from an extensive review of literature on technology transfer (Clarke, 1996a) and the comments of Canadian government scientists and managers who, in the past two years, have attended Stargate Consultants Limited workshops on the commercialization of intellectual property from Canadian government laboratories to industry. It should be noted that no employee of the Health Protection Branch of Health Canada has attended these workshops. The comments reflect the views of the workshop participants from Agriculture and Agri-Food Canada, the Canada Centre for Remote Sensing, the Canadian Food Inspection Agency, Environment Canada and the National Research Council of Canada. (See Appendix One for details of workshop)

To the Public

The majority of the R&D that government laboratories conduct is not intended for commercialization; it is intended for the Public Good. The objectives of the R&D are to enable the research staff to provide scientific information to senior management, policy makers, government ministers, business and the general public.

Workshop participants identified some of the benefits of technology transfer resulting from Public Good R&D as:

- effective regulations that demonstrably improve quality of air, water, food, and health of the public;
- provision of advice to the public on health or environmental issues of concern to them;
- creating awareness of health and environmental factors that effect the quality of life enjoyed by the public;
- development of more environment-friendly processes and products; and
- cost-savings to other government departments or agencies.

To the Government Originator

Workshop participants identified the following as some of the benefits of successful technology transfer to the private sector. These include benefits to the originating department, the scientific personnel and the government in general:

- improved technical capability to solve problems, improve services or develop effective regulations (e.g., reverse technology transfer from external partners to government personnel);
- in-kind resources from collaborative partners;
- new revenues to replace declining and/or inadequate A-base funding allocations;
- increased recognition and credibility from business and the general public;
- new products that the department can use in its operations (e.g., test equipment);
- better data for decision making;
- better understanding of industrial user needs and requirements;
- increased national and international reputations;

- satisfaction from seeing the results of their work improve the health and well-being of Canadians;
- increased tax revenues resulting from increased job and wealth creation;
- improved S&T balance of payments as a result of stronger international sales; and
- a more focussed approach to government research.

Chen, Jr. (1992) describes the proactive technology transfer activities of the American National Institutes of Health (NIH) which provides technology transfer services to Public Health Service (PHS) agencies such as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). One of the key responsibilities of NIH's Office of Technology Transfer is to inform and advise commercial firms about opportunities to collaborate with PHS scientists. Chen states that in addition to expediting public access to government technology developments, there are a number of mutual benefits of collaboration for PHS agencies and commercial firms. He lists these as (p. 216):

Public Health Service Agencies

- improved access to industry scientists and facilities;
- accelerated interaction with industry to transfer basic research findings to the commercial development process; and
- sharing of royalty income for both individual inventors and PHS agencies.

Commercial Firms

- improved access to PHS scientists and facilities;
- better access to expertise related to research results and inventions;
- options to exclusive licenses on inventions made under Cooperative Research and Development Agreements (CRADA's); and
- profitable new products and processes [presumably that benefit the health of Americans].

Another potential benefit of industrial collaboration is the encouragement to patent government developed technologies that can result in licensing revenues. Blumenthal and Causino (1993) found that researchers in the U.S. National Institutes of Health, with industry relationships "are more likely to patent their discoveries than are colleagues without such relationships".

To the Private Sector Adopter

The following are the possible benefits to industry of successful technology transfer from government laboratories to industry (Spann et al., 1993, Roessner, 1993, Clarke, MOD One, 1999):

- cost savings and lessening of technical risks through collaboration;
- productivity gains;
- market share or competitive advantage gains;
- increased number of new products;
- new commercial sales and customers;
- penetration of new international markets;
- jobs created or saved;
- technical problems solved, or dead-ends avoided;
- providing a marketing advantage (national and international) of credibility and legitimacy especially to smaller Canadian firms through technical validation of the originating technology;
- being able to access a source of relatively cheaper R&D;
- assisting in the identification of new markets created by new regulations;
- assisting firms to get their products to market faster;
- provision of technical or scientific training to industrial personnel; and

- supporting the incubation period of new start-up firms.

Possible Difficulties Associated with Technology Transfer

While technology transfer from government laboratories to industry is a desired activity, some difficulties can be associated with it. These difficulties can be divided into two broad categories: process problems and conflict of interest issues.

Process Problems

Process problems are generally associated with the scientists' attitudes to technology transfer and the way in which the government department operates its technology transfer activities. These process problems can become considerable barriers to successful technology transfer if they are not eliminated or resolved. Some of the problems that have been identified by Canadian government scientific personnel in other departments and agencies are (Clarke, 1999):

- researchers don't think about possible commercial applications at the beginning of a research project - too much of an academic attitude within the laboratory;
- government scientists not considering the implications of publishing on patent activities;
- having to work with a bureaucratic technology transfer process;
- too many confusing rules concerned with IP and technology transfer;
- government financial mechanisms are not attuned to working with the private sector;
- inequitable sharing of revenues resulting from IP licensing fees;
- deciding who constitutes the "innovation team" when determining who gets what percentage of IP royalty fees;
- lack of adequate reward and/or recognition for technology transfer activities (i.e., lack of recognition of technology transfer activities during promotion and salary reviews);

- overly aggressive IP ownership positions that jeopardize collaborative arrangements;

- too narrow a definition of the activities that support the departmental mandate that results in restricting scientists from pursuing commercial opportunities; and

- lack of adequate resources assigned to the technology transfer activities to support, for example, marketing, or provision of advice to bench level scientists on IP management.

Conflict of Interest Issues

> "*The right to search for truth implies also a duty: one must not conceal any part of what one has recognized to be true*" - Albert Einstein

Conflict of interest issues are more prominent today as government laboratories increase their involvement with the private sector. This is also an issue in academia, especially in the health/medical field. It is no longer possible to avoid conflict of interest; it has to be managed in an open and honest manner. As Frankel (1996) notes, "The aim [of guidelines] is not necessarily to eliminate such conflicts, but rather to manage them so that they do not unduly influence, or appear to influence, a researcher's judgement".

Thomson (1993) defines conflict of interest as follows:

> A conflict of interest is a set of conditions in which professional judgement concerning a primary consideration is unduly influenced by a secondary consideration.

The secondary consideration may be valid in its own right; it is the relative weight given the secondary consideration in professional decisions which can be the source of problems. The objective of managing conflict of interest is not to eliminate the secondary considerations, but to prevent the secondary considerations from dominating or appearing to dominate the primary considerations during the professional decision-making process (e.g., favouring the research results of a friend rather than challenging them or downplaying negative results unfavourable to a research sponsor).

Blumenthal (1996) states that "conflicts of interest are conditions, not behaviours". He further states that conflicts can exist without causing adverse effects, or any effect at all. He argues, however, that in clinical research neither the investigator nor the institution should have a significant financial interest in the outcome (e.g., modest, non-recurring consulting payments or ownership of a small number of shares in a publicly traded company would be permissible). While this might be appropriate for academic researchers it is questionable whether even modest consulting payments would be appropriate for government scientists engaged in regulatory work. Such consulting arrangements are not allowed, for example, in the U.S. Food and Drug Administration although they are in the National Institutes of Health.

In an earlier study, Blumenthal and Causino (1993) stated that the apparently adverse impacts of industrial funding on university research in the life sciences must be balanced against the benefits of such funding.. They identified the adverse impacts as restrictions on communications (e.g., withholding or delaying the release of research results sometimes beyond the time needed to obtain patent protection), and redirection of university research into more applied, commercially oriented directions (e.g., shorter-term research). They describe the benefits as "potentially increasing the creativity and productivity of some investigators, in encouraging technology transfer, and thereby promoting economic growth and public health".

Blumenthal (1996) concludes that, in the areas of clinical research with patients and use of graduate students who need to publish, conflict of interest (e.g., withholding or unnecessarily delaying dissemination of research results) should not be tolerated. He goes on to say that in other areas, even though conflicts of interest are real and consequential, they are tolerable as long as they are managed to contain the risks while preserving the benefits from such university-industry arrangements.

Rabino (1998) notes that a study of NIH scientists involved in CRADAs by the Office of Technology Assessment (1995) indicated a slight decline in publication rates thus "lending credence" to fears about industrial support reducing the free flow of scientific results. It takes time to prepare and file for patent protection and if one wants patent protection in Europe, any disclosure, of any form, will preclude such protection if it takes place prior to filing. In the U.S. and Canada, there is a one year grace period to file for patent protection. These patenting requirements usually result in requests for delays in publication from the commercializing organization.

The following are some of the actual or perceived conflict of interest issues associated with intellectual property management that Canadian government scientists in other government departments and agencies have identified (Clarke, 1999):

- public perception of "public good" versus "making money";
- adopting good business practices versus being seen to be open and fair;

- government employees actively assisting an adopting firm market the end-product;
- dealing with external access to information requests involving commercially confidential information;
- maintaining "secrecy" in a collaborative work environment that might result in conflict with colleagues (i.e., not disclosing technical details about the IP in an open research environment);
- inventor's inappropriate involvement in the negotiation of licence and royalty fees (e.g., insistence on high fees that may affect choice of licensee);
- inventor's involvement in determining IP ownership issues involving an external contract that makes use of his/her IP as background;
- personnel pursuing the development of technology with commercial potential to the detriment of work in support of internal mandate (i.e., public good research with no commercial potential); and
- personnel filing for patents just to have them on their C.V.s.

It should be noted that issues such as the integrity of the research or the accurate reporting of the results were not mentioned. These issues appear to be more prevalent in the health/medical sciences than they are in the physical sciences.

Korenman (1993) in his review of conflicts of interest and the commercialization of academic research outlines the following problems that might occur:

- loss of objectivity resulting in biased performance or reporting of research;
- a reordering of research priorities favouring more applied research at the expense of basic; and
- a reduction in the free flow of information among researchers to protect potentially valuable IP.

He notes that, "conflicts of interest are inevitable and increasing technology transfer will result in a growing number of instances of conflict". He considers that policies should be in place to reduce the risks of the above problems occurring.

Although the problems identified by Korenman refer to academia, they have also been identified as problems for Canadian government science-based departments and agencies (Clarke and Reavley, 1998).

Industry funding of biomedical or health related research also appears to promote conflict of interest issues. "Whenever an industry funds research that is directly related to its product, there is concern that conflict of interest may influence the research in some way" (Barnes and Bero, 1996). In making this statement they quote the works of Bond, 1991, Hilman et al, 1991, Blank, 1992, Rothman, 1993, and Chren, 1994. The concern is that the sponsor might apply overt or covert pressure on the investigator to produce results that will be favourable. Self-censorship might compel the researchers to publish positive findings or at least ones that are not damaging to their sponsors (Hillman et al, 1991). Fear of having future funding cut-off if they publish negative findings may also influence the researchers' decision to publish.

Barnes and Bero believe that these concerns about conflict of interest are justified. They note that the asbestos, lead and tobacco industries have a history of suppressing or denying the validity of studies showing the hazards of their products. From their review of industrial sponsorships of research, Barnes and Bero state that there is, "compelling evidence that industry funding may influence the type of research conducted and the conclusions drawn from the data".

Another area of conflict of interest unique to the medical/health field is the acceptance of research funds from tobacco companies, for any purposes. In Britain, for example, a policy has been initiated by the "Cancer Research Campaign", a medical charity, that "rules out CRC funding for scientists who work in close proximity to, or share equipment with, those who are funded by the tobacco industry". Other UK medical charities also do not fund scientists who receive tobacco money (Firn, 1999). The reason for these prohibitions are to prevent the tobacco firms from "buying respectability by association with scientific research". The U.S.CDC in its guidelines for collaboration with the private sector does not specifically name tobacco firms as a prohibited partner but does state that a factor to be used in determining the suitability of a partner is, "Do the organization's products or services harm the public's health when used as intended?" Presumably, this would exclude tobacco companies. The guideline goes on to say, "By working with the CDC, organizations producing harmful products or delivering harmful services can gain a measure of respectability". The CDC wants to avoid this.

In the U.S. there is controversy about the pricing policies of end-products of companies that obtain their technology from government laboratories. There is growing pressure for a "reasonable

pricing" clause to be included in CRADAs for any resulting biomedical products. Adoption of this clause is being fought by the biotechnology industries and the Association of University Technology Managers (AUTM). AUTM president Karen Hersey says that "a pricing clause would cause companies to shun agreements with the NIH and other agencies, leaving valuable government research sitting on the shelf" (Wadman, 1998).

A form of conflict of interest that is unique to government-to-industry technology transfer involves the following situation. A laboratory in a government department whose main mandate is to regulate an industry develops a new commercially viable technology. It is transferred out to a private sector firm under a royalty bearing license, for further development. Before the new product can be sold to the public it must be evaluated by the department that developed the original technology in the first place. The department stands to receive intellectual property royalty payments from the successful marketing of the product. Thus the department has a financial interest in the outcome of the evaluation and approval of the product for sale. The concern is how to manage this conflict and still encourage such transfers in the future.

If conflict of interest situations are not addressed, serious problems can arise. A HPB Working Group examining conflict of interest issues in the HPB has listed the following as the consequences of ignoring conflict of interest issues (HPB, April, 1999):

- loss of public confidence in the Health Protection Branch, its employees, and the Government of Canada;
- loss of partnerships or alliances with other research institutions or private sector organizations;
- inaccurate media coverage; and
- disciplinary action, or criminal prosecution of employees.

Possible Solutions to the Identified Problems

Process Solutions

The following solutions have been recommended by Canadian government scientists as a way to overcome the process problems in technology transfer noted earlier:

- provide training for government scientists in technology transfer and IP management;

- provide government staff with clear to read/understand technology transfer and IP policies and procedures;

- provide adequate assistance for the government inventors/innovators in completing invention disclosure or technology marketing documents (i.e., IP disclosure-friendly procedures);

- acquire financial mechanisms that provide more flexibility in working with the private sector (e.g., Specified Purpose Account, Respending Authority, etc.);

- senior management and the business development office establish a procedure to guide in the sharing of IP revenues among the innovation team in line with the 1993 Treasury Board Policy on Rewards to Inventors and Innovators;

- incorporate technology transfer/business development activities explicitly in the performance appraisal of scientific staff, where appropriate;

- take a more realistic approach to ownership of IP resulting from collaborative R&D alliances so as not to scare off potential collaborators; and

- assign adequate resources to the technology transfer/business development function so that marketing activities and advice to bench level scientists will be sufficient to meet the needs of the department;

Possible Solutions to Conflict of Interest

Some government organizations have developed conflict of interest guidelines or guidelines to govern collaborative alliances with the private sector to avoid real or apparent conflicts of interest in the transfer of technology or in business dealings with the private sector.

Environment Canada, for example, has drafted their "National Policy for Commercialization in Environment Canada: Working with the Marketplace" to guide its employees in their dealings with the private sector. The CDC has developed a document entitled, "Guidance for Collaboration with the Private Sector" to assist their employees in determining the suitability and viability of potential collaborations (Appendix Two).

The Working Group on Conflict of Interest in Intellectual Property and Commercialization of the Medical Research Council has prepared a draft report entitled, "Guidelines for the Commercialization of Medical Research" (MRC, 1996) that acknowledges the benefits of commercialization while at the same time sets guidelines to ensure the reputation of MRC and the integrity of its peer review system are not compromised.

Participants in Stargate Consultants government-to-industry commercialization workshop have suggested the following solutions to reduce or more effectively manage conflict of interest issues involving the management of intellectual property:

- more IP issues/management training for the scientific staff;
- having a consistent IP implementation policy that reflects the current climate;
- greater involvement of the Business Development Office in decision-making;
- final decision of royalty fees and distribution being made by someone other than the inventor (i.e., adoption of a uniform policy on rewards);
- having clear administrative and procedural rules that cover things such as Access to Information requests; and
- decisions on what to patent not just left to the inventor.

The HPB Working Group dealing with conflict of interest issues have suggested the following as ways of resolving conflict of interest situations (HPB, April, 1999):

- Avoidance - take measures to avoid the conflict, or even the appearance of conflict, completely;
- Transparency - ensure everyone is aware of the details of the external arrangement;
- Referral - refer a conflict of interest situation to an independent individual or group for a decision; and
- Independent advice - acquire advice on how to proceed with a potential conflict of interest situation from an independent source.

Best Practices in Government to Industry Technology Transfer

In an extensive review of the literature concerned with technology transfer from government laboratories to industry, Clarke (1996a) identified factors or practices that promote the efficient transfer of technology. In a follow-up study, Clarke (1996b) identified the factors/actions that Canadian government scientists and engineers consider inhibit technology transfer from Canadian government laboratories. The complete list from both reports is in Appendix Three. The following are positive factors or practices that specifically relate to this study:

- high and middle level managerial support for the technology transfer activity;
- organization of the technology transfer activity is based within a senior level organizational unit;
- technology transfer is recognized within the government department as a legitimate, valued activity;
- adequate level of resources have been assigned to support the technology transfer activity;
- low level of government red-tape and bureaucratic rules;
- strong intrapreneurial attitudes among the federal government personnel;
- existence of a royalty based incentive system within the government laboratory;
- existence of an inventor-friendly disclosure and patent system;
- a suitable reward and incentive system is in place to motivate and encourage the involvement of the technical staff, and other key contributors to the commercialization and transfer process;
- targeted or highly focussed marketing procedures are used to identify and approach prospective adopters;
- adequate funds are made available to support government personnel travelling to industrial sites and conferences, and for sabbatical leaves in industry;

- all means are used to make prospective adopters/collaborators aware of what is going on in the government laboratory and the laboratory personnel's willingness to work with industry;

- bench level scientists and engineers are provided with training in the technology transfer area; and

- the technology developer is encouraged to work with the adopter and provide on-going technical assistance.

A major determinant of successful technology transfer reported in most, if not all technology transfer literature, is the importance and efficiency of person-to-person relationships between the government technology developer(s) and the adopting organization's scientists or engineers during the transfer process. The government developer's willingness to cooperate and work with the adopting organization's personnel is critical to the success of the transfer of government developed technology or to collaborative R&D alliances.

The lack of these positive actions, factors or relationships usually results in the technology transfer activities being ineffective or haphazard.

Summary of Technology Transfer Literature

Government laboratories around the world, including Canada's, are becoming more involved with their private sectors through technology transfer activities. This is being done with the encouragement of their governments (OECD, 1989, Government of Canada, 1996). Increased technology transfer activities bring both benefits to the country and the specific laboratory, as well as increased administrative headaches in the form of IP ownership issues, allocation of appropriate rewards and recognition of technology transfer personnel, selection of appropriate research partners/licensees and avoidance of real or perceived conflicts of interest.

Among the benefits that Canadian laboratories can receive as a result of successful technology transfer activities are increased revenues to offset A-base reductions, improved technical capability, increased recognition and credibility from business and the general public and satisfaction in seeing their work improve the health and well-being of Canadians. Collaborative R&D alliances with external organizations is seen as an important way of keeping laboratory staff up-to-date with the latest scientific advances.

Previous studies into government to industry technology transfer have clearly identified factors and actions that will promote technology transfer. Organizations that are serious about promoting technology transfer must make sure that the positive factors are present in their organization and that supportive actions are taken.

As Blumenthal (1996) notes, not all conflict of interest situations result in any negative effects. The existence of appropriate guidelines and policies allows potential conflict of interest situations to be managed to the benefit of all concerned.

None of the literature reviewed to-date states that government laboratories must avoid conflict of interest issues at all costs. The literature does, however, identify the various forms that conflict of interest can take when dealing with the private sector. Uppermost is the concern that the integrity of research results and conclusions, the credibility of the organization, and the dissemination of research results to the public and the scientific community in a timely manner be maintained, and not be subservient to financial or other interests.

RESULTS OF INTERVIEWS WITH PERSONNEL IN OTHER ORGANIZATIONS

Telephone and personal interviews were held with sixteen officials in various organizations associated with health or medical research activities and the regulatory side of health protection in Canada, the U.K. and the U.S.

Canadian Associations

Only two associations responded to our request for information. An industrial representative of Canada's Research-based Pharmaceutical Companies did not consider that HPB would be a source of information in the pharmaceutical area, but might be in the biological area. He said that members would go to U.S. firms for testing as the U.S. firms know the regulations and guidelines for other countries. The need to be FDA compliant was also a reason to go to the U.S.

This industrial representative felt that HPB might lose the confidence of the private sector if they were to work on behalf of a company. "Industry needs to have confidence in them and their neutrality". He felt that if HPB was to do work on behalf of industry it should be a very open process.

A representative of the Medical Devices Canada association questioned whether HPB could pay the salaries necessary to attract top researchers. Their members tend to approach universities, centres of excellence or hospital researchers as a source of external technology.

When asked whether HPB could play a greater role in assisting members solve technical or scientific problems, the representative stated that he did not know what HPB had to offer and was not sure of the quality of the work.

He was particularly concerned about the situation where HPB might be in a relationship with a company with whom it jointly develops a technology, which then has to be approved by HPB before it can be sold to the public.

These precautionary statements are in contrast to that of a president of a small Canadian biotechnology firm. During the 1999 Federal Partners in Technology Transfer Conference held in Ottawa, a question was asked whether government departments that have a regulatory role should work with or get involved in collaborative R&D projects with the private sector and appear to be in a conflict of interest situation. John Cross, President of Philom Bios in Saskatoon, responded that there was nothing wrong with government regulatory departments working with the private sector. "If one never has a conflict of interest, you ain't doing things right".

Canadian University Technology Transfer Officers

Two university technology transfer officers who handle the health/biotechnology area for their universities were interviewed. Although this was a small sample, their views were virtually the same.

They stated that the way they handle potential conflict of interest issues is to be as open about them as possible. Conflict of interest generally does not occur on a straightforward license to a firm, but can appear to occur when companies are created as a result of university developed technology and there is an on-going relationship between the originating professor and the firm (i.e., the professor either owns shares in, or is employed by the firm in some research capacity). The university may also be a shareholder in the firm. To avoid the appearance of conflict of interest, the univeristies make these arrangements public.

The one area where serious questions may be raised about real conflict of interest is the involvement of graduate students on industrially funded projects. If there are to be restrictions on publications resulting from the work, it may be inappropriate for graduate students to work on the project as they must publish to receive their degrees and earn their reputations as researchers.

One interviewee emphasized the importance of a good relationship between the technology transfer officer and the scientist/engineers and said that this can only be accomplished by being close to the researchers. This interviewee stated that the technology transfer officer must have a scientific or technical background, otherwise the researchers will have a hard time trusting someone who cannot grasp what the technology is all about. "You would not want to let your stereotypical MBA loose in this area". Both interviewees had advanced degrees in biology or related disciplines.

The interviewees believed that conflict of interest issues could be effectively managed.

U.S. Food and Drug Administration

> Under the Federal Technology Transfer Act of 1986, technology transfer, consistent with mission responsibilities, is also a responsibility of **each** laboratory science and engineering professional.

The following information was obtained from telephone interviews with key officials associated with technology transfer in the U.S. Food and Drug Administration. The FDA has approximately 9,000 employees and a budget of just under one billion dollars. Its research budget has been reduced considerably in the past few years. The FDA representative said "it has been very painful times for our researchers".

Technology transfer, including collaborative R&D, (CRADAs) did not really take off in the FDA until the passage of the Federal Technology Transfer Act of 1986. Once passed, the FDA formed an agency-wide working group comprising representatives from each of their research centres to develop procedures to facilitate technology transfer. An important consideration of the 1986 Act was that it forced the FDA to engage in technology transfer; there was no opting out. "If there had not been legislation, technology transfer/collaborations would have been truly very difficult or impossible."

The working group developed a model CRADA agreement and a formal invention reporting system for pursuing patent protection. They then briefed the scientists and the Directors and staff in each of the Centres through 1988/89.

The FDA's process for identifying promising technology for exploitation is as follows. If scientists think they have something of interest, they will meet with the local Technology Transfer Contact in their Center. The Contact assists the scientist in filling out the appropriate disclosure form. When completed, the form is forwarded to the Technology Transfer Coordinator in HQ who reviews the submission. If she feels the submission has merit, she forwards it to the Office of Technology Transfer of the National Institutes of Health (NIH) which provides an intellectual property management service to the FDA.

In order to avoid future problems, the FDA tries to have the inventors decide among themselves what their share of any subsequent royalties will be if the patent is successfully licensed.

At the start of the FDA's serious technology transfer activities, people who had been with the Agency for many years viewed technology transfer as a deviation, regarded it as wrong. The younger scientists, on the other hand, saw technology transfer as an opportunity for them to receive recognition for their research accomplishments.

The younger scientists saw technology transfer activities as:

- giving them added experience;
- giving them greater exposure to the outside world; and
- helping them to keep up-to-date.

Obtaining additional funding was not considered very important at that time.

The FDA considers that involvement with outside projects helps to keep its people up-to-date, which supports its public good mandate. This is one of the bases on which they justify collaborative R&D alliances.

The FDA feels that it has two options when it comes to collaborative activities; it either allows its researchers to be involved in collaborative R&D activities and thus retains its personnel, or discourages collaborative work because of the drain on resources for the Agency's principal work and runs the risk of losing its best people. For the most part, managers of the Centres have opted to allow collaborative work.

The FDA has an in-depth process to determine the suitability of being involved in a collaborative arrangement with an outside organization (Appendix Four). This process ensures to the best of its ability that financial conflict of interest situations do not occur, and that it does not collaborate with an organization that has a poor track record of supporting the health of Americans (e.g., tobacco companies). Senior line management and officials in an Ethics Office are involved in vetting proposals. The FDA also publish various guidelines for working with outside organizations on its web-site.

Even after ten years, the FDA HQ representative said that technology transfer is only into their culture "to some extent". "It is still somewhat of a stepchild more than it is into the culture". A representative of the Center for Devices and Radiological Health (CDRH) was more positive. She considered that the culture had turned around and that their scientists, especially the younger ones, did consider technology transfer to be a valid part of their mandate.

The major driver of technology transfer, especially CRADAs, has been cutbacks in research budgets. Another FDA representative said that the research budget in the Center for Biologics Evaluation and Research (CBER) had gone from $22 million to $6 million in the past few years. Because of these cuts, researchers had to apply for grants and look for partners with money.

Over the past few years, CRADAs have been promoted to staff as a means of leveraging assets. In addition, any monies from licensing technologies are returned to the laboratory from which the technology emerged.

The FDA has had to deal with the situation of having to approve one of its own technologies for sale to the public. It views the approval of FDA originated technology as not its technology but that of the licensee. The licensee receives no special treatment; if anything the licensee would receive greater scrutiny. The FDA interviewee said that there is no FDA endorsement of the technology when it hits the reviewer's desk. While the FDA "inventor" is not part of the official review and approval process, his/her advice might be requested regarding the licensee's development of the technology.

The FDA's main line of defence against the charge of conflict of interest is to have everything out in the open. It outlines its processes on its web-site and lists the organizations, including the names of individual firms, with whom it had CRADAs.

"We say up front that we cannot totally resolve an appearance of conflict of interest, but we will do everything we can to manage it. If there is an actual conflict of interest then that is the end of the discussion". FDA researchers, unlike NIH researchers, cannot undertake outside consulting projects from firms, nor can they accept free trips to conferences.

Researchers can be adjunct professors but cannot be paid for their work. Instead, the university credits the FDA with teaching hours that people other than the adjunct professor, can tap into. Both the FDA and the university benefit, but not the individual professor. This also saves the FDA training money.

At the moment, the FDA gets approximately $400 thousand in IP royalty payments, depending on the performance of their licensees. They expect to get over a $ 1 million in the next few years. At the moment, they are only offsetting their IP patenting and maintenance costs.

The FDA, like other U.S. government agencies relies to a large extent on the awards of the Federal Laboratory Consortium, an organization established to assist the transfer of U.S. government technology to industry, for recognition of the technology transfer activities of its staff.

When asked what type of organizations the FDA would avoid in a collaborative arrangement, the FDA HQ representative said they would be very careful about becoming involved with a "virtual company" whose resource base might be very fluid. They would also avoid a firm that had been very critical of the regulatory role of the FDA as there would be no basis of trust. The CBER representative said they would avoid product-specific research that would compromise their ability to review the product. As they are thin on scientific expertise in some areas, they would not want to be in the position where the only person capable of reviewing a product was also the person who developed the original technology. CBER would avoid working with a firm that has a history of abusing press releases about its collaborative activities with CBER (e.g., claiming CBER endorses their product).

CBER scientists are engaged in regulatory review as well as research; there is no separation of staff. CBER prefers to work on projects that will affect a class of products, rather than one specific product.

Under its IP rules, the FDA only gives non-exclusive licenses to in-house developed technology, however it can give exclusive licenses to CRADA partners.

The FDA HQ representative said that to be successful in technology transfer, you must build trust with the scientists. She views them as her clients. "In the end, scientists are very important to me".

The CBER representative strongly believes the benefits of technology transfer outweigh any administrative headaches. Among the benefits mentioned were:

- the ability to do research CBER might not otherwise be able to do because of lack of budget;
- the ability to maintain expertise in particular fields;
- scientists receive recognition (higher profile) from the scientific community; and
- people learn new things (i.e., spin-back technology transfer).

The CBER representative was quite adamant that the Center had to do research in order to carry out its regulatory role effectively. He felt that regulators could not become totally familiar with a scientific area by just reading journals and attending conferences.

The CDRH representative stated that working on collaborative projects allows them to see new technology "before it comes in the door".

CBER had approximately ten patent disclosures last year; earned about $200 thousand in IP royalties, and brought in about $200 thousand from five CRADA agreements.

CBER does not have a business development office. Its researchers are instrumental in looking for collaborative opportunities. They advertise their willingness to collaborate through conference attendance and participation at NIH Research Days where they have poster sessions and give presentations. The FDA also has a science forum conference where personnel discuss their research.

The representative from the Center for Food Safety and Applied Nutrition said that they had had only two IP disclosures in the past three years.

Under the U.S. government's standard IP reward policy, FDA researchers can earn 15% of royalties up to a maximum of $150 thousand per year.

It appears that although the FDA has put in place the procedures to support a very proactive technology transfer program, its technology transfer activities, especially identifying and licensing of FDA technology, are more passive and reactive than proactive.

Centers for Disease Control and Prevention

Like the FDA, the CDC has been effectively conducting technology transfer for approximately ten years. The CDC representative said that most of their scientists are not against technology transfer activities, but will fight them if they get in the way of what they want to do. They have enough job experience, however, to understand that one needs a patent to move intellectual property into the public sector.

Technology transfer is actively promoted through top-down support, mentoring by senior managers, and through training workshops. Seeing money coming into the laboratories as a result of CRADAs has also brought people on-side. Originally, CDC's biggest barrier to technology transfer was getting scientists to fill out disclosure forms as they were viewed as just another bureaucratic form.

In 1998, the CDC received $1.5 million in CRADA revenues and $250 thousand in IP royalties. At present, on its web-site, CDC lists 21 technologies available for licensing, on a nonexclusive basis. As noted earlier, the CDC also "publishes" some of its technology transfer policies on its web-site (Appendix Two).

CDC does not advertise CRADA opportunities on its web-site. Its main marketing thrust is through its scientists attending trade or scientific conferences.

CDC has an "Ethics Officer" to ensure real conflict of interest situations do not occur.

CDC considers the major benefit of technology transfer activities to be:

- seeing its science moving from the lab to the market place;
- obtaining additional funding to leverage projects;
- obtaining scientific information from partners; and
- researchers being able to work on projects of their own interest, which helps CDC retain good people.

Although no one at the National Institutes of Health was contacted during this study, its web-site indicates that NIH earned approximately $39.5 million last year from licensing revenues and expect to reach $40 million this year.

U.K. Regulatory Agencies

The British model is to have a total organizational separation between R&D and regulatory activities. Representatives of the Medicines Control Agency (MCA) and the Medical Devices Agency (MDA), said that they do not conduct any R&D but rely on others for any R&D input. The MCA, for example, uses independent laboratories, such as the Laboratory of the Government Chemist.

Both agencies have to be careful that they do not refer any technology they have in for review back to the originating laboratory. Under European Union rules, firms do not have to tell them where they obtained the technology that underlies their products. It is possible that a company might have obtained the base technology from an independent laboratory that the government regulatory agency would usually rely on for advice. The agencies count on the independent laboratory to advise them of any such conflicts of interest. This reliance on external R&D is in sharp contrast with the FDA.

RESULTS OF INTERVIEWS WITH HEALTH PROTECTION BRANCH PERSONNEL

Personal or telephone interviews were held with over 31 administrative or scientific personnel in the Health Protection Branch. Because of the limited number of interviewees and the promise of confidentiality that was given, their names will not form part of this report.

In addition, the various research groups in the directorates of HPB were invited to send bench level personnel to a focus group held in Ottawa. This resulted in additional input from five HPB bench level personnel who had not been interviewed previously.

While a semi-structured interview guide was used for these interviews (Appendix Five) additional probing questions were asked as circumstances permitted.

Feasibility of Expanding HPB's Technology Transfer Activities

Yes, but...

The determination of the feasibility of expanding the technology transfer activities is the primary objective of this study. The comment in the box above sums up the majority of the responses to the question of whether it is feasible to expand HPB's technology transfer activities.

The vast majority of the HPB personnel interviewed considered that there were legitimate opportunities to expand the technology transfer activities of the Health Protection Branch but all qualified their responses. They stated that actions must be taken by senior management to deal with some important issues that exist within the HPB before such attempts to expand proceed. One person said that he thought that there was a lot more work done in HPB that could be transferred successfully if the appropriate facilitating administrative mechanisms were in place. Another believed that HPB was missing an opportunity if it did not get on board with working with the private sector.

Several respondents considered it to be absolutely necessary to be involved in attracting or generating new revenues if their laboratories were to survive. The Winnipeg facility of the Laboratory Centre for Disease Control (LCDC) was mentioned in particular by several interviewees.

Only one respondent said that "technology transfer is not applicable to the Health Protection Branch". But even that person could identify areas where his research team could have greater involvement in technology transfer.

Among the areas where interviewees and focus group participants believed that HPB had unique expertise or facilities that could be employed in expanding HPB's technology transfer activities are:

- development of new analytical methods in the medical device/radiation areas such as development of a chamber to provide measured RF doses;
- vaccines,
- xeno transplants;
- genetic markers for nutrition based diseases;
- study into the effectiveness of functional foods;
- mould allergen detection kits;
- allergen kits for various foods (e.g., peanut protein detection kit)
- micro extraction methodologies;
- engineered rodent cell lines that can more rapidly test for carcinogenic activity of unknown or untested chemical or physical agents;
- transgenic animals of specific animal phenotype/genotype useful in following disease parameters;
- leasing animal facilities for external studies, especially high hazard problems;
- toxicology expertise;
- biomarkers for assessing chemical exposure;
- in-situ immunostaining;
- antibody based assays for allergens;
- high risk containment laboratories of LCDC in Winnipeg;
- HIV facility (monkey colony);

- advice to hospitals on the correct usage of medical equipment;
- environmental contaminant studies;
- inhalation toxicology and pharmacology facilities and expertise; and
- DNA effects of chemicals.

One focus group participant noted that a lot of their expertise and know-how is transferred to universities across Canada and directly to hospitals. In many cases they have been approached by these outside organizations and ask to collaborate. At the moment, the major technology transfer mechanisms used by the HPB laboratories is published papers, conference presentations or collaborative R&D projects.

The benefits and problems associated with expanding HPB technology transfer activities are not very different from those described earlier in the review of the literature. The arguments in favour of technology transfer activities put forward by HPB interviewees are:

- apply the technology and expertise resident within the Health Protection Branch to public health problems in a more proactive way (i.e., to actively support others who are working to develop new products and services to protect and maintain the health of Canadians);
- leverage of dollars from external sources to augment existing R&D budgets, especially funds from the MRC which will not fund government scientists directly;
- collaboration with others allows for a critical mass of scientific effort to be mounted;
- learn about new technologies and techniques developed by their partners (i.e., intellectual stimulation through exposure to new and different ideas);
- gain access to scientific equipment or materials HPB does not possess;
- get to do work that is rewarding;
- see their work benefit mankind;

- seeing their scientists get the recognition they deserve;
- helps to keep HPB scientists up-to-date in their scientific field;
- allows HPB scientists to be players in the scientific field and have information they can trade with international colleagues for information they don't have;
- put Canada in the industrial lead in some health care areas; and
- enables HPB to attract and retain first-class researchers to support HPB's regulatory mandate.

Collaboration on R&D projects, in particular, is generally looked upon by the HPB scientists as a positive technology transfer activity that enables them to acquire much needed funding for their research, keep up-to-date, and access skills their group may not possess. One respondent noted, however, that some managers do not like to see HPB resources tied up in collaborative work. But as one researcher stated, "we are now one-man deep, so if you want to do research, you must bring in outside dollars".

One respondent believed quite strongly that, because of all of the cutbacks, collaborative projects were now the only way to address many of the health protection issues facing Canadians (i.e., put together a team with the necessary breadth of expertise to tackle a problem). In addition this person felt that working in collaboration with an outside partner was the only way to keep on the "cutting edge" of science. Another believed that, "a world of resources are cut off if we don't work with industry".

One researcher said that most of the collaborations in which their group engaged resulted from informal arrangements between researchers rather than more formal approaches of an external agency to Health Canada. They then face the problem of "looking at meagre resources and seeing whether they can eke out enough to support that unofficial R&D project." This person went on to say that many of their researchers had individual research projects through their university affiliations and that those are externally funded. These research projects "maintain our scientific research competence. They keep our scientists alive because it gives them extra funding in order to do basic research".

The major arguments or concerns presented by HPB staff against expansion of technology transfer activities (e.g., commercialization of HPB technology, collaborative alliances, etc.) are:

- the appearance of conflict of interest between their public good mandate of protecting the health and safety of Canadians and promoting revenue generation/wealth or job creation (i.e., "appearance of being in the pocket of industry"). There is a fear that the public will consider working with the Canadian health/medical industry as an abrogation of HPB's primary mandate of protection of the public from unsafe drugs, devices or practices;

- having to approve HPB developed technologies that result from either internal development or as a result of a collaborative R&D project with the private sector and have been licensed to the private sector for commercialization (i.e., concern that the public, which views HPB as a unitary organization, will believe that the HPB is approving its own "products" for monetary gain);

- adds to the bureaucratic burden of the managers and the scientists;

- reduction of A-base funding in proportion to the amount of outside funds brought in (i.e., welfare funding model where you cannot get financially ahead);

- given the limited number of scientific personnel available, one individual might be "working" for a company or industry association, and then, because he or she is the only expert available in HPB, be called upon to provide advice to the Minister on the same project area - a clear conflict resulting in the department not having the expertise to advise the Minister;

- the temptation of revenue generation might result in mission drift away from public good projects towards projects with commercial potential;

- concern that working closely with one company will give it an unfair competitive advantage; and

- being involved with a firm in a collaborative project when they have a product in the regulatory review pipeline.

Issues to Consider in Regard to a Possible Expansion of Technology Transfer Activities

HPB personnel consider that there are many administrative issues that senior management must deal with before any move to expand technology transfer activities is undertaken. These issues were identified by most of the interviewees and focus group participants and are major factors that

will determine the success or failure of future technology transfer activities. [Statements in the boxes are quotes from HPB personnel]

Existing Mandate and Management Culture

> There is no upper management encouragement. Scientists would have to spend time on the commercialization and the culture is not there.
>
> HPB needs to understand that it needs to be more entrepreneurial - think about a dual use for their technology and expertise.
>
> The management culture in Health Canada is behind the times in respect to collaboration with outside stakeholders.

The silence of Health Canada' s mandate on the subject of technology transfer or support of Canada's health industry was noted by several interviewees.

Others stated that unless the mandate made some positive mention of technology transfer, in line with the government's overall policy for science-based departments, they would be reluctant to put a lot of effort into technology transfer activities for fear of being accused of conflict of interest. One interviewee said that HPB's mandate should state the benefits to the Canadian public of doing work in collaboration with the private sector.

One interviewee said, "economic well-being is not in my mandate". This person was told helping industry is not his job. In his group, technology transfer is synonymous with "being in bed with a company". He felt that working with firms to the benefit of Canadians should be a small part of his mandate. Another stated that some of their scientists view interactions with industry as "being in the pocket of industry". This interviewee felt that there must be a change in the culture of HPB so that involvement with intellectual property issues was not viewed so negatively. "The present culture does not have a business focus".

One researcher had a very practical attitude to the Health Canada mandate. He stated that, scientists have no real commitment to the HC mandate, only to their immediate superior who interprets the mandate for them. Working for HPB is "like joining the army, you do what you are told". He went on to state that HPB does not have an explicit mandate to help Canadian industry or to develop a drug for Canadians in areas in which there is no private sector interest. General government policies (as promulgated in the March, 1996 publication Science and Technology for

the New Century) in support of technology transfer are to this person unbelievable unless his immediate supervisor says they are to be acted upon.

Another person was concerned that increased technology transfer activities with the private sector will increase the public's perception that the Branch is in the pocket of pharmaceutical manufacturers; a legacy, he believed, of cost recovery. This interviewee was worried that the integrity of the interpretation of research results might be brought into question. He commented, however, that organizations should be charged a fee if they accrue direct benefits from their interaction with HPB.

Many interviewees made the point that any collaborative activities must reinforce their public good mandate; receiving money should not be the major reason for entering into an agreement. There must be a health impact of the work.

One interviewee questioned why Health Canada appeared to consider contract work with the private sector as an "illegal" activity. "If a government laboratory is the best in the country for a particular technology, why can't they share this expertise and charge for service".

Another interviewee considered that the only way to avoid the perception of being in the pocket of industry was to either have absolutely nothing to do with industry, or to be very public about any HPB-industry interactions or relationships and explain the benefits to the Canadian public of such relations. One interviewee stated that the risks of such an association should be fully addressed before entering into the relationship.

Some interviewees were pessimistic about the ability to change the culture within HPB with the present scientific staff. One person felt that some HPB staff would be unable to accept business concepts. This person considered that it would be better to split R&D off from regulatory activities rather than try to modify the Health Canada mandate. Several interviewees wondered whether such a split might be under consideration.

One interviewee thought that some of the present HPB staff would not take technology transfer initiatives seriously. Their attitude would be to "turtle", keep their heads in, and hope that "this too shall pass". Another interviewee said that for technology transfer to happen, senior and middle management must openly approve of it.

Financial Tools to Support Technology Transfer

> We sometimes give up on a collaborative R&D opportunity because of the difficulties in handling the money, especially if only small sums are involved, not worth the effort.
>
> We have no mechanisms for receiving monies from a private company, any money that comes through the door goes to the Consolidated Revenue Fund.

According to the 1993 Treasury Board Intellectual Property Policy on Retention of Royalties and Fees, departments and agencies are authorized to receive, through Supplementary Estimates, an annual appropriation equal to all revenues arising from the licensing of Crown-owned IP which the department or agency remitted to the Consolidated Revenue Fund in the previous fiscal year. These monies are to be used "toward the costs associated with the incentive awards for technology transfer and other technology transfer activities undertaken by the department or agency". These monies are considered to be over and above the A-base appropriation and are not deducted from the A-base.

Thus in the matter of handling funds arising from the licensing of IP, Treasury Board has provided Health Canada with the necessary authorities.

In the areas of collaborative research, contracting in or any other revenue generating activity, Health Canada does not have respending authority to spend incoming funds as it wishes. Funds from outside sources for specific projects, such as a collaborative R&D project, are usually put into a Specified Purpose Account (SPA) that protects the funds from lapsing at the end of the government's fiscal year. However, any surplus funds remaining, or any funds earned through other activities are lost to the Consolidated Revenue Fund and do not go back to the HPB to further its scientific work. Several interviewees stated that the difficulties they had with their finance officials over handling of incoming funds was a disincentive for establishing future collaborations. One interviewee said that they have great difficulty in setting up SPAs and expending monies from them. They thought that the problem might be their internal processes.

As one interviewee stated, without respending authority the HPB cannot get the money to grow. This interviewee went on to say, "you cannot have all these rigid financial rules if you want to work with the private sector; the rules must be flexible".

One person considered that it was irresponsible for senior management to encourage people to go after external funds and not have the appropriate financial tools already in place to handle the outside money in a professional and timely manner. He believed that delays and having to ask for bureaucratic word changes to agreement documents makes the department look like a bunch of

amateurs in the eyes of foreign funding agencies. He also thinks that the financial administrators have lost sight of why HPB is there and should be more supportive of research that supports the departmental mandate and not put administrative hurdles in their way.

One interviewee noted that Agriculture and Agri-Food Canada (AAFC) has a well established financial system in place to manage externally funded collaboration and Health Canada is still learning how to do it. (i.e., how to manage Specified Purpose Accounts with some flexibility). AAFC had received umbrella approval from Treasury Board to operate up to "X" number of SPAs to a certain value. The interviewee was not aware whether HPB finance people had sought similar approval from Treasury Board. He went on to say that all SPAs must go through Health Canada's finance office in Ottawa and expressed concern that this might introduce unacceptable delays in establishing a collaborative project. He said that external collaborations are driven by somewhat different pressures than are government-based science projects and HPB scientists have to be able to move quickly on setting up and on starting collaborative projects. He added that moving quickly does not appear to be a concern in Health Canada's finance offices. Another interviewee said, "finance officials should advise us how to facilitate collaborative activities, not just say 'no'".

One interviewee said that when monies from external funds are used, they should not be restricted by the Public Service Commission hiring process in order to hire the help needed on an externally funded or collaborative project. A different interviewee said that SPA monies can be used to hire whoever they want on these types of projects. Clearly two perceptions of the flexibilities accorded by SPAs.

Even in the more straightforward area of cost recovery of review and assessment activities, the handling of money is somewhat difficult. If more money is earned in a fiscal year than is authorized by Parliament, problems of accounting for the money arise. If money for a drug evaluation is received in late March (last month in the fiscal year) and cannot be spent in the fiscal year, it is "lost" to the Consolidated Revenue Fund. It then has to be recovered through a request for a supplement to the HPB budget. It was suggested that an easier solution to this problem was to misplace the cheque from the company until April 1st.

At the moment, the Finance group has not been asked to obtain respending authority on the "Provision of Services".

State of HPB's Ability to Provide Unique Technology and Expertise

> Without the freedom and encouragement to do research, why would anyone want to deal with us. We have to develop unique approaches so we have something to offer.
>
> We are below the critical mass of research scientists in this department. There has been an erosion of the scientific competency of Health Canada.

The major reasons for outside organizations to become involved with a government laboratory are because the government laboratory has either very good people doing unique state-of-the-art science/technology and/or the laboratory has some unique facilities, all of which have some value to the outsider. Without these attributes, the government laboratory has nothing to "sell or trade" to the outside world.

Unfortunately, many interviewees questioned whether HPB still had many good researchers left, or was going to keep or attract good people in the future. One interviewee commented that with the cutbacks, their group had no critical mass of expertise in any one area (i.e., expertise was one-person deep). One interviewee said "We don't have good enough quality science to attract private sector collaborators".

Another interviewee questioned whether Health Canada really appreciates its scientists. "Health Canada doesn't really want scientists, they just want to be able to say their decisions have some scientific basis. Scientists are viewed as expensive". A different interviewee commented that Health Canada views its scientists as troublesome.

Another interviewee said that "if Health Canada is in the business of science-based, evidenced-based decision-making they should be providing more support for basic research". "They say this is a science-based organization, but I do not see a lot of evidence that that is what they want. We only get enough money to sustain livelihood, nothing to make science flourish." This interviewee went on to say that Health Canada "does not treat its scientists in a manner that would make them feel proud of the organization and make them stay and want to participate". Another interviewee noted that Dr. Brodeur is a classic example; bright, able to attract good researchers, but the Laboratory Centre for Disease Control (LCDC) could not hang on to him. The interviewee felt that the really good ones left because of the lack of support of science. A third interviewee said the move of a part of LCDC to Winnipeg resulted in a loss of 50% of their highly trained staff.

One interviewee pointed out that their laboratories are being moved into a strictly service role, and as a result they have lost most of their scientific researchers. Another interviewee in the

same area said that laboratory restructuring is basically trying to convert research scientists into technologists and this will drive out the remaining good researchers.

On the topic of attracting new good people, one interviewee said that while they get hundreds of applications, the quality is not there. This interviewee said that Health Canada cannot attract good researchers under the present circumstances. "Salaries are not competitive, there are no perks in the system, there are no incentives and there is no professional development". The departmental policy of adhering to the "two people per conference rule"of Treasury Board and not using the training and development route that allows an unlimited number of people to attend a conference was said to be restricting professional development efforts.

This pessimistic view of recruitment was also noted in the "Your Resource for the Future" report which contains information on Health Canada and the four natural resources departments (Impact Group, 1998). Under the heading of *Short-and Medium-Term Recruitment Challenges*, the report states that, low morale and uncertainty have created short- and medium-term recruitment challenges for many science-based departments. Public service research careers are not so appealing to young scientists and engineers as they once were. .. this does not bode well for future recruitment.

When asked their views on the "joining the army" comment mentioned by an HPB scientist, a senior researcher said that, "it is worse than joining the army. When you go into an army, you go into a very well organized infrastructure where they recognize that they have to do certain things for the employees to maintain the military force, otherwise they are going vaporize and disappear. But here, they do not make any attempt to nurture their scientists and to retain them".

Encouragement to Engage in Technology Transfer

> Every scientist here has the ability to develop a new drug product, but we are not encouraged to do so.
>
> Our efforts and ventures outside of HPB should be recognized and encouraged.

Most of the HPB personnel voiced considerable disappointment with the quality of rewards and recognition available to scientists within the HPB. One described the present reward and recognition structure within HPB as "useless"; another as "a joke". Several said that Health Canada does not generally recognize their scientists' accomplishments; most of their recognition comes from outside organizations and international peers. Another considered the research scientists review process to be archaic as it applies to collaborative research projects (i.e., only taking into account research papers where the person is first author - in collaborative activities the first author is not as significant as in the past).

Other interviewees stated that the present reward/recognition system within HPB does not support either technology transfer or commercialization. "Management is still publications oriented", commented one interviewee. It was noted that in the interdepartmental committee guidelines for RES promotion, technology transfer and collaborative R&D activities are to be considered, but it is questionable in the minds of some HPB staff how much weighting is given to these factors. "There are no benefits to technology transfer, just more work". One researcher stated that "you have to create a reward system that attracts the interest of the scientists to be involved in technology transfer".

One respondent stated that AAFC gives greater weight to technology transfer activities than to traditional publications. This assisted in changing the culture at AAFC to be more supportive of the agricultural industry.

One person warned, however, that while technology transfer activities need to be rewarded, HPB should not punish those who decline to take part. Technology transfer should be facilitated, not pushed.

Mixed Message Regarding Involvement in Collaborative Research

> Management needs to walk the talk on collaboration.
>
> The stance that we are a regulatory agency and therefore cannot be involved in any form of relationship with external parties in the private sector is not only a myth, it is also highly non-productive

It is not clear to HPB scientific personnel that senior management is fully supportive of collaborative R&D partnerships. There has been no clear signal that collaboration is a valid activity.

One interviewee said that top management is too afraid of being accused of conflict of interest and so they are sending out a mixed message " go ahead, but be very careful". They are not sending out a clear message that technology transfer, either licensing or collaborative R&D partnerships, is a valued activity. They avoid business relations with the private sector by hiding behind the theme of "protection of the public's health". They need to understand that working with the private sector is not wrong and does not take away from protecting the health of Canadians. One interviewee stated that, "Every time you bring up the topic of working collaboratively with industry, they zap you with 'conflict of interest' arguments".

Another person said that senior management takes the concept of perceived conflict of interest as being so threatening that they don't really approve of any interaction with private sector organizations. He went on to say that because the way science, in general, is going, the only way that technology is going to be transferred into a useful "product" is through some sort of private sector involvement. Government departments are not in the business of commercializing products.

The possibility that a collaborative R&D partnership might result in HPB having to review and approve its own technology raises some questions in the minds of some interviewees about the propriety of collaborative projects.

Some interviewees believed that senior management's concern with the perception of conflict of interest would undermine any expansion of technology transfer activities.

Another interviewee said it is difficult to enter into collaborative work of any long term duration when there is uncertainty about their research group's survival within HPB. As he put it, people are living in a state of limbo. He went on to say that the best people tend to leave under those circumstances.

One interviewee stated that they were involved in between four to twelve research collaborations in a year but not much money came in. These might be considered to be true R&D collaborations with each partner contributing an equal level of scientific effort to the project.

Two people stated that other than the efforts of Minh Trinh, the Senior Business Development Advisor for HPB, to arrange or facilitate collaborative partnerships, there was no real encouragement to pursue these sources of external funds. "There is no budget for exploratory research that could result in something of interest".

Another researcher was discouraged from obtaining external funding for a partnership with an academic colleague because he was told that it would be unfair to get the money because his HPB colleagues were not in the same position to access such funds. This extreme form of egalitarianism was noted by another interviewee.

One respondent believed that there should be some form of reward to top performers who bring in outside collaborative R&D money.

Collaboration can also take place between researchers in different directorates of HPB. However, one respondent said that in the recent past, they were discouraged from having collaborative R&D projects with fellow HPB scientists as it might look like two people doing the same thing and thus leave HPB open to charges of duplication of efforts which is frowned on in the public service. Such collaborations required extensive paper trails and numerous discussions about who pays for what, all of which are disincentives to collaboration.

Guidance on R&D Collaboration

Establish a clear process for facilitation of technology transfer.

Many interviewees stated that the lack of guidelines on establishing and operating within a collaborative R&D activity was a concern. They would like some written guidelines to assist them in setting up R&D collaborations as well as other technology transfer activities. They believed the guidelines should deal with issues such as IP ownership, handling of outside funds, publication of results, avoidance or management of conflict of interest, and choosing appropriate collaborative partners.

One interviewee said he had a collaborative agreement with a university colleague and there was nothing in writing, it was only a verbal agreement. They plan to jointly own any resulting IP. Their reasons for keeping things informal was the burden of paperwork on both sides. They plan on formalizing their agreement when they know they have something of interest. Given the very aggressive stand by universities on owning IP resulting from government-university research, this verbal agreement on the IP ownership may not stand up.

Another interviewee mentioned he experienced some difficulty with an external collaborator when the collaborator published results first and received all the credit for the work. He felt that if collaborative guidelines had been available, this problem might not have occurred.

Resource Allocation Between Internal and External Projects

The question of whether HPB had the depth of resources to take on additional external work was raised.

Several interviewees said that their people are fully occupied on projects in support of HPB's internal mandate and do not have any slack time to work on extra external projects. One considered this to be a major barrier to increased technology transfer.

One person said that the cutbacks in personnel have resulted in fewer people to do the work they have and there is no time to get involved with collaborative projects. "We are under pressure to show that we are working on something useful; there is a push on for short-term projects with immediate results".

Another issue is the priority of allocation of resources between a project being done for an external client, and one for an internal client in the direct service of the public good mandate. One

person stated that human resources are so thin, that if they were working on an external project and an emergency internal project arose (e.g., coroner's inquiry) they would be unable to do both.

Another concern was whether personal gain might cause a researcher to pick a project with commercial potential over one that simply fulfils the HPB mandate of health protection (i.e., mission-drift).

Past Experiences with Technology Transfer Attempts

Current management views technology transfer as just complicating their lives.

The degree to which the scientists are willing to take part in technology transfer activities is in some part influenced by their past attempts to transfer technology. A common theme among some scientists was the previous lack of support in terms of time and money to pursue technology transfer initiatives. As one scientists stated, "we have never had the luxury to spend time and money to support technology transfer". They had developed something with potential in the past, but resources were not made available to move the project forward.

In another example, attempts to transfer technology failed because faulty calibration of HPB equipment suggested a particular scientific outcome that was incorrect. ISO accreditation was suggested as a way to avoid failures of this nature in the future.

Another interviewee mentioned his group's poor experience with a business manager in their bureau. The manager managed to alienate not only the scientists, but also their prospective customers. A contributing factor was the manager's lack of a scientific background and human relations skills. As a result, the scientists do not want to deal with people who do not understand both the prospective market or how scientists work. He went on to say that previous attempts to get money to advance a technology to the point where an industrial partner might take an interest were ignored.

One person mentioned that licensing of IP has been discouraged in the past and that older scientists who remember this are not especially motivated to disclose inventions. Another said that efforts to attract outside private sector money were blocked by senior management."Doors were slammed shut on the whole idea". HPB scientists also see very little in it for them to get involved in technology transfer. Some are not aware of the TBS guidelines on financial renumeration. They want to be appropriately recognized for going to the extra trouble of inventing something.

One person pointed out that if there is no intention or capability of marketing an HPB patent, then the whole process is a waste of time and unduly delays publishing research results.

Dissatisfaction with marketing efforts could result in a researcher being less forthcoming about possible inventions with a commercial potential in the future.

Lack of Knowledge About the Technology Transfer/IP Management Processes

Several interviewees thought that their bench level people knew very little about technology transfer and especially about intellectual property management. This lack of knowledge is an inhibiting factor in promoting technology transfer. Several interviewees suggested that HPB personnel should have some training in these areas, and that this would help to change the culture.

One interviewee believed that HPB scientists should be educated on the benefits and methods of conducting technology transfer.

A contributing factor to this lack of knowledge is the absence of an Intellectual Property Policy designed specifically for the Health Protection Branch. At the moment, HPB uses the 1993 Awards to Inventors and Innovators Policy of Treasury Board which provides quite a latitude of discretion to departments and agencies.

Approving HPB Originated Technology

Of all the conflict of interest situations that are possible, the situation where an HPB scientists develops IP for commercialization that ultimately has to be approved by HPB, was the one mentioned most. The lack of any guidelines to meet this situation appeared to discourage partnerships.

One interviewee said that Agriculture and Agri-Food Canada had faced the same situation. AAFC obtained a written decision from its legal staff that said that a research scientist who is not part of the evaluations division had no conflict of interest with respect to technology developed during a collaborative R&D project, if the scientist did not take part in the evaluation of the technology.

Many of the interviewees argued for a separation of, or a more arms's length relationship between HPB's research and regulatory activities as a possible solution to some of the perception of conflict of interest. Several suggested this as a way of avoiding the problem of appearing to approve their own technologies for commercialization.

One interviewee warned, however, that he would not like to see research and regulatory staff too far apart as their interaction on scientific matters is a positive attribute of his unit. He feels at the moment that, under the present relationship "we are envied worldwide".

Another related issue specifically mentioned was that of liability. For example, if HPB develops a testing methodology that is used by a company in good faith but a problem arises in the future, who is liable, the firm that uses it, or HPB who originally developed it. Again guidelines were suggested as a solution to this problem (i.e., what to have in the license agreement regarding liability).

Several interviewees agreed that where HPB originally developed the technology that requires approval before use, moving the approval process offshore to a sister organization might be an appropriate solution to the conflict of interest situation. Others thought that for sovereignty considerations this could not be done.

Isolation of the Staff from the Outside Industrial World

> Health Canada interprets Treasury Board rules in the most draconian way.

Several interviewees commented on their inability to interface with their industrial counterparts. Even having HPB scientific staff tour a companies' facilities has raised questions about the propriety of such a visit.

Restrictions on conference attendance (only two personnel per conference) was thought by several interviewees as limiting their researchers from learning about collaborative R&D opportunities. "Our scientists must compete with reviewers to attend conferences hence they do not get to meet their industrial counterparts and potential adopters of HPB technology as they should".

Another stated that senior management sees conference attendance as a perk or a holiday with the result that conference attendance is overly restricted.

One scientist felt isolated from external colleagues as he was not a member of the professional society that served his field of research because the society had a private sector orientation, and presumably the majority of members were either from the private sector or worked closely with the private sector. He thought that membership in such an organization might be viewed negatively by management.

Level of Business Development Activity

> The business development office has to reach out to the individual investigators - not just go through line management.

If technology transfer/business development activities are to be expanded, it is more than a "one-man" job. One interviewee stated that the business development office should have more personnel and it should go out and proactively "sell and promote our technologies".

One interviewee suggested that the business development office should advertise the services it can offer to HPB staff. During the course of this study, several interviewees commented that they didn't know HPB had a business development office.

Interviewees consider that to be effective, there should be business development officers with appropriate scientific or technical backgrounds in each of the program areas. These officers should provide advice on matters such as IP management, marketing, handling outside money, and establishing collaborative R&D alliances. They should also be actively looking for external sources of funds (e.g., looking for R&D partners whose research agenda overlaps that of HPB).

One respondent felt quite strongly that HPB should not expect the scientists to go out and market themselves as has been done in other departments. "Scientists are not good at it". This person also warned, based on their experience in another department, about having business development people make performance promises to clients that the scientists cannot meet. Another concern was that if business development activities were expanded any new people hired must have an appropriate science background, not just an M.B.A. Thus the person would understand both scientists and how they work, and the scientific process.

One interviewee believed that it would be necessary to actively market HPB technologies outside of Canada if no Canadian adopters could be found.

Several interviewees thought that HPB could do more to "advertise" the expertise resident within the laboratories. One person suggested a booklet, along the lines of those produced by N.R.C. "There should be an inventory of our projects, achievements, publications and expertise". Several interviewees suggested that such a "booklet" could also be displayed on an HPB web-site.

On the present Health Canada web-site, it is difficult to find the Health Protection Branch sub-site as it is not listed on the home-page. Once into the HPB site, a visitor does not receive any immediate impression that research is being conducted within the HPB. Some of the links to technical reports deny access to the public. Some of the sites have not been updated in 3 years and there are no contact names in some of the sites. All-in-all, the present Health Canada site is not friendly to technology transfer in the context of building relationships with other researchers.

Several interviewees who have patents in various stages of commercialization have said they appreciated the help and assistance they have received from the HPB business development advisor and the N.R.C. intellectual property management team.

ANALYSIS AND DISCUSSION

> Perception is reality only if people are not told the facts of the situation in advance.

Pros and Cons of Expanding HPB's Technology Transfer Activities

The expansion of HPB's technology transfer activities has both positive and negative aspects. The positive aspects of expanding the Health Protection Branch's technology transfer activities are:

- maintenance of the scientific expertise of the research staff through collaborative R&D projects;
- support of lines of research that HPB can no longer afford, but may still require;
- support of facilities that existing budgets will not be able to maintain;
- recognition by industry, scientific peers and the public of the contribution of HPB scientists to health maintenance and protection;
- acquisition of new scientific knowledge, resources or materials that are provided by a collaborator;
- opportunity for researchers to work on more rewarding, interesting projects and see their expertise more directly applied to public health problems; and
- improvement of the reputation of the research conducted by HPB which in turn, improves HPB's ability to attract and retain first-class researchers.

At the moment, it appears that outside collaborative or contract money is a significant source of funding for HPB research in some directorates. Unfortunately, this is not uncommon in Canadian government laboratories where the A-Base budgets cover salaries but there is little left over to fund the actual research. Research money must come from collaborative research arrangements or other income generating activities.

The negative aspects of expanding HPB's technology transfer activities are:

- a greater administrative burden to ensure that real conflicts of interest between HPB's public good mandate and revenue generation do not occur and that perceived conflicts of interest are managed in a satisfactory way;
- an appearance that revenue generation is taking priority over protection of the public's health;
- insufficient personnel to work with an outside organization and also adequately support the internal public good mandate;
- concern by both industry and the public that HPB is no longer a neutral regulator if it works with individual companies on R&D projects; and
- public perception that large companies can influence regulatory decisions by offering lucrative collaborative R&D projects or overly generous licensing arrangements to HPB.

These aspects, both pro and con, are not unique to the HPB. The FDA and CDC also faced them when they increased their technology transfer activities in 1987, and still face them today. This has not stopped them from engaging in technology transfer activities wherever possible, in support of their public good mandate. They do not see working with the private sector and their public good mandate as being mutually exclusive.

HPB appears to have adopted a model half-way between the U.K. model where the regulators for the most part rely on external scientific expertise, and the U.S. model where the expertise, is maintained in-house. This affects the HPB's ability to be involved in technology transfer.

Not unexpectedly, half-way approaches come with their own problems. This half-way approach has resulted in HPB having a subcritical mass of scientific expertise which limits HPB's ability to enter into technology transfer activities. While not part of this study, no one interviewed mentioned that mechanisms to access external expertise have been established to replace the lost expertise resulting from laboratory downsizing.

An argument put forward by one interviewee in favour of an in-house R&D capability rather than contracting out any review-related R&D was that when one contracts out work, the laboratory usually only gets back what was in the statement of work. However, research work depends on

responding to side issues raised by the work - there may be an unusual result that should be explored further but it will rarely be reported by the outside contractor. These side issues could be the source of valuable technology.

If in-house capability is not maintained, then technology transfer issues become academic, as little or nothing will be developed in-house that will be of interest to external organizations.

Feasibility of Expanding HPB's Technology Transfer Activities

If the decision is to maintain and rebuild an internal scientific capability (as a few interviewees thought), then based on the interviews with HPB personnel and technology transfer officials in the FDA and CDC, expansion of technology transfer activities is technically possible.

This should not result in the abandonment of the Health Protection Branch's primary mandate of protecting the health and safety of Canadians. While collaborative R&D alliances and other forms of technology transfer may become more prominent, the commercialization of HPB technology will always be a secondary, very small part of HPB's activities. The CDC and the FDA have shown that it is possible to conduct technology transfer activities (CRADAs and licensing of technology) while still adhering to the primary mandate of public health protection. They accomplish this by having proper managerial processes that facilitate and guide their researchers in their interactions with the private sector and other external organizations, and by being very open about what they do and what they have to offer.

HPB personnel identified various scientific areas where they feel that expanded technology transfer/business development could take place. They also identified some unique facilities and laboratory tools (e.g., special animals) that might be of interest to external researchers. All respondents, however, pointed out significant problems or administrative barriers not only to expanding but also to maintaining the present level of technology transfer activities within the HPB.

Technology transfer can only take place if technology (hardware, expertise or know-how) of value or interest to an external party is developed in the first place. Most of the HPB researchers interviewed had serious reservations about Health Canada's commitment to research. Without this commitment, HPB had, according to many interviewees, lost a significant number of their best researchers, and some of the remaining are considering employment elsewhere. Several interviewees questioned whether HPB could attract top level replacements. In effect, most of the HPB scientific staff interviewed said that the pool from which unique technology or expertise could flow is drying up. Once a laboratory has a reputation as an unhappy, unsupportive place to work, it is well nigh impossible to attract first-rate people. The laboratory then slides into a downward spiral of mediocrity.

The laboratory's reputation also affects its ability to attract collaborators. At the moment this does not appear to be a serious problem as there are still some good researchers who can attract outside collaborative R&D dollars. Collaboration is seen as the only way of keeping up-to-date as A-base funding is not adequate. However, frustration with the cumbersome financial system when dealing with external funds is causing HPB managers to turn away small collaborative projects that could lead to larger projects once external parties appreciate the quality of the work of the HPB scientists.

Many interviewees considered that senior management's deep concern over the appearance of conflict of interest would prevent management from making the administrative changes needed to facilitate expanded technology transfer operations. It appears that the distinction between real and perceived conflicts of interest is blurred. "Perception is reality" stated one senior manager.

Interviewees noted the lack of any substantive rewards or forms of recognition for being involved in technology transfer activities. Even the monetary awards provided by HPB from the exploitation of intellectual property are at the bottom end of the permissible scale (15-35 %) set forth by Treasury Board.

The present level of resources allocated to technology transfer activities in terms of funds to move projects forward to a stage where they would interest external partners, to conduct adequate marketing activities or to identify potential partners or licensees appear to be inadequate. Neither is relying on one person working out of one location adequate; effective business development activities require at least one person, possibly part-time, working out of each major scientific area, e.g., LCDC, Environmental Health, Food or Natural Products. This parallels what other government organizations with a "spin-off" type technology transfer program such as the British Defence Evaluation and Research Agency (DERA) (Clarke, 1997) and the FDA do to promote technology transfer.

Studies of technology transfer from government laboratories to industry clearly identify senior and middle management support, lack of red-tape, adequate financial and personnel resources assigned to the technology transfer process and an adequate reward system for the research or technical personnel as being some of the prerequisites to successful technology transfer. These are almost completely missing in HPB.

Therefore, under the present management culture, together with the decline in the scientific research capability, the inadequate reward and administrative infrastructure, **expansion of technology transfer activities within the Health Protection Branch would be very difficult, if not impossible.**

Making Expansion of Technology Transfer Work - Overcoming the Hurdles

Expansion and facilitation of technology transfer activities, especially collaborative R&D projects involving new funding, is not a luxury, it is a necessity. Unless there is a marked increase in federal A-base funding of basic and applied research in HPB, several of the laboratories are said to be facing closure. Attracting outside financial sponsors to support research that meets the needs of both the sponsor and Health Canada can keep HPB laboratories alive. Otherwise HPB will have to go to private sector or university laboratories for R&D information to support their regulatory decision-making. This in itself would raise a whole new host of conflict of interest issues.

Researchers also stated that involvement with collaborative or externally funded R&D projects was their only way of "being on the cutting edge" in their scientific fields as A-base funding was not fulfilling this necessity. The scientists' ability to provide up-to-date support to their regulatory colleagues depends on maintaining their skills and knowledge. R&D collaboration is, therefore, as the FDA argues, supportive of the public good mandate of health protection.

The following are suggestions/recommendations on how HPB can put their technology transfer activities on a more firmer footing.

Modifying the Management Culture

> If they tell us we can do it, we will do it.

As noted in the technology transfer "Best Practices" section (pp. 18-19), senior and middle level managerial support for technology transfer together with a clear message that technology transfer is a legitimate, valued activity are two of the prerequisites of a supportive technology transfer climate.

A major impediment to any expanded technology transfer activities is the lack of mention in HPB's operating mandate of working with outside agencies to assist in the development of new drugs, devices, etc. to improve the health of Canadians. The present management culture within HPB does not support working closely with the private sector for fear of being seen to be in the "pay of the enemy". In order to bring the culture more in line with that of other government departments, words should be added to HPB's mandate confirming that technology transfer in general, and collaborating in R&D projects in particular, are a legitimate if they support the health protection mandate.

At the moment, the resistance to increased technology transfer is coming more from senior management in HPB/Health Canada than from the bench level scientists. Some past attempts at

technology transfer have not been supported. If the memory of poor past experiences is to be overcome, senior management must assure researchers that a new approach is being taken and that resources will be committed to supporting technology transfer (e.g., to move projects to the stage where they can attract collaborative R&D partners or potential licensees).

Senior management must look upon external organizations as allies in the fight to protect the health and safety of Canadians. Working with external organizations, including the private sector, is a necessity given the rapid advancements in science.

The fact that technology transfer and, in particular, collaborative R&D projects with external organizations is an explicit requirement of federal government science-based departments should reinforce the need for the change in management culture and a new commitment to technology transfer.

Recommendation # 1 - Senior management should make clear to everyone within the HPB that technology transfer activities that reinforce HPB's ability to meet its primary mandate are legitimate and valued activities that will be supported.

Acquisition of Appropriate Financial and Administrative Tools

Administrative people need to know that they will not get into any trouble for facilitating technology transfer.

As noted earlier in "Best Practices", the lower the amount of government red-tape and the fewer bureaucratic rules, the more likelihood of successful technology transfer.

Health Canada must obtain appropriate respending authorities on the "Provision of Services" so that monies earned can go into building up HPB's R&D capabilities. Without these authorities, much of the reason for encouraging business development or collaborative activities is lost. Health Canada should also obtain clarification of the legitimacy of doing contract work for outside organizations, especially U.S. government agencies. The need to "hide" such contract work under the guise of a collaborative project makes HPB look amateurish. If this need to disguise contract work is the result of a past Treasury Board ruling, submissions should be made to legitimize contract R&D for external clients, as consulting contracts.

In addition, HPB senior management should ask their financial officers to amend their procedures so that they encourage and facilitate collaborative R&D projects rather than hinder them. It was not apparent that Health Canada finance personnel understood the flexibilities that SPAs provide therefore all financial personnel and anyone involved in collaborative R&D alliances need clarification of what can or cannot be done using a Specified Purpose Account. Information from other departments with greater experience in using SPAs in collaborative projects should be sought.

Recommendation # 2 - Health Canada/HPB should obtain the necessary respending authorities on the Provision of Services so that monies earned can be used to strengthen the R&D base of the HPB.

Recommendation # 3 - Health Canada/HPB should review their present financial procedures, including the use of Specified Purpose Accounts, and ensure that they facilitate technology transfer activities.

Managing Conflict of Interest Issues Involving Technology Transfer

Conflicts of interest are conditions, not behaviors - David Blumenthal, 1996

Concern over working with the private sector or other external organizations in collaborative or contractual arrangements must be put in perspective. If working with the private sector advances Canada's ability to protect the health of Canadians, then such relationships should not be avoided. As noted in the government publication entitled, "A New Approach to Health Research for the 21st Century: The Canadian Institutes of Health Research", these new institutes are being encouraged to "promote economic growth and job creation by encouraging innovation and enhancing the commercialization of Canadian research" (p. 8). Why should health research conducted within HPB be exempt from this objective? Real conflict of interest can be avoided by putting in place transparent and open processes and procedures to deal with relationships with external organizations, as is done in the U.S.

To avoid the appearance of conflict of interest, there should be a simple and timely process of approving in advance proposed licensing agreements, R&D collaborations or other efforts to obtain outside funding (e.g., contracting-in) so that the appropriateness of the external project to the mandate of the HPB can be ensured and defended, if necessary. This approval system should alert senior managers when a proposed collaborative project or licensing/contracting opportunity comes from an organization with a "product" in the regulatory pipeline or a poor track record on introducing safe "products" to the public.

The approval process would also ensure that HPB has the resources in place to fulfil their side of the collaboration or licensing activity. **This prior approval process should not be allowed to become an administrative burden to the researchers or business development office and unnecessarily delay licensing or collaborative projects.**

The approval level should be set as low in the management hierarchy as possible. As noted earlier, collaborative partners, in particular, have their own time tables that will not accommodate long bureaucratic delays. Potential licensees also have their eye on the "window of opportunity" for introduction of new products and will also not tolerate long decision delays.

HPB should also put in place an HPB-wide monitoring and tracking system accessible to HPB personnel (i.e., intranet) that identifies collaborative partners, licensees of HPB technology, and sources of funding for externally supported R&D projects. The system should also provide information about the total level of financial or scientific support that HPB receives from outside organizations. This information is difficult to determine at present.

As many interviewees requested, a set of clearly understandable guidelines to assist employees in establishing, monitoring and being part of collaborative R&D projects is needed. In addition, guidelines on licensing arrangements should also be developed. These guidelines should facilitate collaboration and licensing, not mire them in red-tape to make them administratively difficult.

As part of a new openness, some information about externally funded projects, collaborative R&D projects, and the names of HPB technology licensees should be "published" on an HPB web-site. In addition, areas in which HPB is interested in forming collaborative alliances, or technologies available for license should also be listed.

Recommendation # 4 - HPB should establish an efficient, quick screening and approval system for licensing and collaborative projects or other technology transfer activities to ensure that projects support HPB's ability to carry out its mandate, that the licensee/partner is appropriate, and that HPB resources for the project will be available.

Recommendation # 5 - Establish an HPB-wide tracking and monitoring system that identifies and provides information on all licensing and other external collaborative/contractual R&D arrangements. This information should be available on an intranet accessible by all HPB employees.

Recommendation # 6 - Develop a set of clear guidelines to assist (emphasis on facilitation not control) researchers with the administrative aspects of licensing, and establishing and being part of a collaborative R&D agreement with an external partner.

Recommendation # 7 - Post the newly developed guidelines and non-confidential information concerning specific licenses, contractual R&D arrangements or existing or proposed collaborative R&D projects on the HPB web-site.

Managing the Approval of HPB Originated Technology

A standard procedure should be developed to avoid the appearance of conflict of interest when dealing with the "approving our own technology" situation. As mentioned earlier, the FDA, under similar situations does not consider the technology to be their own, but that of the licensee. No special favours or fast-tracking are provided. HPB should adopt the same point-of-view.

If a situation is extremely delicate, HPB should consider arranging an MOU with a sister organization to handle such cases, with the offer to handle similar situations in their organizations, if they arise. As the FDA do not have multiple experts in many fields, they might find this solution beneficial as it would retain their in-house expertise for advice to their government.

Recommendation # 8 - Develop a standard process, which may involve an MOU with a sister organization, for dealing with the approval of new "products" submitted by companies that originally obtained the technology under license from an HPB laboratory.

Educating HPB Staff in Technology Transfer and Intellectual Property Management

Researchers may be reluctant to become involved in technology transfer activities if they do not know what is involved, and what they have to do. Several interviewees recommended that HPB personnel have some training in technology transfer and intellectual property management. This would prepare the scientists to work more effectively with the HPB business development office.

Environment Canada spent over $29 thousand on such training last year as part of their renewed effort to encourage their research staff to be more active in recognizing dual applications

of the work they do in support of environmental protection. Environment Canada used the training as a vehicle to educate their staff on the services offered by their Intellectual Property Office and to familiarize the IPO staff with some of Environment Canada scientists' research activities. (Appendix Six contains an overview of the services offered by the Business Development Office of HPB).

Other departments that have provided training workshops to their scientific staff in the past two years include the National Research Council, the Canadian Food Inspection Agency, Agriculture and Agri-Food Canada, and the Canada Centre for Remote Sensing of Natural Resources Canada.

Offering such a workshop or training sessions to HPB personnel would be a strong signal that a fresh approach to technology transfer is being taken.

Recommendation # 9 - Provide HPB researchers and their managers with the opportunity to attend training sessions on technology transfer and intellectual property management.

Greater Support and Appreciation of Scientific Work of Staff

HPB's present system of reward and recognition for their scientific staff is a failure.

Unless the poor morale of the scientists is turned around, it is unlikely that there will be any increase in technology transfer activities. Demoralized scientists don't invent, nor are they attractive to outsiders who might want access to their skills or to collaborate with them.

The better scientists will leave for an organization that appreciates their contributions. When asked, they will discourage colleagues from joining the HPB. If the poor morale within HPB becomes common knowledge in the health research community, university professors will steer their best graduates to more supportive organizations.

Arguments stating "why should scientists be rewarded and not others", do not hold water. HPB should have an appropriate reward and recognition system that rewards all employees for work above and beyond the "call of duty".Statements from HPB management that, "They should be thankful they have a job" will not motivate first-class scientists to stay. The forms of reward and recognition favoured by scientific staff differ somewhat from that of nonscientific personnel and any system to reward them should reflect this. Information about appropriate reward systems for scientific staff can be found on the Treasury Board web-site (www.tbs-sct.gc.ca/tb/hr/scitech/frm-home.html [Project Team 3: Rewards, Recognition and Incentives]) and on the Stargate web-site (www.stargate-consultants.ca [Focus and Expected Impact of Rewards, Recognition and Incentives for Research Engineers and Scientists, December, 1996]).

HPB must also understand that attempting to convert a research scientist of many years into a service scientist or regulator is an impossible task. The result will be a demoralized scientist or regulator putting in time until retirement, if he/she doesn't quit first. It would be better to try and find displaced researchers work in another department or a university and replace them with someone who has a genuine interest in service science or regulatory work.

Additional funds that allow researchers to take on challenging, interesting projects will help to turn the morale situation around. Token cash incentive awards will only aggravate the situation.

Recommendation # 10 - HPB should examine its present reward and recognition system for their scientific and technical staff and bring it in line with accepted R&D management practice.

Reward and Recognize Technology Transfer Activities

Scientists or other technical staff will cooperate in expanding technology transfer activities **if** they see something in it for them. That something could be money for research or peer recognition, but it could also be the opportunity to work on challenging, interesting external projects that keep their scientific or technical skills up-to-date.

At present, the HPB does not have adequate organizational forms of reward and recognition that encourage technology transfer activities. This situation is a known inhibitor of technology transfer.

An Intellectual Property Policy should be developed to handle the flow of monies from the licensing of intellectual property to make sure that the whole innovation team is rewarded and that the originating laboratory shares in the revenue stream. This is in line with the recommendations in the Treasury Board Team 3 report mentioned above. Reliance on the present vaguely worded Treasury Board policies is not sufficient. Other departments, such as Natural Resources Canada, Environment Canada and the Department of National Defence have had their own versions of an Intellectual Property Policy drafted.

The reward system should also recognize those people who are successful in bringing in large amounts of external funds or setting up significant collaborative projects. N.R.C. for example, has an award of $3,500. for members of successful collaborative teams.

As noted in the "Best Practices" list, a key element in encouraging researchers to disclose potential inventions is the existence of an inventor-friendly disclosure system. Inventors should not be buried under paperwork if they disclose an invention. There should be adequate local guidance available to assist them with the invention licensing process.

Inventors should also be kept advised of the status of their inventions, at least semi-annually, and especially if royalty payments are expected. One example of an inventor not even knowing they were to receive IP royalties was noted.

Recommendation # 11 - HPB should put in place a reward and recognition system that encourages scientific or technical staff to disclose inventions and take part in externally funded technology transfer projects.

Recommendation #12 - HPB should ensure that its invention disclosure and licensing system is "inventor-friendly" and that procedures are established to keep inventors aware of the status of their invention in the licensing system.

Encourage HPB Researchers to Interact with External Colleagues

Some people within HPB believe that it is inappropriate to interact with their professional colleagues in the private sector, even within professional society activities. This isolation can only inhibit HPB's ability to tap into the latest research or learn what research is of interest to their industrial colleagues.

Unduly limiting the attendance of HPB scientific personnel at conferences because of overly restrictive interpretation of conference attendance guidelines will also reduce the ability of the HPB to learn about collaborative opportunities with external agencies or to identify internal HPB capabilities or technologies that might have the potential for transfer or commercialization.

As many interviewees noted, science today has become too complex for one organization to have all the expertise required in-house. In some areas, it may be the private sector, not the academic sector that has the expertise needed by HPB. Even in the academic sector, many of the professors have close working relationships with companies. Does that make them persona non grata to work with HPB research personnel?

Visits to private sector R&D facilities should be encouraged, not discouraged because of some misguided concept about being tainted by association. The FDA takes the stand that interaction with the private sector or academia gives them advance information on what is likely to turn up on their desks for regulation. This information gives them time to prepare and acquire the expertise to assess the new "products" coming from industry. HPB should adopt the same view.

Recommendation # 13 - Interaction between HPB scientists and their colleagues in academia and industry should be encouraged and supported through, for example, increased conference attendance, memberships in industrially oriented professional associations, and visits to private sector and academic research laboratories.

Business Development Effort

It is very difficult for one person to adequately cover all the business development activities of an organizational unit of the size and scientific breadth of the Health Protection Branch. Again, as noted in the "Best Practices" section, adequate resources allocated to the technology transfer activity is a prerequisite for successful technology transfer.

Personal interviews with technology transfer officers in British government laboratories revealed that the closer the working relationship between the technology transfer officers and the bench level scientists, the higher the probability of identifying commercializable intellectual property and obtaining the cooperation of the scientists in the transfer process (Clarke, 1997). This required technology transfer personnel to be located within or very near the laboratories. Technology transfer officers with similar scientific or technical background, was also mentioned as important by numerous interviewees.

Funding is required to support travel to meet with prospective collaborators or technology adopters. Studies have shown that attendance at conferences by entrepreneurially minded scientists is an excellent market intelligence gathering activity (Clarke, 1996b). They can identify prospective technology adopters or collaborators and bring the information to the attention of the business development office. Business development officers need the funds to travel to prospective partners to learn how HPB expertise can help them and, when appropriate, to take scientists with them.

Each directorate should have its own business development officer (possibly a part-time activity depending on work load) who has an appropriate background in the science or technology of the directorate, and has the business and interpersonal skills to go out and market the "scientific products" of the directorate. This would include looking for collaborative R&D opportunities. They should also be able to build up a bridge of trust with the HPB scientists/researchers.

In order that some consistency be achieved in marketing HPB technology and expertise, the activities of the satellite business development officers should be coordinated, but not controlled, from the central business development office in Ottawa. The central office should be concerned about HPB's corporate image, consistency in the application of rewards to inventors and innovators, and the quality and timeliness of the management of external projects, and should provide support to the laboratory business development officers in the management of intellectual property and general marketing.

Additional funds should be made available for marketing activities which at the moment are focussed on a limited number of license opportunities, leaving other opportunities under-marketed.

The HPB web-site is totally inadequate for supporting technology transfer. The business development effort would be enhanced by the creation of a special web-site on the HPB site. It could be used to advertise technologies for license, active research projects to attract collaborators, and the services offered by the business development office to HPB personnel. Contact names should also be provided. It is also important that the material in the site be up-to-date.

A booklet describing HPB projects, expertise, etc., such as those prepared by the Canadian Police Research Centre (R.C.M.P.) and the National Research Council of Canada, should also be prepared as a hand-out at industrial or scientific conferences or workshops.

Recommendation # 14 - Resources should be allocated to the business development office to increase the number of business development officers, the level of marketing of technology and expertise resident within the HPB, and to construct a licensee/collaborator-friendly web-site that advertises HPB research capabilities and HPB's willingness to enter into collaborative R&D projects or licenses.

Comparison of the Findings in this Report with those in the Draft Papers of the HPB Working Groups Examining Partnerships and Conflicts of Interest

The bulk of this report and, in particular, the recommendations were written prior to receiving copies of the draft papers prepared by two HPB Working Groups on partnerships and alliances, and on conflict of interest issues in HPB (HPB, March, 1999 & HPB, April, 1999). This report, therefore, is an independent assessment of some of the same issues dealt with by the working groups.

The following is an examination of where the two draft papers, and this report come to similar recommendations or conclusions.

An overall theme in the two working group papers and in this report is that any and all interactions with external organizations must directly or indirectly support Health Canada's mandate of protecting the health and safety of Canadians.

Both this report and the paper prepared by the conflict of interest working group note the potential for conflict of interest in the approval of HPB originated technology.

The need for HPB scientific staff to interact with, or collaborate with colleagues in external organizations in order to conduct their work efficiently and effectively was identified in both

working group papers and in this report. The working group on partnerships and alliances agrees with this report that expertise in some areas is only "one person deep" and hence there is a need for collaborative R&D activities to fill gaps in the scientific capacity in some directorates (HPB, March, 1999, p. 17)

The working group on conflict of interest also recommends a system of keeping track of activities and collaborations in order to avoid conflict of interest situations (HPB, April, 1999, p. 15). In the same vein, the group also calls for a mechanism to determine the suitability of entering into, "a particular activity or collaboration" early in the decision process (p. 16). These recommendations are in line with Recommendations 4 and 5 in this report.

The need for a guide for HPB personnel on partnerships and alliances is mentioned in both working group papers. A "Reference Manual on Partnerships and Alliances" is being drawn up. Recommendation 6 in this report calls not only for guidance on collaboration, but also on licensing.

The working group on partnerships and alliances point out that to attract collaborative partners, HPB "must maintain an active, ongoing and relevant research program" (HPB, March, 1999, p. 18). This point was also made in this report's section dealing with HPB's ability to provide unique technology or expertise to external organizations (p. 37).

The need for an improved reward and recognition system in the HPB (Recommendations 10 and 11) was also made by the partnership and alliances working group. "... the Branch must create an environment in which both scientific and administrative excellence is valued ..." (HPB, March, 1999, p. 18).

The partnership and alliances working group recommend the establishment of an appropriately resourced business office to support collaborative activities (HPB, March, 1999, p. 21). Given that there is already a business development office in the HPB, the recommendation of this report is to expand its operations beyond being a "one person shop" and ensure that it is adequately resourced for the services required of it.

Overall, where the working group's recommendations and those of this report overlap, there is agreement in the actions that must be taken if technology transfer activities are to be successfully expanded.

CONCLUSIONS

Technology transfer activities can be expanded within the Health Protection Branch, **if** the appropriate management culture, financial tools and processes are established to facilitate interactions with external agencies. If they are not, expanded technology transfer will be virtually impossible.

Expansion of technology transfer activities and, in particular, collaborative R&D with external organizations, including the private sector, would be in line with federal government policy.

Expansion will require concrete actions and commitment on the part of the senior management of HC/HPB to bring about the changes in procedures and management culture necessary to ensure that expanded technology transfer activities will be beneficial to both HPB and the Canadian public.

The benefits of expanded technology transfer activities are new financial resources needed to support research, researchers being able to keep up-to-date, intellectual stimulation from working with research partners, access to the large pool of expertise, knowledge and resources resident in the academic and private sector, the practical application of HPB technology and expertise in protecting and maintaining the health of Canadians, retention of the best researchers and an opportunity for HPB staff to gain recognition for their work from colleagues and the public.

The down side will be the need for increased vigilance to ensure that real conflict of interest situations do not occur, and that perceived conflict of interest situations are well managed. The FDA's experience with technology transfer confirmed that the benefits to the organization and its ability to carry out its public good mandate will outweigh the additional administrative "costs". Being as open as possible about technology transfer activities is the main defence against the perception of conflict of interest.

No HPB interviewee suggested that the primary mandate of the HPB to protect the health and safety of Canadians should be subservient to making money or working with the private sector. HPB interviewees did, however, recognize that working with the private sector and other organizations could enhance their ability to serve the Canadian public. Technology transfer activities at Health Canada will always be of the "spin-off" variety; a dual use that meets the needs first and foremost of Health Canada, and second, those of an external organization.

Fear of conflict of interest issues should not be allowed to paralyse the HPB from taking action that can demonstrably improve its ability to serve its mandate of health protection through expanded technology transfer activities. As several interviewees noted, HPB is missing opportunities now to play a greater role in serving the Canadian public.

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