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

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EXECUTIVE SUMMARY

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. 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 is, however, an explicit part of the mandate of every science-based government department and agency as noted in the Federal Government's March, 1996 report entitled, "*Science and Technology for the New Century: Summary* (p. 10-11).

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 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 over fifty 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 as well as representatives of Canadian medical/pharmaceutical associations were also

contacted. In addition, an extensive review of the literature concerned with 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

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.

"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.

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

Review of the Technology Transfer Literature

A review of the literature concerned with government to industry technology transfer shows that government technology transfer programs can be divided into two categories: "Spin-off" and "Utilization" programs. The former occur in government laboratories where the primary mandate is protection of the public or service to an internal client, while the latter are associated with government departments with a mandate to develop new technologies specifically for transfer to the private sector. Health Canada clearly falls into the "Spin-off Technology Transfer" program category.

Involvement in technology transfer activities provides numerous benefits to a government laboratory and its scientific personnel. Among the most important are:

- improved technical ability to solve problems, improve services or develop effective regulations;

- in-kind resources from collaborative partners;

- better data for decision making;
- satisfaction in seeing their work improve the health and well-being of Canadians;
- increased national and international reputations;
- new revenues to replace declining and/or inadequate A-base funding allocations; and
- a more focussed approach to government research.

There are, however, process and conflict of interest problems that can interfere with the smooth transfer of technology from a government laboratory to industry. Among the process problems are:

- researchers not thinking about possible commercial applications of their research at the beginning of a research project;
- having to work with a bureaucratic technology transfer process;
- government financial mechanisms not being attuned to working with the private sector;
- lack of adequate reward or recognition for technology transfer activities;
- inequitable sharing of revenues from IP licensing fees;
- 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 the provision of advice to bench level scientists on IP management.

The conflict of interest problems include:

- public perception of "public good" versus "making money";
- government employees actively assisting an IP adopting firm market the end-product;
- loss of objectivity resulting in biased performance or reporting of research;
- a reordering of research priorities favouring more applied, commercially oriented research at the expense of basic research; and
- the reduction or delay in the free flow of information among researchers, and to the public.

Management researchers who have studied the conflict of interest issue appear to conclude that given the increased involvement in collaborative R&D activities with partners from various economic sectors, it is no longer possible to avoid conflict of interest, it must be managed.

Previous studies into technology transfer from government laboratories to industry have developed lists of "Best Practices" that support and encourage efficient transfer. Among the best practices mentioned are:

- high and middle level support for the technology transfer activity;
- strong intrapreneurial attitudes among the federal scientists;
- low level of government red-tape and few bureaucratic rules;
- existence of a royalty-based incentive system within the government laboratory;
- adequate levels of resources have been assigned to support technology transfer;
- existence of an inventor-friendly disclosure process;
- bench level scientists and engineers are provided with training in the technology transfer area;

- a suitable reward and incentive system is in place to motivate and encourage technology transfer; and

- technology transfer is recognized within the government department as a legitimate, valued activity.

Both the U.S. FDA and the CDC have technology transfer programs which rely on the National Institutes of Health (NIH) technology transfer office for intellectual property management services. An arrangement similar to that between the HPB and the National Research Council's Intellectual Property Office.

Representatives of the FDA and CDC believe that their technology transfer activities (IP licensing and Cooperative R&D Agreements) have benefited their organizations by:

- allowing them to retain top researchers who might otherwise leave for greener pastures;

- assisting their researchers in keeping up-to-date in their scientific fields;

- giving their researchers greater exposure to the outside world;

- seeing the results of their scientific research move from the laboratory to the market place;

- allowing them to conduct research that they might not otherwise be able to do because of budget cuts; and

- providing their scientists with an opportunity to receive recognition from their scientific peers.

According to an FDA representative, "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".

The FDA's main line of defence against the charge of conflict of interest is to have everything out in the open. FDA processes, procedures and the names of their collaborative partners, are published on their web-site. The CDC does the same.

Two U.K. organizations were contacted; the Medicines Control Agency and the Medical Devices Agency. Unlike the U.S., they rely mainly on external independent laboratories for their scientific advice. Thus, they are not involved in technology transfer activities.

Resultsof Interviews with HPB Personnel

Interviews were held with over 36 HPB administrative and scientific personnel. The vast majority of HPB personnel interviewed believed that there were legitimate opportunities to expand the technology transfer activities of the Health Protection Branch, but all qualified their responses.

Among the areas where interviewees and focus group participants believed that the 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.

HPB personnel identified the following issues that must be dealt with by senior management if the expansion of technology transfer activities is to succeed:

- need to change the existing mandate and management culture to support technology transfer;
- need to change the existing financial and administrative procedures to facilitate technology transfer or collaboration (e.g., lack of respending authority);
- HPB's ability to develop new unique technology or expertise of value to external organizations is in question because recent downsizings and reorganizations have resulted in the loss of scientific staff;

- lack of reward or recognition to engage in technology transfer;
- mixed messages from senior management on the validity of involvement in collaborative research projects;
- lack of guidance on how to proceed with technology transfer activities and, in particular, R&D collaboration;
- lack of knowledge about technology transfer and intellectual property management;
- allocation of HPB resources between internal and external collaborative projects;
- dealing with the memory of previous poor experiences with technology transfer attempts;
- having to "approve" HPB originated technology that has been licensed to a private firm for sale to the public; and
- need for expanded business development/technology transfer support.

Pros and Cons of Expanding HPB's Technology Transfer Activities

The possible expansion of HPB's technology transfer activities has both positive and negative aspects. The positive aspects of expanding the HPB'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 the 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 budget covers salaries but there is little left over to fund the actual research. Research money must come from collaborative research arrangements.

The negative aspects to 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;

- not having sufficient personnel to work with an outside organization and adequately support the internal public good mandate;

- concern by industry 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 to HPB or overly generous licensing arrangements.

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 believe that working with the private sector and their public good mandate are mutually exclusive.

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.

However, 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.

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.

Interviewees noted the lack of any substantive awards or forms of recognition for being involved in technology transfer activities.

The present level of resources allocated to technology transfer activities in terms of funds to move projects forward to a point where they would interest external partners, to conduct adequate marketing activities and to identify potential partners or licensees do not appear to be adequate.

Therefore, under the present management culture, the decline in the scientific research capability, inadequate reward structure and the inadequate 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 the HPB, several of the laboratories are said to be facing closure.

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. Collaboration is, therefore, as the FDA argues, supportive of the public good mandate of health protection.

The following are suggestions/recommendations on how the HPB can improve the working environment in support of technology transfer activities:

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.

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.

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 are 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 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 projects on the HPB web-site.

Recommendation # 8 - Develop a standard process, which may involve a 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.

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

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

Recommendation # 11 - HPB should put in place a reward and recognition system that encourages scientific and 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.

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.

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.

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/collaborative 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. As the gentleman from the FDA's CBER confirmed, 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 a partnering 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 and collaborative activities. As several interviewees noted, HPB is missing opportunities now to play a greater role in serving the Canadian public.

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