

Concurrent Session D: Emerging Public Health Law Issues

Moderator: Derek Jones

*Director, Interagency Advisory Panel and Secretariat on Research Ethics,
Government of Canada*

Derek Jones, Executive Director, Interagency Advisory Panel and Secretariat on Research Ethics, welcomed participants.

Tim Caulfield

*Canada Research Chair in Health Law and Policy
Research Director, Health Law Institute, University of Alberta*

Tim Caulfield, Canada Research Chair in Health Law and Policy, and Research Director, Health Law Institute, University of Alberta, presented a series of collages to highlight some emerging public health issues associated with genomics and genetic technologies.

Most experts accept that genetics affects the health of the population, especially with regard to chronic disease. Genetic research and technologies are also giving rise to many speculative applications including pharmacogenetics and nutrigenomics. Though it is early in the study of these applications, messages are already going out to the public about their presumed risks and benefits.

In this atmosphere of abundant research, speculation, high media interest, and marketing, what are some implications of genetics for public health?

The study of gene-environment interaction is useful for developing prevention strategies and targeting interventions and has generated much excitement, said Mr. Caulfield. Large studies have been initiated around the world—notably, the UK biobank. The X Prize for Genomics has offered US\$10 million for rapid genome sequencing. Here, the Canadian Lifelong Health Initiative is a cohort study of 60,000 people. Big biobanks are increasingly viewed as having economic potential: a recent ad placed by the Government of Newfoundland and Labrador invited genetic research.

Challenges of this area of study include issues of consent and confidentiality in biobank research. Truly full, informed consent is impossible at the outset of a long-term project and is logistically difficult to obtain in progress. Another concern is distraction. A great deal is being invested in speculative genetic research, while other areas receive less funding even though they are known to have a broad impact on public health.

Fatalism arising from public messages about genetics is an emerging problem for the public health field. Genetics receives enormous attention in the popular press—*Time* magazine alone has devoted 13 covers to the topic—and the message in these popular representations is usually that genetics determines health. This has led to the popularization of genetic determinism, which, when applied to a public health concern such as obesity, can contribute to fatalism and discourage lifestyle changes.

Genetic determinism is even applied to socio-economic factors; recent news stories in Scotland refer to research on a “poverty gene.” Research reveals that belief in such determinism is most prevalent in the very populations most at risk, such as groups with low socio-economic status. How can information about genetics research be provided to the public in a way that will be beneficial to public health?

Another issue of concern is the re-emergence of the fallacy of a biological basis for race. Issues of race and public health have not had a wonderful history, Mr. Caulfield said, and now genetics appears to be influencing popular messages about race that would have been considered unacceptable just a few years ago. Recent examples include a *Globe & Mail* story, in which race is discussed as a biological construct, and a men’s health magazine article that advises men on lifestyle choices and anticipated diseases based on race.

Races are socially-constructed categories, not biological ones. Within visible phenotypes, there are genotypes that have real genetic relevance. These phenotypes fall within the broad social categories of races. As a result, “race” is sometimes used as a “rough proxy” in areas like public health.

This trend is reflected in the marketing of race, in which manufacturers target racialized demographics of consumers, using genetically based claims. Examples include a heart medication that is advertised as working best on African Americans. In this, pharmaceutical companies are influenced more by marketing trends than by scientific knowledge. Alcohol and cigarettes are also increasingly marketed by race. This messaging can have real impact on the public’s concept of race and may reinforce racist attitudes.

Mr. Caulfield concluded with some suggestions about possible legal and policy responses to several concerns:

- The development of marketing guidelines;
- The regulation of testing;
- The control of genetics information;
- Attention to these issues in research policy;
- Communication strategies for counteracting some of the misleading genetic information in the popular media.

Trudo Lemmens
Faculty of Law, University of Toronto

Mr. Lemmens delivered the condensed version of a book chapter he co-authored with Ron Bouchard. Though drug regulation is a longstanding issue, this topic is appropriate to a session on emerging issues, because it has not yet received the attention it requires.

The numbers illustrate the difficulty of pharmaceutical regulation in Canada: there are more than 22,000 pharmaceutical products on Canadian markets, and in 2004–2005, more than 378 million prescriptions were issued. In 2005, there were 63 new drug applications, 227 applications for new uses, and 139 new generic drug applications. Global pharmaceutical sales in 2005 amounted to US\$602 billion.

Though pharmaceuticals are undeniably useful, they can cause problems for public health. A recent *Journal of the American Medical Association (JAMA)* study found that 2.5% of US emergency room visits—700,000 per year—were due to adverse drug events and that such events affected 2.4 per 1000 individuals. A 1998 meta-analysis of studies concluded that drug-induced side effects are the sixth leading cause of mortality in hospitalized patients.

Vioxx is a prominent, recent example. Research suggests that Vioxx may have caused 140,000 serious injuries or deaths. At the time it was withdrawn from the market, 80 million people were taking it, and 160,000 per 10 million might have had a stroke.

The state has a range of regulatory interventions at its disposal for ensuring the safe and proper use of pharmaceuticals. The first is direct regulation, including the regulation of entry into the market, control of sales, and information requirements. The second is regulation of the informational environment such as the prohibition of direct-to-consumer advertising. Price controls, taxing, and tort law also serve to regulate pharmaceuticals. The regulatory framework includes areas of federal and provincial jurisdiction.

Legal regulation of food and drugs began in the early 20th century. In the 1960s, the thalidomide crisis led to an increased focus on safety and risk-benefit analysis, even if this delayed access to new drugs. Since the 1980s, regulatory agencies have been under pressure from patient advocacy groups and the industry to shorten review times. Shifts in this period have included the introduction of industry user fees to cover new drug reviews, which account for a large proportion of the regulatory budget. The current regulatory atmosphere is collaborative, with regulatory agencies assuming the dual role of protecting the public while contributing to a healthy pharmaceutical industry.

In addition to the social, political, and economic elements of the regulatory context, a crucial element is the financial impact of entry into the market. Huge annual sales—in the tens of billions of dollars for some drugs and classes—provide a significant financial incentive to push for fast market review. In contrast, the financial incentive for assessing long-term safety is quite low, with lawsuits viewed as part of the cost of doing business. Moreover, the industry wields significant political influence because of its financial power. Huge revenues also create an incentive for market expansion through the “medicalization of everyday life,” in which physical and emotional conditions previously viewed as normal are reframed as treatable illnesses by drug marketing campaigns.

In this context, the regulatory process now is characterized by an emphasis on fast review and approval, strong recognition of the commercially sensitive nature of information, reliance on the integrity of industry and on self-report, and sponsor-designed trials.

The problems with the current system are illustrated by *Attorney General of New York v. GlaxoSmithKline* in June 2004. The pharmaceutical company was charged with engaging in repeated fraud for failing to disclose to physicians information about the safety of Paxil in treating children and adolescents. Though an internal review showed that three studies of this use were not successful, the company found one positive study, which it published in abstract form in a major journal. Copies of the abstract were then distributed by company marketers to doctors' offices. The case cited internal documents stating that the company's intention was to "manage dissemination of the data to minimize negative commercial impact."

This example highlights many problems with the current regulatory process:

- The focus is on the initial review of safety and efficacy.
- The agency has limited authority to impose post-marketing research.
- There is little control of the way drugs are used once they are approved.
- There is a lack of reliable scientific information for health care providers.

In reference to this last point, data submitted by pharmaceutical companies is considered to be commercially sensitive, confidential information under the federal *Access to Information Act*.

Though the trial registration system being considered for drug regulation in Canada is somewhat promising, it is limited. It does not provide the agency access to the raw data in the registry. Nor does it deal with post-market promotion, and the sponsor still controls the design.

Mr. Lemmens concluded that these new initiatives seem to perpetuate the "cozy relationship" between industry and government. He called for greater separation, and stated that Health Canada's Blueprint for Renewal should support structural change, in the form of a new drug regulatory agency. This agency would take over the conduct of clinical trials from industry.

Tina Piper
Assistant Professor of Law, McGill University, Montreal, QC

Tina Piper, Assistant Professor of Law, McGill University, introduced her presentation as "a story about the way patent law is changing in dealing with epidemic diseases." Epidemics, she said, provide an interesting intersection between patent law and public health.

Patents and public health share a chequered history marked by tense moments about access to medications, especially antiretrovirals to combat HIV. Intellectual property law also limits access to testing technologies, basic medical procedures, and the building blocks of research.

Patents are a government-granted monopoly over an innovation in a specific territory. They are important elements of corporate strategy. Patents can be used offensively or defensively, and corporations obtain patents to license them. Patents and licenses are expensive and time-consuming to obtain, especially in multiple jurisdictions. Often companies do not know whether their patents are worth anything until they are challenged. Patents can be revoked or repossessed in some jurisdictions, and when many inventors apply for a similar patent at once, the Patent Office (PO) decides who gets it.

Patents have certain distinct qualities:

- They are slow to obtain or share.
- Once you get a patent, you still cannot be sure you have it.
- Patents are territorial.
- They are managed by a single agency.
- They are granted to promote a private interest.

Epidemic diseases, on the other hand, possess different characteristics:

- They are easily caught and shared.
- Once you have an epidemic, you are sure you have it.
- Epidemics do not respect territorial boundaries.
- They are managed by multiple agencies.
- They are a matter of public interest.

There is a tension between the two that raises ethical questions: is it acceptable to profit from an epidemic? What are the acceptable private interests in an epidemic?

The SARS epidemic of 2002–2003 offered an interesting example. The sequencing of the SARS virus during the epidemic was a hallmark of international scientific cooperation, but more than 200 national agencies and groups have filed for patents on all or parts of the genetic code. There are four main parties: Health Canada, the CDC, CoroNovative, and Versitech.

Questions and Discussion

Dr. Samuel Abraham of the British Columbia Cancer Agency said these patents were tools for ensuring public access because they prevent a single interest from cornering the market. This is an example of defensive patenting and one of four creative solutions to patent-granted monopolies on technologies necessary for the public's health. Other creative solutions include putting information in the public domain, making the basic information available under an open-source license and tweaking patent law to try to increase access.

The problem with defensive patenting, in this case, is that any company planning to develop a vaccine will have to get a license from each of the four major parties. This will introduce extra uncertainty and more work. Vaccine companies will be concerned about whether a market will develop for their products, whether it will be worthwhile defending their patents, whether their license will be exclusive or not, and whether their licensing costs will be recouped. Vaccine creation becomes an uncertain investment, and consumers bear the costs of this uncertainty.

Patent pools—non-exclusive patents available to a wide range of parties—might offer a solution to this dilemma. Vaccine developers would require one license from the pool instead of from multiple patent-holders. Patent pools provide a number of advantages: they reduce risk, increase access, push innovation downstream, and allow for standard setting and coordination. There are also disadvantages: pools are anti-competitive, they increase the value of each patent, and they are not systemic. Patent pools are not necessarily in the public interest.

Ms. Piper closed with a number of questions. Should public health agencies be applying for and managing patents? Who represents the public interest? Should anyone profit? If so, to whom and how are profits distributed? Can a system with national boundaries, regulation, constituents, and accountability mechanisms respond effectively to international problems? And finally, Ms. Piper asked, are patents the most effective tools? What alternatives are possible?

Mr. Jones informed participants that the tri-council will conduct a consultation this fall on issues arising from the suppression and diffusion of clinical trial data, including the possibility of regulation. He invited those present to participate in the online component of the consultation.