Chapter 9

SOME LEGAL AND ETHICAL ISSUES RAISED BY SARS AND INFECTIOUS DISEASES IN CANADA

The SARS outbreak and its aftermath have raised a number of legal and ethical issues. We begin with legal issues, as these are most germane to the Committee's mandate. A number of provider groups, such as the Canadian Healthcare Association, the Canadian Medical Association, and the Canadian Pharmacists Association, raised the need for specific legislative reforms. Indeed, the legal issues raised by SARS speak to the need for a thorough review of the broader constitutional and statutory framework governing infectious disease management in Canada. They include, among others: the efficacy of existing federal and provincial legislation governing responses to communicable disease outbreaks; the legal relationships between local and provincial public health officials; the constitutionality of mandatory isolation, quarantine, and treatment orders under both federal and provincial law in light of the *Canadian Charter of Rights and Freedom*'s guarantees for physical liberty and procedural fairness; workplace legislation and regulations as regards rights to refuse dangerous work and continuation of salary during quarantine or isolation; and the legal framework governing health information privacy under the *Charter*, provincial privacy and health information statutes, and other legislation governing the health sector. Although all of these issues require eventual attention, we focus here on a narrower set of questions.

First, we revisit, following from discussion in Chapters 3 and 4, some of the legal instruments available for the creation of a national infrastructure for the detection and management of infectious disease outbreaks. Second, a draft discussion document on federal legislation dealing with national health surveillance (the Canada Health Protection Act) has recently been circulated. We review the impact of this proposed legislation, and the impact of existing federal legislation (the *Privacy Act* and the *Personal Information Protection and Electronic Documents Act*) and proposed federal legislation on the creation of a national database for infectious disease surveillance and provider reporting. Next, we review aspects of existing public health legislation in three provinces (British Columbia, Ontario and Quebec) that deal with infectious disease outbreaks, and assess this legislation against the benchmark of the US Centers for Disease Control and Prevention's [CDC] Model State Emergency Health Powers Act. The last legal area for review is the matter of federal emergency legislation. The concluding section of the chapter returns to ethical issues and lessons learned from the SARS outbreak.

9A. General Legislative and Governance Issues

9A.1 Legislation and Regulation as Components of the National Public Health Infrastructure

In Chapter 4, we outlined the basic components of the public health infrastructure, indicating that an appropriate legislative and regulatory framework was essential to giving Canada a stronger capacity for coordinating and managing a response to outbreaks such as SARS. What exist now are separate systems within each of the provinces and territories, as well as a federal system that operates primarily at Canada's international borders. These systems are connected by a limited number of intergovernmental agreements, rather than through a systematic set of intergovernmental agreements oriented around an agreed strategic plan or through formal legal instruments that enable the systems to operate collectively and detect and address common challenges.

In legal terms, we are speaking of the need for rules of conduct (public health rules) that could guide the behaviour of all actors in the public health system—health care providers (e.g., physicians, nurses), health care institutions (e.g., hospitals, laboratories), public

health officials from all levels of government (federal, provincial and local), and private individuals potentially subject to quarantine and isolation orders. With respect to surveillance, examples include rules governing the following: case identification (e.g., uniform criteria for diagnosis and laboratory testing), data sharing (e.g., timelines and procedures for reporting new cases and norms governing the protection of privacy), and information dissemination (e.g., responsibility for communicating to national and international audiences and the content of such communications). National public health rules are particularly important with respect to surveillance, because they facilitate the development of a real-time picture of the spread of infectious diseases at the national level.

Obviously, a national infrastructure also involves the creation of new federal and F/P/T *public health institutions*. These have already been outlined in previous chapters. In each case, considerable effort is needed to determine how these institutions will operate, and we have assumed in our budgetary thinking that this in itself will be a non-trivial albeit time-limited cost.

We reviewed in Chapter 4 the role of three policy instruments that operate on an interleaved basis—***grants***, ***contracts***, and ***intergovernmental agreements***. Given the critical nature of public health, and the need for genuine consistency and clarity about who does what, the Committee necessarily returns here to a fourth key policy instrument—legislation and regulation.

Again in simplified legal terms, the federal Parliament or a provincial legislature may (a) enact rules, or (b) delegate the power to make rules either to entities that are part of government (e.g., Cabinet, ministers of health) or arm's length from government (e.g., the Canadian Agency for Public Health, or the F/P/T Network for Communicable Disease Control). Rules enacted by legislatures take the form of legislation, whereas rules enacted by an authority exercising delegated powers take the form of regulations, by-laws, orders-in-council, etc. As an example, legislation could set out processes and authority for establishing a list of reportable and notifiable diseases, and regulations or by-laws could specify the current list of relevant diseases.

The advantage of legislation is that it governs the conduct of public officials and private institutions and individuals with or without their consent. But the limitation of legislation is first, that a legislature can only enact legislation in areas where it has jurisdiction, and second, that legislation represents a visible use of power by government with attendant political costs—particularly in a federation such as Canada where there have been tensions and centripetal forces over many decades. As noted in earlier chapters, the constitutional division of responsibility is not well-aligned with taxation authority in Canada, with the result that successive federal governments have used spending power instead of legislative authority in the health field.

Our recommendations thus far have followed this tradition. In effect, we are recommending that the federal government use grants as incentives for provinces, municipalities and health care providers to participate in a national infrastructure and infostructure (e.g., setting data standards regarding the timeliness and accuracy of information as conditions, agreeing to interoperability for outbreak surge capacity, sharing laboratory resources, etc.), without seeking to establish its jurisdiction over public health aspects of infectious disease management. This new flow of funds would be accompanied by structures to facilitate the attainment of F/P/T consensus and the creation of multiple intergovernmental agreements on the parameters of a renewed and seamless public health infrastructure. However, the Committee sees a continuing issue of governance and legislative authority that requires medium-term consideration.

9A.2 Governance Aspects

In theory, public health norms could be set by the federal government or by the new agency acting on the authority of Parliament. The legislation establishing the agency could set out a comprehensive set of public health norms, and/or delegate the enactment of public health norms to the Cabinet, the Minister of Health, or the new Canadian Agency for Public Health. The act would prevail over conflicting provincial public health legislation, unless challenged in the courts and struck down as unconstitutional.

An existing model for such an approach is the proposed *Assisted Human Reproduction Act*, Bill C-13. Bill C-13 would criminalize certain conduct (e.g., human cloning). It also would permit certain "controlled activities" (e.g., handling of sperm) to be performed only by licensed individuals, and/or at licensed facilities, in accordance with terms spelled out in regulations. The regulations would lay down how "controlled activities" could take place, effectively regulating the work of health professionals in connection with assisted human reproduction. Bill C-13 would also require licensees to report certain health information to a new federal agency, the Assisted Human Reproduction Agency of Canada, which would maintain a personal health information registry that could be used to administer and enforce the Act. Although

there is provision in this scheme for provincial input, and for enforcement to be delegated to the provinces, the Agency would clearly be a federal agency.

A federal model would be the most efficient way to achieve national uniformity in national public health rules, but has drawbacks that we have already indicated. Unless its terms were closely aligned to the collaborative mechanisms set out elsewhere in this report, and unless it carried with it a funding mechanism, a federal model would run the risk of imposing unfunded federal mandates, and spark substantial opposition from provinces. From a policy standpoint, federal uniformity may come at the expense of provincial innovation and experimentation. The measures already set out in the Committee's report should allow the federal government and its provincial/territorial partners to stitch together existing uncoordinated local, provincial and federal public health systems into a national system, with attendant harmonization of existing provincial and local public health rules. A federally-imposed system might instead be viewed as a necessary last resort if collaborative and consensus-building mechanisms fail.

An alternative approach to creating system norms and rules would be for all levels of government to delegate powers to some new steering group. In this instance, public health norms could be set either by federal, provincial and territorial governments acting collectively, or by the new Canadian Agency for Public Health. Local public health authorities would remain in place to implement national public health norms. A weak scheme of F/P/T cooperation to these ends is in place at present, but it is largely informal.

How could this scheme be effected? As indicated in Chapter 4, the new agency would fund and facilitate the implementation of nationally-consistent norms as part of the implementation of various initiatives through the Public Health Partnerships Program. New funds for the National Immunization Strategy could flow to the same effect.

The F/P/T Network for Communicable Disease Control provides another vehicle, one with joint governance to facilitate urgent consensus-building in the realm of disease surveillance and outbreak management, where front line and provincial capacity is essential. It is theoretically possible but unlikely, that federal, provincial and territorial lawmakers would delegate powers to the network, which could then regulate both provincial and local public health responses. On the other hand, since the governance structure for the new network is based on F/P/T co-decision, our expectation is that the network will facilitate a process of harmonization of public health norms in federal, provincial and territorial legislation. In turn, that process could lead to legislative renewal and harmonization.

All these initiatives assume that provincial legislation would remain in place, and would be modified as necessary to comply with either federal conditions or, ideally, an emerging F/P/T consensus. They assume that neither Health Canada nor the new Canadian federal agency has legal authority to regulate provincial, territorial and local public health responses. And they assume, most importantly, that SARS has brought all F/P/T governments to a unanimous view that public health matters should be separated from other jurisdictional tensions, and regulated cooperatively.

The Committee accepts that all of these endeavours could be undermined if provinces and territories refuse to participate collaboratively. Hard decisions must be taken in the early days of the network, for example, as to whether the majority rules or whether a new norm must be adopted unanimously. As described in Chapter 5, an F/P/T process has been underway with respect to disease surveillance for many years, and has made only limited progress on a range of important issues. Accordingly, one might ask: What is the fall-back position if these new investments fail to secure progress?

In this regard, an obvious option is 'federal default'. "Default" public health norms would be set by the federal government, with advice from the new agency. Provincial rules would apply if they were "substantially similar" or "equivalent" to the national public health norms, thereby permitting provincial innovation and experimentation while ensuring national standards. The federal legislation would presumably include a list of notifiable diseases and terms for information sharing that would allow the federal government to meet its national as well as international obligations. Local public health authorities would remain in place to implement the national norms. Examples of federal legislation that set out a federal default position that does not apply in provinces with equivalent or substantially similar schemes include the *Tobacco Act*, the proposed *Assisted Human Reproduction Act*, the *Personal Information Protection and Electronic Documents Act*, and the *Canadian Environmental Protection Act*. The effect of this model is to permit provincial statutes to prevail over federal law in the event of overlap—a reversal of the norm whereby federal law prevails over provincial law in areas of overlapping jurisdiction. The courts have not considered the constitutionality of these provisions.

Federal default legislation charts a middle path that both ensures the creation of a national minimum and permits provincial variation. However, because the federal legislation would impose legal obligations on provincial and local public health officials, this strategy would still engender provincial/territorial opposition unless sufficient progress was made through the new funding mechanisms, strategies, and networks to permit the emergence of a consensus on 'template' provincial legislation and associated federal responsibilities that would be encompassed in the federal default provisions. On the other hand, if insufficient progress is made despite the investment of hundreds of millions of dollars, we believe Canadians would expect the federal government to get on with the task of creating a clearer framework for its own role and the corresponding default legislation for F/P/T interactions.

In all of this discussion, the question remains: Setting aside the various political and practical issues that have been given point above, does the federal government have a constitutional basis for legislating in the public health sphere?

9B. Jurisdictional Issues

9B.1 Background

As noted in Chapter 3, the Canadian Constitution's few explicit references to health-related matters grant *both* levels of government jurisdiction. The Constitution confers jurisdiction over "hospitals" and "asylums" on provinces, and jurisdiction over "quarantine" and "marine hospitals" on the federal government. Since the goal of the drafters of the Constitution in 1867 was to create two levels of government with non-overlapping areas of jurisdiction, these provisions can be interpreted as *dividing* jurisdiction over public health, with the provinces governing local public health matters, and the federal government attending to public health risks that arise at Canada's international borders (hence the references to quarantine and marine hospitals).

Over time, court decisions have placed many aspects of health care regulation within provincial jurisdiction. The courts have held that provinces possess jurisdiction over public health, including legislation for the prevention of the spread of communicable diseases, and sanitation. The provinces have exercised this jurisdiction to engage in health surveillance (including reporting and tracking), outbreak investigations, quarantine, isolation, and mandatory treatment. Moreover, the courts have granted provinces jurisdiction over a variety of related areas: drug addiction (including legislation for involuntary treatment), mental health (including legislation for involuntary committal), the medical profession (including the practice of medicine), workplace health and safety, the regulation of foods for health reasons, the safety and security of patients, and hospitals. The Supreme Court has stated that provinces enjoy jurisdiction over "health care in the province generally, including matters of cost and efficiency, the nature of the health care delivery system, and privatization of the provision of medical services," as well as "hospital insurance and medicare programs."

These areas of provincial jurisdiction are well-established. The central basis of provincial jurisdiction is the provincial power to regulate "property and civil rights". This power has been interpreted very broadly by the courts to encompass rights that individuals possess under the common law of tort (e.g., the right to bodily integrity, which is at issue in medical negligence, assault, and battery), contract, and property. Any public health law that infringes upon these common law rights falls within provincial jurisdiction.

Despite the broad powers of the provinces to regulate public health, federal involvement has also been clearly sanctioned by the courts. Indeed, the Supreme Court has said that "subjects related to 'health' do not exclusively come within either federal or provincial competence," and that "Parliament and the provincial legislatures may both validly legislate" with respect to health.

The firmest basis of federal jurisdiction over the management of infectious disease outbreaks is the federal power over "Criminal Law" although a good argument for federal jurisdiction can also be made on the basis of the federal power to legislate for the "Peace, Order, and Good Government" of Canada (the POGG power). To many, criminal law instruments—consisting traditionally of a criminal prohibition, police enforcement, prosecutions before the courts, and criminal sanctions—would appear to be unsuitable for the information-gathering and treatment goals that would underlie a national infrastructure for infectious disease surveillance. This harkens back to the eighteenth century concept of public health practitioners as the 'medical police', introduced in Chapter 3! The POGG power, which has been interpreted to permit the federal government to address issues with "national dimensions", appears to be a more appropriate vehicle for federal involvement. However, the importance of the criminal law power relative to federal jurisdiction is a function of Canada's constitutional history.

9B.2 Public Health and the Criminal Law Power

Although the Constitution assigns the federal government broad powers, such as the POGG power and the power to regulate "trade and commerce", most of these powers were historically interpreted extremely narrowly by the courts. By contrast, the federal criminal law power has been interpreted very broadly, and as a direct consequence, became the constitutional basis for a wide variety of federal legislation. Thus, the federal criminal law power is the constitutional basis for a wide range of statutes outside the traditional criminal law context, including the former *Combines Investigation Act*, the *Competition Act*, the *Canadian Environmental Protection Act*, and health legislation such as the *Food and Drugs Act*, the *Hazardous Products Act*, the *Tobacco Act*, and Bill C-13, the proposed *Assisted Human Reproduction Act*. The response of the Supreme Court to the federal government's extensive use of the criminal law power has been in many cases to extend its scope even further.

The focus of previous applications of the federal criminal law power to health-related issues has been on *products* that pose a risk to human health. However, through the criminal law power, Parliament has already regulated threats to human health posed by other *individuals* (e.g., the *Criminal Code* prohibitions on assault and murder). By analogy, Parliament might govern individuals who jeopardize human well-being because they have contracted an infectious disease.

The Supreme Court has stated that "[t]he scope of the federal power to create criminal legislation with respect to health matters is broad," and has laid down a three-part test for determining whether a federal law falls within the scope of the federal criminal law power: (a) Does the law prohibit an activity? (b) Are there penal consequences for contravening that prohibition? and (c) Is the prohibition motivated by a criminal law purpose?

Put another way, from a public policy standpoint, the principal limitation of the criminal law power is that it requires the creation of criminal offences. Criminal law offences are usually part of the traditional model of criminal law regulation, which consists of (a) prohibited conduct that is (b) clearly stated in statute, and (c) enforced through *ex post* criminal prosecutions, (d) before the criminal courts. This model is unsuitable for public health laws.

However, the Supreme Court has recently upheld under the criminal law power statutes that tie criminal prohibitions to extensive regulatory regimes, in the firearms and environmental protection contexts. These schemes are a far cry from the traditional model of criminal law, and may be designed to pre-empt the need for criminal prosecutions. An example of a criminal law statute regulating health care that contains an extensive regulatory regime is Bill C-13, the proposed *Assisted Human Reproduction Act* (discussed in more detail above).

Public health legislation, of course, has different goals than the traditional concerns of the criminal law. However, to be a criminal law, a law must be enacted for one of the following reasons: "public peace, order, security, health or morality." Public health laws are clearly enacted for a "health" purpose. Moreover, the Supreme Court has recently loosened up the test even further, now only requiring the law to have been enacted to further "fundamental values", a standard that a public health law would no doubt meet.

A potential advantage of predicating federal legislation on the criminal law power is that strictly intra-provincial activity may be regulated. In contrast, the national dimensions branch of the POGG power (discussed below) enables federal legislation to regulate interprovincial activity. The leading example here is the *Criminal Code* itself, which of course governs crime within any single province. The *Food and Drugs Act* and Bill C-13 also prohibit intra-provincial activity.

On the other hand, courts reviewing federal legislation will examine if it is a disguised attempt by the federal government to regulate areas of provincial jurisdiction (e.g., the practice of medicine). Thus, the legislation would need to be crafted with a view to avoiding those areas where the federal government has no claim to concurrent jurisdiction.

9B.3 Public Health and the POGG Power

Two branches of the federal government's Peace, Order and Good Government [POGG] power are relevant to public health and infectious diseases: (a) the "emergency" branch, which gives the federal Parliament jurisdiction to enact laws that would normally lie in provincial jurisdiction, on a temporary basis, in times of national crisis; and (b) the "national dimensions" branch, which gives the federal Parliament jurisdiction to enact laws in areas of concern to Canada as a whole.

The emergency branch of the POGG power sets aside the division of powers during emergencies, conferring "command-and-control" authority on the federal government. It is applicable to public health, since the courts have referred to epidemics and pestilence as health-related situations in which it could be invoked, but the threshold is very high, and therefore it has no applicability in most situations. More critically, the emergency branch of the POGG power can only be exercised for the duration of the emergency. Thus, the emergency branch of the POGG power could not serve as the constitutional basis of mandatory reporting for a national surveillance system and other components of a national public health infrastructure.

The national dimensions branch of the POGG power has intuitive appeal. It is what, in non-legal terms, most informants have invoked when speaking to the Committee of the legislative imperative facing Canada in the public health sphere. This branch of the POGG power has been used very infrequently by courts to uphold federal legislation, but holds potential as the basis for renewing federal public health regulation, particularly with respect to infectious disease management. The test for the national dimensions branch is (a) the area to be regulated must have a singleness, distinctiveness and indivisibility that clearly distinguishes it from matters of provincial concern; and (b) the area to be regulated must have a scale of impact on provincial jurisdiction that is reconcilable with the division of powers.

The courts have articulated a number of principles in interpreting the national dimensions branch of the POGG power that bear on potential public health legislation. The Supreme Court has invoked the idea of "provincial inability" that, taken literally, suggests that the POGG power permits the federal government to act where the provinces cannot. But the better view is that the POGG power permits the federal government to act alone in areas where provinces could conceivably legislate but are unwilling to do so. Two such situations are (a) inter-jurisdictional spillovers, and (b) federal-provincial collective action problems. Each of these potentially applies to infectious disease surveillance and outbreak management. A spillover is a situation where a province's failure to adequately regulate an activity has negative effects in other provinces, in federal territories, or in other countries. According to the Supreme Court, the federal Parliament can legislate if "provincial failure to deal effectively with the intra-provincial aspects of the matter *could* have an adverse effect on extra-provincial interests" (italics added). This requires little explanation in the context of SARS.

Collective action situations arise where (a) public policy problems straddle the divide between federal and provincial jurisdiction, and require a coordinated federal-provincial response, and (b) the cooperative scheme would be ineffective in every part of the country if one province were to decline to participate. Arguably, the ongoing failure of the federal government and the provinces to agree on a system of national surveillance (discussed in Chapter 5) is an example of just such a federal-provincial collective action problem.

The key limitation of the national dimensions branch of the POGG power is the need for the area to be regulated to be relatively narrow and confined, so as to not intrude too severely on provincial jurisdiction. This raises significant design issues for national public health legislation.

9B.4 The International Imperative

SARS has driven home the international dimension of infectious disease control and, in the view of the Committee's legal consultant, strengthens the constitutional case for a federal public health law under the national dimensions branch of POGG: the Supreme Court has held that where an international treaty stipulates that a policy matter straddles the divide between provincial and federal jurisdiction, the case for federal jurisdiction is much stronger. At present, international public health treaties that address infectious disease management are narrow in scope. The World Health Organization's [WHO] International Health Regulations impose a range of binding legal obligations on WHO member states to stem the international spread of infectious disease.

These International Health Regulations were under revision prior to SARS, and are being reviewed again in light of this outbreak. Draft proposals have not been released yet to the public. However, a WHO discussion document suggests that the revised International Health Regulations require member states to operate a national surveillance system:

> *Rapid identification of urgent national risks that may be public health emergencies of international concern would require that each country have a national surveillance system that feeds data from the periphery to the central governments in a very short time. … Further, the system should be able to analyse such data rapidly and facilitate quick decisions.*

WHO's emphasis on the importance of accurate and comprehensive national data, collected on a real-time basis without regard to provincial boundaries, would serve to strengthen the claim of federal jurisdiction in Canada. Moreover, in another document, WHO proposes that the revised International Health Regulations lay down the following "minimum core requirements" for national surveillance systems. Timely, accurate and complete data are of central importance:

Detection and reporting: *Unusual and/or unexpected* disease events or public health risks in all communities shall be detected and all available *essential information* shall be immediately reported to the appropriate public health response level (e.g., emergency room, village health care worker, etc.).

Response - the first public health response level: The first level shall have the capacity to verify the reported event or risk and to begin implementing *preliminary* control measures immediately. Each event or risk shall be assessed immediately and if found urgent all available and essential information shall be immediately reported to the designated *national focal point*.

Response - national/international level: All reports of urgent events or risks shall be assessed at the national level within 24 hours. If the event/risk is assessed as meeting any of the following parameters for public health emergencies of international concern, WHO must be notified immediately through the national focal point:

- A serious and unusual or unexpected event.
- A significant risk of international spread.
- A significant risk of international travel and/or traffic restrictions on the free movement of persons, conveyances or trade goods.

WHO also stipulates that an additional design feature of national health surveillance systems should be a "single contact point" in a national health surveillance system to communicate information to WHO on a 24/7 basis. This international reporting structure would only reinforce the need for a national infrastructure in which all information is collected at a single point. Again, this supports the case for federal jurisdiction.

9B.5 Other Bases for Federal Legislation

The federal government enjoys jurisdiction over "Quarantine and the Establishment and Maintenance of Marine Hospitals." This power is the constitutional basis of the federal *Quarantine Act*. The scope of the power is unclear, as it has not been the subject of constitutional litigation. Originally, it was thought to be limited to maritime quarantine, given the juxtaposition of "quarantine" and "marine hospitals". Although the means for international travel have expanded, it is still thought to be confined to quarantine at entry into and exit from Canada. New regulations under the *Quarantine Act* have already been issued in response to SARS (see also Chapter 11). Whether this Act could be extended on the basis of interprovincial travel is unknown.

The final basis for federal jurisdiction over public health is its power to regulate trade and commerce. This provision gives the federal government the power to regulate inter-provincial and international economic activity, up to and including the prohibition of interprovincial trade. Subject to the *Charter*, this might permit the federal government to ban the importation of items that carry infectious diseases (if diseases were carried by animals or produce, for example).

9B.6 The US Analogue

The Committee asked the CDC to advise on whether it had jurisdictional power to investigate an outbreak on its own cognizance, or whether CDC involvement occurs secondary to a request for assistance by a state or territory. We also asked what powers the US federal government has to become involved on its own cognizance, absent an invitation from the affected state or states. The CDC responded as follows:

"As a matter of policy, CDC generally requests state health department authorization to conduct activities within their borders. CDC requests this authorization whether the activity involves one state or several, whether CDC staff presence is actual or 'virtual', and whether the invitation to participate comes from within the state or from an outside agency or organization. This policy is based upon the Constitutional relationship between the federal and state governments. While states are reserved the 'police powers,' i.e., the authority of all state governments to enact laws and promote regulations to safeguard the health, safety, and welfare of its citizens within its borders, the federal government retains authority to regulate matters of interstate commerce."[1]

9B.7 Federal Legislation as Default

The early passage of a federal law that imposed unfunded obligations on the provinces and territories, or swept aside provincial authority over public health matters, would run counter to the collaborative framework that underpins our recommendations. The Committee's optimistic view is that if health surveillance and outbreak management were left to health professionals working in Health Canada and the provincial/territorial ministries of health, agreement would be reasonably rapid and comprehensive. Such issues can and should be insulated from the ebb and flow of F/P/T relations through the creation of the Canadian Agency for Public Health and the F/P/T Network for Communicable Disease Control.

The need for federal legislation could be vitiated not only by the piecemeal assembly of a system of national rules through mechanisms described, but by intergovernmental initiatives to upgrade and harmonize legislation. To that end, we believe the federal government should embark on a time-limited intergovernmental initiative with a view to renewal of the legislative framework for disease surveillance and outbreak management in Canada, ideally extending to broader health emergencies from the latter as a starting point.

Only if these initiatives fail to produce a national system of public health norms and rules would we recommend that the federal government move towards legislation along the lines of the 'federal default' provision set out above. Our assumption is that many provinces will be in agreement with the thrust of these legislative reforms and the goal of creating a national system, and that the default legislation would therefore apply only to those provinces that have not undertaken the necessary modernization and harmonization.

Our hesitation arises not just from a deep-seated (and perhaps naïve) belief in collaborative fiscal federalism, but also from two other observations.

First, outbreaks are fought at the local level. SARS was not contained by Health Canada; it was contained by local public health agencies and health care institutions. With our vast geography and cultural heterogeneity, Canada cannot be managed as regards infectious diseases like Hong Kong or Singapore.

Thus, a federal law may be ineffective if general and more harmful than helpful if unduly prescriptive.

Second, and as a corollary, we do not believe that the federal government could commandeer provincial and municipal public health officials to administer a federal public health statute. Politically, the concept of commandeering provincial and local public health officials to deliver federally-framed public policy without their consent strikes at the very idea of federalism. Federal laws do confer on provincial officials' broad grants of discretion, and/or grants of discretion subject to express criteria, and the Supreme Court has upheld federal laws employing both approaches. Here, however, we are considering a federal public health statute that would impose duties on provincial and local public health officials (e.g., a duty to share disease surveillance information with their counterparts in other provinces and with federal officials). The most obvious example of a federal statute imposing duties on provincial officials is the *Criminal Code*, which imposes an enormous number of such duties on provincial officials, ranging from the police and Crown Attorneys all the way up to provincial Attorneys General. Precedents for federal regulation imposing duties on provincial officials also exist outside the *Criminal Code*. In past provincial challenges to the constitutionality of federal laws, the imposition of duties on provincial officials was not itself an issue. Thus, this issue has not been squarely addressed by the Supreme Court. The overwhelming majority of arrangements for co-administration or co-management, however, have been established on a consensual basis, on the ground that provincial governments are not subordinate to the federal government.

9C. Existing and Proposed Federal Legislation

9C.1 The Proposed Canada Health Protection Act

Health Canada recently released proposals for a new Canada Health Protection Act. Health protection is currently governed by eleven federal statutes. Health Canada has deemed the existing scheme unsatisfactory on several grounds. The process of legislative revision has been underway since 1998. Public consultations will commence this Fall, ending at the earliest in December 2003, and may potentially extend until March 2004. Based on these consultations, Health Canada will draft legislation that will be ready for public distribution in 2005, at which point it would proceed through the legislative process.

The goal of the revision is to repeal and replace four statutes—the *Food and Drugs Act*, the *Hazardous Products Act*, the *Quarantine Act*, and the *Radiation Emitting Devices Act*—with a single statute, the Canada Health Protection Act.

The discussion document sets out procedures to deal with communicable diseases in relation to persons entering and exiting Canada, as well as relevant safeguards to ensure compliance with the *Charter of Rights and Freedoms*. Given the federal government's constitutional authority over interprovincial travel, the discussion document suggests that the provisions governing quarantine would also be applicable to movement across provincial and territorial boundaries in Canada, albeit with some modifications. However, the document does not advance any further claims to federal jurisdiction on this basis.

The discussion document also suggests that the Canada Health Protection Act "could articulate a role for the federal government to work with other public authorities inside and outside Canada to ensure a national framework for coordinated public health-related surveillance." More specifically, Health Canada could, "in cooperation with other interested parties," create a national health surveillance system. Health surveillance and research activities would include:

- developing, supporting and participating in national and international networks;
- promoting the use of standard techniques, analytical tools, models, definitions and protocols;
- ensuring surveillance of health events which include several jurisdictions;
- initiating programs to respond to emerging or priority issues;
- establishing, maintaining and operating information exchange systems; and
- undertaking national surveys.

The Act would authorize the Minister of Health to enter into agreements with provinces regarding these matters, including agreements regarding the delegation of enforcement powers to provincial officials.

Thus, the discussion document leaves intra-provincial public health regulation to existing provincial public health systems. The creation of a national infrastructure would be on a negotiated and cooperative basis, with intergovernmental relationships being governed by federal-provincial agreements. These agreements would be formal documents spelling out the terms of cooperation, which would be accessible to the public, and whose contents could be prescribed by legislation.

The measures suggested in the proposed Canada Health Protection Act to both formalize and make more transparent the intergovernmental approach to national surveillance are commendable. In particular, the provision for enforcement agreements between the federal and provincial governments would be a positive development. They are consistent with, and provide legal authority for, mechanisms such as those recommended in this report. Unfortunately, the document makes reference to neither an agency nor a network of the type proposed in Chapters 4 and 5. At the very least, the agency option might be given prominence for reasons already outlined.

9C.2 Federal Privacy Legislation and Public Health

Any national system of health surveillance would entail the collection of vast amounts of personal health information. As a consequence, it would potentially trigger the operation of privacy legislation governing both the private and public sectors.

PIPEDA: The ***Personal Information Privacy and Electronic Documents Act*** (PIPEDA) is a new law that regulates the collection, use and disclosure of "personal information" by a range of non-governmental entities, including corporations, associations, partnerships, trade unions, and private individuals. It is not clear where and how PIPEDA applies to health care providers. To the extent that PIPEDA does apply, provisions in the law appear designed to safeguard provider reporting obligations under federal and provincial law. However, PIPEDA may still impede surveillance because of its tight restrictions on the non-consensual collection of information. We elaborate below.

PIPEDA began to come into force on January 1, 2001, and currently only applies to the federally-regulated private sector (airlines, banking, broadcasting, etc.), as well as to interprovincial information transfers (e.g., communication of personal health information to private insurers from providers) and international information transfers. But it will apply to all entities that fall within its scope on January 1, 2004.

The basic rule of PIPEDA is the need for an individual to consent to the collection, use, and disclosure of her/his personal information. The principal target of PIPEDA is private enterprise. However, PIPEDA has generated controversy in the health sector because its definition of personal information includes "personal health information", which it defines as follows:

(a) information concerning the physical or mental health of the individual;

(b) information concerning any health service provided to the individual;

(c) information concerning the donation by the individual of any body part or any bodily substance of the individual or information derived from the testing or examination of a body part or bodily substance of the individual;

(d) information that is collected in the course of providing health services to the individual; or

(e) information that is collected incidentally to the provision of health services to the individual.

This extremely broad definition of health information covers any health information about an individual, however that information is acquired. Other information acquired incidentally in the provision of health services—e.g., an individual's name, address, or health card number—would also be covered.

If PIPEDA applies to the non-profit health sector, it potentially places into question the legality of a wide variety of existing or potential information-sharing practices. The Canadian Healthcare Association, for example, has argued that it might make difficult the measuring of outcomes and quality of care. The Canadian Pharmacists Association has suggested that PIPEDA could impede providers from submitting insurance claims on behalf of patients. Stakeholders have also suggested that the consent requirement could impede communication between members of a health care team treating a patient (Canadian Medical Association) or among different providers (Ontario Ministry of Health and Long-Term Care). The Canadian Institutes of Health Research has raised concerns that certain of PIPEDA's provisions would impose too onerous a burden on researchers.

These concerns suggest that PIPEDA was not drafted with sufficient attention to the particular issues facing the health sector. The Government of Canada has not clearly addressed these concerns in recent months—a situation that has done little to build confidence in the ability of the federal government to legislate prudently in the public health field. Major stakeholders have called for legislation that would apply to the health sector instead of PIPEDA, or regulations to PIPEDA to clarify its application to the health sector. These concerns are urgent, because the Act will soon be fully in force.

To these concerns we add the fact that PIPEDA may impede provider reporting in a system of infectious disease surveillance. These obstacles could arise not only with respect to any new reporting obligations imposed by federal legislation, but also in connection with *existing* reporting obligations under provincial legislation.

A fuller treatment of these issues can be found in the report prepared for the Committee by Prof. Choudhry. Three points suffice here. First, providers may be partly insulated by the fact that PIPEDA focuses on commercial activity, and the information at issue must be collected, used, or disclosed "in the course of" such activity. However, non-profit providers that enter into commercial contracts involving the transfer of personal health information (e.g., hospitals contracting with investor-owned laboratories and pharmacies) might trigger the operation of PIPEDA with respect to those relationships. Second, it appears that the form of the consent required under PIPEDA may vary, with sensitive information requiring express consent. PIPEDA specifically refers to "medical records" as sensitive information. Third, PIPEDA does allow for non-consensual disclosure if the disclosure is requested "for the purposes of enforcing any law of Canada, a province or a foreign jurisdiction" or "for the purpose of administering any law of Canada or a province." These exceptions would likely extend to reporting requirements under provincial or federal public health legislation provided those laws impose a reporting obligation. Non-consensual disclosure is also permitted "because of an emergency that threatens the life, health or security of an individual." This could apply to infectious disease reporting in an outbreak, but not in ordinary disease surveillance.

If a reporting obligation under existing provincial law conflicts with PIPEDA, PIPEDA would prevail. A province cannot "opt out" of PIPEDA unless the federal government concludes that it has enacted legislation that is "substantially similar" to PIPEDA. Because PIPEDA is not yet fully in force in the provinces, the question of how the federal government will approach the issue of whether provincial laws are substantially similar has not yet been considered. However, the Privacy Commissioner has interpreted "substantially similar" to mean that provincial legislation must provide protection for privacy that is "equal or superior" to that provided in PIPEDA.

In conclusion, PIPEDA could raise significant difficulties for collection of information for disease surveillance purposes under public health legislation, particularly under provincial legislation, and its impact on provider reporting of infectious diseases requires clarification.

***Privacy Act* and the proposed Canada Health Protection Act**. Once health information is passed on to a new federal agency, or the federal government, it might become subject to the federal *Privacy Act* or the proposed privacy measures set out in the Canada Health Protection Act draft discussion document.

Identifiable personal health information is information that identifies an individual or can reasonably be expected (through data linking) to identify him/her. This information is at issue in infectious disease surveillance. The proposed Canada Health Protection Act would grant Health Canada the power to collect identifiable personal health information. A national system of infectious disease surveillance centred either on Health Canada or an independent agency would similarly require a legislative basis for the collection of identifiable personal health information.

The proposed Canada Health Protection Act usefully sets out the principles that should govern the collection and use of identifiable information. *Informed consent* is the presumptive norm based on disclosure of the purposes for which the information is being collected. The non-consensual collection, use and disclosure of identifiable personal health information are subject to *necessity* riders. They are permitted if, and only if, (a) such non-consensual use is necessary in order to promote a legitimate public health objective, (b) the objective cannot be achieved with non-identifiable personal health information, and (c) the public interest in public health outweighs any harm to the particular individual(s) concerned. The collection, use and disclosure of identifiable personal health information must infringe upon privacy interests to the least extent required to achieve the public health objective. This *proportionality* principle has several dimensions: collecting or disclosing as little identifying information as is required in order to achieve the public health objective; conversion to de-identified data as soon as possible and limiting access to identifiable personal health information; prohibiting the use of identifiable personal health information to make decisions about an individual in other contexts (e.g., with respect to disability benefits, income tax credits, etc.); and taking precautions by those to whom Health Canada discloses information to prevent improper use or further disclosure for an unauthorized purpose.

The *Privacy Act* now in force does not fully satisfy these principles. As noted in Chapter 4, a new federal agency for public health would be subject to the Act if so designated through regulation. The consent provisions are weaker than those envisaged in the new act, and there is no specific test of necessity for the collection, use, or disclosure of personal information. Non-consensual disclosure is permitted "for the purpose for which the information was obtained …or for use consistent with that purpose," or "for any purpose in accordance with any Act of Parliament or any regulation." Thus, the importance of the objective, the necessity of using identifiable information, and the weighing of the benefits obtained against the damage done to the individual are neither identified nor considered. The *Privacy Act* does not impose any legal obligation to use those measures which are the least invasive of privacy, such as de-identification, access on a need-to-know basis, etc.

The proposed Canada Health Protection Act discussion document also speaks to the issue of communication of identifiable personal health information between different governments. It suggests that Health Canada may collect and use such information provided to it by other governments without an individual's consent, when that information is provided by another government "performing a public health function", and if that other government was authorized by law to receive the information without consent in the first place. Non-consensual disclosure by Health Canada to other governments or public institutions would be permitted in a narrower range of circumstances—i.e., when consent would be impracticable or would defeat the legislative objective, and the public health interest would outweigh any prejudice to the individual.

The proposed federal act accordingly is contingent in some respects on the provincial laws surrounding privacy and health information. Inconsistencies in provincial legislation, in turn, will lead to variability in what is communicated to the federal government. It is these types of concerns that led the Advisory Council on Health Infostructure to call in its *Final Report* (1999) for the harmonization of provincial and federal privacy legislation.

9C.3 Summary

Two key pieces of federal privacy legislation fall on either side of a divide. One is too sweeping and restrictive, while the other does not conform to protective principles that have been articulated in the proposed Canada Health Protection Act. Federal privacy legislation must be amended to properly accommodate a national system

of infectious disease surveillance. It is not clear if PIPEDA applies to health care providers. To the extent that PIPEDA does apply, it threatens to undermine provider reporting obligations under federal and provincial law, because of its tight restrictions on the non-consensual collection of information. The impediments posed by PIPEDA to federal reporting obligations could be easily handled through appropriate statutory language. However, if applicable, PIPEDA would prevail over provincial public health statutes. Moreover, provinces do not have the ability to "opt out". The potential difficulties posed by PIPEDA to public health and disease surveillance are part of a larger set of concerns regarding PIPEDA's application to the health sector. PIPEDA's application to the health sector requires an urgent review, culminating either in separate federal health information privacy legislation, or amendments to PIPEDA.

On the other hand, the non-consensual collection, use and disclosure of identifiable personal health information by the federal government, or by federally-created agencies, should comply with the principles of necessity and proportionality. The *Privacy Act* falls short of those principles. The proposed Canada Health Protection Act would comply with those principles, except with respect to the treatment of data communicated to the federal government by the provinces where the inconsistencies in provincial privacy legislation lead to concerns.

On both counts, then, as Canada moves to implement a stronger national system of disease surveillance, federal legislation dealing with health information privacy must be reviewed and either amended or its applicability clarified.

9D. Provincial Legislation on Infectious Disease Outbreaks

9D.1 Background

A large number of statutes and regulations set out the legal framework within which provincial public officials, health care professionals, and private individuals operate to manage disease outbreaks. In the wake of SARS, one question that must be asked is whether this legal framework provides public health officials with the tools to tackle infectious disease outbreaks, while at the same time respecting the rights to privacy and physical liberty of persons subject to public health legislation.

A recent report prepared for Health Canada entitled "A Compendium of the Canadian Legislative Framework for the Declaration and Management of Infectious Diseases" collects and summarizes the relevant provisions under various provincial laws. The Committee asked Prof. Choudhry to measure the public health legislation of British Columbia, Ontario and Quebec against the CDC's Model State Emergency Health Powers Act. Although the Model Act may itself contain deficiencies, it was a potential benchmark and springboard for analysis.

9D.2 The Model State Emergency Health Powers Act

The CDC recently released a Model State Emergency Health Powers Act that provides a template for state legislatures to use in modernizing and updating their public health legislation. The Model Act was formulated as part of a broader attempt to examine public health infrastructure in the United States in the wake of the terrorist attacks of September 11, 2001. Even prior to September 11, a leading academic study had concluded that state public health laws were badly in need of revision, because they did not reflect contemporary understandings of disease surveillance, prevention and response; did not accord sufficient weight to individual privacy and liberty; were often fragmented (with multiple laws in place within states applying different norms to different diseases); and did not require planning in advance of public health emergencies (including mechanisms for communication and coordination within and between states, and the clear allocation of responsibilities).

The legal consultant's review focused on provisions in the Model Act dealing with disease reporting and information sharing with other jurisdictions. The relevant provisions are summarized below.

- *Who Must Report:* The Model Act imposes reporting obligations on "health care providers", which includes both institutions (hospitals, medical clinics and offices, special care facilities, medical laboratories) and persons (physicians, pharmacists, dentists, physician assistants, nurse practitioners, registered and other nurses, paramedics, emergency medical or laboratory technicians, and ambulance and emergency medical workers) that provide health care services. The definition is non-exhaustive—i.e., it could apply to other individuals and institutions not listed in the Model Act who provide health care services. Coroners and medical examiners also owe reporting obligations.

- T*riggering Event For Report:* Reporting must take place in "all cases of persons who harbor any illness or health condition that may be potential causes of a public health emergency." The Model Act does not require that the person suffer from the illness, and therefore may include persons who have merely been exposed to or infected with an illness. However, the Model Act does require that the person actually harbor the illness; a "reasonable suspicion" or the prospect that the person "may" harbor the illness do not appear to be sufficient.
- *Reportable Diseases:* The reporting obligation extends to "any illness or health condition that may be potential causes of a public health emergency." Reportable diseases include, but are not limited to, a list of biotoxins issued by the US federal government, and any illnesses or health conditions designated by state public health authorities. A public health emergency—a key concept in the Model Act—is defined as follows:

  an occurrence or imminent threat of an illness or health condition that:

  (1) is believed to be caused by any of the following:
  (i) bioterrorism; (N.B.: bioterrorism is also defined);
  (ii) the appearance of a novel or previously controlled or eradicated infectious agent or biological toxin;
  (iii) a natural disaster;
  (iv) a chemical attack or accidental release; or
  (v) a nuclear attack or accident; and

  (2) poses a high probability of any of the following harms:
  (i) a large number of deaths in the affected population;
  (ii) a large number of serious or long-term disabilities in the affected population; or
  (iii) widespread exposure to an infectious or toxic agent that poses a significant risk of substantial harm to a large number of people in the affected population.
- *When Report Must Be Made:* The report must be made within 24 hours.
- *To Whom Report Must Be Made:* The report must be made to "the public health authority", which is the state public health authority or any local public health authority.
- *What Information Must be Reported:* The report must include: the specific illness or condition; the name, date of birth, sex, race, occupation, and home and work addresses of the patient; the name and address of the person making the report, and any other information required to locate the patient for follow-up.
- *Information Sharing with Other Jurisdictions:* The Model Act requires a state public authority to notify federal authorities if it "learns of a case of a reportable illness or health condition, an unusual cluster, or a suspicious event that may be the cause of a public health emergency." The scope of the information that is shared is limited by a test of necessity—that is, it must be "information necessary for the treatment, control, investigation and prevention of a public health emergency."

9D.3 Initial Assessment of Provincial Laws in light of the Model Act

We review below the differences observed between the Model Act and the public health laws of British Columbia, Ontario, and Quebec.

Who must report: The Model Act imposes reporting obligations on a wide range of individuals and institutions within the health sector. Legislation in British Columbia, Ontario and Quebec generally follows this pattern, albeit through slightly different means. Ontario's legislation is most similar to the Model Act, in that it exhaustively enumerates who is under a reporting obligation. British Columbia, by contrast, imposes a duty on "any person". While this latter provision has the benefit of flexibility and adaptability to an ever-changing landscape of institutional and individual providers, it comes at the expense of clarity and accountability. Quebec's law (which was recently enacted) raises a different sort of concern—the only health professionals with reporting obligations are physicians. Nurses and other health professionals who might be the first to identify a case of infection appear to owe no reporting obligation. As well, hospital administrators do not appear to be under a duty to report, notwithstanding their overall responsibility for the institutions which they manage.

Triggering Event: The triggering event for the reporting obligation under the Model Act is that a person "harbor" an illness, which includes persons who have been infected with and who suffer from the illness. In British Columbia, only physicians are obliged to report cases of infection; other reporting obligations apply if an individual is suffering from or has died from a communicable disease. It would appear that other health care providers need not report instances of infection. Similarly, in Ontario, only physicians and hospital administrators appear to be under an obligation to report instances of infection. Laboratories might be required to report instances of infection, depending on the information yielded by a test. Quebec's broad language, requiring reporting in the case of a suspicion "of a threat to the health of the population" would presumably extend to infections.

List of Reportable Diseases: The Model Act is written against the backdrop of September 11, 2001 and, as a consequence, is focused on public health emergencies, particularly those arising from bioterrorism. In this respect, it is not a good model for a general purpose public health statute. British Columbia, Ontario and Quebec appear to require the reporting of largely similar diseases vis-à-vis one another. One problem is that triggering events are sometimes undefined. For example, in Ontario a "communicable disease outbreak" is undefined, as is a "disease outbreak or occurrence" in British Columbia. Although the lack of definition promotes flexibility, the lack of clear definition might lead to over- or under-reporting.

When Report Must Be Made: The Model Act requires reporting within 24 hours, presumably because of its focus on emergent biological threats. Within British Columbia, there are specific reporting obligations ranging from 24 hours to 7 days. Quebec has a uniform, province-wide standard of 48 hours. Ontario and Quebec both use imprecise language, such as "as soon as possible" and "promptly", which impedes clarity and accountability.

To Whom Report Must be Made: The Model Act requires that all reports be made to the state public health authority, to facilitate data centralization. The overwhelming majority of reporting obligations in British Columbia, Ontario and Quebec require information to be sent to the medical officer of health (British Columbia, Ontario) or the public health director (Quebec). As a consequence, public health laws in these provinces also facilitate data centralization.

What Information Must be Reported: All three provincial acts provide reasonably detailed delineation of what must be reported.

Duty to Share Information with Other Jurisdictions: The Model Act requires that federal officials be notified in the event of a public health emergency. Although provincial laws govern non-emergency situations, they nonetheless should contain some obligation on the part of provincial officials to report information to their provincial and federal counterparts. According to the information contained in "A Compendium of the Canadian Legislative Framework for the Declaration and Management of Infectious Diseases," no such obligations exist. This does not mean that such communications do not occur in practice.

In conclusion, provincial public health laws measure up reasonably well against the CDC state template. Some variation is probably attributable to the emergent focus of the Model Act. However, some standardization across provinces with respect to timelines and legal obligations to share data with federal and provincial counterparts should be considered in the context of the intergovernmental review of public health legislation recommended above.

9E. Federal Health Emergencies

Chapter 5 alluded to the federal *Emergency Preparedness Act* (R.S. 1985, c. 6 (4th Supp.)) proclaimed in 1988. That legislation delineates wide-ranging obligations on ministers to ensure that their departments take action to "develop policies and programs for achieving an appropriate state of national civil preparedness for emergencies." It also specifies a responsibility for liaison with provinces and a coordinating role for the federal government. Its design dovetails with the federal *Emergencies Act* (R.S. 1985, c. 22 (4th Supp.) that received assent in 1989 and replaced the problematic *War Measures Act*.

The *Emergencies Act* describes various categories of emergencies. The most salient is the subcategory of public welfare emergency that includes "an emergency that is caused by a real or imminent...disease in human beings, animals or plants...that results or may result in a danger to life or property, social disruption or a breakdown in the flow of essential goods, services or resources, so serious as to be a national emergency." It defines a "national emergency", in turn, as "an urgent and critical situation ... that seriously endangers the lives, health or safety of Canadians and is of such proportions as to exceed the capacity or authority of a province to deal with it."

The federal government's effectiveness in coordinating health emergencies on a national basis is arguably compromised by the lack of specific legislation. During a truly national health emergency, Health Canada has two vastly different options for asserting a 'command-and-control' function necessary for a national response. Officials refer to these with some frustration as 'the sledgehammer' and the 'tackhammer'. The former option, implementation of the *Emergencies Act*, can only be invoked if a high threshold is crossed as noted above. The *Emergencies Act* confers very wide powers on the federal government and has not been invoked since its passage. The latter option essentially involves "requesting" collaboration from public health partners.

The Canadian Medical Association has argued in a detailed submission that emergency managers require a public health legislative platform that lies between these two extremes and facilitates a coordinated response at all levels of government for public health emergencies. They propose a specific 'Health Emergencies Act' with graded increases in federal responsibility and jurisdiction as the scope and scale of an emergency spreads. Based on their brief and a confidential technical document, the Committee infers that the proposal involves provincial/territorial consultation at every stage and provincial/territorial consent for a claim of jurisdiction only for lower level health emergencies. The Committee agrees with some informants who have suggested that the threshold for non-consensual federal jurisdiction in the Canadian Medical Association scheme should be shifted 'upwards', but this modification does not invalidate the underlying concept.

As the level of government uniquely charged with protecting the national interest, the federal government has the strongest legitimacy to act alone when an infectious disease outbreak potentially has interprovincial and/or international dimensions. Moreover, it enjoys a comparative institutional advantage in regulating matters with an interprovincial or international dimension. Conversely, provincial public health officials enjoy the greatest legitimacy in responding to outbreaks that are largely local in impact. A graded approach to federal intervention would complement, rather than replace, existing provincial, territorial and municipal public health structures, helping again to stitch them together into a national system.

Earlier in this chapter, we signaled our discomfort with the idea that a federally-appointed public health official could commandeer provincial/territorial and local public health officials for matters such as disease surveillance. However, in a public health emergency, where such powers would be exercised only temporarily and then only after an assessment that the gravity of the situation posed a clear danger to the health of Canadians that could not otherwise be managed, the basis for those objections is blunted.

As currently proposed, the Canada Health Protection Act does not include any discussion of health emergencies. In part, this is because the proposed act adheres to a fairly narrow understanding of federal jurisdiction, i.e., jurisdiction over international and interprovincial movement of persons, whereas public health emergencies might encompass a broader range of circumstances. The Canadian Medical Association proposal allows for movement into provincial jurisdiction by the federal government in the event of a truly grave emergency. The constitutional basis for federal emergencies legislation would be the emergency branch of the POGG powers.

The Committee believes that the Canadian Medical Association proposal has merit and recommends that, as part of the legislative renewal process already underway, two steps be taken. First, the intergovernmental initiative in public health legislation should consider extant emergency legislation in the light of public health emergencies with a view to harmonization as appropriate across provinces and territories. Second, consideration should be given to a federal health emergencies act to be activated in lockstep with provincial emergency acts in the event of a pan-Canadian health emergency. We leave to the relevant experts whether this falls under the proposed Canada Health Protection Act, under legislation to establish the new Canadian Agency for Public Health, both, or a separate legislative initiative.

9F. Ethical Issues and Lessons from the SARS Outbreak

The SARS outbreak posed a number of ethical challenges. Decision makers were required to balance individual freedoms against the common good, fear for personal safety against the duty to treat the sick, and economic losses against the need to contain the spread of a deadly disease. Decisions were often made with limited information and under short deadlines.

A working group of the University of Toronto Joint Centre for Bioethics undertook to draw the ethical lessons from the challenges of and responses to SARS in Toronto[2]. The working group identified five general categories of ethical issues arising from the SARS experience:

- Public health versus civil liberties: There are times when the interests of protecting public health override some individual rights, such as the freedom of movement. In public health, this takes its most extreme form with involuntary commitment to quarantine.
- Privacy of information and the public's need to know: While the individual has a right to privacy, the state may temporarily suspend this privacy right in case of serious public health risks, when revealing private medical information would help protect public health.
- Duty of care: Health care professionals have a duty to care for the sick while minimizing the possibility of transmitting diseases to the uninfected. Institutions in turn have a reciprocal duty to support and protect health care workers to help them cope with the situation, and to recognize their contributions.
- The problem of collateral damage: Restrictions on entry to SARS-affected hospitals meant that people were denied medical care, sometimes for severe illnesses. There were also restrictions on visits to patients in SARS-affected hospitals. Decision makers faced duties of equity and proportionality in making decisions that weighed the potential harm from these restrictions against benefits from containment of the spread of SARS through rapid and definitive intervention.
- Global interdependence: SARS underlines the increasing risk of emerging diseases and their rapid spread. It points to a duty to strengthen the global health system in the interests of all nations.

The Joint Centre working group suggests that an ethical framework be developed that would address the five issues noted above, and that would ensure that Canada is better prepared to deal with future health crises involving highly contagious diseases.

Four of these points bear brief elaboration.

Civil Liberties: During both SARS outbreaks, health care practitioners, patients and families were asked to place themselves under ten-day quarantines in their homes in order to reduce the risk of exposure of an infectious disease to the community. Other strategies used during SARS were widespread availability of disposable masks, self-surveillance and work-home quarantine (i.e., limiting contacts to those necessary for duties in the health care setting), and restrictions on assembly of groups. Although the *Health Protection and Promotion Act*[3] gives officials the power to force non-compliant individuals into quarantine, this was used only once during the outbreak.

Applying the principle of reciprocity, society has a duty to provide support and other alternatives to those whose rights have been infringed under quarantine. Intriguingly, after returning from quarantines, some health care practitioners reported feeling disconnected from the current state of the organization[4]. Focus groups with front-line workers also revealed that some in quarantine wished to continue participating in the battle against SARS by contacting patients and families to provide support and answer questions, or by helping with contact tracing.

Privacy: Disease reporting during an outbreak carries the risk of a breach of confidentiality. Boundaries of privacy vary from person to person. Some believe that there is a risk of privacy infringement only if confidentiality is not maintained and a social stigma or loss of employment ensues from the breach. The other view is that a privacy infringement is wrong regardless of whether any harm occurs as a result[5]. In either event, under the ethical value of proportionality, officials must use the least intrusive method to obtain their goal. Legislation such as the *Health Protection and Promotion Act* prohibits the release of personal information except in very specific circumstances where there is a public good to be served or added protection obtained by releasing an individual's name.

During SARS, Toronto Public Health named only two names—that of the deceased index case for Toronto and her deceased son, and this was done with the informed consent of the surviving family members, based on their understanding that this extraordinary step was necessary for the protection of public health. An unknown number of people had attended a funeral visitation at the home of the deceased index case, and public health authorities had no way of contacting these people individually to advise them that they had been exposed and to watch for symptoms and remain in isolation for ten days. Most of the remaining family members were already hospitalized and too ill to provide sufficient detail. Two probable SARS cases identified themselves to Toronto Public Health as a direct result of this announcement. Both were health care workers who could have spread the virus further with disastrous results. These details illustrate the knife-edge on which these decisions rest.

Duty of care: Health care providers constantly weighed serious health risks to themselves and their families against their obligation to care for patients with SARS. A substantial percentage of the probable SARS cases involved front-line providers. Nurses and physicians were at particular risk. Overall, it appears that 168 people or about 40% of those infected were health care workers. The Canadian Medical Association Code of Ethics calls on physicians to "consider first the well-being of the patient[6]," while the Canadian Nurses Association Code of Ethics for nursing stipulates that "nurses must provide care first and foremost toward the health and well-being of the person, family or community in their care[7]." Other health care professions in Canada have considered or adopted similar codes. SARS has taught us, however, that this ethical duty must be balanced by a countervailing duty: not to place others at risk by coming to work while ill and potentially contagious. What remains unclear are the limits to this duty: What is the point at which the duty of care is balanced by a right to refuse dangerous tasks? How is the duty of care modified by the occupational circumstances and professional obligations of different health care workers?

Just as health care practitioners have a duty to care for the sick, health care organizations clearly have a reciprocal duty to support and protect their workers. This meant providing the necessary safety equipment and appropriate education regarding the use of such equipment, providing information on risks and the need for precautionary measures and ensuring a safe working environment. Notwithstanding the enormous efforts that many institutions made with respect to internal communication and safeguards for health care workers, serious tensions arose with respect to occupational health and safety. Many of these were avoidable, as they arose from directives around N95 masks and fit-testing which were either more stringent or interpreted more stringently, than necessary. Health care organizations did offer a variety of psychological supports to their staff, but many of these measures were instituted after SARS, rather than during the outbreak itself. What also emerged very clearly was that health care workers under siege in an emergency such as SARS greatly valued and deserved strong support from community and political leaders as well as co-workers and administrators.

Collateral effects: The ethical trade-offs posed by the collateral effects of caring for SARS patients were numerous. For example, the Catholic Health Association of Canada noted in its submission the serious impact on many patients, friends, and families from restricted visiting hours. Decision making was particularly challenging in critical care units[8]. The principle of equity required that decision makers balance controlling the spread of the disease on the one hand, and the rights of non-infected patients to access medical care, particularly urgent services on the other. The enormous human toll of the disruption to the system lies just beneath the statistics in Chapter 8. Countervailing this impact is the very real likelihood that the uncontained spread of SARS could have killed thousands. Such trade-offs make it very difficult to apply any ethical Procrustean bed in hindsight to the decisions made. However, an ethical framework of some type may be useful for future decision makers.

To this list the Committee would add two other issues.

First, the Canadian Association of Medical Microbiologists has noted the ethical challenges that arose in undertaking research during the SARS outbreak. Issues arose that cut across individual institutions and agencies, necessitating unprecedented coordination of expedited ethical reviews of research protocols and outbreak investigation proposals.

Second, scientific credit and collaboration also pose ethical challenges during an outbreak. For example, while many academic clinicians were fighting the SARS outbreak in Toronto, research scientists were testing the samples that were flooding the National Microbiology Laboratory in Winnipeg. They collaborated with the British Columbia Centre for Disease Control and genomics experts salaried by the British Columbia Cancer Agency to sequence the Toronto strain of the coronavirus. The University of British Columbia subsequently purchased a full-page advertisement during the outbreak to claim credit for the discovery. We thus had the situation where some academics were fighting a battle for

all of Canada against a new infectious agent, and others were consumed with offering scientific advice to bring the outbreak under control, while others capitalized brilliantly on the availability of specimens and data to the benefit of all, winning scientific kudos in the process. How does one apportion a fair distribution of scientific credit in these difficult circumstances? Guidelines are needed to facilitate collaborative research and research publications during infectious disease outbreaks, particularly in a relatively small academic community such as that which exists in Canada.

A related ethical issue that arose from SARS is the seeking of patents on the SARS-associated coronavirus. Researchers in the United States, Canada and Hong Kong[9] have applied for patents on the coronavirus and its gene sequence. The US CDC and the British Columbia Cancer Agency publicly acknowledged taking this course of action to ensure that the virus and the sequence remain in the public domain (it is important to note that the sequences were published in *Science* magazine in early May, 2003)[10]. A news item in the June 20, 2003 edition of *The Lancet* reported that the US National Institute of Allergy and Infectious Diseases is making a SARS genome "chip" available to researchers around the world, free of charge, in an effort to spur research. The "chip" contains the 29,700 DNA base pairs of the SARS coronavirus designed from data from institutes in the US, Canada, and Asia that had sequenced the complete SARS coronavirus genome.

While this is a positive development, the patenting of organisms and genes such as SARS remains an issue and has raised myriad concerns[11,12]. The current patent system in Canada was not designed to address questions of DNA patenting and the commercialization of the human genome. Generally, raw products of nature are not patentable. However, a patent may be granted to the entire process of discovering and isolating, in the laboratory, strings of DNA that were not obvious before, rather than to a gene as it exists in nature. In order to patent a gene, a sequence or other similar material, the inventor must modify or identify the novel genetic sequences. The product of the sequence must be modified and the function in nature must be explained. These matters have been given point in Canada by the narrow decision (5-4) of the Supreme Court, in December 2002, to reject the patent of the Harvard 'Onco-mouse', not because of any primary principled objection to the concept, but because extant Canadian patent legislation did not contemplate such a claim. Patents had previously been granted in Canada for unicellular organisms; thus, there is ample precedent in Canada for patenting the genome of a virus. However, the ramifications of these practices are important, particularly where public funding or public health issues are concerned. This issue falls outside the Committee's mandate, but underscores the continuing uncertainty and concerns from a number of quarters about the patenting of organisms and genes in general. The Committee urges continued vigilance and debate concerning the application of the *Patent Act* and the corresponding frameworks surrounding the patent process to the unique challenges of patenting micro-organisms and other living entities.

9G. Recommendations

In light of the foregoing issues, the Committee recommends that:

9.1 The Government of Canada should embark on a time-limited intergovernmental initiative with a view to renewing the legislative framework for disease surveillance and outbreak management in Canada, as well as harmonizing emergency legislation as it bears on public health emergencies.

9.2 In the event that a coordinated system of rules for infectious disease surveillance and outbreak management cannot be established by the combined effects of the F/P/T Network for Communicable Disease Control, the Public Health Partnerships Program, and the above-referenced intergovernmental legislative review, the Government of Canada should initiate the drafting of default legislation to set up such a system of rules, clarifying F/P/T interactions as regards public health matters with specific reference to infectious diseases.

9.3 As part of Health Canada's legislative renewal process currently underway, the Government of Canada should consider incorporating in legislation a mechanism for dealing with health emergencies which would be activated in lockstep with provincial emergency acts in the event of a pan-Canadian health emergency.

9.4 The Government of Canada should launch an urgent and comprehensive review of the application of the *Protection of Information Privacy and Electronic Documents Act* to the health sector, with a view to setting out regulations that would clarify the applicability of this new law to the health sector, and/or creating new privacy legislation specific to health matters.

9.5 The Government of Canada should launch a comprehensive review of the treatment of personal health information under the *Privacy Act*, with a view to setting out regulations or legislation specific to the health sector.

9.6 The Canadian Agency for Public Health should create a Public Health Ethics Working Group to develop an ethical framework to guide public health systems and health care organizations during emergency public health situations such as infectious disease outbreaks. In addition to the usual ethical issues, the Working Group should develop guidelines for collaboration and co-authorship with fair apportioning of authorship and related credit to academic participants in outbreak investigation and related research, and develop templates for expedited ethics reviews of applied research protocols in the face of outbreaks and similar public health emergencies.

9.7 F/P/T departments/ministries of health should facilitate a dialogue with health care workers, their unions/associations, professional regulatory bodies, experts in employment law and ethics, and other pertinent government departments/ministries concerning duties of care toward persons with contagious illnesses and countervailing rights to refuse dangerous duties in health care settings.

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