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The Merger Between Public Health and Health Law – The US Situation

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Merging Law and Public Health

Law is an essential tool for protecting the public's health. It is often the law that turns public health *science* into public health *action*. Sanitation, clean air and water, universal vaccination, injury prevention, tobacco control, drug policy, and a vast array of other interventions are achieved through a complex web of local, provincial and national statutes, regulations and judicial cases. The Institute of Medicine in the United States defines public health as "what we, as a society, do collectively to ensure the conditions in which people can be healthy."[1] And society acts collectively most often through law.

Thus, the merging of law and public health is not a future goal. It has already happened. This merger has been with us since kings quarantined ships arriving in port to prevent the spread of contagious disease from abroad. Perhaps because law has been a part of public health for so long, we take it for granted and often fail to recognize how it can and should be used. But the expanding domain of public health invites a fresh look at the relationship between law and public health. Two perspectives are the focus of this paper. The first is the need for training health professionals in law in order to achieve public health goals. The second is an important caveat about the role of law in preventing health risks that arise from personal behaviors. This is because many new threats to public health in the northern hemisphere come from personal behaviors, which means that public health solutions often require infringing on individual rights. This can create conflicts between the goals of law and the goals of public health.

The Need for Training in Public Health Law

C.E.A. Winslow's definition of public health, often cited for its comprehensiveness and accuracy, demonstrates the wide range of opportunities for using law:

> *"Public Health is the science and art of preventing disease, prolonging life, and promoting health and efficiency through organized community effort for the sanitation of the environment, the control of communicable infections, the education of the individual in personal hygiene, the organization of medical and nursing services for the early diagnosis and preventive treatment of disease, and the development of the social machinery to insure everyone a standard of living adequate for the maintenance of health, so organizing these benefits as to enable every citizen to realize his birthright of health and longevity."*[2]

Given the importance of law in protecting public health, it is remarkable that (except at Boston University School of Public Health) training in law is not a required component of public health education. Few graduates of schools of public health receive any training in

[1] Institute of Medicine. *The Future of Public Health*. National Academy Press, Washington, DC, 1988.
[2] Winslow, C.E.A. Evolution and Significance of the Modern Public Health Campaign. New York, Arno, 1923.

the law. The Council on Education for Public Health, the accrediting body for schools of public health in the United States, does not list law in its core education criteria. The numerous public health practitioners and government officials who have not received academic public health training are even less likely to have received any training in the law. Given the significance of law in protecting public health and the lack of legal training in the workforce, there is an urgent need for training in public health law.

In the United States, the Centers for Disease Control and Prevention (CDC) have recently recognized the law's significance in protecting public health by organizing Workshops on Public Health Law and creating a new Public Health Law Collaborative, which includes public health practitioners and professors of health law. The goal of the CDC's Public Health Law Collaborative is to improve public health "through clearer understanding and more effective use of law."[3] Effective use of the law is necessary to achieve the recommendations of the US national public health initiative called Healthy People 2010 (analogous to health targets) and the Institute of Medicine's recommendations to improve the skills of the public health workforce as an essential component of improving the public health infrastructure.[1,4,5] Law is essential to public health's core functions of assurance and policy development and often relevant to assessment.[3] Public health training initiatives now specify core competencies. In Essential Service 6 of *Public Health Workforce: An Agenda for the 21st Century*, one core competency is to: "Enforce laws and regulations that protect health and ensure safety."

Where laws are inadequate, ineffective or missing, however, enforcement does little to protect health or safety. Therefore, public health practitioners must be able do more than merely enforce existing laws. They must also identify and develop ways to use law to solve public health problems. Public health professionals are often expected to recommend specific regulations, guidelines or even legislation to solve a problem, but are unfamiliar with their options.

A recent example in the United States illustrates the need for understanding how to use the law appropriately and effectively. The public health community encouraged the federal Food and Drug Administration (FDA) to issue regulations intended to eliminate or restrict cigarette advertising to people less than 18 years of age. The new FDA regulations, issued in 1996, required all printed advertisements to be in black and white (not in color) and to use text only (no pictures or images), unless the publication is read almost exclusively by adults. The regulations also prohibited outdoor advertising within 1,000 feet (300 meters) of any public school or playground. They also prohibited the distribution of promotional items, like hats or T-shirts bearing a cigarette company name, and forbade cigarette companies from using its cigarette brand name to sponsor any athletic, musical, artistic, social or cultural event, such as a football game or concert. The regulations also prohibited the sale of cigarettes to people less than 18 years of age. (However, all states already prohibit minors from buying cigarettes.)

Not surprisingly, a group of tobacco manufacturers and advertisers sued the FDA, claiming that the FDA did not have the legal authority to issue these regulations and that the

[3] The CDC Public Health Law Collaborative. Report of the CDC-Sponsored Workshops and Plans Involving Partner Organizations. Centers for Disease Control and Prevention, Atlanta, GA, 2000.
[4] Healthy People 2000/2010 Objectives for the Nation. http://www.health.gov/healthypeople .
[5] U.S. Dept. of Health and Human Services, Public Health Service. The Public Health Workforce: An Agenda for the 21st Century, http://www.health.gov/phfunctions/pubhlth.pdf, 1997.

regulations violated the companies' constitutional rights to freedom of speech in the form of advertising. In March 2000, the United States Supreme Court decided that the FDA did not have jurisdiction to regulate tobacco at all, so the regulations were invalid.[6] The Court's decision seems to have surprised many people in public health, but it did not surprise many lawyers. The federal legislation that created the FDA did not give it jurisdiction over tobacco products, so it could not impose regulations on how they were advertised. Moreover, the legislation requires the FDA to prohibit the sale of drugs and medical devices that are not safe or effective. Cigarettes are not safe and effective for any therapeutic purpose — indeed the reason the FDA wanted to limit advertising to minors was because cigarettes are addictive and dangerous to health and it wanted to discourage children from smoking them. Therefore, even if the FDA had jurisdiction over cigarettes, it would have to ban them entirely as unsafe drugs or devices.

This case is interesting because a great deal of time and money was spent pursuing a legal strategy that was doomed from the start. It would have been more productive to encourage a different federal administrative agency — one that has jurisdiction over consumer products — to regulate tobacco advertising or to create a new agency dedicated to tobacco regulation.[7] It appears that the public health community was so focused on the goal of limiting tobacco advertising that it did not pay attention to the basic legal structure for regulating products. A little education in law might have saved 4 years of wasted effort.

To be effective, public health professionals must become familiar with basic principles of law in their own country. And the lawyers who advise them must be familiar with the goals and methods of public health. A process of mutual education is absolutely necessary for developing an effective public health system. However, it also presents a challenge. This is because the goals of public health sometimes conflict with the goals of law. It is often convenient or necessary to limit the rights of individuals in order to achieve specific public health goals. And protecting the rights of individuals can sometimes hinder the achievement of public health goals.

Changes in Public Health Risks — From Things to People

Since 1900, life expectancy in the United States has increased almost 60 percent, from 47 to 75 years, largely as a result of preventing infectious diseases. Public health efforts succeeded primarily by making the world safer for people--by cleaning up the water, food, sewage, and housing in the nineteenth century and also the workplace and environment in the twentieth century. Law was the natural ally of public health programs. Legislation created sanitary standards for water, food and housing. There was little opposition to public health programs because they affected things, not people; and things do not have rights.

In contrast, today's major threats to life, such as cancer, heart disease, injuries, stroke, and AIDS, are caused as much by personal behavior as by environmental factors. The majority of leading health indicators identified by the national public health initiative, Healthy People, are the result of personal behavior, rather than external threats. They are: physical activity; overweight and obesity; tobacco use; substance abuse; responsible sexual behavior; mental health; injury and violence; environmental quality; immunization; and

[6] Food and Drug Administration v. Brown & Williamson Tobacco Corporation, et al., 120 S.Ct. 1291 (Mar. 21, 2000).
[7] Glantz LJ & Annas GJ. Tobacco, the FDA, and Congress, *The New England Journal of Medicine* 2000 (in press).

access to health care. Improving the public's health is no longer as straightforward as taking the pump handle off the cholera-infected well. It requires persuading or coercing people to change personal behaviors that they find pleasurable, exciting, or habitual. Thus, increasingly, promoting health means making people safer for the world. This presents a conflict between the values of personal liberty and the values of public health. Unlike things, people do have rights. How far can and should the state go to make people safe in this next century?

Courts in the United States have recognized that the state has substantial discretion to adopt even coercive measures to protect the health of the larger society. In 1905, for example, the United States Supreme Court upheld compulsory smallpox vaccination when an epidemic threatened the City of Cambridge, Massachusetts.[8] But seemingly sensible decisions can create troublesome precedents. Twelve years later, when confronted with the question of whether another state (Virginia) could forcibly sterilize mentally retarded persons, the Court said, "The principle that sustains compulsory vaccination is broad enough to cover cutting the Fallopian tubes."[9] If Massachusetts could invade a person's body to stop an epidemic of smallpox, then Virginia could invade people's bodies to stop an "epidemic" of mental retardation. In effect, the Court recognized the notion that people could be used as a means to an end.

Public health advocates applaud the Supreme Court's decision on vaccination, and recall the sterilization opinion with horror. But the principles underlying both decisions appear to be the same. Thus, it is important for public health professionals to recognize the legal principles that justify specific public health actions in order to predict how those principles might be used in different circumstances.

Public Health Paternalism or Individual Autonomy in Health and Safety?

Public health programs use several forms of persuasion and legal coercion to change personal behavior, including giving people information about risks, taxing products to discourage their use, banning dangerous products, and requiring the use of safety devices. How do we decide whether to use coercion to force people to behave in ways that will protect health? In the United States, we have traditionally distinguished between behavior that threatens other people — the larger society — and behavior that only harms oneself. In principle, the state has more power to control individual behavior when that behavior poses a risk of death or injury to other people. It has much less power to interfere with personal liberty when an individual's behavior only harms that individual and no one else.

Public health programs often contain an element of paternalism. They encourage people to take care of their own health for their own sake, not merely to protect other people from harm. This is a laudable public health goal. But when encouragement is backed up by the force of law, paternalism can create a dangerous conflict of principles. It assumes that people should not have the legal right to make choices that increase their own risk of harm or death. This contrasts with the field of medicine and the law of patient rights, in which paternalism has been rejected.

[8] *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).
[9] Buck v. Bell, 274 U.S. 200 (1927).

In the United States, courts and legislatures recognized patient rights in order to protect patients from inappropriate paternalism by physicians.[10,11] Historically, physicians wanted patients to obey their orders to get well and most patients were willing to obey physicians for their own good. In the second half of the 20th century, however, as medicine became more scientific, more effective, and more complicated, it became more difficult for patients to appreciate just what was happening to them during medical treatment. In particular, the risks involved were less obvious to patients. When anesthesia put a patient to sleep during surgery, the patient could no longer monitor the operation. As pharmaceuticals were used to treat many diseases, patients, by themselves, could not predict what might happen to them when they took a drug. Therefore, the courts required physicians to provide patients with information about their medical conditions and possible benefits and risks of alternative treatment approaches.[12]

Fundamentally, the courts recognized that patients have the right to decide whether or not to accept any medical care offered by a physician.[13] The reason for vesting this right in the patient, and not the physician, is that it is the patient who suffers the consequences of treatment. The old paternalistic idea that patients should accept whatever the physician recommended (or ordered) for their own good was completely discredited and rejected. Today, the law is clear that patients have the right to refuse any medical care at any time for any reason whatsoever. Patients can even refuse medical care that will save their lives. The medical model in health law puts individual autonomy ahead of personal health.

This approach contrasts sharply with the assumptions underlying public health. The goals of public health are to prevent death, disease and injury and to promote health and survival. If people reject public health recommendations, then they may increase their risks of death, disease or injury. Of course, people who reject medical recommendations made by their physicians may also increase their risks of death, disease or injury. We insist that patients have the right to refuse any kind of medical care, yet we often force people to comply with public health requirements. Why is this?

The different approaches can be explained in part by who is affected. We find it acceptable to force people to take some actions (or to stop certain behaviors) that threaten the health of other people. But we reject pure paternalism, because we do not require people to protect themselves when other people are not affected.[14] This distinction, which comes easily to lawyers, is not always persuasive to public health professionals who are concerned with the health of the entire society and seek to have everyone take better care of themselves for their own sake.

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[10] Annas GJ. A National Bill of Patients' Rights, The New England Journal of Medicine 1998; 338:695-699.

[11] Mariner WK. Standards of Care and Standard Form Contracts: Distinguishing Patient Rights and Consumer Rights in Managed Care, The Journal of Contemporary Health Law and Policy 1998; 15: 1-55.

[12] Mariner WK. Informed Consent in the Post-Modern Era. *Law & Social Inquiry* 1988; 13:384-406.

[13] Annas GJ. *The Rights of Patients, 2d ed.* Humana Press, Totowa, NJ, 1992.

[14] Of course, this distinction is imperfect. There are cases in which refusing medical treatment does have adverse consequences on others, such as leaving a family without the care or financial support of a mother or father who dies after refusing live-saving treatment. And there are public health laws that claim to protect others but really only protect the person from personal injury, such as laws requiring motor vehicle drivers to wear seat belts and motorcycle drivers to wear helmets.

Of course, the public health community itself has not always been consistent in its approach to personal behavior. In the middle of the 1900's, public health officials justified quarantining people with leprosy on the ground that personal liberty must give way to protecting the health of the community. But, in the 1980's, public health officials argued that subjecting people with HIV infection to quarantine would violate their liberty. Similarly, in the 1960's, public health professionals argued that government prohibitions on advertising by abortion clinics violated the principle of free speech. But today, they advocate prohibitions on cigarette advertising. These inconsistent positions can undermine the credibility of the public health community and discourage the public from following their recommendations. Thus, it is especially important today that those in law and those in public health come to a better understanding of the legal principles that should underlie public health programs.

Understanding principles helps us adopt sound policies. Should employers be prohibited from firing employees who smoke at home? Are public health advocates who wish to reduce the prevalence of smoking in favor of employers having the authority to control the lives of employees off the job? Should society be in favor of advertising bans on alcohol or should they support the same freedom of speech rights that prohibit states from banning contraceptive advertising? Should society support random drug testing or protect people from unreasonable searches and seizures? Should public health officials overstate the risk of breast cancer in order to encourage woman to get mammograms? Should society refuse to require pregnant women and newborns to be tested for HIV and support mandatory PKU testing of newborns when the vast majority of parents would consent to such testing if asked? Should society adopt mandatory screening for the breast cancer gene? Should public health advocates support laws making expensive medical therapies conditional on compliance with dietary and exercise standards? Some commentators dismiss such questions as academic. But ten years ago, no one would have believed that major American cities would ban smoking in bars. As more becomes known about the causes of illness and injury, more opportunities arise for actions that pose conflicts between the values of public health and value of personal liberty.

There remains controversy in the United States about the principles that determine when state power should properly be used to force people to do or not do something in order to achieve public health goals. At one extreme libertarians argue there is no justification for prohibiting individuals from doing anything that does not threaten imminent physical harm to others. In the extreme communitarian view, the good of society trumps individual rights. Legislatures, professional organizations, courts, philosophers, historians, sociologists, and economists have given different reasons for selecting different types of interventions, from risk disclosure to quarantine, to achieve different types of objectives. We have yet to fully recognize, much less achieve, a universally acceptable conceptual framework for more consistent decisions about regulating personal behavior to prevent disease and promote health.

Public health problems have become more complex with more diffuse effects on people, paralleling the evolution of medical science. It is often difficult to identify, much less quantify, the precise effect of pollutants or personal behavior on other people. While we recognize the probability of a risk, it may not be possible to blame a single source for a specific harm. This suggests that the medical model of health law and patient rights, which gives people more information and protects their right to choose, may become increasingly relevant to public health programs, especially those directed at these less well understood sources of risk. It is also consistent with the growing recognition of human rights around

the world. Jonathan Mann brought needed attention to the relationship between public health and human rights, emphasizing that health status is a function of social factors like wealth, civil justice, equality, and political freedom.[15] George Annas has argued that the Universal Declaration of Human Rights offers the ethical principles against which public health programs should be evaluated.[16] This suggests that the role of law in public health is not merely to improve general health status. Rather we should reach for a more ambitious goal—to improve public health while preserving human rights. Ultimately, protecting and enforcing human rights may do more to protect public health than a simplistic use of law to prevent health risks.

Conclusion

The merger of law and public health has already happened. But the development of a modern jurisprudence of public health law remains an unfinished task. Like the evolution of patient rights, public health law is changing in response to changes in the medicine, science, cultural attitudes about personal rights and responsibilities, and international attention to human rights. Today, public health law and medical law look at individual rights from different perspectives. Will modern public health law look more like the public health legislation of the 19th century or the medical law and patient rights legislation of the 20th century? Our hope is that it can combine both these precedents to create a more comprehensive and integrated set of principles to protect both health and human rights.

Summary of Forum V

Hanna Pava

1. On the merger between public health and health law

- Health law regulates the promotion and protection of health, health services, equitable distribution of available resources and the legal position of all parties; there is an increasing trend to use legal instruments to shape health policy and health systems;
- The definition of public health law depends on the definition of public health: whether the traditional/preventive approach is looked at or the modern perspective of public health related to lifestyle and individual behavior;
- The merger of law and public health has already started. But the development of a modern jurisprudence of public health law remains an unfinished task. Like the evolution of patients' rights, public health law is changing in response to changes in the medicine, science, and cultural attitudes about personal rights and responsibilities;
- Some European developments: internationalization, increasing awareness for consumer protection, legalization of society and the expansion of medical

[15] Mann JM. Medicine and Public Health, Ethics and Human Rights, reprinted in JM Mann, S Gruskin, MA Grodin, GJ Annas, eds., Health and Human Rights, Routledge, NY, NY, 1999, pp. 439-452.
[16] Annas GJ. Human Rights and Health—The Universal Declaration of Human Rights at 50, The New England Journal of Medicine 1998; 339:1778-1781.

science and technology which should be stimulated and monitored at the same time.

Tentative recommendation:

Make people safer for their society and society safer for its people by:

1. acknowledging and promoting **fundamental rights and values**;
2. including health law and ethics in the curricula of health education;
3. **evaluating** policies and legislation;
4. stimulating effective **cooperation** between countries and transnational bodies; and
5. focusing on the **implementation of health legislation** and policies.

2. On the protection of consumers of health services in the information age

- Protection from whom and from what? As patients, we want our medical attendants to have all the relevant information about us at their fingertips when making a diagnosis and determining the appropriate action. However, we need to be sure that the information is accurate, relevant, up-to-date and the use that will be made of it will be appropriate and proportional;
- Genetic data as a predictive medicine is a new paradigm aimed at information on future health risks; affects everybody; results in personal advice rather than interventions; and entails examination of body substances;
- Four crucial issues were identified:
  - Recognition and protection of the rights to know/not to know;
  - Privacy protection and the use of information to provide genetic services to relatives;
  - Collection of genetic information by prospective employers and insurers should not be allowed;
  - Use of genetic data for research purposes requires informed consent of involved individuals.
- As a result of IT the processing and storage of data has changed, endangering patients' privacy and their right to secrecy and confidentiality;

Tentative recommendation:

Technology should adapt to the **values of society** and further requirements are needed in terms of public policy, such as:

- Elaboration of **individual rights** with regard to genetic testing in particular the **control** over the use of blood and tissue;
- Better **protection** from discrimination on the basis of genetic information;
- Define **criteria and appropriate guidelines** on genetic testing and medical research;

3. On citizens and patients as partners of health services

- as more and more effective but costly treatments are developed, health care providers are trying to ensure that the gap between demand and supply of health services does not run out of control;
- increase promotion of citizens' involvement through three main aspirations:
  - to reduce dependence on health services;
  - to improve the quality of services; and
  - to increase understanding of the need for hard decisions about priorities.
- involving citizens in decision-making related to rationing implies:
  - Legitimacy = the gap between public resources and demand needs to be addressed through shared decision-making;
  - Efficiency = a needs-based health care with emphasis on the preferences of the public; and
  - Justice = the process of decision-making and the criteria for rationing are transparent.
- public expectations are often different from one country to another depending on the available resources;

Tentative recommendation:

If health services are to be **truly responsive** to the needs of those they are supposed to serve, we should listen to the **views of users** and take full account of them. **Strategies** to promote participation should be encouraged but **evaluated critically** by **sharing the lessons** and learning from the failure as well as the successes.