

Public Health Law in a New Century

Part III: Public Health Regulation: A Systematic Evaluation

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THE PREVIOUS ARTICLES IN THIS SERIES^{1,2} EXAMINED THE tradeoffs between the collective benefits of public health and personal interests in liberty and property. But how do we know when the public good to be achieved is worth the infringement of individual rights? This article proposes a systematic evaluation of public health regulation that analyzes regulatory justifications, public risks, the intervention's effectiveness, economic costs, personal burdens, and the policy's fairness.

GENERAL JUSTIFICATIONS FOR PUBLIC HEALTH REGULATION

Government intervention designed to promote population health and well-being is often considered an unmitigated good. Why would society not want to organize itself in ways that maximize the health of populations? To fulfill many of the aspirations of human life requires a healthy mind and body. Because health is so highly valued, sometimes society assumes that government need not justify public health interventions. But government should justify interventions because, almost invariably, they intrude on individual rights and interests and incur economic costs. Before proposing a systematic evaluation of public health regulation, it will be helpful to think about the 3 general justifications commonly asserted: risk to others, protection of incompetent persons, and risk to self.³

Risk to Others: The Harm Principle

The avoidance of serious harm to other persons is the most commonly asserted justification for public health regulation. The so-called harm principle holds that competent adults should have freedom of action unless they pose a risk to the community. The reason for permitting such a wide range of freedom is that people have a strong interest in autonomy.

Autonomy, literally, self-governance, has acquired meanings as diverse as liberty, privacy, individual choice, and even economic freedom. The legal community uses autonomy to support rules, such as informed consent and privacy. At its core, autonomy is the personal governance of the self that is free from controlling interferences.⁴ Autonomous persons are free to hold views, make choices, and take actions based on personal values and beliefs.

Public health interventions need justification because they intrude on individual rights and incur economic costs. Coercive interventions can be justified in only 3 cases: to avert a risk of serious harm to other persons, to protect the welfare of incompetent persons, and, most controversially, to prevent a risk to the person himself/herself.

This article proposes a systematic evaluation of public health regulation. The article recommends that public health authorities should bear the burden of justification and, therefore, should demonstrate (1) a significant risk based on scientific evidence; (2) the intervention's effectiveness by showing a reasonable fit between means and ends; (3) that economic costs are reasonable; (4) that human rights burdens are reasonable; and (5) that benefits, costs, and burdens are fairly distributed.

The 3 articles in this series have sought to provide a fuller understanding of the varied ways in which law can advance the public's health. Public health law should be seen broadly as the government's power and responsibility to ensure the conditions for the population's health. As such, public health law has transcending importance in how we think about government, politics, and policy.

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Theories of autonomy hold that government, or others, should not restrain competent adults in the absence of some overriding justification. Avoidance of serious harm to others usually is regarded as an adequate reason for constraining autonomy. This is a classic argument that personal freedoms extend only so far as they do not intrude on the health, safety, or other legitimate interests of the population. Under this view, public health authorities could override the competent wishes of persons if necessary to avert injury or disease to other individuals or groups. The harm principle, for example, justifies interventions to prevent the spread of infectious disease through mandatory vaccination, screening, partner notification, or treatment; or it justifies laws forbidding the dumping of toxic waste because of the detrimental effects on communities.

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Protection of Incompetent Persons: Best Interests

A second commonly asserted justification for public health regulation is to defend the interests of incompetent persons who are not in a position to protect themselves. If persons are incompetent, government may safeguard their welfare either by making decisions in their best interests or by making decisions that they would have made if competent.

The rationale for government making decisions on behalf of incompetent persons is that they have insufficient understanding to make informed choices, deliberate, and act according to their desires or plans. Children and persons with mental illness or mental retardation may, to a greater or lesser degree, have diminished capacity. In these circumstances, government may step in to ensure their health or safety, such as by civilly committing a person with mental illness or controlling the financial affairs of a person with mental retardation. Since the rationale for interference with autonomy is to make those decisions a person would have made if he/she were competent, the government should act beneficently in the individual's interests.

Risk to Self: Self-regarding Behavior

Of the 3 traditional justifications for public health regulation, risk to self is, by far, the most contentious. Risk to self is highly controversial because the behavior is self-regarding, which means that the conduct appears to affect only the person concerned and not others. Classic regulation of self-regarding behavior includes mandatory motorcycle helmet and seatbelt laws, gambling prohibitions, and fluoridation of drinking water. In addition to direct control over personal activity, government heavily taxes and restricts advertising of cigarettes and alcoholic beverages.

Regulation of self-regarding behavior is warranted, if at all, by paternalism. Under this rationale, interference with a person's liberty of action is justified exclusively by the need to protect the health, safety, welfare, happiness, or other interests, or values of the person subject to coercion.⁵ The case against paternalism rests on the assumption that individuals are most informed about their needs and value systems, and most self-interested. After all, a person declines to wear a motorcycle helmet not because he/she is oblivious to the risk, but presumably because he/she places one value (freedom) above another (physical security).

A defense of paternalism usually relies on the fact that people face constraints (both internal and external) on the capacity to pursue their own interests.⁶ First, individuals have cognitive limits of either inadequate information or the inability to process complex scientific information. People frequently make choices without being fully informed of the potential hazards. Messages about children being at-risk of severe injury from front-seat air bags or that in many homes radon is present and dangerous are not heard by everyone. Even when information is available, consumers may misapprehend the risks. Media discussions of a healthy diet or the health effects of vigorous exercise are, at best, contradictory and confusing.

Second, individuals have limited willpower. They may know, objectively, what is in their best interests, but find it difficult to behave accordingly. This point is obvious in the case of physical and psychological dependencies on illicit drugs, alcoholic beverages, tranquilizers, diet medication, or nicotine. But, individuals may have difficulty controlling many behaviors that are not conventionally regarded as addictive. A person may understand that high-fat foods cause adverse health effects or that excessive spending or gambling causes financial hardship, but may not refrain from these activities.

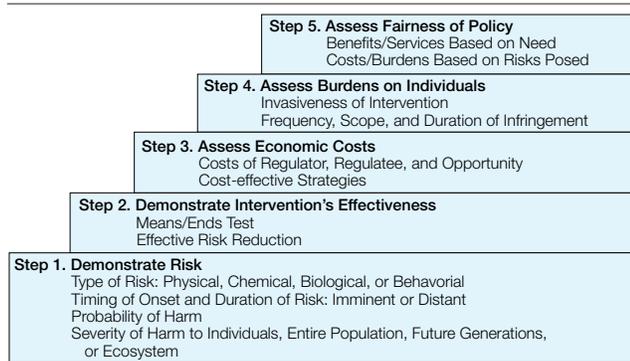
Finally, individuals face social, economic, and environmental constraints on their behavior. Human behavior is influenced by many external factors including parents and family, peers and community, media and commercial advertising.⁷ For example, a person's decision about what to eat and whether to smoke cigarettes or drink alcoholic beverages (and what brand) is influenced by commercial messages. Social, structural, and physical factors in the environment also influence behavioral decisions. Consider a poor inner-city neighborhood in which the only food choice is fast food because there are no supermarkets to purchase fresh fruits and vegetables at reasonable prices. In such an environment, voluntary choice is constrained even if public health messages about a healthy diet are being heard and understood.

The courts routinely uphold regulation of classic self-regarding behaviors, emphasizing the aggregate consequences for society's health and economic resources: the risk to safety (eg, a motorcyclist without a helmet presenting a traffic hazard),⁸ health (eg, secondhand tobacco smoke),⁹ or the economy (eg, urgent care costs and burdens on government benefits, such as Medicaid).¹⁰ For example, one court observed:

From the moment of the [motorcycle] injury, society picks the person up off the highway; delivers him to a municipal hospital . . . ; provides him with unemployment compensation if, after recovery, he cannot replace his lost job, and, if the injury causes permanent disability, may assume the responsibility for his and his family's continued subsistence. We do not understand a state of mind that permits the plaintiff to think that only he himself is concerned.¹¹

These kinds of judicial decisions, while understandable, fail to confront the real issue of paternalism. After all, the principal reason that society requires citizens to wear motorcycle helmets or seatbelts is to protect the person himself/herself. These court decisions reduce the justification for regulation of self-regarding behavior to a strained conception of social harms rather than recognizing certain public health interventions as justified paternalism.

Having thought about the general justifications for public health regulation, it is important to evaluate systematically whether particular interventions are warranted. Next, I propose that public health authorities should bear the burden of justification and, therefore, should demonstrate (1) significant risk based on objective scientific methods; (2) the intervention's effectiveness by showing a reasonable fit between means and ends; (3) economic costs are reasonable when compared with the probable benefits; (4) hu-

Figure. Evaluation of Public Health Regulation

man rights burdens are reasonable when compared with the probable benefits; and (5) benefits, costs, and burdens are fairly distributed so that services are provided only where needed and regulatory burdens are imposed only where a risk to community health exists (FIGURE).

STEP 1: DEMONSTRATE A SIGNIFICANT RISK BASED ON SCIENTIFIC METHODS

The mission of public health is to identify risks and prevent and/or ameliorate harms or other undesirable consequences to humans and what they value. Populations face hazards from many different sources: physical forces (eg, radioactivity, sound waves, magnetic fields), chemicals (eg, ozone, mercury, dioxins, drugs), organisms (eg, viruses, bacteria), and human behavior (eg, sex, smoking, drunk driving, firearm use). People also face social consequences from the unauthorized disclosure of health information, such as embarrassment, stigma, and discrimination in employment, insurance, and housing.¹² Risk is a highly complex concept, and a vast literature exists about the assessment, communication, and management of risk.¹³

Public health regulation is an attempt to control risk. However, we need to know more about the evidence needed to assess the risk and the seriousness of the risk that warrants regulation. Risk assessments are almost always made in circumstances of uncertainty, so an accurate calculation is usually difficult. Nevertheless, to the extent possible, risk assessments should be based on objective and reliable scientific evidence provided by the multiple disciplines of public health, including medicine, virology, bacteriology, and epidemiology. Science-based risk assessments provide a more secure ground for decision making and avoid reflexive actions based on irrational fears, speculation, stereotypes, or pernicious mythologies.

Risk assessments should also be made on a case-by-case basis. Individualized risk assessments avoid decisions made under a blanket rule or generalization about a class of persons. A fact-specific, individualized inquiry is more likely to result in a well-informed judgment grounded in a careful and open-minded weighing of risks and alternatives.

Finally, public health regulation should be based on risks that are significant, not speculative, theoretical, or remote. The level of risk needed to justify a regulatory response varies depending on the policy's economic costs and human burdens. If the costs and burdens are small, public health authorities need to demonstrate lower levels of risk to justify the intervention. As the policy's costs and burdens increase, public health authorities need to demonstrate ever greater levels of risk.

Several factors are helpful in risk assessments¹⁴: (1) nature of risk: some risks are immediate (eg, contaminated food or water), some long-term (eg, toxic exposures resulting in cancer), and some depend on the mechanism of transmission (eg, airborne, food-borne, or blood-borne); (2) duration of risk: coercive regulation is appropriate only for the period of time that the risk continues to exist (eg, during the period of infectiousness); (3) probability of harm: the likelihood that the risk will materialize and cause harm; and (4) severity of harm: if the risk materializes the degree of harm that will affect populations.

In assessing the validity of public health powers, a rough inverse correlation exists between the severity of harm and the probability of its occurrence. As the seriousness of potential harm to the community increases, the level of risk needed to justify the public health power decreases. Central to the understanding of the significant risk standard is the fact that even the most serious potential for harm does not justify public health regulation in the absence of a reasonable probability that it will occur. For example, transmission of human immunodeficiency virus (HIV) results in a major harm because the disease can be seriously debilitating and potentially life threatening. Yet, if the probability of transmission were negligible (eg, transmission from health care workers to patients), then coercive measures would not be warranted.

Public health regulation entails tradeoffs between competing risks to health—so-called risk-risk tradeoffs.¹⁵ Frequently, when government intervenes to diminish one risk, it simultaneously increases another risk. Thus, drinking water standards requiring chemical disinfection decrease risks of *Cryptosporidium*, but increase risks of cancer.¹⁶ Nuclear power regulation reduces radiation risks, but drives the market toward coal or oil-based energy, thus increasing other hazards to humans and the environment. When agencies act to avert a given risk, they should be cognizant that the intervention may increase another kind of risk.

STEP 2: DEMONSTRATE THE EFFECTIVENESS OF THE REGULATION (THE MEANS/ENDS TEST)

The objective of public health regulation is to avert or diminish a significant risk to health. While courts and the public readily understand the need for a substantial health objective, they pay less attention to the methods used to achieve the goal. Instead, the intervention's effectiveness is simply assumed or, more likely, the courts and the public trust the experts to develop, implement, and evaluate the intervention. It is unwise to assume that public health interventions are al-

ways effective. In fact, since the proposed regulation entails personal burdens and economic costs, government should affirmatively demonstrate, through scientific data, that the methods adopted are reasonably likely to achieve the public health objective. This is called the means/ends test and it is the government's burden to defend and rigorously evaluate the effectiveness of regulation.

The fact that government regulates in a particular area does not necessarily mean that it is doing something about the problem. Think about legislative initiatives to reduce the risk of HIV transmission, such as mandatory screening of newborns, practice limitations on health care workers, or criminal penalties for having unprotected sex. These interventions may be designed to avert a health risk, but the methods used may fail to achieve the goal. Sometimes, legislation can even thwart public health objectives such as criminal prohibitions on the distribution and possession of sterile drug injection equipment.¹⁷

To determine whether the means are likely to achieve their objectives, agencies should ask a series of questions. First, can the health risk be accurately measured? For example, if a regulatory response to radioactivity, magnetic fields, or lead paint is considered, public health authorities should understand the health risks posed. How much is known about the hazard? How much exposure, and of what duration, is safe? How much reduction in exposure is necessary to reduce the risk to acceptable levels? Second, will the intervention effectively reduce the risk or ameliorate the harm? For example, do reliable data exist to demonstrate the effectiveness of traditional public health interventions? Finally, what plans exist to evaluate the intervention?¹⁸ Admittedly, scientific evaluation is complex because many behavioral, social, and environmental variables confound objective measurement of the causal connection between an intervention and a health outcome. Nevertheless, asking an agency to measure the outcomes of its interventions is important to demonstrate whether they work.

STEP 3: DEMONSTRATE THAT ECONOMIC COSTS ARE REASONABLE WHEN COMPARED WITH BENEFITS

Public health regulations impose economic costs. Agency resources are used to devise and implement the regulation, there are costs to individuals and businesses subject to the regulation, and opportunities to intervene with a different, potentially more effective, technique are lost (opportunity costs). A major issue, much debated in the literature, is the relevance of cost in regulatory decisions designed to safeguard the public's health. Economists argue that government should prefer regulatory responses that provide the most health benefits (eg, saving the most life-years, or quality-adjusted years of life) at the least cost. Using cost-effectiveness analysis, health economists estimate the net health effects of a regulatory program or intervention.¹⁹

Society cannot escape the role that cost plays. Few people question the premise that society has finite, and relatively

scarce, resources available for public health regulation. Given the reality of scarcity, hard choices must be made between regulatory alternatives. Do we spend large sums to avert relatively trivial risks, or do we devote resources to more serious risks that can be ameliorated at significantly lower cost? While society cannot tally up costs and benefits into a tidy number, it can make sensible choices in prioritizing regulatory expenditures.²⁰

Why is it a problem if public health regulations impose inordinate expense with relatively modest benefits? At least part of the answer is that whenever government regulates it foregoes opportunities for other interventions that can improve community health. If government adopts an ineffective strategy, it loses opportunities to intervene with a different, potentially more beneficial, technique. If government adopts an unduly costly strategy, it wastes scarce resources. There is usually limited political will and agency resources to adopt multiple methods of intervention simultaneously. When ineffective or expensive regulations are seen as lost opportunities, it becomes clearer that the operable tradeoff is not money for lives, a choice that understandably generates public concern. Rather, the tradeoff is health for health or lives for lives because a choice to spend excessively wastes not only dollars, but also opportunities to promote health and longevity.

STEP 4: DEMONSTRATE THAT PERSONAL BURDENS ARE REASONABLE WHEN COMPARED WITH BENEFITS

A public health policy may be well designed, cost-effective, and likely to promote the health and well-being of the population, but still be unacceptable from an individual rights perspective. Public health regulations impose various human rights burdens: (1) compulsory vaccination, physical examination, and treatment intrude on autonomy, bodily integrity, and religious freedom; (2) screening, reporting, and partner notification invade privacy; (3) isolation and quarantine restrain liberty; (4) limits on advertising and mandatory labeling curtail expression; and (5) licenses, inspections, and nuisance abatements impede professional opportunities and diminish property interests.

In thinking about personal burdens, it is important to measure the intervention's (1) invasiveness: to what degree does the public health intervention intrude on the right in question? (2) frequency and scope: does the infringement of rights apply to one person, a group, or an entire population? and (3) duration: how long of a period is the person or group subject to the infringement? For example, counseling and testing is less invasive than mandatory treatment; isolation of a single individual is less extensive than quarantine of a geographic area; and short-term isolation for measles is less burdensome than indefinite isolation for HIV/AIDS (acquired immunodeficiency syndrome).

Public health authorities should choose the least restrictive alternative. This means that agencies should prefer mini-

mally intrusive interventions that achieve the public health objective as well, or better, than more restrictive interventions. For example, directly observed therapy for tuberculosis is less invasive than civil commitment. This principle does not require public health authorities to adopt measures that are ineffective, but only those that will accomplish the agency's mission with the fewest burdens on human rights.

STEP 5: DEMONSTRATE THAT PUBLIC HEALTH INTERVENTIONS ARE FAIRLY DISTRIBUTED

Public health policy allocates benefits, burdens, and costs. Everyone realizes that to achieve the common good it is sometimes necessary to confer benefits and impose regulatory costs and burdens. The mark of a desirable public health policy is when benefits, burdens, and costs are equitably distributed. But how are we to judge whether these distributions among populations are inherently just? The final step in a systematic evaluation of public health policy is an examination of fairness.

Public health policy is just if, to the extent possible, it provides services to those in need and imposes burdens and costs on those who endanger the public's health. Services provided to those without need are wasteful and, given scarce resources, may deny benefits to those with genuine need. Similarly, coercion aimed at persons or businesses in which there is no actual danger imposes costs and burdens without a corresponding public benefit. Ideally, services should be allocated on the basis of need and burdens should be imposed only when necessary to prevent a health risk.

At the same time, policies should not be disproportionately targeted toward, or enforced against, vulnerable groups such as racial minorities. Most public health authorities, for example, favor primary enforcement of seatbelt laws, empowering police to stop vehicles solely because of noncompliance with those laws. Yet, if police enforce seatbelt laws disproportionately against racial minorities, they become unjust.

In summary, public health authorities should justify regulation by demonstrating a significant risk, the intervention's effectiveness, reasonable economic costs and human rights burdens, and fundamental fairness. This proposed evaluation will not necessarily lead to the best policy because any analysis is fraught with judgments about politics and values and is confounded by scientific uncertainty. Nevertheless, the evaluation at least requires public health authorities to think systematically and apply consistent standards when making policy.

THE FUTURE OF PUBLIC HEALTH LAW

This series of articles has sought to provide a fuller understanding of the varied roles of law in advancing the public's health. The field of public health is purposive and interventionist. It does not settle for existing conditions of health, but actively seeks effective techniques for identifying and reducing health threats. Law is an important, but, perennially neglected, tool in furthering the public's health. Public

health law should not be seen as an arcane, indecipherable set of technical rules. Rather, public health law should be seen broadly as the authority and responsibility of government to ensure the conditions for the population's health. As such, public health law has transcending importance in how we think about government, politics, and policy.

While government has responsibility to ensure the conditions for health, it cannot overreach in a democratic society. This leads to one of the most complicated problems in the field, which is how to balance the collective good achieved by public health regulation with the resulting infringements of individual rights and freedoms. The difficult tradeoffs between collective goods and individual rights form a major part of the study of public health law.

Finally, it is important to recall that public health, and the law itself, is highly political, influenced by strong social, cultural, and economic forces. As these forces shift over the years, and as different political ideologies and economic conditions take hold, the field of public health will change and adapt. It has always been that way in public health, and it is likely to remain that way for the future, providing intellectually enticing, and socially important, terrain for scholars and practitioners to explore.

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