For the Public's Health: Revitalizing Law and Policy to Meet New Challenges

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Committee on Public Health Strategies to Improve Health

Board on Population Health and Public Health Practice

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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This report has been reviewed in draft form by individuals chosen for their diverse perspectives and technical expertise, in accordance with procedures approved by the National Research Council's Report Review Committee. The purpose of this independent review is to provide candid and critical comments that will assist the institution in making its published report as sound as possible and to ensure that the report meets institutional standards for objectivity, evidence, and responsiveness to the study charge. The review comments and draft manuscript remain confidential to protect the integrity of the deliberative process. We wish to thank the following individuals for their review of this report:

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Although the reviewers listed above have provided many constructive comments and suggestions, they were not asked to endorse the conclusions or recommendations nor did they see the final draft of the report before its release. The review of this report was overseen by **Mark R. Cullen,** Stanford University, and **Hugh Tilson,** University of North Carolina. Appointed by the National Research Council and Institute of Medicine, they were responsible for making certain that an independent examination of this report was carried out in accordance with institutional procedures and that all review comments were carefully considered. Responsibility for the final content of this report rests entirely with the authoring committee and the institution.

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Preface

Introduction to the Series of Reports

In 2009, the Robert Wood Johnson Foundation asked the Institute of Medicine (IOM) to convene a committee to examine three topics in relation to public health: measurement, the law, and funding. The committee's complete three-part charge is provided in Box P-1. The IOM Committee on Public Health Strategies to Improve Health explored the topics in the context of contemporary opportunities and challenges and with the prospect of influencing the work of the health system (broadly defined as in the report summary) in the second decade of the 21st century and beyond. The committee was asked to prepare three reports—one on each topic—that contained actionable recommendations for public health agencies and other stakeholders that have roles in the health of the U.S. population. This report is the second in the series.

BOX P-1
Charge to the Committee

Task 1 (completed)
The committee will review population health strategies, associated metrics, and interventions in the context of a reformed health care system. The committee will review the role of score cards and other measures or assessments in summarizing the impact of the public health system, and how these can be used by policy makers and the community to hold both government and other stakeholders accountable and to inform advocacy for public health policies and practices.

Task 2 (accomplished in the present report)
The committee will review how statutes and regulations prevent injury and disease, save lives, and optimize health outcomes. The committee will systematically discuss legal and regulatory authority; note past efforts to develop model public health legislation; and describe the implications of the changing social and policy context for public health laws and regulations.

Task 3 (to be addressed in a forthcoming report)
The committee will develop recommendations for funding state and local health systems that support the needs of the public after health care reform. Recommendations should be evidence based and implementable. In developing their recommendations the committee will:

- Review current funding structures for public health
- Assess opportunities for use of funds to improve health outcomes
- Review the impact of fluctuations in funding for public health
- Assess innovative policies and mechanisms for funding public health services and community-based interventions and suggest possible options for sustainable funding.

The committee's three tasks and the series of reports prepared to respond to them are linked by the recognition that measurement, laws, and funding are three major drivers of change in the health system. Measurement (with the data that support it) helps specialists and the public to understand health status in different ways (for example, by determinant or underlying cause

where national, local, and comparative evidence is available), to understand the performance of the various stakeholders in the system, and to understand the health-related results of investment. Measurement also helps communities to understand their current status, to determine whether they are making progress in improving health, and to set priorities for their next actions. Although the causal chains between actions of the health system and health outcomes are not always clearly elucidated, measurement is a fundamental requirement for the reasons listed above.

Laws transform the underpinnings of the health system and also act at various points in and on the complex environments that generate the conditions for health. Those environments include the widely varied policy context of multiple government agencies, such as education, energy, and transportation agencies, as well as many statutes, regulations, and court cases intended to reshape the factors that improve or impede health. The measures range from national tobacco policy to local smoking bans and from national agricultural subsidies and school nutrition standards to local school-board decisions about the types of foods and beverages to be sold in school vending machines.

Funding that supports the activities of public health agencies is provided primarily by federal, state, and local governments. However, government budgets must balance a variety of needs, programs, and policies, and the budgets draw on different sources (including different types of taxes and fees), depending on jurisdiction. Therefore, the funds allocated to public health depend heavily on how the executive and legislative branches set priorities. Other funding sources support public health activities in the community, including "conversion" foundations formed when nonprofit hospitals and health insurers became privatized (such as The California Wellness Foundation). Additionally, funds for population health and medical care activities may be provided by community-based organizations with substantial resources, not-for-profit clinical care providers, and stakeholders in other sectors.

The subjects addressed in the three reports are not independent of each other and, indeed, should be viewed together. For example, measurement of health outcomes and of progress in meeting objectives can provide evidence to guide the development and implementation of public health laws and the allocation of resources for public health activities. Laws and policies often require the collection of data and can circumscribe the uses to which the data are put, for example, prohibiting access to personally identifiable health information. Similarly, statutes can affect funding for public health through such mechanisms as program-specific taxes or fees. And laws shape the structure of public health agencies, grant them their authority, and influence policy.

In the three reports, the committee will make a case for increased accountability of all sectors that affect health—including the clinical care delivery system, the business sector, academe, nongovernment organizations, communities, and various government agencies—wherever possible, with coordination by the government public health agency leading or coordinating activities and sectors. The committee's first report, released in December 2010, focused on measurement of population health and related accountability at all levels of government. The present report reflects the committee's thinking about legal and public policy reform on three levels: first, pertaining to the public health agencies' powers, duties, and limitations as defined in enabling statutes (i.e., that establish their structure, organization, and functioning); second, the use of legal and policy tools to improve the public's health; and third, pertaining to other sectors of government at the national, state, and local levels, and the role of a diverse set of private and not-for-profit sector actors. The committee's final report on funding,

will consider resource needs and approaches to addressing them in a predictable and sustainable manner to ensure a robust population health system.

Summary

For the Public's Health: Revitalizing Law and Public Policy to Meet New Challenges, the second of three reports by the Committee on Public Health Strategies to Improve Health, builds on earlier Institute of Medicine efforts to describe the activities and role of the public health system. As defined in the 2003 report *The Future of the Public's Health in the 21st Century* (IOM, 2003), the system is multi-sectoral and comprises governmental public health agencies and various partners, including the community (individuals and organizations), the clinical care delivery system, employers and business, the mass media, and academia, or more broadly, the education sector. The committee's first report (IOM, 2011) redefines the system as simply "the health system." By using this term, the committee seeks to reinstate the proper and evidence-based understanding of health as not merely the result of clinical care, but the result of the sum of what we do as a society to create the conditions in which people can be healthy (IOM, 1988).

The committee's charge in preparing the current report was to "review how statutes and regulations prevent injury and disease, save lives, and optimize health outcomes" and to "systematically discuss legal and regulatory authority; note past efforts to develop model public health legislation; and describe the implications of the changing social and policy context for public health laws and regulations."

"Law is foundational to U.S. public health practice. Laws establish and delineate the missions of public health agencies, authorize and delimit public health functions, and appropriate essential funds," wrote Goodman and colleagues (2006, p. 29). The law is also one of the main "drivers" facilitating population health improvement. The committee believes now is a critical time to examine the role and usefulness of the law and public policy more broadly, both in and outside the health sector, in efforts to improve population health. This sense of urgency is due to recent and evolving developments in the following areas: the sciences of public health; the economy (i.e., the economic crisis and the great uncertainty and severe budget cuts faced by governmental public health agencies); the social and legislative arenas (e.g., the *Affordable Care Act*); the functioning of public health (e.g., fragmentation of government response to public health issues, lack of interstate and intersectoral coordination of policies and regulations); and the health of the population (e.g., data on the increasing prevalence of obesity and poor rankings in international comparisons of major health indicators).

In the report's first chapter, the committee examines the laws that codify the mission, structure, duties, and authorities of public health agencies. The chapter also examines the loci—federal, state, and local—of government action to manage different types of health risk, as well as the interaction among the levels of government. In the second chapter, the committee discusses statutes, regulations, and court litigation as tools specifically designed to improve the public's health. In the third chapter, the report explores non-health laws and policies that are enacted or promulgated in other sectors of government, but have potentially important impacts on the public's health. These include public policy in areas such as transportation, agriculture,

and education. Numerous examples of policies adopted in various sectors of government have had unintended consequences for health. These include (1) agricultural subsidies that spurred the development of inexpensive sweeteners, which are a key component of nutrient-poor foods and beverages, and (2) a national education policy that has led to diminished and even non-existent physical education in schools.[1] The chapter discusses the intersectoral nature of the influences on the public's health, and refers to structured ways to consider health outcomes in all policymaking—a "Health in All Policies" (HIAP) approach. This approach takes into account health-producing or health-harming activities in all parts of government, as well as those of private sector actors. In this chapter, the committee also continues its discussion of the broad determinants of health begun in its first report, but now in the context of legal and policy interventions, many located outside the health sector or involving multiple sectors. The chapter ends with a discussion of the evidence needed for "healthy" policy-making.

The report's key messages focus on three major areas. First, the committee finds that laws and public policies that pertain to population health warrant systematic review and revision, given the enormous transformations in the practice, context, science, and goals of public health agencies and changes in society as a whole. Second, the committee urges government agencies to familiarize themselves with the toolbox of public health legal and policy interventions at their disposal. Also, the report discusses evidence of the effectiveness of legal and policy tools, as well as efforts to advance the science needed to inform policymaking to improve the public's health. (The effectiveness of policy interventions is especially noteworthy against a backdrop of current and future economic exigencies and the high premium placed on efficiency and accountability.) Third, the committee encourages government and private sector stakeholders to explore and embrace HIAP for their synergistic potential. The consideration of health in a wide range of public- and private-sector policymaking will lead both to improvements in population health and to the achievement of priority objectives in other sectors, such as job creation and educational reform, and a more vibrant and productive society. The report offers 10 recommendations and a conclusion to address the challenges it identifies and enhance the use of law and public policy to improve population health.

RECOMMENDATIONS

Public health statutes—the laws that define the authorities and roles of federal, state and local public health agencies—were enacted when major population health threats were due to: hygiene factors (water, food, sanitation), communicable diseases, public safety issues, maternal and child health challenges, and occupational injury and illness. The contemporary burden of disease has shifted increasingly to chronic conditions and injuries as infectious disease declined, but the evolving physical, social, and built environments have contributed new challenges. In addition to the health hazards of another era, older public health laws currently "on the books" were informed by the scientific standards of the day and the statutory context and constitutional jurisprudence of their time, including conceptions of individual rights. Some laws were enacted in piecemeal fashion in reaction to contemporary epidemics, leading to layers of statutory accretion rather than holistic or comprehensive legislation (Gostin et al., 2008).

[1] For a discussion of the effect of the No Child Left Behind policy on physical education in schools, see http://sports.espn.go.com/espn/otl/news/story?id=4015831.

Two major efforts to review and update public health law took place around the turn of the 21st century. These were the *Turning Point Model State Public Health Act* (1997–2003) and the *Model State Emergency Health Powers Act* (MSEHPA) (2001–2002). The *Turning Point Model Public Health Act* was a broad (though not comprehensive) model law composed of nine articles and incorporating two other model acts—a revised version of the MSEHPA in the article pertaining to emergency powers, and the *Model State Public Health Privacy Act* (Gostin et al., 2001, 2002). Despite the development and dissemination of these model acts, their use for widespread updating or modernization of public health statutes has been limited. Most public health law in jurisdictions today remains grounded in late 19th and early 20th century experiences. The *Turning Point Model State Public Health Act* and the *Model State Emergency Health Powers Act* drew on actual high-quality laws already in place in various jurisdictions around the country, and could continue to serve as benchmarks (i.e., legal best practices) in the process of reviewing and updating enabling statutes. Efforts may be made to identify statutory benchmarks in additional areas not explicitly covered in the existing model acts, such as performance measurement and accreditation, and contemporary leading causes of disease and death.

Recommendation 1: The committee recommends that state and local governments, in collaboration with their public health agencies, review existing public health laws and modernize these as needed to assure that appropriate powers are in place to enable public health agencies to address contemporary challenges to population health.

The 10 Essential Public Health Services (10 EPHS) (see Box S-1) are widely accepted and often incorporated into public health practice and in current strategies to measure and improve public health performance. However, the 10 EPHS are generally not incorporated into public health agency that enables statutes as standard of practice in public health (Meier et al., 2009). Exceptions are largely found in states that have updated their statutes (Meier et al., 2009). The committee believes all communities deserve access to the public health protections and services embodied in the language of the 10 EPHS and codified in the referenced model acts.

BOX S-1
The 10 Essential Public Health Services

1. Monitor health status to identify and solve community health problems.
2. Diagnose and investigate health problems and health hazards in the community.
3. Inform, educate, and empower people about health issues.
4. Mobilize community partnerships and action to identify and solve health problems.
5. Develop policies and plans that support individual and community health efforts.
6. Enforce laws and regulations that protect health and ensure safety.
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
8. Assure a competent public and personal health care workforce.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services.
10. Research for new insights and innovative solutions to health problems.

SOURCE: Public Health Functions Steering Committee (1994).

Changes in agency structure and organization are necessary to enable all jurisdictions to provide access to the full array of public health services. The wide range of programs and interventions that are consistent with operating under the 10 Essential Public Health Services can be (and in some cases are being) delivered directly by the state health department, by each local health department, by public health system partners, or by various permutations thereof including through centralization, regionalization, or inter-jurisdictional compacts among different agencies.

Many local public health agencies are small and have limited capabilities. Proposals have been made to explore different ways to reorganize local public health structure toward greater effectiveness, including through organizational restructuring, such as consolidation of services among public health agencies (IOM, 2003). However, multiple formidable barriers exist to such actions including state constitutions and court rulings as well as statutory requirements of local and state governments (Baker and Koplan, 2002; IOM, 2003; Libbey and Miyahara, 2011). These legal impediments urgently need to be re-examined and revised to improve the effective use of existing public health resources and broaden the impact of needed investments.

Recommendation 2: The committee recommends that states enact legislation with appropriate funding to ensure that all public health agencies have the mandate and the capacity to effectively deliver the Ten Essential Public Health Services.

Public health accreditation has been discussed for decades in the U.S. public health community, and many public health agencies have engaged in a variety of certification, accreditation, and performance measurement activities at the national, regional, and local levels. However, public health is far behind its clinical care system counterparts in implementing accreditation standards as uniform measures of performance. Despite a rich literature on health care accreditation, the empirical evidence for accreditation correlations between accreditation and performance is uneven, with modest positive findings for certain outcomes (e.g., promoting change through the self-evaluation that occurs in preparation for accreditation).

Nevertheless, the field of accreditation is moving in the direction of better data collection and more research. The committee believes that national public health accreditation, which is evolving and is not yet a mature process, holds the potential of becoming a mechanism toward certifying that an agency's delivery of the core public health functions and 10 EPHS meets uniform standards, and at a future date, perhaps, can be positioned to certify that they are executed with excellence.

The public health accreditation movement shares elements with many activities in and outside the public sector. These include measurement and reporting of performance, transparency in operations, and accountability for process and outcome. These contemporary values are reflected in the *Government Performance and Results Act* of the 1990s and in the current administration's OpenGovernment initiative. Existing public health statutes often do not reflect current demands for accountability and its relationship to the structure, function, and authority of public health agencies. As discussed in the committee's first report, it is necessary to integrate accountability into the way public health agencies *and* their partners perform their functions.

For the reasons described—the widespread use of accreditation in health care, and the public and policymaker familiarity with the notion; the need for a higher level of accountability and transparency; and the potential usefulness of accreditation in improving quality and other

outcomes— the committee finds that national accreditation holds promise as a conduit in aiding governmental public health agencies to demonstrate minimum structural and quality process capabilities.

Recommendation 3: The committee recommends that states revise their laws to require public health accreditation for state and local health departments through the Public Health Accreditation Board accreditation process.

Several states have their own accreditation processes in place. These should resemble or be as rigorous as those set by the Public Health Accreditation Board. All states should set goals to have these standards in place no later than 2020.

Legal Capacity

Appropriately trained legal counsel needs to be readily accessible for all policy discussions in public health agencies to facilitate clear understanding of the legal basis for public health initiatives or interventions. The increasing availability of legal technical assistance from several existing national academic or not-for-profit sources, while beneficial, cannot take the place of an official legal advisor who is recognized by, and part of the same team as the health officer and the jurisdiction's chief executive. The committee recognizes that many agencies are too small to have their own dedicated counsel, and that some type of resource-sharing arrangement, aside from broader restructuring such as consolidation or regionalization, would be needed.

Public health agency legal counsel requires training in public health and in public health law. Attorneys counseling public health agencies also must possess knowledge and experience in the following areas: laws that establish the public health agency and set forth its jurisdiction and authorities, programmatic aspects of the agency's work, and procedures and processes consistent with applicable laws and policies. Such training, knowledge, and experience can be obtained through adequate career ladders within a health department, through education or, ideally, through a combination of both. One of the prerequisites for strengthening public health law capacity in health departments is the availability of legal training in schools of public health (for example, for individuals wishing to pursue a JD/MPH, and for other public health students) and in schools of law for individuals interested in public policy, and especially its health dimensions.

Recommendation 4: The committee recommends that every public health agency in the country have adequate access to dedicated governmental legal counsel with public health expertise.

Federalism and Preemption

"Preemption occurs when a higher level of government restricts, or even eliminates, a lower level of government's ability to regulate an issue" (NPLAN and Public health Law Center, 2010, p. 1). Preemption can advance or impede the achievement of population health objectives. States and localities play a vital and historic role in safeguarding the public's health and safety. They can be "laboratories" of innovation, with greater flexibility than at the national level. Consequently, unless there are compelling reasons to the contrary, the federal government ought not preempt state and local authority in advancing the public's health. A provision of the *Affordable Care Act*, for example, preempts state and local authority to require menu labeling in

restaurants and vending machines that diverges from (e.g., is stricter than) the federal standards outlined in the Act. Although federal oversight of food manufacturing and processing may be appropriate because of its close nexus to interstate commerce, restaurants are locally regulated relative to sanitary standards and are locally permitted establishments. Other federal statutes, like the *Health Insurance Portability and Accountability Act*, create a national protective floor, but allow the states to enact stricter standards. This kind of "floor preemption" is usually preferable, enabling states and localities to enact more protective public health regulations.

Preemption in the field of public health may also lead to non-enforcement of a preemptive federal standard. When a federal agency is given preemptive authority to regulate in an area where local public health agencies have a greater capacity and infrastructure to regulate, the result is likely to be that the public health measure will not be enforced. In such instances preemption, and certainly "ceiling" preemption, should be avoided or arrangements for local enforcement should be put in place.

When considering the appropriateness of preemption the impact on public health and enforceability must be assessed. As the federal government embarks on a regulatory review to determine whether federal regulations unnecessarily hamper business activity, the committee urges that this principle be upheld and efforts be made to avoid creating new or interpreting existing preemptive laws in ways that may have unintended and unhealthful consequences.

Recommendation 5: The committee recommends that when the federal government regulates state authority, and the states regulate local authority in the area of public health, their actions, wherever appropriate, should set minimum standards (floor preemption) allowing states and localities to further protect the health and safety of their inhabitants. Preemption should avoid language that hinders public health action.

Some recent legislation, such as the *Affordable Care Act's* establishment of menu labeling requirements, extends particular public health protections nationally, but also vests the Food and Drug Administration with regulatory authority over facilities it has not previously regulated, such as food service establishments that have been in the purview of state or local public health agencies. In these types of settings, the federal agency is unable to adequately enforce these requirements. Furthermore, federal efforts would be duplicative of state or local enforcement. Statutes and regulations need to allow public health agencies to enforce standards as necessary to protect and promote the public's health. Collaborative efforts are needed to facilitate enforcement of federal standards by states or localities. However, mandating that states and localities assume this federal responsibility would not be helpful unless they have adequate funding to do so.

Recommendation 6: The committee recommends that federal agencies, in collaboration with states, facilitate state and local enforcement of federal public health and safety standards, including the ability to use state or local courts or administrative bodies where appropriate. Federal, state and local agencies should combine their resources, especially in areas where regulatory authority is vested in one level of government, but enforcement capacity exists in another level.

Intersectoral Laws and Policies That Contribute to the Publics' Health

Significant and compelling evidence indicates that policies enacted by government agencies beyond the health sector have substantial effects on the health of the population. A Health in All Policies approach requires policymakers, with the support of public health agencies, to adopt a collaborative and structured approach to consider the health effects of major public policies in all governmental sectors. This "all-of-government" approach offers the benefits of improving health while also achieving key objectives in other parts of government. Seen from the perspective of other sectors, HIAP approaches could enhance their ability to achieve their own objectives because improvements in population health can have wide-reaching effects on many aspects of society.

A multi-sector strategy that explicitly considers the impact of non-health sector action on US health can create progress in that sector (e.g., transportation, agriculture) while simultaneously increasing the quality of life, longevity and economic productivity of the population.

Recommendation 7: The committee recommends that states and the federal government develop and employ a Health in All Policies (HIAP) approach to consider the health effects—both positive and negative—of major legislation, regulations, and other policies that could potentially have a meaningful impact on the public's health.

As acknowledged in the committee's report on measurement, there is no formal accountability process for private-sector entities that influence, for good or bad, the health outcomes for the community (IOM, 2011). This is significant because an estimated half of overall public health expenditures are incurred by non-governmental public health partners, such as employers and schools (Mays et al., 2004). Although the committee proposed a measurement framework for accountability in its first report, it did not discuss in any detail the issues of governance and the types of organizational structures that may be useful in operationalizing the framework, especially outside governmental agencies.

As noted in the first report, private sector employers, community organizations, and other stakeholders in the multisectoral health system can contribute to health through their actions including through policy. These actions range from employee health and wellness initiatives to efforts to strengthen potentially health-enhancing features of communities. In its present discussion about law and policy, the committee uses the model of the National Prevention, Health Promotion, and Public Health Council and its associated public-private advisory group as a point of departure for envisioning how intersectoral action on population health could be planned and implemented across government agencies and between the public and private sectors.

Recommendation 8: The committee recommends that state and local governments

- **Create health councils of relevant government agencies convened under the auspices of the chief executive;**
- **Engage multiple stakeholders in a planning process; and**
- **Develop an ongoing, cross-sector, community health improvement plan informed by a HIAP approach. Stakeholders will advise in plan development and in monitoring its implementation.**

Evidence to Inform Policy

The rationale for all population health interventions, including laws, must be based on the best evidence available while taking into consideration the strength of the available evidence, the level of uncertainty surrounding the evidence, and the risk of harm (economic or health-related) that arises from implementing or failing to implement. In some cases, the best available evidence may be limited. In those cases, new laws and judicial review of public health legal interventions will need to be built on sound theory and the opinion of content experts. Such limited evidence may be used to craft legal interventions when health threats and potential harms from inaction are large; when opportunity costs and unintended harms from action are within acceptable limits; and when the time or costs required for gathering more definitive evidence are substantial relative to the expected value of the additional evidence.

In some cases, assessments of health impact may not be necessary or useful, such as in the cases of modest-size commercial developments in a community or policies that are largely unrelated to or expected to have negligible health impacts. In other cases, assessing the impact is imperative to determine a policy's likely extent of negative or positive effects on population health and to take action to avert damaging consequences. Such cases would include several major health-consequential federal laws that require periodic reauthorization (e.g., the transportation bill).

Accurate and complete assessment of the outcomes and benefits of public health laws is complicated by the fact that the effects of laws are frequently distributed across multiple segments within the population, and affect multiple health and social endpoints over long periods of time. Thus, outcome measures for public health laws need to consider not only measures of mortality and morbidity, but also important intermediate outcome measures.

Legal interventions merit study for their effectiveness and comparative effectiveness (both against other legal intervention and compared to other kinds of interventions). Furthermore, a system of surveillance could be developed and pilot-tested to track the progress of efforts to expand the geographic reach of effective policies and laws, and to identify unmet needs for policy development and advocacy strategies. Although the administrative and methodological task of such research is challenging, the committee asserts as a general principle the obligation of policymakers to study, to whatever degree possible, the potential ramifications of policies in any sector that could substantially affect the health of the public.

> **Recommendation 9: The committee recommends that state and federal governments evaluate the health effects and costs of major legislation, regulations, and policies that could have a meaningful impact on health. This evaluation should occur before and after enactment.**

This recommendation applies to both public health and non-public health agencies, working in concert. Before or after enactment, a scientific assessment would be conducted whenever possible. Before enactment of such policies, the vested authority (e.g., the public health agency) would study the potential health impact and/or cost-effectiveness. After enactment, the authority would review the health outcomes and costs associated with implementation of the policy and would, where appropriate, offer recommendations to the chief executive and legislature on changes that would improve outcomes.

Such evaluation and assessment could be conducted by the responsible agency, such as through *National Environmental Policy Act* (NEPA) requirements, or by the public health

agency. Several models exist for requiring and conducting assessments of health policy impact, including government commissioning of assessments (e.g., actuarial analyses) of the impact of all health policies, and the requirements of NEPA. A knowledge base exists for crafting an accepted framework for evaluating the evidence of public policies, but an interdisciplinary team of experts is needed to build on the existing literature, review methodological challenges, and arrive at a consensus on preferred criteria.

> **Recommendation 10: The committee recommends that HHS convene relevant experts to enhance practical methodologies for assessing the strength of evidence regarding the health effects of public policies as well as to provide guidance on evidentiary standards to inform a rational process for translating evidence into policy.**

Such guidance would include: (1) methods for assessing the certainty of effectiveness (benefits and harms), and if a law or policy is effective, the magnitude of effect, for suitable populations; (2) methods for assessing the effectiveness of interventions (policies and programs) when used alone or in combination (i.e., their incremental and or synergistic benefits); and (3) priorities for and consideration of the contextual issues when determining whether (and where) to implement policies. The contextual issues to be considered include: importance of the problem (severity, frequency, burden of disease, cost), feasibility (affordability, acceptability), availability of alternatives, demand, fairness (equity), preferences and values, cost-effectiveness, potential to advance other societal objectives, potential for harms, legal and ethical considerations, and administrative options.

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Introduction:
Why Law and Why Now?

The Committee on Public Health Strategies to Improve Health was given a three-part task by the Robert Wood Johnson Foundation, to address the following major topics in public health: measurement, the law, and resources. This report represents the committee's response to its second task, which was to do the following:

> Review how statutes and regulations prevent injury and disease, save lives, and optimize health outcomes. The committee will systematically discuss legal and regulatory authority; note past efforts to develop model public health legislation; and describe the implications of the changing social and policy context for public health laws and regulations.

"Law is foundational to U.S. public health practice. Laws establish and delineate the missions of public health agencies, authorize and delimit public health functions, and appropriate essential funds" (Goodman et al., 2006). The law is one of the essential ingredients in public health practice. Two others, measurement and funding, are the subjects of this committee's first report released in December 2010 and its third, forthcoming, report. The law is also one of the main "drivers" facilitating population health improvement. Laws, and public policy more broadly, play three roles in population health. Laws may be (1) infrastructural, referring to the statutes that describe the duties, functions, and authorities of governmental public health agencies; (2) interventional, referring to the use of the law as a tool for achieving specific health objectives; and (3) intersectoral, referring to laws enacted in other sectors of government that may or may not have health as an explicit objective, but nevertheless have effects on population health (see Burris et al., 2010; Gostin, 2010; see Box I-1).

BOX I-1
Three Types of Public Health Law and Other Public Policy

Infrastructural: So called "enabling" public health statutes, which typically specify the mission, function, structure, and authorities of state or local public health agencies (also known as health departments).

Interventional: Federal, state, or local law or policy designed to modify a health risk factor.

Intersectoral: Federal, state, or local law or policy implemented by a non-health agency for a primary purpose other than health, but which has intended or unintended health effects.

The committee believes timing is critical to examine and make the most of the role and usefulness of the law and public policy to improve population health. This sense of urgency emerges from the juxtaposition of recent or evolving developments, as follows:

- In the sciences of public health;
- In the economy (i.e., the financial crisis and the great uncertainty and severe budget cuts faced by public health agencies and by government in general);
- In the social and legislative arenas (e.g., the *Affordable Care Act*);
- In the functioning of public health (e.g., fragmentation of government response to public health issues, lack of interstate coordination of policies and regulations, and lack of coordination among a broad range of actors that affect the public's health); and
- In the health of the population (e.g., data on the increasing prevalence of obesity in the population and poor rankings in international comparisons of major indicators of health).

The committee's charge specifies the review of laws and regulations, but the committee interpreted its charge broadly to include public policy in general. This is consistent with discussions of public health law in conjunction with policy elsewhere, including in the work of the Center for Health Law, Policy and Practice at Temple University and of Public Health Law and Policy, a California non-profit organization that provides tools and technical assistance to public health officials, communities, and advocates. In general, public policy refers to the broad arena of positions, principles, and priorities that inform (and constitute) decision making in all branches of government. However, the term is also used to refer collectively to laws, regulations and rules, executive agency strategic plans, executive agency guidance documents, executive orders, and judicial decisions and precedents (see Box I-2 for definitions of some key terms). Put simply, laws (also called statutes) are one type of public policy, but not all public policy is enacted through law. Some items of public policy are not "legal" in any meaningful sense, but may have impact that is similar to that of law in the actions they produce. Examples include policy statements, such as the recent statement of the US Department of Transportation regarding bicycle and pedestrian accommodation in transportation planning. The statement itself is not a law, but it contains a suite of recommendations for transportation agencies, and includes references to a range of pertinent statutes and regulations (DOT, 2011).

In addition to understanding the categories of law and public policy, it is useful to recognize that the processes of legislating or regulating occur in the context of a spectrum of private sector and local-level public sector policies that sometimes interact with and have effects on state and federal public policy. At one extreme are local public sector policies, such as school board decisions to source cafeteria food from a community garden. At the other extreme, there are international laws and policies that may have ramifications for US policymaking, such as the International Health Regulations or the Framework Convention on Tobacco Control.

BOX I-2
Defining Laws, Regulations, Statutes, Public Policy, and Constitutional History and Judicial Precedents

Laws (statutes and ordinances): These are generally produced by the legislative branch of government—Congress, state senate or assembly, city council, etc., to institute and maintain orderly coexistence. Laws passed by local units of government are called ordinances.

Regulations: These are rules, procedures, and administrative codes promulgated (i.e., put forth) by the executive branch of government, such as federal or state agencies, to achieve specific objective or

discharge specific duties. These are applicable only within the jurisdiction or purpose for which they are made.

Public Policy: This term refers to the broad arena of positions, principles, and priorities that inform high-level decision making in all branches of government, but is often used to refer collectively to laws, regulations and rules, executive agency strategic plans, executive agency guidance documents, executive orders, judicial decisions and precedents (see usage in Moulton et al., 2007). Some public policies are not "legal" but may have impact that is similar to that of law in the actions they produce.

Each branch of government makes contributions to public policy.

Constitutional history and judicial precedents: These refer to current courts' interpretation of the Constitution and their determinations based on decisions made by courts that preceded them.

Statutes enacted by the Legislative Branch and rule making by the Executive Branch drive policy. For example, the *Food, Drug, and Cosmetics Act* and the *Food Safety Modernization Act* are the laws enacted by Congress to grant powers to the Food and Drug Administration to regulate (i.e., through rule-making) select products for the public's health. Those products include human drugs, devices, tobacco, and foods not regulated by the US Department of Agriculture. However, the mere existence of legal power does not ensure public health improvement in the absence of resources and enforcement. Conversely, the absence of specific legislative power does not mean that government cannot act, as it possesses other public policy tools such as issuing guidance and implementing executive orders.

In the public sector, policy-based interventions may include health promotion such as social marketing campaigns, and awards or similar incentives for private sector policy changes. Legal or policy interventions may be highly effective. This report provides examples of areas of population health where public policy change has had significant effects in changing the conditions for health and facilitating healthier choices by communities and individuals.

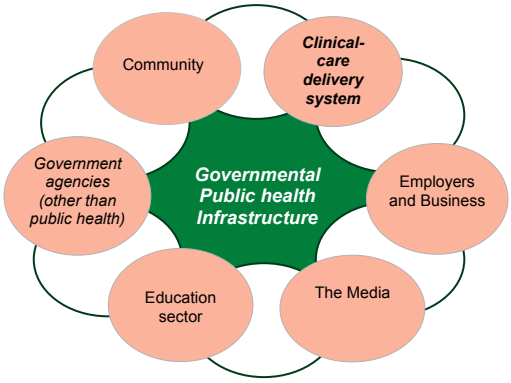
The report is organized to roughly correspond to the typology described above. The first chapter focuses on laws that establish the structure, function and authority of public health agencies at all levels of government. The second chapter reviews the potential of the law (and public policy) as a type of intervention for population health improvement. The third chapter addresses cross-sector or intersectoral public and private policy approaches (policy decisions made in disparate fields, ranging from education to agriculture to transportation) that may affect the health of the public.

In the introduction to its first report, *For the Public's Health: The Role of Measurement in Action and Accountability*, the committee aimed to change the terms of discourse about health. The committee wrote:

> The overall public health system represented in Figure 1-1 (I-1 in this document) is renamed simply *the health system,* with the health care delivery oval described more specifically as the *clinical-care delivery system*. The modifiers *public* and *population* are poorly understood by persons other than public health professionals and have made it harder to understand that public health is about the population as a whole and easier to misinterpret or overlook the collective influence and responsibility that all sectors have for creating and sustaining the conditions necessary for health. In describing the system that comprises public health agencies, the clinical-care delivery system, communities, and other partners as *the health system*, the committee seeks to reclaim the proper and evidence-based understanding of health not merely as clinical care, but as the entirety of

what we do as a society to create the conditions in which people can be healthy (IOM, 1988, 2011).

FIGURE I-1 The health system.



This figure illustrates some of the many sectors and stakeholders that contribute to population health and that may be brought to the table. The governmental public health infrastructure—agencies at all geographic levels, with their varying capabilities—stands at the center due to its special statutory role and expertise in protecting the public's health.

The present report addresses laws and public policy as they pertain to public health practice in both its institutional and programmatic aspects, and it also examines laws and public policy—and to a limited extent, policy in the private sector—as they pertain to population health more broadly. Table I-1 provides some examples of the health-supporting policies that may be enacted and implemented by the stakeholders depicted in Figure I-1.

Table I-1 Examples of Policy by Stakeholder

Stakeholder	Policy Examples
Clinical care delivery system	Adopting standards to improve quality of care, providing preventive services
Employers and business	Providing employee wellness tools and incentives, developing policies adopting voluntary standards improving healthfulness of products
The media	Requiring relevant training for health journalists, formulating standards for conveying health and scientific information
Education sector	Adopting nutritional standards, developing and implementing physical activity guidelines for the school day, incorporating health information in the curriculum with the explicit goal of improving health literacy, making schools into community centers—supporting families, opening playing fields and playgrounds to community use (through joint use agreements), etc.
Government agencies (other than public health)	Implementing health in all policy approaches—considering potential health impacts of policies, adopting policies with the secondary goal of improving health
Community (including individuals and families, organizations, faith groups)	Advocating for healthier community environments in interactions with legislators, government executives, and private sector

The major themes examined in this report include the current state of laws (infrastructural, interventional, and intersectoral) across the country and the need both for reform and improved policymaking; the implications from a public policy perspective of the public health field's evolving understanding of the factors that create or interfere with good health; and the different and sometimes conflicting sets of values and public norms that inform the availability, use, and acceptance of laws and public policy to improve public health.

In its first report, the committee made the case that the time has come for the United States to begin moving away from a primarily medical-care-oriented response to poor population health outcomes and toward a more broad-based response that engages multiple sectors and considers all the determinants of health, including socioeconomic factors. In the present report, the committee asserts that the law specifically, and public policy more generally, are among the most powerful tools to improve population health. Laws and policies undergird the practice of public health. They are responsible for many of the social and economic structures across government and society that put in motion chains of causation that contribute to health outcomes. Public policy interventions, which have been studied in selected areas of public health practice, have proven to be more effective and efficient, and offer greater value than individual based interventions in a number of circumstances. For example, counseling to prevent alcohol abuse is not very effective in the absence of policy interventions, such as enforcement of laws, increasing taxes, and regulating alcohol outlet density. This is due in large part to the fact that health education seeks to change behaviors and lifestyles that are "too embedded in organizational, socioeconomic, and environmental circumstances for people to be able to change their own behavior without concomitant changes in these circumstances" (Ottoson and Green, 2008, p. 607). Gains in reducing tobacco use provide one of the best examples in this area.

Public health practitioners are working to employ legal or policy tools to influence physical activity, nutrition, and other behaviors by making the environment in which these occur more conducive to health-enhancing choices. Many determinants of health are not under the direct influence of public health agencies; thus action in those areas involves a variety of sectors, either catalyzed by public health's convening role or, as is sometimes the case, by health-oriented initiatives of other actors in those sectors. Health in all policies (HIAP) is a term that is sometimes used to describe policy action located outside the traditional domain of public health, but that considers health effects as part of the decision process. The concept of HIAP is explored in Chapter 3.

To ensure that policies are effective in improving the public's health, policy makers must continuously evaluate their activities and investments (Council on State Governments, 2008). Results-based policies and investments are becoming apparent in the clinical care system, where the drive to increase the practice of evidence-based, high-value medicine has become pervasive. There are indications that the policymaking process can be influenced by data (Burris et al., 2010; Clancy et al., 2006). One example of the influence of evidence of effectiveness on policymaking is found in the Task Force on Community Preventive Services recommendation on laws that make it illegal to drive with blood alcohol concentration (BAC) levels of 0.8 percent or higher (Shults et al., 2001). This recommendation, informed by evidence of the effectiveness of BAC laws in reducing motor-vehicle crash-related fatalities, directly led to changes in the transportation laws, which now incentivize states to enact laws lowering the BACs to secure highway funds. The Congressional Budget Office and the Office of Management and Budget noted this shift in public policy, and acknowledged proof of its effectiveness (OMB, 1998). The rapidity of these changes is notable because many population-level interventions (e.g., to prevent

or lower rates of chronic diseases) take years to decades to demonstrate effectiveness. Here is an example of a legal intervention that was capable of rapidly demonstrating its effectiveness in decreasing the morbidity and mortality associated with motor vehicle associated injury.

The 2010 *Affordable Care Act*, intended to make quality clinical care services available to all Americans, also includes provisions related to prevention and population health. These components of the law are in some ways peripheral to the law's central purpose, but they reflect the fact that some of the discussions that led to the writing of the law revolved around health, not merely health care (Chernichovsky and Leibowitz, 2010). This represents recognition on the part of some lawmakers, advocates, and health professionals that the nation's health problems are not just lack of access or less than optimal quality, but include far more complex challenges that explain the nation's poor return on investment. Unfortunately, this recognition ultimately played a small role in the law itself (Gostin et al., 2011).

As the scientific understanding of the determinants of health evolves, public health professionals continue to gain insights on how the social, built, and natural environments influence health. Building on this learning is essential by applying it to the full range of population health interventions, including public policy. This must be a priority at all levels of government. That means public health statutes, which are often antiquated, need to be revisited and revised in the context of new scientific knowledge and evolving priorities in population health. This is particularly important in a time of scarce resources, when effective public policy can diminish or obviate the need for less efficient interventions (Council of State Governments, 2008). Sociopolitical currents now present both opportunities and challenges to changing public health law. On the one hand, the political environment emphasizes market forces, individual responsibility, and a perception of government interventions in health as paternalism (these issues are discussed elsewhere in the report). On the other hand, the strategic planning processes of government, including public health agencies, are more intensely focused than ever before on the need for efficiency (Millhiser, 2010). The United States makes enormous investments in health—largely clinical care services. These expenditures exceed 17 percent of the Gross Domestic Product (Truffer et al., 2010), yet they yield relatively unfavorable health outcomes for the nation. This informed, in part, the committee's recommendation in its first report that a summary measure of population health and other sets of standard measures be adopted to help understand and convey information about the nation's health to health professionals, policy-makers, and the public.

From the History of the Law and Public Policy in Public Health

In the following section, the committee provides examples to illustrate two points: (1) the close relationship between breakthroughs in population health and public policy; and (2) the multi-sectoral history of interventions intended to address threats to the public's health.

Public health history is full of compelling narratives about scientists, physicians, civic leaders, and others who saw the potential of public policy to assess, monitor, and improve the public's health. For example, William Farr was instrumental in creating a national system of vital statistics and of public health surveillance in England to inform policymakers about infectious disease outbreaks as a necessary first step in controlling them (Langmuir, 1976). Farr also demonstrated the potential of health data to test social hypotheses and use the conclusions to inform public policy, such as sanitary reforms (Whitehead, 2000). Farr's colleague, John Snow, the public health hero who identified the source of London's 1854 cholera outbreak, secured

permission from the parish board of governors to remove the handle of the Broad Street pump (Moulton et al., 2007). His efforts contributed to the passage of laws promoting sanitary reforms—the *Public Health Act* in 1858 and the *Sanitary Act* in 1866.

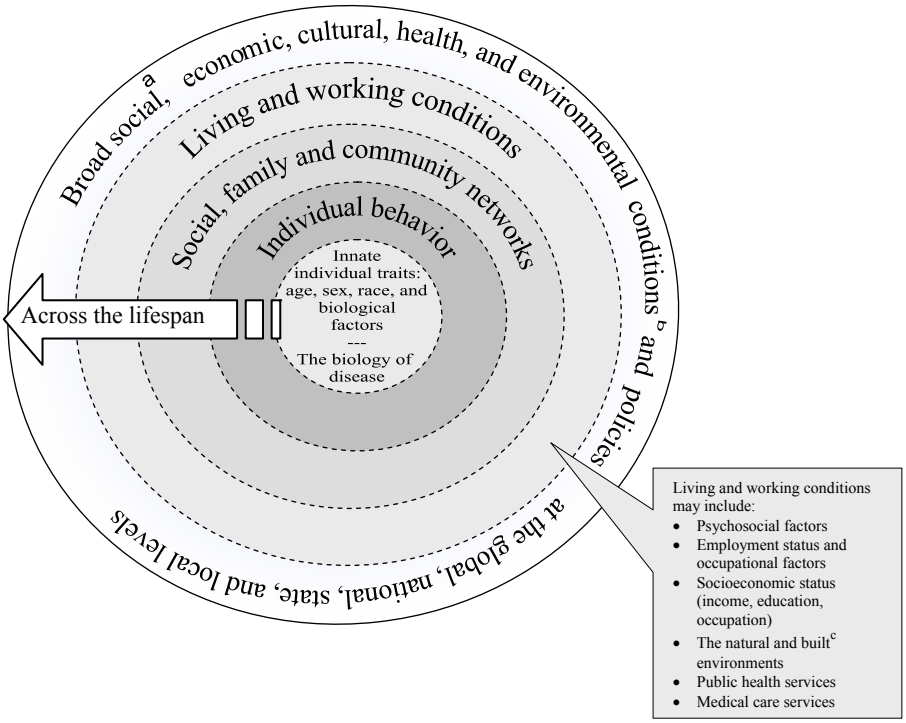
Throughout its history, public health has identified health problems, their causes, and potential solutions, including legal interventions. Public health agencies, however, often lack the power to implement solutions, which often reside in other sectors of government as well as in the private and not-for-profit sectors. For example, as municipal authorities grew in complexity, different sectors assumed responsibility in arenas of population health relevance. Public health identified threats to health, but other government entities came to be charged with addressing them. Agriculture, transportation, zoning, and other government departments all play crucial roles in addressing many of the leading causes of poor health. Historically, unhygienic practices led to regulation and inspection of abattoirs by the agriculture department, safe water by civil engineers, and housing standards reflected in and enforced through building codes.

Public health practitioners have a long and rich history of engaging with other sectors and disciplines to address health challenges outside explicitly health-oriented domains. That was certainly the case in the 18th and 19th centuries, when early public health practices were developed to address industrial and occupational threats to health. It remains true in the 21st century, as knowledge of the social and environmental determinants has evolved and evidence has begun to show that solutions increasingly lie in interventions that may be undertaken in the fields of education and social services, and in planning and revenue (e.g., financial incentives) departments. Moreover, non-governmental organizations (e.g., community and advocacy entities) play an important role in identifying threats to health, bringing them to the attention of public health agencies and policymakers, and contributing to developing and implementing solutions. One of the major challenges to putting forth public policies and laws pertinent to population health is that such actions may be incompatible with economic objectives and priorities of the marketplace. That was the case during the Industrial Revolution, where the health and safety of the workforce often came second to the engines of economic progress, and remains true today, as, for example, businesses seek to maximize profits by both shaping and satisfying consumer desires, even when those desires detract from good health (e.g., sugar-sweetened beverages, tobacco).

The committee's first report introduced and discussed at length the multiple social and economic determinants that influence health (see Figure I-2), and offered a brief overview of the evidence indicating that individual behaviors and access to clinical care account for only a part of what creates population health (see Braveman et al., 2011; Cutler et al., 2006; McGinnis et al., 2002). One area of evidence on the limitations of medical care in influencing health status is found in examining socioeconomically disadvantaged populations that—even under universal medical insurance—experience worse health than their counterparts. For example, Alter and colleagues (2011) conducted a study of insured, low-income individuals in Canada's universal medical care system, and found that they use more services and still have poorer health outcomes compared to their more advantaged peers. They concluded that countries should not rely on universal insurance alone "to eliminate the inequities that disadvantaged sectors of their populations continue to experience today. Rather, these countries need to pay additional attention to far broader strategies to change the conditions that influence health outcomes" (Alter et al., 2011, p. 281). The concentric circles in Figure I-2 show the progression from downstream (closest to the individual's underlying biology) to upstream (deeper social, economic, and environmental determinants, also described as the "causes of causes" of poor health outcomes).

As discussed in the pages that follow, public health attention to the more distal social and environmental determinants of health is often controversial in that it occurs against the interplay between the values of society and elected officials, and among disagreements about the ascendance of particular values. Moreover, these determinants have the longest time line and most complex—and often poorly elucidated—pathways (i.e., pathophysiologic links) from cause to effect. This presents challenges both for establishing what interventions are most effective and for compelling pertinent parties to act. The conceptual and statutory relationship to public health practice—and thus, for undertaking legal or policy interventions—is more complicated to explain and trace as one moves from the inner circles of the figure, from genetic factors and individual behaviors to the outer circles, which denote broad, high-level policies related to characteristics such as education and income.

FIGURE I-2 A guide to thinking about the determinants of population health.



SOURCE: Adapted from Dahlgren and Whitehead (Dahlgren and Whitehead, 1991). Dotted lines between levels of model denote interaction effects between and among various levels of health determinants (Worthman, 1999).

[a]Social conditions include economic inequality, urbanization, mobility, cultural values, and attitudes and policies related to discrimination and intolerance on the basis of race, sex, and other differences.

[b]Other conditions at national level might include major sociopolitical shifts, such as recession, war, and government collapse. The built environment includes transportation, water and sanitation, housing, and other dimensions of urban planning.

VALUES, SOCIAL NORMS, AND THE PUBLIC VIEW OF HEALTH

> *Much contemporary discussion about reducing health inequalities by increasing access to medical care misses the point. We should be looking as well to improve social conditions—such as access to basic education, levels of material deprivation, a healthy workplace environment, and equality of political participation—that help to determine the health of societies.* (Daniels et al., 2000, p. 4)

Discussing the law and public policy is not possible without addressing the societal context—the national and community values, norms, and popular attitudes (i.e., toward government, toward public health) and perspectives that influence American policymaking and Americans' understanding of the "good life." At a time when the evidence base establishing social and environmental factors as instrumental influences to health continues to grow, four aspects of the worldview of many Americans make it difficult to operationalize this evidence in the practice of public health and of the broader health system. These include:

- *The rescue imperative (or the rule of rescue).* People are more likely to feel emotionally moved and motivated to act in the case of specific individual misfortune (e.g., the plight of baby X highlighted on the evening news), but far less inclined to respond to bad news conveyed in terms of statistical lives (Gostin, 2004; Hadorn, 1991;Hemenway, 2010);
- *The technological imperative*. Cutting-edge biomedical technologies have far greater appeal (and historically, government funding) than population-based interventions, including public policies (Fuchs, 1998;Gillick, 2007;Koenig, 1988);
- *The visibility imperative*. Activities that occur behind the scenes, such as public health practice, remain invisible and are taken for granted in the public sphere until and unless a crisis arises, such as an influenza pandemic or radiation threats. The other contributor to the invisibility of public health is the fact that the fruits of its labors are often far in the future (Hemenway, 2010); and
- *The individualism imperative.* American culture generally values individualism, heavily favoring personal rights over public goods (Gostin, 2004).

On the last point, John Stuart Mill's notions of self-regarding and other-regarding actions are useful when discussing the issues of individual freedom and the common good in the context of public health. Some individual actions primarily affect only the individual, but others have social and economic consequences (e.g., a person with infectious tuberculosis who goes untreated, a drunk driver who kills or injures others).

The mounting evidence about the most distal determinants of health calls for an examination and application of the core values of public health law, including government power and duty, the nature and limits of state power, a focus on population and prevention, community engagement, and fairness (Gostin, 2006). These values and the ways in which they appear to conflict or intersect with contemporary societal values are discussed in more detail in subsequent chapters of this report. This also has implications for the relevance and success of the committee's recommendations.

Health is a foundational requirement for the social, economic, and political activities critical to the public's welfare and to the strength of a nation (its governmental structure, civil society organizations, cultural life, economic prosperity, and national security) (Gostin, 2006). For this reason, health must be a high priority for individuals and society as a whole, but getting widespread support for this position requires reframing the importance of health in achieving

goals consistent with other societal values, such as prosperity, economic development, and longevity.

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1

The Law and Public Health Infrastructure

This chapter first describes the basic components of the public health infrastructure[1] and the organization of governmental public health in the United States. Next, the committee discusses the laws that establish the mission, mandate, structure, capacity, governance, powers, and limits of public health agencies at the national, state, tribal, and local levels. The committee then reviews the recent history of public health law reform, and discusses the changes needed to equip the governmental public health sector to lead and support efforts to improve population health. Finally, the committee discusses the critical question of public health federalism—that is, the optimal locus of responsibility and authority among the levels of government with regard to health-relevant public policy.

THE ORGANIZATION OF GOVERNMENTAL PUBLIC HEALTH IN THE UNITED STATES

The primary reason for the existence of government is to provide for the health, safety, and welfare of the people (Gostin, 2010; Lopez and Frieden, 2007). In the United States, governmental public health responsibilities and roles exist at three different levels: federal, state/tribal, and local/municipal. The fundamental division of responsibility among these levels is defined primarily by the Constitution, which gives the states sovereign power (sometimes called "police powers", discussed below) over most health issues and limits the role of the federal government primarily to (1) regulation of foreign and interstate commerce issues—and by extension, health issues and threats that could affect commerce, and (2) the power to tax and spend for the public welfare (Gostin, 2010; Grad, 2005).

The organization of public health at the federal level consists of the Department of Health and Human Services (HHS), which includes the Centers for Disease Control and Prevention (CDC) that function as the nation's lead public health agency, the Food and Drug Administration (FDA), and several other pertinent agencies each of which has multiple functions relevant to health. Other federal departments and agencies have health-related duties. These include the Department of Agriculture, whose functions include setting dietary guidelines, ensuring food safety, and administering the national program that sets and enforces organic standards; the Environmental Protection Agency, which is charged with protecting Americans from risks to health and to their environment; and the Occupational Health and Safety Administration, in the

[1] The 2003 report *The Future of the Public's Health in the 21st Century* used the term public health infrastructure in reference to the array of public entities charged with keeping the public healthy (e.g., agencies, laboratories, and partners) and to their operational capacity. CDC has also defined three components of the basic public health infrastructure: workforce capacity and competency, information and data systems, and organizational capacity (CDC, 2008).

Department of Labor, which is given oversight of workplace safety and health issues. The federal public health agencies were created by administrative statute, and their actions are authorized by the Public Health Service Act first passed by Congress in 1944 and by a host of other laws (Goodman et al., 2006).

Below the federal level, the organization of public health is similarly complex, and the existing classification system for how public health is structured has had numerous iterations over several decades (see for example the earliest descriptions in Miller et al., 1977 and DeFriese et al., 1981). Each structural arrangement may have advantages and disadvantages in terms of the agencies' ability to function and shape public policy, cultivate legislative champions, and secure needed funding, but given the heterogeneity among agencies and locales, there is little research on the topic and very limited resources to support it. First, there are four primary organizational models for state public health agencies, depending on whether the public health component is stand-alone or combined with other functions, such as mental health, substance abuse and human services programs, although this typology is often abridged to stand-alone agencies and umbrella agencies (ASTHO, 2007) (see Box 1-1). The statutes or laws that authorize state public health agencies are grounded in the US Constitution which both constrains their actions and allows them significant powers. Second, three models describe the administrative relationship between state and local public health organizations (or how states deliver services). These include a decentralized or home rule arrangement, under which local public health agencies operate independently of the state and report to local government; a centralized model in which there are no local public health agencies, though the state agency may have regional offices; and shared and mixed authority models where the local agencies are responsible to both the state public health agency and to local government, or where some local agencies in a state report to the state agency while others operate solely under local government control (NACCHO, 1998; Novick and Mays, 2005). Local public health agencies in 29 states have decentralized (also called "home rule," or local) governance; local agencies in 6 states and the District of Columbia have centralized (or state) governance, and 13 have shared or mixed (state and local) governance (NACCHO, 2008). Local public health agencies may also be categorized by geographic distribution as county, city, city/county, township, and multi-county/district/regional—60 percent are classified as county-type (NACCHO, 2001, 2008).[2]

BOX 1-1
Four Models of State Public Health Agency

Traditional Public Health Agency—an agency that oversees public health and primary care only. While it may also administer one other health-related program (i.e., environmental health, alcohol and drug abuse), its responsibilities are usually limited to improving or protecting the overall health status of the public

Super Public Health Agency—an agency that oversees both public health and primary care and substance abuse and mental health. This usually includes administering services supported by the federal Substance Abuse Prevention and Treatment Block Grant and the Community Mental Health Services Block Grant programs

Super Health Agency—an agency that oversees public health and primary care as well as the state Medicaid program

[2] A similar typology, but one that describes five types of local public health agencies, may be found in NACCHO's *Local public health agency infrastructure: A Chart book* (2001).

Umbrella Agency—an agency that oversees public health and primary care, substance abuse and mental health, the Medicaid program, and other human services programs"

Source: ASTHO, 2007

Public health responsibilities at both the state and local levels generally reside in multiple agencies, in addition to the public health agency. Each state has its own legal framework for public health. All state public health agencies have one or more foundational (or enabling) statutes (laws) that provide the agencies with authority to conduct public health activities and permit them to promulgate regulations and take action. Some state statutes are detailed in outlining duties and powers, while others are broadly worded and permit the agency to promulgate regulations as needed (ASTHO, 2007). State public health statutes have been reviewed and well-characterized by model Act efforts such as the Turning Point Model State Public Health Act and the Model State Emergency Health Powers Act, both of which provide templates for updating the statutory foundations of public health practice. The rights, powers, and authorities of local governments have no special standing under the U.S. Constitution, and are instead "either delegated by the state legislature or derived directly as a grant of authority from the state constitution" (Goodman et al., 2007). Public health statutes of local governments are less well characterized, in part because there are 2,794 local public health agencies and 18,000 local jurisdictions (e.g., counties, cities, boroughs, and special districts). McCarty et al. (2009) have begun a process of identifying the major categories of local ordinances that pertain to public health for a range of local jurisdictions (Gostin, 2010).

Boards of health are a historical mechanism for public health governance at the state and local level, but their roles have evolved over time, and some have been dismantled entirely (Nicola, 2005). Eighty percent of local public health agencies have an associated local board of health, and 23 states have a state board of health (Hughes et al., 2011). Some local boards are advisory, and others play a role in governance and policymaking. Their functions may include: adopting public health regulations, setting and imposing fees, approving the agency budget, hiring or firing the top agency administrator, and requesting a public health levy (Beitsch et al., 2010; Leahy and Fallon, 2005). State boards play varying roles as well, including agency oversight, appointing the health officer, and a quasi-legislative function (i.e., adopting/rejecting rules) and a quasi-judicial function (i.e., enforcing rules) (Hughes et al., 2011).

State Police Powers

Police powers, which the states possess as sovereign governments preceding the US Constitution, are the powers to safeguard the health, safety, welfare, and morals of the population and may be exercised by public health agencies (also called health departments), along with police, fire, and sanitation departments (Lopez and Frieden, 2007) (see box 1-2). States may delegate this power to local governments and for health purposes to public health and related agencies. Surveillance and required disease reporting are exercises of state police powers. In some states, disease reporting is mandated in decades-old statutes, while in others, the statutes may be general, and simply empower the state health commissioner or board of health to "create, monitor, and revise the list of reportable diseases and conditions" (Neslund et al., 2007). In other states, this may be done either by statute or by regulations promulgated by the health department. The Fourth, Fifth and Fourteenth Amendments provide procedural safeguards that constrain the exercise of police powers, such as due process and equal protection of the laws (Gostin, 2010).

BOX 1-2 State Police Powers

Refers to authority of state to enact laws, promulgate regulations, and adjudicate to:

(1) Protect, preserve, and promote:
- Health
- Safety
- Morals
- General welfare

(2) Restrict private interests (within limits set by federal and state Constitutions):
- Personal interests – Autonomy, privacy, association, expression, liberty
- Economic interests – Contractual freedom, property uses, pursue trades and occupations

SOURCE: Gostin, 2010

The 3 Core Functions and 10 Essential Public Health Services

The fundamentals of government public health work have been distilled in three Core Public Health Functions outlined in the Institute of Medicine (IOM) report *The Future of Public Health* (IOM, 1988). The functions are assessment, policy development, and assurance. In 1994, the Core Public Health Functions Steering Committee, which included federal government agencies and major public health organizations, developed the 10 Essential Public Health Services (10 EPHS) framework (see Box 1-3).[3] The 10 EPHS have been used as a tool for planning, implementation, and evaluation in public health. Given their purpose to illustrate the range of public health practice, they are extremely broad and somewhat vague. Also, the 10 EPHS are not simply the province of governmental public health agencies. Other organizations deliver services and conduct activities that may be categorized under one or more of the EPHS. However, the 10 EPHS do necessarily spell out the roles of non-health or non-governmental public health actors, or provide a map for implementing health in all policies approaches (intersectoral efforts to consider the health implications of non-health policies).

BOX 1-3 The 10 Essential Public Health Services

1. Monitor health status to identify and solve community health problems.
2. Diagnose and investigate health problems and health hazards in the community.
3. Inform, educate, and empower people about health issues.
4. Mobilize community partnerships and action to identify and solve health problems.
5. Develop policies and plans that support individual and community health efforts.
6. Enforce laws and regulations that protect health and ensure safety.
7. Link people to needed personal health services and assure the provision of health care when otherwise unavailable.
8. Assure a competent public and personal health care workforce.
9. Evaluate effectiveness, accessibility, and quality of personal and population-based health services.

[3] The American Public Health Association, the Association of Schools of Public Health, the Association of State and Territorial Health Officials, the Environmental Council of the States, the National Association of County and City Health Officials, the National Association of State Alcohol and Drug Abuse Directors, the National Association of State Mental Health Program Directors and the Public Health Foundation.

10. Research for new insights and innovative solutions to health problems.

SOURCE: Public Health Functions Steering Committee 1994.

Essential Service 7 warrants attention in the context of implementing the Affordable Care Act. For decades, the public health practitioner community has expressed ambivalence about its role in the provision of limited, generally primary clinical care services as part of a safety net for uninsured and vulnerable populations. This role—providing, not just assuring the delivery of care—has channeled some additional resources to public health agencies, but has both perpetuated the misperception of public health as primarily publicly-funded medical care for the indigent and has been seen by many public health leaders as a programmatic distraction from discharging population-oriented responsibilities (Brooks et al., 2009; IOM, 2003a). Work by Honoré in Missouri (2007) and Brooks and colleagues in Florida (Brooks et al., 2009) has showed that a large, disproportionate percentage of public health funds are dedicated to Essential Service 7 to the detriment of agency ability to adequately attend to the other nine essential services. As discussed in and since the IOM report *The Future of the Public's Health in the 21st Century* (IOM, 2003b), many public health commentators believe that a well-functioning medical care system and expanded access to all or most of the population will free the public health agencies to focus on the "assurance" aspect of Essential Service 7 (e.g., ensuring access to care, linking people to needed care, assessing the quality of the care delivered in the community, and assessing and strengthening community supports for good health), rather than engage in the direct provision of clinical services (IOM, 2003b).

MODERNIZING PUBLIC HEALTH STATUTES

Many public health statutes have not been systematically updated in decades or more. They do not reflect current circumstances, provide insufficient mandates and powers, and guarantee human rights protections that might be interpreted judicially as overbroad (National Association of Attorneys General, 2003; Meier et al., 2009b). Antiquated laws can be confusing, fragmented, and duplicative. Older public health laws were, of course, informed by the scientific standards of the day and by the statutory context and constitutional jurisprudence of their time, including conceptions of individual rights. In addition, some laws were enacted in piecemeal fashion in reaction to a specific health problem (e.g., a disease outbreak), leading to layers of statutory accretion rather than holistic or comprehensive legislation (Gostin et al., 2008: 676).

Public health laws need to be sufficiently broad to deal with unforeseen threats, while still giving public officials clearly specified powers and limits. Many of the antiquated laws currently on the books focus on infectious diseases, but lack specific powers and responsibilities for chronic diseases and injuries. They also lack specific authority to exercise modern functions such as managing immunization registries and syndromic surveillance systems, and conducting interventions, in collaboration with other sectors, to alter the built environment. At the same time, antiquated statutes predate the vast expansion of knowledge about the socioeconomic determinants of health and their role in the complex pathways to chronic disease and other poor health outcomes. Extant statutes also frequently fail to protect individual rights such as privacy, non-discrimination, and due process. Consequently, policymakers must systematically and comprehensively review public health statutes to ensure that sufficient and clear authority is in place, together with safeguards of individual rights.

The challenges presented by outdated laws are most starkly apparent in the context of preparedness for public health emergencies (see Box 1-4). The preparedness component of public health agency activities developed significantly in the last decade of the 20th century because of federal and congressional interest in public health readiness for deliberately introduced biological, chemical and other threats to the public's health. These efforts, which received legislative attention in the late 1990s, intensified after the events of September and October 2001, including a major focus on the legal aspects of preparing for bioterrorism and other types of disasters. Goodman and colleagues have described the core elements of public health legal preparedness: essential legal authorities, competencies to apply laws, coordination across jurisdictions and sectors, and information about public health law best practices (Goodman et al., 2006). Preparedness cuts across many of the 10 EPHS.

BOX 1-4 Preparedness Laws: Still in Need of Reform

"Existing state laws may thwart effective surveillance activities. Many states do not require timely reporting for the most dangerous agents of bioterrorism. Most states do not require immediate reporting for all the critical agents identified by the CDC [Centers for Disease Control and Prevention]. At the same time, states do not require, and may actually prohibit, public health agencies from monitoring data collected through the health care system. Private information held by hospitals, managed care organizations, and pharmacies that might lead to early detection of a public health threat, such as unusual clusters of fevers or gastrointestinal symptoms, may be unavailable to public health officials because of insufficient reporting mechanisms or privacy concerns."
SOURCE: The Centers for Law and the Public's Health, The model state emergency health powers act.

Although the Model State Emergency Health Powers Act was implemented to varying degree by a number of jurisdictions around the country, the general state of legal preparedness of public health emergencies such as epidemics and bioterrorist attacks remains deficient.

The CDC, the nation's top public health agency, has powers "to quarantine, inspect, disinfect and even destroy animals that are sources of dangerous infection to humans" that have "limited applicability to a few diseases. If the CDC did try to exercise power in response to swine flu, its legal authority would surely be challenged, causing needless delays and uncertainty—and its actions might be ruled unconstitutional. To its credit, the CDC has tried for more than a decade to modernize its legal authority. But its proposed fundamental revision was submitted more than three years ago, and regulations have yet to be finalized" (Gostin and Gostin, 2009).

In addition, based on reports from Association of State and Territorial Health Officials (2010) and the National Association of County and City Health Officials (2010) that were prepared for the CDC following the H1NI epidemic, O'Connor and colleagues (2011) identified several areas where laws and policies at all levels of government were not adequate to meet the needs of the public. They stated that "although progress in public health legal preparedness has been made since 2001, it is apparent from the law and policy challenges encountered during H1N1 that no single U.S. jurisdiction—state, local, tribal, or federal—is yet fully legally prepared to respond to a major public health threat." Key issues they identified include: vaccine allocation, distribution, and dispensing issues; coordination among levels of government about the use of stockpiled material; and the need for sustainable public health response funding. The authors noted that the laws and policies related to the vaccine campaign "presented significant challenges, especially for state and local public health responders," including decisions on vaccine availability, formulation, allocation, prioritization, and guidance as well as tracking, recalls, and adverse event reporting. 'Use and accounting for stockpiled materiel raised many policy and legal questions during 2009 H1N1.' Funding from Public Health Emergency Response was also restricted. The allowable methods for distributing the funds limited state and local flexibility for their use which ultimately slowed their ability to implement public health measures (O'Connor et al., 2011).

In addition to the factors described above, other major shifts have occurred in the backdrop to public health laws, including demographics, health challenges, and in aspects of public health practice. For example, the population lives much longer and the age distribution of the population ranges across a much wider lifespan than was the case when some early public health laws were framed. Americans live very different lives than they did even 30 years ago. Examples are changes in how they communicate, grow food, and transport themselves. The infectious diseases common a century ago pose far less of a threat in contemporary life in the United States compared to chronic disease and the potential of longer life in diminished health (Kominski et al., 2002; Vaca et al., 2011; Woolf et al., 2010). Approximately two thirds of the adult population (Calle and Kaaks, 2004) and a growing proportion of children are overweight or obese (Center for Health Improvement, 2009), changing the profile of chronic disease patterns in the U.S. population. The empirical evidence about what creates and impairs health on the population level has continued to evolve, clarifying that medical care contributes far less to health outcomes than do the broader societal, environmental, and economic conditions that strongly influence human behavior (see Braveman et al., 2011; Cutler et al., 2006; McGinnis et al., 2002). Given the enhanced and evolving understanding of the causes of poor health and death in the population, public health tools and approaches are also changing. Also, fundamental transformations are taking place in public health practice and in the health system in general. These changes offer opportunities for legal reforms to ensure modern laws and regulations meet contemporary needs, in addition to conforming to evolving science and evidence to address the major health hazards facing the population.

Public health statutes at the state level do not generally reflect the contemporary causes of poor health. State laws often feature specific references to communicable disease duties of public health agencies, while making no explicit reference to chronic diseases and injuries. Meier et al. (2009a) conducted a 50-state comparison of enabling public statutes against the standards of the 10 Essential Public Health Services and the 6-part mission of public health (like the EPHS, the mission[4] was defined in the 1994 HHS document *Public Health in America*). The study's findings aside, it is important to note that the mission statements refer to injuries and infectious disease, and the 10 EPHS refer very broadly to "health problems." However, the lack of explicit reference to, for example, the leading causes of death, i.e., chronic disease, may lead to a limited understanding among policymakers and the public about the role of public health agencies. Such narrow understanding leads to inadequate funding for the full breadth of public health services necessary to safeguard the health of the public.

When considering the need for change in contemporary public health law, there are several contextual factors and fundamental transformations must be considered, including:

- National health legislation that holds the promise of expanding access to medical care, thus partially releasing public health agencies from the need to provide safety net clinical services;
- A renewed emphasis on and commitment to quality performance and accountability of public health agencies (e.g., the national Public Health Accreditation effort, the 2008 HHS Consensus Statement on Quality in the Public Health System, and the 2007

[4] The mission of public health: 1. Prevents epidemics and the spread of disease; 2. Protects against environmental hazards; 3. Prevents injuries; 4. Promotes and encourages healthy behaviors; 5. Responds to disasters and assists communities in recovery; 6. Ensures the quality and accessibility of health services (Public Health Functions Steering Committee, 1994).

Pandemic and All Hazards Preparedness Act provision requiring development of performance standards and measures by (Nelson et al., 2007); and

- Multiple recent developments—legislative, technologic, and practical or operational—in the health information arena that have profound implications for public health practice and for its relationship to clinical care (e.g., the American Recovery and Reinvestment Act of 2009 provisions for health information technology, including payments to spur adoption of electronic medical records; the establishment of Regional Health Information Organizations to facilitate health information exchange across institutions in a community or region; and the development of the Meaningful Use concepts which include some consideration of public or population health needs as part of health information networks).

The changes outlined above are likely to have implications for the legal and policy aspects of public health practice. The growing understanding of the multiple determinants of health also requires attention to the adequacy of existing public health statutes. It also will require public health agencies to have greater public policy expertise and capacity in interactions with the heads of the Executive Branch to whom they report (e.g. mayors, governors), the Legislative Branch, and other sectors of government.

Prior Efforts To Update Public Health Law

Two major efforts to review and update public health law took place around the turn of the 21st century: the Turning Point Model State Public Health Act (1997–2003) and Model State Emergency Health Powers Act (MSEHPA, 2001–2002) (Gostin et al., 2002). The Turning Point Model State Public Health Act was a broad (though not comprehensive) sample law comprised of nine articles and incorporated two other model acts—a revised version of the MSEHPA in the article pertaining to emergency powers, and the Model State Privacy Act (Gostin et al., 2001). The Turning Point Act presents the broad mission of state and local public health agencies to be conducted in collaboration with other stakeholders, and provides language for updating laws pertinent to the traditional powers of public health agencies (e.g., communicable disease control nuisance abatement, inspections) (Public Health Statute Modernization National Excellence Collaborative, 2003:5). As of August 2007, "subject matter or specific language from the Turning Point Act" was featured or introduced in whole or part through 133 bills or resolutions in 33 states, and 48 of these bills or resolutions have passed (The Center for Law and the Public's Health, 2007). Box 1-5 provides some lessons from the experience of four states that participated in the Turning Point Collaborative. These illustrate how widely circumstances may vary from one state to another: the level of interest of public health attorneys in the public health agency; the array and relationships among champions and advocates of public health law reform; the nature of the political establishment; and the level of interest in the administration and legislature currently in power.

BOX 1-5 Using the Turning Point Model Act: Lessons from Four States

Meier and colleagues (2007) developed detailed case studies of four state efforts (Alaska, South Carolina, Nebraska, and Wisconsin) to enact public health reforms that provide useful lessons on factors that impeded or facilitated changes in public health law. Despite some important differences among these states, some of the themes that emerged are frequently encountered across the country.

All four states participated in the Turning Point Collaborative and considered changes to their public health statutes. However, in each case study, the facts on the ground were somewhat different, as were the outcomes—three out of four states successfully enacted legislation adopting some aspects of the model Act. In Alaska, public health statute reform coincided with the looming threat posed by Severe Acute Respiratory Syndrome, and this helped to generate broad support for legal changes. It is also instructive that there were two attempts at reform in two consecutive sessions of the legislature. The first, advanced by the state public health association, failed because it did not find "the support of those with the political capital necessary to advance these ideas into law" given the majority in power in the Alaskan legislature, but the second emerged from the Republican governor's administration, developed by highly competent leadership of the state public health agency, and was successfully enacted.

In the South Carolina case study, a beleaguered public health leadership did not want to risk existing authority by trying to get greater specificity in their enabling statutes, and ultimately did not seek to enact public health reform.

Wisconsin proponents of public health statute reform (under the lead of the state public health agency) were highly successful, in part because the state legislature included a committee on public health, which called for a comparison of current law to the Model Act, including determining what was most important for the Wisconsin public health system and assessing political feasibility.

The Nebraska case study is interesting because it occurred in the context of public health reorganization from a previous total of 12 health departments covering 22 of 93 counties in the state, to the addition of 4 new health departments and reorganization of 16 single or multi-county agencies to cover all 93 counties in the state.

Despite the development and dissemination of the model Acts and their generally partial adoption, by some state governments, much of public health law in jurisdictions around the country was crafted in the late 19th and early 20th centuries and remains largely unchanged. Also, Meier et al. (2009a) have demonstrated on the basis of an analysis of state codes in comparison to the public health mission and essential services described in the Turning Point Model Act that statutes in only 17 of the states are highly congruent with the services (defined by Meier and colleagues as 7 or more of the essential services are reflected in their enabling statute), 26 are congruent (4 to 6 of the essential services are reflected in their statutes), and 7 remaining states have divergent statutes (defined as having statutes that reflect zero to 3 of the essential services). As learned from the Turning Point experience, the condition of state public health laws varies greatly in completeness, quality, quantity, and the level of flexibility they permit, as does lawmakers and practitioners' satisfaction with what is available in a given state, and the two are not necessarily connected. At the local level, the picture is similarly complex. As in the case of states, laws that protect the public's health may be found scattered throughout a local jurisdiction's entire body of law. Under the best of circumstances, e.g., a focus on optimizing the statutory underpinnings for population health, bodies of public health law (and law in general) at all levels of government would be subjected to close examination to assess their applicability and usefulness to addressing current public health challenges and would be updated, or "modernized" to effectively meet those challenges. Although this can be accomplished at the state level, it may be less immediately realistic at the local level given the existence of 18,000 local jurisdictions.

Recommendation 1: The committee recommends that state and local governments, in collaboration with their public health agencies, review existing public health laws and modernize these as needed to assure that appropriate powers are in place to enable public health agencies to address contemporary challenges to population health.

The phrase "contemporary challenges to population health" refers to the range of problems handled by public health agencies, including chronic diseases, injuries, new and (re)emerging infectious diseases (some facilitated by globalization and travel), and deliberate threats to health such as those presented by terrorism. The term "modernize" is used to denote updating laws to address contemporary circumstances and challenges, such as those described above. The committee also suggests that periodic (e.g., every 5 to10 years) review of recent legislation could be conducted by each jurisdiction. The committee believes that benchmarking may be useful, given that most of the laws contained in the model Acts were drawn from extant high-quality law in place in various jurisdictions. In other words, Turning Point and MSEHPA provide some benchmarks, as would a comparison of public health priorities to the statutory authorities available to address them (especially in the area of chronic diseases, which were not a focus of the extant model laws).

Although the 10 EPHS are widely accepted and incorporated in the practice of public health and in current strategies to measure and improve public health performance, they are generally not incorporated into law (with the exceptions noted above by Meier et al (2009b)—there is no statutory obligation to provide these services as the standard of practice in public health. The committee believes that all people deserve access to the same public health protections and services regardless of where they reside in the country. A consistent set of public health services is needed, to not only protect and improve the health of residents in all jurisdictions, but to ensure that diseases are less likely to be transmitted across the nation. There is an urgent need to re-examine and revise these legal impediments to improving the effective use of existing public health resources and improving the impact of needed investments.

Recommendation 2: The committee recommends that states enact legislation with appropriate funding to ensure that all public health agencies have the mandate and the capacity to effectively deliver the 10 Essential Public Health Services.

Recommendation 2 has the purpose of alerting decision makers to the importance of adequate support for and the potential need for structural transformation to develop public health agency capacity to fulfill statutory duties. The 10 EPHS can be delivered directly by the state health department, by each local health department, by public health system partners, or by various permutations thereof through shared services, centralization, regionalization or inter-jurisdictional compacts. One way to verify a level of capability or offer sample mechanisms available to help enforce a standard is to link to quality improvement and performance measurement efforts, including actual or potential strategies such as public health accreditation, continuous quality improvement efforts, peer ranking, performance measurement by third parties, and evaluation (Lewis, 2007).

Public Health Accreditation

The national public health accreditation effort has intensified discussions about the challenges and opportunities of restructuring local public health in order to enhance capacity and quality of service delivery. These discussions have also sharpened the debate about agency size and ability to meet standards of organizational competence or performance.

The public health field has long engaged in a variety of evaluation, accreditation, and performance measurement activities, some at the national level and others in regional or local use. These include the National Public Health Performance Standards developed by the CDC. However, the field has lagged far behind many social services, education, and medical systems in the uniform adoption of external assessments of quality assurance and improvement systems by professional accreditation bodies.

Reviews of accreditation efforts across different fields have concluded that the evidence about the effectiveness and value of accreditation as a quality improvement tool is uneven, though there are some encouraging findings as well as some lessons (see, e.g., Lewis, 2007; Hamm, 2007; Mays, 2004). Although accrediting bodies generally find an association between accreditation and performance improvement, academic researchers often measure different things, and may draw different conclusions about the effects of accreditation on performance (Lewis, 2007). For example, agencies that are accredited may be committed to a specific set of metrics, and may to some extent "perform to the test." Unaccredited organizations may simply prefer other sets of metrics. In his summation of the defense and critique of accreditation Lewis (2007) found evidence that accreditation alone is not a guarantee of high performance, may be too occasional and general, may mask deficiencies due to incomplete data, and may value uniformity over performance. On the positive side, he found that accreditation does ensure a minimum level of quality, provides a common basis for comparison, is relatively inexpensive and cost saving compared to other quality improvement strategies, and prevents many disasters.

Accreditation efforts in multiple fields have inadequate quantitative data to help document quality improvement (Hamm and Associates, 2007; Lewis, 2007). Mays (2004) wrote that "[r]elatively few accreditation programs rely on evidence-based performance standards that are tightly linked to desired service outcomes", although there is some movement in that direction, and he also found that the successful adoption of accreditation programs depends "on the strength of the incentives faced by organizations within the industry to pursue and maintain accreditation." Greenfield and Braithwaite (2008) conducted an extensive review of the clinical care accreditation literature and found a fragmented evidence base and highly uneven evidence on the correlation between accreditation and performance (e.g., the outcome of quality), and the gaps filled by anecdotes, preferences, and ideology. However, they also found evidence that accreditation was correlated with improvements in professional development and promoting change through the organizational activities and preparation required for accreditation.

The rationale for the public health accreditation effort includes addressing the gaps and variations and inadequacies in public health infrastructure. The literature on clinical care system accreditation appears to indicate that the success of accreditation in improving or raising the bar on quality is dependent on factors such as institutional commitment and the collection of quality and better data collection (Greenfield and Braithwaite, 2008; Lewis, 2007). Additional research seems to indicate that steps are being taken across the accreditation enterprise in the United States, Australia, and other countries to expand and strengthen the evidence base on accreditation (Chuang and Inder, 2009; Greenfield and Braithwaite, 2008).

Given the longstanding requirements for and widespread use of accreditation in clinical care and the limited, but promising evidence about the effectiveness of accreditation in improving some aspects of performance under certain conditions, the committee views it as desirable that the public health community adopt a system of accreditation as a first step in the direction of guaranteeing a standard of quality across governmental public health agencies. Although the subject of public health accreditation has been under discussion for decades, and

was noted in the 2003 IOM report on public health, a national accreditation effort began only in 2007 (with the founding of the Public Health Accreditation Board), beta-testing of accreditation standards was finalized in 2010, and the national launch of the program is scheduled for 2011. Implementing public health accreditation has several barriers, including the capacity of smaller agencies, resource requirements, and existing accreditation or similar programs at the state and local level. Some states, such as Illinois, Michigan, Minnesota, Missouri, North Carolina, and Washington operate their own accreditation or performance and capacity assessment and reporting systems for public health agencies (sometimes along with other government agencies) (Beitsch et al., 2007; Minnesota Department of Health, 2010; Public Health Law Network, 2010). Some of these states have enacted legislation that may deter the participation of their public health agencies in national accreditation because they require specific participation in state level accreditation or certification activities (see Table 1-1).

The committee believes that governmental public health agencies need to adopt an accreditation process to demonstrate minimum structural and quality process capabilities as performance evaluation is extended to the governmental public health sector. States that have their own accreditation processes in place will ideally ensure that these resemble (i.e., require no less than) those set by the Public Health Accreditation Board. Although the committee recognizes that the national accreditation effort is not mature, continues to evolve, and must remain dynamic and responsive to a changing system, the committee believes that all states need to move in the direction of implementing the actual Public Health Accreditation standards no later than 2020. By calling for support of national public health accreditation, the committee calls on state legislatures or agencies that do not permit participation in national accreditation to modify their laws or requirements to allow, and then require their health departments to participate.

Recommendation 3: The committee recommends that states revise their laws to require public health accreditation for state and local health departments through the Public Health Accreditation Board accreditation process.

TABLE 1-1: The Relationship Between Existing State-Based Accreditation or Performance Assessment Systems and State Statutes

State	Type of program	Relationship to statute
Illinois	Certification program required for counties wanting responsibility for delegated public health programs	Not addressed in statute, but supported under authorities of the state department of public health
Michigan	Accreditation program based on minimum program requirements and required to receive state funding	No specific references in statute, but agency draws general authority from statute
Missouri	Voluntary accreditation program for local public health agencies	Not specifically called for in legislation; independent accreditation body for resource reasons
North Carolina	Accreditation	Required by state legislation that even specifies three categories of accreditation status
Washington	An assessment program for each local health department or state public health program (Public Health Improvement Plan)	Required by legislation

SOURCE: Beitsch et al., 2007.

Legal and Policy Capacity and Resources of Public Health Agencies

The issue of local agency capabilities and human resources is relevant to this report for two reasons. First, it may in part be remedied through legal means, by addressing statutory obstacles to consolidation or regionalization of agencies into, for example, multi-county health departments. Second, one crucial element that is lacking in many smaller health departments is legal, policy development, and policy analysis capability.

Addressing Capacity Challenges of Multiple Small Public Health Agencies

The local level of the public health infrastructure described above is highly fragmented among 2,794 local public health agencies (Fielding et al., 2010; Salinsky, 2010), many of which are small agencies with limited resources and capabilities in many areas, including legal and policy analysis capabilities. Sixty percent of public health agencies serve populations of 50,000 or less (Salinsky, 2010). The size of local public health agency is the strongest predictor of performance of the 10 EPHS, so combining resources and operations, and sharing different types of capacities (e.g., legal guidance and policy analysis) and specialized positions (e.g., epidemiologists) could help smaller agencies meet standards (Konkle, 2009; Libbey and Miyahara, 2011; Mays et al., 2006).

Frequent calls have been made for organizational restructuring (consolidation of services or merging of) public health agencies, including in the IOM report *The Future of the Public's Health in the 21st Century* (2003b), but multiple barriers exist, including: concerns about diminished service and responsiveness to communities; loss of local control over the provision of

public health services; questions about formal governance mechanisms that may be adopted; and the statutory requirements of local and state government (Baker and Koplan, 2002; IOM, 2003b). However, given the social, political, scientific, and disciplinary complexity of the contemporary public health landscape, and the exigencies imposed by great economic strain, the existence of myriad small agencies appears increasingly untenable and inefficient. Proposals have been made on different ways to reorganize local public health structure toward greater effectiveness. Understandably, given the difficulty and lack of resources invested in studying and interpreting findings on this subject, there is a dearth of research and evidence on optimal public health agency structures and related statutory and governance issues. The Robert Wood Johnson Foundation has included organizational restructuring on its list of possible areas of focus for its practice-based research networks program.[5] In addition to experiments in some states, such as Connecticut, Kansas and New Jersey, some research or analysis on the subject of agency structure has been conducted by Libbey and Miyahara (2011), Bates et al. (2010), Koh et al. (2008), Stoto and Morse (2008).[6] This work has described rationales, barriers, and benefits of regionalization, and has reviewed evidence on structural changes in police and fire organizations, but findings have been inconsistent about effects of various arrangements. Other examples of organizational restructuring and associated debates may be found in the realm of environmental protection, such as regionalization of water systems.[7] Koh and colleagues and Stoto have described the objectives of restructuring approaches, including: improving local public health capacity, making more efficient use of funds and achieving economies of scale, and optimizing coordination, for example in managing social problems that are not bounded by municipal borders (Koh et al., 2008; Stoto and Morse, 2008). Libbey and Miyahara (2011) conducted a series of interviews with public health officials from Colorado, Wyoming, South Carolina, Connecticut, New Hampshire, Nebraska, and Illinois, and with the leaders of pertinent national organizations ranging from the U.S. Conference of Mayors to the National Governors' Association. They found, in discussions about cross-jurisdictional sharing, "state and local public health interviewees tended to focus on efforts to collaborate as a means to accomplish a specific purpose or address a programmatic need, such as chronic disease prevention, rather than to create a shared generic capacity that could be applied to a broad range of issues as the jurisdictions saw fit" (Libbey and Miyahara, 2011).

The issues of restructuring or at least of regionalization or other ways to expand local public health capacity have arisen most prominently in the context of emergency preparedness in public health. Disasters and major public health threats cast a bright light on public health agency capabilities and limitations. The National Association of City and County Health Officials has identified four structural and operational approaches to achieving optimal emergency preparedness functioning, but these may be more broadly useful in describing what is currently available in the field. These include: (1) networking, consisting of sharing of plans and other information; (2) coordinating, consisting of joint planning among entities in a region; (3) standardizing, denoting uniformity across a region through mutual adoption of the same planning

[5] See for example the Foundation's 2009 call for proposals on Public Health Practice-Based Research Networks (RWJF, 2009).

[6] See for example HHS's testimony before the assembly joint legislative committee on consolidation and shared government services (David gurber: Testimony before the assembly joint legislative committee on consolidation and shared government services, 2006) and New Jersey Health Officers Association's Testimony before the local unit alignment reorganization and consolidation commission (Peter n. Tabbot: Testimony before the local unit alignment reorganization and consolidation commission, 2008).

[7] For an example, see Jesperson (2004).

and communication tools and response procedures; and (4) centralizing, referring to bringing together resources under one entity (Koh et al., 2008).

Specific Requirements for Public Health Legal Capacity

The considerations brought forth in this chapter regarding critical needs in public health, such as updating or modernization of statutes and modification of public health infrastructure, clarify the need for dedicated legal counsel to serve as advisor to the agency and its leadership. Having dedicated in-house legal counsel is the gold standard in legal and policy capability, and ideally, counsel would serve the entire department, and preferably report to the health officer as opposed to the mayor or other executive (Monroe, 2010; Stier, 2010). However, the committee recognizes that an agency's ability to retain and make the most use of in-house counsel depends on an agency's size, resources, and agenda (e.g., does it have a policy orientation, or is it more intensely involved in service provision?). Legal counsel to a public health agency helps the agency carry out the core functions of "assessment, policy development, and assurance" as set forth in the agency's enabling statutes, which typically focus on the agency's role of mitigating morbidity and mortality (Lopez and Frieden, 2007). The roles of legal counsel to the health officer and agency include:

1. Legal advisor: Participates in policy planning discussions to advise on legal authority for, exposure to liability inherent in, and procedural requirements of a given course of action; and undertakes research and provides legal opinions
2. Protector of confidentiality: Exercise vigilance to protect information in the custody of a health department from Freedom of Information Law[8] (FOIL) requests and subpoenas, but also role as educator on the public health exception to Health Insurance Portability and Accessibility Act (HIPAA) (disclosures required by law, e.g., in the case of public health surveillance or epidemiologic investigations)
3. Legislative and regulatory counsel: Ensure that changes to the health code or regulations enacted comply with the law (will analyze the statutory basis and legal viability of health officer's proposals, will prepare language for the basis and purpose of the rule, and the actual language of the resolution)
4. Enforcement: Agency exercises police powers by issuing valid and enforceable orders (compelling directly observed tuberculosis treatment, or ordering lead abatement in a rental residence with peeling lead paint and children ages 10 or younger).
5. Miscellaneous duties: Public health counsel may be called on to carry out additional duties, including preparing contracts with outside organizations and vendors; advise in cases of employee-related conflicts of interest; handle disciplinary matters (other than criminal or corrupt behavior requiring the inspector general); investigate when human rights cases, such as involving discrimination or sexual harassment are brought against the department; and act as litigation liaison in cases of litigation against the health agency or by the local government (Lopez and Frieden, 2007).

Public health agencies access legal counsel in different ways, and their choices may in part be influenced by their size, governance structure, or both (IOM, 2010b; Pestronk, 2010). Some agencies have internal counsel that is part of the agency staff. Other agencies have external counsel that is drawn from the state attorney general's office, state health department, county or city counsel, or simply private counsel. Some agencies may have both types. The type of legal

[8] In some states, this is known as the Open Records Act.

counsel available to a public health officer may present challenges for the work of agencies. For example, legal counsel that serves another client (e.g., local government or the mayor) may be influenced by potentially conflicting agendas, political influences, timelines, and various priorities. This may also mean that counsel has expertise in public policy, but not necessarily specific public health knowledge or any appreciable understanding of public health law. Respondents to an Association of State and Territorial Health Officials surveys reported that many local public health agencies have counsel that is only part-time and frequently lacks public health knowledge (ASTHO, 2008).

Although it is preferable for the public health counsel to report to the health officer, sometimes it may be necessary for the attorney to organizationally report to an outside entity such as an attorney general. Because the vast majority of attorneys general are independently elected, such arrangements raise the potential for the public health legal advisor to report to someone other than the person to whom the health officer reports, typically the chief executive. Adequate legal counsel needs to be readily accessible to be present at all high-level policy discussions in the department to facilitate clear understanding of the legal rationale underlying public health initiatives or interventions before issues become crises. Hiring attorneys with grant funds and embedding them within particular grant-funded programs to work in an isolated manner may also not be optimal.[9] Moreover, the increasing availability of legal assistance from several existing national academic or not-for profit sources such as the Public Health Law Network, while beneficial, cannot take the place of an official legal advisor that is recognized by, and part of the same team as the health officer and the jurisdiction's chief executive.

Public health agency legal counsel would require training in public health and in public health law, and should have knowledge and experience in the following areas:

- Laws that establish the public health agency and set forth its jurisdiction and authorities
- Programmatic aspects of the agency's work; and
- Procedures and processes consistent with applicable laws and policies

Such experience can be obtained through adequate career ladders within a health department, through education or, ideally, a combination of both. One of the prerequisites for strengthening public health law capacity in health departments is the availability of legal training in schools of public health (e.g., for individuals wishing to pursue a J.D./M.P.H. and for other public health students) and in schools of law for individuals interested in public policy and especially health policy. Schools of law offer little on public health law, and the professional education resources available to train public health personnel and legal professionals on public health law are generally limited (Goodman et al., 2002; IOM, 2003c; PHLA, 2004).

Recommendation 4: The committee recommends that every public health agency in the country have adequate access to dedicated governmental legal counsel with public health expertise.

[9] Personal communication with Wilfredo Lopez, Former General Counsel for Health to the New York City Department of Health and Mental Hygiene Current Counsel Emeritus to the New York City Health Department and Board of Health , May 19, 2011 and Steve M. Teutsch, Chief Science Officer Los Angeles County Public Health, May 19, 2011.

The committee emphasizes "access to" to make it clear that it is not recommending a one-size-fits-all approach (e.g., a full-time public health attorney for every public health agency, no matter how small), but rather, that different strategies are needed to ensure that public health agencies can obtain quality legal advice from attorneys with pertinent expertise. For example, approaches such as regionalization will be needed to ensure that every public health agency possesses the needed capabilities, either on its own, or through collaborative linkages.

Even in today's constrained fiscal environment, solutions to a shortage of adequate legal counsel could potentially be addressed by placing a lawyer from the attorney general's office who is currently assigned to advise the health department within the health department thus facilitating close working relationships between counsel and practitioners.

THE LOCUS OF GOVERNMENT RESPONSIBILITY FOR THE PUBLIC'S HEALTH

In this section, the committee addresses central issues that emerge from the preceding discussion of the ways in which laws define and constrain the roles and authorities of the federal, state, and local levels of government. These include the duty and responsibility of each level of government pertaining to population health and the optimal level of government to act to create the most beneficial conditions for the population's health.

Gostin has written that "[t]he level of government best situated for dealing with public health threats depends on the evidence identifying the nature and origin of the specific threat, the resources available to each unit for addressing the problem, and the probability of strategic success" (Gostin and Powers, 2006). Following logically from this is that national-level crises such as pandemics and bioterrorism threats require the substantial resources of the federal government, while a localized environmental threat may only require the involvement of the local public health agency.

Preemption is an area of considerable contention among the three levels of government because it involves a higher level of government restricting or eliminating a lower level of government's regulatory ability on an issue (NPLAN and Public Health Law Center, 2010). The Constitution grants Congress and federal regulators broad authority to preempt, and states have similarly broad powers to preempt municipalities (this may depend somewhat on how municipal powers are granted or revoked by the state) (Public Health Law Center, 2010).

"Floor" preemption refers to federal or state laws or regulations that set and enforce a minimum standard, and permit lower levels of government to not enact statutes or promulgate regulations that go above that minimal standard. For example, the Health Insurance Portability and Accessibility Act, HIPAA, sets a protective floor for privacy protection, but allows the states to enact stricter privacy standards. Ceiling preemption refers to federal or state laws or regulations that set a maximum standard that lower-level governments may not exceed. The recently passed federal *Affordable Care Act* effectively preempts state and local authorities from requiring menu labeling that differs from the federal standards in restaurants and vending machines covered by the federal law. Many public health advocates express concern with ceiling preemption because it does not allow ample scope for states and localities to innovate in the field of public health (NPLAN, 2009). Federal or state (ceiling) preemption of state and local authority can often be harmful from a public health standpoint because it can compromise the ability of public health practitioners to implement more stringent standards that may be important and well accepted in a local setting. Ceiling preemption also interferes with local

control over local needs and with local-level accountability, and it could limit the ability of jurisdictions to meet the needs of constituents.

In a few areas of public health, federal preemption seems highly appropriate. For example, federal oversight of food manufacturing and processing may be appropriate because of its close nexus to interstate commerce. (However, localities regulate sanitary standards for and grant permits to food establishments.) Another example may be found in the federal ban on smoking on airplanes—the interstate nature of airline flight makes this area ideally suited to federal preemption. Ceiling preemption is appropriate in situations where national uniformity is absolutely necessary and only after the impact on public health and enforceability has been thoroughly assessed and mitigated. A good example of preemption with strong public health benefit is found in the 2011 U.S. Supreme Court case of *Bruesewitz v. Wyeth LLC*. In that case, the Court held that the National Childhood Vaccine Injury Act of 1986 preempts all claims against vaccine manufacturers for injuries or death purported to be related to a vaccine (NEDSS, 2001). The Court's decision upheld the law that established the Vaccine Injury Compensation Program that requires vaccine safety and effectiveness while removing the threat of litigation from vaccine manufacturers.

A recent White House document cautioned against excessive agency preemption because "[t]hroughout our history, state and local governments have frequently protected health, safety, and the environment more aggressively than has the national government."[10] Furthermore, the federal government does not have the police powers granted to states in the area of health and safety.

Another example where federal ceiling preemption is relevant is the content, packaging or labeling of packaged foods that are manufactured or processed in one state and shipped across many states in packaged form for distribution and consumption. However, in an area such as public health that is primarily the province of a state's police power, the need for preemption and the kind of preemption that may be warranted should be closely examined on a case-by-case basis, and the presumption should be that "floor" preemption is the more appropriate option in the area of public health. For example, one can argue that the preemption provisions put into the 1969 amendments to the Federal Cigarette Labeling and Advertising Act should not prohibit a local health department from requiring local cigarette retailers to post warning signs about the dangers of smoking. Such a requirement would not affect the manufacturing, packaging or labeling of cigarettes produced in one state and transported in interstate commerce. Yet, a recent federal court decision struck down such a requirement in New York City on the grounds that it was preempted by the language of the federal statute.[11] Here, the need for preemption would seem to be outweighed by the detrimental impact on public health and local control.

Preemption in the field of public health may also lead to non-enforcement of a preemptive federal standard. As discussed below, when a federal agency is given preemptive authority to regulate in an area that local public health agencies have a greater capacity and infrastructure to regulate, the result will likely be that the public health measure will not be enforced. In such instances preemption, and certainly "ceiling" preemption, needs to be avoided or arrangements for local enforcement should be put in place.

The use of law as a tool often requires an integrated strategic approach. When considering the appropriateness of preemption the impact on public health and enforceability

[10] See *Memorandum for the Heads of Executive Departments and Agencies,* Office of the Press Secretary, The White House, 2009 WL 1398319 (May 20, 2009).
[11] See Grocery Corps v. New York City Health Department Case 1:10-cv-04392-JSR Document 63 (12-29-10).

must be assessed. As the federal government embarks on a regulatory review to ascertain if federal regulations unnecessarily hamper business activity, the committee urges that this principle be upheld and efforts be made to avoid creating new or interpreting existing preemptive laws in ways that may have unintended and unhealthful consequences.

Recommendation 5: The committee recommends that when the federal government regulates state authority, and the states regulate local authority in the area of public health, their actions, wherever appropriate, should set minimum standards (floor preemption) allowing states and localities to further protect the health and safety of their inhabitants. Preemption should avoid language that hinders public health action.

The IOM recently recommended that the FDA modify its GRAS (Generally Regarded As Safe) standard relative to the amount of sodium in packaged food and in food prepared in restaurants (IOM, 2010a). Such an initiative would extend helpful public health protections nationally, but they would vest the FDA with regulatory authority over facilities that it has not regulated in the past. Food service establishments such as restaurants have historically been regulated and inspected by state and local health departments, and these agencies have well-established, albeit strained, inspection workforces in place. There is also an adjudicatory infrastructure, such as state courts or administrative tribunals, to enforce the sanitary laws and regulations under the auspices of public health agencies. Whether a state or local health department can enforce a federal health standard in a restaurant, for example, can be a legally complex matter potentially subject to interpretation. One example of such complexity can be found in Section 337(a) of the Food, Drug, and Cosmetics Act (FDCA), which in part reads, "Except as provided in subsection (b) of this section, all such proceedings for the enforcement, or to restrain violations, of the chapter shall be by and in the name of the United States." That is, only the federal government can enforce that chapter. However, subdivision (1) of subsection (b) specifies that, "A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations of" eight listed sections of the FDCA. This provision would seem to authorize at least states, if not their municipal subdivisions, to enforce those listed sections in state courts and possibly state tribunals.

The intended point is that in times of increasing fiscal distress at all levels of government, protective federal health measures that are vested within the jurisdiction of a federal agency to enforce should not be allowed to go unheeded, unimplemented, and unenforced if there are cost-effective means to implement them. For example, if a state or local health department has a workforce that regularly inspects restaurants, and a judicial or administrative body to adjudicate violations, it would appear obvious that it would be more efficient for such an agency to enforce a federal standard than it would for the federal agency to create a new infrastructure to directly enforce a federal standard in a domain entirely new to it. Federal agencies must make every effort to leverage resources, and work cooperatively with the states to facilitate enforcement of federal standards by states or localities where the statutory or regulatory structure would allow. However, it would not helpful to mandate that states and localities assume this federal responsibility without adequate funding to do so.

Recommendation 6: The committee recommends that federal agencies, in collaboration with states, facilitate state and local enforcement of federal public

health and safety standards, including the ability to use state or local courts or administrative bodies where appropriate. Federal, state, and local agencies should combine their resources, especially in areas where regulatory authority is vested in one level of government but enforcement capacity exists in another level.

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2

Law and the Public's Health: Law as a Tool for Improving Population Health

This chapter focuses on the category of laws, regulations, and other public policies primarily designed to protect the public's health or safety, especially by targeting individual or private sector behaviors that present health or safety hazards to the population. Examples include driving without a seatbelt, smoking in bars, and creating exposures to toxic substances or advertising tobacco products to minors. Chapter 3 continues the discussion by focusing on intersectoral policies that—without being designed primarily to protect health—affect health outcomes, and call for incorporating consideration of health effects (both positive and negative) in policymaking in other sectors of government and in the private sector.

Below, the committee discusses the major ways in which laws enacted by federal, state, and local legislatures, regulations promulgated by the Executive Branch and its agencies, and to a lesser extent, litigation through the judicial system may be used as public health interventions. They provide examples of some prominent areas for policymaking, and explore the roles of public health agencies (and associated boards of health or other government executives) in making or shaping health policies. Government policy interventions work at a level far above the individual to transform the conditions for health and can achieve efficiencies and economies of scale that are not possible with one-on-one health education or clinical encounters.

MODELS OF LEGAL INTERVENTION

Government has a toolbox of law and public policy tools to improve population health (Gostin, 2010a; Gostin et al., 2008). Some are in areas where the public health agency plays a critical or lead role and policies are designed explicitly to affect health. These are the focus of this chapter. Legal and public policy tools for the public's health include:

- Taxation, incentives, and spending (e.g., cigarette and other "sin" taxes and allocation of the tax to combat the problem, may include pricing policies and financial incentives);
- Altering the informational environment (e.g., food or drug labeling, and disclosure of health information);
- Altering the built/physical environment (e.g., zoning, toxic waste);
- Altering the natural environment (e.g., clean water, air, environmental justice);
- Direct regulation (e.g., seatbelts, helmets, drinking water fluoridation, folate fortification of grain-based products, iodized salt; licensure of medical care providers and facilities);
- Indirect regulation (e.g., tort litigation in tobacco); and
- Deregulation (e.g., distribution of sterile injection equipment or criminalization of HIV risk behaviors).

Most of the tools above refer largely to interventions aimed specifically at improving or protecting health, and some involve public health agencies directly. However, the distinctions between health-oriented and non-health policy are blurred in some areas, especially the built/physical environment, where zoning and land use have become increasingly focused on health. Chapter 3 offers further discussion of non-health policies with implications for health. Box 2-1 provides examples of public policies in each of the categories above as applied to food and nutrition.

BOX 2-1 Actual and Hypothetical Examples of the Legal Models of intervention Applied to Food and Nutrition

a. **Tax and spend:** Subsidies for healthy school lunches
b. **Informational environment:** Laws requiring disclosure of calories on restaurant menus
c. **Built/physical environment:** Laws on fast-food or liquor store density
d. **Natural environment:** Food safety laws that order changes to the disposal of animal waste contamination of water sources
e. **Direct regulation (of persons, professionals, businesses):** Requiring fortification of cereal grains with folate to prevent birth defects
f. **Indirect regulation:** Tort liability lawsuit brought by overweight adults or children against fast-food chain[a]
g. **Deregulation:** End subsidies of agricultural products that contribute to unhealthy eating, including corn, soy used for feed, meat, and dairy

[a] See Mello et al., (2003). The case *Pelman v. McDonald's* was initially dismissed "without prejudice" and with detailed guidance on how to refile. It was later refiled, [I.4] amended to reflect two more narrowly constructed claims of negligence, that is, failure to warn consumers about the "danger and hazard" created by the ingredients and additives in the food, and fraud (fraudulent and deceptive business practices). The re-filed claim was dismissed because the plaintiffs failed to prove they had viewed the advertising they claimed was misleading and deceptive about the ingredients in the restaurant chain's products (e.g., claim that fries were cooked in zero-cholesterol oil, but failure to inform that they were cooked in even more unhealthy trans fats).

Using the Law to Achieve Population Health Objectives

The principles that form the basis for legal interventions by public health agencies and others in government to protect and improve the public's health include discharging the statutory duty to protect from harm and promote health and safety. In many cases, this is done by intervening to attenuate externalities—negative side effects of individual actions such as speeding, addressed by imposing speed limits, and of business sector actions such as emitting air pollution, addressed by setting and enforcing air quality standards. Some legal interventions are more controversial than others and starkly illustrate the challenge of balancing public goods and individual freedoms due to varying norms/attitudes, expectations, and values that may inform both public opinion and decision-making by legislators in different jurisdictions.

The history of motorcycle helmet laws—using the tool of direct regulation—illustrates the arguments on both sides of a piece of legislation, and the fact that empirical evidence is sometimes outweighed in the legislative arena by ideological or moral arguments. The *Highway Safety Act of 1966* required that states enact and enforce motorcycle helmet laws to receive highway funding. By 1975, 47 states and the District of Columbia had done so. However, organized opposition by national- and state-based anti-helmet advocacy groups succeeded in overturning the federal sanctions, and a later effort to provide a financial incentive for such laws

failed. In 2007, three decades after nearly universal enactment of state helmet laws, only 20 states and the District of Columbia required all riders to wear helmets (Moulton et al., 2007). Three states have no helmet laws, and in 27 of the remaining states, only young people under age 18 or 21, depending on the state, were required to wear helmets, and new riders were required to wear helmets for a year. Six of these states required that adult riders obtain $10,000 of medical insurance coverage, or that novice riders wear a helmet for the first year (Jones and Bayer, 2007).

The evidence base demonstrating the efficacy of helmet laws in reducing rates of death and serious head trauma is robust, and includes a Cochrane Collaboration review (Liu et al., 2009). Additional research indicates that the economic burden of treating unhelmeted compared to helmeted motorcyclists in the hospital is a considerable amount: $250,231,734 (Eastridge et al., 2006). Rich natural experiments of the effects of the repeal of helmet laws showed dramatic increases in injuries and deaths. However, because the evidence of harm reduced or prevented by helmets has not persuaded antihelmet advocacy groups, a discussion of the ethical and conceptual dimensions of the debate is clearly needed (Cherry, 2010; Gostin and Gostin, 2009; Jones et al., 2006). Antihelmet activists argued that helmet laws infringed on their individual liberties and violated the due process clause under the 14th Amendment to the United States Constitution. They argued that their choice to ride without a helmet affected their personal well-being alone and had no effects on others. Proponents of helmet laws made three types of arguments: (1) an economic/utilitarian argument on the basis of direct and indirect costs incurred by society from motorcycle deaths and injuries; (2) an evidence-based argument about the proven effectiveness of helmets in preventing severe injuries and fatalities; and (3) a moral/paternalistic argument that civilized governments protect their citizens from inflicting great, but preventable, damage to themselves and burdening their families with wrenching grief and cost. Gostin and Gostin (2009) have shown that the debate about individual freedoms, especially in this particular context, may be one sided, emphasizing the rights of individuals to freedom of actions that do not harm others—physically, at least. However, this arguments shows little regard for the attendant freedom that accrues to the same individuals from avoiding disability, and the averted burden to society, by preventing crash-related permanent injuries and death.

BOX 2-2 Lessons from the History Of Tobacco Policy

The case of tobacco illustrates why a multi-faceted approach is needed to address some health threats (although, given the incomplete success of anti-tobacco campaigns, it also illustrates the enormous challenge of addressing complex health problems). The tobacco story also provides a rich example of a suite of public health interventions (including the power to tax and spend, indirect regulation through litigation, and intervening on the information environment), several of them public policies, to improve population health, specifically by reducing mortality and morbidity due to its use.

It is important to note that the anti-tobacco campaign illustrates that the Laws enacted at the federal, state, and local levels include a variety of taxes on tobacco products, bans on indoor smoking (first in workplaces, and later in restaurants and bars), restrictions and enforcement on sales to minors, and a range of advertising regulations. The 58.2 percent decrease in the prevalence of smoking among adults since 1964 ranks among the 10 great public health achievements of the 20th century (CDC, 1999; IOM, 2007). Although the public health effort to lower tobacco use continues, many important lessons have been learned, some of which may be relevant to other areas where policy action is needed to change the conditions for health. Despite considerable gains, 2007 data show that approximately a fifth of US adults smoke, resulting in 443,000 premature deaths yearly and annual costs of $193 billion in direct health-care expenditures and productivity losses each year (CDC, 2009). Only two states, California and Utah, reached the Healthy People 2010 objective of a 12 percent smoking rate. Although Utah's rate is

linked with the religious beliefs of a majority of state residents, California's low rate has been shown to be associated with that state's aggressive and multifaceted strategies against tobacco use (Graff and Ackerman, 2009).

Cigarette smoking is an individual behavior that affects both the health of the smoker and the health of others who are exposed to the secondhand smoke. For decades, a debate has occurred in multiple settings over the individual liberty of smokers, and the appropriateness of government interference with personal choices regarding tobacco use. The 2007 Institute of Medicine report, *Ending the Tobacco Problem: A Blueprint for the Nation*, eloquently summarizes the key elements of the debate, including those that began to shift social norms:

> For many years, a policy paradigm emphasizing consumer freedom of choice and decrying unwarranted "paternalism" dominated public opinion and policymaking on tobacco. In retrospect, however, the committee believes that predominant emphasis on consumer choice in public opinion during this period was largely shaped by the tobacco industry's successful efforts to deny and obscure the addictiveness and health consequences of tobacco use, and on an array of resulting market failures, including information asymmetry between producers and users, distorted consumer choice due to information deficits, and product pricing that did not reflect the full social costs (especially the effects on nonsmokers). As the scientific evidence about addiction and the health effects of tobacco use has grown, and the industry's deceptive strategies have been exposed in the course of state lawsuits and other tobacco-related litigation, public understanding of tobacco addiction has quickly deepened and the ethical and political context of tobacco policymaking has been transformed (IOM, 2007, p. 33).

As public health practitioners have turned to the tobacco example for lessons that may be used to address other health threats that may be effectively targeted through legal or policy means, especially nutritional factors associated with the increasing prevalence of adult and child obesity, several things have become clear (Kline et al., 2006). Although food products, unlike tobacco, are generally not carcinogenic products, there are some parallels between the ethical and civil liberties arguments used in both cases, and in the "ecologic" aspects of unhealthy foods and those of tobacco. In the case of smoking, data indicate that most addicted adults began smoking in adolescence and before developing mature judgment, and that earlier life preferences tend to ignore long-term risks and are generally replaced by health-oriented preferences later in life (IOM, 2007). These factors indicate that smoking often begins at a vulnerable time of life, before autonomy or true independence can be said to emerge. Smoking behavior is associated with education level, parental occupation, and household poverty status, illustrating that factors beyond individual choice are highly influential in shaping smoking behavior.

As is the case with use of tobacco products (see Box 2-2), the consumption of unhealthy foods has serious implications not only for the individual, but for the common good. Smoking presents a threat to the health of others through environmental tobacco smoke, and an economic threat to businesses, which face higher medical care costs and losses in productivity, and to society in general.[1] Similarly, the consumption of unhealthy foods—whether containing trans fatty acids (shown to increase the risk factors for heart disease [Mensink et al., 2003], the leading cause of death in the United States), high in salt (known to increase blood pressure, a known risk factor for cardiovascular disease), or high in sugars (contributing to weight gain, which is related to a variety of chronic illnesses)—presents high costs to employers and society as a whole. The annual economic cost of obesity-related health conditions is an estimated $117 billion (Mello et al., 2003). Although some critics of policy interventions in the area of nutrition in general and trans fats in particular charge that such interventions interfere with consumer freedom to enjoy doughnuts, fried chicken, and other products prepared using partially hydrogenated vegetable

[1] The economic impact of smoking is complex. Data indicate that the societal costs of caring for ill smokers are in some ways offset by the savings incurred when smokers die, generally at younger ages than non-smokers.

oils, the reality is that consumer autonomy is overestimated for a number of reasons (Resnik, 2010; Wilson and Dawson, 2010). The belief in consumer autonomy is based on an assumption that people are entirely free agents in the marketplace. However, this overlooks what is known about human behavior (such as underestimating risk, optimism bias) and the fact that companies marketing products known to have deleterious health effects use highly sophisticated advertising and product labeling developed to exploit known consumer vulnerabilities (IOM, 2007;Wilson and Dawson, 2010). As is the case with smoking, people who are poor and less educated have higher levels of exposure to unhealthful foods, in part because they often live in neighborhoods where choosing less healthy options is facilitated by a high ratio of fast-food purveyors to fresh fruit and vegetable retailers.

OTHER EXAMPLES OF LEGAL AND POLICY TOOLS

Policy Interventions on the Informational Environment

Unhealthy foods and beverages may be targeted from different angles, including compelling or requiring manufacturers or retailers to take or avoid certain actions and modifying the informational environment. Industry packaging, labeling, and multimedia advertising of such products are based on market research, and the results are highly attractive products accompanied by confusing or misleading information (Gostin, 2010b; Mello et al., 2006; Pomeranz, 2011). Several federal agencies have the authority to regulate businesses that produce some types of health-related information. For example, the Food and Drug Administration (FDA) has oversight of food labeling; the US Department of Agriculture has oversight of food safety; and the Federal Trade Commission (FTC) has oversight over food advertising. An industry policy to adopt a third-party certified "Smart Choices" labeling convention to identify certain foods as healthier garnered a warning letter from the FDA due to concerns about the potential of misleading consumers with labeling that suggested healthfulness (Layton, 2009; Taylor and Mande, 2009). Similarly, a food company's claims about the benefits (i.e., increased child attentiveness) of its sugary breakfast cereal was charged and settled with the FTC for false advertising (FTC, 2009, 2010). The FTC's authority allows it to intervene in the marketplace when a company makes deceptive claims. Although this authority is narrowly drawn, the increase of evidence about nutrition-related television advertising and the proportion that is misleading or inaccurate may allow the Commission to take action in a wider range of cases. The primary challenge to public policy on the informational environment in which the public makes health-promoting or health-damaging choices lies in the protections afforded by the First Amendment to "commercial speech" to further both a business's economic interests and the audience's need for information (Mello et al., 2008).

Although FDA and other agencies—either explicitly mandated to protect population health or like FTC, indirectly responsible for overseeing and controlling certain market phenomena that may have some health consequences—have authority to take certain regulatory actions against industry, there are some statutory or resource-related gaps in their ability to enforce. For example, the Government Accountability Office recently concluded that unlike the FTC, which can require companies to provide evidence in support of their advertising claims, "FDA bears the burden of proving that a structure/function claim is false or misleading without having the authority to compel companies at the investigation stage to produce the evidence that

the companies assert as support for their advertising claims" (GAO, 2011, p. 25). The FDA does possess this authority for drug and device regulation. Also, federal agencies sometimes lack the resources to enforce the law. Fines thus become simply the cost of doing business, and lack of agency authority to require removal of misleading information rather than requiring highly-publicized corrections of that information leave a considerable gap in the application of agency authority. This is an area where the collaboration with state and local governments discussed in Chapter 1 may prove helpful, as they often have the capabilities to enforce federal law that federal agencies themselves may lack.

Direct and Indirect Regulation: Deregulation

In recent years, the model of direct regulation that has been used successfully in the context of smoking and other health challenges has been explored for its potential in addressing food-based threats to population health. Sugar-sweetened beverages represent one of many products that contribute to Americans' intake of excess calories. However, efforts to legislate relative to this and other unhealthy food products will become politically feasible only when the proponents of regulation are able to "show that the industry is not behaving responsibly on its own—neither market forces nor the industry's own professional codes of ethics lead it to conform to public expectations" (Mello et al., 2008, p.4). Industry's attempts at self-regulation have been limited primarily to collaborating with schools, communities, and local governments—a decision that allows companies to maintain greater flexibility—and avoiding more stringent attention from state governments. Relationships with schools and communities also meet the industry preference for statements of principles rather than binding commitments (Mello et al., 2008).

Other forms of regulation involve actions that build safety into a product or environment rather than attempting to modify human behavior. For example, setting standards (this may also be done through legislation, tool [c] in Box 2-1) to improve the safety of motor vehicles by changing certain features to reduce different types of risks has been more effective and efficient than teaching people to be better drivers (Vernick, 2011). That is also true of building safer roads and enforcing existing safety laws.

Indirect regulation through litigation has been successfully employed by tobacco control programs. The Master Settlement Agreement with 46 state attorneys general who had brought litigation against tobacco companies was the major event in the tobacco battles. The agreement required seven tobacco companies to change their strategies for marketing tobacco products, pay the states an estimated $206 billion, finance a $1.5 billion antismoking campaign, open previously secret industry documents, and disband industry trade groups believed to be concealing damaging research from the public (Office of the Attorney General, 2011).

Litigation has been contemplated or attempted in a range of areas, including firearm and motor vehicle safety. However, Congress can preempt litigation by enacting legislation that provides special protection for some types of products, rather than allowing the courts to make determinations about a case's worthiness (Vernick, 2011). This is the case with firearms litigation. Congress enacted the *Protection of Lawful Commerce in Arms Act* in 2005, which gives firearms manufacturers and retailers broad immunity from litigation (Vernick et al., 2007).

Capewell and Lloyd-Jones (2010) offer several powerful, recent examples of public policies that can facilitate the prevention of cardiovascular disease at the most upstream or distal

level possible.[2] These include deregulation, such as the public policies enacted in Poland, Finland, and the European Union, that have shifted government agricultural subsidies in ways that are designed to change national nutritional patterns or norms, such as away from an emphasis on meat and dairy and toward fresh fruits and vegetables.

Incentives: A Step Down from Regulation, or in Combination with Regulation

Although there are numerous examples where industry is mandated by the government to bear the cost of harms created by its products (i.e., when harms cross a certain threshold, often based on evidence about dose-effect relationships, e.g., for toxic waste and cleanup, and chemical contamination of groundwater), the notion of a less antagonistic way to engage industry bears greater consideration than it has received (EPA, 2004). Examples of incentives include labeling, such as obtaining an "organic" label, subsidies, government purchasing, and food policies, such as sale of food in government cafeterias, public parks, and beaches.

In addition to using the tool of direct and indirect regulation described above, requiring industry to make certain changes to their products or requiring consumers to operate within certain limits, the government may use the influence of its "bully pulpit" to motivate shifts in how private-sector entities operate with regard to products that are known to have the potential to harm health. One example comes from the United Kingdom, where the government has used a policy of collaboration and the incentive of public reporting to engage the food industry in taking voluntary steps to meet or exceed government-set guidelines for sodium levels in food. British and American analyses have shown that even small reductions in population risks, such as sodium intake, can lead to considerable improvements in population health and corresponding economic savings realized by governments and employers (see Box 2-3). Another example of setting voluntary guidelines and working with industry to adopt them comes from the FDA, which is developing a uniform system for front-of-package food labeling and will attempt to implement it through voluntary guidelines and then move on to a mandated approach if necessary (Pomeranz, 2011).

BOX 2-3
Reducing Salt Intake: Examples of the Potential of Laws to Affect Health Outcomes

Beginning in 2003, UK health authorities began a dialogue with the food industry about the levels of salt in food products and a collaborative effort to lower the salt intake in the population. In 2005, the UK's Food Standards Agency Strategic Plan 2005–2010 established a target to reduce the average salt intake to 6g (approximately a teaspoon) per day by 2010. Voluntary salt reduction targets for the salt content of key food categories (e.g., breads, breakfast cereal, prepared cheeses and meat products, different types of snacks) were published in 2006, and revised in 2009. In 2008, the agency found that the nation's average daily salt consumption fell from 9.5 g in its 2000–2001 national nutrition and diet survey to 8.6 g. The agency regularly reports on the progress of major food companies in meeting the voluntary targets. As examples, an update in March 2010 noted that a major brand of chips contained 55% less sodium, with several companies already meeting the 2012 targets for specific categories of foods. The agency estimates that meeting the target of 6 g daily intake of sodium will result in the prevention of 20,200 premature deaths per year (Food Standards Agency, 2008, 2009a,b, 2010).

The National Institute for Health and Clinical Excellence commissioned an economic model to measure the potential effects on cardiovascular disease risk factors of enacting legislation to eliminate

[2] The term primordial prevention, used by Capewell and Lloyd-Jones (2010), has been defined as "intervention at the most distal point in the chain of causality" (Starfield, 2001, p. 454) and preventing the emergence of predisposing social and environmental conditions that can lead to causation of disease (Starfield et al., 2008).

trans fats or reduce dietary salt consumption by 3 grams per day. Modelers estimated that each of these proposed interventions could lead to discounted savings of more than $1 billion per year.

In 2008, the US Congress asked the Institute of Medicine to make recommendations for reducing sodium intake of Americans. US dietary guidelines call for no more than 2,300 mg per day for persons ages 2 or older. This is equivalent to approximately 6 g of salt per day. The average American consumes more than 3,400 mg of sodium per day. Decreasing salt intake could have dramatic effects on population health outcomes and medical expenditures.

In a modeling study, Palar and Sturm (2009, p. 49) found that reducing Americans' sodium intake to the recommended level (2,300 mg) would "reduce cases of hypertension by 11 million, save $18 billion health care dollars, and gain 312,000 QALYs [quality-adjusted life years] that are worth $32 billion annually." Danaei and colleagues (2009) estimated that high dietary sodium is responsible for more than 100,000 US deaths. This is clearly an area ripe for policy interventions.

One legal scholar has proposed policy strategies for holding industry financially responsible for negative health effects related to the use of its products. Sugarman (2009) has described this approach as "performance-based regulation" that would offer an alternative to litigation or to mandating a certain way to operate. It would compel industries to act to lessen the externalities, or collateral damage, caused by different types of consumer products that are linked with a great proportion of morbidity and mortality and cause harm to the individuals consuming or using them and to others (in some cases the harm is economic). This type of regulatory approach would seek to "harness private initiative in pursuit of the public good" by setting regulatory targets for the industry to reach (Sugarman, 2009, p.1035). Companies would be allowed to employ existing methods or create new ones to decrease the harm of their products (or, in the case of tobacco, to lower the rates of consumers using their products). Companies reaching prescribed targets would receive public recognition (similar to the UK publishing the sodium-lowering efforts of specific food companies), and those failing to reach targets would be required to pay a fine.

An Example of the Cost-Effectiveness of Policy Approaches

The discussions leading up to and subsequent to the passage of the *Affordable Care Act*, and the political dialogue on other topics, made clear that getting value for major national investments is important to Americans and to their elected representatives. The committee believes that policy interventions can be effective and of high value in addressing major causes of death, disease, and disability at the population level. The committee's belief is based on evidence reviews of the effectiveness of public policies aimed at injury prevention, tobacco control and prevention of environmental tobacco smoke, prevention of excessive alcohol consumption, and requirement of immunization for school entry (Hopkins et al., 2001; Task Force on Community Preventive Services et al., 2005; Elder et al., 2010; Task Force on Community Preventive Services, 2009). CDC has examined the effectiveness of state school-entry immunization requirements and found that they can be effective at achieving the high immunization rates needed to protect the population, but their effectiveness depends on the quality of enforcement (CDC, 2007).

The California Tobacco Control Program illustrates the powerful impact of that state's tobacco taxation policy on adult and youth smoking rates and on medical care costs (Graff and Ackerman, 2009). In California, between 1989 and 2004, $1.8 billion was spent on the tobacco control program, and $86 billion was saved in personal health care expenditures alone (and 3.6

billion fewer packs of cigarettes were bought) (Lightwood et al., 2008). Two additional examples of the cost-effectiveness of legal interventions are found in immunization and in alcohol taxation. Elder et al. (2010) conducted a systematic review of the literature on alcohol tax policy for the *Guide to Community Preventive Services.* The researchers found robust evidence (across countries, study designs and analyses, and time periods) that alcohol pricing and taxation are inversely associated with excessive alcohol consumption and related harms. Two studies included in the review estimated the cost-effectiveness of alcohol tax interventions based on modeling. One study examined "costs and outcomes of 84 injury prevention interventions for the U.S. and found that an alcohol tax of 20 percent of the pretax retail price offered net cost savings (i.e., the savings outweigh the costs) even after taking into account the adverse economic impact of reduced alcohol sales," and the other study examined the cost-effectiveness of alternative policies to address excessive alcohol use and "found that taxation was the most effective and cost-effective intervention in populations with a 5 percent or greater prevalence of heavy drinkers" (Elder et al., 2010, p. 223).

Evidence to Inform Policymaking

The committee's discussion about the role of evidence in policymaking cuts across two distinct, but increasingly overlapping, categories of public policy: health policies and intersectoral policies with health effects. Chapter 3, which describes intersectoral or "health in all policies" approaches, also provides more extensive discussion of the process of assessing the evidence for and health impact of all policies that affect or could affect health.

CONCLUSION

Based on its review of the literature and information obtained at its information-gathering meetings with pertinent experts,

> **The committee concludes that an array of legal and policy tools is available to help local, state, and federal governments promote and protect the public's health, and urges legislatures and government agencies to familiarize themselves with and to deploy such tools in addressing the leading causes of disease, injury, and early death in every community.**

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3

Intersectoral Action on Health

Live in fragments no longer. Only connect....

—E.M. Forster, (1910)

The health of a nation is shaped by more than medical care, or by the choices that individuals make to maintain their health, such as quitting cigarette smoking or controlling diabetes. The major contributors to disease—risk factors under the control of individuals (e.g., obesity, tobacco use), exposure to a hazardous environment, or inadequate health care—are themselves influenced by circumstances that are nominally outside the health domain, such as education, income, and the infrastructure and environment that exist in workplaces, schools, neighborhoods, and communities. In this chapter, the committee discusses the implications of the social determinants of health for the actions of various stakeholders, with a focus on non-health policies that affect population health (see Box 3-1 for a few examples). Here, the committee reviews the frameworks and models that exist for the engagement of non-health actors in considering the health outcomes of their policies, and even, perhaps, in improving their positive contributions to achieving health objective.

BOX 3-1: Examples of Non-Health Policies with Health Effects

Federal agricultural subsidies are enacted with agricultural, economic, and trade objectives in mind, but their effects on health are significant. Similarly, transportation planning may have as a primary objective the optimal way to facilitate goods movement or to commute between home and work, but related issues must be considered, including local economic development that may be enhanced or impaired by public transportation, road design and other physical features (access to public transportation); community functioning (e.g., when a busy highway divides a neighborhood); and health, which may be positively or negatively impacted depending on the extent to which transportation planning considers whether to encourage and facilitate pedestrian and bicycle traffic.

The literature linking population health outcomes with these antecedents (i.e., the determinants of health) is robust and includes decades of work by Marmot, Wilkinson, and colleagues (Marmot et al., 1997; Marmot et al., 1991; The Marmot Review, 2010), including the World Health Organization Commission on the Social Determinants of Health, Adler and the MacArthur Research Network on Health and socioeconomic status (SES), and many others.

The health significance of "non-health" factors is often overlooked. Education is a prime example. People with a college degree are one third less likely to smoke than those who have not completed high school. Miech et al. (2009) reported that adults ages 40 to 64 with only a high school education are more than three times more likely to die from diabetes than those who have

graduated from college. Educational attainment determines whether individuals can obtain good jobs and whether they acquire the knowledge, health literacy, and other tools needed to make informed choices about their health.

Income is another important factor. Certainly, low-income individuals are less likely to have health insurance, but income also affects health by enabling families to live in healthy neighborhoods and housing and to afford nutritious groceries, fitness clubs, copayments for doctor's visits, and prescription medications. Income is a health determinant in all social classes, not just for the poor. Americans with incomes that were 201 to 400 percent of the poverty level had shorter lives and a greater likelihood of fair or poor health than were those with incomes more than 400 percent of the poverty level (Braveman and Egerter, 2008). Woolf and colleagues (2007) reported that 25 percent of all deaths in Virginia would have been averted if the entire state experienced the mortality rate of those living in the five most affluent counties and cities.

Place affects health—neighborhood and community environments exert their own health influences, independent of the risk factors associated with individuals and households. Research links social and economic features of neighborhoods "with mortality, general health status, disability, birth outcomes, chronic conditions, health behaviors and other risk factors for chronic disease, as well as with mental health, injuries, violence and other important health indicators" (Cubbin et al., 2008). People living in poor neighborhoods with inadequate housing, high levels of crime, high density of alcohol outlets, and a scarcity of fresh food retailers are more likely to experience a range of health problems. These problems are related to obesity, physiologic consequences of chronic exposure to stress, living in an environment lacking in social capital, and other factors.

Pathways Between Health and its Determinants

"Upstream" or distal determinants of health—conditions that influence the more proximal factors such as blood pressure and health care services—include individual, household, and area-based factors. Examples of *individual* factors include a person's race or ethnicity, which cannot be changed, and modifiable factors such as behavioral choices and educational attainment.[1] *Household-level* health factors define a family's income level, health insurance coverage, and housing conditions. *Area-based* or place-based conditions affect individuals and households throughout the neighborhood and community and are characteristics of a geographic area, such as a Census tract or block. Examples include ambient air pollution, crime rates, social cohesion, walkways and green space, the quality of local schools, health care facilities, access to healthful foods, the density of fast-food restaurants, marketing of tobacco and liquor, and access to affordable public transportation.

Individual, household, and environmental factors form a complex causal web that complicates observed associations between health outcomes and any one factor in isolation. For example, in the arena of environmental factors, substandard housing is a known associate of poor health. However conditions other than housing itself (e.g., pests, proximity to sources of pollution, unsafe streets, unhealthful occupations, lack of medical care) also explain occupants' greater experience of asthma, mental illness, and malnutrition (e.g., examples of research on the links between housing and health can be found in Braveman et al., 2010; Britten, 1938; Dalla Valle, 1937; EPA, 2011; Erickson and Marks, 2011; Krieger and Higgins, 2002. Confounding

[1] There are also levels of modifiability, including the degree of difficulty, time requirements, and the importance of a given factor compared to others potentially implicated in causing the health outcome of concern.

relationships between interrelated causal factors make it important to determine the degree to which socioeconomic and contextual conditions are markers for other factors that play equally important causal roles (for an illustration of the multiple pathways linking education and health, see Braveman et al., 2011a). For example, the evidence linking income and health is extensive and goes back decades and even centuries, but questions about causality remain pervasive and further research is needed to disentangle the complexity of the pathways linking the two (see, for example, Chandra and Vogl, 2010; Muennig, 2008).

THE ROLE OF POLICY AS A DETERMINANT OF HEALTH

Although many socioeconomic and environmental factors affect health, only some are under the personal control of individuals and families. People can make the effort to complete high school, pursue higher education, make informed choices to improve their health, and obtain a job that is good for health—a job that promotes wellness, limits exposure to occupational stress or injuries, offers health insurance benefits, and provides an income that makes health care, healthy behaviors, and healthy neighborhoods affordable. However, the success of these efforts depends in part on factors outside the control of individuals and families. The quality of schools, the strength of the job market, worksite safety, and the healthfulness of neighborhoods and communities are determined by decisions taken by policymakers outside the family and the health sector (Adler et al., 2007; Commission on Social Determinants of Health, 2008; Lovasi et al., 2009; Marmot and Wilkinson, 1999; Marmot and Bell, 2011; Marmot et al., 1997; The Marmot Review, 2010).

In corporate boardrooms, legislatures, and the executive branches of government, decisions that ultimately affect the public's health emerge from policies that few view as health decisions. Initiatives to promote jobs, corporate growth, transportation infrastructure, and community development are deliberated by officials, executives, and other decision-makers who often are unaware of or overlook the connection to health. School boards, educational agencies, and ballot initiatives determine funding for local schools and set policies that affect children's learning, educational attainment, physical activity, and diet. The ability of adults to find work, a stable income, and good health insurance benefits is shaped by legislation, labor policy, economic strategy, the tax code, and deals negotiated between managers and unions.

The healthfulness of neighborhoods and communities is shaped by the decisions of private developers, local officials, businesses, and voters. Federal tax policy, corporate competition, zoning regulations, advertising, and the local economy influence whether residents have access to supermarkets and parks or are exposed to air and water pollution, fast foods, liquor stores, and tobacco advertising. Land use decisions determine whether the built environment is conducive to physical activity, for example, whether builders add sidewalks, bicycle paths, and greenways (e.g., paths or trails for recreation, pedestrians, and bicycles) to roadway construction projects (APA, 2002; Cubbin et al., 2008). Decisions to forego economic development and community investment set the path for neighborhood deterioration and the emergence of urban decay, unhealthy housing, pollution, violent crime, and the departure of businesses, jobs, schoolteachers, and quality medical care—and their attendant health benefits—to more attractive neighborhoods (Kelly, 2004). Decisions about public transit serve not only to limit exposure to automobile emissions, but also to help individuals reach jobs with health

benefits, medical care, educational opportunities for themselves and their families, and nutritious groceries (Cubbin et al., 2008).

Specific policy examples of these connections between non-health policies and health effects are increasing. For example, in agricultural policy, evidence shows that corn subsidies may contribute to unhealthful American diets (see Alstona et al., 2008; Harvie and Wise, 2009; Wallinga, 2010), which in turn contribute to obesity, diabetes and cardiovascular disease. Other countries have shifted government agricultural subsidies to gradually modify industry practices and to support the cultivation and increase the affordability of more healthful crops, such as vegetables and fruits (Capewell and Lloyd-Jones, 2010). Urban planning provides another example. Freeways that divide neighborhoods to facilitate commuter traffic can harm health, quality of life, and community well-being (Wier et al., 2009). One group of researchers summarized the recent efforts directed at freeway "deconstruction" as reflective of urban and land use planning priorities that are "shifting away from designing cities to enhance [car] mobility toward promoting economic and environmental sustainability, livability, and social equity" (Cevero et al., 2009, p.).

In its information gathering, the committee learned about New York City's FRESH program that represents a collaboration among the health and planning agencies and the local economic development corporation and provides incentives to bring grocery stores to areas that lack access to fresh fruits and vegetables (Bryon, 2010; IOM, 2010). In San Francisco, the Federal Reserve Bank has been exploring opportunities for cross-sectoral partnership between community development and health (see, for example, Federal Reserve Bank of San Francisco, 2010). Other examples of links between non-health policies and health outcomes have been building over decades of experience and research. These include a rich evidence base that has demonstrated that the poor health outcomes in adulthood that is associated with disadvantage in childhood can be effectively prevented by policy interventions as varied as home health visiting programs, early stimulation in child care programs, and preschool settings (i.e., Early Head Start and Head Start) (Adler and Stewart, 2010; Braveman et al., 2010; Evans and Kim, 2010; Kawachi et al., 2010; Mathmatica Policy Research, 2001).

In 2009, the National Center for Healthy Housing conducted a review of the evidence of the health effects of housing policies (Jacobs and Baeder, 2009). They found evidence for the use of several housing interventions, including rental housing vouchers, structural modifications (e.g., asthma interventions, pest management, and radon mitigation), as well as smoking bans and lead hazard control. In 2010, the Urban Institute published findings from their evaluation of the *Chicago Family Case Management Demonstration*, which is an "effort to test the feasibility of using public and assisted housing as a platform for providing services to vulnerable families (The Urban Institute, 2010)." Participants in the program reported gains in employment, housing, neighborhood conditions, and health with reduced fear and anxiety (Popkin et al., 2010; The Urban Institute, 2010).

Altering the Built/Physical Environment

The notion that communities can shape the environment to be healthier or more health supportive is a fundamental belief underlying this report. A wide range of policy tools (included among the tools described in Chapter 2) are available to address features of the built environment, and several jurisdictions across the country have successfully experimented with land use interventions, including in the areas of zoning and transportation. This type of tools,

however, differs somewhat from many others listed earlier because they go beyond the purview of the public health agency and require involvement and leadership from other parts of government and from the private sector.

The boundaries between health and non-health policies, such as zoning, are not always sharply delineated. For example, in recent years, zoning decisions have increasingly incorporated health as a specific objective, so-called "health zoning" (Abdollah, 2007; Chen and Florax, 2010; Mair et al., 2005). Local governments have banned gun dealers in residential areas to reduce crime and violence in communities, and have made zoning decisions to limit the density or avoid school proximity to alcohol sources and more recently, fast-food outlets (Chen and Florax, 2010; Gostin, 2010). In some cases, urban planners, transportation officials, and other non-health professionals have been the ones to initiate activities to redesign the built environment in ways that promote and support healthier choices.

The built environment is strongly linked with several types of health outcomes in the population (Bauman and Bull, 2007; Brownson et al., 2006; Communities Count, 2008; TRB and IOM, 2005). Obesity is perhaps the most prominent current concern, and is related not only to the food one consumes and one's level of physical activity, but to environmental features such as:

- A community's zoning laws that dictate the density of fast-food outlets, and incentivize (or not) the introduction of supermarkets and other fresh-food outlets (California Center for Public Health Advocacy et al., 2008; Diller and Graff, 2011);
- Transportation plans and laws that encourage (or not) pedestrian and bicycle use rather than motor vehicle use (Brownson et al., 2005; McCann et al., 2009);
- Planning guidelines that expand green and recreational spaces, and school requirements that allow community use of athletic fields (Garcia and White, 2006; Lovasi et al., 2009); and
- A community's ability to set aside and use land for community gardens (NPLAN, 2010; Twiss et al., 2003).

Laws and other types of public policy can change these and other aspects of physical or built environment.

THE 'HEALTH IN ALL POLICIES' MOVEMENT

Interest has been growing both in the United States and abroad, in "Health in All Policies" (HIAP), an approach to policymaking in which decision-makers outside the health sector routinely consider health outcomes: benefits, harms, and health-related costs. Kickbush and Buckett (2010) define HIAP as "public service agencies working across portfolio boundaries to achieve a shared goal and an integrated government response to particular issues. Approaches can be formal or informal, and can focus on policy development, program management and service delivery." Although the HIAP concept emerged in connection with government organizations, its meaning has been extended to include private and non-profit policies as well. Examples of public health-relevant policies in the private and non-profit sectors include employer policies and practices (e.g., in response to safety requirements imposed by insurers), building standards that exceed government requirements (such as LEED[2] "green" building

[2] Originally denoted "Leadership in Energy and Environmental Design."

certification), and principles for sustainable investment (e.g., yielding financial, social, and environmental returns[3]).

Rationale

Most decision-makers who set policies on housing, agricultural crop incentives, or highway construction do not usually consider the public health dimensions, in part because they have not had traditional, or statutory, responsibility for those areas. Also, health entities in the government, private, and not-for-profit sectors are similarly unlikely to connect or collaborate with those who may be considered stakeholders in the public's health. These failures to connect have consequences for all involved. Too often, proponents of a policy overlook potential health benefits in making their case or in calculating the return on investment to argue the value proposition.

Conversely, advocates of a policy do not always consider the potential harms to public health, and resulting costs, or how those harms could be mitigated. Overlooking health seems incompatible with good policymaking, not only because it creates an incomplete picture of the full outcomes of a proposed course of action, but also because it can undermine the ability to coordinate efforts across sectors to address important public health and economic priorities. For example, a coordinated approach to the obesity epidemic—a health outcome that imposes great cost on the economy (CDC, 2010; Wang et al., 2008; Wolf and Colditz, 1998) and on employers (Finkelstein et al., 2005; Goetzel et al., 1998; Schmier et al., 2006), and may present a risk for developing other poor health outcomes such as diabetes and heart disease— requires synergistic changes in schools, workplaces, advertising, the food industry, restaurants, parks, public transportation, tax policy, and clinical care. A coordinated approach to this problem therefore requires policymakers in each of these sectors to consider their respective role in addressing obesity and how best to harmonize their efforts with other sectors. Working across sectors can improve effectiveness in addressing public health problems by tackling root causes that are outside the traditional health sector. It could also maximize the use of existing government, institutional, and policy resources by promoting synergy, identifying economies of scale, and reducing duplication of effort (Baxter, 2010). Adopting a HIAP approach could cost little or nothing in many areas of local government. For example, in transportation, land use, or zoning decisions, some modifications that influence health may have minor or no budgetary implications for the implementing agencies (Boufford, 2011 offers the example of using regularly scheduled bus stop renovations to make them more accessible to older adults, and thus provide support for healthier aging).

Cross-governmental collaboration is hardly a novel notion for public health agencies. Those capacities were evident after September 11, 2001, when bioterrorism preparedness planning brought public health practitioners into closer discussions with fire, law enforcement, and emergency management communities. A need for broader collaboration to address the rising prevalence of chronic disease has strengthened the imperative for coordinated efforts across the public and private sector.

Ultimately, the health of a nation is instrumental in its economic strength and competitiveness. Businesses can rise and fall on the strength of their employees' physical and mental health, which influence levels of productivity and, ultimately, the economic outlook of employers (World Economic Forum, 2008). The United States' lower life expectancy and lower

[3] See, for example, Emerson et al. (2008).

health-related quality of life has implications for all sectors in society in terms of opportunity and other costs (financial, human potential, social, and other). Reform of the medical care delivery system is envisioned to handle issues of quality and cost of services, but the committee concurs that "[h]ealth in all policies represents the most comprehensive level of health reform" and "broadens the definition of health reform to include a consideration of the intentional or unintentional impact of all policies—health, social, economic and others—on individual or population health" (Georgia Health Policy Center, 2008).

HIAP and the Federal Government

In the past several years, reports from US blue ribbon panels have offered recommendations for a coordinated, intersectoral approach to governing. For example, the Center for the Study of the Presidency and Congress issued a report by its Commission on US Federal Leadership in Health and Medicine, which recommended the implementation of a HIAP approach across federal departments and agencies, including the creation of a federal coordinating council (Commission on the U.S. Federal Leadership in Health and Medicine, 2009). This approach was consonant with that expressed in a 2008 report from the Center for American Progress and the Institute on Medicine as a Profession, *The U.S. Health Care System: A Blueprint for Reform*, as follows:

> National and local policies, programs, and funding allocations that support health—not just health care—must be realigned and prioritized in order to meaningfully improve population health. This process can be informed by examining the factors underlying the health status measure "life expectancy from birth" which incorporates the main causes of premature death. These reside in five domains: behavioral patterns, social circumstances, environmental exposures, health care, and genetics (Center for American Progress and The Institute on Medicine as a Profession, 2008, p. 98).

Many of the themes of HIAP surfaced in the evolution of health care reform legislation and took statutory form in some of the provisions included in the *Affordable Care Act* (ACA) by Congress in 2010. Specifically, the law called for the establishment of the National Prevention, Health Promotion, and Public Health Council. The Council, created by executive order of the President and convened by the Surgeon General of the US Public Health Service, constitutes the highest-profile HIAP action in the federal government. It brings together cabinet secretaries and heads of major agencies to develop a prevention strategy for the nation and to address national health priorities from an interdepartmental and interagency perspective. Despite the distinct statutory roles, responsibilities and priorities of the separate agencies, the Council calls on its executives to think creatively about ways in which their interests may be furthered by contributing to the nation's prevention, health promotion, and public health strategy.

Another example of HIAP in action is the Partnership for Sustainable Communities, a joint initiative by the Environmental Protection Agency (EPA), the Departments of Transportation (DOT), and Department of Housing and Urban Development (HUD) that is intended to "stimulate a new generation of sustainable and livable communities that connect housing, employment, and economic development with transportation and other infrastructure improvements (EPA, 2011)." The partnership has identified six livability principles, two of

which explicitly refer to health.[4] The initiative, which includes $100 million to fund regional plans in 45 regions of the country, exemplifies a holistic, or cross-cutting public policy approach that aims to "connect the dots" among the many factors that make communities livable and healthy: good schools, economic development, decent and affordable housing, accessible transportation infrastructures, and other features.

The Healthy Food Financing Initiative is another example of intersectoral action on health. The initiative "supports projects that increase access to healthy, affordable food in communities that currently lack these options" through a range of programs at Departments of Agriculture, Treasury, and Health and Human Services (HHS)" (HHS, 2010). State food financing initiatives, such as the Pennsylvania Fresh Food Financing Initiative begun in 2004, have led to the establishment of supermarkets in underserved areas. These not only make fresh and healthier foods available to communities, but they also serve as anchors for other types of economic activity, including other retail outlets (Cantor et al., 2009; PolicyLink, 2010; The Reinvestment Fund, 2008).

HIAP in State and Local Governments

Some state and local governments have already adopted HIAP approaches. In February 2010, the governor of California issued Executive Order S-04-10, which authorized the California Strategic Growth Council (SGC) to establish a Health in All Policies Task Force as part of its larger mission to develop a sustainable economy for the state. This action explicitly linked economic growth to the health of the people of California. The Task Force was charged with identifying "priority programs, policies, and strategies to improve the health of Californians while advancing the SGC's goals." To accomplish this, a multi-agency council was assembled to facilitate collaboration in several areas, including air and water quality, protection of natural resources, availability of affordable housing, promotion of public health, sustainable land use planning, and climate change goals (Health in All Policies Task Force, 2010b). The SGC-convened Task Force includes 19 agencies, including the Office of the Attorney General, business, transportation, education, social services, and housing (Health in All Policies Task Force, 2010b). After a process that included soliciting and receiving public input and defining a vision of a healthy community, the task force developed a report with 34 recommendations based on a set of criteria, including population health impact, overlap with SGC objectives, availability of supportive evidence, ability to foster collaboration, equity impact, measurability, feasibility, and ability to transform state government culture (Health in All Policies Task Force, 2010a). The report was adopted by the Strategic Growth Council.

A HIAP approach has also been adopted in the master plan for Fort McPherson, an army base in Atlanta that is slated for closure (McPherson Planning Local Redevelopment Authority, 2006). A major objective of the redevelopment partnership's effort is to meet a range of community needs, including those of vulnerable disadvantaged populations living in neighborhoods surrounding the installation. The partnership (involving the local redevelopment authority and public health experts) developed a list of guidelines that would be incorporated in

[4] "Provide more transportation choices. Develop safe, reliable, and economical transportation choices to decrease household transportation costs, reduce our nation's dependence on foreign oil, improve air quality, reduce greenhouse gas emissions, and promote public health." . . . . and "Value communities and neighborhoods. Enhance the unique characteristics of all communities by investing in healthy, safe, and walkable neighborhoods—rural, urban, or suburban."

the Master Plan for redevelopment and would call for specific features that benefit health (McPherson Planning Local Redevelopment Authority, 2006). The city of Atlanta agreed to incorporate the partnership's recommendations for zoning requirements. Multiple efforts were made to involve surrounding communities in the planning discussions, which led to a plan based on principles of sustainable urbanism, including promoting public health. Access to a full-service supermarket, multi-income housing, recreation, green spaces, public transportation, and other amenities were among planners' objectives (Avey, 2011).

In an effort facilitated by the New York Academy of Medicine, and with the collaboration of the American Association of Retired Persons, the city of New York has implemented a variety of activities to become one of the World Health Organization's (WHO) network of 35 age-friendly cities. The effort began with convening 22 city agencies, and has led to a range of commitments to make the city's transportation, education, business, and other sectors and systems accessible to people of any age (Boufford, 2011). The WHO guidelines identify the following domains of urban life necessary for healthy aging: outdoor spaces and buildings, transportation, housing, social participation, respect and social inclusion, civic participation and employment, communication and information, and community support and health services (WHO, 2009).

The field of community development finance is finding synergies with community health improvement efforts. Richter (2009) has observed that the vulnerable groups targeted by the *Community Reinvestment Act* are not only at risk financially, but also in terms of their health. These two conditions, poor health and low income, are mutually exacerbating, and community development financial institutions (CDFIs) have been making investments that aim to improve both the conditions for health and for future financial well-being of disadvantaged families. For example, CDFIs have invested in bringing supermarkets to underserved areas, and in increasing the availability of early child care, quality education, affordable housing, and recreational opportunities for youth. Models of community development finance investment in health and human development are being tested (Richter, 2009).

The HIAP approach offers great promise not as an approach that prioritizes health above other important societal objectives, but rather, as a wide range of intersectoral efforts to achieve synergies from policy action. Seen from the perspective of other sectors, HIAP could enhance their ability to achieve their own objectives because improvements in population health will have wide-reaching effects on many aspects of society. For example, in the case of the Atlanta military base closure, the HIAP effort being planned means that government property has the potential of being redeveloped in a manner that can lead to the creation of a thriving community. If the community succeeds in meeting HIAP objectives, the community will enhance the economic and social vitality of the area, and benefit diverse groups in surrounding neighborhoods by expanding housing, employment, recreational and educational opportunities. The committee finds that multi-sector strategies that consider the impact of non-health sectors' action on the health of Americans can create progress in those sectors, while increasing the quality of life, longevity and economic productivity of the population.

Recommendation 7: The committee recommends that states and the federal government develop and employ a health in all policies (HIAP) approach to consider the health effects—both positive and negative—of major legislation, regulations, and other policies that could potentially have a major impact on the public's health.

HIAP: Some Findings from International Examples

The pertinence of intersectoral policies to population health status was a key message of WHO conferences in the 1970s, 1980s, and 1990s. HIAP became a signature focus of the Finnish presidency of the European Union—a significant fact because of Finland's North Karelia health promotion project, launched in 1972, which exemplified one of the early uses of a HIAP approach to address a major and pervasive health challenge. In the 1970's Finland had the highest rate of cardiovascular disease (CVD) in the world. The North Karelia project targeted CVD by forming a collaboration among government and private and civil society sectors to change the social, physical, and policy environment. Over a 30-year period, mortality from CVD decreased by 85 percent (Puska, 2008). (For more information see Box 3-2.)

Box 3-2: North Karelia: An Early Example of Multi-sector Action for Health

"[C]omprehensive approaches were needed to make healthier dietary habits easier for people."

The Finnish government heavily subsidized the dairy industry which specialized in the butter, full-fat milk, and other products favored by consumers. Gradually, industry opposition and concern were addressed and the industry shifted to producing lower-fat dairy products. The meat industry similarly shifted to producing more lean meat products. Also, subsidies were changed to encourage berry and vegetable production. A variety of communication strategies involving community groups were implemented to replace butter with canola and other vegetable oils for cooking, among other changes.

SOURCE: Puska and Ståhl (2010)

Another example of intersectoral action to improve the health of a population is found in the French project Ensemble Prevenons l'Obesite Des Enfants (EPODE), which aimed to develop local land use planning processes to create a "healthy town" and involved a partnership of planners, the non-profit sector, health professionals, and the education sector (Aylott et al., 2008). EPODE succeeded in significantly reducing the rate of overweight in boys (by half) and in girls in the project area.

Climate change is one area of national policy where HIAP could play a crucial role, but at this point that role has been minimally explored. On the one hand, there are examples of sectors working in isolation and not considering the potential of common means to achieve complementary ends. For example, researchers or decision-makers who are concerned about global climate change and its consequences for food, water, weather, and biodiversity may not consider health impacts as seriously or at all (McMichael et al., 2009). On the other hand, the British government's report *Tackling Obesities* noted that the goal of slowing down climate change and the goal of reversing obesity trends are linked. For example, avoiding motor vehicle use in favor of walking or riding a bicycle implies no greenhouse gas emissions and has the added benefit of facilitating the burning of calories consumed (Butland et al., 2008). This recognition offers an opportunity for intersectoral action.

The Law and HIAP

HIAP in its broadest form involves collaboration among government and the private and not-for-profit sectors to fully implement coordinated strategies. Redesigning the built environment, promoting healthier diets, improving education, and creating jobs are tasks that

require leadership by businesses and community organizations. Later, this chapter returns to a discussion of this important public-private nexus of HIAP and proposes a mechanism for building that collaboration, but the paragraphs that follow focus on the role the government plays in HIAP and the place of the law as a tool for implementation.

The implementation of HIAP by government agencies requires policymakers, with the support of the public health agency, to adopt a collaborative and structured approach to considering the health effects of major public policies across government sectors. Although HIAP initiatives in government do not necessarily involve explicit legal authorities, the law is often an important tool for institutionalizing an infrastructure for HIAP and for requiring agencies to ensure that the policies they pursue serve to protect and promote public health. The most effective health-improvement tools available at a population level are often legal and policy tools.

Based on its reading of the pertinent literature, the committee notes a continuum of objectives and actions where HIAP can be applied within law and public policy.

- HIAP can be seen, at a minimum, as a manifestation of the precautionary principle: first, do no harm to health through policies or laws enacted in other sectors of government.
- HIAP can be used affirmatively to improve population health by maximizing a non-health policy's positive effects on health.
- HIAP can be used as a proactive, targeted approach to addressing the most distal factors (i.e., the socioeconomic fundamentals of jobs, schooling, and financial stability and self-sufficiency) that are associated with poor population health outcomes.

The first type of application for HIAP, that is, as an embodiment of the precautionary principle, is exemplified by California's *Clean Air Act*. The Act marked the culmination of multiple activities, including efforts by community groups who sought to address the environmental triggers of asthma attacks in children. High asthma rates bore a known association with exposure to agriculture-related sources of pollution that had been exempted from the state's older air quality laws (Bell and Standish, 2005). The Act's objective was to set, within environmental law, a standard for air quality that would mitigate asthma attack rates. An example of the second application of HIAP, that is, the implementation of a non-health policy that achieves a positive impact on health, is the case of agricultural subsidies. Laws that are intended to protect the viability of American farmers can also be designed to have a positive impact on health by changing what crop is subsidized. Increasing access to fruits and vegetables by subsidizing foods that have greater nutritional value and away from agricultural products such as corn, which find their way into unhealthful foods, can be done in ways that support farmers and health simultaneously. The third application of HIAP is seen in the federal partnership among the EPA, DOT, and HUD as described above—an effort that is premised on an acknowledgment of the deep interconnections among the various dimensions of the built and natural environments and their effects on human health and community well-being.

In some cases this continuum of objectives is achieved through legislation, as illustrated earlier by the HIAP initiatives stipulated by Congress in the provisions of the *Affordable Care Act* and the Prevention Council, or through actions of the chief executive, as illustrated by the creation of the HIAP task force by California's governor. In other cases, the law invokes public health concerns as a basis for placing restrictions on commerce, transportation, and other domains outside the normal auspices of public health agencies. Examples include laws regarding the sale of firearms, the design and use of safety features in motor vehicles, environmental

protections, agricultural subsidies and tax incentives, food labeling, and indoor smoking bans. More broadly, legislatures and the agencies of the Executive Branch of the federal, state, and local governments—acting on their constitutional authorities—exert broad influence on the design of economic policy, employment opportunities, the tax code, school reforms, financial aid for college, and other factors that, as noted earlier, are strongly associated with health outcomes.

Challenges to Implementing HIAP

The ease of implementation and the success of HIAP approaches is dependent on: (1) the level of compatibility of interests among the relevant sectors; (2) the extent to which health policy or intersectoral action of some sectors can bring about the desired change on their own (compared to how much of it is dependent on changes or constraining factors in other sectors); and (3) the costs of strategies (e.g., financial, political, social) and the fact that benefits are often harder to calculate than immediate costs (Sihto et al., 2006). Challenges to implementing health in all policies approaches also include the health sector's limited connectedness to other sectors; intersectoral differences in aims and values and organizational culture and politics; and the costs and opportunity costs of focusing on health as a primary outcome of policy (see, for example, Ollila et al., 2006; Piot et al., 2010; Sihto et al., 2006); and Box 3-3).

The challenges for HIAP are reflected at their most fundamental level in vigorous debates surrounding legislation that simply seeks to use the precautionary principle. For example, for many years, legal arguments have surrounded the constitutionality of imposing restrictions on the sale of tobacco, firearms, and alcoholic beverages. The tobacco impasse was due in part to the deeply entrenched interests of the agricultural sector and tobacco-growing states. Such debates are partly a matter of legal argument, but they are also political. The debates focus on where to balance the responsibility of government to protect the health of the public against its obligation to preserve individual autonomy and a free market in which consumers, rather than government, determine their actions and consumption of products and services. Another example comes from the contentious realm of firearms, where making reasonable public policy requires that policymakers "take into account conflicting constitutional claims and divided public opinion as well as facts about the relationship between guns and violence. And in doing so they must try to strike what they regard as a reasonable balance between the costs and the benefits of private gun ownership" (IOM, 2004).

Politics and political acceptability form an important backdrop to HIAP approaches, which seek to coordinate efforts to implement a policy. Conflicting political ideologies sometimes complicate the effort to determine preferred policy directions. For example, education and income are universally valued by American society and, as noted earlier, have powerful associations with improved health outcomes, but conservatives and liberals favor different strategies to achieve these common aims. All sides share the desire to improve the education of America's children, but some policymakers favor greater competition and voucher programs for private schools, while others want to raise tax revenue for public schools. All policymakers want Americans to earn more income. Some believe this is best accomplished by removing tax and regulatory burdens on businesses to help them thrive and create more jobs, while others favor direct assistance programs for low-income families and the unemployed. The HIAP approach is inherently non-partisan; it calls on policy makers of all political persuasions to consider the health implications of a new or revisited policy or law. For example, an advocate of lowering taxes on businesses might cite the health benefits to workers if tax relief prevents layoffs and

creates new jobs: stable incomes, health insurance coverage, and the ability to afford to live in a healthier neighborhood. Another policy maker might champion the extension of unemployment benefits to protect individuals from poverty. Both policy initiatives can be readily reviewed through the lens of HIAP development. However, because HIAP could be subject to political manipulation, with claims made based on political ideology, evaluation of the impact of all policies created under this banner is imperative. The committee returns to the area of evaluating the evidence of policy effectiveness later in this chapter.

The notion that policymakers should be obliged to consider the health outcomes of proposed policies raises philosophical questions about the limits of jurisdiction and responsibility. Although public health professionals believe health is a primary value and that value is self-evident, policymakers in non-health sectors have portfolios that require them to advance other public goods of high priority to government and society. As a practical matter, in a resource-strained environment, energy, transportation, or national security may gain more prominence for the public and its elected officials than improvements in population health.

Therefore, it is important to note that a HIAP ethos need not limit actions that are critical to accomplishing work in other sectors. Rather, the HIAP approach asks all sectors, including public health, to direct attention to ways in accomplishing their objectives that will not detract from, and may at times enhance, the health of the public. Public health leaders and practitioners need to listen to colleagues in other sectors of government, understand their agendas and priorities, and find ways to identify mutually beneficial approaches to communicating and accomplishing their objectives. The public health community must also learn to convey clearly and compellingly the linkages between health with its multiple determinants and other societal objectives, such as prosperity, productivity, and competitiveness.

For their part, public health officials may themselves resist the premise that their mandate extends beyond core public health functions to include transportation, housing, and school reform. Is it appropriate for public health professionals and scientists to cast their gaze on the broader causes of poor health and thus enlarge their field's purview and sphere of influence and the breadth of their interventions? Or should the field remain focused on the more proximal causes of poor health, such as risky behaviors and infectious diseases, and refrain from attempts to influence and intervene in distal policy spheres? Thoughtful reflection on the statutory and professional responsibilities of governmental public health requires these organizations to communicate about data and evidence, and convene other sectors and stakeholders toward health-supporting policy action that extends beyond the historical arenas in which these institutions have worked.

Apart from politics and philosophical questions, the fragmented structure of government is itself an obstacle to the HIAP approach. Federal, state, and local governments are often balkanized in silos—agencies with discrete policy interests and regulatory concerns that lack the culture, tools, and language to cross boundaries and coordinate with counterparts in other agencies. An infrastructure that supports such collaboration, such as an interagency task force, cannot be formed or operate effectively without hard work to build relationships and solve interagency barriers that impede communication, collaboration, and the sharing of resources. The committee believes these philosophical and structural obstacles—both external and internal to the public health community—need to be overcome through concerted efforts by all governmental actors. These actions will allow this nation to make good on the promise of the level of health that a wealthy nation should furnish its population.

STRUCTURES TO SUPPORT COLLABORATION IN PROMOTING HEALTH IN ALL POLICIES

In its purest form, the HIAP approach entails collaboration among multiple sectors, reaching beyond the government, to foster the conditions for good health. Public health agencies or, more broadly, government, cannot alone be effective in helping a community to address tobacco use, reduce obesity, redesign the built environment, produce jobs, and improve the schooling of children. Nor can the private sector do this alone. Effective strategies require collaboration as well as coordination, with the latter being important to marshal and leverage limited resources, avoid duplication, and use the talents and assets that each partner offers. Few would dispute the merits of coordination and collaboration, but the infrastructure for forming such partnerships is lacking in most communities.

What is the role of the public health department in facilitating action? Two key roles of governmental public health agencies to date have not been systematized to their full potential: (1) as communicators/reporters about a community's health and its causal or associated factors, and (2) as conveners/facilitators of independent and collaborative action by other organizations and sectors (Pomeranz, 2011)[5]. Across the nation, new working relationships are being formed among private, non-profit, and governmental agencies, bringing new challenges and bridging to enable shared responsibilities. Policy, in both the public and private sectors, can facilitate and guide these partnerships.

In its first report, the committee discussed the topic of accountability for population health and presented a measurement framework for accountability in two contexts. The first is contract accountability, applicable to the funding, statutory, and fiduciary relationships among those who are funded to "do" public health work (government agencies and others) and their funders (i.e., higher level of government, taxpayers) to whom they are accountable. The second is compact or mutual accountability, which characterizes the relationships among public health agencies and the many stakeholders in the health system: schools, businesses, community organizations, medical care providers, and community members. The framework for accountability in any context can be outlined in three steps: (1) agreement among implementers and those holding them accountable on specific plans of action targeting health priorities; (2) holding implementers accountable for execution of agreed-on plans; and (3) measurement of execution and outcomes of those plans, and further agreement on revisions to the action plan.

In the present report, the committee endeavors to give structure to the process described in the first report. For example, given the notion of non-public health implementers (e.g., diverse arrays of community organizations, medical care organizations, employers, and others) holding each other and the group accountable for accomplishing intended improvements in a community's health requires some type of governance entity, such as a coalition or board. The question the committee seeks to answer in this section is: how do legal, or more broadly, policy frameworks, inform the structures needed for effective multi-sector engagement on population health, where there are and where there are not statutory or funding relationships that serve as the natural bases for holding participants accountable? Despite the fact that an estimated half the overall public health expenditures are incurred by non-governmental actors (see Mays et al.,

[5] Pomeranz (2011) writes: "By coordinating cross-agency conversations and policymaking, health departments can insert health concerns into a vast range of policymaking activities within their jurisdictions. This approach, called health in all policies, brings health issues from the traditional health sectors into other government entities, thereby positively influencing transportation, housing, environment, education, and fiscal policies."

2004) mechanisms to track the achievements and create accountability for those investments are often limited to reporting obligations between funders and grantees, but are not easily identified for use with larger, intersectoral networks of actors with multiple crisscrossing relationships. Such a mechanism is needed to give some organizational structure to the diagram provided in Figure 3-1 (from the committee's report on measurement [IOM, 2011]), which describes the multi-sectoral, multi-stakeholder health system and a measurement framework to enable it to plan, implement, and evaluate its effects on the community's health.

Accordingly, the committee looked for models that could create accountability that span public and private action and investments. Several models are available to inform efforts to develop advisory mechanisms that involve the private sector. These may be drawn from the Healthy Cities/Healthy Communities movement, which included the development of multi-sectoral coalitions that planned, implemented, and evaluated their efforts (Kegler et al., 2009). Other examples of governance mechanisms, including some oriented toward public oversight of government expenditures, are found in the context of international urban governance arrangements (Burris et al., 2008). Fawcett and colleagues (2010; 2000) have also described community partnership models. Other examples may be found in foundation-supported efforts around the country, such as the California Endowment's Building Healthy Communities Initiative, a 10-year community grant program that includes the establishment of hubs, or "central tables," around which all stakeholders gather to plan, assess, and celebrate achievements.

The model the committee found most useful is the National Prevention, Health Promotion, and Public Health Council established by ACA. The National Council is an attractive model in that it: (1) creates a structure that specifically crosses government lines and brings different sectors of government to the table to talk about health in a structured way; (2) engages both the Legislative and Executive Branches at very high levels in an ongoing fashion; (3) focuses on creation and agreement on strategy to achieve outcomes, one of the key points in the committee's first report; and (4) enables engagement of a broader range of non-government interests and input through an advisory mechanism.

The committee believes that state and local versions of the National Prevention Council can create opportunities for private and civil society engagement, similar to what federal legislation has envisioned for the National Prevention Council. The organizational structure in Figure 3-1 (from the committee's report on measurement [(IOM, 2011)]) describes a multi-sectoral, multi-stakeholder health system and a measurement framework that enables it to plan, implement, and evaluate its effects on the community's health.

In the context of this report, developing a structure to operationalize intersectoral action on health is useful for several reasons. First, it establishes a forum for stakeholders to come together and creates mechanisms for interested parties to provide input, and it also creates an entity that is appropriately placed and configured to adopt a HIAP approach. Finally, a multi-sectoral group that brings together the thinking, experience, and financial resources of many community actors will facilitate more nuanced planning, implementation and evaluation of policies that are intended to simultaneously serve both health and other key objectives of a local community. The following recommendation intends to describe the role of the public and private sectors in jointly implementing health in all policies approaches.

Recommendation 8: The committee recommends that state and local governments

- **Create health councils of relevant government agencies convened under the auspices of the Chief Executive;**
- **Engage multiple stakeholders in a planning process; and**
- **Develop an ongoing, cross-sector, community health improvement plan informed by a HIAP approach. Stakeholders will advise in plan development and in monitoring its implementation.**

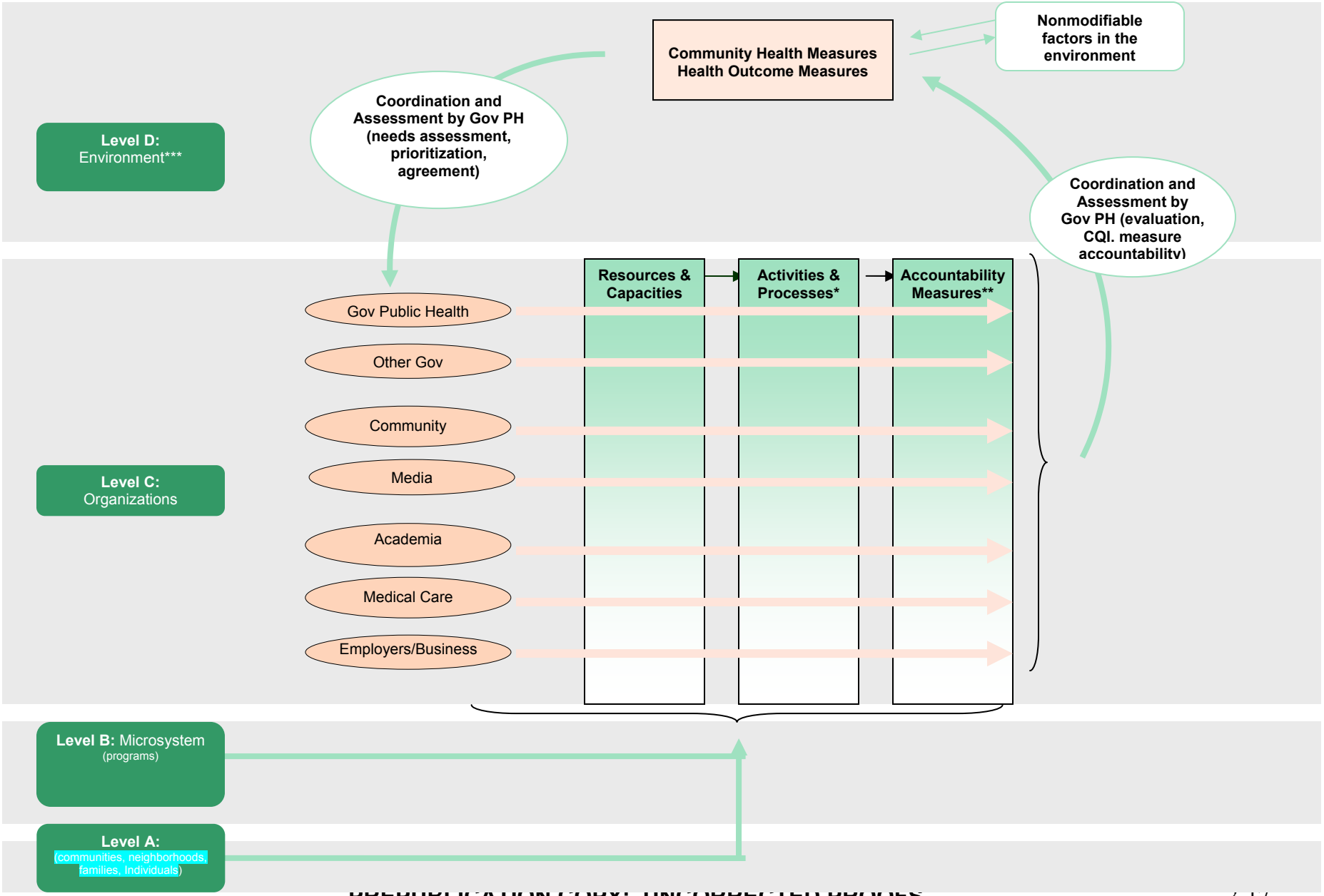

FIGURE 3-1 A framework for measurement in accountability
* Activities and processes are influenced by agreed-on strategies (strategies agreed on by those being held accountable and those holding accountable through contracts or compact agreements)
** Accountability measures assess how well the agreed upon strategies are executed and this may also be thought of as strategy execution measures
***Stakeholder activities both influence the environment and work within it to shape outcomes.
SOURCE: Adapted from IOM (2001); Berwick (2002)

Figure 3-1 depicts a framework for the measurement dimension of accountability that draws on the work of the IOM Committee on Quality of Health Care in America (see Berwick, 2002; IOM, 2001). In that context, a framework was provided to demonstrate the changes needed in the US medical care delivery system, and four levels were described: Level A, the experience of patients and communities; Level B, the microsystem of care (for example, provider practices); Level C, organizations (for example, managed-care organizations); and Level D, the environment shaped by policy, payment, regulation, and accreditation. The present committee believes that that framework holds relevance for its own examination of measurement in the context of accountability and has adapted it for its own purposes. The cycle begins after a needs assessment has been done, priorities set, and a plan agreed on. Level A in the committee's adaptation of the framework includes communities, neighborhoods, families and individuals (whose aggregated health information constitutes health-outcome measures) and neighborhoods. Level B refers to microsystems, which in the context of population health[6] are programs, policies, and interventions that may be thought to refer to the points of contact or interactions between community groups, local businesses, others in the neighborhood, and their local public health agencies and allied entities. An example of microsystems is an interaction among a health department, a local medical care provider, community coalition, or local business concerning a particular health outcome. Specifically, a health department could assist a food retailer in facilitating healthful customer choices or could support a local business in developing a workplace prevention and wellness program. Often in public health, such microsystems need to align and integrate across organizations; for example, the local cancer-control program should feed into the statewide cancer-control program, which feeds into the national program. Level C consists of organizations described as actors in the public health system in the 2003 IOM report *The Future of the Public's Health in the 21st Century* (IOM, 2003) and as components of the health system. The organizations include the local public health agency, hospitals and other clinical-care entities, community organizations, schools, businesses, religious congregations, and many others that perform roles that influence health outcomes. Level D refers to the environment, which includes a variety of social, physical (both naturally occurring and constructed), and economic factors and is shaped in part by social realities, large-scale policies (and political will), and economic arrangements (Syme and Ritterman, 2009). Figure 3-1 also depicts accountability pathways for all levels but focuses on Level C—the organizations that perform functions that affect health outcomes.

[6]As is sometimes pointed out, the patient in public health practice is the community.

THE ROLE OF SCIENTIFIC EVIDENCE IN HIAP

When a policy is considered worth enacting, the key government sector or organization will work to bring together the relevant stakeholders and find ways to align their interests and compel them to engage in action. At that point in the process, all involved stakeholders would work on identifying data from which to project effects, that is, benefits, harms, and costs, and refining analytic methods, including attribution. Stakeholders will examine a policy idea through multiple lenses, including feasibility, effectiveness, acceptability, affordability, and legality.[7] Policymakers seek evidence about the effectiveness, projected outcomes, and value to judge the merits of proposed policies. This is particularly true when policies are seen as posing a risk to public health.

The effectiveness of public policies in general, and of legal interventions in particular, historically has been poorly studied, although the body of evidence is growing (see Burris et al., 2010). Some of the strongest examples are found in the work of the Task Force on Community Preventive Services and of the Cochrane Collaboration, both of which use the approach of systematic assessment of the effectiveness of certain laws and their enforcement on behaviors with health consequences. The Task Force has identified and recommended effective legislative or regulatory interventions in several areas of interest to public health. These include the prevention of motor vehicle injuries and deaths, where the evidence supports recommending laws and enforcement of child safety seat use (Evans and Graham, 1990; Guerin and MacKinnon, 1985; Margolis et al., 1988; Rock, 1996; Seekins et al., 1988; Sewell et al., 1986; Wagenaar et al., 1987; Wagnenaar et al., 1987; Williams and Wells, 1981), and laws, primary enforcement, and enhanced enforcement programs of safety-belt use (Barancik et al., 1988; Bernstein et al., 1989; Campbell et al., 1991; Chorbat et al., 1988; Desai and You, 1992; Preusser et al., 1987; Streff et al., 1990; Thyer and Robertson, 1993; Ulmer et al., 1995). Another example is state and municipal clean indoor air-laws to reduce exposure to secondhand tobacco smoke (a risk factor for cancer, heart disease, and child health problems, including Sudden Infant Death Syndrome). Bans on indoor smoking have led, within months, to decreases in hospital admissions for acute coronary heart disease events such as heart attacks (Juster et al., 2007; Sargent et al., 2004). Other examples include the effect of Corporate Average Fuel Economy standards on lowering energy consumption and carbon dioxide emissions; the effect of state immunization requirements for school and child care entry on increasing immunization rates; the effect of primary education requirements on educational achievement; and the effects of ignition interlock policies, retail outlet density, and taxation on high-risk alcohol consumption. An example of an assessment done before a law's enactment is the menu labeling analysis in Los Angeles that led to the passage of a menu labeling ordinance (Simon et al., 2008) that was eventually pre-empted by both the state of California and by ACA. Post-enactment evaluations are sometimes done, though not necessarily by the government. Examples include gun control ordinances, ignition interlocks for drivers with alcohol-related driving convictions, alcohol outlet density restrictions, and tobacco laws.

Burris and colleagues (2010) have described the growing body of public health law research as the "scientific study of the relation of law and legal practices to population health." This young field, they assert, can help to make the case for laws that improve health, not only through the realm of laws intended to influence population health and establish the power, duties,

[7] The discussion of scientific evidence here is framed in terms of governmental laws and policies, but the approach also holds relevance to major changes in private sector policies.

and infrastructure of public health, but also through laws in other sectors of government, which may powerfully influence health, but have not until recently been examined for their implications for health.

Health Impact Assessments

"In the environmental field, new construction projects are required to file an environmental impact report. In the health field, there should be a similar health impact report that makes explicit what effect new social policies will have on population health and how negative results could be mitigated," wrote Schroeder and Hughes (2008). Health impact assessments (HIAs) have emerged as an important tool to assist policymakers with weighing the merits of a proposed policy. As defined by the Health Impact Project, a HIA is a policymaking tool "that identifies the health consequences of new policies and develops practical strategies to enhance their health benefits and minimize adverse effects."[8] Ongoing HIAs listed by the Health Impact Project are addressing questions such as the effect on air pollution of a new light-rail transit line to connect Minneapolis and St. Paul; the potential health effects of a proposed subway and other mass-transit alternatives through Los Angeles' high-density, high-traffic Wilshire Corridor; the trade-off of increased employment versus increased emissions from a coal gasification project in Owensboro, KY; the optimal agriculture plan in Hawaii; the health benefits of having a Chicago electric utility use "smart meters;" a proposed "cap-and-trade" regulation in California; and the benefits of proposed legislation in Oregon to use state funds to purchase locally-grown foods for schools and establish school teaching gardens. The San Francisco Bay Area's Health Impact Assessment Collaborative provides several specific examples of policy discussions that explicitly incorporated a health assessment component, and engaged a variety of stakeholders to examine all facets of considered public policy decisions (Health Impact Assessment Collaborative-San Francisco Bay Area, 2010).

HIAP is frequently conflated with HIAs. Although HIAP and HIAs are closely related concepts, the former refers to a broad approach to public policy and the latter to a decision-support tool that may be used in evaluating that approach. It has been asserted that the health consequences of policies can be predicted, and tools such as the health impact assessments and simulation modeling can be used to enable policy-makers to foresee the outcomes of choosing different options (Burris et al., 2010; Kemm, 2006). However, HIAs can be difficult, time-consuming, and costly to complete. As noted below, meaningful evidence and data are not always available to arrive at definitive conclusions. It is therefore important for the law to impose some parsimony in dictating requirements for conducting HIAs. Apart from the administrative burden, it is neither necessary nor useful for policymakers to commission HIAs for every policy proposal. For example, enacting a modest retail redevelopment policy where the health impact is foreseen (i.e., through a "back of the envelope," informal analysis) to be negligible would likely not benefit from the development of a full or comprehensive HIA. In other cases, assessing the evidence is critical, as in the cases of federal laws with the potential for broad health impact that require periodic authorization. Examples here include the federal farm bill, which pertains to agricultural subsidies and policies on production and distribution of farm products; the transportation bill, which includes allocations for alternative transportation, such as bike paths, and public transportation in addition to roads and infrastructure; large local/state

[8] An RWJF and PEW national initiative based is San Francisco that has done many HIA's and is one of the leaders in the field (see Health Impact Project, 2010).

projects, for example, water distribution in Western states; and proposed large scale industrial plants or major redevelopment efforts. Although the administrative and methodological tasks of such research are challenging, the committee adopts as a general principle the obligation of policymakers to study, to whatever degree possible, the potential ramifications of policies in any sector that could substantially affect the health of the public.

> **Recommendation 9: The committee recommends that state and federal governments evaluate the health effects and costs of major legislation, regulations, and policies that could have a meaningful impact on health. This evaluation should occur before and after enactment.**

This recommendation applies to both public health and non-public health agencies working in concert. Before and after enactment, a scientific assessment would be conducted whenever possible. Before enactment of such policies, the vested authority (e.g., the public health agency) would study the potential health impact and/or cost-effectiveness. After enactment, the authority would review the health outcomes and costs associated with implementation of the policy and would, where appropriate, offer recommendations to the chief executive and legislature on changes that would improve outcomes.

Box 3-3 Making Evidence Useful to Policy Makers

Other researchers have sought to understand and explain the attitudes and behaviors of policymakers with regard to evidence. Researchers have found that evidence evaluation and reporting tools such as systematic reviews may not be helpful to policy makers because they do not make clear the reviews of policy applications (Jewell and Bero, 2008). Clancy et al. (2006) found that evidence syntheses for policymakers must be structured to answer policy questions and provide policy conclusions and also identified certain features of policymakers that make them better consumers of evidence. Both Sorian and Baugh (2002) and Clancy et al. (2006) report that two types of products are useful in communicating with policymakers about evidence on health policy: short summaries or briefs and longer, more detailed and technical studies or reports. Also, researchers found that it is useful to policymakers if the policy briefs and other materials prepared for them are designed to communicate about impacts in concrete ways, explaining benefits, harms, and costs; who will be affected; and how different policy options would work (Jewell and Bero, 2008; Sorian and Baugh, 2002). Additional essential ingredients include personal contact between policy researchers and policymakers, and timeliness or relevance of research (Innvaer et al., 2002).

Such evaluation and assessment could be conducted by the responsible agency, such as through *National Environmental Policy Act* (NEPA) requirements, or by the public health agency. There are several existing models for requiring and conducting assessments of health policy impact (see Box 3-3 for examples of tools available to support implementing health in all policies). These include the state of California, where a consortium of universities conducts assessments, including actuarial analyses, of the impact of many health policies, and the requirements of NEPA, which calls for an environmental assessment to first determine whether an action or project is environmentally significant. If yes, an environmental impact statement must be prepared. If no, a Finding of No Significant Impact may be issued by the responsible agency.

Scientific and Methodological Challenges to Measuring the Outcomes of Public Policies

Data and analytic methodology are often lacking for estimating the likely outcomes of proposed policies, laws, and regulations. The interventions that such proposals advocate are rarely the subject of empirical studies, making it difficult for policymakers to adopt the degree of evidence-based rigor that has become more common in medicine and public health practice. Even when such studies are available, accepted criteria for grading the quality of studies are lacking. The classic gold-standard in evaluating the efficacy of clinical interventions is the randomized controlled trial, followed by observational studies (time series, cohort studies, natural experiments). Braveman and colleagues (2011b) have outlined the deficiencies of this traditional evidence hierarchy in evaluating population-based interventions. The somewhat limited applicability of this hierarchy to public health interventions is well-discussed in the literature, but the classic evidentiary standards seem even less useful to the domains of laws, regulations, and policies.

Many other useful approaches and tools from other disciplines are available and can be applied with methodological care and rigor. For example, various forms of simulation and predictive modeling can be useful in projecting the likely outcomes of proposed policies by piecing together bodies of evidence and data from different domains (see, for example, the SIM SMOK tobacco control simulation model) (Levy et al., 2006). A need exists for experts from multiple disciplines to pool their knowledge in marshalling the proper methodologies for evaluating the effects of public policy and for reaching consensus on criteria for grading their quality. That effort would build on several decades of literature that has proposed various schemes for evaluating the evidence for population-based interventions.

Prior work has identified a variety of methodological challenges of measuring outcomes in this context. Accurate and complete assessment of the outcomes and benefits of laws, in public health or other arenas, is complicated by the fact that the effects are often distributed across multiple segments within the population, across multiple health and social endpoints, and across long time horizons. For example, laws that address the built environment through promotion of active transportation may have short-term effects on the well-being and quality of life of users; intermediate effects on neighborhood desirability, housing prices, and air quality; and longer-term effects on chronic disease incidence and progression, including cardiovascular disease, diabetes, and asthma. Assessing the impact of public health laws requires careful measurement and analytic strategies that take these details into consideration. Also, the work of the Task Force on Community Preventive Services indicates that multiple, different, and ongoing interventions are sometimes necessary to achieve a substantial and sustained effect on health outcomes and health behaviors (this was the case with tobacco, as discussed in Chapter 2, and similarly multi-faceted interventions are likely needed to address physical activity, high school graduation rates, and living wages).

Ideally, outcome measures for public health laws should consider not only epidemiological measures of mortality and morbidity but also measures of population preferences, well-being, and quality of life. Just as the development of patient-centered outcome measures has become a priority for comparative effectiveness research and evaluation under health reform, to be implemented through the Patient-Centered Outcomes Research Institute (PCORI), community-centered outcome measures, together with distal outcomes such as health-adjusted life expectancy, are needed to evaluate the full impact of laws on outcomes of importance to the public.

Although the committee accepts the principle that all population health interventions, including laws, should be based on the best evidence available, it notes that the policy context determines the level of acceptable uncertainty in the data. In particular, the risk of harm (economic or health-related) that arises from implementing or failing to implement a law is highly relevant. More limited evidence may be used to craft legal interventions when health threats and potential harms from inaction are large; when opportunity costs and unintended harms from action are within acceptable limits; and when the time demands and/or other costs required for gathering more definitive evidence are large relative to the expected value of the additional evidence (a "value of information" analysis).[9] Using weaker forms of evidence has the potential to increase the risk of false positives—the consequences of assuming a public health law is effective when in fact it is not—but this risk needs to be balanced against the risk of false negatives—the consequences of inaction and delays in the implementation of potentially effective new laws. When weaker levels of evidence are used to justify new laws, stronger prospective evaluations are needed to assess impact and produce additional evidence over time. According to Kindig (2010), early childhood intervention is one area where inaction may have grave consequences. The evidence for various policy and other approaches is mixed and there are important remaining gaps in our knowledge, but the risk from not acting on what is known, or even partially supported by the evidence, can be great, as a generation of children grows up without some of the potentially essential ingredients for healthy development.

A framework or matrix could be developed to illustrate the level of certainty and magnitude of effects that policymakers need depending on the type of policy decision.[10] Variables that could be used to structure such a framework would include the level of risk presented by the legal intervention, the population impact of the health risk factors being targeted, and the type of legal action. Other factors include the potential scope of the policy, severity and frequency of the potential health effects, availability of other options, prior experience using the intervention, and acceptability of potential risks. Such a framework could help policymakers determine what type of evidence would be sufficient to enact a proposed policy: a recommendation from a credible source such as the Task Force on Community Preventive Services or the Cochrane Collaboration, a well-conducted evaluation of another jurisdiction's experience with the policy, or simulation modeling that estimates the policy's potential impact. In the case of a policy targeting a major risk factor for poor health, the combination of a well-constructed hypothesis and high risk to the population may call for applying the precautionary principle and for taking action even in the absence of definitive evidence.

Costs, along with health benefits and harms, are an increasingly important concern in evaluating the likely outcomes of proposed laws, policies, and regulations. Strategic planning requires the allocation of scarce resources. It is often assumed that legal interventions have few costs. However, the cost analyses may not account for all relevant costs and externalities and may apply an individual or government perspective rather than tabulating costs to society or to the agencies responsible for implementation and monitoring. Ultimately, the population health

[9] In some cases, it may be possible to undertake research during policy implementation (including so-called natural experiments that compare a jurisdiction that implements a specific policy to a similar jurisdiction that does not), or to implement in a manner that allows study of a policy's effects.

[10] A comprehensive discussion of evidentiary standards for population health interventions is available at: http://healthypeople.gov/2020/default.aspx

benefit and cost effectiveness of legal interventions might be compared directly with other investments, including medical care, designed to improve individual and/or population health. Finally, legal interventions deserve to be studied not only for their effectiveness, but for their comparative effectiveness (both against other legal intervention and compared to other kinds of interventions). In an example of the former, Sturm et al. (2010) found that taxes applied to carbonated beverages that are reflected in the price on the shelf (i.e., excise tax) are more effective than taxes applied at the register (i.e., sales tax) in deterring consumer selection of such products. Moreover, the experience with tobacco taxes has taught public health officials about price elasticity—the extent to which smokers reduce demand for cigarettes as a result of cost increases (IOM, 2007).

Research on the comparative effectiveness and health impact of public health laws and policies could be conducted by documenting geographic variation and temporal change in population exposure to specific policy and legal interventions. The system also can be used to track the progress of efforts to expand the geographic reach of effective policies and laws, and to identify unmet needs for policy development and advocacy strategies. A knowledge base exists for crafting an accepted framework for evaluating the evidence of public policies, but work by an interdisciplinary team of experts is needed to build on the existing literature, review methodological challenges, and arrive at a consensus on preferred criteria. An expert panel, given dedicated time and resources for the effort, could consider the various schemes that have been proposed for grading the evidence for outcomes assessments of policies and regulations and derive new guidelines that the HIAP movement could embrace in setting evidence-based policy.

> **Recommendation 10: The Committee recommends that HHS convene relevant experts to enhance practical methodologies for assessing the strength of evidence regarding the health effects of public policies as well as to provide guidance on evidentiary standards to inform a rational process for translating evidence into policy.**

Although functioning as convener, HHS would be one actor among many in this process. The guidance developed would include: (1) methods for assessing the certainty of effectiveness (benefits and harms), and, if effective, the magnitude of effect, for suitable populations; (2) methods for assessing the effectiveness of interventions (policies and programs) when used alone or in combination, i.e., their incremental and or synergistic benefits; and (3) priorities for and consideration of the contextual issues that should be taken into account when determining whether (and where) to implement policies. The contextual issues to be considered include: importance of the problem (severity, frequency, burden of disease, cost), feasibility (affordability, acceptability), availability of alternatives, demand, fairness (equity), preferences and values, cost effectiveness, potential to advance other societal objectives, potential for harms, legal and ethical considerations, and administrative options. The intention of this recommendation is to develop methodologies, but not to assess each individual policy. Not all policy that impacts health has governmental origins. Because the vast majority of US economic activity is in the private sector, formal and informal policies adopted by business, foundations, and others have the potential to profoundly influence health. However, public health practitioners have limited knowledge of policy development and implementation in the non-governmental sectors.

Another important priority is to establish a clearinghouse of evidence to which policymakers (and developers of HIAs) can turn to study the outcomes of prior legal interventions. The practice of evidence-based medicine and public health is aided by the existence of powerful search tools that enable users to query bibliographic databases and professional publications to identify, often within seconds, the best evidence for a clinical intervention. Building a similar capacity to evaluate the effects of agriculture, tax, housing, economic, and education policies is a worthy priority:

> Unlike many other areas of public health research, research on public health law and policy has developed few surveillance systems. . . . Gathering information about the patterns of public health law adoption and implementation across states and local governments over time generally is done de novo in each research project. Maintaining and updating databases of laws would dramatically improve researchers' ability to conduct rigorous policymaking, mapping, intervention, implementation, and mechanism studies at low cost. High standards of transparency concerning the data-collection and coding protocols for such databases would allow subsequent researchers to update publicly available data sets at reasonable marginal cost (Burris et al., 2010, p.194-195).

A pilot project could be developed and implemented to assess the feasibility of monitoring and measuring this activity. To track laws and policies (largely public sector, but including, where practical, major policy areas in the private sector) that successfully influence the health of populations, a health policy surveillance system could be developed, pilot-tested, and supported by CDC. Such a system would gather information on the geographic reach, scope, and timing of significant new laws and policies designed to promote health and prevent disease and disability at the population level.

The surveillance system could include such health-related laws and policies adopted at federal, state, and local government levels, including laws that define regulatory and enforcement powers and duties for public health agencies and for other governmental entities. Although more difficult to capture and assess, significant new health-related policies adopted by private organizations could also be included in the surveillance system, such as those adopted by employers, schools, health care institutions, and community-based organizations, to the extent such policies are made public and are brought to the attention of the surveillance system. A range of different methodologies for capturing information on private-sector health policies could be tested to determine an appropriate balance of validity, reliability, and feasibility. Some combination of active surveillance approaches and passive surveillance reporting through local public health agencies may be required.

This second report of the committee has identified historical and extant approaches to the use of law and policy in protecting and improving the health of the public. Law has been and will remain critical for creating the infrastructure that supports directed and accountable action, as well as for limiting some actions that diminish health, or requiring actions that enhance it.

As the nation looks to true reform in its health system, and the ultimate goal of optimizing the health of the public, challenges, but also opportunities, exist in revisiting, re-fashioning, and applying laws to improve the health of Americans. The challenges are by no means minimal. The committee is aware of the bureaucratic and administrative burdens and political turbulence that sometimes accompany the development or implementation of legislation, regulations, and policies. In addition, building the evidence base as it relates to

forecasting potential benefits, harms, and costs, will be methodologically challenging, and will itself consume resources. Mandating efforts to do so is only appropriate when the methods, evidence and analytic capacity are present. But building capacity to conduct this type of evidence-based evaluation and governance is key to understanding what works, to bring data and facts to a domain populated by opinions and politics, and to implement policies that are successful and efficient.

The opportunity to substantially enhance public health—and with it the nation's economy and workforce productivity—turns on the ability of government and the private sector to shape public policies with closer and more mindful attention to health outcomes. Working together toward a goal of common interest—better health, a stronger economy, a vibrant society—also provides an opportunity for communities to build new models of collaboration and coordination that reduce inefficiency and maximize impact. This effort to bring partners and stakeholders together thereby becomes a vehicle not only for healthier communities but also a model for more productive discourse and policy formulation in other sectors.

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Appendix A

Acronyms

ACA	Affordable Care Act, 2010
ACO	accountable-care organizations
AHR	America's Health Rankings
AHRQ	Agency for Healthcare Research and Quality
ARRA	American Recovery and Reinvestment Act
ASTHO	Association of State and Territorial Health Officials
BAC	Blood Alochol Contents
CDC	Centers for Disease Control and Prevention
CVD	cardiovascular disease
EHR	electronic health record
EPA	Environmental Protection Agency
FOIL	Freedom of Information Law
GAO	Government Accountability Office
GASB	Government Accounting Standards Board
GDP	gross domestic product
HALE	health-adjusted life expectancy
HALY	health-adjusted life year
HHS	Department of Health and Human Services
HIA	health impact assessment
HiAP	Healt in All Policies
HIPAA	Health Insurance Portability and Accessibility Act
HITECH	Health Information Technology for Economic and Clinical Health
IOM	Institute of Medicine
NACCHO	National Association of County and City Health Officials

NCHS	National Center for Health Statistics
NIH	National Institutes of Health
NPHPPHC	National Prevention, Health Promotion, and Public Health Council
OECD	Organisation for Economic Co-operation and Development
PHAB	Public Health Acceditation Board
PPACA	Patient Protection and Affordable Care Act, 2010

Appendix B

Meetings Agendas Held by the Committee on Public Health Strategies to Improve Health (May 2010-December 2010)

Meeting Four: May 18, 2010
Keck Center of the National Academies, Washington, DC

8:00 – 8:10 am	Welcome and introductions *Marthe Gold, IOM Committee Chair, and Steve Teutsch, IOM Committee Vice-Chair*
8:10 – 9:10 am	HHS Community Health Data Initiative *Todd Park, Chief Technology Officer, Department of Health and Human Services* *Linda Bilheimer, National Center for Health Statistics, Centers for Disease Control and Prevention (CDC)*
9:10 – 9:30 am	The role of the executive branch in public health law and regulation *Mariano-Florentino (Tino) Cuéllar, Special Assistant to the President for Justice and Regulatory Policy, White House Domestic Policy Council*
9:30 – 9:50 am	Committee questions and discussion
9:50 – 10:30 am	Panel I. Authorities, organization, and key issues in (and between) federal, state, and local public health agencies. Moderator: Lawrence Gostin, IOM Committee Member *Judith Monroe, Director, Office of State, Tribal, Local and Territorial Support, CDC* *Patrick Libbey, Eld Inlet Associates*
10:30 am	Break
10:40 – 11:40 am	Panel I. (Continued) *James G. Hodge, Lincoln Professor of Health Law and Ethics, Director,*

	Public Health Law & Policy Program, University of Arizona *Gene W. Matthews, Senior Fellow, North Carolina Institute for Public Health, UNC Gillings School of Global Public Health* *Dan Stier, Consulting Attorney, Public Health Law Center, William Mitchell College of Law*
11:40 am – 12:15 pm	Committee questions and discussion
12:15 pm	Lunch
1:15 – 2:15 pm	Panel II. Different perspectives on using the law to improve population health: tobacco, obesity, and beyond. Moderator: Leslie Beitsch, IOM Committee Member. *Marice Ashe, Director, Public Health Law & Policy* *Steven D. Sugarman, Roger J. Traynor Professor of Law, University of California, Berkeley* *Scott Burris, Professor of Law, Temple School of Law*
2:15 – 2:45pm	Committee questions and discussion
2:45 pm	Break
3:00 – 4:00 pm	Panel III. Public health law at the local level. Moderator: Wilfredo Lopez, IOM Committee Member. *Wendy Perdue, Georgetown University Law Center* *Lynn Silver, Assistant Commissioner, NYC Department of Health and Mental Hygiene*
4:00 – 4:30 pm	Committee questions and discussion
4:30 – 4:45 pm	Closing comments and discussion
4:45 pm	Adjourn

Meeting Six: September 30, 2010
Keck Center of the National Academies, Washington, DC

10:00 am	Welcome and introductions *Marthe Gold, IOM Committee Chair, and Steve Teutsch, IOM Committee Vice-Chair* *Moderator of morning presentations: Wilfredo Lopez, IOM Committee Member*

10:15 am	Obesity and beyond: local public health ordinances to improve health *Marty Fenstersheib, Health Officer of Santa Clara County, CA*
10:45 am	Questions from the Committee
11:05 am	Advocating for policy change to improve health *Harold Goldstein, Executive Director, California Center for Public Health Advocacy*
11:35 am	Questions from the Committee
12:00 – 1:00 pm	Lunch *Moderator of afternoon presentations: Les Beitsch, IOM Committee Member*
1:00 pm	Using Law, Policy, and Research to Improve the Public's Health – Conference Report; Health Impact Assessment Project Update and Q&A *James G. Hodge, Lincoln Professor of Health Law and Ethics, Director, Public Health Law & Policy Program, Arizona State University* *Via teleconference*
1:30 pm	New Partnerships for Healthier Neighborhoods: The Public Health Role in the Planning Process *Heather Wooten, Senior Planning and Policy Associate with Planning for Healthy Places, Public Health Law and Policy*
2:00 pm	Planning: many avenues to toward health improvement *Jodi Bryon, New York City Department of Planning*
2:30 pm	Questions from the Committee
3:30 pm	*Wrap-up discussion with all speakers* *Moderator, Larry Gostin, IOM Committee Member*
4:15 pm	Closing comments
4:30 pm	Adjourn

Meeting Seven: Tuesday, December 7, 2010
Beckman Center of the National Academies, Irvine, CA

1:00 pm	Welcome and introductions *Marthe Gold, IOM Committee Chair*
1:10 pm	The scope of public health and the role of government in assuring the conditions for improving population health – opening comments and discussion with the committee Moderator: Lawrence O. Gostin, IOM Committee member Discussants: Richard Epstein (via phone) Laurence A. Tisch Professor of Law New York University School of Law (until fall 2010, James Parker Hall Distinguished Service Professor of Law University of Chicago) Michael Cannon Director of Health Policy Studies Cato Institute
3:00 pm	Adjourn

Appendix C

Committee Biosketches

Marthe R. Gold, MD, MPH *(Chair),* is the Logan Professor and chair of the Department of Community Health and Social Medicine of the Sophie Davis School of Biomedical Education of the City College of New York. She is a graduate of the Tufts University School of Medicine and the Columbia School of Public Health. Her clinical training is in family practice, and her clinical practice has been in urban and rural underserved settings. She served on the faculty of the University of Rochester School of Medicine from 1983 to 1990, and from 1990 to 1996 she was senior policy adviser in the Office of the Assistant Secretary for Health in the US Department of Health and Human Services (HHS). Her focus at HHS was on financing of clinical preventive services and the economics of public health programs. Dr. Gold directed the work of the Panel on Cost-Effectiveness in Health and Medicine, an expert panel whose report, issued in 1996, remains an influential guide to cost-effectiveness methods for academic and policy uses. Dr. Gold's current work is on public and decision-maker views on the use of economic analyses to inform resource-allocation decisions. She is also involved in funded initiatives that seek to increase the level of patient engagement and activation in community health-center settings. A member of the Institute of Medicine, she has contributed to a number of its reports and has served most recently on the communication collaborative of the Evidence-Based Roundtable.

Steven M. Teutsch, MD, PhD *(Vice Chair),* became the chief science officer of Los Angeles County Public Health in February 2009, where he will continue his work on evidence-based public health and policy. He had been in the Outcomes Research and Management Program at Merck since October 1997, where he was responsible for scientific leadership in developing evidence-based clinical-management programs, conducting outcomes research studies, and improving outcomes measurement to enhance quality of care. Before joining Merck, he was director of the Division of Prevention Research and Analytic Methods (DPRAM) in the Centers for Disease Control and Prevention (CDC), where he was responsible for assessing the effectiveness, safety, and cost-effectiveness of disease and injury prevention strategies. DPRAM developed comparable methods for studies of the effectiveness and economic impact of prevention programs, provided training in the methods, developed CDC's capacity for conducting necessary studies, and provided technical assistance for conducting economic and decision analysis. The division also evaluated the effects of interventions in urban areas, developed the *Guide to Community Preventive Services*, and provided support for CDC's

analytic methods. He has served as a member of the U.S. Preventive Services Task Force, which develops the *Guide,* and on America's Health Information Community Personalized Health Care Workgroup. He currently chairs the HHS Secretary's Advisory Committee on Genetics, Health, and Society (at NIH's Office of Science Policy) and serves on the Evaluation of Genomic Applications in Practice and Prevention Working Group. Dr. Teutsch received his undergraduate degree in biochemical sciences at Harvard University in 1970, an MPH in epidemiology from the University of North Carolina School of Public Health in 1973, and his MD from Duke University School of Medicine in 1974. He completed his residency training in internal medicine at Pennsylvania State University, Hershey. He was certified by the American Board of Internal Medicine in 1977 and the American Board of Preventive Medicine in 1995 and is a fellow of the American College of Physicians and the American College of Preventive Medicine. Dr. Teutsch is an adjunct professor in the Emory University School of Public Health Department of Health Policy and Management and the University of North Carolina School of Public Health. He has published over 150 articles and six books in a broad array of fields in epidemiology, including parasitic diseases, diabetes, technology assessment, health-services research, and surveillance.

Leslie Beitsch, MD, JD, is the associate dean for health affairs and directs the Center for Medicine and Public Health of Florida State University. Before joining the Florida's College of Medicine, Dr. Beitsch was Commissioner of Health for the state of Oklahoma from June 2001 to November 2003. Earlier, he had held several positions in the Florida Department of Health for 12 years, most recently as deputy secretary. He received his BA in chemistry from Emory University and his MD from Georgetown University School of Medicine and completed his internship at the Medical College of South Carolina. He received his JD from Harvard Law School.

Joyce D.K. Essien, MD, MBA, is director of the Center for Public Health Practice at the Rollins School of Public Health of Emory University and Retired Medical Officer, Captain US Public Health Service at the Centers for Disease Control and Prevention. Dr. Essien leads a team in collaboration with the Sustainability Institute that is building and applying simulation and syndemic modeling applications to diabetes to inform cross-sectoral strategy, deliberation, and decision support for policy formulation and strategic interventions at the national, state, and local levels to reduce the present and future burden of diabetes. Dr. Essien was one of nine members who received the 2008 inaugural Applied Systems Thinking Award from the Applied Systems Thinking Institute for the magnitude of the problems that were being addressed (chronic-disease syndemics and health-system transformation) , the interdisciplinary composition of the team, and the long track record of engagement and application in applied settings. Dr. Essien is coauthor of the *Public Health Competency Handbook—Optimizing Individual and Organizational Performance for the Public's Health* (www.populationhealthfutures.com). She serves on the Executive Committee of the Atlanta Medical Association; the boards of directors of the VHA Foundation, the Atlanta Regional Health Forum, and ZAP Asthma Consortium, Inc.; and the advisory committees for the Association for Community Health Improvement, the Association for Health Information Management Foundation, and the MPH Program at Florida A&M

University, where she serves as chair. She is a member of the Bon Secours Hospital System Board Quality Committee and the Institute for Alternative Futures Biomonitoring Futures Project and Disparity Reducing Initiative. The ZAP Asthma Consortium, Inc., co founded by Dr. Essien, is the recipient of the Rosalyn and Jimmy Carter Partnership Award (www.zapasthma.org). For her service and contributions, Dr. Essien was a recipient in l999 of the Women in Government Award from Good Housekeeping Magazine, the Ford Foundation, and the Center for American Women and Politics at Rutgers University. She is also the recipient of the Thomas Sellars Award from the Rollins School of Public Health and the Unsung Heroine Award from Emory University. Dr. Essien is one of three recipients of the 2008 Excellence in Medicine Award from the American Medical Association Foundation.

David W. Fleming, MD, is director and health officer for Public Health–Seattle & King County, a large metropolitan health department with 2,000 employees, 39 sites, and a budget of $306 million serving a resident population of 1.9 million. Before assuming that role, Dr. Fleming directed the Bill & Melinda Gates Foundation's Global Health Strategies program, in which capacity he oversaw the foundation's portfolios in vaccine-preventable diseases, nutrition, newborn and child health, leadership, emergency relief, and cross-cutting strategies to improve access to health tools in developing countries. He is a former deputy director of the Centers for Disease Control and Prevention. Dr. Fleming has published on a wide array of public health issues and has served on multiple boards and commissions, including the board of the Global Alliance for Vaccines and Immunization. Dr. Fleming received his medical degree from the State University of New York Upstate Medical Center in Syracuse. He is board-certified in internal medicine and preventive medicine and serves on the faculty of the departments of public health at the University of Washington and Oregon Health Sciences University.

Thomas E. Getzen, PhD, is professor of risk, insurance and health management at the Fox School of Business at Temple University and executive director of *iHEA*, the International Health Economics Association, which has 2,400 academic and professional members in 72 countries. He has also served as visiting professor at the University of Toronto, the Woodrow Wilson School of Public Policy at Princeton University, the Wharton School of the University of Pennsylvania, and the Centre for Health Economics at the University of York. His textbook *Health Economics: Fundamentals and Flow of Funds* (Wiley; 4th ed., 2010) is used in graduate and undergraduate programs throughout the world. His research focuses on the macroeconomics of health, finance, forecasting of medical expenditures and physician supply, price indexes, public health economics, and related issues. He recently completed a model of long-run medical-cost trends for use by the Society of Actuaries, building on the work of economists at the Centers for Medicare & Medicaid Services and the Congressional Budget Office..

Lawrence O. Gostin, JD, LLD (Hon.), is the Linda and Timothy O'Neill Professor of Global Health Law and the director of the O'Neill Institute for National and Global Health Law at Georgetown University. He served as the associate dean of Georgetown Law until 2008. He is also a professor at the Johns Hopkins Bloomberg School of Public Health and a visiting professor at Oxford University in the United Kingdom. He is a

fellow of the Hastings Center, the Kennedy Institute of Ethics, and the Royal Society of Public Health. Professor Gostin is on the editorial boards of several journals and is law editor of the *Journal of the American Medical Association*. He directs the World Health Organization and Centers for Disease Control and Prevention Collaborating Centers on Public Health Law. Professor Gostin is a member of the Institute of Medicine (IOM) and has chaired four IOM committees.

George Isham, MD, MS, is medical director and chief health officer for HealthPartners. He is responsible for the improvement of health and quality of care and for HealthPartners research and education programs. Dr. Isham chairs the Institute of Medicine (IOM) Roundtable on Health Literacy. He also chaired the IOM Committee on Identifying Priority Areas for Quality Improvement and Committee on the State of the USA Health Indicators. He has served as a member of the IOM Committee on the Future of the Public's Health and on the Subcommittee on the Environment of the Committee on Quality in Health Care, which produced the reports *To Err Is Human* and *Crossing the Quality Chasm*. He has served on the Subcommittee on Performance Measures for the Committee on Redesigning Health Insurance Performance Measures, Payment and Performance Improvemtn Programs charged with redesigning health-insurance benefits, payment, and performance-improvement programs for Medicare and was a member of the IOM Board on Population Health and Public Health Practice. Dr. Isham was founding cochair of and is a member of the National Committee for Quality Assurance's Committee on Performance Measurement, which oversees the Healthcare Effectiveness Data and Information Set (HEDIS), and he cochairs the National Quality Forum's Advisory Committee on Prioritization of Quality Measures for Medicare. Before his current position, he was medical director of MedCenters Health Plan in Minneapolis and in the late 1980s was executive director of University Health Care, an organization affiliated with the University of Wisconsin–Madison.

Robert M. Kaplan, PhD, is Distinguished Professor of Health Services at the University of California, Los Angeles (UCLA) and Distinguished Professor of Medicine at the UCLA David Geffen School of Medicine, where he is principal investigator of the California Comparative Effectiveness and Outcomes Improvement Center. He leads the UCLA/RAND health-services training program and the UCLA/RAND–Centers for Disease Control and Prevention's Prevention Research Center. He was chair of the Department of Health Services from 2004 to 2009. From 1997 to 2004, he was professor and chair of the Department of Family and Preventive Medicine of the University of California, San Diego. He is a past president of several organizations, including the American Psychological Association Division of Health Psychology, Section J of the American Association for the Advancement of Science (Pacific), the International Society for Quality of Life Research, the Society for Behavioral Medicine, and the Academy of Behavioral Medicine Research. He is a past chair of the Behavioral Science Council of the American Thoracic Society. Dr. Kaplan is editor-in-chief of *Health Psychology* and former editor-in-chief of *Annals of Behavioral Medicine*. He is the author, coauthor, or editor of more than 18 books and some 450 articles or chapters. ISI includes him in its list of the most cited authors in the world (defined as above the 99.5th percentile). In 2005, he was elected to the Institute of Medicine.

Wilfredo Lopez, JD, is currently providing professional consulting services in the field of public health law to the Centers for Disease Control and Prevention (CDC), through an independent contractor of CDC. Previously, he was a consultant to the New York City Department of Health and Mental Hygiene from 2007 to 2009 spearheading the NYC Health Code Revision Project. From 1979 to 2006, Mr. Lopez served as a staff attorney, Deputy General Counsel and, from 1992, as General Counsel to the NYC Department of Health. Upon his retirement in December of 2006, he was vested with the titles General Counsel Emeritus to the NYC Department of Health and Counsel Emeritus to the NYC Board of Health. Mr. Lopez has authored articles in the field of public health and public health law. In 2007 Mr. Lopez, in collaboration with the CDC, served as Executive Editor of *The National Action Agenda for Public Health Legal Preparedness*. He is the co-editor and co-author of a text book entitled *Law in Public Health Practice*. Mr. Lopez' other professional activities in the field include serving as a member of the National Advisory Committee to the Public Health Law Research Program of the Robert Wood Johnson Foundation, and as a member of a workgroup assisting the CDC's National Center Health Statistics to revise the Model State Vital Statistics Act and Regulations.

Glen P. Mays, PhD, MPH, serves as professor and chairman of the Department of Health Policy and Management of the Fay W. Boozman College of Public Health, University of Arkansas for Medical Sciences (UAMS). He also directs the PhD program in health-systems research at UAMS. Dr. Mays's research focuses on strategies for organizing and financing public health services, preventive care, and chronic-disease management for underserved populations. He has led a series of national studies examining how public health services are organized, financed, and delivered in local communities and what factors influence the availability and quality of these services. The work has included the development of instruments and analytic techniques for measuring public health system performance and studies of the health and economic consequences of geographic variation in public health spending in the United States. He directs the Robert Wood Johnson Foundation (RWJF) Public Health Practice–Based Research Networks Program, which brings together public health agencies and researchers from around the nation to study innovations and improvements in practice. Dr. Mays's public health systems research has been funded by RWJF, the Centers for Didease Control and Prevention, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, and the National Institutes of Health and has been published in leading journals, including *Health Services Research*, *Health Affairs*, *Inquiry*, and the *American Journal of Public Health*. Dr. Mays has published more than 50 journal articles, books, and chapters on these issues. He received his PhD and MPH in health policy and administration from the University of North Carolina at Chapel Hill and completed a postdoctoral fellowship in health economics at Harvard Medical School.

Phyllis D. Meadows, PhD, MSN, RN, is associate dean for practice in the Office of Public Health Practice and clinical professor in the Department of Health Management and Policy of the University of Michigan (UM) School of Public Health, where her responsibilities include developing and teaching courses in public health administration and public health policy in the department and overseeing leadership training of public

health professionals for the officee. As a senior fellow of health for the Kresge Foundation, Dr. Meadows is designing a national initiative for community health centers. Most recently, she served as director and public health officer of the City of Detroit Department of Public Health and Wellness Promotion. Before that, she spent over a decade as a program director of the W.K. Kellogg Foundation, where she worked in youth, health, health-policy, and education programming. Dr. Meadows joined the UM School of Public Health faculty in February 2009 as a clinical professor and associate director of public health practice. She holds a bachelor's degree and a master of science degree in nursing and a PhD in sociology from Wayne State University (WSU). She is the recipient of numerous honors and awards, including the WSU School of Nursing Lifetime Achievement Award, the UM Distinguished Public Health Practitioner Award, and the Michigan Department of Community Health Director's Award for Innovation in Public Health.

Mary Mincer Hansen, RN, PhD, is director of the Master of Public Health program and adjunct associate professor in the Department of Global Health of Des Moines University. She is the former director of the Iowa Department of Public Health in the cabinet of Governor Vilsack, where she was his designee to Governor Huckabee's National Governors Association Chair's Initiative Healthy America, which focused on addressing the obesity epidemic in America. Dr. Mincer Hansen also accompanied Governor Vilsack on his visit to China and while there met with Chinese public health leaders in Hebei Province and Beijing. In addition, she testified before the US Congress on pandemic-influenza preparedness and the Institute of Medicine Committee on Pandemic Community Mitigation. Before being appointed as director of public health, she was an associate professor in the Drake University Department of Nursing, director of the Drake University Center for Health Issues, president of the Iowa Public Health Foundation, and a research fellow on a Centers for Disease Control and Prevention patient-safety grant in the Iowa Department of Public Health. Dr. Mincer Hansen has served in many national positions; she has been a member of the Robert Wood Johnson Foundation Advisory Committee for Partners Investing in Nursing's Future, a member of the Council of State Governments Public Health Advisory Committee, and president of the Association of State and Territorial Health Officials (ASTHO). Dr. Mincer Hansen is an appointee to the new National Health Care Workforce Commission. She also serves on the Iowa Department of Public Health Advisory Council and Senator Harkin's Nurse Advisory Committee and as president of the ASTHO Alumni Association.

Poki Stewart Namkung, MD, MPH, received her AB from the University of California (UC), Berkeley; her MD from UC, Davis; and her MPH from UC, Berkeley. She is a fellow of the American College of Preventive Medicine. Dr. Namkung served as the health officer and director of public health for the city of Berkeley from 1995 to 2005 and is now the health officer and chief medical officer in the Santa Cruz County Health Services Agency. She has been received many honors, including selection as a state scholar for the Public Health Leadership Institute in 1996, the California Public Health Association-North Leadership Award in 2003, and the Outstanding Berkeley Woman Award in 2005. She has served on many advisory boards and commissions and was elected president of the California Conference of Local Health Officers for 2001-2003,

president of the Health Officers Association of California for 2003-2005, and president of the National Association of County and City Health Officials (NACCHO) for 2006-2007. She cochairs the Joint Public Health Informatics Taskforce, serves on NACCHO's Informatics and Immunization workgroups, and chairs the NACCHO Adolescent Health Advisory Taskforce.

Margaret O'Kane, MHSA, is president of the National Committee for Quality Assurance (NCQA), an independent nonprofit organization whose mission is to improve the quality of health care everywhere. Under Ms. O'Kane's leadership, NCQA has developed broad support among the employer and health-plan communities; today, many Fortune 100 companies will do business only with NCQA-accredited health plans. About three-fourths of the nation's largest employers use Healthcare Effectiveness Data and Information Set (HEDIS®) data to evaluate the plans that serve their employees. Ms. O'Kane was named Health Person of the Year in 1996 by *Medicine & Health* magazine. She also received a 1997 Founder's Award from the American College of Medical Quality, recognizing NCQA's efforts to improve managed-care quality. In 1999, Ms. O'Kane was elected a member of the Institute of Medicine. In 2000, she received the Centers for Disease Control and Prevention's Champion of Prevention award, the agency's highest honor. Ms. O'Kane began her career in health care as a respiratory therapist and went on to earn a master's degree in health administration and planning from the Johns Hopkins University.

David Ross, ScD, directs the Public Health Informatics Institute (PHII), a program of the Task Force for Global Health, which is affiliated with Emory University, and serves as corporate secretary of Global Health Solutions, Inc., a nonprofit subsidiary of the Task Force. PHII supports public health practitioners in their use of information and information systems to improve community-health outcomes. He received his ScD in applied mathematics and operations research from the Johns Hopkins University. His career spans health-care research and administration, environmental-health research, and public health and medical-informatics consulting. He became the director of All Kids Count, a program of PHII supported by the Robert Wood Johnson Foundation (RWJF), in 2000, and later began PHII, also with funding from RWJF. Dr. Ross was an executive with a private health-information systems firm, a Public Health Service officer with the Centers for Disease Control and Prevention (CDC), and an executive of a private, nonprofit health system. In 1983, he joined CDC's National Center for Environmental Health. During his career at CDC, he worked in environmental health, CDC's executive administration, and public health practice. Dr. Ross was founding director of the Information Network for Public Health Officials, CDC's national initiative to improve the information infrastructure of public health. His research and programmatic interests reflect those of PHII: the strategic application of information technologies to improve public health practice. He served as director of the RWJF national program Common Ground and its InformationLinks national program. He served on the Institute of Medicine (IOM) core committee for the evaluation of the US government's global HIV/AIDS PEPFAR program and on the IOM panel recommending the research agenda for public health preparedness, is a commissioner on the Certification Commission for

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Martín J. Sepúlveda, MD, FACP, is an IBM Fellow and vice president of integrated health services for the IBM Corporation. He leads a global team with responsibility for health-care policy, strategy, and design and the management system and services supporting the health and well-being of IBM's workforce and work environments. His interests and research include patient-centered primary care and medical homes, care management and coordination, total health management, workplace health promotion, risk-reduction program measurement, value-based health-care purchasing, and global occupational and health-services delivery. He is a fellow of the American College of Physicians, the American College of Occupational and Environmental Medicine, and the American College of Preventive Medicine. Dr. Sepúlveda was recently awarded honorary membership in the American Academy of Family Physicians for his work in primary-care transformation, received the 2008 John D. Thompson Distinguished Fellow Award from Yale University for Innovation in Healthcare, and received the Distinguished Alumnus Award for Professional Achievement from the University of Iowa. He serves on the Institute of Medicine's Board on Population Health and Public Health Practice, the Board of Directors of the Employee Benefit Research Institute, the Board of Advisors to the School of Public Health of the University of Iowa, and the Board of the National Business Group on Health and chairs the Global Health Benefits Institute. He received his MD and MPH from Harvard University and completed an internal-medicine residency at the University of California, San Francisco Hospitals & Clinics, an internal-medicine fellowship at the University of Iowa Hospitals and Clinics; and an occupational-medicine residency at the National Institute for Occupational Safety and Health; and served with the Epidemic Intelligence Service at the Centers for Disease Control and Prevention.

Steven H. Woolf, MD, MPH, is a professor in the Departments of Family Medicine, Epidemiology, and Community Health at Virginia Commonwealth University (VCU). He received his MD in 1984 from Emory University and underwent residency training in family medicine at VCU. Dr. Woolf is also a clinical epidemiologist and underwent training in preventive medicine and public health at the Johns Hopkins University, where he received his MPH in 1987. He is board-certified in family medicine and in preventive medicine and public health. Dr. Woolf has published more than 150 articles in a career that has focused on evidence-based medicine and the development of evidence-based clinical-practice guidelines, with a focus on preventive medicine, cancer screening, quality improvement, and social justice. From 1987 to 2002, he served as science adviser to and then a member of the U.S. Preventive Services Task Force. Dr. Woolf edited the first two editions of the *Guide to Clinical Preventive Services* and is author of *Health Promotion and Disease Prevention in Clinical Practice*. He is associate editor of the *American Journal of Preventive Medicine* and served as North American editor of the *British Medical Journal*. He has consulted widely on various matters of health policy with government agencies and professional organizations in the United States and Europe and in 2001 was elected to the Institute of Medicine.