Making the Case for Laws That Improve Health:

A Framework for Public Health Law Research

Scott Burris, JD
Beasley School of Law
Temple University

Alexander C. Wagenaar, PhD
Department of Epidemiology and Health Policy Research
University of Florida College of Medicine

Jeffrey W. Swanson, PhD
Department of Psychiatry and Behavioral Sciences
Duke University School of Medicine

Jennifer K. Ibrahim, PhD
Department of Public Health
Temple University

Jennifer Wood, PhD
Department of Criminal Justice
Temple University

Michelle M. Mello, JD, PhD (*corresponding author)*
Department of Health Policy and Management
Harvard School of Public Health
677 Huntington Ave., Boston, MA 02115
Tel. (617) 835-4784; Fax (617) 432-4494
mmello@hsph.harvard.edu

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Abstract

Context: Public health law has received considerable attention in recent years and is assuming the role of an essential field within public health. Public health law *research* has received less attention.

Methods: Expert commentary.

Findings: This paper explores the boundaries and promise of public health law research, defined as the scientific study of the relation of law and legal practices to population health. The paper offers a logic model of public health law research and a typology of approaches for studying the effects of law on public health. Research on the content and prevalence of public health laws; processes of adopting and implementing laws; and the extent to which and mechanisms through which law affects health outcomes can be pursued using methods drawn from epidemiology, economics, sociology, and other disciplines. The maturation of public health law research as a field depends on overcoming several challenges, including the need to assure methodological rigor, adequate research funding, access to appropriate data sources, and uptake of research findings by policy makers.

Conclusions: Public health law research is a young field, but holds great promise for supporting evidence-based policy making that will improve population health.

Keywords: public health; law; legal; scholarship; research

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Law is an important discipline within public health (Gostin, Burris, and Lazzarini 1999). Legal "powers, duties and restraints" structure the mission of public health agencies and shape how it is carried out (Gostin 2008). Law is a prominent intervention tool to achieve particular public health goals. Laws and their implementation also have important unintended effects, both positive and negative, on population health. Although public health law has a long pedigree in the United States (Tobey 1939), it was one of the fields of public health that fell into neglect during the time that public health was thought to have conquered infectious disease. Over the past two decades, the reemergence of infectious disease as a major public health concern, and a growing awareness of the complexity of health regulation at the local, national and global level, have restored law to an important place within public health and academic law. No longer confined to end-of-the day conference panels on "legal and ethical issues," public health law now has its own office at the Centers for Disease Control and Prevention, academic centers, journals, national and international professional societies, and a shelf of important treatises (Larkin and McGowan 2008).

Notwithstanding all the writing and commentary on public health law, there has been little discussion of public health law *research* and its place within the fields of law and public health. The evidence produced by empirical research plays an important role in both public health law practice and scholarship. It constitutes the "facts" justifying regulatory action and supporting normative arguments about what policies are most desirable, most effective or most consistent with human rights or other legal standards. To be sure, law legitimately serves as a site for the articulation and clash of values and lawmaking often necessitates decisions that cannot await full information. Not all law is

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or can be "evidence-based," even in public health. At the same time, empirical research is not just an ammunition dump for adversarial legal battle. The responsible use of law as a tool for improving public health requires a commitment to the pursuit and consideration of scientific evidence when possible. In public health, just as in health care (Sox and Greenfield 2009), evidence should inform the investment in and implementation of policy, and a consciousness of data and the scientific method can improve the decisions of policy makers and practitioners even in the absence of data. This is the promise of public health law research. At a moment when empirical health law has emerged from a general flowering of empirical legal research as a distinct scholarly field (Mello and Zeiler 2008), scientific research is a tie that can now bind law to public health. In this paper, we describe and chart a future for public health law research. Our discussion is occasioned by the launch of a major initiative by the Robert Wood Johnson Foundation to sponsor public health law research and expand the field (Robert Wood Johnson Foundation Public Health Law Research Program 2009). It is an opportune time to reflect on the field: its definition and boundaries; the types of research that a robust field of public health law research should include; and the challenges to be faced in growing and strengthening the field. (Although we are participating in the RWJF initiative as leaders of its National Program Office, this paper is about the field of public health law research generally, not the specific priorities or funding areas of the Public Health Law Research program.)

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Defining Public Health Law Research

We define public health law research (hereinafter "PHLR") as *the scientific study*

of the relation of law and legal practices to population health. This includes both direct relationships between law and health, and relationships mediated through impacts of law on health behaviors and other processes and structures that affect population health. In this section, we elaborate on this definition to distinguish PHLR from other fields and forms of public health law knowledge.

Distinguishing PHLR from Public Health Law

Lawrence Gostin's widely cited definition of public health law is "the study of the legal powers and duties of the state to ensure the conditions for people to be healthy (e.g., to identify, prevent, and ameliorate risks to health and safety in the population), and the limitations on the power of the state to constrain the autonomy, privacy, liberty, proprietary, or other legally protected interests of individuals for protection or promotion of community health"(Gostin 2000). Using this power/duty/restraint formula, Gostin succeeds in focusing the field on the state's role in managing collective action to protect population health, while still encompassing a diverse range of cooperating actors and related functions, including private actors and the health care system. His claims for public health law are broad enough to earn libertarian criticism: scholars have argued from diverse standpoints that Gostin and his colleagues in public health are expanding the jurisdiction of public health beyond its legitimate mission and into a realm of wrongful – and counterproductive – meddling in the autonomy of citizens (Epstein 2003; Hall 2003; Rothstein 2002). Yet for others this definition may be too narrow. Regulatory researchers, for example, question the importance of the distinction between public and private actors in health governance (Black 2008; Lobel 2004; Trubek 2006). Other commentators insist that public health law must include the role of law as a determinant

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and mechanism for the health effects of social and physical environments (Burris, Kawachi, and Sarat 2002; Magnusson 2007; Mariner 2009).

Debate over the boundaries of public health law plays out differently in the realm of public health law *research*. In defining PHLR, we are concerned not with what is right, proper or legitimate to include within the jurisdiction of public health law, but with whether law can be empirically shown to have an impact on the health of the population. Commentators might disagree upon whether equality, for example, ought to be considered a public health issue, but that is a different question than whether it is possible to empirically identify ways in which law affects health inequalities. Empirical data can be highly salient to disputes about normative concepts and positions, but do not in and of themselves resolve disputes about the legitimate scope of public health or public health law or the extent to which health promotion should be traded off against other social goods, such as civil liberties. PHLR, then, is distinguished from public health law by its focus on description, explanation, and prediction—that is, its focus on empirical investigation.

Research versus Scholarship

When we refer to "research," we intend a particular meaning: the use of systematic methods within an explicit theoretical framework to collect and analyze data. PHLR seeks methodological rigor in all phases of research, from carefully articulating and operationalizing theory through thoughtful and innovative study design, to analysis, interpretation, and dissemination.

PHLR includes both qualitative and quantitative studies using experimental, quasi-experimental, observational, or participatory designs. It ranges from health impact

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assessments gathering limited data on legal effects in order to inform policy making in real time, on the one hand, to complex experiments and quasi-experiments studying the effects of law on health over extended periods of time, on the other. Formal decision analyses, simulations, econometric analyses, laboratory and social experiments, survey, interview, and focus group studies, systematic reviews, and meta-analyses are included, as is legal research to systematically and reproducibly collect, classify, and quantify laws and judicial decisions for analytic purposes (Hall and Wright 2008; Tremper, Thomas, and Wagenaar forthcoming 2010).

Theory and methods may be drawn from a variety of disciplines in the social sciences, including epidemiology, biostatistics, law, sociology, history, political science, economics, anthropology and psychology. From the natural sciences, PHLR imports the scientific method, approaching research questions with a hypothesis to be tested rather than a position to be defended; gathering data for the purpose of proving or disproving the hypothesis (or disproving a null hypothesis); and reaching conclusions based on a careful and restrained analysis and interpretation of all relevant data.

Public health law research as we define it is thus distinguishable from public health law scholarship. “Scholarship” embraces a range of non-empirical but nevertheless valid and useful work about public health law, ranging from work grounded in philosophy or ethics (Ruger 2006), to doctrinal exegesis (Lazzarini and Rosales 2002) to the crafting of model laws, to legal analysis arguing how the law ought to be applied in various situations (Ruhl, Stephens, and Locke 2003). What we call PHLR does not exhaust all forms of knowledge gathering or analysis concerning public health law.

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Public health law scholarship includes many outstanding and influential works that have shaped the field of public health law, but do not fall within our definition of PHLR.

"Law" and "Public Health"

A key challenge in defining PHLR arises from the potential breadth of the definitions of "law" and "public health"(Magnusson 2007). In linking the two in PHLR, we take a broad sociological stance, encompassing not simply written laws on one side and morbidity and mortality on the other, but the whole range of institutions, practices and beliefs through which laws influence health and the determinants of health. This is particularly important given that the timelines for law to influence health may be long and data on key outcome variables scarce; it may be important to examine effects of law on mediating factors such as health behaviors. The key aspect of such a study, from the perspective of whether it is properly classified as PHLR, is that it examines the relationship between a law variable and a public health variable.

Social epidemiology, the branch of epidemiology aimed at understanding social determinants of health (Berkman and Kawachi 2000), provides a theoretical framework into which PHLR can readily fit (Burris, Kawachi, and Sarat 2002). Most things human beings do, and most characteristics of our environments, have some impact on the level and distribution of health in a population. Whether styled as health inequities or health disparities, differences in health among identifiable subpopulations have become a major concern in health and policy (Commission on Social Determinants of Health 2008). Health law scholars, too, increasingly recognize the need to examine individual interests and choices through the lens of population health, recognizing that "the choices individuals exercise and the health risks they face are determined, to a large degree, by

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the environments they experience and the populations they comprise"(Parmet 2009; Sage 2008). However, PHLR does not encompass the full scope of social epidemiology. We confine our definition of PHLR to the study of law and regulatory practices and not the full spectrum of contributing factors.

Another distinctive aspect of PHLR's conception of "law" is that it is not confined to "law on the books" – constitutions, statutes, judicial opinions, and so on. The mainstream of empirical legal research over the past thirty years has acknowledged the salience of law as it is implemented in practice and experienced by those it targets. Studies of legality or legal consciousness (Ewick and Silbey 1998), behavioral law and economics research (Jolls 2006), scholarship on compliance theory (Tyler 1990), scholarship on deterrence theory and tort law (Mello and Brennan 2002), and regulation and governance studies (Braithwaite, Coglianese, and Levi-Faur 2007) all explore this theme. PHLR is necessarily interested in the psychosocial mechanisms through which compliance is achieved (Tyler 1990), the range of regulatory techniques that may be deployed (Braithwaite, Coglianese, and Levi-Faur 2007), and how law "operates through social life as persons and groups deliberately interpret and invoke law's language, authority and procedures to organize their lives and manage their relationships" (Ewick and Silbey 1998) [at 20-23]. Law is fundamentally a social practice embedded in institutions and implemented by agents. It is part of, not distinct from, the social environment whose influence on health is the focus of social epidemiology.

PHLR also properly encompasses both laws that were intended to affect population health and laws that have unintended health effects. What has been referred to as "Interventional Public Health Law" is law or legal practices that are intended to

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influence health outcomes or mediators directly. Likewise, "Infrastructural Public Health Law" establishes the powers, duties, and institutions of public health (Moulton et al. 2009). But much of the law that influences population health was not adopted for that purpose, and may on its face seem to have no connection to health at all. For example, criminal laws aimed at controlling illicit drug use may increase the risk of users acquiring HIV (Friedman et al. 2006). Research that investigates the relationship of law and legal practices to population health falls within PHLR when it investigates health effects or otherwise deploys an explicit population health framework, whether or not the law itself is health-oriented on its face. We label this important category of PHLR "Incidental Public Health Law."

Finally, PHLR is distinguishable from other kinds of public health research in that it evaluates not merely the effectiveness of a public health intervention, but the effectiveness of *law* as the tool used to implement or facilitate the intervention. For example, research on whether abstinence-only education reduces teenage pregnancy is not PHLR merely because abstinence-only education happens to be required by law, but PHLR does encompass research on how abstinence-only education rules are implemented (Sonfield and Gold 2001) and whether the existence of state-level, abstinence-only legal mandates is associated with differences in state reproductive health outcomes.

Health Services Research and Public Health Systems and Services Research

It is useful to delineate relationships between PHLR and several contiguous domains of empirical research. Access to health care is an important determinant of population health, and health care is widely acknowledged to be a key component of the public health system (Institute of Medicine 2003). The study of how law affects

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population health through the mediating structure of the health care system falls squarely within the definition of PHLR. PHLR therefore overlaps with the field of health services research, "the multidisciplinary field of scientific investigation that studies how social factors, financing systems, organizational structures and processes, health technologies, and personal behaviors affect access to health care, the quality and cost of health care, and ultimately our health and well-being" (Academy Health 2009). The impact of law on racial disparities in cardiac care outcomes, for example, is an important question for both HSR and PHLR.

The area of overlap, however, is limited to research that focuses on *law* as an independent variable and population health (or an intermediate outcome with a well-demonstrated relationship to population health) as the outcome of interest. Research is not PHLR if it merely examines the impact of some element of health care organization, financing, or delivery on health, without an important connection to law—for example, a study of the effect of capitated reimbursement in private managed care plans on utilization of branded drugs.

Public Health Systems and Services Research (PHSSR) is an emerging field of study that "examines the organization, financing, and delivery of public health services within communities and the impact of those services on public health" (Scutchfield 2009). PHLR overlaps with PHSSR to the extent that law is an important factor in the organization of public health systems and agencies and the delivery of public health services (Henry, Scutchfield, and Perez 2008; Pérez and Larkin 2009). A study of racial disparities in the use of involuntary civil commitment, an important legal tool for public health, could be considered both PHSSR and PHLR to the extent it focuses on how the

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organization or operation of civil commitment influences the outcomes the system produces(Swanson et al. 2009). Conversely, PHSSR that examines the flow of resources to and within the public health system (Mays and Smith 2009), though it might well inform PHLR on the implementation of a legal intervention, would not itself be PHLR.

One feature of PHLR not shared by PHSSR or health services research is its consideration of incidental public health law—that is, the effects on population health of law, agencies, and private actors not commonly understood to be pursuing a public health mission. For instance, a growing body of cross-disciplinary research centers on the effects of criminal laws and the practices of criminal justice agencies, such as the police, on the spread of communicable disease (Burris et al. 2004). Research on this topic would fall under PHLR but not HSR or PHSSR.

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A Logic Model of PHLR

A wide range of laws and legal practices affects the health of the population in cities, counties, states and nations. Cataloging all such possible effects of law is impossible, and any schema for organizing such effects is characterized by tradeoffs and simplifications. Nevertheless, the field of PHLR is advanced by a shared understanding of the range of possible effects of laws, and potential mechanisms for such effects, encompassed within the field.

The range of studies that empirically evaluate the effects of law on population health is depicted in Figure 1. Generally, the independent variable in PHLR will be some aspect of lawmaking, laws, or the activities of legal agents. These will be studied in relation to dependent variables that can be arrayed along the presumed causal chain that

includes key mediators as well as the distal or ultimate outcomes of interest—population morbidity and mortality.

//Insert Figure 1 about here//

First are studies of policy making—the factors that influence which laws are enacted and that shape the specific characteristics of the statutes and regulations adopted (path A in Figure 1). In these studies, public health laws (or judicial decisions) themselves are the outcome variable and political and other jurisdictional characteristics are often the key explanatory variables tested.

Paths B and C examine key mediators in the causal chain linking laws and health outcomes. Studies of legal practices (path B) focus on the implementation or enforcement of the law on the books, including how the law affects the structure or operation of various regulatory systems. Laws may vary considerably in the degree to which they are effectively implemented; for example, whether a legal mandate for health education in schools translates into all pupils receiving the education that legislators envisioned may depend critically on the appropriation attached to the bill. There are opportunities and resources for litigation in some matters and not others. Unfunded mandates, unclear statutory provisions, the failure to identify an administrative agency responsible for issuing implementing guidelines and overseeing rollout of the new legal provisions, lack of political commitment, and many other factors may undermine implementation. Similarly, laws may induce varying levels of compliance on the part of the regulated entities or population, depending on the degree of political resistance, the extent to which the administering agency is armed with effective enforcement mechanisms, the litigation environment, and many other factors. The completeness of

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implementation and the effectiveness of mechanisms for ensuring compliance with the law are critical elements influencing the law's effect on health outcomes. Legal practices studies explore these influences as mediators of the statute or regulation's impact on health.

Path C involves study of the effects of the law (as implemented through legal practices) on environments and health behaviors. We use the term "environment" broadly to refer not only to the physical environment, but also social structures and institutions. Even institutions that are private, such as corporations or the family, are deeply influenced by law. Laws and their implementation affect social institutions and environments by creating or reducing opportunities, increasing or decreasing available resources, expanding or reducing rights and obligations, and creating incentives and penalties. Research in this area examines these mechanisms of influence and how they shape the conditions for people to be healthy.

Law may affect health behaviors both directly and by shifting the environmental conditions that make particular behavioral choices more or less attractive (path D). For example, land use laws may influence where supermarkets and restaurants are located, affecting the availability of healthy food options and the healthfulness of the diet of local residents. Ultimately, changes in environments and behaviors lead to changes in population-level morbidity and mortality (path E).

PHLR may examine health outcomes directly or may use mediating environmental and behavioral changes as proxy outcome variables. While directly measuring health effects is generally desirable because it provides more information to policy makers about the public health returns to lawmaking, a focus on mediating factors

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is often appropriate. For example, laws designed to improve rates of immunization with the human papillomavirus (HPV) vaccine might best be evaluated in terms of their effects on the prevalence and burden of cervical cancer, but the time horizon for observing such effects is on the order of forty years. Consequently, measuring rates of HPV vaccinations is a reasonable intermediate measure.

PHLR in Practice

The contours of PHLR as a distinct field are only beginning to emerge. Based on the extant scholarship in the field and the conceptual model we have described, it is possible to generate a typology of the principal forms of PHLR studies (Table 1). In this section, we describe the major methodological approaches that are relevant to studying each of the paths described above.

Policy Making Studies

Studies of policy-making processes are a mainstay of political science and sociology. They explore issues such as the determinants of legislative, administrative and judicial lawmaking (Law 2005; McDougall 1997; Waters and Moore 1990); lawmaking processes (Rosenberg 1991); and stakeholders' use of law to achieve their goals (McCann 1994). Although in broad terms the policy process does not vary by topic area, health policy making has generated a substantial research literature focusing on how generic policy-making processes unfold in a health context. This literature treats policy-making processes as among the legal practices that affect the potential for law to promote health.

Advocacy groups have traditionally been crucial instigators of health law, and researchers of "legal mobilization" have studied how advocates have integrated

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legislation and litigation into their strategies (Ashe et al. 2003; Mamudu and Glantz 2009). The relative advantages of litigation versus legislative approaches have been investigated empirically and debated in PHL scholarship (Jacobson and Soliman 2002; Jacobson and Warner 1999; Parmet and Daynard 2000; Wagenaar 2007), as have the factors influencing legislative outcomes and the legislative process (Backstrom and Robins 1995; Corrigan et al. 2005). Of particular interest for PHLR are studies that examine how research evidence influences policy makers (Cochrane Collaboration 2009; Innvaer et al. 2002; Jewell and Bero 2008; Lavis et al. 2008b)Chalkidou, 2009 #7684}. Other work has examined the behavior and strategies of policy actors; for example, how they use devices such as preemption and litigation to shift policy battles into fora where they have a greater expectation of success (Jacobson and Wasserman 1999), how community organizations may be brought more effectively into the lawmaking or law enforcement process (Tyler and Markell 2007), or how consulting can be used to more effectively translate research knowledge for policy makers (Jacobson, Butterill, and Goering 2005). There has been growing interest in the question of how model laws are developed for public health purposes, and whether and under what circumstances model legislation is more likely than other proposals to be enacted (Hartsfield, Moulton, and McKie 2007).

Both quantitative and qualitative methods may be appropriate for policy-making studies. Econometric analysis is useful for examining the extent to which various observable characteristics of a state or local government—for instance, the political party in control of the legislature and the health status of the population—predict the likelihood that a particular kind of law will pass. For example, researchers have used multivariate

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regression to examine predictors of state legislative action on childhood obesity (Boehmer et al. 2008; Cawley and Liu 2008). Such research may make important contributions by identifying "friendly" venues for experimentation with new public health law approaches and suggesting strategies for spreading successful strategies to other jurisdictions.

For obtaining a rich understanding of the policy-making process, qualitative methods are unmatched. Interview methods are commonly and effectively deployed to understand the factors that lead policy makers to take or fail to take particular actions. Researchers have, for instance, conducted key informant interviews with state legislators and their staff to examine factors enabling and inhibiting the passage of obesity prevention laws (Dodson et al. 2009). Content analysis is another useful method of exploring political deliberations that occur "on the record"—for example, legislative hearings and debate concerning particular public health issues or legislation, and the notice-and-comment process of administrative agency rulemaking. Researchers have used content analysis to explore, for example, the use of evidence and argumentation in debates over workplace smoking legislation (Apollonio and Bero 2009; Bero et al. 2001). Although it may be difficult to generalize the results of qualitative studies across jurisdictions, the high-resolution picture of the policy-making environment that they provide can have great value in formulating strategies for advancing evidence-based public health law.

Mapping Studies

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PHLR includes studies that gather purely legal data for empirical purposes: information about the prevalence and distribution of specific laws (Gostin et al. 1996; Hodge et al. 2008), what levels of government have relevant authority (Horlick, Beeler, and Linkins 2001), and variation in characteristics of the law across jurisdictions and over time (Center for Disease Control 1999; Chriqui et al. 2008; Shaw et al. 2007; Wells, Williams, and Fields 1989). Methods may include content analysis of legal texts (laws, regulations, court decisions, etc.), qualitative research designed to elicit information from officials and others who are knowledgeable about the state of the law, or a combination of the two approaches (Horlick, Beeler, and Linkins 2001). Although no independent/dependent variable relationship is studied, these studies can be scientific–and therefore fall within the field of PHLR–if they involve the systematic collection and analysis of data using replicable methods.

Mapping studies often contribute information that is useful in its own right—state and local policy makers are keen to know what other jurisdictions are doing and what they might consider borrowing or learning from policy experiments in other jurisdictions. However, mapping studies are typically an early phase of larger projects designed to evaluate the magnitude and nature of the effects of laws on health. Properly conducted, they provide for the reliable and valid measurement of the key explanatory variable(s) in such studies. Thus, a rigorously conducted mapping study will follow a systematic review protocol. It will specify a definition of the type of law being investigated, perhaps with explicit inclusion and exclusion criteria; a search methodology that acknowledges the strengths and weaknesses of extant databases; and a coding scheme identifying key features of the laws, such as the population covered and enforcement mechanisms

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specified (Tremper, Thomas, and Wagenaar forthcoming 2010). They may also characterize laws according to some overall scale of stringency, scope, or strength through transparent and reproducible means. For example, a recent mapping study of state laws regulating sales of sugar-sweetened beverages in schools coded laws according to 7 substantive features and 8 process features and then grouped laws into "strong", "moderate", and "weak" categories (Mello, Pomeranz, and Moran 2008). We stress that analysis of this kind, though essential to empirical legal research, does not exhaust legal scholarship on laws, eliminate the serious challenges that are often entailed in interpreting what the law "is," or replace serious discussion of what the law ought to be.

Implementation Studies

For a law to be effective, its implementation must be such that it will actually influence the behavior of its targets. The process of putting a law into practice can be understood in terms of a series of mediating factors, including the attitudes, management methods, capacities and resources of implementing agencies and their agents; the methods and extent of enforcement; the relationship between the legal rules and broader community norms; and the attitudes and other relevant characteristics of the population whose behavior is targeted for influence. The text of the law and the resources appropriated for its enforcement constrain, but do not eliminate, the discretion of bureaucratic entities to reshape the rules to fit their existing culture and mission (Deflem 2004).

Implementation research classically starts with investigating the "transformation process" that occurs along path B in Figure 1, the differences between the goals and methods of the law as explicitly or implicitly contemplated in the "law on the books" and

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the “law on the streets” actually put into practice by legal agents charged with enforcing the law (Percy 1989). Case studies or other analyses of how health agencies have organized their mission or performed in a given mission are a common form of implementation research (Buehler, Whitney, and Berkelman 2006) and often look at the question of what legal powers an agency had or how it used them (Lawson and Xu 2007). Creative compliance and outright resistance on the part of the targets of regulation is also studied (Nakkash and Lee 2009). Implementation research in PHLR includes studies of the relationship between “legal infrastructure,” legal or other competencies, and agency function (Kimball et al. 2008). Such studies may examine effects of law on private agencies operating under a legal authorization, such as the effect of legal authorization on syringe exchange programs (Bluthenthal et al. 2007). Implementation researchers will also measure proximate outcomes of new rules that may provide an early indication of their true behavioral effects—for instance, the actual speeds observed on highways after a change in the nominal speed limit (Retting and Cheung 2008).

Research on legal practices in PHLR may investigate the means through which systems may be better governed or regulation better designed in order to achieve their goals. Although it has as yet had little impact on PHLR, the study of techniques of regulation and governance has become an important part of empirical legal research and scholarship (Ayres and Braithwaite 1992; Croley 2008; Moran 2002; Rhodes 1997). For nearly three decades, regulation in the U.S and many other developed countries has exhibited an increasing pluralism, not just in spreading of regulatory functions beyond government to private parties and public-private hybrids (Burris, Kempa, and Shearing 2008; Lobel 2004; Osborne and Gaebler 1993), but also in the use of a wide range of

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strategies beyond detailed rules backed by carrots and sticks (Parker and Braithwaite 2003). Contemporary regulators use cooperation, deliberation, education, competition and other "soft" strategies that can be more effective than traditional command-and-control bureaucracy (Lobel 2004). Theory and research in governance have highlighted the importance of actors outside of government–such as advocacy groups, corporations, and gangs–in managing the course of events in social systems, and investigated how these actors regulate governments and each other (Buse and Lee 2005; Scott 2002).

New regulatory and governance approaches have raised a fascinating range of empirical questions, from the role of audit as a compliance tool (Power 1997) to the design and effectiveness of public/private and self-governing regulatory structures (Gunningham 2009; Ostrom 2005). This work resonates with research in behavioral law and economics, captured in Sunstein and Thaler's best-seller, *Nudge*, which describes how regulators can creatively structure options to systematically influence behavior by means other than simple legal rules (Sunstein and Thaler 2008).

Because so much regulation is now conducted outside of traditional bureaucratic frameworks (and indeed outside of the government), scholars working in this area begin with a generic definition of regulation and its constituent elements. "Regulation" is the "sustained and focused attempt to alter the behaviour of others according to defined standards or purposes in order to address a collective issue or resolve a collective problem"(Black 2008). It uses a combination of basic strategies of control, including standard setting, monitoring, and enforcement (Scott 2001). The use of these strategies can be studied regardless of the particular mode through which the regulatory task is accomplished, and without regard to what sort of entity is performing it (Braithwaite and

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Drahos 2000). This analytic approach allows researchers both to better capture the regulatory role of actors outside of traditional regulatory agencies–for example, the role of Mothers Against Driving Drunk in fostering stronger social norms condemning drunk driving–and to offer more creative approaches to regulation, as exemplified by *Nudge* and other works of behavioral law and economics (Lobel and Amir 2009).

Although research in regulation and governance has been limited in public health law (Biradavolu et al. 2009; Burris 2008; Trubek 2006), its applicability is plain (Magnusson 2009). Public health services are provided by a diversity of public and private actors and private entities play an important role in practicing and promoting standards of healthy behavior and health-promoting practices (Institute of Medicine 2003). We recognize that complex systems like health care cannot simply be managed by top-down rules, but require the use of a range of flexible tools, like professional self-regulation, ethics, accreditation, collaborative and deliberative decision-making, continuous quality improvement, and market incentives (Braithwaite, Healy, and Dwan 2005; Brennan 1995; Lobel 2004; Trubek 2006). Internationally, health governance has been dramatically altered by the rise of new public/private hybrid institutions like the Global Fund to Fight AIDS, tuberculosis, and malaria, the enormous wealth of the Gates Foundation, and the consolidation of authority over national health, safety, and intellectual property law in the World Trade Organization (Hein, Burris, and Shearing 2009; McCoy and Hilson 2009). The Framework Convention on Tobacco Control is a typical instance of the "soft law" approach, setting broad goals for national action but minimizing binding rules in favor of deliberation and flexibility. Legal scholarship has

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begun to explore the "constitutional" implications of these structural changes (Fidler 2004), but they have not been extensively investigated in PHLR.

Intervention Studies

Intervention studies evaluate the intended and incidental effects of legal interventions on health outcomes or key mediating factors that drive health outcomes. They may focus on "law on the books"—for example, examining the effect of states' passage of graduated drivers license statutes on rates of injury-causing crashes (Foss, Feaganes, and Rodgman 2001)—or on legal practices, such as the effect of issuing restraining orders against perpetrators of domestic violence on future victimization (Harrell and Smith 1996). Intervention studies can be deployed to evaluate interventional health law, but also to investigate the health effects of public health's legal infrastructure and the unplanned impact of what we have called incidental public health law. Intervention studies lay at the heart of PHLR, as they most directly address the core question of the field: when it comes to using legal tools to promote health, what works?

Intervention studies can draw from an extensive methodological toolkit (Table 1). The strongest designs are experimental or quasi-experimental designs employing careful controls. Variation in how and when laws are implemented from jurisdiction to jurisdiction provide a rich set of opportunities for quasi-experimental studies, although sophisticated methods may be required to account for other ways in which jurisdictions may differ from one another. Useful study designs and analytical methods for this purpose can be borrowed from the fields of econometrics and epidemiology (Ludwig and Cook 2000). Real-world, randomized experiments are extremely rare, but have been employed to study judicial-branch reforms such as specialized courts (Gottfredson,

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Najaka, and Kearley 2003). Experimental studies can also be carried out using simulations, such as tabletop exercises (Dausey, Buehler, and Lurie 2007; Hupert, Mushlin, and Callahan 2002; Lurie et al. 2004).

There is already a substantial evidence base investigating the effectiveness of interventional public health law, ranging from single studies through literature reviews to meta-analyses and systematic reviews conducted by entities like the Campbell Collaboration (Campbell Collaboration 2009) and the U.S. Task Force on Community Preventive Services (The Community Guide 2009). There is also a rich, if less well organized, research literature on incidental public health law. For example, researchers have studied the unintended consequences of HIV reporting laws on attitudes towards testing, time of testing, and willingness to be tested (Hecht et al. 2000; Tesoriero et al. 2008). Research on the health effects of infrastructural health law has been more limited.

Consistent with ecological models in public health, intervention studies may investigate how laws influence health by changing environments. For example, zoning rules, clean indoor air laws, and laws regulating the condition of rental properties can directly shape residents' exposures to noise, environmental toxins, and stress, as well as their activity patterns, social connections, collective efficacy, and many other factors that appear to influence population health outcomes (Browning and Cagney 2002; Maantay 2002; Schilling and Linton 2005). Occupational health and safety laws affect workers' exposure to hazardous conditions on the job. Product regulations protect consumers from a range of hazards arising from the use of products, from herbal supplements to firearms (Larsen and Berry 2003; Robson 2007; Vernick and Teret 2000).

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Interventional research focuses not only on how the law changes physical environments, but also how it may change the social environment in ways that affect health or health behaviors. Law may shape people's health knowledge and attitudes, the way they perceive the risks and benefits of different choices, the frames through which they view particular choices, and the social norms against which their health decisions are set. PHLR can measure any or all of these dependent variables, as well as changes in health behaviors. There are many examples: research on the effects of indoor smoking prohibitions on social expectations about exposure to secondhand smoke in public (Kagan and Skolnick 1993); the effect of laws requiring disclosure of calorie information on restaurant menus on consumers' awareness of calorie content and attitudes about the role of calorie information in food purchasing decisions (Bassett et al. 2008); and the effect of punitive laws concerning substance abuse during pregnancy on the prenatal care seeking behavior of pregnant women (Poland et al. 1993), to name a few.

Finally, intervention research can illuminate policy choices under conditions of uncertainty. When problems or policy responses are new, there will naturally be little or no intervention research directly on point. Policy making can still be informed by evidence about analogous policies or by an understanding of how law typically works to influence environments and behaviors, although all analogies are, of course, imperfect proxies for the situation at hand. An example is the area of legal restrictions on cell phone use by drivers. Although public health research recently has provided good evidence of the injury risk associated with this behavior, evidence about the effectiveness of different legal and policy approaches to the problem is not yet available. Until it is, lawmakers seeking to respond to what is clearly a significant health risk might be guided by the

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lessons learned about the design and enforcement of laws requiring seatbelt and helmet use and prohibiting driving under the influence of alcohol. Health impact assessment has also emerged as useful way to use mixed methods to develop and inform policy decisions with reliable data on possible effects, intended and unintended (Collins and Koplan 2009; Lee et al. 2007; Mindell et al. 2004). Finally, Monte Carlo simulations, widely in use in the field of decision science but rarely used in PHLR (Studdert et al. 2007), offer an intriguing method for accounting for uncertainty about multiple parameters of importance to evaluating the likely effect of law.

Mechanism Studies

To advance the field, we not only need to have more evidence of law's health effects, but a greater understanding of *how* law has the effects it has. There are a number of reasons this is important. Evidence of mechanisms strengthens specific causal claims. Understanding how a particular intervention influences environments and behavior facilitates identification of further interventions, or of alternatives to eliminate superfluous requirements or unintended side effects and strengthen the mechanisms that are working. The better we understand how law works, the better we can deploy it, replicate its successes across jurisdictions, and extend its approach to other kinds of health risks. Informed by theories of health behavior, PHLR can develop and test models to explain the manner in which public health law effectuates change in health behaviors and ultimately health outcomes.

At the most basic level, laws encourage healthy, safe, and socially beneficial behaviors and discourage unhealthy, dangerous, and socially deleterious ones by shaping incentives (rewards) and deterrents (punishments). Though the theory may be simple, the

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process is not. There are myriad levers and tactics that regulators can use to influence behavior directly or through manipulation of the environment, and each choice in a regulatory system can and should be studied for its effectiveness, both in absolute terms and relative to less burdensome alternatives. Among the mechanisms listed in a typology developed by Lawrence Gostin are taxation and subsidies, changes in the information environment, changes in the built environment, and signals sent by tort litigation (Gostin, Thompson, and Grad 2007).

With respect to laws imposing outright prohibitions on particular behaviors, many of the key research questions relate to mechanisms of implementation and enforcement: What penalties are applied to violators of legal rules? What processes are used to detect violators? With what degree of certainty and swiftness will sanctions ensue from a violation? Sociolegal research drawing on disciplines such as psychology, criminology, and sociology has a great deal to contribute to mechanism studies in PHLR. The psychological literature has explored contingencies of reinforcement, criminologists have fleshed out the factors influencing deterrence, and sociology research has plumbed the normative effects of standard setting. Tom Tyler's influential work, for example, has shown the importance of experiences of procedural fairness to compliance with law (Tyler 1990).

A classic example of compliance research in public health law is investigation of primary versus secondary enforcement of seatbelt laws. Primary enforcement laws permit police to pull over motorists for not wearing a seatbelt, while secondary enforcement laws permit policy to issue a ticket for not wearing a seatbelt only when the motorist has been pulled over for another reason. Because secondary enforcement relies

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primarily on social norms to enforce seatbelt use, with the threat of a ticket serving a greatly subordinate role, studies comparing these approaches to enforcement are essentially a test of the relative effectiveness of punishment versus social norms as a means of encouraging compliance (Dinh-Zarr et al. 2001). Among the most interesting findings of this PHLR is that the relative benefits of primary enforcement laws varied across population subgroups, with the greatest marginal benefit observed for groups that tend to have lower rates of seatbelt use, including males, young people, African Americans, and American Indians (Beck et al. 2007).

These and other studies make clear that deterrence is a complex phenomenon. The deterrent effect of law often seems to be assumed, without appreciation of the factors that will influence whether a person's behavior will be influenced by a fear of detection or punishment. Threat of fines may have a different effect than threat of jail (Wagenaar et al. 2007). Deterrence may be weak or incomplete because people are ill informed about what the law requires, because they do not believe violation will result in a sanction, because they are insulated from the adverse effects of a sanction (for instance, by insurance coverage), or because the sanction is not strong enough to outweigh the perceived benefits of noncompliance with the law (Mello and Brennan 2002). Uncertainty about legal standards can also have the opposite effect, fostering overcompliance in an attempt to avoid sanctions (Mello et al. 2006). Mechanism studies can examine all of these phenomena. Survey methods, interviews, focus groups, and formal decision analysis can be used to deconstruct how people think through the costs and benefits of different actions. Analysis of administrative data on enforcement actions

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can shed light on the degree to which popular perceptions reflect what actually happens when a law is transgressed.

Another variable of interest in mechanism studies that focus on compliance with legal rules is the perceived legitimacy of the body imposing the legal rule. Weber classically tied obedience to law to the acceptance of the legitimacy of the system. Even people who are aware of the law may not trust the system, or may see strategies other than compliance as more useful to them in achieving their goals (Burris 1998). Studies of the perceived legitimacy of public health lawmakers and law enforcers may be particularly useful in understanding differences in compliance across population groups whose historical experience in the U.S. has led to different levels of trust in government.

Mechanism studies may also focus on understanding how law shapes behavior in ways more subtle than outright prohibitions. How do regulatory tools such as taxes and subsidies, mandated disclosure or receipt of information, default rules, accreditation and certification, and delegations of authority to private institutions shape how individuals and organizations behave? When are these alternatives more effective and desirable than traditional, command-and-control regulation utilizing rigid rules and penalties? For many of these forms of regulation, understanding the cognitive biases and heuristics that affect individual decision making about risk is critical (Kahnemann, Slovic, and Tversky 1982) and empirical research can examine how these biases operate to influence health outcomes.

PHLR takes a number of forms, each utilizing diverse methods (Table 1). By illuminating the paths we have delineated in our logic model, these forms each play

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important roles in establishing how law is being deployed to promote population health, and how and to what extent it is achieving its intended purpose.

Challenges Facing PHLR

We have argued that PHLR is a distinct and important field of research, but it faces a set of challenges shared with social research of other kinds. These include increasing methodological rigor, assuring adequate research funding, identifying data sources, expanding the knowledge base about mediators of health outcomes, and ensuring the impact of PHLR on policy. We describe how each of these challenges takes shape in PHLR and explain why we are optimistic that they can be met.

Increasing Methodological Rigor

PHLR is part of a recent "explosion in empirical work" in law (Pfaff 2009). Some are concerned that legal scholars are producing empirical work faster than the field can create the mechanisms necessary to assure its rigor (Pfaff 2009). The fact that much PHLR is published in peer-reviewed health journals helps avoid one of the major problems confronting empirical legal studies more generally—the rarity of peer and expert editorial review in law journals. But the further the development of PHLR as a distinct field within empirical legal and public health research will be instrumental to defining and maintaining high standards of scientific rigor.

One challenge is how to draw new investigators with the right expertise into the field. Perhaps to a greater extent than other areas of empirical legal research, PHLR must grapple with how to integrate individuals who are primarily practitioners into the field. Their involvement in PHLR can improve research in many ways: practitioners bring an

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intimate knowledge of what the cutting-edge public health problems are and of the practical realities of policy making and implementation, and they constitute a pipeline for putting research into practice. However, they typically lack both significant training in research methods and experience conducting empirical research. Similarly, even methodologically expert health researchers often lack any grounding in empirical legal scholarship, hampering their ability to conceptualize or measure legal influence on environments, behavior or health outcomes.

The involvement of traditional legal scholars in PHLR raises similar challenges. Among the assets they bring to PHLR are a commitment to thinking deeply about the law's form, evolution, and function; the capacity for nuanced argument in favor of or against particular legal approaches; and an appreciation of how social values and other normative considerations guide the law's path. Among the things they typically lack are expertise in quantitative methods, an allegiance to the scientific method, and an inclination to think about qualitative data collection and analysis in systematic terms.

These shortcomings are surmountable through greater interdisciplinarity. Increasingly, law faculties are experiencing a "PhD-ification" (Pfaff 2009), bringing aboard junior scholars dually trained in law and economics, political science, or another social science discipline. These scholars are well-positioned to transition from empirical legal studies generally to PHLR specifically. Even more promising is the trend toward pursuing PHLR in multidisciplinary teams. Research partnerships between practitioners and scholars represent the future of the best research in this field, and interdisciplinary collaborations of scholars will become the "standard of care" very soon. Team-based approaches preclude the need for traditional legal scholars and practitioners to climb the

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steep learning curve necessary to conduct highly rigorous quantitative and qualitative investigations. At a minimum, however, these scholars and practitioners should receive enough training in empirical methods to be able to be informed consumers of empirical studies and active participants in team decisions about study design.

Another challenge relating to methodological rigor—one that cuts across fields of social-science research—is how to adequately control for confounding variables in observational studies. This is particularly difficult in intervention studies that exploit cross-sectional variation in state laws, because states differ in so many other ways, many of which are not captured in data (Mello and Zeiler 2008). Such studies are usually retrospective, relying on extant data, rather than employing prospective designs that collect data on all important variables. Statistical techniques such as fixed-effects models and difference-in-different models provide a means of minimizing this problem in repeated cross-section studies, though analysts need to carefully consider whether such designs are appropriate given the nature of their data. Prospective studies and/or studies involving original data collection are an even stronger approach to the problem, but are expensive, time consuming, and not feasible for studying some public health law questions.

Yet another methodological challenge for the field relates to the interpretation of empirical findings. Empirical legal studies scholars have lamented the limited development of approaches for dealing with the problem of induction. The field of epidemiology has developed and refined tools for evaluating when it is appropriate to draw causal inferences from statistical associations, but the same cannot be said for empirical legal studies (Pfaff 2009). The temptation to infer causality from association,

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or even to infer association from observation of small, non-systematic sample of actors or jurisdictions, has been problematic in PHLR. Here, PHLR can and should draw on epidemiology: Sir Austin Bradford Hill's classic work on indicators of causality in environment exposures and disease, for instance, is useful in a broad swath of observational work (Hill 1965). Addressing the question, "What aspects of that association should we especially consider before deciding that the most likely interpretation of it is causation?" Bradford Hill listed strength, consistency, specificity, temporality, "biological gradient" (a dose-response relationship), biological plausibility, coherence with known facts, availability of experimental evidence, and availability of analogous phenomena.

As the factors inhibiting greater rigor are gradually overcome, PHLR will move from its current state, in which simple descriptive studies, non-systematic qualitative work, and overly simplistic regression modeling are common, to greater use of more sophisticated study designs. This process will be guided by the application of methodological standards developed in related fields of research. For example, the Society for Prevention Research has identified a set of criteria for judging whether laws and policies aimed at disease prevention are efficacious, effective, and ready for dissemination (Flay et al. 2005). The U.S. Preventive Services Task Force has developed a rating system for the strength of evidence for preventive health measures provided by different types of study designs, ranging case reports to randomized controlled trials (Harris et al. 2001). The Campbell and Cochrane Collaborations are highly informative examples of how work in PHLR can be systematically evaluated and, through this evaluation, spurred to higher levels of rigor (Campbell Collaboration 2009; Cochrane

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Collaboration 2009). The process will also be driven by the increasing extent to which PHLR scholars view themselves as a professional community engaged in the process of stimulating, collaborating in, and critiquing one another's work. Ultimately, a clear professional identity for the field will emerge, and at its core will be a commitment to the disciplined application of the scientific method and most sophisticated methodological approaches to study public health law questions.

Assuring Adequate Research Funding

Collecting, analyzing and communicating research data all cost money. Although the problem of securing research funding is not unique to PHLR, it poses special problems in that field because many public health law researchers work in soft-money environments and extramural funding for PHLR is sparse. The recent commitment of The Robert Wood Johnson Foundation (RWJF) to building PHLR represents a milestone in the evolution of the field. First through its overall public health law portfolio (which has also included support for policy-related initiatives like the Substance Abuse Policy Research Program, Healthy Eating Research, Active Living Research, and PHSSR) and now through its program in Public Health Law Research, RWJF has supported PHLR at an unprecedented level. Previously, researchers relied on small programs such as the National Science Foundation's Law and Social Science program and the Centers for Disease Control and Prevention's (CDC's) short-lived Public Health Law research opportunities, or attempted to shoehorn legal research projects into health research solicitations—for example, NIH and CDC requests for proposals on drug addiction or injury prevention. While these attempts have often been successful, they have limited the researchers' ability to frame research questions to address the core areas of inquiry of

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PHLR, and they have precluded ready identification of studies that constitute the PHLR literature across a wide array of health topics. The RWJF initiative will not only pay for research, but also build the field of PHLR by stimulating new investigators to enter the field, bringing researchers together, signaling what constitutes rigor in the field, and gathering together PHLR studies across diverse topics and methods.

The question of sustainability does arise, however. A longer-term and more broad-based commitment on the part of research sponsors is needed to support the continued flourishing of the field. This is most likely to occur if public health law researchers give generously of their time to educate sponsors and policy makers as to the significance of the problems the field addresses as well as researchers' ability to provide useful, credible answers. Empirical research examining how research influences policy has emphasized the centrality of relationships between researchers and their audience (Lavis et al. 2008a). We hope that, over time, law and policy studies will become seen as a core component within all public health research solicitations, the way ethics is increasingly viewed in the context of genomic, cancer, and other population health research.

Identifying Data Sources

Although a wide array of datasets on health risk exposures, health behaviors, and health outcomes is available, data on health laws are much harder to find (Hadfield 2006) (Heise 1999; Mello and Zeiler 2008). Unlike many other areas of public health research, public health law and policy research has developed few surveillance systems (Brownson et al. 2006; McGowan et al. 2003). Gathering information on the patterns of public health law adoption and implementation across states and local governments over time generally

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is done *de novo* in each research project.

Maintaining and updating databases of laws would dramatically improve researchers' ability to conduct rigorous policy making, 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 datasets at reasonable marginal cost. In the few instances in which such databases have been made available—for example, Ronen Avraham's contribution of a database of state tort reforms, funded by the National Science Foundation (Avraham 2006)—they have enjoyed wide uptake by researchers and quickly become the gold standard source of data in that area of research.

Such examples point to three measures that would help bridge the data gap in PHLR. First, research sponsors need to provide funding for database compilation. Second, database architects need to develop and share systematic protocols for finding and classifying relevant laws and regulations. These protocols are best developed in consultation with other researchers in the field so that definitions and typologies are widely recognized as appropriate and suitable for use in other studies. Third, databases need to be made publicly available and easy to locate online. .

A final measure that would contribute to the available data resources for PHLR is better linkages between researchers and public and private holders of relevant data. Hospitals and clinics, public health agencies, insurance companies, and product manufacturers are just some of the entities that hold a treasure trove of data relevant to PHLR. Building trust with these data holders, so that they feel confident that shared information will be appropriately safeguarded and research findings responsibly reported,

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takes time and care, but is well worth the effort. The widespread adoption of standard protocols for use, protection, and reporting of proprietary data could help establish trust, but much will remain dependent on carefully cultivated personal relationships.

Promoting Uptake of PHLR Findings by Policy Makers

The most fundamental challenge confronting PHLR is an all-too-common one in research: rigorous research may be relevant to policy in theory, but too often is neither salient nor useful to policy makers and advocates in practice. The elements of the problem are well documented. Researchers are often isolated from the policy process and disconnected from policy makers and public health practitioners, making it difficult for them to identify salient topics for study and produce knowledge that can both respond to policy makers' concerns and drive policy agendas toward evidence-based innovation (Brownson, Chriqui, and Stamatakis 2009). Academics tend to follow their own interests and, in policy makers' eyes, often do not successfully anticipate where policy agendas will be in the short- and medium-term (Jewell and Bero 2008). Rigorous research–not to mention peer review and publication–take time, but policy actors need information when they need it. Even when results are available, a lack of understanding of policy makers' perspectives, time constraints, and level of scientific literacy hampers researchers' ability to craft research reports that are likely to be read and understood by the policy and practice communities (Jewell and Bero 2008). Policy makers, for their part, report being overwhelmed by the volume of information presented to them, particularly the quantity of dense, detailed material (Sorian and Baugh 2002). State legislators face particular challenges due to their lack of research training, the breadth of issues they must be knowledgeable about, the short timelines involved, the high turnover of legislators and

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legislative staff, and the leanness of legislators' staff and resources (Jewell and Bero 2008).

Solutions, like the problems, are not unique to PHLR (Greenhalgh et al. 2004; Mitton et al. 2007). Transferring knowledge from research to policy generally requires careful attention to a set of key questions: What precisely is the information to be transmitted? Who exactly are the targets? Who are the best messengers? What media can most effectively be used to transfer the knowledge? For what purposes, exactly, is the information likely to be used (Lavis et al. 2003)? Commentators emphasize the importance of ongoing contact between research producers and research consumers (Innvaer et al. 2002; Lavis et al. 2008a). Systematic reviews are repeatedly identified as an effective strategy for distilling a large evidentiary field into useable format (Fielding and Briss 2006; Jewell and Bero 2008; Lavis et al. 2003; Moulton et al. 2009; Robert Wood Johnson Foundation 2009; Sweet and Moynihan 2007; The Community Guide 2009). Policy briefs and other translational materials should be geared for the recipient and should "concretize impact"—that is, delineate specific benefits, harms, and costs, including the specific populations affected, and how particular policy strategies can alter them (Jewell and Bero 2008; Sorian and Baugh 2002). Nor does the entire responsibility lie with researchers. Effective practices have also been identified for organizations engaged in knowledge transfer (Lavis et al. 2008b).

Training and mentorship within the field can move PHLR towards these practices, as can hands-on experience when researchers spend time working in policy settings. But there are no panaceas here. Even when research findings are effectively communicated to policy makers, a variety of forces can get in the way of policy makers' ability and

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willingness to translate evidence into policy proposals. Among these are the influence of interest groups, the power of anecdotes that run contrary to research findings, force of habit, cultural norms and values, and political compromises and expediency (Brownson, Chriqui, and Stamatakis 2009; Brownson et al. 2006; Jewell and Bero 2008).

At some level, there is little researchers can do to overcome these forces. However, well-designed translational materials and strategies that reflect an understanding of the constraints policy makers face certainly have a greater chance of carrying the day than research reports that are physically and cognitively inaccessible to policy makers. Additionally, building strong relationships with public health law practitioners can help ensure that researchers and their work are responsive to practitioners' needs. When the streams of problem, policy and politics merge, events often move quickly (Brownson, Chriqui, and Stamatakis 2009). Policy actors need answers to specific questions when the time is right for them, not when it serves the needs of funding, peer-reviewed publication, and promotion. As a field, PHLR must be dedicated to both long-term work that builds a rigorous evidence base for policy, and to a practice of "translational service." The latter includes maintaining contact with policy actors, pursuing models of scholarship that can generate answers on a policy-relevant timeline (such as synthesizing existing evidence and applying it to current issues, or conducting simulation studies), and ceding time from academic pursuits to serve as consultants (Jacobson, Butterill, and Goering 2005)(Fielding and Briss 2006). In the long run, all participants in PHLR–researchers, funders, consumers–have to work to narrow the gap between research that is fundable and what is needed, and to invest in knowledge translation for its own sake. None of this is peculiar to PHLR, but researchers in this

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emerging field can aspire to be exemplary in their efforts, attending to and putting into practice the insights of research on translating evidence into policy.

Conclusion

Lawyers have long proclaimed the maxim that "the health of the people is the supreme law," but in practice, making law work for public health is a constant challenge. PHLR's contribution is to provide the evidentiary foundation for these efforts. Through policy-making studies, PHLR can identify forces that shape public health policy and strategies for effecting policy change. Through mapping studies, it can illuminate what has been done, and thus, what kind of action it is possible for various government units to take. Through implementation studies, it can provide information about how best to ensure that "law on the books" becomes effective "law on the streets". Through intervention studies, it can determine which legal approaches are most efficacious in improving health environments, behaviors, and outcomes, and identify harmful legal side effects. Finally, through mechanism studies, it can tell us why laws have the effects they do, and what mechanisms are at our disposal for improving the effectiveness of legal interventions.

Researchers carrying out this work and collectively advancing this vision face significant challenges. However, a combination of forces has made the potential for overcoming these challenges greater than ever before. The interest of research sponsors, the broader trend toward interdisciplinary research, the increasing number of legal scholars trained in social science disciplines, and signals from Washington that policy will increasingly be driven by evidence and expertise are all cause for optimism (Obama

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2009).

A recent post on a law professors' blog raised the question of "whether empiricism is a methodology or a philosophy"(Lipshaw 2009). We argue it is both. We urge scholars of public health law to explore and recognize the value of empirical methods. We also hope that scholars and policy makers will adopt the philosophy that evidence derived from rigorous research ought to inform, if not drive, health policy decisions. Through the production of knowledge and conscientious efforts to translate research findings for decision makers, PHLR can make the case for laws that improve health.

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Figure 1. Logic Model of Public Health Law Research

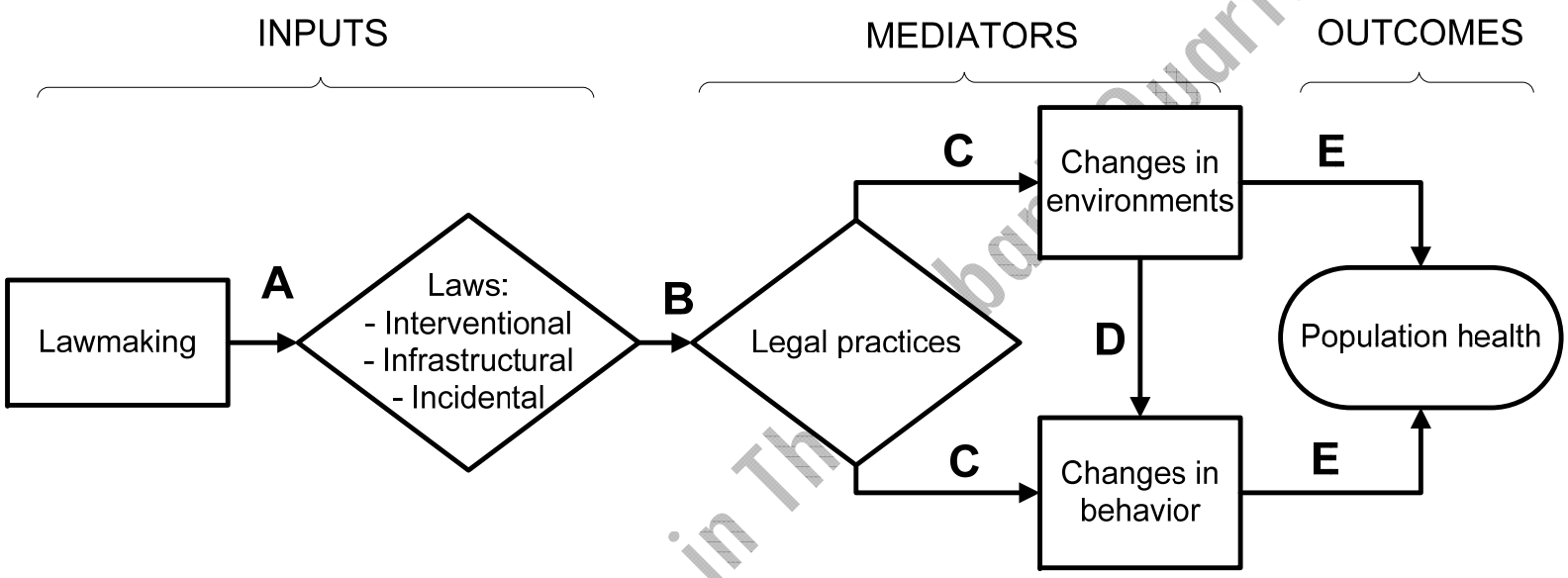

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Table 1. Typology of Public Health Law Studies

Study Type	Purpose	Methods
Policy-making studies	To identify factors influencing the likelihood that public health laws will be adopted, the nature of laws adopted, and the process through which they are adopted	• Multivariate regression • Key informant interviews • Content analysis of transcripts, rulemaking notices, memos, and other policy materials • Surveys of policy makers
Mapping studies	To analyze the state of the law or the legal terrain and the application of laws surrounding a particular public health topic	• Content analysis of statutes, administrative regulations, and formal policy statements • Key informant interviews • Surveys of state and local policy makers
Implementation studies	To examine how and to what extent the "law on the books" is implemented and enforced through legal practices	• Content analysis of administrative agency documents, including public communications • Key informant interviews • Direct observation of enforcement actions • Examination of business records of regulated entities • Surveys of regulators, regulated entities, and the public
Intervention studies	To assess the effect of a legal intervention on health outcomes or mediating factors that influence health outcomes	• Descriptive analysis of outcomes data • Multivariate regression • Case/control designs • Controlled experiments • Simulations • Surveys of persons targeted by the law
Mechanism studies	To examine the specific mechanisms through which the law affects environments, behaviors, or health outcomes	• Controlled experiments • Surveys, focus groups, or interviews of persons targeted by the law

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