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Empirical Health Law Scholarship: The State of the Field

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DISEASE PREVENTION AND HEALTH OUTCOMES

Empirical Health Law Scholarship: The State of the Field

MICHELLE M. MELLO* & KATHRYN ZEILER**

The last three decades have seen the blossoming of the fields of health law and empirical legal studies and their intersection—empirical scholarship in health law and policy. Researchers in legal academia and other settings have conducted hundreds of studies using data to estimate the effects of health law on accident rates, health outcomes, health care utilization, and costs, as well as other outcome variables. Yet the emerging field of empirical health law faces significant challenges—practical, methodological, and political. The purpose of this Article is to survey the current state of the field by describing commonly used methods, analyzing enabling and inhibiting factors in the production and uptake of this type of research by policymakers, and suggesting ways to increase the production and impact of empirical health law studies. In some areas of inquiry, high-quality research has been conducted, and the findings have been successfully imported into policy debates and used to inform evidence-based lawmaking. In other areas, the level of rigor has been uneven, and the best evidence has not translated effectively into sound policy. Despite challenges and historical shortcomings, empirical health law studies can and should have a substantial impact on regulations designed to improve public safety, increase both access to and quality of health care, and foster technological innovation.

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INTRODUCTION

In recent years, the field of empirical legal studies has grown exponentially.[1] Although empirical methods have been used to study some areas of law—corporate law, securities regulation, antitrust, family law, and criminal law, for example—more than others, nearly every area of law has been explored using empirical methods. Undoubtedly, health law and policy have been among the most widely studied areas. Examples include, but certainly are not limited to, studies estimating the influence of statutory damages caps on medical-malpractice insurance premiums[2] and physician location decisions,[3] the influence on job mobility of tax laws that encourage employers to provide health insurance as an employee benefit,[4] the impact of regulation of prices and hospital investment on hospital investments and quality of care,[5] the impact of government regulation on tobacco consumption,[6] and the effects of basing Medicare physician payment on performance or on quality of care.[7]

Although the field of empirical health law (EHL) is still in its adolescence, the increased visibility of this research and its ever-increasing policy salience make it timely to survey the field. In this Article, we take up this task—describing commonly used methods, analyzing enabling and inhibiting factors in the production and uptake of EHL research by policy makers, and suggesting ways to increase the volume, rigor, and impact of EHL studies.

We define the field of EHL to include *quantitative and qualitative investigations of the effects of enacted and proposed health laws, regulations, and policies on economic, social, and health outcomes*. Two key features distinguish methods used in EHL research from other approaches to legal scholarship:

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1. *See* Lee Epstein et al., *On the Effective Communication of the Results of Empirical Studies* (pt. 1), 59 VAND. L. REV. 1811, 1816 (2006) (summarizing recent developments in the field of empirical legal studies); Tracey E. George, *An Empirical Study of Empirical Legal Scholarship: The Top Law Schools*, 81 IND. L.J. 141, 142 (2006) (documenting the rise in empirical legal scholarship); James Lindgren, *Predicting the Future of Empirical Legal Studies*, 86 B.U. L. REV. 1447, 1452–54 (2006) (summarizing recent developments in the field of empirical legal studies); Richard H. McAdams & Thomas S. Ulen, *Empirical and Experimental Methods in Law*, 2002 U. ILL. L. REV. 791, 791 (2002). The first annual Conference on Empirical Legal Studies was held at the University of Texas Law School in October 2006, during which scholars presented more than eighty empirical studies.

2. For a review of the literature, see Patricia M. Danzon, *Liability for Medical Malpractice*, *in* 1B HANDBOOK OF HEALTH ECONOMICS (A.J. Culyer & J.P. Newhouse eds., 2000).

3. *See, e.g.*, Jonathan Klick & Thomas Stratmann, Medical Malpractice Reform and Physicians in High Risk Specialties (Apr. 10, 2007) (unpublished manuscript, on file with authors), *available at* http://www.gmu.edu/jbc/stratmann/reformDDDJLS.pdf.

4. *See, e.g.*, Brigitte C. Madrian, *Employment-Based Health Insurance and Job Mobility: Is There Evidence of Job-Lock?*, 109 Q.J. ECON. 27 (1994).

5. For a review of the EHL literature on this topic, see David S. Salkever, *Regulation of Prices and Investment in Hospitals in the United States*, *in* HANDBOOK OF HEALTH ECONOMICS, *supra* note 2, at 1489.

6. *See, e.g.*, Peter Bardsley & Nilss Olekalns, *Cigarette and Tobacco Consumption: Have Anti-Smoking Policies Made a Difference?*, 75 ECON. REC. 225 (1999); Eugene M. Lewit et al., *The Effects of Government Regulation on Teenage Smoking*, 24 J.L. & ECON. 545 (1981).

7. For a review of EHL studies on this topic, see David A. Hyman & Charles Silver, *You Get What You Pay for: Result-Based Compensation for Health Care*, 58 WASH. & LEE L. REV. 1427 (2001).

utilization of data of some kind and employment of the scientific method as opposed to legal argumentation or other forms of advocacy. Research designs used to conduct EHL research range from pure qualitative studies to controlled observational studies to experimental designs. We assess how well these methods are used in EHL research and discuss major methodological challenges, including the dearth of available data, difficulties in controlling for confounding variables, and obstacles to communicating results to policymakers.

We also assess whether and how EHL scholarship has impacted policy.[8] We present two case studies—motor vehicle safety-related laws and medical malpractice reform—that demonstrate the successful and unsuccessful application, respectively, of social-science research to public policy. Studies of motor vehicle safety regulation provided rigorous and timely evaluations of initial experiments with new laws relating to young drivers and identified desirable laws. Political interest groups helped to disseminate study findings to policymakers. As a result, effective laws were adopted widely. Conversely, studies of medical malpractice have had little effect on policy. This is partly because the research is not uniformly of high quality, partly because the studies are too methodologically complex for easy digestion by non-experts, and partly because some interest groups have undermined rather than promoted policymakers' uptake of rigorous, scholarly work.

Although some barriers that hinder EHL's impact on policy are beyond researchers' control, EHL scholars can take steps to increase the impact of research findings on policy. Available steps include: attracting more funding to obtain useful data, encouraging interdisciplinary collaborations, and training emerging legal scholars in scientific and empirical methods. Additionally, scholars can strive to increase the rigor of EHL studies, improve dissemination efforts, and help policymakers to become educated consumers of empirical legal research. Our aim is to propose a roadmap for those in the academy interested in increasing the impact of EHL scholarship and to encourage legal scholars interested in using empirical data to influence health policy to transform their scholarly approach, thereby moving away from the role of the expert-advocate and toward the social-science model of scholarship.

In Part I of this Article, we offer an account of why empiricism has gained popularity in health law and policy. In Part II we describe methodological

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8. Several scholars have investigated whether and how empirical legal studies more generally have helped shape law and policy, though they do not consider issues unique to the health law context. *See, e.g.*, Dean M. Hashimoto, *Justice Brennan's Use of Scientific and Empirical Evidence in Constitutional and Administrative Law*, 32 B.C. L. REV. 739 (1991) (providing examples of Justice Brennan's use and nonuse of empirical studies in the resolution of legal claims); John O. McGinnis, *Age of the Empirical*, POL'Y REV., June–July 2006, at 47 (discussing the rise of empirical research and its potential to influence policy); Carl E. Schneider & Lee E. Teitelbaum, *Life's Golden Tree: Empirical Scholarship and American Law*, 2006 UTAH L. REV. 53 (arguing the benefits of using empirical scholarship generally to get the law right); Elizabeth Warren, *The Market for Data: The Changing Role of Social Sciences in Shaping the Law*, 2002 WIS. L. REV. 1 (discussing the role—and sometimes non-role—of empirical research in the effort to rewrite American bankruptcy law).

approaches and challenges. In Part III we examine enabling and inhibiting factors in EHL research through the lens of case studies in motor vehicle safety laws and medical malpractice reform. Finally, in Part IV, drawing on lessons learned from the case studies, we offer suggestions for increasing EHL's rigor, prevalence, and impact on policy.

I. WHY EMPIRICISM HAS COME TO HEALTH LAW

Empirical scholars have investigated the connections between legal rules and outcomes over a wide range of legal topics, but health law has been a particularly active field. This development is a positive one given that empirical investigations of health law are a necessary component of sound policymaking. Policy proposals often emanate from theories of how changes in policy will impact various outcome measures or claims about the status quo (for example, the impact of large jury awards on medical malpractice insurance premiums). Empirical verification of the theoretical predictions, assumptions, and rhetorical claims on which policy proposals are based increases lawmakers' confidence in the likely efficacy of proposals. It is critical, therefore, for empiricists to provide information about the relationship between health law and outcomes.

Several reasons account for the popularity of health law as a topic of investigation among empiricists. First, data produced by and gathered from health care industries have become increasingly available along with a great deal of administrative and survey data on health status and conditions. Second, the dominance of state regulation in health care has generated variation and natural experiments that can be exploited to estimate the effects of various health laws on outcomes. Third, in recent years, law schools have hired a greater number of faculty trained in both law and empirical methods, which has increased the capacity for and interest in empirical legal studies generally. Fourth, the audience interested in the findings of EHL research has expanded, increasing the demand for it. Finally, demand has also been expanded by the positive impact the EHL field has had on policy and by growing concern among policymakers about health care spending and perceived crises in several corners of the health care system, including the medical malpractice liability system and health care insurance markets. We cover each of these in more detail below.

A. DATA ON OUTCOME VARIABLES

Despite the recent explosion in empirical legal research, many corners of the field are plagued by a paucity of accessible data that could be used to estimate the effects of legal rules on outcomes of interest.[9] Although EHL scholars also

9. *See, e.g.*, Gillian K. Hadfield, *Judging Science: An Essay on the Unscientific Basis of Beliefs About the Impact of Legal Rules on Science and the Need for Better Data About Law*, 14 J.L. & POL'Y 137 (2006) (discussing the general dearth of data necessary to study the impact of legal rules and policy); Michael Heise, *The Importance of Being Empirical*, 26 PEPP. L. REV. 807, 822 (1999) (pointing to underinvestment in data production as the reason for the dearth of data).

grapple with difficulties in obtaining data useful for advancing our knowledge of the connections between health law and outcomes,[10] there has been relatively good access, in some cases for decades, to various datasets on health care utilization and health outcomes.[11] Regulators continue to open useful datasets to the research community,[12] and researchers have often convinced market actors to do the same. The data usually come with strict confidentiality agreements, limiting the potential for other research teams to test the validity and robustness of the reported results, but the data have allowed researchers to explore interactions between markets and legal rules that formerly resided in black boxes.

B. STATE-BASED LAW

A second competitive advantage for EHL researchers is that states have been the primary loci of lawmaking around important aspects of health care markets, including insurance coverage, regulation of health care delivery, and tort law.[13] The state-based nature of legal rules confers two specific advantages for research. First, adoption of legal reforms generally happens in waves rather than in all states at once. This pattern provides the cross-sectional and longitudinal variation researchers need for robust analysis of the effects of changes in legal rules on health outcomes. Second, that health care markets are made up of a large number of moving pieces increases the likelihood that legal rules are adopted for reasons unrelated to the outcome variable of interest—an important precondition for empirical models to produce unbiased estimates of the effects of the rules on the outcome variable.[14]

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10. *See infra* Part IV.

11. Examples include the Healthcare Cost and Utilization Project (available since 1988), the Longitudinal Study of Aging (available since 1984), and the National Health Interview Survey (available since 1957). On the other hand, developments in privacy law have made it more difficult for researchers to access individual patients' medical records for purposes of doing chart review studies (the Harvard Medical Practice Study, see *infra* note 60, is an example of such a study).

12. Examples of datasets that have more recently become available online include the National Practitioner Data Bank (reporting data on medical malpractice payments and various sanctions against practicing physicians since 1990), the Dartmouth Atlas of Health Care (reporting on hospital expenditures and costs, hospital capacity, physician and specialist work forces, frequency of diagnostic and surgical procedures, and Medicare payments for care provided by hospitals since 1996), and the Employer Health Benefits Survey (providing data on employer-sponsored health benefits since 1998).

13. Examples of legal rules related to health care adopted at the state level include: tort reform and legal standards of care enforced by tort law; safety regulations such as seatbelt and workplace smoking laws; information disclosure regulations such as mandated disclosure of provisions of contracts between managed care organizations and physicians; regulation of health insurance coverage; taxation and other forms of regulation related to vices such as tobacco and alcohol; and regulation of access to unhealthful foods and beverages in schools. Of course, empirical researchers in other areas of law, including criminal law, contract law, and property law, enjoy similar benefits bestowed by gradual and partial adoption of reforms by states.

14. When there is a two-way relationship between the legal reform adopted and the outcome it aims to improve—for example, states with high malpractice insurance premiums are more likely to adopt malpractice damages caps, and damages caps have the effect of reducing premiums—a problem of endogeneity results, necessitating the use of sophisticated (and sometimes infeasible) analytical meth-

C. HUMAN RESOURCES

Historically, the bulk of EHL research has been conducted outside law schools, in public health and public policy schools, business schools, and social science departments—including economics, political science, and psychology departments. This is unsurprising in light of the fact that this type of research arises out of scientific and social-scientific traditions.

In recent years, however, we have witnessed an increase in EHL research performed within the legal academy and published in law journals. Several factors may account for this. Pioneering work by "bridge" scholars, such as Dan Kessler and Troy Brennan, who are dually trained in law and empirical methods, has been important in establishing prominence and respectability for this research within the legal academy.[15] Health economists' interest in regulatory questions—propelled by Kenneth Arrow's influential article,[16] which helped shape health economics as a field—spurred recognition of potential synergies of interdisciplinary collaborations between legal scholars and economists. Interest in these same health care regulatory questions within the legal academy has led to the creation of interdisciplinary health law research programs at leading universities, including Georgetown/Johns Hopkins and Harvard, which provide dedicated institutional support for collaborative, empirical research. Finally, carried by this momentum, a number of law schools recently have appointed faculty members trained in both law and empirical methodology and interested in EHL research.[17]

D. EXPANDING AUDIENCE

The move to increase production capacity for EHL research has been fueled by an increasing demand for this type of scholarship in several quarters. Physicians and institutional health care providers, who highly value quantitative research and evidence-based decisionmaking, are regular consumers of EHL research as a source of information about how the law potentially impacts their practice and industry. This has recently become true of other health-care-market actors as well, including medical malpractice insurers, health insurers, employers who provide health insurance as a benefit to their employees, and government agencies that finance health care purchases for subsets of the population.

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ods. For a more technical explanation, see JEFFREY M. WOOLDRIDGE, INTRODUCTORY ECONOMETRICS: A MODERN APPROACH 521–29 (3d ed. 2006).

15. *See, e.g.*, Troyen A. Brennan et al., *Incidence of Adverse Events and Negligence in Hospitalized Patients: Results of the Harvard Medical Practice Study I*, 324 NEW ENG. J. MED. 370 (1991); Daniel P. Kessler & Mark B. McClellan, *Do Doctors Practice Defensive Medicine?*, 111 Q.J. ECON. 353 (1996).

16. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941 (1963).

17. In addition to one of the authors, recent hires include Jill Horwitz (University of Michigan Law School), Anup Malani (University of Chicago Law School), Jonathan Klick (Florida State University Law School), Ronen Avraham (Northwestern University Law School), and Daniel Ho (Stanford Law School).

Public health communities also are regular consumers of EHL studies. These stakeholder groups value studies focused on potential legal solutions to, and sometimes law-related causes of, public health problems (for example, obesity, tobacco- and alcohol-related illnesses, and limited access to care). In addition, EHL studies focused on the impact of various legal institutions on the health and safety of at-risk populations are of interest to public health organizations (for example, studies shedding light on how tort reform impacts subsets of potential victims of medical malpractice). Empirical studies of legal rules intended to control the spread of infectious diseases, including compulsory vaccination and compulsory treatment, are also of special interest.

Legal system insiders, including advocates, judges, and legislators, have also increased their demand for EHL research. More than ever before, lawyers rely on empirical studies to support legal arguments made to courts, arbiters, and administrative agencies in health-related matters. For example, the Supreme Court brief filed by the respondents in *Ashcroft v. Raich* (later known as *Gonzales v. Raich*) cited a General Accounting Office study of the experience with medical marijuana laws in four states.[18] Likewise, judges themselves refer to empirical research to justify their holdings. For example, in another recent Supreme Court decision, Justice Souter cited an empirical study to support claims regarding the influence of managed-care contracts with physicians on physician satisfaction.[19] Legislators also find these studies instructive for shaping policy and useful as ammunition to support their positions.[20]

E. GROWING POLICY SIGNIFICANCE

In 2005, the United States spent $2 trillion on health care, an average of $6700 per person and 16% of the country's Gross Domestic Product (compared to 5% in 1960, 12% in 1990, and 13% in 2000).[21] Most ($1.7 trillion) of this spending is devoted to personal health care costs. The federal government financed 34% of personal health expenditures and state and local governments covered 11%.[22] The sheer size of the industry and the growing burden on taxpayers have ignited public demand for policymakers to take affirmative steps

18. Brief for Respondents at 17–18, Gonzales v. Raich, 545 U.S. 1 (2005) (No. 03-1454) (citing U.S. GEN. ACCOUNTING OFFICE, MARIJUANA: EARLY EXPERIENCES WITH FOUR STATES' LAWS THAT ALLOW USE FOR MEDICAL PURPOSES 21 (2002)).

19. Pegram v. Herdrich, 530 U.S. 211, 221 (2000) (citing Grumbach et al., *Primary Care Physicians' Experience of Financial Incentives in Managed-Care Systems*, 339 NEW ENG. J. MED. 1516 (1998)).

20. See, for example, CONG. BUDGET OFFICE, THE PROPOSED TOBACCO SETTLEMENT: ISSUES FROM A FEDERAL PERSPECTIVE 4 (1998), *microformed on* CIS No. 98-J932-24 (Cong. Info. Serv.), which was written at the request of the then-Senate Assistant Majority Leader and reviews the empirical literature on the connections between cigarette price increases and tobacco consumption.

21. NAT'L CTR. FOR HEALTH STATISTICS, U.S. DEP'T OF HEALTH & HUMAN SERVS., HEALTH, UNITED STATES, 2007: WITH CHARTBOOK ON TRENDS IN THE HEALTH OF AMERICANS 26 (2007), *available at* http://www.cdc.gov/nchs/data/hus/hus07.pdf.

22. *Id.* at 26–27.

to ease this burden and fix other perceived health care market problems. The availability of data, advances in techniques for estimating the effects of legal interventions, and public intolerance for policy failures in this critical area have pushed policymaking toward a more evidence-based approach.

A number of political interest groups have responded by churning out their own empirical research in an effort to sway the political process in their favor. In many cases, the research is simplistic and, by academic standards, of poor methodological quality. This has raised the stakes for EHL scholars to contribute a better alternative.

These developments illustrate the potential for growth and impact in the field of EHL. We further explore the status of the field by considering the state of the methods used to conduct EHL research and the uptake of research by the policy community as illustrated by two case studies.

II. METHODS OF EMPIRICAL HEALTH LAW RESEARCH

The methods used in EHL research are as diverse as the topics investigated. In this Part, we discuss major methodological approaches and their relative representation in the field and then examine some of the significant challenges that empirical legal scholars confront in researching health law issues.

A. THE SPECTRUM OF ANALYTIC METHODS

A wide spectrum of methods has been used to empirically study developments in health law. We review the most common methodologies, ordered from least to most scientifically rigorous, below.[23]

First, case studies occasionally have been used to examine health law problems, particularly problems that are unique or for which examination of extreme examples is of interest.[24] Because case studies are not controlled analyses and the example selected for study may be unrepresentative of the broader population, case studies have limited generalizability.[25] They can, however, provide a rich, vivid, and detailed lens on a particular example of a problem or policy innovation. A well-known example is the fascinating chronicle of the federal government's response to a perceived threat of epidemic swine flu in 1977,

23. This is not an exhaustive list. We do not include analytical methods that are extremely rare in health law research, for example, epidemiological research designs.

24. *See, e.g.*, ROGAN KERSH, THE POLITICS OF MEDICAL MALPRACTICE IN PENNSYLVANIA, 1975–2005 (2005, on file with authors) (examining a state that has suffered extreme difficulties in its malpractice insurance market); Michelle M. Mello & Troyen A. Brennan, *The Controversy over High-Dose Chemotherapy with Autologous Bone Marrow Transplant for Breast Cancer*, 20 HEALTH AFF. 101 (2001) (discussing the role of mandated-benefit laws and judicial decisions in forcing insurers to cover an experimental therapy for breast cancer that was later shown to be ineffective). By "case study," we do not mean anecdotes strategically selected to support a foregone conclusion. *See* David A. Hyman, *Lies, Damned Lies, and Narrative*, 73 IND. L.J. 797 (1998) (criticizing the use of anecdotes in health care policymaking).

25. Arend Lijphart, *The Comparable-Cases Strategy in Comparative Research*, 8 COMP. POL. STUD. 158, 160 (1975).

including how it addressed vaccine manufacturers' liability concerns.[26]

A second, quite prevalent form of analysis in EHL research is qualitative analysis of judicial opinions.[27] This approach bears some resemblance to traditional legal scholarship, which focuses on deep doctrinal analysis of a small number of judicial decisions. It differs in two key respects: expansion of the sample to include a larger number of cases and use of systematic methods of content analysis. A typical research design involves random selection of a sample of cases meeting certain subject-matter criteria, application of a detailed coding and content-analysis methodology, and drawing of inferences based on both thematic analysis and frequency counts of various case characteristics.[28]

This design offers a broader and more systematic examination of judicial decisionmaking than more traditional forms of doctrinal analysis, and is very useful for getting the "lay of the land" in an area of litigation that has not yet been broadly characterized. Like all studies that rely on published judicial decisions, it is limited by the potential unrepresentativeness of published decisions.[29] Content analysis has also been criticized for being too subjective.[30]

Another application of qualitative methods in health law research is the collection of survey and interview data used to examine the impacts of health laws or litigation. In addition to performing content analysis, such studies may analyze survey and interview data quantitatively. Major challenges that compromise the quality of these studies are the difficulties in avoiding selection bias and in obtaining an adequate response rate and concerns about respondents' self-interest in the outcome of the study.

Occasionally, researchers have conducted descriptive studies in health law involving quantitative analysis of data from outside the legal system. The aim typically is to contribute suggestive evidence about the impact of a law or to test assumptions or claims policymakers and other researchers rely on to argue a position or develop theories. Simple descriptive statistics such as the mean and standard deviation, or frequency and proportion, are presented and may be

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26. *See* RICHARD E. NEUSTADT & HARVEY V. FINEBERG, THE SWINE FLU AFFAIR: DECISION-MAKING ON A SLIPPERY DISEASE (1978), *cited in* DAVID C. HOAGLIN ET AL., DATA FOR DECISIONS: INFORMATION STRATEGIES FOR POLICYMAKERS 120–23 (1982).

27. *See* Heise, *supra* note 9, at 824 ("Much of the existing empirical legal scholarship falls loosely into one or more of three broad categories: judicial opinion coding or case content analysis, descriptive, and inferential.").

28. *See* Kevin M. Clermont & Theodore Eisenberg, *Litigation Realities*, 88 CORNELL L. REV. 119, 125–26 (2002); Mark A. Hall & Ronald F. Wright, *Systematic Content Analysis of Judicial Opinions* 11 (Wake Forest Univ. Legal Studies, Working Paper No. 913336, 2006), *available at* http://ssrn.com/abstract=913336.

29. Clermont & Eisenberg, *supra* note 28, at 125–26 (discussing several ways in which published decisions may be unrepresentative of the broader population of judicial decisions); William M. Sage, *Judicial Opinions Involving Health Insurance Coverage: Trompe L'Oiel or Window on the World?*, 31 IND. L. REV. 49, 61–68 (1998) (describing a number of limitations of content analyses of judicial decisions).

30. *See, e.g.*, Heise, *supra* note 9, at 825.

supplemented by bivariate analyses estimating associations between variables.[31] Univariate analyses have no explanatory power but can provide useful information on the nature of a health law problem or be used to support or call into question conventional wisdom—for example, the extent to which physicians are personally exposed to malpractice settlements in excess of their policy limits.[32] The major weakness of bivariate studies is that, although some analyses may be stratified,[33] they otherwise do not control for confounding variables.[34] This limits their usefulness in supporting inferences about causal connections between the variables. Therefore, although these methods can produce very useful information for policymakers and theorists, if limitations are not fully and clearly disclosed, readers may incorrectly attribute observed differences between comparison groups to the variables studied, when in reality other factors drive the differences.

More sophisticated designs—controlled observational or quasi-experimental studies using multivariate regression techniques—constitute the bulk of empirical legal studies conducted by law-and-economics scholars.[35] Such studies attempt to overcome the problems with drawing causal inferences from univariate and bivariate analyses by employing techniques to control for confounding variables. The simplest variant is the pre/post analysis, sometimes called an

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31. Bivariate analyses involve two variables and typically consist of cross-tabulations comparing the relationship between an outcome variable and an explanatory variable—for example, rates of mammography in states that do and do not mandate that insurers cover routine mammography. Univariate analyses provide summary statistics about a single variable—for example, mean and variance of mammography rates across all states.

32. *See* Charles Silver et al., *Malpractice Payouts and Malpractice Insurance: Evidence from Texas Closed Claims, 1990–2003*, GENEVA PAPERS ON RISK & INS.: ISSUES & PRAC. (forthcoming Apr. 2008), *available at* http://ssrn.com/abstract=983199; Kathryn Zeiler et al., *Physicians' Insurance Limits and Malpractice Payouts: Evidence from Texas Closed Claims, 1990–2003*, J. LEGAL STUD. (forthcoming) (on file with authors).

33. A stratified analysis is one that divides observations into groups, or strata, based on their value of some potentially confounding variable and then performs bivariate analyses within each stratum. For example, a researcher might be interested in the relationship between state mandates for physical education in schools and the prevalence of overweight and obesity among schoolchildren, but suspect that the effect will be different for girls and boys. A simple way to investigate that hypothesis would be to stratify by sex and analyze the relationship within each stratum.

34. If an analysis does not control for confounding variables, then variation in an outcome variable may be incorrectly attributed to the explanatory variable of interest. For example, tort reforms are often implemented as packages that include several different types of reforms (for example, damages caps plus joint-and-several liability reform). If joint-and-several liability reforms are not included in the analysis, observed reductions in the costs of malpractice claims might appear to be due to damages caps when, in fact, they may be caused in part by joint-and-several-liability reform.

35. Thomas E. Willging, *Past and Potential Uses of Empirical Research in Civil Rulemaking*, 77 NOTRE DAME L. REV. 1121, 1132 (2002). Quasi-experimental studies involve observing some variable of interest before and after a change that affects the entire population. If the change affects only a subset of the population, each subject in the affected group can be matched to a subject in the non-affected group based on important characteristics to allow for comparison of differences in some variable of interest before and after the change across groups (this is sometimes referred to as "difference-in-difference"). Alternatively, multivariate regression analysis can be used to control for potential confounding variables.

event study, which employs no explicit controls but simply measures the outcome variable before and after the intervention. This design's major weakness is that it does not control for exogenous changes in the environment over time that may introduce confounding variables.[36]

Alternatively, multivariate regression techniques may be applied in cross-sectional or time-series analyses.[37] Longitudinal designs may be employed to maximize the amount of information that can be gleaned from a limited number of cross-sectional units (such as states) and to analyze changes over time. These studies take advantage of variation in legal rule adoption and outcomes over units of observation and time and implement controls to rule out alternative explanations, allowing the researchers to conclude, with some level of confidence, that the findings either support or reject claims and theories positing causal connections. While these studies are useful as evidence for or against particular theories of causal connections, they should not be viewed as conclusive or touted as such.

Virtually absent from the EHL literature are experimental designs. Randomized experiments are the "gold standard" for testing the effects of interventions;[38] the use of random treatment assignment is ideal for reducing the influence of confounding variables.[39] Although experimental designs have occasionally been used to test the effect of changes in health care organizational policy that could be implemented as public policy—for example, imposing copayments on enrollees in a private or public insurance program[40]—for obvious reasons they are almost never an option for evaluating the effects of health laws.[41]

In evaluating the rigor of EHL scholarship as a whole, it is useful to consider evaluative tools that reviewing organizations use to judge the scientific rigor of

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36. *See* M. Eccles et al., *Research Designs for Studies Evaluating the Effectiveness of Change and Improvement Strategies*, 12 QUALITY & SAFETY HEALTH CARE 47, 50 (2003).

37. Cross-sectional designs measure many units (for example, health care consumption for all fifty states) at one point in time, while time-series data captures just one unit (for example, health care consumption in Texas) at different points in time. For an in-depth discussion of experimental design, see generally THOMAS D. COOK & DONALD T. CAMPBELL, QUASI-EXPERIMENTATION: DESIGN AND ANALYSIS ISSUES FOR FIELD SETTINGS (1979).

38. *See* Eccles et al., *supra* note 36, at 48; *see also* A.L. COCHRANE, EFFECTIVENESS AND EFFICIENCY: RANDOM REFLECTIONS ON HEALTH SERVICES 2, 22 (1972); Rachel Croson, *Why and How To Experiment: Methodologies from Experimental Economics*, 2002 U. ILL. L. REV. 921, 945 ("Experiments can accomplish objectives that other forms of analyses cannot. They can offer clean tests of economic theories by constructing experiments that meet the assumptions of the theories, and observing the outcomes. They can investigate alternative causes of observed anomalies . . . by independently manipulating factors that in reality are confounded.").

39. *See* Eccles et al., *supra* note 36, at 48; Willging, *supra* note 35, at 1127.

40. *See* Willard G. Manning et al., *A Controlled Trial of the Effect of a Prepaid Group Practice on Use of Services*, 310 NEW ENG. J. MED. 1505 (1984).

41. Notable exceptions exist. *See, e.g.*, Lauren A. McCormack et al., *Health Plan Decision Making with New Medicare Information Materials*, 36 HEALTH SERVICES RES. 531 (2001) (reporting results from controlled experiments to determine the impact of Medicare informational materials on new and experienced Medicare beneficiaries).

various study designs. Among the most prominent typologies of research designs is that of the U.S. Preventive Services Task Force.[42] In considering whether an adequate evidence base exists to support recommending a particular preventive health measure, the Task Force applies the following rating system, which flows from strongest to least strong research design:

I Evidence obtained from at least one properly randomized controlled trial.

II-1 Evidence obtained from well-designed controlled trials without randomization.[43]

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group.[44]

II-3 Evidence obtained from multiple time series with or without the intervention . . . .[45]

III Opinions of respected authorities, based on clinical experience, descriptive studies and case reports, or reports of expert committees.[46]

This typology emphasizes the importance of randomized studies, places little weight on descriptive studies, and views quasi-experimental designs as a heterogeneous group with some designs superior to others. To our knowledge, the overwhelming bulk of EHL research conducted to date can best be classified as category "II-3" or "III" studies. In addition to the paucity of controlled trials, another notable gap in the EHL literature is the scant use of techniques of meta-analysis or systematic review. Meta-analysis uses sophisticated statistical methods to aggregate and collectively analyze data from multiple studies on the same topic using similar designs. Systematic reviews apply a structured process to compare and evaluate the relative strength of findings from a number of

42. *See generally* Russell P. Harris et al., *Current Methods of the U.S. Preventive Servs. Task Force: A Review of the Process*, 20 AM. J. PREVENTIVE MED. 21 (2001).

43. Controlled trials without randomization are experimental studies that compare a treatment group to a control group, but the groups are formed based on subject characteristics rather than random assignment. The experimenter, however, maintains control over the application of the treatment. The analysis must control for confounding effects potentially arising from self-selection into groups or other sources of difference between groups.

44. Cohort and case-control study designs are observational, not experimental, designs. Both allow the researcher to examine the association between one or more risk factors and an outcome variable. In a cohort study, the researcher identifies a group (cohort) of subjects based on their exposure to some risk factor and then observes their experience over time to see which subjects develop the outcome condition of interest (for example, a disease). RAYMOND S. GREENBERG ET AL., MEDICAL EPIDEMIOLOGY 106 (2d ed. 1996). In a case-control study, the researcher selects a group of subjects (cases) who have a particular condition, such as a disease. The researcher then selects a control group consisting of subjects from the same population who do not have the condition and examines the ways in which they differ on various risk factors. *Id.* at 120–21.

45. "With intervention" indicates that the researcher controls the application of the treatment over time.

46. Rating system quoted from Harris et al., *supra* note 42, at 26 tbl.2.

studies examining the same phenomenon. These approaches are not without methodological controversy,[47] but they have the advantage of harnessing the power of multiple studies. They are rarely used, however, to study the effects of legal rules on outcomes.[48] As with all empirical studies, meta-analyses and research syntheses have limitations, but they can help to provide broader views of treatment effects identified in different studies especially when the studies report divergent results. Overall, the field of EHL lags well behind the standard of evidence that researchers and policymakers aim for in other areas of evaluation of health interventions.[49]

B. MAJOR METHODOLOGICAL CHALLENGES

Empirical health law studies confront several significant methodological challenges that may explain why the field has not advanced farther. Three issues that cut across many areas of inquiry within health law are particularly troubling.

First and foremost is the problem of data availability. Although there are excellent datasets on health care utilization and many health outcomes, the investment that government and private research sponsors have made in building health datasets for research purposes is not mirrored in the realm of health law. The government's most significant commitment to empirical legal research, the Bureau of Justice Statistics, has made only occasional forays into health law, all limited to descriptive studies of medical malpractice claims[50] and relying on data aggregated from other sources. There are few examples of government-funded or government-run projects aimed at building databases of health laws.[51] The best known recent instance may be the National Science Foundation's grant to Ronen Avraham at Northwestern University Law School to create a comprehensive database of state malpractice tort reform laws.[52] Some private organizations, most notably the National Conference of State Legislatures, maintain

47. *See, e.g.*, Peter C. Gotzsche et al., *Data Extraction Errors in Meta-analyses That Use Standardized Mean Differences*, 298 JAMA 430 (2007).

48. Recently published studies suggest that these approaches may be gaining traction in EHL research, though. *See, e.g.*, Caroline M. Fichtenberg & Stanton A. Glantz, *Effect of Smoke-Free Workplaces on Smoking Behaviour: Systematic Review*, 325 BRITISH MED. J. 188 (2002) (systematically reviewing primary empirical studies to compare the efficacy of workplace smoking bans and tax increases); Stephen Kisely et al., *Randomized and Non-randomized Evidence for the Effect of Compulsory Community and Involuntary Out-Patient Treatment on Health Service Use: Systematic Review and Meta-analysis*, 37 PSYCHOL. MED. 3 (2006).

49. Of course, the explanation rests in part on the difficulties with conducting experimental studies in health law, as we discuss further in Part II.B.

50. *See generally* Bureau of Justice Statistics Publications, http://www.ojp.usdoj.gov/bjs/pubalp2.htm#M (last visited Aug. 20, 2007).

51. This is a particular challenge for EHL researchers attempting to identify the impact of tort reforms on medical malpractice insurance premiums and other relevant outcome variables. *See infra* Part III.B.

52. *See* Ronen Avraham, *Database of State Tort Law Reforms* (Nw. Sch. of Law. & Econ., Research Paper No. 06-08, 2006), *available at* http://ssrn.com/abstract=902711.

useful lists of pending and enacted state laws on health topics,[53] but these are not organized into a database, nor do they provide detailed information about the laws.

Without databases custom-built for research, EHL scholars must rely on administrative data collected for other purposes or build their own datasets from the ground up. For research topics related to health or liability insurance, administrative data held by private insurers, state departments of insurance, state medical boards, and state health departments are attractive options. Unfortunately, such databases can be difficult to access; states and insurers hold them tightly[54] due to a combination of legal concerns[55] and anxieties about the potential political fallout from adverse study findings. Additionally, data-collection processes and data fields often are not standardized across states. Single-state datasets are rarely nationally generalizable, and datasets from multiple states cannot easily be aggregated to support national studies.

In the medical liability realm, the National Practitioner Data Bank and jury verdicts databases offer two alternatives, though each captures only a portion of all filed claims and includes a limited number of variables. The Data Bank most likely suffers from underreporting[56] and restricts the data fields the public may access.[57] Jury verdict reports have also been criticized for their unrepresentativeness and incompleteness.[58]

Administrative datasets also have the obvious shortcoming of not having been constructed with researchers' needs and objectives in mind. They may omit data fields that researchers view as crucial to a rigorous analysis, and the data may not have been collected with the degree of completeness and accuracy that researchers desire.[59] Finally, researchers external to the organization that

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53. These lists are collected at National Conference of State Legislatures, NCSL 50-State Legislative Tracking Resources, http://www.ncsl.org/programs/lis/lrl/50statetracking.htm (last visited Oct. 22, 2007).

54. *See* NEIL VIDMAR, MEDICAL MALPRACTICE AND THE TORT SYSTEM IN ILLINOIS: A REPORT TO THE ILLINOIS STATE BAR ASSOCIATION 5–6 (2005), *available at*, http://eprints.law.duke.edu/archive/00001125 (click on PDF) (reporting that the Illinois Department of Insurance refused to grant permission to analyze its claims data); Sage, *supra* note 29, at 59 ("[H]ealth insurers often assert proprietary interests in their coverage standards.").

55. *See* Michelle M. Mello et al., *Market Watch: Changes in Physician Supply and Scope of Practice During a Malpractice Crisis: Evidence from Pennsylvania*, 26 HEALTH AFF. w425, w433 (2007) (describing an instance where an insurance department expressed concerns about violating its confidentiality obligations under state law).

56. *See* U.S. GEN. ACCOUNTING OFFICE, NATIONAL PRACTITIONER DATA BANK: MAJOR IMPROVEMENTS ARE NEEDED TO ENHANCE DATA BANK'S RELIABILITY 10–13 (2000), *available at* http://www.gao.gov/new.items/d01130.pdf.

57. U.S. Department of Health and Human Services, Practitioner Data Banks Branch, Public Data Files, http://www.npdb-hipdb.com/publicdata.html (last visited Oct. 22, 2007) (noting that the Data Bank omits certain information).

58. *See, e.g.*, Neil Vidmar, *Pap and Circumstance: What Jury Verdict Statistics Can Tell Us About Jury Behavior and the Tort System*, 28 SUFFOLK U. L. REV. 1205, 1210–11, 1225–28 (1994).

59. For a discussion of the ways in which databases maintained by health insurers fall short of providing sufficient information to evaluate medical appropriateness decisions, see, for example, Maxwell J. Mehlman, *Getting a Handle on Coverage Decisions: If Not Case Law, Then What? Comments on a Paper by Professor William Sage*, 31 IND. L. REV. 75, 75–78 (1998). On the other hand,

collected the data may find it challenging to become familiar with the dataset and its quirks and quality problems. Unless an organizational insider is willing to spend the time to brief the researchers on the dataset and respond to their queries, important data-quality issues and definitional issues may go unnoticed.

Engaging in primary data collection to build new datasets is a possibility in many areas of empirical health law research, but it can be prohibitively expensive and few extramural research sponsors are interested in funding such enterprises. Additionally, projects that require on-the-ground data collection (for example, reviewing medical charts to identify instances of malpractice or reviewing insurance claims to identify wrongful denials) require substantial infrastructure to train, house, and support a large data-collection staff. Few law schools can afford to meet these demands, so scholars tend to rely on readily available but very limited administrative datasets and what they can cull from judicial opinions and electronic databases of statutes and regulations. Data-collection efforts are more common in schools of public health and medicine,[60] but their heavy reliance on extramural funding can make it difficult for faculty to pursue such projects if grants are not available to support them.

The second major methodological challenge is the difficulty of controlling for confounding variables—a problem common to all observational studies.[61] As previously discussed, the ideal method to implement such controls is through the use of experimental designs including randomized studies. Although there has been some use of experimental designs in other areas of empirical legal research focusing on judicial processes,[62] there are few opportunities to conduct pure experimental studies in health law. Judicial processes are of less interest, and the agendas and actions of state legislatures cannot be dictated by a randomization process. Thus, as in other areas of social science,[63] researchers must rely on carefully controlled quasi-experimental designs.

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administrative data may be more accurate than data collected for research purposes because the information providers may have stronger incentives to treat the task seriously and provide truthful responses. HOAGLIN ET AL., *supra* note 26, at 159.

60. The most famous example may be the Harvard Medical Practice Study, a review of approximately 30,000 medical records that measured the incidence of medical negligence and malpractice claiming. The main study findings are collected at PAUL C. WEILER ET AL., A MEASURE OF MALPRACTICE: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION 42–59, 68–76, 92–109 (1993).

61. *See generally* U.S. DEP'T OF HEALTH & HUMAN SERVS., FACT SHEET: RATING THE STRENGTH OF SCIENTIFIC RESEARCH FINDINGS (2002), http://www.ahrq.gov/clinic/epcsums/strenfact.pdf. For a general discussion of the threats to internal validity in quasi-experimental studies, see COOK & CAMPBELL, *supra* note 37, at 50–59.

62. *See, e.g.*, Croson, *supra* note 38, at 935 (describing experiments that tested the effect of a damages cap law on pretrial bargaining among parties in a hypothetical personal injury case); Willging, *supra* note 35, at 1128–29 (describing an experiment with mandatory attorney conference prior to briefing and arguing appeals in the U.S. Court of Appeals for the Second Circuit).

63. Among the barriers to randomized experiments in social-science research generally are ethical concerns about randomization in some circumstances, differences between experimental and actual delivery of the intervention, time and money costs, and controlling the integrity of the experiment in the field. *See* PETER H. ROSSI & HOWARD E. FREEMAN, EVALUATION: A SYSTEMATIC APPROACH 290–93 (5th ed. 1993) (describing limitations on the use of randomized experiments in evaluating "social programs").

Controlling for confounding variables is particularly hard in studies of innovations in state law, due to the profound and multifaceted cross-sectional variation. Finding appropriate data to control for variables that might be correlated with state enactment of health laws can be a difficult, and sometimes impossible, task. Fixed-effects models offer a possible solution,[64] but only where the laws in question exhibit a reasonable amount of variation over the study period, the number of cross-sections (for example, states) is small relative to the number of time periods covered by the data, and the unobservable heterogeneity is constant over time.[65] Difference-in-difference models are more attractive in some cases,[66] but have rarely been used in health law studies,[67] and some researchers who have used them do not appear to have incorporated appropriate adjustments for the inconsistency of standard errors that arises from serially correlated data.[68] Due to these complexities, there is a substantial risk of omitted variable bias in studies of many kinds of health laws. By properly controlling for this bias, however, parameter estimates can be used to draw causal inferences.

The third major challenge is how to model state laws that may have similar aims and general approaches but exhibit considerable heterogeneity in their specific provisions. For example, some laws that aim to ensure that women will be protected from "drive-through" breast cancer surgeries set a specific minimum hospital stay, while others provide that the length of stay shall be determined by the woman and her physician rather than her insurance company.[69] There is no consensus within the field about whether such diverse laws should be modeled using a single dummy variable (indicating whether a law of

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64. Fixed-effects models are used to control for unobservable heterogeneity that is constant over time. *See* CHENG HSIAO, ANALYSIS OF PANEL DATA 30–33 (2d ed. 2003).

65. Given the limited time horizon of many studies, this often will not be the case. For example, medical malpractice tort reforms in the states were largely time-invariant between the late 1980s and the early 2000s. Y. Tony Yang et al., *A Longitudinal Analysis of the Impact of Liability Pressure on the Supply of Obstetrician-Gynecologists*, J. EMPIRICAL LEGAL STUD. (forthcoming 2008).

66. Difference-in-difference models are used to distinguish effects caused by an "exogenous shock" such as a legal reform from differences attributable to time trends driven by other causes.

67. Among the rare instances in which such models have been used are William E. Encinosa & Fred J. Hellinger, *Have State Caps on Malpractice Awards Increased the Supply of Physicians?*, 24 HEALTH AFF. w5-250 (2005); Kessler & McClellan, *supra* note 15; Daniel P. Kessler et al., *Impact of Malpractice Reforms on the Supply of Physician Services*, 293 JAMA 2618 (2005); Klick & Stratmann, *supra* note 3.

68. Year-to-year correlations in the dependent variable may bias standard errors downward, resulting in overestimation of significance levels. Marianne Bertrand et al., *How Much Should We Trust Differences-in-Differences Estimates?*, 119 Q.J. ECON. 249 (2004). This problem also applies to fixed-effects models. To make matters more complicated, others have argued that feasible general least squares models produce more efficient estimators in some cases than those proposed by Bertrand and colleagues. *See* Jerry Hausman & Guido Kuersteiner, *Difference in Difference Meets Generalized Least Squares: Higher Order Properties of Hypotheses Test* (Boston Univ. Dep't of Econ., Working Paper No. WP2005-010, 2005), *available at* http://www.bu.edu/econ/workingpapers/papers/Guido/wp2005/didgls23_MainB.pdf.

69. John Bian et al., Spillover Effects of State Mandated-Benefit Laws: The Case of Outpatient Breast Cancer Surgery 4, 8–9, 18 tbl.1 (Sept. 12, 2007) (unpublished manuscript, on file with authors).

that general type is present or absent) or a series of variables that compares different variations of the law to one another. The latter approach avoids the dilution effects that may occur if some variants of the law are more effective than others but all are lumped together in the analysis. But in some cases, as in the mastectomy law example, not enough states have adopted laws of that type to permit such detailed classification. Grouping heterogeneous legal mandates together can lead to greater parsimony, but at the price of less helpful results.

These challenges require considerable expertise and resources to surmount. For reasons we discuss later in the Article, scholars in law schools may struggle to find them. In summary, the field of EHL presents a wealth of opportunities for scholars to make important contributions to expanding the relatively small knowledge base; however, these opportunities are costly to pursue. The EHL literature to date has been dominated by descriptive analyses and quasi-experimental designs. The challenge for empirical legal researchers is to find the proper balance between expediency and rigor[70] in selecting a study design, keeping in mind the quality of evidence they would like to contribute and the constraints of the research environment in which their work is conducted. It is also to ensure that their findings are interpreted—in their own reports and in policy debates—in a way that reflects the limitations of their data and analytical methods.

With this survey of the field in mind, we now turn to the question of how EHL scholarship has impacted policy.

III. THE IMPACT OF EMPIRICAL HEALTH LAW SCHOLARSHIP ON POLICY: TWO CASE STUDIES

In this Part, we juxtapose two policy histories that illustrate, respectively, the promise and the pitfalls of building a reliable evidence base for legal reforms and ensuring that policymakers respond to it. As an example of successful, evidence-based health law, we offer the history of laws aimed at reducing motor vehicle injuries to young drivers. As an illustration of where policymaking can depart significantly from the best evidence about what is likely to succeed, we offer the case of medical malpractice reform during the most recent insurance "crisis."

A. MOTOR VEHICLE SAFETY LAWS

Injuries from motor vehicle accidents are the leading cause of death among youth aged sixteen to twenty in the United States.[71] In 2000, there were 5600

70. *Cf.* Kaveh G. Shojania & Jeremy M. Grimshaw, *Evidence-Based Quality Improvement: The State of the Science*, 24 HEALTH AFF. 138, 141–42 (2005) (describing a similar tradeoff in the choice of designs for studying quality-improvement initiatives in health care).

71. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., U.S. DEP'T OF TRANSP., 2004 MOTOR VEHICLE OCCUPANT PROTECTION FACTS 12 (2004), *available at* http://www.nhtsa.dot.gov/people/injury/airbags/MVOP2004/images/2004MVOPFactsLo.pdf.

adolescent fatalities in traffic crashes, and the economic cost of accidents involving drivers under age twenty-one was $32.8 billion.[72] The high burden of injury, coupled with the long history of state and federal regulation of highway safety, has made vehicular injuries involving young people an obvious target for legal interventions. These interventions have been plentiful (and not restricted to adolescents). The best known are seatbelt laws, motorcycle helmet laws, speed limits, laws relating to alcohol consumption and driving, and driver's education, testing, and licensing provisions.

Motor vehicle safety policy is an EHL research success story. The Centers for Disease Control and Prevention has identified the massive reduction in motor vehicle fatalities in the latter half of the twentieth century as one of the century's ten greatest public health achievements, and it has credited public health law as a major contributor.[73] Not only have public health laws in this area proved effective, but evidence of their effectiveness has influenced their spread across the states. There are many areas in which EHL research contributed to the widespread adoption of efficacious motor vehicle laws, but we will focus on two of the best-documented successes: graduated driver licensing (GDL) and minimum legal drinking age (MLDA) laws, both of which aim to reduce traffic accidents involving young drivers.[74]

1. Graduated Driver Licensing

To address the risks arising from driver inexperience, GDL laws provide that young drivers initially will be issued restricted licenses and will gain full privileges only after they have acquired more experience. Typical GDL provisions require: holding of a learner's permit for a minimum amount of time (during which time the learner may only drive with an older person present); restricting the number of passengers that young drivers may carry; prohibiting freeway, highway, and nighttime driving; and requiring zero blood alcohol content.[75] In some countries, such as Canada, GDL schemes apply to all new drivers regardless of age, but laws in the United States focus on young drivers.[76]

The story of GDL laws illustrates how empirical research can play an integral

72. Christine Branche et al., *Graduated Licensing for Teens: Why Everybody's Doing It*, 30 J.L. MED. & ETHICS 146, 146 (2002).

73. Ctrs. for Disease Control & Prevention, *Ten Great Public Health Achievements—United States, 1900–1999*, 281 JAMA 1481 (1999); Richard A. Goodman et al., *Law and Public Health at CDC*, 55 MORBIDITY & MORTALITY WKLY. REP. (SUPP.) 29 (2006) (describing the supportive role of laws and legal tools).

74. We thank David Hemenway for suggesting these examples and referring us to pertinent research, which he summarizes in his book, DAVID HEMENWAY, WHILE YOU WERE SLEEPING: SUCCESS STORIES IN INJURY AND VIOLENCE PREVENTION (forthcoming 2008) (manuscript at 21, 23, on file with authors).

75. Herb M. Simpson, *The Evolution and Effectiveness of Graduated Licensing*, 34 J. SAFETY RES. 25, 27 (2003).

76. INS. INST. FOR HIGHWAY SAFETY & TRAFFIC INJURY RESEARCH FOUND., GRADUATED LICENSING: A BLUEPRINT FOR NORTH AMERICA 1–2 (2004).

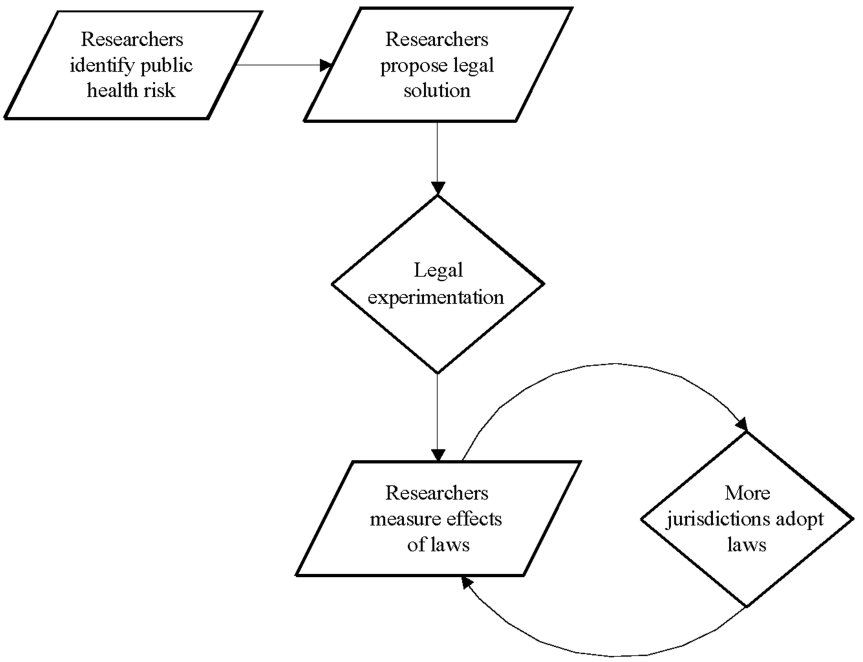


Figure 1. Lifecycle of an Empirical Health Law Success Story

role in both policy generation and policy evaluation, leading to successful, evidence-based lawmaking. In brief, GDL laws emerged from public health research highlighting a risk factor for serious injury. In response to these findings, experimentation with GDL laws ensued in a small number of jurisdictions. The pioneer laws were evaluated rigorously and in a timely fashion. The findings were impressive and led other jurisdictions to adopt similar laws. This, in turn, led to additional evaluations and more widespread adoption of the laws. This iterative process of research and policymaking constitutes an ideal "lifecycle" for a health law (Figure 1).[77]

The first stage in this lifecycle was the identification of a health risk factor based on sound epidemiological research. In 1971, the North Carolina Highway Commission reported findings indicating that young drivers were disproportionately represented in motor vehicle accidents.[78] The risk was particularly elevated at night and when young drivers were accompanied by young passengers in the front seat. These findings served as the original inspiration for GDL

77. This lifecycle bears some resemblance to the framework for evaluating complex interventions for improving health suggested by Michelle Campbell and colleagues, which has four stages: "definition of components of the intervention," development of study and intervention design, addressing methodological issues, and "promoting effective implementation." Michelle Campbell et al., *Framework for Design and Evaluation of Complex Interventions to Improve Health*, 321 BRITISH MED. J. 694 (2000).

78. Patricia F. Waller, *The Genesis of GDL*, 34 J. SAFETY RES. 17, 17–18 (2003).

proposals.[79]

The earliest proposals were made in the late 1970s by a transportation safety researcher, and the National Highway Transportation Safety Administration (NHTSA) developed a model GDL program in 1977.[80] The idea did not immediately take root among policymakers, however; only a few states implemented GDL legislation over the next decade.[81] Meanwhile, other countries were also considering GDL schemes. In 1983, an international symposium on young drivers held in Canada endorsed the idea of GDL systems.[82] The notion received further support after publication in 1990 of a highly influential Canadian study that definitively linked increased driver experience with decreased collision rates.[83]

The second stage of the lifecycle—pioneering policy experiments—emerged around this time. In 1987, New Zealand implemented a GDL program in response to data demonstrating that young drivers were at a highly elevated risk for accidents and also in response to suggestions from a leading traffic safety researcher that a GDL system would be helpful.[84] This pioneering law was studied from its earliest days in order to ascertain its effectiveness. Anecdotal evidence of reductions in traffic accidents began to surface in New Zealand almost immediately. A series of more rigorous evaluations, the first of which was published in 1992, showed dramatic results.[85]

This third stage in the lifecycle—evaluation of policy experiments—led swiftly to the fourth—emulation of successful experiments. Ontario, Canada adopted a GDL program in 1994 based on the New Zealand results. Nova Scotia did the same later that year, and four more provinces followed over the next five years.[86]

These laws, too, were evaluated and shown to be highly effective. In 1998, a

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79. *Id.* at 18.

80. U.S. DEP'T OF TRANSP., MODEL FOR PROVISIONAL (GRADUATED) LICENSING OF YOUNG NOVICE DRIVERS (1977).

81. *See* Simpson, *supra* note 75, at 27. There was some limited state action in response to the NHTSA report—Maryland adopted a nighttime driving restriction in 1979 and California and Oregon introduced provisional licenses in 1983 and 1989, respectively—but comprehensive GDL schemes did not emerge until the 1990s. Allan F. Williams, *Earning a Driver's License*, 112 PUB. HEALTH REP. 453, 455 (1997).

82. YOUNG DRIVER ACCIDENTS: IN SEARCH OF SOLUTIONS (D.R. Mayhew et al. eds., 1983).

83. D.R. MAYHEW & H.M. SIMPSON, NEW TO THE ROAD: YOUNG DRIVERS AND NOVICE DRIVERS: SIMILAR PROBLEMS AND SOLUTIONS? (1990).

84. Dorothy Begg & Shaun Stephenson, *Graduated Driver Licensing: The New Zealand Experience*, 34 J. SAFETY RES. 99, 99–100 (2003) (reporting that drivers aged fifteen to nineteen accounted for 27% of all drivers in traffic accidents notwithstanding the fact that they drove only 8% of the total mileage driven in New Zealand) (citing N.Z. MINISTRY OF TRANSP., A GRADUATED DRIVER LICENSING SYSTEM (1985)).

85. Simpson reports that the initial evaluations of the New Zealand program found reductions in the per-capita crash rate on the order of 25%, while later studies found longer-term effects around 7%. Simpson, *supra* note 75, at 29; *see also* Begg & Stephenson, *supra* note 84, at 100–03 (summarizing study findings).

86. Simpson, *supra* note 75, at 28.

pre-post analysis of the Ontario law showed a 31% decrease in the collision rate for novice drivers, a 27% drop in alcohol-related collisions, a 62% drop in collisions between midnight and 5:00 a.m., and a 61% decline in freeway crashes.[87] Controlled studies of the Canadian programs were available by the year 2000, showing reductions in Nova Scotia's per-capita crash rate in the 24% to 36% range[88] and a 5% reduction in fatalities and 14% reduction in injuries in Quebec.[89]

The Canadian laws appear to have sparked interest in GDL in the United States. In 1996, Florida became the first U.S. state to adopt GDL.[90] By 1997, six states had adopted GDL laws. Around this time, the Insurance Institute for Highway Safety and the Traffic Injury Research Foundation of Canada issued a joint report, which subsequently was updated several times, outlining detailed recommendations for GDL programs.[91] By 1999, seventeen states had adopted them.

The early state laws were evaluated in relatively short order, and a series of studies published around 2001 reported uniformly significant results.[92] The magnitude of the decreases in rates of fatal crashes, injury crashes, and all crashes varied across states, but in some states the decrease was staggering: North Carolina, for example, experienced a 57% drop in the per-capita fatal crash rate among sixteen-year-old drivers.[93] Based on data reported in a 2004 review of thirteen studies evaluating seven GDL schemes in the United States and five in foreign countries, the median reduction in per-capita crashes was 31% among sixteen-year-olds and the median reduction in injury crashes was 28%.[94] Statistically significant effects of the laws have been observed in all states that have been studied.[95] Many of these studies used quite sophisticated designs to control not only for confounding variables but also for uncertainty

87. PAUL BOASE & LEO TASCA, ONT. MINISTRY OF TRANSP., GRADUATED LICENSING SYSTEM EVALUATION: INTERIM REPORT (1998).

88. Daniel R. Mayhew et al., *Impact of the Graduated Driver Licensing Program in Nova Scotia*, 2 J. CRASH PREVENTION & INJURY CONTROL 179 (2001), *cited in* Simpson, *supra* note 75, at 29. Subsequent studies confirmed this impact, but found that most of it occurred during the learner's permit stage rather than among drivers who held a restricted license. Simpson, *supra* note 75, at 29.

89. Simpson, *supra* note 75, at 30 (citing Joann Bouchard et al., *The Quebec Graduated Licensing System for Novice Drivers: A Two-Year Evaluation of the 1997 Reform*, PROCEEDINGS OF THE 15TH INTERNATIONAL CONFERENCE ON ALCOHOL, DRUGS, AND TRAFFIC SAFETY, STOCKHOLM, SWEDEN (2000)).

90. Simpson, *supra* note 75, at 28.

91. The most recent version is INS. INST. FOR HIGHWAY SAFETY & TRAFFIC INJURY RESEARCH FOUND., *supra* note 76.

92. See studies collected in Simpson, *supra* note 75, at 31 tbl.2. Another excellent literature review is Jean T. Shope & Lisa J. Molnar, *Graduated Driver Licensing in the United States: Evaluation Results from the Early Programs*, 34 J. SAFETY RES. 63 (2003).

93. Robert D. Foss et al., *Initial Effects of Graduated Driver Licensing on 16-Year-Old Driver Crashes in North Carolina*, 286 JAMA 1588, 1588 (2001).

94. L. HARTLING ET AL., COCHRANE COLLABORATION, GRADUATED DRIVER LICENSING FOR REDUCING MOTOR VEHICLE CRASHES AMONG YOUNG DRIVERS (REVIEW), 24 tbl.04, 25 tbl.06 (2006).

95. Shope & Molnar, *supra* note 92, at 67.

about the time frame in which the effects of the laws would be seen.[96] Overall, the evidence for the laws' effectiveness is strong.[97]

Over the past decade, the results of the evaluations have led forty-seven states and the District of Columbia to adopt some kind of GDL law.[98] GDL researchers have noted that "the primary driving force" in the proliferation of GDL laws across states has been not merely "the cascading effect of follow the leader" but the scheme's "proven effectiveness."[99] Thus, in GDL laws we see initial policy experiments maturing into a dominant policy approach through an iterative cycle of evaluation and emulation.[100]

2. Minimum Legal Drinking Age Laws

The MLDA is the best-studied alcohol policy in the United States,[101] and another example of a success story for health law and EHL research. Aimed at reducing alcohol consumption by young adults, the MLDA has been set by state law and historically has varied from state to state between eighteen and twenty-one. In 1970, thirty-three states set the age at twenty-one. Between 1970 and 1975, twenty-nine states lowered their MLDA to eighteen, nineteen, or twenty. This occurred as part of the broader social recognition of eighteen- to twenty-year-olds as legal adults that occurred with the passage of the Twenty-Sixth Amendment in response to the Vietnam War draft.[102]

When the MLDA was first lowered, it provoked considerable social controversy concerning the effect on alcohol-related motor vehicle accidents involving young drivers. The available evidence at this point in time consisted largely of small, uncontrolled studies, fueling debate about whether observed increases in crash rates in states that lowered the MLDA were due to the legal change or

96. *See, e.g.*, Michael R. Elliott & Jean T. Shope, *Use of a Bayesian Changepoint Model To Estimate Effects of a Graduated Driver's Licensing Program*, 1 J. DATA SCI. 43 (2003); John D. Langley et al., *An Evaluation of the New Zealand Graduated Driver Licensing System*, 28 ACCIDENT ANALYSIS & PREVENTION 139 (1996); *see also* Hartling et al., *supra* note 94, at 6 (summarizing study designs in a comprehensive literature review).

97. *See* HARTLING ET AL., *supra* note 94, at 9.

98. INS. INST. FOR HIGHWAY SAFETY, U.S. LICENSING SYSTEMS FOR YOUNG DRIVERS (2007), *available at* http://www.iihs.org/laws/pdf/us_licensing_systems.pdf. This resource provides a detailed summary of the features of each state's GDL law.

99. Simpson, *supra* note 75, at 29.

100. In reviewing the literature on GDL laws, we also examined whether empirical legal research was influential in judicial decision making, for example, in adjudicating constitutional challenges to the laws. We found that GDL laws were not challenged in the courts.

101. *See* Alexander C. Wagenaar & Traci L. Toomey, *Effects of Minimum Drinking Age Laws: Review and Analyses of the Literature from 1960 to 2000*, 14 J. STUD. ALCOHOL (SUPP.) 206, 206 (2002) [hereinafter Wagenaar & Toomey, *Effects*] (citing Alexander C. Wagenaar & Traci L. Toomey, *Alcohol Policy: Gaps Between Legislative Action and Current Research*, 27 CONTEMP. DRUG PROBS. 681 (2000)); *see also id.* at 206 (counting 132 studies on the effect of MLDA changes published between 1960 and 1999).

102. Alexander C. Wagenaar, *Research Affects Public Policy: The Case of the Legal Drinking Age in the United States*, 88 ADDICTION (SUPP.) 75S, 76S (1993).

broader secular forces, such as improved police reporting practices.[103]

By the mid-1970s, controlled studies had become available. These generally confirmed the initial study findings: a lower MLDA was significantly associated with elevated risk of alcohol-related crashes among young drivers and increased alcohol consumption.[104] Effect sizes varied somewhat across studies, but clustered in the range of a ten to thirty percent increase in crashes.[105]

In light of this evidence, many states moved back in the other direction. Maine was the first, in 1977, and several others quickly followed. The experience of these early movers was promptly studied, and the evaluations demonstrated a reduction in alcohol-related crashes. By 1983, sixteen states had moved to a MLDA of twenty-one. Researchers continued to evaluate these changes, and by 1983, five studies had been published on the effect of raising the MLDA on traffic crashes; four demonstrated statistically significant effects on at least one type of crash.[106]

Political interest groups, particularly Mothers Against Drunk Driving, used these findings to press the case for reform at the national level.[107] Their advocacy was extremely effective, and in April 1982, President Reagan established a Presidential Commission on Drunk Driving at the urging of more than 300 members of Congress.[108] While the Commission was carrying out its work, the National Transportation Safety Board recommended a national minimum drinking age of twenty-one.[109] This recommendation appeared in the Commission's interim report in December 1982 and headlined its final report in November 1983.[110]

The Commission's work quickly led to congressional action. In October 1982, the Congress enacted the Alcohol Traffic Safety and National Driver Register Act,[111] which mandated that the Secretary of Transportation consider a state MLDA of twenty-one as a criterion for awarding supplemental grants to states. In December, it inserted a statement in its highway funding act that "[t]he Congress strongly encourages each State to prohibit the sale of alcoholic

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103. *Id.*

104. *See id*. at 207, 210 (listing studies on lowering the MLDA and their findings).

105. *Id.* at 209, 212–13, 215 (tallying outcomes among 132 studies).

106. *See* Wagenaar & Toomey, *Effects*, *supra* note 101, at 210.

107. Mary Pat Treuthart, *Lowering the Bar: Rethinking Underage Drinking*, 9 N.Y.U. J. LEGIS. & PUB. POL'Y 303, 311–12 (2005–2006); Wagenaar, *supra* note 102, at 76S, 79S.

108. MIGDON SEGAL, CONG. RESEARCH SERV., DRUNK DRIVING AND THE NATIONAL DRIVER REGISTER 2 (1985).

109. *Id.* at 3.

110. PRESIDENTIAL COMM'N ON DRUNK DRIVING, FINAL REPORT: THE NEW HOPE OF SOLUTION 10–11 (1983).

111. Pub. L. No. 97-364, 96 Stat. 1738 (1982) (codified as amended at 23 U.S.C. § 408 (2000)); *see also* National Highway Transportation Safety Administration, Incentive Grant Criteria for Alcohol Traffic Safety Programs, 48 Fed. Reg. 5545, 5549 (Feb. 7, 1983) (announcing a final rule incorporating the MLDA requirement and citing supportive research findings from the Presidential Commission and the National Transportation Safety Board).

beverages to persons who are less than 21 years of age."[112]

When the states did not immediately adopt laws enshrining this recommendation, Congress sought to increase its leverage. Initial legislation proposed a national minimum drinking age to be imposed on states by Congress under its interstate commerce power.[113] The Reagan Administration had originally opposed a federal mandate, preferring to inspire states to act on their own, but quickly reversed its position.[114] The initial legislation nonetheless failed, but Congress responded with an alternative proposal. In 1984, it passed the National Minimum Drinking Age Act (NMDA),[115] which, rather than imposing a national drinking age outright, tied the national minimum drinking age to federal highway funds. The Act withheld five percent of highway funding from states that did not raise their MLDA to twenty-one,[116] increasing to ten percent beginning in fiscal year 1988.[117]

Empirical legal research played prominently in hearings on both versions of the NMDA legislation. Witnesses offering testimony cited research by University of Michigan researchers, the Insurance Institute for Highway Safety, the National Highway Traffic Safety Administration, and law professors at the University of Chicago.[118] Although there was some dispute among witnesses about how to interpret and credit the studies, the Congress ultimately appeared to find the evidence persuasive. The NMDA was passed, and in response, all states moved their MLDA to twenty-one by 1988.[119]

Research continued to be conducted after implementation of the NMDA, and

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112. Surface Transportation Assistance Act of 1982, Pub. L. No. 97-424 § 209, 96 Stat. 2097 (1982).

113. A Bill to Restrict the Sales of Alcoholic Beverages in Interstate Commerce, H.R. 3870, 98th Cong. (1983).

114. SEGAL, *supra* note 108, at 3.

115. Pub. L. No. 98-363, § 6(a), 98 Stat. 435, 437 (1984) (codified as amended at 23 U.S.C. § 158 (2000)).

116. *Id.* §6(a)(1).

117. 23 U.S.C. § 158(a)(1) (2000). The 1988 sunset provision on the original legislation was removed by the Consolidated Omnibus Budget Reconciliation Act of 1985, which made the ten percent withholding permanent. Pub. L. No. 99-272, § 4104a, 100 Stat. 82, 114 (1986).

118. *National Minimum Drinking Age: Hearing Before the Subcomm. on Alcoholism and Drug Abuse of the S. Comm. on Labor and Human Resources*, 98th Cong. 38 (1984) (testimony of Christine Lubinski, Director, Public Policy Office, National Council on Alcoholism); *id.* at 80–81 (testimony of Michael M. Birkley, Executive Director, Tavern League of Wisconsin); *id.* at 130–31 (statement of the National Restaurant Association); *Prohibit the Sale of Alcoholic Beverages to Persons Under 21 Years of Age: Hearing on H.R. 3870 Before the Subcomm. on Commerce, Transportation, and Tourism of the H. Comm. on Energy and Commerce*, 98th Cong. 10–11 (1983) (statement of Candy Lightner, President, Mothers Against Drunk Drivers); *id.* at 59 (written testimony of Michael M. Birkley, Executive Director, Tavern League of Wisconsin); *id.* at 66–67 (written testimony of Allan F. Williams, Senior Behavioral Scientist, Insurance Institute for Highway Safety); *id.* at 73–74 (statement of Charles A. Hurley, Executive Director for Federal Affairs, National Safety Council); *id.* at 240 (statement of Ben Kelley, Senior Vice President, and Allan F. Williams, Senior Behavioral Scientist, Insurance Institute for Highway Safety).

119. Wagenaar & Toomey, *Effects*, *supra* note 101, at 206.

these studies confirmed the earlier findings.[120] A comprehensive evaluation of the evidence base requested by Congress and reported in 1987 by the General Accounting Office (GAO)[121] raised the profile of the evidence and dispelled any lingering doubts about the effectiveness of raising the drinking age. The GAO's thorough, 111-page review concluded that "the evidence is persuasive" that raising the MLDA has significant effects on alcohol-related crashes among eighteen- to twenty-year-olds, and that the observed effects were consistent across studies in different states and with different designs and methods.[122]

The GAO scrutinized the methodologies of the existing studies and found that although the studies varied in strength, a number of reliable, high-quality analyses were available. The designs of MLDA studies have ranged from simple pre/post studies to cross-sectional studies to the more tightly controlled, longitudinal and time-series analyses. The best analyses[123] exploit not only variation over time as the law changed, but also variation across age groups (eighteen- to twenty-year-olds, who were affected by the law, to twenty-one-and-over groups, who were not).

MLDA laws have been challenged infrequently in court, but the three cases that have been litigated have produced memorable results. The earliest case was an equal-protection challenge to a Michigan constitutional amendment raising the MLDA from nineteen to twenty-one. The federal district court's opinion in *Felix v. Milliken*[124] contained an exhaustive discussion of two studies of Michigan's law by Dr. Richard Lee Douglass on the effect of lowering the drinking age on traffic accidents in Michigan.[125] The court's exposition of the studies is remarkably detailed, and after this review of the evidence, the court had little trouble in concluding that Michigan's voters had a reasonable basis for changing the law.[126]

The second case was South Dakota's famous challenge to the NMDA, which

120. *See id.* at 211–12 (collecting studies). Some of these studies have focused on the interactions of the MLDA law change with other alcohol-related laws. *See, e.g.*, William R. Ponicki et al., *Joint Impacts of Minimum Legal Drinking Age and Beer Taxes on US Youth Traffic Fatalities, 1975 to 2001*, 31 ALCOHOLISM: CLINICAL & EXPERIMENTAL RES. 804 (2007) (examining interaction with beer taxes); Robert B. Voas et al., *Assessing the Effectiveness of Minimum Legal Drinking Age and Zero Tolerance Laws in the United States*, 35 ACCIDENT ANALYSIS & PREVENTION 579 (2003) (examining interaction with 0.02% blood alcohol concentration limit for drivers under age twenty-one). Twenty-four evaluations of MLDA laws were published in the two years following the adoption of the NMDA alone. U.S. GEN. ACCOUNTING OFFICE, DRINKING-AGE LAWS: AN EVALUATION SYNTHESIS OF THEIR IMPACT ON HIGHWAY SAFETY 11 (1987).

121. U.S. GEN. ACCOUNTING OFFICE, *supra* note 120.

122. *Id.* at 39.

123. *See, e.g.*, Alexander C. Wagenaar, *Effects of an Increase in the Legal Minimum Drinking Age*, 2 J. PUB. HEALTH POL'Y 206, 211–12 (1981); Alexander C. Wagenaar, *Raising the Legal Drinking Age in Maine: Impact on Traffic Accidents Among Young Drivers*, 18 INT'L J. ADDICTIONS 365 (1983).

124. 463 F. Supp. 1360 (E.D. Mich. 1978).

125. *Id.* at 1379–82. Michigan lowered the drinking age to eighteen in 1972, and then raised it to nineteen in 1978. *Id.* at 1364.

126. *Id.* at 1389.

culminated in the U.S. Supreme Court's decision in *South Dakota v. Dole*,[127] upholding the statute against challenges under the Spending Clause and the Twenty-First Amendment. The Court's Spending Clause analysis cited findings of the Presidential Commission, which had concluded that varying drinking ages across the states fostered drunk driving by encouraging young people to commute to states where the drinking age was lower,[128] and concluded that the Act pursued "the general welfare"[129] and directly related to the federal purpose for which highway funds were spent.

The third case, *Manuel v. Louisiana*,[130] is a relatively recent challenge to a post-NMDA state law. Ruling on an equal-protection challenge, the Louisiana Supreme Court held that the MLDA survived even intermediate scrutiny due to the extensive evidentiary record that the higher MLDA substantially furthered the state's important interest in reducing alcohol-related crashes involving youth.[131] The court's decision on rehearing overturned its initial holding[132] on the grounds that it had been based on the wrong piece of statistical evidence.[133] The rehearing opinion contained in an appendix an extensive discussion of the evidence base on MLDA laws,[134] specifically referencing the GAO's report as proof that the efficacy of MLDA laws was "widely accepted by experts."[135] In summary, the courts, as well as state and federal legislatures, have made good use of high-quality empirical research on the efficacy of MLDA laws.

Overall, MLDA laws have had a lifecycle similar to GDL laws, characterized by iterative interactions between lawmaking and empirical research. The MLDA story is even more dynamic than the history of GDL laws, however, because of the presence of not one, but two, natural experiments. Twenty-nine states first lowered their MLDA laws, then sixteen states reversed that decision within a short period of time. After the drinking age was lowered, empirical evaluations provided evidence that the change in the law created a health risk. A common-sense solution was clear, and many states adopted it. These changes in the law were then extensively evaluated and the positive findings disseminated to state and federal policymakers through the efforts of political interest groups. They were deemed sufficiently compelling to support federal action, which led to universal adoption by the states. Finally, research and evaluation continued well

127. 483 U.S. 203 (1987).

128. *Id.* at 209 (citing PRESIDENTIAL COMM'N ON DRUNK DRIVING, *supra* note 110, at 11).

129. *Id.* at 206.

130. 677 So. 2d 116 (La. 1996).

131. *Id.* at 125.

132. Manuel v. Louisiana, 692 So. 2d 320, 321, *rev'd*, 677 So. 2d 116, 118 (La. 1996).

133. The court originally held that the state had not demonstrated the efficacy of its scheme because the number of alcohol-related crashes was higher among drivers aged twenty-one to twenty-three than among those aged eighteen to twenty. *Manuel*, 692 So. 2d at 327. On rehearing, the court decided that the correct statistic was the proportion of alcohol-related traffic crashes attributable to each group. Finding that the younger group was proportionally the most dangerous group, it upheld the law. *Manuel*, 677 So. 2d at 122–23.

134. *Manuel*, 677 So. 2d at 128–32.

135. *Id.* at 125.

after universal adoption, providing a continually growing evidence base that can be used to head off efforts to reverse the laws or challenge them on constitutional grounds.

This is an unqualified success story for EHL research. The National Highway Traffic Safety Administration has estimated that 17,359 traffic fatalities were averted between 1975 and 1997 as a result of a higher MLDA.[136]

3. Enabling and Inhibiting Factors

What accounts for the success of EHL research in the area of motor vehicle safety? Four enabling factors appear to have considerable explanatory force: the presence of natural experiments, the ready availability of data, the uncontested framing of the issue as a public health problem, and the facilitating role of political interest groups.

First, natural experiments with changes to GDL and MLDA laws provided opportunities for controlled testing of hypotheses about the efficacy of these changes. This was particularly true for MLDA laws because the pioneering experiments took place in the United States and because states moved their MLDA from high to low and back again, providing two points at which to observe the effects of this change.

Second, researchers were able to take advantage of these natural experiments because of the ready availability of good data on the outcome variables of interest. The primary outcome variable for GDL laws is the overall rate of motor vehicle crashes involving young drivers. Secondary outcomes include rates of injury crashes, fatal crashes, hospitalizations related to crashes, crashes during nighttime, alcohol-related crashes, and crashes involving property damage.[137] In MLDA studies, the outcome variables have included traffic crashes involving alcohol, rates of alcohol consumption among under-twenty-one-year-olds, alcohol sales levels, and rates of driving while under the influence of alcohol.[138]

For some of these measures, researchers have had to rely on self-reports on youth surveys, impressions of police officers responding to accidents, or statistical surrogates for alcohol involvement in a crash (for example, crashes that occur at nighttime and involve an unaccompanied male driver).[139] In general, however, the quality of the data has been good, and its availability has been very good, compared to other areas of health law. State departments of public safety, police departments, or divisions of motor vehicles maintain electronic databases of motor vehicle accidents. Characteristics of drivers are often available from police reports or by searching driver's license databases. Reliable

136. NAT'L HIGHWAY TRAFFIC SAFETY ADMIN., TRAFFIC SAFETY FACTS 1997: ALCOHOL 4 (1998).

137. HARTLING ET AL., *supra* note 94, at 3.

138. Wagenaar & Toomey, *Effects*, *supra* note 101, at 207–12 (listing outcome measures in all MLDA studies published between 1960 and 1999); U.S. GEN. ACCOUNTING OFFICE, *supra* note 120, at 21–23.

139. U.S. GEN. ACCOUNTING OFFICE, *supra* note 120, at 24–25.

measures of alcohol involvement in crashes—for example, breath tests and blood-alcohol content tests conducted by police officers and coroners—have often been available.

Since the 1980s, the federal government and many states have invested in maintaining and improving their traffic crash databases. This has enabled researchers to overcome some of the criticisms of early studies—for example, the objection that many MLDA studies relied on proxy measures of alcohol involvement in crashes rather than actual evidence of driver impairment.[140] Advances in statistical modeling and computing in the 1980s and 1990s also made it possible for researchers to employ more sophisticated models that addressed concerns about confounds in studies from the 1970s and took full advantage of the available data.

A third enabling factor had to do with the framing of the issue in policy debates. From the earliest days of the debates, motor vehicle accidents involving young people were framed as a public health problem. Research had clearly established the high rate of crashes involving young drivers and the devastating injuries that resulted. Injury prevention was an established subfield of public health, and prevention of harm to children was a core concern of the field. As a result, it was natural to look to public health research for policy solutions. Indeed, framing the issue as a public health problem attracted the interest of a number of skilled public health researchers. The overwhelming bulk of the empirical scholarship on GDL and MLDA laws was conducted not by legal scholars, but by researchers in the public health community. Finally, the clear public health ramifications of the problem drew the interest of influential and relatively apolitical federal agencies, such as the NHTSA, which provided funding and a receptive ear for empirical research.

The fourth enabling factor was the facilitative role played by political interest groups. In the case of GDL laws, no influential interest groups emerged to oppose the policy change or dispute the evidence base that supported it. This was partially related to the issue's framing; characterizing the problem as a public health threat and a pediatric problem made it a highly sympathetic cause.[141] No interest group contested that reducing the rates of crashes due to driver inexperience or alcohol use among young people was a worthy target for

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140. *Id.* at 13.

141. In contrast, motorcycle helmet laws, which have also been proven to be highly effective in preventing injuries, have faced strong opposition on antipaternalism grounds, probably because they affect primarily adults. *See, e.g.*, City of Adrian v. Poucher, 247 N.W.2d 798 (Mich. 1976) (upholding Michigan's motorcycle helmet law despite defendant's claim that the law unlawfully invades individual rights). Indeed, the recent trend in state motorcycle helmet laws has been to scale them back so that they cover only young people. Marian Moser Jones & Ronald Bayer, *Paternalism and Its Discontents: Motorcycle Helmet Laws, Libertarian Values, and Public Health*, 97 AM. J. PUB. HEALTH 208, 215 (2007) ("In 1997, after pressure from state-level motorcycle activists, Arkansas and Texas repealed their universal helmet laws and instead required helmets only for riders aged younger than 21 years. These repeals were followed by similar actions in Kentucky (1998), Louisiana (1999), Florida (2000), and Pennsylvania (2003).").

policy interventions. This paved the way for rapid policy responses. The only industry group that played prominently in the policy debate was the Insurance Institute for Highway Safety, which favored GDL laws and funded and participated in studies to build the evidence base for them.[142] In the case of MLDA laws, there was organized opposition to raising the drinking age, primarily alcohol industry groups. But interestingly, the influence of these organizations may actually have helped promote high-quality research. They did not produce a raft of poor-quality studies of their own,[143] but rather dedicated themselves to criticism of academic research demonstrating a public health benefit to raising the MLDA. Researchers were aware that these groups would try hard to discredit their studies and, as a result, took a great deal of care in designing them, so it would be difficult to find scientific flaws.[144] Political interest groups that favored raising the MLDA were also crucial to the success story of MLDA laws. Groups such as Mothers Against Drunk Driving partnered with researchers who were committed to ensuring that their findings reached a policy audience, resulting in a highly successful dissemination effort.[145]

To be sure, these enabling factors operated in the face of several factors that inhibited the successful production of reliable empirical legal research. These were primarily methodological problems. A key shortcoming of the empirical base regarding GDL laws is the studies' consistent focus on evaluating GDL laws one state (or country) at a time. Single-state studies suffer from clear generalizability issues. Perhaps more importantly, because each state's GDL scheme consists of a number of different features, finding that one state's scheme had a bigger effect than another state's provides little information about exactly which features were most important.[146] GDL laws are highly variable across states—for example, in the age groups covered and the particular restrictions imposed.[147] This heterogeneity may help explain the variability in the magnitude of effects found among studies of GDL laws in different states.[148] Along with variations in study methodologies, it makes it difficult to directly compare individual states' evaluation results.[149]

For MLDA, one challenge for empirical evaluation of the laws has been that studies have found very low rates of enforcement actions (such as compliance

142. *Cf.* Simpson, *supra* note 75, at 28 (noting that the Institute "had played a dominant leadership role for years, not only in the research that provided the groundwork for graduated licensing but also in actively promoting its adoption").

143. In other debates, industry groups have produced their own studies to counter those produced by organizations advocating changes disfavoring them. *See, e.g.*, *infra* notes 180–82 and accompanying text.

144. Wagenaar, *supra* note 102, at 80S.

145. *Id.*

146. Shope & Molnar, *supra* note 92, at 67 ("Understanding which components of GDL have contributed to the crash reductions is difficult because programs are implemented as a total package.").

147. *See* INS. INST. FOR HIGHWAY SAFETY, *supra* note 98 (outlining several dimensions of variation).

148. Simpson, *supra* note 75, at 33.

149. *See* Shope & Molnar, *supra* note 92, at 64.

checks on alcohol retailers) in some states.[150] If alcohol sellers are aware that the probability of an enforcement action is low, they may not comply with MLDA laws. Assuming that this is likely the case, effect sizes observed in MLDA studies probably underestimate the potential effects of raising the MLDA on traffic crashes were states to enforce the laws vigorously.

Despite these methodological issues, the empirical research base around MLDA and GDL laws is impressive, and policymakers' response has been equally impressive. Motor vehicle safety laws are one area that demonstrates the power of empirical legal research to contribute to enormous reductions in the burden of injuries.

B. MEDICAL MALPRACTICE REFORM

1. The Production of Scholarship and Policy

In striking contrast to the story of motor vehicle safety laws, the story of medical malpractice reform laws exemplifies a missed opportunity to use rigorous EHL research to develop evidence-based policy. Legislative consideration of liability-limiting tort reforms for medical malpractice has a long and cyclical history[151]—interest in reform waxes and wanes with trends in the cost of medical malpractice liability insurance. Despite the accretion of a substantial base of scholarly research studying the effects of these reforms over time,[152] the policy debates have had the same disappointing tone, focus, and outcomes over three successive malpractice "crises," which are characterized by spikes in malpractice insurance premiums and/or reductions in the supply of malpractice insurance.

During the first malpractice crisis, in the mid-1970s, the empirical research base was extremely thin. Little was known about the extent to which malpractice reforms achieved their four primary aims: stabilizing liability insurance premiums, controlling the frequency of malpractice claiming, reducing the severity (average cost) of malpractice claims, and preventing physician behaviors that are believed to be correlated with high-risk malpractice environments, such as leaving practice and practicing defensive medicine.

The first serious attempt to synthesize the literature to aid policymaking came in 1973 with the report of the Secretary of Health, Education and Welfare's Commission on Medical Malpractice,[153] in which most of the studies identified were not of sufficient rigor or scope to generate useful broad conclusions about

150. Wagenaar & Toomey, *Effects*, *supra* note 101, at 218.

151. Rogan Kersh, *Medical Malpractice and the New Politics of Health Care*, *in* MEDICAL MALPRACTICE AND THE U.S. HEALTH CARE SYSTEM 43, 43–67 (William M. Sage & Rogan Kersh eds., 2006) [hereinafter MEDICAL MALPRACTICE IN THE U.S.], provides an excellent summary of this history.

152. To limit the scope of our discussion, we will focus on the role that empirical studies of malpractice reforms have played during the most recent crisis from 2000 to 2006.

153. U.S. DEP'T OF HEALTH, EDUC. & WELFARE, REPORT OF THE SECRETARY'S COMMISSION ON MEDICAL MALPRACTICE (1973).

the malpractice environment.[154] In the late 1970s, the National Association of Insurance Commissioners advanced the empirical base significantly by collecting and tabulating three years' worth of insurance-carrier data on closed malpractice claims.[155] The availability of this database made malpractice a more attractive and feasible topic for empirical scholars to study.[156]

Although Patricia Danzon and other analysts contributed a handful of carefully conducted, controlled analyses of the effects of tort reforms over the next decade,[157] when the next malpractice crisis struck in the mid-1980s, policymakers still had relatively little in the way of empirical research to illuminate the path to effective reforms.[158] The federal government again appointed a task force, which issued its findings as the crisis began to wane.[159] Notwithstanding this contribution, the policy debates tended, as in the 1970s, to be dominated by political interest groups representing the medical profession on the one hand, and the legal profession on the other.[160] Scholars and their research findings rarely played a role.[161] The results were similar to those of the mid-1970s: through the end of the 1980s and into the early 1990s, legislatures reached for a limited set of reforms, such as damages caps and collateral-source offsets, making few innovations.[162] Notably, the few studies of damages caps available at this time had determined that although they reduced the average value of awards, they did not significantly affect the frequency of claiming or the level of malpractice insurance premiums.[163]

Over the next fifteen years, the body of scholarly literature evaluating the effects of tort reforms grew significantly. A number of top-flight economists,

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154. Stephen Zuckerman et al., *Information on Malpractice: A Review of Empirical Research on Major Policy Issues*, 49 LAW & CONTEMP. PROBS. 85, 86–87 (1986).

155. NAT'L ASS'N OF INS. COMM'RS, MALPRACTICE CLAIMS: FINAL COMPILATION (M. Patricia Sowka ed., 1980).

156. Randall R. Bovbjerg & Joel M. Schumm, *Judicial Policy and Quantitative Research: Indiana's Statute of Limitations for Medical Practitioners*, 31 IND. L. REV. 1051, 1055 (1998).

157. Patricia Danzon, *The Frequency and Severity of Medical Malpractice Claims*, 27 J.L. & ECON. 115 (1984); Patricia M. Danzon, *The Frequency and Severity of Medical Malpractice Claims: New Evidence*, 49 LAW & CONTEMP. PROBS. 57 (1986); Frank A. Sloan, *State Responses to the Malpractice Insurance "Crisis" of the 1970s: An Empirical Assessment*, 9 J. HEALTH POL. POL'Y & L. 629 (1985).

158. *See* Zuckerman et al., *supra* note 154, at 110 (reporting that in 1985, "comparatively little generalizable empirical data, and even less explanation or analysis of the causes or effects of such quantitative phenomena, is available").

159. U.S. DEP'T OF HEALTH & HUMAN SERVS., REPORT OF THE TASK FORCE ON MEDICAL LIABILITY AND MALPRACTICE (1987).

160. *See* Bovbjerg & Schumm, *supra* note 156, at 1055–56.

161. Zuckerman et al., *supra* note 154, at 111.

162. Bovbjerg & Schumm, *supra* note 156, at 1055–56; Eleanor D. Kinney, *Malpractice Reform in the 1990s: Past Disappointments, Future Success?*, 20 J. HEALTH POL. & POL'Y L. 99, 112 (1995). Bovbjerg and Schumm note that one area of innovation was the creation of administrative compensation funds for serious neurological birth injuries in Virginia and Florida. Bovbjerg & Schumm, *supra* note 156, at 1056.

163. These studies are summarized in Michelle M. Mello & David M. Studdert, Understanding Medical Malpractice Damages Caps 30–43, 63–64 (Dec. 7, 2005) (unpublished manuscript, on file with authors).

law professors, and public-policy scholars contributed studies that controlled (more or less successfully) for variations in state environments that might explain gaps in premium levels, physician supply, or claiming levels and costs.[164] When the third malpractice crisis hit, around the turn of the twenty-first century, scholarly interest in the topic redoubled. Various arms of the federal government published studies of varying quality in the early years of this crisis. The lifecycle of academic studies was considerably longer, but by 2004, scholarly studies capturing data through the early 2000s began to surface.

The academic studies of this period have been, as a group, quite rigorous and carefully conceived. They have made it possible to draw a few fairly definitive conclusions about damages caps and other conventional tort reforms.[165] Noneconomic damages caps appear to have statistically significant effects on premiums and physician supply, but the effect sizes are quite modest.[166] Caps have a larger effect on award amounts, as might be expected, but there is no evidence that they affect claims frequency.[167] Joint-and-several liability reform has been found to be significantly negatively associated with premium levels but not other outcome variables.[168] "Study findings [regarding shorter] statutes of limitations [and] repose are mixed, but some strong studies have found an effect on claims frequency and premiums . . . ."[169] The weight of the evidence suggests that attorney-fee limits, collateral-source rule reform, pretrial screening panels, and periodic payment have little to no effect on relevant outcome variables.[170]

High-quality empirical research on malpractice reforms continues to be produced at a high rate. The question is: is anyone listening? Unfortunately, the answer for legislators appears to be "no." Although the evidence taken as a whole does not support a clear regulatory solution, broad conclusions about the connection between malpractice reforms and outcome variables could be helpful for policymakers as they attempt to fashion sensible reforms. Despite this, little of this research has found its way into policy debates over reforms during the latest malpractice crisis. To the extent that it has, policymakers have tended to use the studies more to support their *ex ante* policy preferences than to determine optimal regulation.

The Congress has been focused narrowly on legislation proposing a federal cap on noneconomic damages. The House and Senate held several hearings on medical liability from 2003 through 2006 to consider this legislation (and, on a

164. For a full discussion, see *id.* at 30–47.

165. *See* MICHELLE M. MELLO, THE ROBERT WOOD JOHNSON FOUND., MEDICAL MALPRACTICE: IMPACT OF THE CRISIS AND EFFECT OF STATE TORT REFORMS 9–12 (2006), *available at* http://www.rwjf.org/pr/synthesis/reports_and_briefs/pdf/no10_researchreport.pdf.

166. *Id.* at 11–12.

167. *Id.* at 11.

168. *Id.* at 9.

169. *Id.*

170. *Id.*

smaller number of occasions, bills to authorize grants to support demonstration projects of experimental tort reforms such as administrative compensation programs and early-offer programs). The hearings on caps were remarkably consistent in the composition of the panel of invited witnesses, the kinds of arguments and evidence offered by the witnesses, and the tenor of the dialogue between witnesses and committee members.[171] The panels usually consisted of one or more malpractice "victims" who told their personal stories, one or more representatives of physician or hospital organizations, an insurance industry representative, a representative of the trial bar, and a representative of a consumer organization (often one with ties to the bar). Occasionally, a lone academic would appear.

Many witnesses did cite data in their testimony, but they almost uniformly relied on descriptive studies, eschewing more complex, controlled studies produced by academics.[172] Testimony was liberally peppered with anecdotes about persons affected by medical errors or high insurance costs.[173] Questioning of the witnesses by the committee members rarely addressed data, and when it did, it typically focused on analyses conducted by interest groups rather than academics.[174]

The policy process at the state level was somewhat better, in that a number of state governors and legislators appointed study commissions to investigate the evidentiary basis for a range of proposed reforms. These commissions, however, tended to fall back on familiar strategies of information-gathering—namely, assembling a panel of witnesses, most of which represented the various stakeholder groups. Little independent investigation and review of scholarly literature appears to have been conducted.

The experience of the Florida Governor's Select Task Force on Healthcare

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171. The hearings on demonstration projects featured a much larger role for academics and discussion of scholarly studies. *See generally Medical Liability: New Ideas for Making the System Work Better for Patients: Hearing on S. 1337 Before the Comm. on Health, Education, Labor, and Pensions*, 109th Cong. (2006); *Innovative Solutions to Medical Liability: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 109th Cong. (2006).

172. *See, e.g.*, *Medical Liability Reform: Stopping the Skyrocketing Price of Health Care: Hearing Before the H. Comm. on Small Business*, 109th Cong. 13–14 (2005) (statement of Lawrence E. Smarr, President, Physician Insurers Association of America) (citing simple descriptive statistics from studies by the GAO, the National Association of Insurance Commissioners, and AM Best). *But see Assessing the Need to Enact Medical Liability Reform: Hearing on H.R. 5 Before the H. Comm. on Energy and Commerce*, 108th Cong. 42–48 (2003) (testimony of Fred J. Hiestand, President, Californians Allied for Patient Protection) (citing several controlled studies along with simple descriptive studies).

173. *See, e.g.*, *Harming Patient Access to Care: The Impact of Excess Litigation: Hearing Before H. Comm. on Energy and Commerce*, 107th Cong. (2002) (testimony of Lauren Townsend, Director, Coalition for Consumer Justice).

174. One colorful example is an exchange between Rep. John Conyers and an insurance association executive, in which Conyers administered a "true or false" exam in an attempt to force the executive to acknowledge the findings of a consumer group, the Center for Justice and Democracy, whose work the executive believed to be of poor quality. *See Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) Act of 2003: Hearing on H.R. 5 Before H. Comm. on the Judiciary*, 108th Cong. 86–87 (2003).

Professional Liability Insurance is illustrative. Appointed by Governor Jeb Bush in 2002, the Task Force was directed to examine Florida's medical liability environment and make recommendations for improving it. The Task Force had a blue-ribbon roster, including former Secretary of Health and Human Services Donna Shalala, and ended up recommending to the legislature that it adopt a package of tort reforms. The proposed package included a $250,000 noneconomic damages cap, expert-witness qualifications, periodic payment, joint-and-several liability reform, and small-scale demonstration projects of administrative compensation.[175] It took its work seriously, meeting ten times over five months, holding several hearings, producing a 345-page report, and submitting thirteen volumes of supporting materials along with it.[176] Despite this seemingly comprehensive investigation and the fact that scholarly studies have generated evidence in support of many of the reforms the Task Force recommended, nothing indicates that the Task Force considered the academic research. Its discussion of expert-witness qualifications, joint-and-several liability reform, and periodic payment contained no citations to empirical studies of any kind and no references to information provided by academics.[177] Its findings concerning administrative compensation also cited no scholarly studies of such systems, but did at least reference a report by the Institute of Medicine and testimony from a handful of scholars familiar with the literature.[178] Its discussion of damages caps is, from an academic's perspective, highly unsatisfactory. The Task Force referenced not a single published study of the effects of damages caps, relying instead on proprietary analyses performed by a consultant, William Hamm, under a contract with an advocacy organization whose purpose is to preserve California's cap on noneconomic damages.[179]

Similar processes and conclusions played out in other states. The dominance of uncontrolled, descriptive studies conducted by political interest groups in these debates has been striking. A typical report compares premiums in states with caps on noneconomic damages, to premiums in other states that do not have caps, without controlling for any of the ways in which the states may differ.[180] These studies suffered from numerous other methodological problems including inappropriate comparison groups, failure to adjust for inflation, and

175. The Task Force's work is described in its final report. GOVERNOR'S SELECT TASK FORCE ON HEALTHCARE PROF'L LIAB. INS., FINAL REPORT vii–xvi (2003), *available at* http://www.doh.state.fl.us/myflorida/DOH-Large-Final%20Book.pdf (listing the Task Force's sixty recommendations).

176. *Id.*

177. *See id.* at 235–39, 260–61, 276–77.

178. *Id.* at 159–70.

179. *See id.* at 193–200. The organization, Californians Allied for Patient Protection, commissioned a series of such reports from Dr. Hamm. Based on a review of the one report we could obtain from the organization, the estimates generated by Dr. Hamm were not on very solid evidentiary footing (details available from authors upon request); *see* WILLIAM G. HAMM, LECG, HOW THE MICRA CAP INFLUENCES HEALTH CARE COSTS FOR SAFETY NET PROVIDERS AND MEDI-CAL. (1999).

180. *See, e.g.*, Am. Ass'n for Justice, Medical Malpractice Insurance: Do Caps Reduce Insurance Premiums?, http://www.atla.org/pressroom/FACTS/medmal/AvgPremiums_1104.aspx (last visited Oct. 22, 2007).

selective reporting of data.[181] They were, however, presented simply, in straightforward language, with vivid charts and graphs, in short briefing papers that were far more accessible (physically and cognitively) to policymakers than scholarly journal articles.[182] The academic articles described complicated multivariate regression models in lengthy and pointy-headed presentations—hardly fodder for headline-grabbing hearings.

As a result, to the extent that enacted policies reflected empirical findings, it was largely a matter of luck rather than deliberate process. Examining the relative prevalence of various kinds of tort-reform legislation at the state level over the past two years (Table 1),[183] the most encouraging observation is that the reform with the greatest amount of empirical support from well-designed studies, damages caps, has been considered by more states than any other reform. On the other hand, many other reforms with little or no evidence to support them have been repeatedly considered and, on several occasions, enacted. Similar observations can be made from an examination of the prevalence of state reforms enacted in recent years (Figure 2).[184]

At the federal level, the tort-reform debate during the last malpractice crisis has been "much sound and fury, yielding no substantive policy change."[185] The House repeatedly passed the federal damages cap legislation, and the Senate repeatedly rejected it, until the Democrats took control of Congress following the 2006 election and definitively killed the initiative. Overall, in assessing the results of the federal reform effort, Rogan Kersh has written that "the contrast between expectations and legislative outcome has never been starker in U.S. malpractice politics."[186] A sunny reading of this history is that a litany of single-minded lobbyists and second-rate analyses failed to sway Congress. A realist view is that the advocates, and the legislators sympathetic to them, quickly came to irremediable gridlock.

What about judicial decision making? This scholarship certainly is relevant to questions of whether tort reforms reasonably advance a state interest, as re-

181. For a full discussion, see MELLO, *supra* note 165, at 22–23, and Mello & Studdert, *supra* note 163, at 20–30.

182. *See* WILLIAM HALTOM & MICHAEL MCCANN, DISTORTING THE LAW: POLITICS, MEDIA, AND THE LITIGATION CRISIS 101, 102 (2004).

183. These frequencies were compiled by the National Conference of State Legislatures. *See* Nat'l Conference of State Legislatures, Medical Malpractice Tort Reform: 2005 Enacted Legislation in the States, http://www.ncsl.org/standcomm/sclaw/medmalenacted2005.htm (last visited Oct. 22, 2007); Nat'l Conference of State Legislatures, Medical Malpractice Tort Reform: 2006 State Introduced Legislation, http://www.ncsl.org/standcomm/sclaw/medmalreform06.htm (last visited Oct. 22, 2007); Nat'l Conference of State Legislatures, State Medical Malpractice Reform: 2005 Numbers at a Glance, http://www.ncsl.org/standcomm/sclaw/medmalataglance.htm (last visited Oct. 22, 2007).

184. Data come from Avraham, *supra* note 52, at 8. Year-to-year variations represent both new adoptions of laws and existing laws being struck down by courts.

185. Kersh, *supra* note 151, at 49.

186. *Id.*

Table 1. Number of State Legislatures Considering and Enacting Malpractice Reform Legislation, 2005–2006

	Evidence of Efficacy*	2005		2006	
		Considered	Enacted	Considered	Enacted
Damages Caps	Some	28	5	14	1
Shortening Statute of Limitations	Some	13	1	5	1
Joint-and-Several Liability Reform	Some	12	2	2	1
Collateral-Source Rule Reform	Virtually None	9	0	5	0
Screening Panels	Virtually None	13	2	5	0
Periodic Payment	None	11	0	4	0
Attorney-Fee Limits	None	12	1	4	1
Expert Witness Standards	Not Studied	17	5	7	0

* As measured by effects on insurance premiums, claim frequencies, and claims costs.

quired by equal protection and due process analysis.[187] Yet, empirical legal studies are rarely discussed in these judicial opinions. For example, in rejecting an equal protection challenge to Louisiana's $500,000 damages cap in 1992, the Louisiana Supreme Court considered no empirical evidence of the cap's effectiveness whatsoever. Applying rational basis review, it simply concluded, without marshaling facts or argument, that the legislation "furthers the state's purpose of compensating victims" by increasing the likelihood that physicians would be

187. *See* Ronen Avraham, *An Empirical Study of the Impact of Tort Reforms on Medical Malpractice Settlement Payments* 3 (Nw. Law Sch. Law & Econ. Research Paper Series, Paper No. 06-07, 2006), *available at* http://ssrn.com/abstract=912922 (finding little evidence of an association between reforms and medical malpractice insurance premiums and arguing that courts should consider the empirical evidence when evaluating the constitutionality of reforms). Most states require only a showing of a reasonable relationship, but a few apply intermediate scrutiny and require that tort reforms substantially advance the state's interest. *See* Carly N. Kelly & Michelle M. Mello, *Are Medical Malpractice Damages Caps Constitutional? An Overview of State Litigation*, 33 J.L. MED. & ETHICS 515, 522–23 (2005).

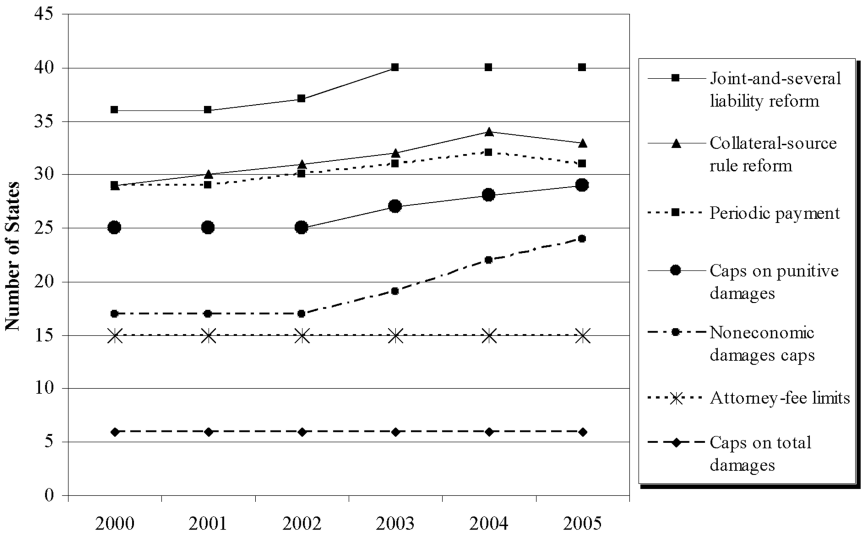


Figure 2. Prevalence of State Malpractice Reforms, 2000–2005

able to maintain insurance.[188] A dissenting justice, in contrast, criticized the majority for overlooking several empirical studies showing that caps had not had their intended effects.[189]

An exception to the general trend is the Wisconsin Supreme Court's 2005 decision in *Ferdon v. Wisconsin Patients Compensation Fund*,[190] holding that the state's noneconomic damages cap violated equal protection.[191] The court cited several descriptive studies of damages caps that suggested caps were unlikely to have much of an effect because only a small proportion of all awards were high enough to implicate the cap. The court also discussed the limitations of other studies investigating the connection between caps and malpractice insurance premiums.[192] It also cited descriptive studies concerning caps' effects on physician migration.[193] The court's discussion of these studies is relatively sophisticated, compared to other judicial opinions, but that sophistication is undermined by the fact that in selecting studies for citation, the court excluded so much wheat and included so much chaff.[194] Scrutiny of the citations reveals

188. Butler v. Flint Goodrich Hosp., 607 So. 2d 517, 521 (La. 1992).
189. *Id.* at 527 (Dennis, J., dissenting).
190. 701 N.W.2d 440 (Wis. 2005).
191. *Id.* at 491.
192. *Id.* at 469–71.
193. *Id.* at 485–86.
194. For example, the court relied heavily on two student papers and cited studies commissioned by interest groups. *See id.* at 448, 470, 473, 474, 483, 484 (citing HEALTH INS. ASS'N OF AM., ISSUE BRIEF: WHY DO HEALTH INSURANCE PREMIUMS RISE (2002), *available at* http://downloads.heartland.org/14402.pdf; Kevin J. Gfell, Note, *The Constitutional and Economic Implications of a National Cap on Non-economic Damages in Medical Malpractice Actions*, 37 IND. L. REV. 773 (2004); Elizabeth Stewart Poisson, Comment, *Addressing the Impropriety of Statutory Caps on Pain and Suffering Awards in the*

the key selection criterion for studies: the court cited what it could read full-text on the internet or in Westlaw or LexisNexis. Other works in medical and health policy journals do not appear.

2. Enabling and Inhibiting Factors

When we look broadly at this history, several factors appear to have encouraged the production of empirical malpractice scholarship and held promise for its potential incorporation into policymaking, but these factors have been overshadowed by a number of substantial barriers.

On the research side, a key catalyst for growth in the field was the development of closed-claim datasets, such as the National Practitioner Data Bank and state insurance department databases. This spurred a cottage industry in malpractice research among a cadre of well-known economists. The high visibility and policy salience of the issue may also have helped attract highly qualified scholars to the field.

Second, as with motor vehicle safety laws, malpractice reforms offer a large number of natural experiments that create ready opportunities for study. The long history of states' reform efforts has generated substantial variation in the explanatory variable both across time and across states, facilitating powerful (if complicated) models.

Third, organizations have provided funding to support malpractice research. The Robert Wood Johnson Foundation (RWJF), for example, has made a major financial commitment in this area.[195] The fact that the topic has clear implications for core areas of health services research, such as the financing and quality of health care, has made it possible for researchers to compete for funding under general solicitations for health policy and health services research projects as well. The availability of extramural funding has made it possible for scholars in soft-money environments to enter the field and for researchers to carry out large data-collection efforts.

Less evident are the enabling factors that allow for the use of this research in malpractice reform efforts. Although academics have sometimes been invited to give testimony in state and federal hearings and to brief legislative staff, they have not had the kind of access that lobbyists for stakeholder organizations have

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Medical Liability System, 82 N.C. L. REV. 759 (2004)). Yet, the court utterly dismissed a controlled, multivariate analysis by a well-regarded health economist on the basis that it included states that capped total damages as well as states that capped only noneconomic damages. *See id.* at 505 (citing Kenneth E. Thorpe, *The Medical Malpractice 'Crisis': Recent Trends and the Impact of State Tort Reforms*, 23 HEALTH AFF. w4–20 (2004), *available at* http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.20v1.pdf. The inclusion of those four states may have affected the study findings, but the Thorpe study certainly still had more explanatory power than the other cited sources. Moreover, the court omitted any mention of a large number of other controlled studies. *See* MELLO, *supra* note 165, at 24–25 (collecting studies).

195. *See* ROBERT WOOD JOHNSON FOUND., IMPROVING MALPRACTICE PREVENTION AND COMPENSATION SYSTEMS (2002), *available at* http://www.rwjf.org/reports/npreports/impacs.htm. More recently, the Foundation has funded malpractice research out of its Pioneer Portfolio and its Health Care Financing and Organization program.

had.

One way to counter this problem is to make EHL research more accessible to the policy community. Perhaps the most important means to this end has been the dedication of research sponsors and organizations to generating and disseminating high-quality malpractice research for consumption by policymakers. RWJF and AcademyHealth have been at the leading edge of these efforts, employing skilled communications staff to translate complex research findings into easily digestible policy briefs that are then aggressively disseminated to the policy community.[196] RWJF's Synthesis Project, for instance, "produce[s] concise and thought-provoking briefs and reports that translate research findings on perennial health policy questions" by "synthesizing what is known, while weighing the strength of the research evidence and exposing gaps in current knowledge."[197] Indeed, the Synthesis Project engaged one of the authors of this Article to synthesize the literature on tort reforms, and based on this analysis, Project members created briefs and forums for the dissemination of the results, and made the products freely downloadable on the internet.[198] Few other areas of empirical health law research have received so great a commitment to dissemination.

A number of challenges have made it difficult for EHL research to achieve its scientific and policy aims, however. Many of the richest datasets on claims exist at the insurer or state level and are not clearly generalizable or integrable with one another. All existing datasets that have supported secondary analyses have significant limitations. For example, jury verdicts exclude settlements; the Data Bank excludes unpaid claims; and state closed-claim databases omit unpaid claims and some kinds of health care providers, may have suboptimal data accuracy, and include reporting fields that may vary over time.[199] The best data remain proprietary: the records of liability insurers and the providers they insure. These data are difficult to gain access to and cumbersome and expensive to extract. This, too, leads to datasets that are limited in geographic scope; it is not practicable to review thousands of litigation records in every state. When only a few states are represented, there are very limited possibilities for evaluating state tort reforms. For this reason, although studies based on insurers' litigation records and/or medical chart review have made seminal contributions to describing the epidemiology of medical injury and malpractice

196. *See, e.g.*, Christal Stone, *Findings Brief: Investment Returns and Size of Damage Caps Impact Rising Cost of Malpractice Premiums*, ACADEMYHEALTH, Apr. 2007, at 1, *available at* http://www.hcfo.net/pdf/findings0407.pdf.

197. Robert Wood Johnson Found., *About the Project*, SYNTHESIS PROJECT (2004), http://www.rwjf.org/pr/synthesis/about_the_project/index.html (last visited Oct. 22, 2007).

198. These works are collected at Robert Wood Johnson Found., *Medical Malpractice: Impact of the Crisis and Effect of State Tort Reforms*, SYNTHESIS PROJECT (2006), http://www.rwjf.org/pr/synthesis/reports_and_briefs/issue10.html (last visited Oct. 22, 2007).

199. AM. ACAD. OF ACTUARIES, IMPORTANT CONSIDERATIONS WHEN ANALYZING MEDICAL MALPRACTICE INSURANCE CLOSED-CLAIM DATABASES (2005), *available at* http://www.actuary.org/pdf/casualty/medmal_042005.pdf.

claiming,[200] they have not evaluated tort reforms.

There are also real methodological challenges to modeling the complex tort-reform environment. Controlling for other state characteristics which may affect the outcome variables can be difficult, and fixed-effects models are not feasible for some periods when tort reforms were time invariant in nearly all states. There are also concerns about endogeneity, because tort reforms are most likely to be passed by states that are experiencing volatility in insurance premiums or claims costs, and there are questions about how to construct variables to represent a large and heterogeneous group of reforms.

The main barrier to the productive use of malpractice research in policymaking has been that the involved political interest groups have not played a facilitative role. Throughout the past three malpractice crises, the policy debate has been dominated by two interest groups—trial lawyers and health care providers—and their allies.[201] Their focus has been single-minded: Are noneconomic damages caps a good idea or a bad idea?[202] Although empirical legal scholars have repeatedly tried to shift policymakers' focus to reforms that are more likely to address fundamental and well-documented problems with the medical liability system, few interest groups have followed their lead.[203] Groups have instead homed in on the narrow, if important, problem of spiraling liability costs and the reform that most directly addresses the size of malpractice awards.[204]

These groups have been fiercely adversarial in their postures and have appeared to believe that maintaining those postures requires the utter rejection of empirical evidence that does not support their position. This has resulted in a highly polarized debate with none of the nuance that characterizes evidence-based policy making,[205] and in which "[e]ach side portrays the other in very harsh language and portrays the other side's position as disastrous for society."[206] Rather than nurturing policymakers' interest in data, these interest groups have tended to strongly emphasize anecdotes featuring sympathetic victims of malpractice and the malpractice crisis. These narratives have strong appeal to legislators and journalists because they are easy to understand and

200. The best-known such study is the Harvard Medical Practice Study, discussed *supra* note 60.

201. See Kersh, *supra* note 151, at 54–55, for a historical account of this adversarial policy debate.

202. William M. Sage, *Malpractice Reform as a Health Policy Problem*, *in* MEDICAL MALPRACTICE IN THE U.S., *supra* note 151, at 30, 31 ("Both long-standing antipathy between doctors and lawyers and the macro-politics of tort law tend to fixate the malpractice debate on lowest-common-denominator reforms of the legal process that are familiar to the medical profession and that translate readily to nonmedical litigation.").

203. William M. Sage, *Medical Malpractice Insurance and the Emperor's Clothes*, 54 DEPAUL L. REV. 463, 463–64 (2005).

204. Robert L. Rabin, *The Politics of Tort Reform*, 26 VAL. U. L. REV. 709, 715–16 (1992).

205. Neil Vidmar et al., *Uncovering the "Invisible" Profile of Medical Malpractice Litigation: Insights from Florida*, 54 DEPAUL L. REV. 315, 317 (2005) ("Angry rhetoric and poorly substantiated claims often substitute for systematic data . . . .").

206. Anthony J. Sebok, *Dispatches from the Tort Wars*, 85 TEX. L. REV. 1465, 1466 (2007) (book review).

have a human face.[207] Statistical studies, in contrast, require a great deal of cognitive work and often lead to a grey, rather than black or white, view of the world.

Scholars have not had the incentives that interest groups have had to make participation in and influence over the policy debate a priority.[208] While professors have struggled to find time and money to attend briefings and hearings, well-financed advocates have been working full-time to press their agendas in those settings and through extensive behind-the-scenes lobbying.[209] It is not surprising that it is their position papers that get read, nor that these rarely include data from scholarly studies.

A second problem has been that over time the evidentiary field has become quite crowded. The number of analyses by academics, government agencies, and political interest groups and their consultants has skyrocketed during the latest malpractice crises. There are now so many studies of tort reforms that it requires considerable effort to find and review them all, much less evaluate which are of good or poor quality. In other areas of health policy, communities of scientists have come together to rigorously catalog and analyze the literature on topics of great importance for health care providers and policymakers, but there are few such efforts in health law.[210]

The problem of evaluation is exacerbated by the great complexity of many academic studies of tort reforms. Some legislators struggle with even basic statistical concepts,[211] and as methodological innovations in econometrics have led to ever more sophisticated analyses, it has become increasingly difficult for

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207. *Id.* at 1500.

208. HALTOM & MCCANN, *supra* note 182, at 101. Haltom and McCann also note that scholars' "very claim to authority as professional experts has limited the scholars' public visibility," *id.* at 17, presumably because it requires a heavy investment of time to maintain the necessary base of expertise, and scholars may consider it unseemly to descend into political fights rather than focus on perfecting their craft.

209. Sebok, *supra* note 206, at 1501 ("The sociolegal scholars, as full-time academics, had neither the time nor the resources to promote themselves like the tort reformers at the Manhattan Institute." (citing HALTOM & MCCANN, *supra* note 182, at 101)).

210. The Cochrane and Campbell Collaborations conduct systematic reviews of the evidence on matters of clinical care and select areas of social policy (including a few public health interventions), respectively. *See* Campbell Collaboration, About the Campbell Collaboration, http://www.campbellcollaboration.org/About.asp (last visited Oct. 22, 2007); Cochrane Collaboration, Cochrane Reviews and the Cochrane Library—An Introduction, http://www.cochrane.org/reviews/clibintro.htm (last visited Oct. 22, 2007). Although systematic reviews potentially are useful for policymakers in deciding which health care services should be funded by government programs, this method is not commonly used to study the impacts of specific legal rules on outcomes.

211. An example is a member of Congress's attempt to cross-examine a witness at a committee hearing using data from the National Practitioner Data Bank. The witness, an insurance association representative, had offered insurer data indicating that the mean malpractice payout was $496,000. Rep. Bart Stupak asserted that that figure did not "jibe" with Data Bank data indicating that the median payout was $125,000 and appeared not to understand the witness's explanation that the mean and median are two different statistics. *See Assessing the Need To Enact Medical Liability Reform: Hearing Before the Subcomm. on Health of the H. Comm. on Energy and Commerce*, 108th Cong. 145–46 (2003) (testimony of Lawrence E. Smarr, President, Physicians Insurers Association of America).

non-experts to decipher and critically evaluate their findings. Adversaries in the policy debate use this to their advantage by attempting to discredit the studies,[212] leading to further confusion.

Finally, the way in which malpractice has been framed as a policy issue has inhibited deliberative lawmaking. Framing the problem of rising liability insurance costs as a "crisis,"[213] however defensible from the perspective of those who have to pay those costs, has driven policymakers toward a narrow goal—stabilizing premiums—and a narrow solution—damages caps. The atmosphere of emergency has made it difficult to engage policymakers in deliberations about persistent, fundamental problems with the malpractice system and far-reaching reforms that could address those problems along with the problem of insurance costs.[214] Rather, policymakers have been attracted to seemingly simple fixes that can satisfy powerful interest groups' demands to *do something*.[215] It is one of the great paradoxes of malpractice politics that the conditions that maximize the chances that legislators can mobilize enough support to pass legislation also minimize the chances that the legislation will reflect careful, thorough consideration of what the best evidence suggests will be a successful reform. Together, these factors explain why empirical research on malpractice reforms has not lived up to its promise for shaping policy.

C. SUMMARY

Viewed together, the two case studies help to identify a common set of factors that affect the likelihood EHL research will influence policy decisions. In general, EHL research is more plentiful and impactful when (1) there is a considerable amount of variation in the health laws in question across jurisdictions and over time, which strengthens researchers' ability to statistically estimate the effects of the laws; (2) data on laws, their outcomes, and other factors that might confound analysis of the relationship between the laws and the outcomes are readily available; (3) the issue is convincingly framed as a public health issue and visible enough to attract skilled empirical researchers and

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212. *See, e.g.*, Don Finley, *Study Says Medical Malpractice Crisis Is a Myth*, SAN ANTONIO EXPRESS-NEWS, Mar. 11, 2005, at 3B (quoting Dr. Bohn D. Allen, President of the Texas Medical Association, as saying, "The authors of this study used data that was inflation-adjusted, population-adjusted, and health-care-cost adjusted. It was so adjusted that it became truth-adjusted."). The study to which Allen referred reported time trends in medical malpractice filing rates and payouts size. The authors wished to examine whether out-of-control juries were behind increases in medical liability insurance premiums; therefore, they adjusted their estimates to eliminate obvious alternative explanations, including increases in damages due to rising health care costs and general inflation and increases in the quantity of medical services provided due to population growth. *See* Bernard Black et al., *Stability, Not Crisis: Medical Malpractice Claim Outcomes in Texas, 1988–2002*, 2 J. EMPIRICAL LEGAL STUD. 207 (2005).

213. *See* Kersh, *supra* note 151, at 50 (discussing the influence of framing on the politics of malpractice reform).

214. *See* TOM BAKER, THE MEDICAL MALPRACTICE MYTH 180 (2005).

215. Michelle M. Mello, *Managing Malpractice Crises: Why Is It So Hard?*, 33 J.L. MED. & ETHICS 414 (2005).

funders of both primary studies and systematic reviews; (4) infrastructures exist within the academy to support the production and dissemination of empirical research; (5) interest groups act as facilitators rather than barriers to basing policy decisions on the best available evidence; and (6) policymakers understand and have confidence in the methods used to produce relevant empirical findings.

When these stars do not align, empirical research, if any exists, has less impact on policy decisions. Although some of the factors surely are out of the control of the legal academy, steps can be taken inside the academy to increase the likelihood that the enabling conditions are satisfied. In the following Part we offer specific suggestions for ways in which the legal academy can both increase the production of high-quality EHL studies and increase the impact of these studies on the implementation of health law and policy.

IV. FUTURE DIRECTIONS

The case studies examined in Part III serve as a useful jumping-off point to consider more generally the barriers that impede the production of EHL research and limit its impact on health law and policy. While many impediments are common to EHL research conducted both within and outside the legal academy, several are unique to legal academia. Pushing the field forward will require that these barriers be addressed. We offer a few suggestions along these lines, some of which emanate from the case studies we have analyzed.

A. WAYS TO INCREASE PRODUCTION OF HIGH-QUALITY EHL STUDIES

Although production of EHL studies has increased substantially over the past three decades, as evidenced in the two cases discussed in Part III, a broader view of the field suggests that much more research is needed to develop a fuller picture of how health law and policy influence outcomes. Several reasons account for the gaps in knowledge and the fact that a relatively small portion of this literature is produced by scholars within the legal academy. In particular, production of EHL studies is hindered by a lack of easy and inexpensive access to reliable data, institutional barriers, and a general lack of acceptance of the scientific approach within law schools. These inhibiting factors present challenges, but interested parties within the legal academy can take specific steps to break down these barriers and increase the number of high-quality EHL studies produced by legal scholars. In particular, they can work to attract more funding to obtain data, encourage collaborations between legal scholars and methodologists, and educate law students and faculty on empirical methods and the merits of employing a scientific approach.

1. Increase Access to and Collection of Reliable Data

As we discussed in Part II.B., a major factor inhibiting the production of EHL

research is the difficulty of accessing reliable data.[216] Although EHL studies often employ data that directly measure the variables of interest, empirical findings are often based on proxies—variables the researchers hope are positively correlated with the true variable of interest—because data on the variables of interest are not available or are too expensive to collect. In the most troubling cases, connections between legal rules and outcomes go unexplored because data allowing either direct measurements or proxy-based measurements are unavailable.

For EHL research to evolve, availability of data and data-collection methods need to evolve. We offer two suggestions. First, EHL scholars should more aggressively seek out funding to collect or obtain data not currently available.[217] Research sponsors will be more likely to view EHL study proposals favorably if these proposals are not anomalies among the submissions they receive, and if the proposals make a strong case that such research is important and can make a difference to public health. As we increase our production of impactful research, it will become easier to demonstrate this.

Second, scholars should also encourage government agencies that collect data for regulatory purposes, as well as private organizations in the health care market, to make their data more available and useful to researchers.[218] These entities should move toward collecting data with the same contemplation of their possible research uses as occurs in other fields, such as labor and health care. We need to move from a world where researchers peck around at datasets collected for other purposes to a world where data are collected systematically with research in mind. We also need to better address agencies' and companies' concerns about data confidentiality and security. Methods widely in use in other areas of health research, such as development of limited, deidentified (or partially deidentified) datasets for public use and execution of data-use agreements, could be applied here.

2. Break Down Institutional Barriers

Legal scholarship traditionally has been produced under a model emphasizing theoretical analysis and solo authorship.[219] Although it has begun to expand outside this model, general adherence to and preference for the traditional

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216. *See, e.g.*, Deborah L. Rhode, *Legal Scholarship*, 115 HARV. L. REV. 1327, 1353–54 (2002) (discussing difficulties with data collection and other obstacles to producing empirical legal studies).

217. *See id.* at 1360 ("Many academics are strikingly clueless about how to market their scholarship to funders and the media. Writing effective grant proposals and press releases is an acquired skill—and one not taught in law schools. It should be taught, at least to faculty.").

218. One recent example is the involvement of academics in the debate over the National Association of Insurance Commissioners' (NAIC) model law requiring disclosure by medical malpractice insurers of closed-claim data. *See* NAIC Statistical Info. Task Force, http://www.naic.org/committees_c_sitf.htm (last visited Oct. 22, 2007).

219. *See* Tracey E. George & Chris Guthrie, *Joining Forces: The Role of Collaboration in the Development of Legal Thought*, 52 J. LEGAL EDUC. 559, 560 (2002) ("[M]ost law review articles seem to be written by one author."); Heise, *supra* note 9, at 812 ("[T]he amount of theoretical and doctrinal

approach has created institutional barriers within the legal academy to the production of empirical legal research.[220] Because health law enjoys little prestige among legal scholars, EHL studies are especially marginalized, as these studies lie at the intersection of two nontraditional areas of scholarship.[221]

One challenge is overcoming the traditional model's low esteem for collaborative research.[222] A large portion of the most compelling EHL research has been produced though collaborations between legal scholars and scholars from other fields who contribute disciplinary grounding and methodological expertise. Collaborations are more likely to form when academic environments create incentives for faculty to seek them out (for example, in "soft money" settings, collaborations are essential because strong teams have a competitive advantage in grant seeking). At present, these incentives do not exist in law schools, and the emphasis on sole-authored work in the promotion process is a strong disincentive to engage in collaborative work.[223] There are signs of change in some law schools—for example, establishing centers for health law research with faculty affiliates from around the university,[224] sponsoring interdisciplinary workshops and conferences,[225] and providing grants for collaborative research.[226] We would submit, however, that the balance of incentives will not tip until coauthored work comes to enjoy greater legitimacy.[227]

Preference for the traditional model has afforded less prestige to the use of empirical, rather than theoretical, research approaches.[228] Various factors ac-

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scholarship that presently fills many law review pages overwhelms the amount of empirical scholarship.").

220. Thomas S. Ulen, *The Unexpected Guest: Law and Economics, Law and Other Cognate Disciplines, and the Future of Legal Scholarship*, 79 CHI.-KENT L. REV. 403, 413 (2004) ("[T]here seems to be a widely held belief in the legal academy that the scientific method is inappropriate for the study of law.").

221. *See* Mark A. Hall & Carl E. Schneider, *Where Is the "There" in Health Law? Can It Become a Coherent Field?*, 14 HEALTH MATRIX 101 (2004).

222. George & Guthrie, *supra* note 219, at 571 ("Collectively, the comprehensive citation-count studies demonstrate that articles by coauthors have had less impact than we would have expected given the rate at which coauthored articles have been published.").

223. *See id.* at 560 ("[T]here are practical impediments to collaboration in law schools that may not exist in law practice. For example, law schools often give faculty only token credit for coauthored works.").

224. Harvard Law School's Petrie-Flom Center for Health Law Policy, Biotechnology and Bioethics and Georgetown University Law Center's O'Neill Institute for National and Global Health Law are two recently established examples.

225. The Petrie-Flom Center has sponsored a number of such conferences and runs an annual semester-long health law and policy workshop.

226. For example, Georgetown University Law Center provides research grants for collaborative research to cover costs of travel and other expenses.

227. Others have suggested collaborations as one way to help mitigate the difficulties in meshing legal scholarship and social science. *See, e.g.*, Jeremy A. Blumenthal, *Law and Social Science in the Twenty-First Century*, 12 S. CAL. INTERDISC. L.J. 1, 37–38 (2002).

228. *See* Robert W. Gordon, *Lawyers, Scholars, and the "Middle Ground,"* 91 MICH. L. REV. 2075, 2085 (1993) ("[Empirical legal research] remains to this day the most neglected and ridiculously undervalued as well as the most potentially fruitful branch of legal studies."); Craig Allen Nard, *Empirical Legal Scholarship: Reestablishing a Dialogue Between the Academy and Profession*, 30

count for this disparity, but chief among them are a lack of familiarity with empirical methods, a lack of appreciation for the ways in which observation and measurement can enrich (rather than replace) theory, and an understanding of the concept of intellectual creativity that focuses on the development of innovative ideas rather than discoveries about the world. Closing this gap requires educating legal scholars in empirical methods, clarifying the role of empirical research in theory development, demonstrating the impact of empirical research on policy and human welfare, and nurturing the idea that such real-world impact is an important measure of the excellence of scholarship. As it becomes clearer that the usefulness of theory hinges, in part, on whether a theory's predictions are consistent with observations from the field or the laboratory, legal scholars will come to appreciate more fully the value of empirical work. As more law schools offer courses in empirical research methods,[229] the cadre of scholars able to conduct empirical research will grow.

As familiarity with and appreciation for empirical work grows, the preferred model of legal scholarship will continue to evolve. Furthermore, as empirical and collaborative research becomes more common, legal scholars will gain experience evaluating the work for purposes of hiring and promotion. This will further break down the barriers that discourage legal scholars from engaging in this type of research.[230]

Of course, the proposals set out here are not meant to imply that empirical studies should replace non-empirical research or that resources should be shifted away from non-empirical research. Clearly, empirical methods are not well suited for all important investigations. Empirical research depends in many cases on theoretical and doctrinal research for grounding.[231] Although a large portion of EHL research is purely descriptive, much of it is performed to test theoretical predictions and assumptions about causal connections on which theorists and policymakers commonly rely. Our intent is to argue for an increase in the production of high-quality empirical research while at the same time preserving the important role of and respect for theoretical and doctrinal analysis.

WAKE FOREST L. REV. 347, 361–65 (1995) (offering reasons why empirical legal research has taken a back seat to other forms of legal scholarship).

229. *See* Theodore Eisenberg, *Why Do Empirical Legal Scholarship?*, 41 SAN DIEGO L. REV. 1741, 1742 & n.3 (2004) (mentioning a short course for law professors offered at Washington University-St. Louis School of Law and a number of other such programs at various law schools); Howell E. Jackson, *Analytical Methods for Lawyers*, 53 J. LEGAL EDUC. 321 (2003) (discussing methods courses for law students).

230. *See* Nard, *supra* note 228, at 363 (finding that "twenty-five percent of non-tenured professors were concerned that empirical research would not be viewed favorably by their respective tenure committees"); Ulen, *supra* note 220, at 418 ("Junior law faculty may perceive making a commitment to empirical techniques as a high-risk, and, therefore, unattractive strategy for promotion . . . .").

231. *See generally* Thomas S. Ulen, *A Nobel Prize in Legal Science: Theory, Empirical Work, and the Scientific Method in the Study of Law*, 2002 U. ILL. L. REV. 875 (describing the relationship between theory and empirical work and arguing the benefits of using the scientific method to study law).

B. WAYS TO INCREASE THE IMPACT OF EHL STUDIES ON HEALTH LAW AND POLICY

Increasing production of EHL studies is but a first step. These studies create minimal value if they have little or no impact on the structure of law and the shape of policy. As the case studies presented earlier demonstrate, high-quality EHL studies do not always impact law and policy to the extent they should. Several reasons account for this, including lack of rigor, failure to aggressively disseminate new findings, and difficulties policymakers have in reading, interpreting, and critiquing empirical studies. As with the production barriers, interested parties within the academy can take steps to mitigate or eliminate these barriers.

1. Strengthen Rigor

Although much EHL research can be classified as rigorous according to scientific standards, this is not uniformly the case. As EHL scholarship produced by legal scholars continues to converge toward social-science research with respect to the methodology employed and the presentation of results, publishers and consumers of EHL research will demand that it meet the standards of scientific rigor to which other kinds of social-science research are held.[232] The legal academy can help strengthen the rigor of EHL studies by fine-tuning hiring and tenure standards and making greater use of peer-review processes.

Law schools traditionally have not been in the business of hiring empiricists; therefore, law faculties have relatively little experience evaluating the quality of empirical studies produced by job candidates. Promotion committees and processes also do not make much effort to understand the dynamics of collaborative research, and thus may misapprehend or underappreciate the unique intellectual contributions that faculty have made in collaborative projects. Even such basic matters as how the order of authors listed on articles in different disciplines reflects the authors' contributions may be mysterious. Constituting hiring and promotion committees such that candidates know that good-quality research and important contributions will be recognized and rewarded, and that sloppy studies and free-riding in collaborations will be duly noted in the committees' decisions would do a great deal to spur the kind of EHL research we want and need. Involving reviewers from other departments within the university would be a low-cost way to bring in additional expertise. Hiring committees can also encourage the growth of EHL research by favoring candidates who have formal methods training or a demonstrated record of engaging in collaborations with methodologists that produce high-quality, impactful EHL

232. Although this section contains suggestions for interventions to increase the rigor of empirical health law research, some have argued that the large and growing number of empiricists and ready availability of data will allow the public easily to debunk "outlandish or mistaken claims." *See, e.g.*, McGinnis, *supra* note 8, at 51 ("[T]he large number of empiricists will create a rich market for empirical work and provide greater incentives to get the facts and models absolutely correct. There are now so many investigators and the computer technology is so pervasive that results are constantly checked.").

studies.

Consideration should also be given as to how to more fully reap the advantages of peer-review processes to improve empirical legal scholarship. The formal standards (for example, criteria for authorship) and informal norms (for example, minimum response rates for surveys) of peer-reviewed journals in other fields may be appropriate to apply to some kinds of EHL studies. The most rigorous journals require authors to submit data and logs of procedures used to derive reported results.[233] After the paper is published, some journals post the data and result logs on their websites.[234] These procedures make replication and further investigation easier for other researchers.

EHL scholars should also be encouraged to submit their work to peer-reviewed journals in both the legal and health fields and serve as referees for these journals.[235] Undergoing the peer-review process, though time consuming and often burdensome for authors, can markedly improve the quality of a research paper, as well as facilitating the match between the quality of the research and the prestige of the journal in which it appears. This match is important because journal reputation has a signaling effect for consumers of research, indicating the quality and reliability of the research published there. We readily concede that peer-review processes and their results are far from perfect,[236] but submit that they are more reliable than the methods by which most student-run law journals screen articles for publication.[237]

Law reviews and journals can also take steps to ensure the rigor and reliability of results they publish. They can request reviews by faculty with empirical methods training for portions of submitted articles that student editors are not qualified to evaluate. The journals also can require submission of data and results logs or encourage authors to post this information on their own websites.[238]

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233. *See, e.g.*, American Economic Review: Data Availability Policy, http://www.aeaweb.org/aer/data_availability_policy.html (last visited Oct. 22, 2007) (requiring authors to submit "data, programs, and other details of the computations sufficient to permit replication").

234. *See, e.g.*, *id.* (noting the posting of the authors' submitted information).

235. *See* Gregory Mitchell, *Empirical Legal Scholarship as Scientific Dialogue*, 83 N.C. L. REV. 167 (2004) (suggesting a disclosure system that law reviews can implement to increase critical peer review of empirical legal research). Our malpractice case study might suggest, however, that this might limit access of the research to judges who seem to use primarily legal databases and internet searches. Public access to peer-reviewed journals, though, is improving as more make their full-text articles available online.

236. *See* Frank B. Cross, *The Naïve Environmentalist*, 53 CASE W. RES. L. REV. 477, 486 (2002) ("Peer review is demonstrably unreliable at screening research for validity. It tends to be infected by ideological biases and replicate the preferences of the editor and reviewers. Simply because something is peer-reviewed does not make it true, nor does the absence of peer review make information false.").

237. *See* Rhode, *supra* note 216, at 1356 (discussing problems with student-run review processes); Schneider & Teitelbaum, *supra* note 8, at 103–04 (same).

238. *Cf.* Mitchell, *supra* note 235, at 176 (recommending that law reviews adopt a "set of stringent disclosure requirements" rather than a peer-review process). Authors can also voluntarily post datasets and result logs on their own websites for public access. For an example, see John Donohue's website

2. Increasing Widespread and Effective Dissemination of New Findings

Increasing the quality of EHL studies is the first step toward increasing their impact on policy. Once produced, however, the studies will have little influence on policy unless the results end up in the hands of policymakers. The first obvious step to disseminate findings is publication. As the *New York Times* recently reported, however, legislators and judges might not read scholarly journals as often as we might hope.[239] Therefore, we need to take additional steps to increase our impact on policy debates.

Medical and public health schools have established dedicated personnel in offices of communications to disseminate faculty research findings. For example, faculty members at the Harvard School of Public Health have a press officer assigned to them who becomes familiar with their portfolio of work.[240] When a new paper is about to be published, faculty can send the galleys to their officer and discuss the message the authors would like to convey. If appropriate, the press officer then drafts a press release, contacts reporters who might be interested in the work, and arranges interviews. He also disseminates the research on the school's website and through podcasts and listservs. These arrangements are expensive, but highly effective, because they utilize media professionals and minimize demands on faculty members' time. Building such structures in law schools would do a great deal to raise the public profile of EHL research.

Widespread dissemination is necessary for EHL researchers to impact policy but may not be sufficient. A second measure that our case studies clearly suggest would be helpful is for scholars to engage in efforts to make their empirical research more comprehensible to policymakers and judges.[241] Legal scholars now have more to offer to policymakers than mere learned opinion, but scientific results can be difficult to explain and to understand and can be challenged on many different bases. By describing results in a manner that law audiences can understand and providing clear warnings regarding limitations, researchers can help policymakers import the studies into debates in appropri-

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providing data and result logs for several empirical publications at http://islandia.law.yale.edu/donohue/pubsdata.htm (last visited Oct. 22, 2007).

239. Adam Liptak, *When Rendering Decisions, Judges Are Finding Law Reviews Irrelevant*, N.Y. TIMES, Mar. 19, 2007, at A8. Rhode has remarked that "[a]cademics write mostly for one another and for others in their profession. Seldom do we [consciously] seek a mass audience, and rarely do we find one." Deborah L. Rhode, *A Bad Press on Bad Lawyers: The Media Sees Research, Research Sees the Media*, *in* SOCIAL SCIENCE, SOCIAL POLICY, AND THE LAW 139, 140 (Patricia Ewick et al. eds., 1999), *quoted in* HALTOM & MCCANN, *supra* note 182, at 73; *see also* Michael D. McClintock, *The Declining Use of Legal Scholarship by Courts: An Empirical Study*, 51 OKLA. L. REV. 659 (1998).

240. *See* Harvard School of Public Health, Office of Communications, http://www.hsph.harvard.edu/administrative-offices/communications/ (last visited Oct. 22, 2007).

241. For a useful discussion of the history of attempts to inform policymakers about empirical findings, see Daniel M. Fox & Lee Greenfield, *Helping Public Officials Use Research Evaluating Healthcare*, 14 J.L. & POL'Y 531 (2006).

ate, useful, and defendable ways.[242] They might also consider creating "policymakers' digests"—short issue briefs accompanying research findings relevant to active policy debates. In health research, study sponsors routinely produce such briefs[243] and disseminate them to policymakers, making liberal use of electronic newsletters as well. Finally, participation in legislative briefings and hearings, though time-consuming and subject to receipt of an invitation, can be an important means of clarifying the message of one's research; the motor vehicle safety law case study suggests that such participation can be effective in shaping policy. Similarly, scholars can help ensure that study findings are not "spun" too much for political purposes by responding to such misuse through op-eds and other outlets.

The story of medical malpractice reform also indicates that for some policy issues, it is critical for scholars to help policymakers sort through a large body of conflicting empirical analyses of varied quality, fit individual studies into the larger policy picture, and understand what policy prescriptions emerge from the empirical findings. Otherwise, there is a danger that they will not rely on the best available evidence or will draw faulty implications from the results of narrow studies.[244] One way to assist policymakers is to publish literature reviews with an emphasis on determining what conclusions can be drawn from the available body of evidence and identifying areas where there is insufficient data to draw reliable conclusions.[245]

In addition, systematic reviews modeled on structured methods would be invaluable in helping policymakers draw conclusions from bodies of EHL research. Such reviews have been powerful and useful tools for advancing clinical and public health practice. The reviews produced by the Cochrane Collaboration and Campbell Collaboration, for example, rigorously evaluate the available evidence regarding a clinical issue or social program, respectively. [246] Their rigor is such that they are widely recognized as the definitive statements of the evidence on a particular issue. Similarly, the Centers for Disease Control and Prevention has convened an independent Task Force on Community Preventative Services to produce systematic reviews of primary research studying the

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242. *Id.* at 538; *see also* Lee Epstein et al., *On the Effective Communication of the Results of Empirical Studies (pt. 1)*, 59 VAND. L. REV. 1811 (2006). To reach judges, further measures may be required, such as greater representation of empirical scholars in amicus briefs.

243. *See, e.g.*, The Synthesis Project, http://www.rwjf.org/pr/synthesis/index.html (last visited Oct. 22, 2007) (collection of recent Synthesis Project briefs).

244. *See* Christal Stone, *Issue Brief: Medical Malpractice: Strengthening the Evidence Base*, ACADEMYHEALTH, Dec. 2006, at 1, 1, *available at* http://www.hcfo.net/pdf/issue1207.pdf (last visited Oct. 22, 2007).

245. *See, e.g.*, MELLO, *supra* note 165; *see also* Randall R. Bovbjerg & Robert A. Berenson, *Surmounting Myths and Mindsets in Medical Malpractice*, URB. INST. HEALTH POL'Y BRIEFS, Oct. 2005, at 1, *available at* http://www.urban.org/UploadedPDF/411227_medical_malpractice.pdf (identifying sound conclusions and "myths" in the medical malpractice policy debate). Because many courts look only to law reviews, EHL scholars should also aim to publish literature summaries in law reviews. As courts gain the capacity to search additional databases, publication venue will become less of a concern.

246. Campbell Collaboration, *supra* note 210; Cochrane Collaboration, *supra* note 210.

effectiveness, economic efficiency, and feasibility of interventions to promote community health and disease prevention.[247] Among the interventions evaluated to date have been public health laws and policies aimed at reducing tobacco use,[248] encouraging physical activity,[249] and reducing firearm injuries.[250] Such evaluations could be much more widely applied to health laws.

A second way researchers can help is to explicitly bridge individual study results into the policy debates. Primary EHL studies usually are insufficiently broad to generate specific policy recommendations because they tend to focus on narrow components of multi-faceted issues. By including a discussion of the implications individual results have for the larger policy debate, researchers can help policymakers understand the power and the limitations of narrow results.

How can law schools facilitate these initiatives? Again, tweaking the incentive structure for faculty is key. Hiring and tenure standards can be adjusted to encourage empirical scholars to take active steps to inject their research into policy debates. Current standards emphasize a candidate's publication record and number of citations to the candidate's work by other legal scholars over evidence that a candidate's scholarship has been read, cited, and relied upon by policymakers and judges. Readiness for promotion should be evaluated not only by reference to how the individual's work has advanced her field of scholarship, but also by how it has impacted the world outside the legal academy. Adding this standard to the criteria for promotion and tenure decisions will create incentives for empirical scholars both to increase the rigor of their work and to disseminate their findings widely.

3. Educating Consumers of EHL Research

Finally, in addition to strengthening the rigor of EHL research and improving dissemination and communication, we can increase the impact of our research by helping to educate potential audiences for EHL about how to read, interpret, and evaluate empirical studies. Some in the legal academy have been engaged in this endeavor for many years,[251] but as the production of empirical studies

247. *See* Task Force on Cmty. Preventative Servs., The Community Guide: Overview, http://www.thecommunityguide.org/about/default.htm (last visited Oct. 22, 2007).

248. *See* Task Force on Cmty. Preventative Servs., *Effectiveness of Smoking Bans and Restrictions To Reduce Exposure to Environmental Tobacco Smoke (ETS)* (Jan. 3, 2003), *available at* http://www.thecommunityguide.org/tobacco/tobac-int-smoke-bans.pdf.

249. *See* Task Force on Cmty. Preventative Servs., *Creating or Improving Access to Places for Physical Activity Is Recommended To Increase Physical Activity* (Nov. 15, 2005), *available at* http://thecommunityguide.org/pa/pa-int-create-access.pdf.

250. *See* Task Force on Cmty. Preventative Servs., *Review Finds Insufficient Evidence To Assess the Effects of Eight Firearms Laws on Violence* (Sept. 9, 2003), *available at* http://www.thecommunityguide.org/violence/viol-int-firearms.pdf.

251. *See, e.g.*, Fox & Greenfield, *supra* note 241, at 538–50 (describing methods used to educate both public officials and members of the judiciary on health services effectiveness research methods); Daniel L. Rubinfeld, *Guide to Multiple Regression*, *in* 1 MODERN SCIENTIFIC EVIDENCE: THE LAW AND SCIENCE OF EXPERT TESTIMONY 147, 147–83 (David L. Faigman et al. eds., 1997) (educating lawyers about regression analysis); Daniel L. Rubinfeld, *Reference Guide on Multiple Regression*, *in* REFERENCE

increases, we likely will see an increase in the demand for education on the part of legislators, legislative staff, judges and clerks, and law faculty.

Because lawyers dominate all of these groups of constituents for EHL research, one approach is to include this type of training as part of the standard legal education curriculum.[252] While many law schools offer quantitative-methods courses, they are not universally available, much less required. Those that do not offer such courses should consider hiring faculty or adjunct staff to teach them. Short courses, similar to those offered to train judges in scientific research methods so that they can serve as quality gatekeepers at trial, can also be an effective way to give jurists a basic familiarity with empirical research and how to find it.

The politics of health policy decisions will continue to create pressures for lawmakers to focus on the desires of special interest groups and their lobbyists even when sound empirical evidence counsels that policy should move in a different direction. For some issues and some policymakers, increases in the funding, volume, visibility, quality, comprehensibility, and accessibility of empirical research will be insufficient to change this focus. But addressing these conditions will reduce the time costs and cognitive barriers, if not the political barriers, to greater use of evidence in policymaking. We believe that many in the policy community will respond positively.

C. SUMMARY

Our proposals, in some ways, amount to no less than a call for a culture shift within the legal academy. We suggest that legal scholars transform themselves from expert-advocates into scientists who approach inquiries through hypotheses, grounded in theory or commonly-held assumptions, rather than a particular position; who give equal weight to all available evidence, whether favorable or unfavorable to the hypotheses; who report all empirical results, regardless of whether they confirm or call into question their initial position; and who affirmatively disclose the shortcomings of their work. We further suggest that legal scholars should acquire additional expertise (either personally or through collaborations) to accomplish this objective, even though their investment will not be rewarded (at least initially) in the usual processes through which the legal academy recognizes scholarly achievements. Despite the challenges rooted in the different and sometimes conflicting methodologies of legal scholars and

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MANUAL ON SCIENTIFIC EVIDENCE 179 (2d ed. 2000), *available at* http://www.fjc.gov/public/pdf.nsf/lookup/11.mult_reg.pdf/$File/11.mult_reg.pdf (educating judges about regression analysis); Jeffrey C. Lerner, Book Review, 28 J. LEGAL MED. 283, 290–91 (2007) (reviewing RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH (Wendy Wagner & Rena Steinzor eds., 2006), which describes a program at Brooklyn Law School that educates judges on empirical methodology, including systematic reviews).

252. Eisenberg, *supra* note 229.

social scientists,[253] we can do much to bridge the gap and increase the impact of empirical legal studies on policy.

Clearly, this is not for everyone, or even every law school. And indeed, it is critical to preserve what is distinctive and valuable about traditional modes of legal scholarship—for example, the depth of study and exposition, the consideration of political and moral dimensions of policy problems, and the normative recommendations that point judges and policy makers in a clear direction. Our claim is simply that empirical legal research should be afforded the same respect and nurtured to the same extent as more traditional forms of inquiry. This involves recognizing the unique challenges that empirical legal studies face, as well as the special contributions it has made and can make toward betterment of public policy.

CONCLUSION

The field of empirical health law is in its infancy, but it is growing quickly. Several forces have aligned to support its continued expansion. Unless law schools undergo substantial changes, however, this expansion will continue mostly outside the legal academy with limited involvement of legal scholars, who have the potential to bring a deep understanding of law and legal institutions to the enterprise. Empirical health law research stands to benefit greatly from changes within the legal academy to foster an increase not only in the production of this research but also in the impact it has on enactment of effective legislation and dispute resolution. Despite the challenges we have outlined, we remain optimistic that the field of empirical health law will continue to grow and mature, and that the great public health achievements of the twenty-first century, like many of those of the last century, will owe much to its contributions.

253. *See* Blumenthal, *supra* note 227, at 47 ("(1) [S]ocial science is innovative, while law resists innovation, (2) social science is based on data and observation, while law is based on precedent and hierarchy, (3) social science seeks an objective answer to problems, while law seeks an adversarial victory, (4) social science is descriptive, while law is prescriptive, (5) social science is nomothetic, while law is idiographic, (6) social science conclusions are probabilistic and tentative, while legal conclusions are irrevocable and must appear certain, (7) social science is proactive, while law is reactive, and (8) social science is abstract, while law deals with concrete issues." (quoting J. Alexander Tanford, 66 IND. L.J. 137, 156 (1990))).