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HEALTH LAW AND POLICY

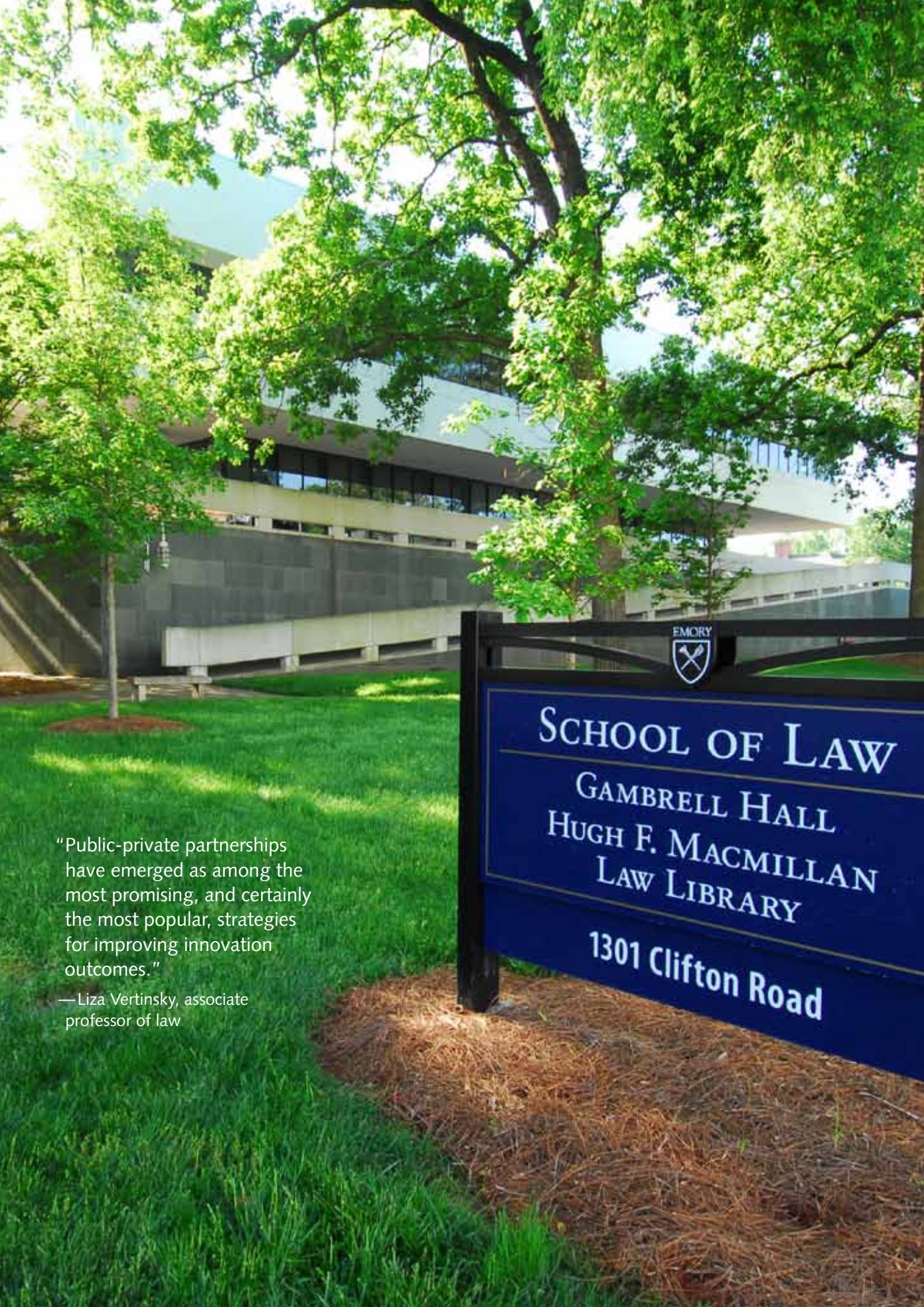
Patents, Partnerships, Pharmaceuticals: The Pre-competitive Myth

Liza Vertinsky on the new era of
drug research and development

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- David Partlett: How damage caps hurt the neediest victims
- Polly Price: What the Ebola scare revealed about the US health system
- Ani Satz on health care fragmentation after the Affordable Care Act





“Public-private partnerships have emerged as among the most promising, and certainly the most popular, strategies for improving innovation outcomes.”

—Liza Vertinsky, associate professor of law



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About Emory Law Insights

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“Pure” Research in the Age of Global Profit



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SELECTED PUBLICATIONS

Articles

Making Room for Cooperative Innovation, 41 *Florida State University Law Review* 1067 (2014)

Making Knowledge and Making Drugs? Experimenting with University Innovation Capacity, 62 *Emory Law Journal* 741 (2013)

Universities as Guardians of Their Inventions, 2012 *Utah Law Review* 1949 (2013)

Presentations

“The State as Entrepreneur: Moving from Laws that Stifle to Laws that Foster,” Innovation Law Beyond IP 2 Conference at Yale Law School, on March 28, 2015

“Public-Private Partnerships as Innovation Strategies: Implications for Patent Policy,” University of Toronto Innovation Law and Policy Workshop, on October 15, 2014

“Hybrid Patents for Hybrid Partners? Application to Alzheimer’s Disease,” Medical Commons Workshop at New York University Law School, on May 16, 2014

Getting a new drug to market is never easy. The process can take a decade or more and cost billions of dollars. In the end, 95 percent of potential drug candidates don’t make it. And this failure rate is for drugs aimed at markets that can afford to pay for them. The challenges are more severe for finding and developing drugs to treat neglected diseases such as Chagas disease and dengue fever, which occur primarily in the world’s poorest countries.

Liza Vertinsky looks at the innovation challenges that confront modern drug discovery and development efforts through a legal lens. In particular, she focuses on the role of hybrid systems of innovation, such as public-private partnerships, for overcoming pharmaceutical innovation roadblocks.

“I was drawn to this area by the critical challenges this industry faces, and also by the research opportunities that our proximity to the Centers for Disease Control and Prevention (CDC), the Emory Global Health Institute, and drug development initiatives at Emory offers,” says Vertinsky.

Development of new drugs for complex diseases may sometimes be hampered by a patent system that was developed at a time

Excerpt: The Pre-competitive Collaboration Myth in Pharmaceutical Innovation

Progress in keeping our bodies alive has not been matched by progress in keeping our minds functioning as we live longer. As a result, a recent study suggests that Alzheimer's disease, the most common form of dementia, may now be the third rather than the sixth leading cause of death in the United States, just after heart disease and cancer. Of the top 10 leading causes of death, Alzheimer's disease stands alone as the only disease with no effective treatment. While Alzheimer's disease is ultimately fatal, the average patient can expect to live for as long as a decade after the onset of symptoms in a state of debilitating decline requiring extensive long-term care. This makes the disease one of the nation's most costly. The magnitude of the global economic costs imposed by Alzheimer's and related dementias is even more daunting. The burdens that this disease imposes on the US economy and its population will continue to grow as its population ages unless effective treatments are found.

The substantial public interest in finding a way of preventing, delaying, or even just slowing the progression of Alzheimer's disease is matched by significant private sector interest in finding and commercializing an Alzheimer's drug. The profit to be reaped from producing an effective treatment for Alzheimer's is immense. Yet even with strong public and private incentives in place, and despite billions of dollars in public and private investment and scientific and technological advances that generate new ways of understanding the brain and its malfunctioning, traditional modes of proprietary commercial drug development have failed to produce effective treatments. While these costly failures are often blamed on the complexity of the disease and the research challenges that it poses, this article suggests that they are symptomatic of broader problems with the existing system of drug discovery and development.

For decades, drugs for ailments such as Alzheimer's, cancer, and diabetes that have large commercial markets have been developed pursuant to a model that moves from largely publicly funded and publicly disseminated research on the nature of disease and ways of modifying the disease to a private, proprietary development process for promising drug candidates. Drug development has been primarily the domain of large and intensely secretive pharmaceutical companies. These companies have relied heavily on patent protection and trade secrecy to stake their claims in promising drug candidates as they push them through the long, expensive, and risky drug development process. The approach has persisted with relatively little change even as research and development costs have soared,

the number of costly failures of drug candidates in late stages of development has increased, and the number of new drugs reaching the market has dropped. It is estimated that bringing a new drug to the market now costs over \$1 billion, and only 20 percent of approved drugs make enough money to recover their research and development costs. The chance, when starting a drug development program, of actually getting a drug approved for sale by the Food and Drug Administration (FDA) 10 or more years later is now well under 1 percent, and many of the failures occur in late stages of development after much time and money has been wasted. The costs and the odds for success of drug development programs targeting Alzheimer's disease are even worse. While inadequacies in existing approaches to drug discovery and development are easy to identify, industry incumbents show little interest in restructuring their role in the drug development process and policymakers have been slow to intervene. Things are only slowly starting to change.

Public-private partnerships have emerged as among the most promising, and certainly the most popular, strategies for improving innovation outcomes in complex major disease areas such as Alzheimer's, diabetes, and cancer. By pooling resources and expertise, increasing knowledge sharing, and reducing duplication of efforts and mistakes, public-private partnerships have the potential to reach public health goals that have eluded each sector acting independently. Unfortunately, current knowledge of how to make these partnerships work effectively in environments where commercial interests are strong is limited. Wary of the challenges that patents and other market-based incentives can create for public-private partnerships, policymakers have focused their efforts on areas of drug discovery and development deemed to be "pre-competitive"—areas of collaboration without competition. This typically confines partnerships to limited areas of early stage research where the knowledge, results, and materials that are shared do not—at least purportedly—confer a competitive advantage by being shared. In many cases the collaborators agree not to patent in these areas. This approach has the effect of segmenting the pharmaceutical innovation process into areas deemed by private participants to be "pre-competitive," often with contractual restrictions on patenting and requirements to share information, and areas that are driven by competitive market forces.

This article addresses a gap in the innovation law and policy literature by exposing two fundamental flaws with the reliance on "pre-competitive" *(continued on following page)*

partnerships to spur pharmaceutical innovation. First, the “pre-competitive” approach to public-private partnerships ignores both the competitive ways in which the boundaries of these partnerships are fashioned and the inevitable tensions within them between cooperative and competitive mechanisms for the production and sharing of knowledge. Second, this approach limits partnerships to areas of intellectual production where knowledge sharing is already likely to occur rather than concentrating them in areas where greater sharing of knowledge is badly needed.

Instead of trying to segment the innovation process into competitive areas that are left to the market and seemingly “pre-competitive” areas where partnerships play a role, policymakers should encourage public-private partnerships in areas of drug discovery and development that are inherently competitive but also in need of greater collaboration. In order to do so, they need to find ways of mitigating the negative effects of market

incentives on cooperation without removing market incentives altogether from this process. This requires strategies for confronting and reducing the tensions between private and public incentives to create and share knowledge. The article suggests that these tensions can be reduced by recalibrating the balance of access to and exclusion from knowledge that patents and other intellectual property rights, along with data exclusivity rules, provide in areas where both cooperative and competitive approaches to the production and sharing of knowledge are important. It proposes a modest change in patent law, a limited statutory patent fair use, as one way of beginning a process of recalibration that could facilitate an industry shift towards more collaborative drug discovery and development.

—from *Patents, Partnerships, and the Pre-competitive Collaboration Myth in Pharmaceutical Innovation*, 48:4 *UC Davis Law Review* 1509 (April 2015)

when collaborative innovation was rare. Today, especially in the biomedical area, it is not only common but essential. Collaboration is necessary to solve complex problems in a world of shrinking resources.

“Public entities are having to bear risks that private companies won’t in efforts to find effective therapies for major diseases such as Alzheimer’s and diabetes,” says Vertinsky. “Conversely, public funding is drying up, so public entities must turn to industry. In today’s environment, everyone must work together. And when you combine public and private entities, as we are doing increasingly in biomedical innovation and health care technologies, we have to think, ‘How does the legal framework facilitate these partnerships? And where does it interfere?’”

The NIH and FDA contend collaboration can be fostered through “pre-competitive” partnerships. Basically, that means competitive pharmaceutical companies work together in the early stages of drug discovery and development, sharing information that doesn’t confer any competitive advantage on proprietary drug development.

The problem with this approach, says Vertinsky, is that it relies on a group of competitors deciding what they are willing to share. “Once something looks interesting, they are going to pull out,” she says. “There is really no such thing as ‘pre-competitive.’ Moreover, government is increasingly involved in later phases of drug discovery and development, areas that are most definitely

susceptible to competitive market pressures.”

Universities are similarly involved in these later phases. They have long played a major role in the basic science discovery preceding drug development. The process was based on norms of open science, with information shared freely. Once a new drug had been successfully developed, the project was shifted to a pharmaceutical company for testing and commercial development. But those norms no longer hold true today. Now, some universities are trying to perform both functions. Vertinsky points to the Emory Drug Discovery Institute as an example. The institute was created to provide organization, facilities, and resources to translate academic drug discovery into clinical candidates, essentially cutting out the pharmaceutical companies.

The greater involvement of public entities, and private entities charged with a public mission, in commercial activities raises new challenges for legal policymakers. “When universities start focusing on making drugs, they may be less keen to have their research published early,” she says. “They may be less keen on working on areas, such as neglected diseases, where market returns will be low or nonexistent. Market forces threaten an institution formerly focused more on curiosity-driven science.”

Similarly, the role of government in downstream drug development activities involves not only opportunities but also risks. Vertinsky (*continued on page 14*)

Legislating Away Malpractice Damages



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LLM, University of Sydney School of Law, 1970
LLM, University of Michigan Law School, 1974
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Scholarly interests: judicial remedies, products liability, professional liability, torts

SELECTED PUBLICATIONS

Books

Remedies: Cases, Practical Problems and Exercises (3rd ed., West Academic Publishing 2014) (with Russell Weaver, Michael Kelly & W. Cardi)

The Right to Speak III: Defamation, Reputation and Free Speech (Carolina Academic Press 2006) (with Russell L. Weaver, Andrew T. Kenyon & Clive P. Walker)

Book chapters

Defective Structures and Economic Loss in the United States: Law and Policy, in *Emerging Issues in Tort Law* (Jason Neyers, Stephen Pitel & Erika Chamberlain eds., 2007)

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A Tale of Two Ironies: In Defense of Tort, 25 *Pacific McGeorge Global Business & Development Law Journal* 343 (2012)

BP Oil Spill: Compensation, Agency Costs, and Restitution, 68 *Washington and Lee Law Review* 1341 (2011)

Efforts by state lawmakers to control medical malpractice liability are nothing new. But damages caps invariably penalize the severely injured patients who are most in need of relief, says Asa Griggs Candler Professor of Law David Partlett.

And once set, caps typically don't age well. Forty years ago, California's Medical Injury Compensation Reform Act of 1975 capped "pain and suffering" damages at \$250,000. That amount still stands, after voters rejected a 2014 proposition that would have adjusted the cap for inflation to about \$1.1 million. A Georgia Senate bill gained national attention this year for its workers' compensation-like scheme to handle medical malpractice claims.

"When you're talking about where a person, say, has been rendered a paraplegic or a quadriplegic or suffered brain damage ... or paralysis—those claims tend to be hit quite disproportionately by these caps. A person who can't work anymore, whose life is very much compromised by the injury suffered, may suffer

Excerpt: Compensation Systems as Substitutes for Tort Law

Although tort law has moved to cover more widely economic interests, its home is its protection of physical integrity. Tort lawyers are usually pictured as inhabiting courtrooms to argue personal injury claims.

This book's cases and materials show that tort law has been subject to both judicial and legislative changes, but these changes have not altered the basic picture of lawyers in the courtroom. About a century ago a more radical change occurred—no-fault workers' compensation. About 40 years ago, approaches were suggested and adopted in various states for automobile no-fault compensation systems. These developments are reviewed before turning to other no-fault compensation systems, some targeting particular problems (e.g., vaccine-related injuries) or resulting from catastrophic events (e.g., the 9/11 terrorist attack), others of a broader nature which would replace the entire body of tort liability for personal injury with a governmental no-fault compensation system. As you review these schemes ask about the nature and function of tort liability. What are its purposes and are they adequately reflected in compensation systems? Should those purposes be captured in any tort system or is it appropriate to forfeit some (for example, deterrence) in the interest of maximizing others (for example, compensation to a wide class of injured persons)? Are there ways of formulating the approaches as to preserve the benefits of tort liability while remedying its ills?...

Who are the winners and losers under these compensation schemes? Could they be the precursors of a general no-fault compensation scheme for all injuries? Remember that Congress provides a social security "safety net" covering, in varying degrees, unemployment, hospital and medical expenses, disability, retirement and survivor's benefits. Should the tort system be abolished and compensation integrated with a revamped social security system that could deliver benefits more efficiently?

Medical Malpractice. Periods of high tort claim frequency and severity have, in certain geographical areas, like Dade County, Florida, sharply raised insurance premium levels or made insurance difficult to obtain. Chapter 4 noted legislative reforms that have ensued. Often the reforms have capped damages, reduced limitation periods, abolished the collateral benefits rule, required arbitration, regulated contingent fees, and provided for periodic payments.

More thoroughgoing systemic reforms have been suggested. Paul Weiler, *Medical Malpractice on Trial* (1991), urges the adoption of a no-fault scheme. His work derives from a large empirical study on medical malpractice in New York (Harvard Medical Malpractice Study, *Patients, Doctors, and Lawyers: Medical Injury, Malpractice Litigation, and*

Patient Compensation in New York). Institutional coverage may have advantages over traditional liability insurance, since premiums may be aligned more readily with risk and institutions may effectively monitor physician behavior.

The American Medical Association has suggested an approach to take adjudication from the hands of the courts. One study of Florida closed claims demonstrates that claimants sue for a variety of reasons, including vindication or to uncover information. What does this imply about no-fault reform?

In another study, Viscusi and Born examined the property and casualty insurance files of the National Association of Insurance Commissioners for 1984–1991 to assess the effect of medical malpractice reforms pertaining to damage levels and the degree to which damages are insurable. The authors found the limits on noneconomic damages had the most impact on insurance market outcomes. They found also that punitive damage reforms have expected impacts. In consequence, insurer profits were enhanced.

The public prominence of medical malpractice reform highlights the journey of tort law from the fustian courtroom and lawyer's office to the razzmatazz of the political stage. Medical malpractice has been propelled into the political maelstrom of health care reform; reform of medical malpractice is urged as a means of lowering the cost of health care. Unfortunately, rational analysis is often abandoned for the *Sturm und Drang* of slogans and shoddy analysis. For example, in a government study, evaluation of the costs of medical malpractice systems turned on reports of physician attitudes and fears. For a criticism of the methodologies and conclusions of those advocating draconian reform, see Tom Baker, *The Medical Malpractice Myth* (University of Chicago Press 2005).

The critical stimulus to good health outcomes is an appropriate array of incentives, including liability rules. It is not enough to say that the liability is costly; the question is whether the costs are justified in preventing bad outcomes and promoting good outcomes.

The claims made about tort reform and no-fault schemes, and modifications thereto, have been episodically examined. Empirical studies concentrate on cost savings, but these are contested, and their savings may be radically less than claimed. Some reforms also produce untoward results in equalities in classes of persons compensated. Moreover, the issue cannot exclusively turn on cost savings, but must be purposed toward the optimal reduction of medical mishaps.

The Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) is

landmark legislation. The reform, during its long gestation period, was roundly attacked for failing to address medical malpractice issues. However, the legislation addresses the reform issue in a deliberate and constructive fashion. Section 10607 provides grant support for “State Demonstration Programs to Evaluate Alternatives to Current Medical Tort Litigation.”

Do you think that the federal government ought to take a role in reforming medical malpractice law?

In pondering the desirability of reforms, bear in mind that the capacity to sue at common law not only is justified by compensation and deterrence, but also in according to claimants a sense of vindication and satisfaction in discovering the circumstances surrounding the medical incident causing the injury.

—from *Compensation Systems as Substitutes for Tort Law*, in *Prosser, Wade and Schwartz’s Torts: Cases and Materials* (13th ed., Foundation Press 2015) (internal citations omitted)

damages of five million dollars,” Partlett says. “So caps are rather vicious ways of reducing the incidence and the severity of claims. They’re at the cost of the catastrophically injured patient.”

In addition to being something of a blunt remedy, Partlett says, caps fail to consider other taxpayer burdens. While they may reduce malpractice claim costs, those who are severely injured or incapacitated often seek public assistance for health care, loss of work, and other aid, if they are unable to obtain damages that reflect their true loss.

Georgia’s proposed legislation would create an administrative system to handle all patient malpractice claims, rather than the courts.

“Substituting a compensation scheme for tort liability is a very comprehensive way of trying to reform the medical negligence system,” Partlett says. “You’re really knocking out a large part of liability.”

“That’s not to say, of course, that the tort system is some perfect system. It has real problems and is very costly. What you need to do, I think, is have a much more careful, nuanced, reasoned approach to these issues of liability, and try to rid them of political grandstanding and the use of information and data that is highly problematical,” Partlett says. “It’s questionable, to say the least, and it cherry-picks information, when there are other factors that are ignored.”

The most recent Georgia bill (The Patient Compensation Act) has been compared to a workers’ compensation model. Claims would be administered by a state board, and physicians and health care providers would be required to pay into a fund to cover them. Proponents say the injured would receive fair compensation sooner, while avoiding expensive lawsuits that may take years to settle or go to trial. Another benefit, they say, would be a decrease in “defensive medicine,” or the idea that health care costs are driven higher

when physicians order unnecessary tests and treatment to avoid being sued.

“It’s got all the problems that workers’ compensation systems have,” Partlett says. “For example, how far do you exclude any kind of tort liability? This happens in workers’ compensation in that the lower the benefits for workers’ compensation you get on a no-fault basis, the more pressure exists on courts to try and make exceptions by allowing tort liability in some situations. That’s precisely what’s occurred in workers’ comp, and it also would occur under this kind of medical malpractice compensation scheme.”

“Caps are rather vicious ways of reducing the incidence and the severity of claims. They’re at the cost of the catastrophically injured patient.”

Caps also reduce the odds that attorneys will take on malpractice cases. A national survey by Emory Law Professor Joanna Shepherd, published in 2012, found that more than half of the attorneys responded that, “even for a case they are almost certain to win on the merits, they will not accept the case unless expected damages are at least \$250,000,” Shepherd wrote. “For a case in which winning is less certain, most attorneys require minimum expected damages of \$500,000.”

Partlett says legislative reform is typically politically driven to benefit one camp or another. To create a compensation alternative that would provide remedies suited to the individual would require unbiased research either by academia, principled nonprofits, or both, he says.

“This is where Joanna Shepherd’s work is excellent in the sense that she actually digs into the data so that you’ve got a much better basis for
(continued on page 15)

The Intersections of Immigration and Public Health



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Scholarly interests: American legal history, immigration and citizenship, legislation and regulation, global public health law, public health law, torts

SELECTED PUBLICATIONS

Books

Judge Richard S. Arnold: A Legacy of Justice on the Federal Bench (Prometheus Books 2009)

Property Rights: Rights and Liberties under the Law (ABC-Clio 2003)

Book chapters

Jus Soli and Statelessness: A Comparative Perspective in the Americas, in *Citizenship in Question: Evidentiary Encounters with Blood, Birthright, and Bureaucracy* (Benjamin N. Lawrance and Jacqueline Stevens eds., forthcoming 2015)

Articles

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Stateless in the United States: Current Reality and a Future Prediction, 46 *Vanderbilt Journal of Transnational Law* 443 (2013)

Federalization of the Mosquito: Structural Innovation in the New Deal Administrative State, 60 *Emory Law Journal* 101 (2010)

When 42-year-old Thomas Eric Duncan died from Ebola after entering the United States by way of Dallas-Fort Worth International Airport, the result was widespread fear. When two nurses who treated Duncan contracted the virus, that fear escalated. Public health law expert Professor Polly Price was widely quoted in the news on the outbreak, but she says

Excerpt: Sovereignty, Citizenship, and Public Health in the United States

Sovereign boundaries, state borders, and distinctions between citizens and noncitizens undermine public health in the United States in a number of ways. Historically, federal authority over immigration alleviated some costs otherwise borne by state and local governments. Today, however, states are primarily responsible for the prevention and control of communicable disease for all residents. The federal and state governments confront a stark division of authority with respect to noncitizens: The federal government decides which noncitizens to admit into the country and the terms under which they may stay, while states must cover the costs of those who present a public health threat within the United States.

Our system of federalism and a fragmented public health infrastructure mean that the cost of health control measures falls on state and local governments, with uneven effectiveness and greatly disproportionate impact in some communities. The problem is thus systemic: the fragmented structure of public health agencies in the United States can prevent an effective response to even wholly local epidemics. Nonetheless, because immigration laws affect public health in many complicated ways, we can make progress by addressing the externalities of public health problems through creative approaches to federal law, along with providing the resources needed to support these changes.

While the specter of fast-spreading, pandemic disease arriving from abroad focuses attention on preventive measures at US borders, the greater threat to public health occurs within our borders. Temporary visitors and undocumented migrants, as well as many legal permanent residents, are excluded from access to preventive health care and often fall off the radar with respect to public health control measures.

Despite our much stronger medical understanding of communicable disease today, the legal safeguards against the spread of disease have become less effective over time. Government structures for both immigration and public health were established in the 19th century. We continue them as a matter of course, with one important exception: the federal government no longer operates hospitals or other facilities for the care of sick immigrants at ports of entry. The federal government now has no resources to pay for health care for foreign nationals. This may be because the historical purpose of its power over immigration was not to treat or handle cases but to turn them away. But at the same time, the US Public Health Service provided humanitarian aid for immigrants at hospitals it once administered.

At present, federal immigration law sets the terms for admission into the country without any public health regulatory or financial element. Those without

legal status pose the greatest public health risk, not because they arrived with a contagious disease (although some may have), but because they consider it strongly in their interest to avoid the public health radar screen. Illegal immigration, resulting from both visa overstays and surreptitious border entry, is a significant side effect of backlogs and complexity in the US visa system. This illegal immigration is often undertaken for family reunification. Labor needs in the United States also encourage undocumented workers. Both of these are motivations that will typically override health concerns among prospective illegal arrivals.

Public health departments in the United States struggle to provide effective health measures even for US citizens. The nation's public health authority is divided among 2,684 state, local, and tribal health departments. Many services offered by public health departments are free of charge for all residents, but funding for health departments is local and dependent upon the political process. As a result, some health departments are well funded and staffed, but many are not.

Furthermore, jurisdictional boundaries for the approximately 2,800 individual health departments are jealously guarded to preserve limited budgets. The federal Centers for Disease Control and Prevention may not fund direct clinical care or treatment of patients. The CDC provides some supplemental funding to local departments earmarked for particular prevention or prophylactic programs, but fragmentation of public health authority continues. And while the CDC offers expertise and guidance, there is little quality control or coordination of local health jurisdictions at the national level.

The millions of foreign nationals legally present in the United States are placed into complex and often confusing categories with respect to rights and obligations. They rarely have access to employment-based health insurance and are often not entitled to government safety-net programs.

Undocumented persons are not eligible to purchase private health insurance under the Affordable Care Act. But, in addition, many if not most of those legally present cannot do so either. This applies even to the "Dreamers"—undocumented children brought to the United States by undocumented parents. Noncitizens granted "deferred action for childhood arrivals" under President Obama's plan may not participate in the ACA exchanges and are not eligible for Medicaid. Their numbers are estimated to be 1.7 million.

This result is perverse, especially from a public health perspective. Preventive care for individuals is *(continued on following page)*

an important tool for overall population health and containment of contagious disease. One result is reliance on hospital emergency rooms for preventable conditions, taxing the resources of hospitals even with the availability of Medicaid reimbursement in some states. Citizens and noncitizens alike who rely on emergency room care often arrive with an advanced state of illness, and poor health greatly enhances susceptibility to contagious disease.

The consequences affect everyone, especially if lack of preventive care contributes to drug resistance in contagious disease. Drug-resistant tuberculosis is already at the level of a “serious threat” to the United States, according to the CDC. The threat could change from “serious” to “urgent” if infection rates were to increase because treatment options are very limited.

All of the issues described above coalesce with border security, choices made in immigration policy, and a powerful historical legacy. It is difficult, if not

impossible, for border security procedures to prevent the introduction of contagious disease. Given that reality, national public health defense becomes the responsibility of state and local health departments. Moreover, these public health agencies—already under-resourced because public funding is politically tenuous—must work within a system in which citizens and noncitizens are segregated with respect to access to health care.

Collectively, these observations at least establish that public health defense cannot safely be contingent upon citizenship status. All public health is essentially local, dependent upon the weakest link in a community. That link may or may not be a US citizen. The historical determinants of the current state of affairs have thus far prevented fashioning a better system.

—from *Sovereignty, Citizenship, and Public Health in the United States*, 17 *New York University Journal of Legislation and Public Policy* 919 (2014)

most media coverage fueled an uninformed public reaction that quickly subsided after the November election.

“Ebola was never a serious threat here. Unlike other contagious diseases already present in the United States, Ebola generated disproportionate media and political interest,” Price says. “On the other hand, it woke up a lot of people to the fact that we need to think about how we respond to public health threats in the future. Who makes these decisions? How can local governments respond effectively in a highly regulated field?”

With the exception of the two nurses in Texas, no one contracted Ebola within the United States, and no one who was quarantined when they returned from West Africa developed the disease. Price points out that during roughly the same period, four people in Atlanta’s homeless shelters died of drug-resistant tuberculosis.

Also concurrent with the Ebola headlines, Texas public health resources were stretched thin when they learned that a hospital health worker had potentially exposed a large group to tuberculosis. They ended up testing 800 people, Price says.

Price is also a legal historian who says in the United States, the conflict between the federal government’s authority over immigration and border control and states’ responsibility for public health isn’t seriously considered by lawmakers until there is a crisis.

She has firsthand experience studying tuberculosis, which she views as a greater threat to the

US than Ebola. As she wrote in a 2014 *New York Times* article, the US health system is unwieldy; responsibility for controlling the spread of tuberculosis is divided among 2,684 state, local, and tribal health departments.

Supported by a grant from the Robert Wood Johnson Foundation, Price spent summer 2013 at the El Paso quarantine station of the Centers for Disease Control and Prevention, studying tuberculosis control measures in a cross-border setting. The course of treatment for drug-resistant tuberculosis can take up to two years and costs more than \$500,000 per case. While US cases have declined in the past decade, it’s on the rise elsewhere.

“The disease in all its forms is second only to AIDS as an infectious killer worldwide,” Price wrote in the *Times*. And the problem is not restricted to foreign-born individuals—the Atlanta outbreak spread from citizen to citizen.

“For historical reasons, we are prone to view immigration and public health as separate interests, but they are, in fact, convergent,” Price wrote in a 2014 journal article. Because of political battles over immigration, the Affordable Care Act specifically excludes noncitizens, even those here legally, which makes dealing with public health issues in border zones even more difficult.

Outbreaks of yellow fever in the late 19th century pushed states to request federal help, which included giving federal immigration officers “explicit direction to exclude people with
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Vulnerability's Effects on Health Care Policy



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Scholarly interests: health law, disability law, law and philosophy, animal law, torts

SELECTED PUBLICATIONS

Books

Disability and Discrimination: Cases and Materials (Aspen, forthcoming)

Book chapters

Epilogue, in *Beastly Morality: Animals as Moral Agents* (Jonathan K. Crane ed., forthcoming 2015) (with Lori Marino & Cynthia Willett)

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Articles

Fragmented Lives: Disability Discrimination and the Role of "Environment-Framing," 68 *Washington & Lee Law Review* 187 (2011)

While the 2010 Patient Protection and Affordable Care Act (PPACA) makes progress in addressing fragmentation under the United States' health care system, Ani B. Satz says there is still a chasm between "the lived and legal patient experience," especially for individuals with serious illnesses or disabilities.

The degree to which PPACA addresses fragmentation, as Satz conceptualizes it, has not yet been examined in the legal literature, and she hopes to start discussion with a forthcoming article. (See excerpt, page 12.)

Fragmentation is typically viewed as a breakdown in care resulting from having multiple decision-makers deliver, regulate, and fund health care, which could be solved or improved by better coordinating both care and how it's paid for, Satz says.

Satz's definition is broader.

"I view fragmentation as occurring when the lived experience of an individual with an illness differs from what is recognized or assumed by the law," she writes. A basic example would be

Excerpt: Fragmentation after Health Care Reform

The Patient Protection and Affordable Care Act of 2010 (PPACA) is the first major federal expansion of health care coverage since President Lyndon B. Johnson signed Medicare and Medicaid into law in 1965. PPACA was enacted during a period of financial crisis in the US. The media were replete with stories of illness and death due to lack of insurance or underinsurance, and personal bankruptcy rates resulting from medical costs were high. Meanwhile, health care costs were rising, and medical outcomes often were not improving despite, and sometimes due to, medical technology. Medical error was on the rise.

Congress intended PPACA to fill gaps in health care coverage as well as to improve the quality and outcomes of patient care. PPACA seeks to accomplish this through governmental and private expansion of health insurance; individual and employer mandates to purchase and to provide insurance, respectively; and reforms that target the type, manner, and circumstance of health care delivery. The reforms pertaining to health care delivery in part seek to coordinate better the manner in which health care is provided and billed. Such coordination is believed to improve health care outcomes as well as to generate administrative cost savings that may be passed on to health care consumers.

Thus, PPACA speaks to remedying health care fragmentation as it is commonly understood, namely, lack of coordinated care or payment. PPACA contains many initiatives to address this type of fragmentation, including: streamlining enrollment for public health insurance, improving coordination of health care services for individuals enrolled in both Medicare and Medicaid, providing bonuses for Medicare Advantage (Medicare private insurance) plans based on care coordination, requiring Health and Human Services (HHS) to establish a national strategy for improving health care delivery, and establishing new patient care models to coordinate care better.

PPACA also bears on health care fragmentation as I interpret it in this article and elsewhere, that is, as the disjunction between the actual and legally recognized experience of illness. This disjunction may occur in a number of ways. Some health insurance plans and institutions are structured in a manner that fail to respond to patients' health care needs across a lifetime. Others may not otherwise adequately address patients' needs, for example, by providing inappropriate diagnosis, treatment, or support. As a result, individuals may become unable due to illness to participate in social and civic realms. PPACA addresses this type of fragmentation by closing gaps in needed health care coverage when the law fails to appreciate an ongoing need for health services as well as recognizing health care needs with more accuracy in other ways. These reforms take at least two forms:

providing more comprehensive care and providing more appropriate care to meet patients' needs.

PPACA provides more comprehensive care by funding care, facilitating enrollment in health insurance, and providing physical access to medical services, largely in rural or underserved areas. The Act funds health care by providing or subsidizing health insurance, mandating private employers with more than 50 employees provide insurance, and requiring insurance market reforms to extend and to provide continuity within insurance—insuring an additional 43 million US citizens and documented immigrants. PPACA creates a demonstration program that allows hospice patients to receive Medicare and reauthorizes funding of state and medical school support for children's emergency and critical care treatment. Additionally, it limits co-insurance and deductibles. It also addresses access to pharmaceuticals as a form of health care by reducing gaps in prescription drug coverage for adults and providing drug discounts for children and underserved communities. Enrollment in health insurance is mandated for most individuals, and employers with more than 200 employees must enroll their employees in health plans automatically. Enrollment is facilitated in government programs through a universal website as well as a yearlong enrollment period for disabled veterans and their dependents.

Additionally, PPACA seeks to respond better to patient needs through a number of initiatives. It is intended to ensure a range of necessary health care services in the least restrictive environment, namely, community-assisted living over institutionalization. The Act requires governmentally sponsored health care exchanges and individual and small group plans to provide "essential health benefits." It increases access to preventative health care services in schools and for Medicare and Medicaid (if states opt to participate in the latter) recipients as well as provides support for assessing workplace health promotion, responses to infectious disease, and pain management. It favors community-assisted living with the Community First Choice Option, providing community-based services for individuals with disabilities, and grants to combine primary and specialty care in community-based mental and behavioral health facilities. PPACA also provides for programs to prevent abuse within nursing homes, facilities that treat patients with dementia, and amongst elderly patients generally (known as the "Elder Justice Act").

Nevertheless, the degree to which PPACA addresses fragmentation—as both traditionally understood and as I conceptualize it—has not yet been addressed in the legal literature. This article is intended to begin that discussion. The article

examines the concept of health care fragmentation and the ways in which PPACA seeks to address it. I conclude that while PPACA remedies fragmentation in part, it does not go far enough. Part I of this article defines and describes health care fragmentation. Parts II and III explore some meta-level issues associated with fragmentation, namely, social expectations and legal assumptions about health care, respectively, that contribute to the misalignment between the actual

and legally recognized patient experience. Part IV explores the legal assumptions about the patient experience within PPACA itself. Part V proposes some steps toward solutions to account better for the lived experience of patients after federal health care reform. —from *Fragmentation after Health Care Reform*, 15 *Houston Journal of Health Law & Policy* (forthcoming 2015)

when an individual is ill, “but is not recognized as eligible for health care, or, alternatively, qualifies for insufficient health care services.” She continues, “fragmentation as I understand it also may occur when the law responds to a health care need in a manner that fails to appreciate the patient’s actual need.”

But perhaps the biggest difference in Satz’s view of fragmentation is that it recognizes the need for access to health care over a lifetime, rather than as something episodic and mostly administered during a crisis.

“The law treats human illness as an exception to the human condition, rather than as part of it.”

“Vulnerability to illness is universal and constant, affecting the entire population over the lifecycle, not only certain ‘vulnerable populations,’ or discrete periods of time” she says, citing the vulnerability theory work of colleague Martha Albertson Fineman, Robert W. Woodruff Professor of Law. Fineman directs the Vulnerability and the Human Condition Initiative, an international consortium of scholars, which includes Satz.

The state should acknowledge access to health care is universally required throughout life and invest accordingly in infrastructure and programs to provide it—and not just when an individual becomes a patient, Satz says.

The law “treat[s] human illness as an exception to the human condition, rather than as part of it,” Satz writes. “It fails to reflect the reality of the beginning and end of life when health care services are required for most people, as well as the life of individuals with chronic disease. It also does not recognize preventative care as necessary throughout the lifecycle. Further, the law fails to account for barriers to participation in the health care insurance market and to access to health care

services once insured, such as discrimination.

“The only way to address gaps in access to a basic level of health care services completely is through universal health care coverage throughout the lifecycle that does not require an emergency event or a catastrophic health condition,” she adds.

Often, health benefits are contingent upon certain stages or stations of life—being a child, indigent, over age 65, active in or retired from the military, or a federal employee. “But we don’t have the concept of health care needs continuing across the lifecycle, and that’s part of the reason we have so many uninsured and underinsured individuals,” she says.

Evidence suggests that providing services before someone finds themselves a patient is not only more economical, but also likely to address vulnerability to illness at a more appropriate point, Satz says.

PPACA goes some distance in recognizing constant vulnerability to illness by requiring companies with 50 or more full-time employees to provide insurance (or to pay a fee), subsidizing Health Care Exchanges where insurance may be purchased, and supporting a voluntary state Medicaid expansion. Another area where PPACA brings the lived experience more into alignment with the legally recognized one is its emphasis on community-based treatment, rather than institutionalization, for some individuals with disabilities.

Satz’s current work is informed by her earlier research on how fragmentation affects disability law and how difficult it can be for patients to obtain legal benefits and workplace accommodations that truly reflect their needs. While the 2008 Americans with Disabilities Act Amendments Act significantly broadens the definition of disability, “there are still a number of problems I see with obtaining relief under the Act,” Satz says. “One of the issues is accommodation. Now that we’ve *(continued on page 14)*

focuses on issues at the boundaries of these collaborations, examining ways of managing the tensions between market and nonmarket incentives and goals, as public and private actors collaborate.

The daughter of two university professors at the University of British Columbia, Vertinsky was always drawn to academia. She earned a PhD in economics and a JD from Harvard University and Law School respectively in 1997, focusing her dissertation work on the economic organization of street gangs. She then worked for two Boston law firms for about 10 years, focusing on intellectual property and technology transfer. In 2007 she joined Emory's faculty.

Outside of the classroom, Vertinsky lends her expertise to several Emory organizations. She serves as an advisor to a student group called Universities Allied for Essential Medicines. This

group looks at universities' obligation to ensure access to drugs they develop. "For example, when Dennis Liotta discovered Emtriva [a breakthrough for the treatment of persons with HIV/AIDS], Emory licensed it to a pharmaceutical company without building in access terms that would have ensured developing countries could get the drug at affordable prices," says Vertinsky.

She also serves as a project leader for Emory's Global Health Law and Policy Project. The project provides a multidisciplinary platform for developing, exploring, and evaluating global health initiatives. "Working with these groups, I am able to apply the work I do domestically on drug discovery and development to global issues," she says.

Her future research agenda will focus increasingly on the intersection of innovation and global health.

broadened the definition of disability, we have to ensure that individuals with disabilities are adequately accommodated under law."

Another prong of Satz's recent fragmentation work is identifying social and legal assumptions that shape health care legislation and serve as sources of fragmentation.

Some social assumptions that influence how citizens view health care policy and delivery are: rationing is detrimental to patient care; patients benefit from directing their own care; patients benefit from accessing the most advanced medical technology; and medical specialization is required for the best patient care.

Those premises are largely false, Satz says. And worse, they generate expectations about the availability of health care resources that are reflected in laws that fragment health care.

For example, legal structures support consumer-driven health care (CDHC) initiatives such as high deductible or co-insurance plans with health savings accounts, health reimbursement accounts, and health plans that allow more patient choice in providers. All provide patients with significant autonomy in making health care choices. But evidence suggests that patients do not have the knowledge or skills to make such choices, and, poor patient choice may result in interruptions in care or inconsistent or substandard care. Patients also may fail to allocate their

resources over a lifetime, resulting in gaps in care. Thus while legal structures supporting CDHC are designed to provide continuous care, the actual patient experience may be different.

Legal assumptions also contribute to fragmentation and are reinforced within PPACA, Satz says. They include assumptions that individuals are fully functioning over a lifetime, capable of laboring for wages, and able to perform and to order preferences in order to participate in the health care market. While PPACA goes some distance in addressing the first and last, it strongly reinforces the second by relying in part on employer mandates to expand health insurance coverage.

The path to better health policy may include politicians who employ and articulate facts rather than assumptions.

"While increasing material benefits would assist with reducing gaps in health care that may frustrate the patient experience, other reforms to address fragmentation entail simply a better understanding of the patient experience and how resources are best directed," Satz writes. "Since key social assumptions about health care paradoxically support fragmentation, lawmakers have a difficult task of first educating the public about their own misperceptions and then battling deeply entrenched legal views about health and illness that also fragment care in order to bring about reform to serve patient goals best."

principled reforms than just these assertions about defensive medicine and the costs of premiums for doctors—and these claims that somehow doctors can't practice because of medical malpractice insurance premiums," Partlett says. "That's simply not true. If you go into this and look at it carefully, you find that the costs of insurance are extremely low compared with other costs that doctors bear. They're not overwhelming at all."

Another difference between a compensation scheme versus torts, Partlett says, is one that involves no dollar figure. Lawsuits allow clients to get to the bottom of what happened.

Partlett co-authored *Suing for Medical Malpractice* (The University of Chicago Press 1993), which examined a series of Florida malpractice cases involving emergency room birth injuries.

contagious disease," Price says.

"The federal government still decides who comes in, and most importantly, the terms under which they may stay," she says. "But the states then assume the burden of preventing disease outbreaks, as they do for all residents." So identification and treatment can vary widely depending on the resources of the particular state or county.

While the Ebola crisis made us aware of shortcomings in this system, Price hasn't yet seen meaningful change.

"I think we will still have, by default, this patchwork of public health authority, each with its own policies and procedures, and with vastly different access to resources—some poor districts, some rich districts," she says. "The fact is that it's really dependent upon whether voters are willing to pay taxes for this, to pay for preparation."

During the Ebola crisis, "the governors of New Jersey, New York, and Georgia said, 'We don't believe the federal guidelines are enough. We can implement our own,'" Price says. "And they are absolutely right about their prerogative. But governors in those states added to the fear and uncertainty," she says, illustrating how the current public health structure can lead to conflict between state and federal directives.

The solution? Congress needs to create "a clear federal quarantine authority," Price says. "The CDC is not funded or equipped, nor does it have

"That's a benefit that is worth some cost ... the idea that the medical profession can't keep these facts to themselves—that you can go in and find out what happened to your baby, what happened in the operation," Partlett says. "You can hold the doctors to task. It's an important element."

"We found ... that people are generally satisfied with medical malpractice claims. They find that the system, although it may not have given them compensation—they at least had a chance to vindicate their rights and find out what actually happened. The common law system does that," Partlett says.

a mandate to actually provide medical care and disease control measures directly in states.

"What scientists really fear is some fast-moving epidemic that is spread through the air," Price says. "Ebola was not." She points to the 1918 flu, a global pandemic. An estimated one-fifth of the world's population fell ill, and roughly 50 million people died—many of them young, healthy adults. "Like SARS, MERS (Middle Eastern Respiratory Syndrome), and H1N1 flu, it's inevitable. ... The scientific view is that this will happen at some point, and we may even be overdue."

Price continues to work with the US-Mexico Border Health Commission, and plans to write a book on the development of public health regulatory structure. And as a member of Emory's new Antibiotic Resistance Center, Price will address regulatory and policy aspects of how to combat drug resistance.

Any epidemic "requires a balance of public interest and government authority against individual interest," she says.

In the Dallas Ebola case, public health officials had to react quickly to implement contact tracing and quarantine. "They were using old structures for a new situation, and anytime that happens, that's useful," she says. "It's an exercise in whether our laws are flexible enough to allow medical and public health professionals to do their job. If it's too complicated, if it's too restrictive, they can't do their job effectively."

New, Visiting Faculty Join Emory Law



Dinner

Deborah Dinner

This fall, **Deborah Dinner** will join Emory Law, from Washington University School of Law, as an associate professor. She will teach a **legal history seminar** called Law and Social Movements: Historical and Theoretical Perspective. Future courses will include Fourteenth Amendment: Equal Protection and Due Process, Property, Family Law, and Employment Discrimination. Dinner's scholarship examines the **historical relationship between social movements, political culture, and legal change**. Dinner's current research project is a book entitled *Contested Labor: Social Reproduction, Work, and Law, 1964–2010*. The book examines legal and political debates among feminists, employers, and social conservative activists about the relationship between motherhood and women's labor market participation.



Bagley 96L

Margo Bagley 96L

Margo Bagley 96L, Hardy Cross Dillard Professor of Law at the University of Virginia School of Law, will return to Emory Law in spring 2016 as a visiting professor, teaching an accelerated course on **International Patent Law and Policy**. Bagley's teaching and writing focus on US, international, and comparative patent law issues, particularly relating to biotechnology and pharmaceutical protection. Bagley is a member of the board of directors for the Public Patent Foundation and also served on the National Academy of Sciences' Committee on University Management of Intellectual Property.



Smith

Fred Smith Jr.

Fred Smith Jr. will visit Emory Law from the University of California-Berkeley School of Law during the 2015–16 academic year. He is a scholar of the **federal courts and constitutional law**, and at Emory, he will teach courses on both. Smith's research focuses on state sovereignty and representative government. His work has appeared or will appear in the *Stanford Law Review*, *Columbia Law Review*, *New York University Law Review*, and *Fordham Law Review*. Recent works include: Local Sovereign Immunity, 115 *Columbia Law Review* (forthcoming 2016); Due Process, Republicanism, and Direct Democracy, 89



Harris

New York University Law Review 582 (2014); and *Awakening the People's Giant: Sovereign Immunity and the Constitution's Republican Commitment*, 80 *Fordham Law Review* 1941 (2012). Smith clerked for US Supreme Court Justice Sonia Sotomayer in 2013–2014.

Leetra Harris, Robert Parrish

Emory Law will welcome two new instructors to its first-year, two-semester legal writing program. **Leetra Harris** is an assistant US attorney in the Western District of Tennessee and an adjunct professor of legal methods at the University of Memphis Cecil C. Humphreys School of Law. **Robert Parrish** is currently an associate professor at Elon University School of Law in Greensboro, North Carolina. In addition to his legal work, Parrish is an **oral historian and published archivist**. He worked for the Center for Documentary Studies' Behind the Veil project, which produced "Remembering Jim Crow"—a compilation of interviews with African Americans born between 1900 and 1940. He is a co-editor of *Remembering Jim Crow: African Americans Tell About Life in the Segregated South* (The New Press 2001). Parrish will also teach a judicial clerkship writing course at Emory Law.

Nicole Morris

Nicole Morris is joining the faculty as the law school's TI:GER program director. TI:GER (Technological Innovation: Generating Economic Results) is an innovative partnership between Emory and The Georgia Institute of Technology that brings together graduate students in law, business, science, and engineering to work on start-up projects. Morris has been an adjunct professor teaching **patent litigation** at Emory Law. She also is an **intellectual property** attorney practicing with Parks Wood LLC in Atlanta. Morris was previously the managing patent counsel at The Coca-Cola Company in Atlanta, where she was responsible for the company's global patent strategy as well as for advising and counseling business and scientific stakeholders. Formerly an engineer, she also has experience working with manufacturing and consumer products.



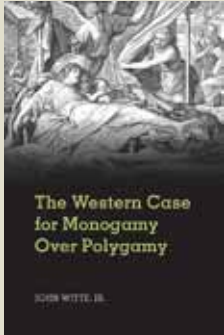
Parrish



Morris

Recent Faculty Scholarship

The Western Case for Monogamy Over Polygamy (Cambridge 2015)
by John Witte Jr.



For more than 2,500 years, the Western tradition has embraced monogamous marriage as an essential institution for the flourishing of men and women, parents and children, society and the state. At the same time, polygamy has been considered a serious crime that harms wives and children, correlates with sundry other crimes and abuses, and threatens good citizenship and political stability. The West has thus long punished all manner of plural marriages and denounced the polygamous teachings of selected Jews, Muslims, Anabaptists, Mormons, and others. Witte carefully documents the Western case for monogamy over polygamy from antiquity until today. He analyzes the historical claims that polygamy is biblical, natural, and useful alongside modern claims that anti-polygamy laws violate personal and religious freedom. While giving the pro and con arguments a full hearing, Witte concludes that the Western historical case against polygamy remains compelling and urges Western nations to hold the line on monogamy.

Fact Investigation (2nd ed., LexisNexis 2015)
by Paul Zwier (with Anthony J. Bocchino)



A litigator's investigation begins where the "official" investigation ends. Informal fact investigation requires an attorney to engage clients so they will share critical facts and stories for use in developing and implementing a winning case theory. Zwier and Bocchino define how to build effective alternative case theories to inform the fact investigation process, and lay a foundation for efficient use of formal discovery devices. The authors model these practice skills via four cases: *Quinlan v. Kane Electronics* (business/contract), *Brown v. Byrd* (auto accident/personal injury), *State v. Lawrence* (criminal robbery), and *United States ex rel. Rodriguez v. Hughes* (False Claims Act). The second edition is fully revised, with an emphasis on the impact of the proposed Federal Rules of Civil Procedure changes. It also features a new chapter on e-discovery. Most cases now involve some form of electronic evidence, and the book examines how e-discovery strategies differ from plaintiff to defendant, and how to manage clients' competing rights to both speech and privacy, in a highly discoverable online world. Topics range from explaining how to use an opposing party's social media indiscretions to the impact of new federal rules that limit the use of electronic evidence.

International Encyclopedia of the Social and Behavioral Sciences, 2nd ed.
(James Wright ed., 2015)
Law Section by Kay Levine (with Rosann Greenspan)



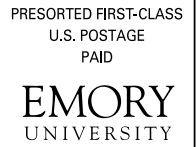
Fully revised and updated, the second edition of the *International Encyclopedia of the Social and Behavioral Sciences* (first published in 2001) offers a source of social and behavioral sciences reference material that is broader and deeper than any other. Associate Professor Kay Levine served as co-editor for the law section, which includes approximately 150 entries. Other Emory Law authors involved in this work are: Martha Fineman, Robert W. Woodruff Professor of Law; Peter Hay, L. Q. C. Lamar Professor Emeritus of Law; Jonathan Nash, David J. Bederman Research Professor; Rafael I. Pardo, Robert T. Thompson Professor of Law; Sasha Volokh, associate professor; and Yvana Mols and Stu Marvel, both post-doctoral fellows with the Vulnerability and the Human Condition Initiative. Available both in print and online, the encyclopedia comprises more than 3,900 articles commissioned by 71 section editors. It includes 90,000 bibliographic

references as well as comprehensive name and subject indexes. The 26-volume set includes articles on psychology, neuroscience, evolution, artificial intelligence, human/computer interaction and more. It includes writing by leading scholars from around the world.



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ALSO INSIDE

“For historical reasons, we are prone to view immigration and public health as separate interests, but they are, in fact, convergent.”

—Polly Price, professor of law