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Larry I. Palmer

*William & Mary Law School*

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## What is Urban Health Policy and What's Law Got To Do With It?

Larry I. Palmer\*

"The experts concluded that if the community were to be healthy, if it were not to revert again to a blighted or slum area, as though possessed of a congenital disease, the area must be planned as a whole. It was not enough, they believed, to remove existing buildings that were insanitary [sic] or unsightly."<sup>1</sup>

More than half the world's population now lives in cities.<sup>2</sup> Legal scholars are beginning to explore the global implications of urban poverty on the health of various segments of the population.<sup>3</sup> Scholars from a variety of disciplines have assumed that our domestic policy problems such as health disparities—however defined—will be solved by enactment of various pieces of national legislation. Even those whose ideological commitments lead them to favor "market-based" solutions over government involvement in the "health care reform" debate assume the need for national or state solutions in the form of tax incentives or deregulation.<sup>4</sup>

I propose to enrich scholarship and discourse on health policy by shifting the focus away from global, national, and state action to that which is most local—the neighborhood, the community, and the city.<sup>5</sup> Our public discourse no

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\* Professor of Law, The College of William & Mary School of Law. This Article was inspired by my position as Distinguished Visiting Professor Law, O'Neil Center for Global and National Health, Georgetown Law School, Fall 2007. I wish to acknowledge the students at Georgetown Law School in my seminar, Emerging Problems of Urban Public Health, who raised many provocative questions about my approach. I further wish to acknowledge the assistance of Juliana Frisch, The College of William & Mary Law School Class of 2008 and Leah Kaufman, The College of William & Mary Law School Class of 2010 for their assistance with the footnotes. © 2009, Larry I. Palmer.

1. *Berman v. Parker*, 348 U.S. 26, 34 (1954) (upholding the constitutionality of legislation authorizing "urban renewal" that allowed a public condemnation of commercially "healthy" property to be turned over to a private developer for demolition).

2. UNITED NATIONS POPULATION FUND, STATE OF WORLD POPULATION 2007: UNLEASHING THE POTENTIAL OF URBAN GROWTH 1 (2007), available at [http://www.unfpa.org/swp/2007/presskit/pdf/sowp2007\\_eng.pdf](http://www.unfpa.org/swp/2007/presskit/pdf/sowp2007_eng.pdf) (last visited Nov. 9, 2008).

3. See generally Lawrence O. Gostin, *Meeting Basic Survival Needs of the World's Least Healthy People Toward a Framework Convention on Global Health*, 96 GEO. L.J. 331 (2008) (arguing in part that the poorest people in the poorest countries have the worst health, and that this has effects across the globe).

4. See, e.g., John McCain 2008, Straight Talk on Health System Reform, <http://www.johnmccain.com/Informing/Issues/19ba2f1c-c03f-4ac2-8cd5-5cf2edb527cf.htm> (last visited July 28, 2008).

5. What constitutes a city or urban area is a matter of state law in this country and has been recently undergoing change as some traditional cities have combined with the surrounding counties to form

longer embraces Justice Douglas' metaphor of the city as inherently sick as a social and physical phenomenon, or, in his words, as "possessed of a *congenital disease*."<sup>6</sup> We are just as likely to hear calls for a "new urbanism" that decries the ill health consequences of "suburban sprawl" as a sort of panacea for a host of health issues facing the nation.<sup>7</sup>

Yet there are reminders of our lack of understanding about the nature of modern urban living in the attempted rebuilding of parts of New Orleans and other Gulf Coast cities after Hurricanes Katrina and Rita. In the immediate aftermath of the flooding in 2005, it was as if the nation discovered for the first time that there were poor people living beyond the French Quarter in New Orleans. Old fashioned public health concerns—clean water, sewage, retrieval of bodies, and so on—were the subject of the nightly news.<sup>8</sup> The term "refugees" was used to describe residents of an American city when they sought reprieve from rising flood waters.<sup>9</sup> Despite promises by politicians at all levels of government to "rebuild" New Orleans, many of us wonder if a city with the population and the ethnic, racial, and socio-economic diversity of New Orleans as of August 2005 will ever exist again in our lifetimes.<sup>10</sup> Whatever the demographic and physical layout of the "new" New Orleans, it is increasingly clear that we do not understand how statutes, regulations, and court decisions at

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metropolitan governments, such as in Louisville, Kentucky, Memphis, Tennessee, and Indianapolis, Indiana. *See* IND. CODE ANN. § 36-3-1-1 (LexisNexis 2008) (the merger of Indianapolis and Marion County, known as UniGov, began in 1970 and was ordered by state legislation); KY. REV. STAT. ANN. § 67C.101 (LexisNexis 2008) (the merger of Louisville and Jefferson County began in 2003 via a referendum, for which the legislature gave permission through special legislation); TENN. CODE. ANN. § 7-1-101(4), (5) (2007) (providing definitions for "metropolitan government" and "metropolitan government charter commission"). *See also* FRANK GAMRAT & JAKE HAULK, ALLEGHENY INST. FOR PUB. POLICY, MERGING GOVERNMENTS: LESSONS FROM LOUISVILLE, INDIANAPOLIS, AND PHILADELPHIA (2005), available at [http://www.allegenyinstitute.org/reports/05\\_04.pdf](http://www.allegenyinstitute.org/reports/05_04.pdf) (last visited Nov. 9, 2008) (providing an overview of the processes in Louisville, Indianapolis, and Philadelphia).

6. Berman, 348 U.S. at 34 (emphasis added).

7. *See, e.g.*, Ernie Hood, *Dwelling Disparities: How Poor Housing Leads to Poor Health*, 113 ENVTL HEALTH PERSP. A310 (2005); David E. Jacobs, Tom Kelly & John Sobolewski, *Linking Public Health, Housing, and Indoor Environmental Policy: Successes and Challenges at Local and Federal Agencies in the United States*, 115 ENVTL HEALTH PERSP. 976 (2007); Jennifer Medlin, *Dwelling on Differences in Health*, 113 ENVTL HEALTH PERSP. A592 (2005).

8. *See, e.g.*, Elizabeth Agnall, *Next Threat: Illness; Experts Anxious to Contain Disease Outbreaks, Rumors*, WASH. POST, Sept. 13, 2005, at F01; Timothy Dwyer & Michael A. Fletcher, *Residents Stay Put, Despite Orders; Officials Warn of Floodwaters' Health Threat*, WASH. POST, Sept. 8, 2005, at A13; Jessica Heslam, *Katrina's Wrath: Health Crisis Looms in Bayou*, BOSTON HERALD, Sept. 1, 2005, at 2; Robert D. McFadden & Ralph Blumenthal, *Bush Sees Long Recovery for New Orleans*, N.Y. TIMES, Sept. 1, 2005, at A1; Bruce Nichols, *Waterborne Bacteria Suspected in Some Deaths*, DALLAS MORNING NEWS, Sept. 8, 2005, at 1A; Jonathan D. Rockoff, *Health Officials Focus on Infectious Diseases*, BALT. SUN, Sept. 7, 2005, at 10A.

9. *See, e.g.*, *Calling Katrina Survivors 'Refugees' Stirs Debate*, ASSOCIATED PRESS, Sept. 7, 2005, available at <http://www.msnbc.msn.com/id/9232071/> (last visited Nov. 15, 2009).

10. *Cf. e.g.*, Jenny Jarvie, *A Fury in New Orleans as Housing Demolition Ord; Protesters, Police Clash During a City Council Hearing Where a Plan to Raze Public Projects is Unanimously Approved*, L.A. TIMES, Dec. 21, 2007, at A19; Adam Nossiter & Leslie Eaton, *New Orleans Council Votes for Demolition of Housing*, N.Y. TIMES, Dec. 21, 2007, at A37.

every level of government affect where people live and how that “built environment” conditions individual and collective health risks. One symbol of our concern for what is happening not only in New Orleans, but in many older cities<sup>11</sup> across this country, is the indefinite closure of Charity Hospital—often called Big Charity for its public service to the poor—in New Orleans.<sup>12</sup>

I propose to shed light on analytical methods likely to generate solutions to post-Katrina confusion by focusing on a question: What is urban health policy? This question is useful in the current era when many assume that anything not based on science or black-letter legal precedent should be lumped under the vague rubric of “policy.” This misconception assumes “values” or “emotions”<sup>13</sup> are the primary drivers of decision-making. When this notion is applied to health policy, we further make a normative assumption that different perspectives on health risk are best navigated by the political and regulatory processes and avoided by courts. My answer here is grounded in the scholarship of institutional choice.<sup>14</sup> Using a form of comparative institutional analysis, I will also answer the subsidiary question of what role law plays in urban health policy by illustrating how various legal institutions—courts, legislatures, regulatory bodies of various kinds—and “the market” become the primary forum for policy-making. Such an analytical approach may assist us to see the limits of law in some instances, but also illuminates instances in which the law has provided incentives for social and economic institutions adverse to the health and well-being of the most vulnerable in our urban communities. Ultimately, my analysis emphasizes that lawyers should view health policy discourse as intrinsically multidisciplinary, even when we are engaged in litigation before courts.

My analysis is in four parts. Part I develops a framework for defining urban health policy in the context of an institutional analysis of law. I propose that the

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11. None of *MONEY Magazine*’s ten best cities to live in are what I would refer to as an “older city.” See Kate Ashford, et al., *Best Places to Live*, *MONEY*, Aug. 2007, available at [http://money.cnn.com/galleries/2007/moneymag/0707/gallery.BPTL\\_top\\_100.moneymag/index.html](http://money.cnn.com/galleries/2007/moneymag/0707/gallery.BPTL_top_100.moneymag/index.html) (last visited Nov. 9, 2008) (reporting that the ten best cities are Middleton, Wisconsin, Hanover, New Hampshire, Louisville, Colorado, Lake Mary, Florida, Claremont, California, Papillion, Nebraska, Milton, Massachusetts, Chaska, Minnesota, Nether Providence, Pennsylvania, and Suwanee, Georgia).

12. For more about the closure of public hospitals in Louisiana, *see generally* Elizabeth A. Weeks, *Shaping A New Direction for Law and Medicine: An International Debate on Culture, Disaster, Biotechnology and Public Health*, 10 DePaul J. Health Care L. 251 (2007). For more on the closure of public hospitals as a general matter, *see generally* Julie J. Piotrowski, *How Secure is the Safety Net? Public Hospitals Learn to Survive in an Increasingly Tight Market by Closing, Building, Replacing, and Sometimes Converting*, Modern Healthcare 32, no. 8 (2002).

13. Cf. MARTHA NUSSBAUM, *UPHEAVALS OF THOUGHT: THE INTELLIGENCE OF EMOTIONS* 420-25 (2001) (arguing that empathy could influence the way judges construct issues).

14. *See generally*, e.g., NEIL K. KOMESAR, *LAW’S LIMITS: THE RULE OF LAW AND THE SUPPLY AND DEMAND OF RIGHTS* (2001); William W. Buzbee, *Sprawl’s Dynamics: A Comparative Institutional Critique*, 35 WAKE FOREST L. REV. 509 (2000). *See also* Nancy J. Knauer, *The Recognition of Same-Sex Relationships: Comparative Institutional Analysis, Contested Social Goals, and Strategic Institutional Choice*, 28 U. HAW. L. REV. 23 (2006).

Supreme Court's opinion in *Berman v. Parker*<sup>15</sup> illustrates the continuing debate over the role courts play in shaping the built environment of cities in the United States. Relying solely on the analysis of courts as emblematic of the Rule of Law, however, ignores the dynamic nature of the impact that legal institutions—including courts at the local and state level, as well as political bodies at various levels of government—have on shaping the social ecology of American cities, together with social and demographic factors. Combining a market analysis with a systemic approach to analyzing the impact that legal institutions have on that market produces a set of empirical questions all legal institutions must address. The dearth or uncertainty of data central to a particular issue is not a limitation that affects only the courts; it impacts political bodies as well.<sup>16</sup>

Part II uses this institutional definition of urban health policy to analyze the problem encountered by researchers conducting empirical studies about "healthy" and "unhealthy" housing. There has been considerable commentary on litigation over attempts to find cost effective means to eliminate health risks posed by lead paint in older urban dwellings.<sup>17</sup> What has not been fully discussed is the ongoing shift in how we frame the problem of unhealthy housing in urban areas. Rather than seek the surgical removal of blighted housing, as was done in the era of urban renewal, the emphasis has shifted to "curing" lead-laden housing of its illness. This new emphasis on restoring existing housing stock comes at a time when the federal government is supporting the replacement of older public housing projects with mixed income housing.<sup>18</sup> In addition, little attention has been paid to the response of other institutions to the Maryland court's decision in *Grimes v. Kennedy Krieger*, which held that a research organization could be liable for a faulty consent process in lead paint research. *Kennedy Krieger* has negatively impacted the ability of empirical scientists to gather data on the effects housing has on its residents. Political bodies have responded to the opinion, but not in the way desired by in the dissent in *Kennedy Krieger*, or by public interest parties involved in the case.<sup>19</sup> Of even greater significance is the response of the research community and its allies in the federal agencies that fund most housing

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15. See generally *Berman*, 348 U.S. 26.

16. See KOMESAR, *supra* note 14.

17. See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807 (Md. 2001). Most legal commentary on *Kennedy Krieger* focuses on bioethical issues, informed consent, and experimental procedures. See, e.g., Carl H. Coleman, *Duties to Subjects in Clinical Research*, 58 VAND. L. REV. 387, 431-32 (2005); Doriane Lambelet Coleman, *The Legal Ethics of Pediatric Research*, 57 DUKE L.J. 517, 523-603 (2007); Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605, 614 (2007).

18. See, e.g., U.S. Department of Housing and Urban Development, HOPE VI, <http://www.hud.gov/offices/pih/programs/ph/hope6/> (last visited Nov. 9, 2008). For a critique of HOPE VI, see NATIONAL HOUSING LAW PROJECT, ET AL., FALSE HOPE: A CRITICAL ASSESSMENT OF THE HOPE VI PUBLIC HOUSING REDEVELOPMENT PROGRAM (2002).

19. *Kennedy Krieger*, 782 A.2d at 862 (Raker, J., dissenting) (arguing that the issue of a parent or guardian's ability to consent to the participation of a minor child in a nontherapeutic research study is an important public policy consideration best dealt with by the legislature).

research. Once again, the response differs from what researchers and research organizations involved in *Kennedy Krieger* might have wanted.<sup>20</sup> This more nuanced analysis of the various institutional actors involved in healthy housing problems illustrates that a new actor—one for the moment identified as “the community”—must become involved, not only in creating solutions to the healthy housing problem, but also in formulating the research questions themselves.<sup>21</sup> More generally, I contend that the shift in framing the healthy housing problem, from surgical cure to renewal and restoration of a community, illustrates that policy development and policy-making are two different types of processes in public health systems.

Part III uses the legislative debate over mandating the Human Papillomavirus (HPV) vaccine and the New York City’s diabetes surveillance regulations to argue that the legal tools of the “old public health” will not be effective in the “new public health” milieu.<sup>22</sup> Noble goals, such as ensuring the most vulnerable populations receive vaccination or optimal diabetes management, by themselves will not solve the complex questions of whether law, in whatever form, does or can achieve the optimal amount of health in an urban population, or any subgroup within that population. The new public health is not simply a matter of public health officials assuming new conditions to be within the purview of their expertise or function. Rather, the science underlying public health must now incorporate the new knowledge generated by genomics.<sup>23</sup> An HPV vaccine represents a new definition of how to interrupt the disease process that would not have been possible prior to the Human Genome Project.<sup>24</sup> Furthermore, the global social and economic systems render the traditional public health tools—legal isolation and quarantine—of limited utility as old diseases such as tuberculosis evolve. My critique points to the need for a new legal framework rather than the traditional balancing of interests analysis.<sup>25</sup>

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20. See generally *ETHICAL CONSIDERATION FOR RESEARCH ON HOUSING RELATED HEALTH HAZARDS INVOLVING CHILDREN* (Bernard Lo & Mary Ellen O’Connell eds., 2005).

21. See generally *DAVYDD GREENWOOD & MORTEN LEVIN, INTRODUCTION TO ACTION RESEARCH: SOCIAL RESEARCH FOR SOCIAL CHANGE* (2nd ed. 2007).

22. The “new” public health has been characterized as a broad-based private and public effort to reduce the social burdens of disease, including chronic diseases such as diabetes, obesity, and cancer. Compare Richard A. Epstein, *Let the Shoemaker Stick to His Last: A Defense of the “Old” Public Health*, 46 PERSP. BIOLOGY & MED. S138, S139 (Supp. 2003) (arguing against broad regulatory intervention in areas of public health outside traditional notions of infectious diseases and epidemics) with Lawrence O. Gostin & M. Gregg Bloche, *The Politics of Public Health: A Response to Epstein*, 46 PERSP. BIOLOGY & MED. S160, S163-165 (Supp. 2003) (arguing that regulatory intervention is justified if there is strong data suggesting the need for far-reaching public health interventions).

23. See generally, *WHO WILL KEEP THE PUBLIC HEALTHY?: EDUCATING PUBLIC HEALTH PROFESSIONALS FOR THE 21<sup>ST</sup> CENTURY* (Kristine Gebbie et al. eds., 2002).

24. See Larry I. Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1, 2 (2002).

25. Cf. Amy L. Fairchild, *Diabetes and Disease Surveillance*, 313 SCIENCE 175, 176 (2006) (arguing for a gloss on traditional balancing of privacy and public health by suggesting a distinction between soft and hard paternalism).

Part IV uses the problem of cardiovascular research and risk to illustrate that health policy must incorporate social and economic costs into its legal analysis without falling victim to the false promises of “consumer driven health care.”<sup>26</sup> Cardiovascular treatment and prevention is an area of health care delivery whose cost effectiveness has been studied extensively, perhaps because of the rate of innovation in the field as a consequence of new drugs, surgical techniques, and devices for assisting or replacing heart functions.<sup>27</sup> On the other hand, many of the conditions affecting vulnerable urban populations—for instance, obesity and diabetes—increase the risk of cardiovascular disease. Therefore, framing the problem more broadly as *cardiovascular risk and research* allows for consideration of these additional factors in determining what data is needed to arrive at an effective policy.<sup>28</sup> The most important insight from this application of comparative institutional analysis to a problem in urban health is the discovery that attempts to measure “cost” should be replaced by efforts to measure “value” to patients.<sup>29</sup>

### I. Do CITIES MAKE PEOPLE HEALTHIER?

At the turn of the last century, industrial cities were the antithesis of a healthy built environment. The relatively well-off among city dwellers retreated to their summer places for fresh—and presumably cleaner and healthier—air. This literal and imaginative escape from the social and ecological ills of cities—polluted air, crime, overcrowded housing, and traffic congestion—led to two parallel movements after World War II: urban renewal (the destruction of older residences and businesses and their replacement by new construction),<sup>30</sup> and a strong preference among Americans for suburban living away from urban centers.

Early migration from the urban center was built around rail (streetcar) transportation during the early twentieth century.<sup>31</sup> Transportation technology—

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26. See generally, CONSUMER-DRIVEN HEALTH CARE: IMPLICATIONS FOR PROVIDERS, PAYERS AND POLICY MAKERS (Regina E. Herzlinger ed. 2004). Herzlinger argues that consumer control will “reward innovative insurers and providers for creating the higher-quality, lower-cost services we want and deserve. In this consumer-driven system, government will protect us with financial assistance and oversight, not micromanagement.” *Id.* at xvii.

27. The AbioCor implantable heart is only the latest in a long list of cardiac assist devices. See, e.g., AbioMed, <http://www.abiomed.com/products/index.cfm> (last visited Nov. 9, 2008).

28. We should be mindful that determining what data to use in studies of health disparities generally is itself a problem for researchers and policy makers. See Risa Lavizzo-Mourey & James R. Knickman, *Racial Disparities—The Need for Social Action*, 349 NEW ENG. J. MED. 1379, 1380 (Oct. 2. 2003).

29. See MICHAEL E. PORTER AND ELIZABETH OLMS TED TEISBERG, REDEFINING HEALTH CARE 97, 99 (2006).

30. For a short overview of the legislative and legal history of “fighting blight,” see Colin Gordon, *Blighting the Way: Urban Renewal, Economic Development, and the Elusive Definition of Blight*, 31 FORDHAM URB. L.J. 305, 311-312, 315 (2004).

31. See, e.g., The Official Website for the City of Richmond, Virginia, Department of Economic Development, <http://www.richmondgov.com/departments/econdev/mbe/history.aspx> (last visited Nov. 9, 2008) (pointing out that Richmond, Virginia had the world’s first successful electric street car system).

particularly the widespread use of the automobile—along with a number of changes in federal, state, and local zoning laws surrounding the financing of highways, the construction of new housing, and the uses of land gave rise to the current social and demographic structure of the suburbs. Zoning law—something that is almost always a matter of local control—is one of the chief vectors enabling development of the modern suburban subdivision. Single use zoning gave rise to suburbanizing developments like the archetypal Levittown, Long Island, where the mixed-use buildings so common in urban settings, such as residential space above a retail establishment, were prohibited in favor of single-use structures.<sup>32</sup> Embedded within zoning laws were social policies that contrasted with the goal of the city as a center of economic, social, racial, and ethnic diversity.<sup>33</sup> Justice Douglas, writing on behalf of the Supreme Court in 1974, concluded in *Village of Belle Terre v. Boraas* that a local zoning ordinance limiting the number of unrelated persons living in a single “family” residence was constitutional.<sup>34</sup> Justice Douglas was perhaps imagining a community that was not a city, but a “village” that could use the local political process to preserve a certain commonality among residents. At a technical level, the Court held only that local government has enough latitude under the Constitution to develop a statutory definition of “family” that applied only to zoning laws.<sup>35</sup> More broadly, the decision indicated that local political processes would be the locus of decision-making for what public health scholars now identify as the “built environment.”<sup>36</sup>

Justice Marshall’s dissent in *Belle Terre* foresaw many social disadvantages of the opinion’s vision of community. The victims of “family zoning” in the case before the court were college students seeking to rent a house. Justice Marshall perceived the potential impact of the decision on the disadvantaged or members of minority groups who might seek to live in a given “village.”<sup>37</sup> A plurality of the Court in a subsequent case, *Moore v. City of East Cleveland, Ohio*, found it unconstitutional to apply a “family zoning” ordinance in such a way as to force a grandmother to remove one of her two grandsons, who were cousins rather than brothers, from her dwelling.<sup>38</sup> Had the court ruled otherwise, the Moore family would have been torn apart because it did not fit a very constrained definition of “family.” One reason why courts might be reluctant to delve into underlying

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32. See, e.g., Joshua Ruff, Levittown: The Archetype for Suburban Development, <http://www.historynet.com/levittown-the-archetype-for-suburban-development.htm> (last visited Nov. 9, 2008); Matt Rosenberg, Levittown, <http://geography.about.com/od/urbaneconomicgeography/a/levittown.htm> (last visited Nov. 8, 2008).

33. This vision of the city may not be that shared by everyone, and may in fact be contrary to some notions of community and neighborhood as articulated in community action research literature.

34. *Belle Terre v. Boraas*, 416 U.S. 1 (1974).

35. *Id.* at 8.

36. See, e.g., KOMESAR, *supra* note 14.

37. *Belle Terre*, 416 U.S. at 16-17 (Marshall, J., dissenting).

38. *Moore v. City of East Cleveland*, 431 U.S. 494 (1977) (Powell, J., plurality opinion).

social issues in such zoning cases, however, is that the emotional—and therefore the political—impact of zoning decisions can be painfully intense because they impact in very fundamental way the manner in which people live and their sense of home, as well as, in some cases, homelessness.

I suggest that most people concerned about poverty do not want to default to some notion of the “market” or the old public health law paradigm<sup>39</sup> for determining where people live. We are becoming more aware of how the housing market is currently structured by existing regulation as well as by deregulation.<sup>40</sup> We know that how individuals live is a combination of individual preference, economic and social conditions, and complex legal structures. We also know that how and where people live has some impact on their health—mental and physical.<sup>41</sup> We have, however, neither a systemic way of thinking about the health impacts of living conditions nor the role of law or legal institutions in defining those living conditions. This problem is symbolized by the variety of meanings we attribute to the term “health policy.” The term could encompass everything from some idealized process in which policy makers use scientifically developed data to guide their decisions, to the often contentious process of obtaining local zoning variance for a home for the mentally disabled, or repealing the “tax subsidy” for health insurance premiums.<sup>42</sup> All disciplines, but in particular legal professionals, need to develop a clear definition of health policy.

I propose a broader definition of health policy: It includes any attempt by private or public actors to shape the framing and resolution of decisions of institutional actors—the market, political processes, regulatory and administrative processes, and courts—in the health system. The health system includes all processes that support health in a given society. It has two important subsystems, the health care delivery system and the public health system, which are of particular significance to the construction of the legal system. Urban health policy is thus defined by the conduct of institutional actors who influence the health systems of particular communities. I will illustrate how the growth in knowledge regarding health has changed the way that legal institutions respond to urban health issues. At the same time, I will delineate the role of regulatory agencies, legislatures and courts in developing health policy for urban areas. The role of these legal institutions varies depending upon the particular locality’s markets, political structures, and cultures, and the nature of the problem being addressed. I began with the problem of healthy housing because institutional

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39. See generally Epstein, *supra* note 22.

40. The current mortgage crisis is an example of this understanding. Cf. Emergency Economic Stabilization Act of 2008, HR 1424 (providing the federal government with authority to purchase certain “troubled assets” related to the mortgage crisis).

41. There is plenty of evidence to support these intuitive assumptions, but this evidence is at best at the level of proving an “association” between living conditions and health. The gold standard of “causation” in public health sciences has not been met.

42. See generally Mark V. Pauly, *Blending Better Ingredients for Health Reform*, *Health Affairs* 27, no. 6 (2008).

actors at every level—state, local, national, and even global<sup>43</sup>—have some influence on the framing and optimizing of solutions.

## II. POLICY CHOICE: THE ROLE OF COURTS IN CREATING HEALTHY HOUSING

The health risks created by lead paint in older housing stock are now a major issue in older cities. For instance, federal regulations prohibit the use of lead painting in residences built after 1978.<sup>44</sup> Such regulations impose costs, leading some to argue that overregulation could impact the market by encouraging landlords to simply abandon older housing with lead paint. This regulatory and economic background provides part of the context for the case of *Grimes v. Kennedy Krieger Institute*,<sup>45</sup> where the court held that a research organization could be liable for failures in the consent process in what I will call “healthy housing research.”

I frame *Kennedy Krieger* as a healthy housing research case rather than a case about “bioethics” or “public health ethics” for several reasons related to scholarship on institutional choice.<sup>46</sup> First and foremost, scholarship on comparative institutional analysis often starts with a case concerning with liability. These liability cases illustrate the need for courts to determine which institution is best-positioned to take responsibility for abating risk. The most famous of these cases, *Boomer v. Atlantic Cement Company*,<sup>47</sup> involves what we might call a public health problem in that the plaintiff landowners claimed the pollution from the plant created health risks to them. When the court ruled that the remedy for nuisance would be damages rather than an injunction, the court was suggesting that pollution (more broadly speaking, environmental health) was now a problem for political institutions rather than for courts.<sup>48</sup> Thus, invoking a liability case to illustrate the analytical advantages of comparative institutional analysis is a technique used by many scholars following this approach to law and economics. It should be noted, however, that few scholars have used this approach on

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43. The sub-prime mortgage crisis is simply an illustration of how the financing of housing has become a global enterprise. See Martin Fackler, *Global Finance Leaders Warn of Risk from U.S. Housing Woe*, N.Y. TIMES, Feb. 10, 2008, at A16; Mark Landler, *Housing Woes in U.S. Felt Around the Globe*, N.Y. TIMES, Apr. 14, 2008, at A1.

44. Ban of Lead Containing-Paint and Certain Consumer Products Bearing Lead Containing-Paint, 16 C.F.R. § 1303 (2008). See also, Residential Lead-Based Paint Hazard Reduction Act of 1992, 42 U.S.C. § 4851 (1992); 105 MASS. CODE REGS. 410.502 (2008).

45. Kennedy Krieger, 782 A.2d 807. Part of the analysis developed in this paper started with my previous work, Larry I. Palmer, *Genetic Health and Eugenics Precedents: A Voice of Caution*, 30 FLA. ST. U. L. REV. 237, 241-52 (2003), but without the emphasis on the need to build costs into the framework argued for in this paper.

46. See KOMESAR, *supra* note 14.

47. See generally *Boomer v. Atlantic Cement Co.*, 257 N.E.2d 870 (N.Y. 1970).

48. See KOMESAR, *supra* note 14, at 12-26 for an extensive discussion of this case and its implications for comparative institutional analysis.

problems of the health system.<sup>49</sup>

Second, starting the analysis with *Kennedy Krieger* facilitates an explicit discussion of goals in legal and health policy analysis. One of the mantras of comparative institutional analysis is that social goals or values provide insufficient explanations for how institutional processes, including courts, operate. Public health law, and in the case of *Kennedy Krieger*, public health research, is full of individuals with noble goals, which in the course of litigation are labeled pejoratively as having “conflicts of interests.” I will illustrate that courts are in fact engaged in more than a hindsight analysis of the ethics of particular individuals or organizations or “balancing of interests.” Rather, my analysis of *Kennedy Krieger* demonstrates that the various public and private individuals caught up in the court’s process of adjudication are best characterized as “good people, operating under bad institutional arrangements.”<sup>50</sup>

Third, using a case provides a more nuanced understanding of the role for courts in the debate over “who decides.” Comparative institutional analysis is, in part, a critique of the over-emphasis in legal scholarship and education on the role of courts in resolving important social problems. On the other hand, courts are arguably the best (or the least bad) forum for framing, if not resolving, some controversial issues. I have argued, for example, that the abortion issue, or as I prefer to frame it, the issue of family formation, is for courts, acting as constitutional adjudicators, despite the deep religious and values conflict about the appropriateness of termination of pregnancy in particular.<sup>51</sup> Just because the United States Supreme Court frames the issue of family formation does not mean that the political process or state courts do not participate in constricting family formation decisions.<sup>52</sup> Thus, *Kennedy Krieger* illustrates a situation in which state courts use common law notions of “duty” to allow disadvantaged urban dwellers to question the control of the “health knowledge market” by professionals and their organizations. By signaling that “market failures”—inadequate informed consent processes—might lead to court intervention, the court turns a new page in the debate about who should decide whose health is put at risk to discover the most cost efficient means of reducing health risks to a certain community. Rather than think of the case as a failure to obtain appropriate informed consent, institutional analysis suggests this is a case about the duty to

49. The issues of property law and the law of damages tends to dominate the scholarship on comparative institutional analysis, although Komesar acknowledges the applicability of the approach to health related issues. See his citation of my patient safety work in *Law's Limits*. KOMESAR, *supra* note 14, at 177. Even scholars concerned about the health of disadvantaged community frame the issues from the perspective of property law and the law of remedy. See, e.g., Rachel D. Godsil, *Viewing the Cathedral from Behind the Color Line: Property Rules, Liability Rules and Environmental Racism*, 53 EMORY L.J. 1807 (2004).

50. Larry I. Palmer, *Paying for Suffering: The Problem of Human Experimentation*, 56 MD. L. REV. 604, 611 (1997).

51. See LARRY I. PALMER, *ENDING AND BEGINNINGS: LAW, MEDICINE & SOCIETY IN ASSISTED LIFE AND DEATH* 45-51 (Praeger Publishers 2000).

52. *Id.*

disclose certain information.

Looking at the “facts” of *Kennedy Krieger* through the lens of institutional analysis encourages us to broaden the context before looking at the very narrow issue decided in the case.<sup>53</sup> But first consider the facts from the perspective of the narrowest legal question presented: Did the lower court err in granting summary judgment for the defendant under the facts as alleged by the plaintiffs? As the court described the issue:

Was the trial court incorrect in ruling on a motion for summary judgment that as a matter of law a research entity conducting an ongoing non-therapeutic scientific study does not have a duty to warn a minor volunteer participant and/or his legal guardian regarding dangers present when the researcher has knowledge of the potential for harm to the subject and the subject is unaware of the danger?<sup>54</sup>

There are a number of facts essential to answering this narrow question. The Kennedy Krieger Institute undertook a study to find the most cost-efficient way of reducing the health risks of lead paint in residences in the city of Baltimore. The study required the periodic testing of levels of lead present in the dwellings and as well as the levels of lead present in the blood of the children living in the dwellings. The plaintiffs were children whose lead blood level was at the “normal level” as determined by the guidelines developed by the Centers for Disease Control and Prevention (CDC).<sup>55</sup> These blood levels became above normal after testing indicated there was lead paint or “hot spots” in their dwellings.<sup>56</sup> There was a delay between Kennedy Krieger’s receipt of the blood test results and their communication of the results to the parents or guardians of the plaintiffs. The court concluded that the Kennedy Krieger Institute *might* have a duty to warn the parents of their children’s individual health risks discovered in the course of a lead paint abatement study involving their residences.<sup>57</sup>

As noted previously, there is considerable commentary on the court’s broad discussion of the regulatory oversight of the research process.<sup>58</sup> Unlike many of those commentators, I believe the court understood that it was dealing with a major problem in urban health policy and sought to frame the debate about “healthy housing,” not simply for courts, but for other institutions—legislatures,

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53. The dissenting judge proposes a narrow framing of the issue on the theory that the legislature ought to deal with the complexity of ethics and research policy implicit in the majority’s ruling on summary judgment. What the legislature in fact did after the case, as will be discussed *infra* may indicate that majority was more aware of where the political process was on this type of research than the dissent. *See Kennedy Krieger*, 782 A.2d at 862.

54. *Id.* at 818.

55. *Id.* at 825.

56. *Id.*

57. *Id.* at 818-19.

58. *See* sources cited in *supra* note 17.

regulatory bodies, and the professionals engaged in the knowledge market. The case is significant because the court explains the complexity of the problem in a way that establishes a role for courts without implying that a court can solve the healthy housing problem. Consider some of the salient things we discovered about the participants in the market and political processes surrounding lead in houses in the city of Baltimore.

In our modern era, governmental agencies provide funds for research regarding many problems facing society. By the 1990s, federal and state agencies had concluded it was not economically feasible to remove all lead paint from older housing stock.<sup>59</sup> Some of those agencies provided the funds for Kennedy Krieger's research and helped individual researchers at Kennedy Krieger to develop a complex research network. The Environmental Protection Agency (EPA) provided a grant to the Kennedy Krieger Institute to pay for some of the researchers' time as well as other expenses of the project.<sup>60</sup> The two lead researchers on the projects held appointments at Johns Hopkins Schools of Medicine and Public Health,<sup>61</sup> and the Institutional Review Board at Johns Hopkins, apparently under contract, conducted the human subject review required by federal regulations for the Kennedy Krieger Institute.<sup>62</sup> The researchers needed additional organizational partners to conduct this complex project because they needed to have dwellings with different levels of lead abatement and families with children living in those dwellings.

To achieve these goals, the researchers facilitated loans from the Maryland Department of Housing and Community Development to landlords<sup>63</sup> and enlisted a not-for-profit organization to assist with the recruitment of families with children to live in the various housing units.<sup>64</sup> There was a Lead Hazard Abatement Research Department at Kennedy Krieger in 2002<sup>65</sup> and the Institute was the major center for testing for lead poisoning in Maryland and surrounding states. The individual researchers were thus able to act as "knowledge entrepreneurs" prior to the litigation partially because of their affiliation with an organization that took a systemic approach to the problem of childhood disabilities of all kinds, including the disabilities caused by lead poisoning. In many respects, this is the kind of public health research one might want to

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59. One does not have to accept this statement as the empirical truth to accept this statement as part of the context of the research. In point of fact, the researchers involved in this study had received a previous grant on lead abatement that led to the grant at issue in the case. *See* Larry I. Palmer, *Genetic Health and Eugenics Precedents: A Voice of Caution*, 30 Fla. St. U.L. Rev. 237, 245 (2003).

60. Kennedy Krieger, 782 A.2d at 819.

61. Palmer, *supra* note 59, at 250.

62. Kennedy Krieger, 782 A.2d at 811-12.

63. *Id.* at 820.

64. *Id.* at 819. *See also*, *Lead Paint Poisoning of Children: Progress and Misplaced Self-Congratulation*, EJ ACTIVIST (The Sierra Club, Prescott, Ariz.), Oct. 2004, at 1-2, available at [http://www.sierraclub.org/ej/downloads/Oct\\_2004.pdf](http://www.sierraclub.org/ej/downloads/Oct_2004.pdf) (last visited Nov. 9, 2008) (discussing various approaches to lead abatement).

65. Palmer, *supra* note 59, at n. 67.

encourage since it is so steeped in the practical problems policy makers face. Presumably, the more economical the means of removing lead to label housing "healthy," the more healthy housing would be available for low-income renters.

Despite these noble goals, the courts used the case to make two institutional points. First, the regulatory framework for human subjects established by the federal government had failed, in the court's view, perhaps because it had been captured by the researchers themselves. The court spent considerable time analyzing and critiquing the working of the Institutional Review Board at Johns Hopkins<sup>66</sup> and was perhaps even aware of the fact that Johns Hopkins' internal regulatory process for protecting subjects of research had been recently criticized by the federal government.<sup>67</sup> The dissent and concurring judge invited the legislature to join the discussion by narrowing the scope of the court's opinion.<sup>68</sup> The state legislature did react to the decision, but not in the way the researchers or the dissent and concurring judges might have wanted. The legislature sought to create public awareness of the working of IRBs by requiring minutes of institutional review boards, with the names and other private information redacted, to be made available to the public after those meetings.<sup>69</sup> Thus, one aspect of the political regulatory process in effect affirmed the idea that something was malfunctioning in the research regulatory system and sought not a solution, but more data or knowledge about the actual process.

The other participants in the knowledge-creation market, the research community engaged in housing research, were in fact quite upset by the court's ruling and convinced the three major funders of this type of research to fund a study. The U. S. Department of Housing and Urban Development, the CDC, and the EPA requested that the National Research Council and the Institute of Medicine of the National Academic of Sciences conduct a study entitled "Ethical Considerations for Research on Housing-Related Health Hazards Involving Children."<sup>70</sup> One recommendation of the study provides additional post-litigation evidence that something is awry with the research oversight process. The report suggests that the "community" should be involved in the design of the health-related housing research.<sup>71</sup> The implication of this recommendation is that the professionals must lose their monopoly on knowledge-creation in the healthy housing debate in line with other recommendations to "democratize the research process,"<sup>72</sup> particularly as it relates to low-income residents.

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66. Kennedy Krieger, 782 A.2d at 849-52.

67. See Palmer, *supra* note 59, at n. 81.

68. Kennedy Krieger, 782 A.2d at 862 (Raker, J., concurring in part, dissenting in part).

69. H. Res. 917, 416th Sess. (Md. 2002).

70. See ETHICAL CONSIDERATIONS FOR RESEARCH ON HOUSING-RELATED HEALTH HAZARDS, *supra* note 19.

71. *Id.* at 2.

72. There is perhaps a growing awareness of the need to "democratize" research through community participation. See GREENWOOD & LEVIN, *supra* note 20, at 175-78. Even the federal government is calling for "Community-Based Participatory Research." In a recent request for proposals to establish multi-

Of course, the researchers might see the report's recommendations and call for a systems approach to research oversight in housing research as adding to the costs for doing this type of research. The court is not unmindful of those costs, but it is responding to what one might see as a major shift in "the political equilibrium" in the market for knowledge creation about healthy housing. In asserting a policy role in the urban healthy policy space, the court is engaging in raising questions rather than providing answers. Some of the questions that might need to be addressed in healthy housing research are:

- Under what circumstances would an urban community attempt less than full abatement after *Kennedy Krieger* and the IOM reports on the ethics of this type of research? The costs effectiveness of lead abatement is still an issue to be resolved.
- Will the leadership for such efforts come from "social entrepreneurs" who could garner the human and other resources to further research on the most cost effective and ethical methods of creating healthy (not necessarily lead-free) housing?
- Would such research necessarily involve some forms of "community participatory action research?"<sup>73</sup>
- Could the goal of preventing disability in children of low income coexist with the goals of actors in the private market interested in "urban revitalization?"

Wholesale destruction of all the houses with lead paint, or for that matter, lead pipes—"urban renewal"—is no longer viewed as a viable option for social policy, particularly when there are tax incentives at the local, state, and federal level for private investments in some, but not all, older urban neighborhoods. Courts can in some situations perform an important health policy function by effectively reframing issues for both market actors and political institutions.

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disciplinary centers to study health disparities, the funding agencies required that each center have at least one project that develops, evaluates, or implements one such participatory action research project. *See* Request for Application, Ctrs. for Population Health & Health Disparities, NIH, RFA: ES-02-009 (April 1, 2002), available at <http://grants1.nih.gov/grants/guide/rfa-files/RFA-ES-02-009.html> (last visited Nov. 9, 2008). At least one of the researchers involved with the lead paint reductions study in *Grimes v. Kennedy Krieger Institute*, Farfel, appears to be involved as a technical consultant to a community based group. *See* Community Environmental Health Resource Center, Consultants and Advisors, <http://www.cehrc.org/about/consadv/index.cfm> (last visited Nov. 9, 2008). Whether his involvement constitutes the kind of "participatory action research" as defined by Greenwood, however, cannot be determined.

73. "Community-based participatory research" (CBPR) is defined as "collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community, has the aim of combining knowledge with action and achieving social change to improve health outcomes and eliminate health disparities." *See* Community-Campus Partnerships for Health, <http://depts.washington.edu/ccph/commbas.html> (last visited Nov. 9, 2008).

### III. POLICY DEVELOPMENT VS. POLICY MAKING: DISEASE SURVEILLANCE AND VACCINATION IN THE “NEW PUBLIC HEALTH”

*Kennedy Krieger* illustrates how courts can frame a question for society without asserting that the court is the ultimate policy maker or even the institutional framer of the issues for most urban health problems. Markets as well as political and administrative institutions each have the capacity to become the primary framing institution for health problems, depending on the context. Two recent controversies—disease surveillance for diabetes in New York City and legislation to make the Human Papillomavirus (HPV) vaccine mandatory for girls—illustrate the need to distinguish between the role of policy development and policy making in the health system. With this examination, we will be able to discern that the court in *Kennedy Krieger* was actually engaged in the process of policy development within the overall health system.

#### A. *The Health System and Chronic Disease Surveillance: the Case of Diabetes*

New York City’s disease surveillance system for diabetes at one level revives the debate between proponents of the “old public health” and those who support “new public health.”<sup>74</sup> Those who frame the growth rate of diabetes in these terms often perceive major legal issues in terms of risks to privacy or liberty interests and overall population health.<sup>75</sup> Within this framework, the question for political institutions, in this case the New York City legislative body and its public health authority, is whether a traditional public health law tool—creating regulation that obliges health care providers to report patient information—should be used for chronic diseases such as diabetes. The assumption is that if surveillance was one of the legal tools used to reduce the incidence of infectious diseases, legally mandated surveillance would probably be equally effective at mobilizing the society to deal with the “epidemic” of diabetes.

This framing of chronic disease surveillance ignores the growing body of knowledge that encourages systems-thinking in analysis of health problems.<sup>76</sup> Systems-thinking requires a concept of a health system that understands the

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74. See *supra* note 21 and accompanying text.

75. Even critics of New York City’s program frame the issues in terms of balancing. See Wendy K. Mariner, *Medicine and Public Health: Crossing Legal Boundaries*, 10 J. HEALTH CARE L. & POL’Y 121 (2007). The proponents of New York City’s chronic diseases surveillance program simply strike a different balance. See, e.g., Lawrence O. Gostin, “Police” Powers and Public Health Paternalism: HIV and Diabetes Surveillance, HASTINGS CENTER REP., Mar.-Apr. 2007, at 9.

76. The Institute of Medicine has been a pioneer in promoting a systems approach to the quality problem in the health system starting with its reports on patient safety. See INSTITUTE OF MEDICINE, *To Err is Human: Building a Safer Health System*, (Linda T. Kohen et al. eds., 2000) and COMMITTEE ON QUALITY OF HEALTH CARE IN AMERICA, INSTITUTE OF MEDICINE, *Crossing the Quality Chasm: A Health System for the 21<sup>st</sup> Century* NATIONAL ACADEMY PRESS (2001). Even its recent reports on problems involving research emphasize a systems approach. See, e.g., INSTITUTE OF MEDICINE, *Ethical Considerations for Research Involving Prisoners* (2006).

differences and interrelationship between the subsystems of public health and health care delivery system. I propose the following schema as a starting point for describing and providing an alternative approach to the problem of diabetes management:

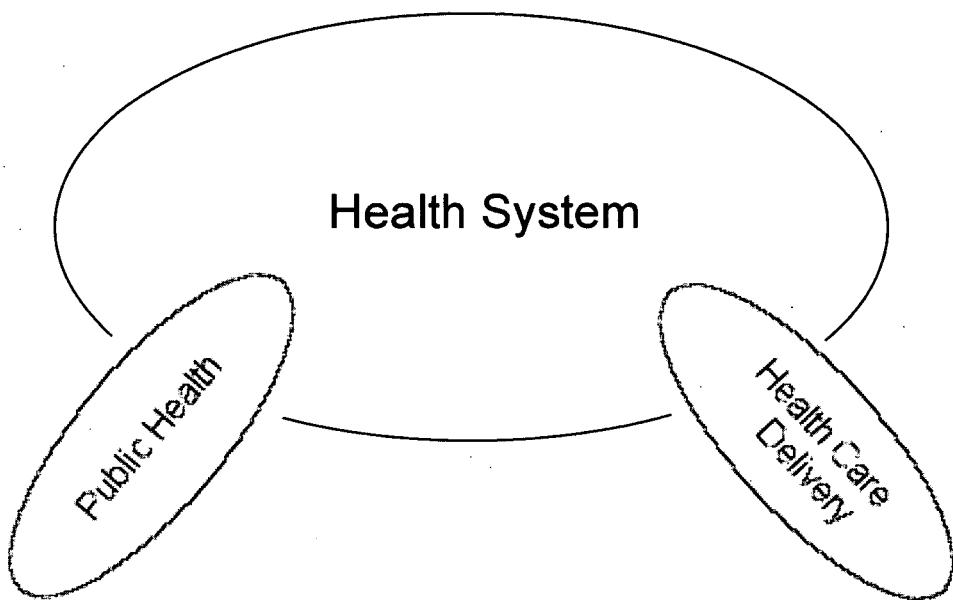


FIGURE.

Think of the health system as all of the things that might support the health of individuals in a given society. At the basic level, we would know that the availability of water, food, shelter, and caregivers for infants and children form the components that support the health of a society. There are many factors influencing how those various systems are organized. For instance in a technologically advanced society such as ours, some might argue that our food system is a factor in the rise in obesity.<sup>77</sup>

We also know that public infrastructure such as sewer systems, immunizations against infectious disease, and even parks and sidewalks influence the overall level of health in a society or a community.<sup>78</sup> This is a starting definition of what is pictured as the public health system in the graphic above. It does not

77. See, e.g., Adam Benforado, Jon Hanson, & David Yosifon, *Broken Scales: Obesity and Justice in America*, 53 EMORY L.J. 1645, 1793-94 (2004). The authors argue that cheap and subsidized corn production encourages the over-production of corn, leading to the widespread use of cheaper corn syrup as a substitute for sugar in all kinds of goods. Rather than reduce the price of soda, for instance, cheaper corn syrup allows manufacturers of soda to increase the size of soda from seven ounces to twenty ounces.

78. Richard J. Jackson & Chris Kochtitzky, CENTERS FOR DISEASE CONTROL AND PREVENTION, *CREATING A HEALTHY ENVIRONMENT: THE IMPACT OF THE BUILT ENVIRONMENT ON PUBLIC HEALTH* (2001).

necessarily matter that for a particular purpose the discussion of public health “expands” from its traditional base and tries to engage the issue of whether it is safe to use the park for walking under the systems view I propose. It would help to point out, however, that there are legal limitations on the extent to which public health officials can “mandate” that parks be safe. More important, this analysis emphasizes the role of public health agencies in providing health data on issues that are sometimes contentious, such as local smoking ordinances as part of the prevention function traditionally assigned to public health as a distinction from health care delivery, particularly physicians, who “treat” diseases.

Our modern health care delivery system, however, has started to assume, at the individual level, some of these traditional functions, like prevention or smoking cessation. This blurring of the distinction between what is a public health function and what is a health care delivery function occurs not because the health care delivery system is necessarily more effective at prevention. Rather, the blurring of the distinction is a result of the private and public investment in the health care delivery system over time. Given the way health care delivery is organized and financed, the resources that are counted as “health care costs” are currently concentrated in the health care delivery system. For lawyers, it is important to remember that the current structure of our health care delivery system is not simply a reflection of “market forces” but also a function of the incentives provided by the legal structure.<sup>79</sup>

This systems view would allow us to reframe the efforts of New York City’s public health department to create more “effective” diabetes management by delivering individual patient information to patients and their physicians as part of the health care delivery system. The city seeks to achieve its public health goal by requiring laboratories to report glucose levels to the public health department.<sup>80</sup> The hope is that when patients and physicians then receive information indicating that diabetes management techniques have been ineffective, they will be prompted to take positive steps toward “good” control. The city piloted this program in the South Bronx, one of the most disadvantaged parts of New York City, presumably on the theory that if it could work there, it could work anywhere.<sup>81</sup>

Given what we know about the factors influencing diabetes rates, I propose that the Department confused its role as policy maker with its role as policy developer. For a variety of reasons, diabetes management, even for the poorest of

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79. See PORTER & TEISBERG, *supra* note 29, at ch. 8. Chapter 8 has a bold list of reforms necessary to change the health system including eliminating the notion that the physician are legally always independent contractors—the “corporate practice of medicine doctrine.”

80. I am deliberately ignoring the details of whether the patient needs to consent to this transfer of the information so passionately debated in the public health and bioethics literature. For a detailed account of this debate, see sources cited *supra* note 17. I will also not address the question of whether the public health exceptions in the HIPPA regulations are broad enough to exempt the public health department’s request for the electronic transfer of data.

81. *Roll-out in South Bronx Planned*, NYC Diabetes Newsletter, Issue 1, Spring 2007, at 1.

our urban residents is a function that is now centered in the health care delivery system. The actual capacity of publicly managed clinics and hospitals has been dramatically reduced as public funds—Medicare and Medicaid—have been shifted to hospitals, nursing homes, and other health care service providers. The prominence of buzz words such as “public/private partnerships” and “new form of health governance” to refer to health care delivery systems reflects this dramatic change in the market for health services in recent years. To put it bluntly, public health programs that encourage people with diabetes to exercise without access to the most appropriate medications and professional knowledge about diabetes management and risks seems a cruel joke.

The New York City program and its supporters might counter this critique by pointing out that their program is aimed at the most disadvantaged communities<sup>82</sup> and will reach those individuals with access to the health care delivery system. Furthermore, it helps those with diabetes who have not yet been diagnosed. The surveillance approach of this program, however, seems to be based on the theory that lack of knowledge is the main factor limiting good decisions, and that the public health system can provide the needed knowledge to patients and their physicians. This theory reflects the idea that data or knowledge automatically drives policy.

Before other urban communities consider adopting the New York model, let me propose an alternative use of our limited resources. The public health department should have considered developing partnerships with a variety of health care delivery practices in distressed areas in order to uncover the actual barriers to “good” diabetes management in those populations. In addition, the department should have examined whether or not it had the legal authority to develop a competitive grant process that would encourage health care delivery organizations to develop new ways to meet patient needs. For instance, healthcare practitioners may have been able to develop new ways of addressing “diabetes self management”<sup>83</sup> using new technologies in a low-income community. There are a host of issues involved in diabetes self-management that range from whether Medicaid will pay for daily testing to who will absorb the cost of “diabetes educators.”

Furthermore, there is another looming problem which has not been systematically studied in the inner city context, namely constraints on access to health care delivery—as distinct from access to health insurance. Public health agencies, as the sponsors of “organizational experiments,” are well-positioned to stimulate new professional analysis of how to effectively deliver health care. Indeed, these agencies understand the fundamental problem of health care: that the outcome of a service depends not simply on physician performance but also on how the

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82. Gostin makes the point that it is cruel, especially on the HIV/AIDS front, to make sure that the disadvantaged do not get the best treatments. *See Gostin, supra* note 75, at 10.

83. *See generally* Larry I. Palmer, *LAW, MEDICINE, AND SOCIAL JUSTICE* (Westminster/John Knox Press) (1989).

patient responds to his encounter with the health care delivery system. I propose that the public health care system needs a new type of data that can only be produced by comparing and contrasting the results of providing services to the disadvantaged with the highest quality outcomes being produced in the arena of diabetes management.

The disproportionate burden of diabetes on disadvantaged groups should not blind us to the need for system level change or the need for lawyers to help discover the legal barriers to more effective systems-functioning in the health care delivery system. This means there will be a period of policy development to discover the most effective methods of change, in contrast to old-fashioned health policy which takes the form of rules and mandates. This will require careful attention to how new knowledge is developed from data, and how to protect the interests of the individuals involved. Accordingly, throughout this process lawyers should ask themselves the following questions:

- Would comparative knowledge about actual “organizational performance” encourage health care providers to innovate as a means of achieving “quality” improvements in chronic disease management?
- Is there a danger that the public costs, as presently measured, will lead to mandatory disease management for the poor and those underserved by the health care delivery system?
- What type of data about health care delivery organizations will make them accountable to their patients and to the public?

#### *B. Vaccine Policy in the Genomic Era: The HPV Vaccine*

Only one state has made the new HPV vaccine “mandatory,” despite intense lobbying by various groups across the country, with financial support from the vaccine manufacturer, Merck.<sup>84</sup> Political opposition to state legislation proposed to require the vaccine became entwined with the debate over termination of pregnancy and other female reproductive health practices. The interest group analysis proposed by comparative institutional analysis scholars,<sup>85</sup> however, instructs us *not* to dismiss these intense feelings or personal sensibilities as non-scientific fears, as some commentators have done.<sup>86</sup> Rather, we should examine the HPV vaccine debate in light of new market conditions that have

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84. Virginia passed a law in early 2007 requiring mandatory vaccinations for girls entering the sixth grade but also granted parents generous “opt-out” provisions. *See* VA. CODE ANN. § 32.1-46 (2008). *See also* Lawrence O. Gostin & Catherine D. DeAngelis, *Mandatory HPV Vaccination: Public Health v. Public Wealth*, 297 JAMA 1921, 1921 (2007); Tim Craig, *Kaine Says He'll Sign Bill Making Shots Mandatory*, WASH. POST, Mar. 3, 2007, at B10; Stephanie Saul & Andrew Pollack, *Furor on Rush to Require Cervical Cancer Vaccine*, N.Y. TIMES, Feb. 17, 2007, at A1.

85. *See* KOMESAR, *supra* note 14.

86. *See generally* R. Alta Charo, *Politics, Parents, and Prophylaxis—Mandating HPV Vaccination in the United States*, 356 NEW ENG. J. MED. 1905, 1905 (2007).

changed vaccine development. The advent of genomics and the ability to interrupt disease processes in new ways is one of those market forces. As I have suggested elsewhere, the knowledge-creating enterprise, science, is itself an important institutional force shaping the health care delivery system.<sup>87</sup> In addition, the widespread use of patenting, even among university researchers,<sup>88</sup> will make vaccines relatively expensive initially as compared to earlier vaccines such as polio. We should remember that Jonas Salk, inventor of one of the earliest polio vaccines, refused to patent his discovery.<sup>89</sup> The strong emotions about HPV on all sides of the political spectrum and the economics of new vaccine development make it a good example of the “supply and demand of rights” in health policy making.<sup>90</sup>

Reframing the HPV vaccine debate in terms of institutional choice illustrates the importance of having an interactive analysis of political processes and courts—what I call “institutional balance.” The primary focus of this interaction thus far in the literature on mandatory vaccination is on the issue of whether “religious exemptions” are constitutional.<sup>91</sup> As we move into the genomic era<sup>92</sup> of vaccine development, it becomes apparent that market forces, including the use of intellectual property law, have made more visible the issues of costs. Courts may be called upon to decide a new constitutional issue: Are political bodies that decide to enact mandatory vaccine laws required to provide indigents free vaccines? The drafters of the only “mandatory” HPV vaccine law thus far anticipated this possible “equality” claim by conditioning the effective date of the mandate on the legislature appropriating adequate funds for indigent girls.<sup>93</sup> The drafters of the law were undoubtedly aware that previously the political process had neglected to provide such funding. The federal government established a reimbursement program to the states in exchange for their enactment and enforcement of federal vaccine regulations.<sup>94</sup> However, the existence of a federal funding program does not mean that funds allocated for the vaccine program necessarily meet existing needs<sup>95</sup> prior to the introduction of HPV. These issues

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87. See PALMER, *supra* note 51, at ch.1. It is worth noting that the co-winner of the Nobel Prize in Medicine or Physiology in 2008 was the person who discovered the HPV virus that causes cervical cancer. See Press Release, The Nobel Assembly at Karolinska Institutet (Oct. 6, 2008), available at [http://nobelprize.org/nobel\\_prizes/medicine/laureates/2008/press.html](http://nobelprize.org/nobel_prizes/medicine/laureates/2008/press.html) (last visited Nov. 9, 2008).

88. See Amy R. Schofield, *The Demise of Bayh-Dole Protections Against the Pharmaceutical Industry's Abuses of Government-Funded Interventions*, 32 J.L. MED. & ETHICS 777 (2004).

89. See Jonas Salk Biography, Academy of Achievement, available at <http://www.achievement.org/autodoc/page/sal0bio-1> (last visited Nov. 9, 2008).

90. See KOMESAR, *supra* note 14.

91. See, e.g., Gostin & DeAngelis, *supra* note 84, at 1922.

92. See Palmer, *supra* note 24.

93. See VA. CODE ANN. § 32.1-46(A)(12) (2008).

94. See Public Health Service Act, 42 U.S.C. § 247(b) (West Supp. 2008); 42 C.F.R. § 51b.204 (2007).

95. See Grace M. Lee et al., *Gaps in Vaccine Financing for Underinsured Children in the United States*, 298 JAMA 638 (2007).

of underlying costs led some proponents of a mandatory HPV vaccine to drop their support when faced with the possible impact on an additional HPV mandate on their state Medicaid budget.<sup>96</sup> This tradeoff between existing programs and a proposed new program is not that unusual.

What is unusual concerning the Virginia mandatory HPV vaccine is the manner in which “rights” were also part of the legislative tradeoffs. On its face, the new statute adds HPV as one of the vaccines required for school attendance, with respect to female students. However, additional statutory provisions create a special exemption applicable only to HPV, allowing parents to opt out of the mandate without claiming a religious or philosophical objection to vaccines as a general matter.<sup>97</sup> This statutory exemption—a legislative “right”—illustrates how the supply and demand for “rights” will likely play out along side the hidden resources questions in the market for vaccines and government funding. Those parents who both agree with the health benefits of HPV and have health resources in the form of private insurance will have their daughters vaccinated.

Merck’s extensive lobbying efforts for “mandatory” HPV vaccine laws in fact were aimed at getting information about the vaccine to this particular group—the willing insured. Merck is not naive enough to believe it could overcome the intensive opposition to laws that appear to condone or admit that teenagers might be sexually active. Rather, the sponsorship of bills throughout the country could be viewed as the first phase of its consumer advertising program for its vaccine in advance of the arrival of a rival vaccine by a competitor.<sup>98</sup> On the other hand, those parents with strong concerns about the health or moral risks of the HPV vaccine are likely to opt out of the vaccine requirement, and, if indigent, are unlikely to draw on public funds. If the parents who opt out are generally less wealthy than those who obtain the vaccination, the net effect of this optimization is that the “most vulnerable” will not receive the vaccine.<sup>99</sup> This disparity cannot, unfortunately, be overcome through the enactment of mandatory vaccination laws.

In any event, technological advances have in essence led to a transformation of the meaning of the term “vaccine.” Scientists are not simply trying to prevent the transmission of diseases through person-to-person contact. HPV clearly is infectious, but the “endpoint” of the HPV vaccine is the prevention of cervical

96. See, e.g., Laura Ungar, *Requiring Vaccine for Ky Girls Unlikely*, COURIER-JOURNAL, Mar. 7, 2007, at 1A (reporting that the bill requiring mandatory HPV vaccination is stalled in the Senate Appropriations and Revenue Committee because of opposition to reopening the state budget).

97. See VA. CODE ANN. § 32.1-46(D)(1) (2008).

98. See *Merck Launches National Advertising Campaign for Gardasil®, Merck’s New Cervical Cancer Vaccine*, BUS. WIRE, Nov. 13, 2006, available at [http://findarticles.com/p/articles/mi\\_m0EIN/is\\_2006\\_Nov\\_13/ai\\_n16836248/pg\\_1?tag=artBody;coll](http://findarticles.com/p/articles/mi_m0EIN/is_2006_Nov_13/ai_n16836248/pg_1?tag=artBody;coll) (discussing Merck’s extensive advertisement campaign launched prior to the arrival of its competitor vaccine, GlaxoSmithKlein’s Cervarix®).

99. Cf. Larry I. Palmer et al., *Chemopreventive Drug Treatment in Subjects with Genetic Predisposition to Cancer: Prescriber Liability and Health Care Disparities*, 5 PHARMACOGENOMICS 319 (2004) (explaining how courts may use liability doctrines to raise questions about the intersection of health disparities and medical technologies that may prevent certain kinds of cancers).

cancer. The HPV vaccine symbolizes progress in the molecular understanding of cervical cancer, and this progress is transforming the idea of “prevention.” The vaccine is thus one of several tools for prevention used by women. Other tools include medical screenings such as the Pap smear and steps to decrease the risks of transmission through sexual practices. These alternative forms of prevention mean cervical cancer has a much greater impact in the less developed and resource-constrained nations of the world than it does in the United States and the industrialized West. This type of global disparity leads to a new question: Will private actors such as the Bill & Melinda Gates Foundation become the “knowledge entrepreneurs” who bring together pharmaceutical companies, governments, and international financial institutions to establish subsidies for the HPV vaccine, and who decide which countries to target?<sup>100</sup> Domestically, we need to rethink the role of law—courts, legislatures, and administrative agencies—in assuring access to public health measures such as vaccines,<sup>101</sup> while struggling with the demand and supply of resources and rights. As we start to consider these issues of access, we may find that courts will shift away from “liberty” concerns to “equality” concerns in judging the constitutionality of public health legislation.<sup>102</sup>

#### IV. URBAN HEALTH POLICY RESEARCH: PROFESSIONAL KNOWLEDGE, CARDIOVASCULAR DISEASE RISK, AND RESEARCH

Nowhere is the framing of the issue in urban health policy by legal institutions and lawyers more important than in cardiovascular disease. On the one hand, we are bombarded with data indicating cardiovascular disease is the leading cause of death in the United States, and presumably associated with individual behaviors such as smoking, improper diet, and obesity.<sup>103</sup> In a simple model of health policy where data drives policy, one would focus on determining which legal tools would assist the public health prevention function. On the other hand, the actual death rate from cardiovascular diseases in the United States has fallen dramatically over the past quarter of a century, primarily due to a decrease in risk-creating behaviors such as smoking, and due to innovations in treatment of

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100. See, e.g., Sue J. Goldie et al., *Cost Effectiveness of HPV 16, 18 Vaccination in Brazil*, 25 VACCINE 6257 (2007) (study was funded by the Bill & Melinda Gates Foundation).

101. The Virginia statute on immunization appears to grant the state board of health to enact regulations to accord with the CDC recommendations in § 32.1-46: “The required immunizations . . . shall be those set forth in the State Board of Health Regulations for the Immunization of School Children.” VA. CODE ANN. § 32.1-46(A) (2008). Even though in theory the State Board could have enacted regulations requiring HPV, it was perhaps wise to let proponents go to the legislature for mandatory HPV.

102. Cf. Daniel Markovits, *Quarantines and Distributive Justice*, 33 J. L. MED. & ETHICS (2005)

103. ARIALDI M. MINIÑO ET AL., CTR. DISEASE CONTROL, DEATHS: FINAL DATA FOR 2004 (2007) (citing cardiovascular disease as the leading cause of death in the United States).

various forms of cardiovascular diseases.<sup>104</sup> As long we are reducing the risk factors for cardiovascular disease and developing new and more effective therapies, the age-adjusted death rate will continue to fall. Public health scientists have concluded that the declining death rate is due in equal parts—50% each—to the reduction of risk factors and to new and more effective treatments.<sup>105</sup> One therefore could draw the optimistic conclusion that current health policies are moving us in the right direction. We could further assume that the health policy process and law's role in that process are currently optimal for addressing the complex problem of cardiovascular disease.

I propose two reasons for rejecting this optimistic view of the cardiovascular disease health policy process. First, data about health outcomes in our current era of evidence-based therapies cannot be evaluated without considering the looming problem of costs in the health system. New therapies, and even the reduction of risk factors in some cases,<sup>106</sup> initially are perceived as costly. For instance, reducing the effects on air pollution lowers the risks of cardiovascular disease in some populations,<sup>107</sup> but those reductions are often viewed as costly. Furthermore, the relatively new field of “medical economics” has begun to analyze the relative cost effectiveness of various approaches to cardiovascular disease treatment and management.<sup>108</sup> As the economic analysis of the cost of any particular intervention becomes a part of the mainstream political discourse, a legal framework without a space for cost analysis becomes more problematic.

Second, “health disparities” or “health inequities” are hidden in the overall health outcome and cost figures used to describe “progress” in cardiovascular diseases. There is a lot of data that informs us that the most vulnerable members of our society, particularly in urban areas, are exposed to a greater share of the burden of disease. It comes as no surprise, for instance, that some data suggests an association between crime rates, unemployment, and cardiovascular disease.<sup>109</sup> More significant, it should come as no surprise that despite political and scholarly rhetoric about eliminating health disparities, very little progress has been made—by almost any measure—over the past decade.<sup>110</sup> Setting as a

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104. See Earl S. Ford et al., *Explaining the Decrease in U.S. Deaths from Coronary Disease, 1980-2000*, 356 NEW ENG. J. MED. 2388 (2007).

105. *Id.*

106. See Barak D. Richman, *Behavioral Economics and Health Policy: Understanding Medicaid's Failure*, 90 CORNELL L. REV. 705, 765-67 (2005) (describing the difficulties incorporating the true social and psychological costs of preventative services into the Medicaid program in the states).

107. See Douglas W. Dockery & Peter H. Stone, *Cardiovascular Risks from Fine Particulate Air Pollution*, 356 NEW ENG. J. MED. 511 (2007).

108. See Daniel B. Mark & Mark A. Hlatky, *Medical Economics and the Assessment of Value in Cardiovascular Medicine: Part II*, 106 CIRCULATION 626 (2002).

109. See Kristina A. Sundquist et al., *Neighborhood Violent Crime and Unemployment Increase the Risk of Coronary Heart Disease: A Multilevel Study in an Urban Setting*, 62 SOC. SCI. & MED. 2061 (2006).

110. See Rebecca Voelker, *Decades of Work to Reduce Disparities in Health Care Produce Limited Success*, 299 JAMA 1411 (2008). See also M. Gregg Bloche, *Health Care Disparities—Science, Politics,*

national goal “eliminating health disparities” by 2010<sup>111</sup> does not seem to lead to measurable progress.

One response to the suggestion that “progress” in dealing with cardiovascular disease has not dealt with the elephant in the room—health disparities—is simply to call for more research to eliminate disparities. Presumably, if the professionals in the health care delivery system knew more about the causes of the disparities and the health professional workforce became more diverse, the diffusion of professional knowledge throughout the health system would stimulate the discovery and elimination of policy barriers to a more just distribution of the burdens of disease. But even proponents of this view are starting to wonder about the effectiveness of accumulating knowledge without a conceptual framework to link an increase in knowledge with some type of policy process that is accountable not only to the agencies funding health research, but also to those individuals and communities that are most at risk. Increasingly, there are calls—but not necessarily additional funding—for “community-participatory action research” as a way to increase the effectiveness of the health equity movement.<sup>112</sup> These quandaries about health disparities signal a failure to frame a complex problem in a fashion that highlights the trade-offs involved and the ethical dilemmas we need to address as citizen/lawyers.<sup>113</sup> The underlying ethical dilemma I have identified in cardiovascular treatment and research is that we may develop new treatments that improve overall health outcomes without addressing the disparities in outcomes between the majority of Americans and those urban populations that are most vulnerable.

Let me illustrate this point by sketching how different the policy questions appear from my perspective by focusing on cardiovascular assist devices over time. Dr. Denton Cooley’s implantation of the first implantable artificial heart in the late 1960s led to litigation over whether the patient/human subject had given adequate “informed consent.”<sup>114</sup> Regulatory oversight of the use of these new devices grew out of the ethical concerns about the appropriateness of one surgeon—admittedly a very skilled one—nonetheless being the sole decision maker in using an experimental device. In addition, some proponents of regulations hoped that supervised clinical trials could make these devices more effective over time, even if their initial costs would be so high that few could

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and Race, 350 NEW. ENG. J. MED. 1568 (2004) (indicating that political considerations can influence the federal reporting of the health disparities data).

111. Healthy People 2010, <http://www.healthypeople.gov/About/goals.htm> (last visited Nov. 9, 2008).

112. See generally COMMUNITY-BASED PARTICIPATORY RESEARCH FOR HEALTH (MEREDITH MINKLER ET AL. EDS., Jossey-Bass 2003).

113. A symposium of the *William & Mary Law Review* held on February 8-9, 2008 critically examined the idea of the “citizen lawyer.” See <http://law.wm.edu/academics/intellectuallife/researchcenters/ibrl/pastevents/symposia/index.php> (last visited December 15, 2008). The implications of how the citizen/lawyer idea would change legal education were explored by one of the participants. See Edward Rubin, *The Citizen Lawyer and the Administrative State*, 50 WM. & MARY L. REV. (forthcoming 2009).

114. See *Karp v. Cooley*, 493 F.2d 408 (5<sup>th</sup> Cir.1974).

afford them.<sup>115</sup> This problem of equitable distribution of the benefits of cardiovascular innovation was highly visible, at least to scholars in 1970s, because of scarcity problems regarding human hearts for transplantation.<sup>116</sup>

Fast forward a few decades and the ethical issues have been transformed by technological progress in the effectiveness of heart assist technology as well as a change in the institutional processes. The new regulatory environment for medical devices seems to have eliminated the specter of a surgeon implanting a heart device without any constraints. For a variety of reasons, not to be developed here, the Food and Drug Administration required clinical trials. The AbioCor implantable heart illustrates this practice, even though only eight patients were approved for the first round of trials. The complex system of ethical review established by the manufacturer for these transplantation trials<sup>117</sup> further indicates an acceptance of "ethics" as a part of the health policy process.

A more significant change is the fact that the providers' "market"—manufacturers, physicians, and payers—has accepted the idea that a heart devices' effectiveness should be determined through large scale "clinical trials" as defined by epidemiologists rather than clinicians, the reporting of which has to some degree been professionalized by the establishment of standards for reporting randomized clinical trials.<sup>118</sup> The implantable cardioverter defibrillator (ICD) is an example of an assist device whose effectiveness in reducing the risk of heart attack by monitoring and stimulating heart rhythms has been extensively studied. The electronics and mechanics of ICDs have constantly improved and the risks of implantation diminished over the past twenty-five years. Various manufacturers now produce ICDs, with costs of a single implantation around \$25,000.<sup>119</sup> Vice President Cheney's highly publicized periodic check-ups of his ICD have helped to make the avoidance of a heart attack part of the health policy discourse in this country.<sup>120</sup>

Recent randomized clinical trials have indicated the potential benefits of ICDs for certain patients at risk of heart attacks. The Food and Drug Administration has already approved the use of ICDs for those who previously suffered and survived a heart attack.<sup>121</sup> But with a 38% mortality rate for U.S. heart attack victims (new

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115. See Sandeep Jauhar, *The Artificial Heart*, 350 NEW ENG. J. MED 542 (2004).

116. See generally GUIDO CALABRESI & PHILIP BOBBITT, *TRAGIC CHOICES* (1978).

117. See E. Haavi Morreim, *The Case of the AbioCor Heart*, HASTINGS CENTER REP., JAN.-FEB. 2004, at 11.

118. See <http://www.consort-statement.org/> (last visited Dec. 15, 2008)

119. Mark A. Hlatky et al., *Evidence-Based Medicine and Policy: The Case of Implantable Cardioverter Defibrillator*, 24 HEALTH AFF. 42 (2005).

120. See, e.g., *Cheney's Heart is Deemed Stable: Checkup Find No Problems*, WASH. POST, July 2, 2006, at A07; *Cheney's Heart Device is Working Fine*, WASH. POST., July 9, 2003, at A02; Dana Milbank, *Cheney to Get Routine Heart Check*, WASH. POST, Sept. 13, 2002, at A04.

121. See <http://www.fda.gov/bbs/topics/ANSWERS/2002/ANS01159.html> (last visited Dec. 15, 2008).

and recurrent),<sup>122</sup> we can imagine the pressure on conscientious clinical researchers to expand the benefits of ICDs to those patients without prior heart attacks. Medicare announced a new payment program for ICDs in the same issue of the *New England Journal of Medicine* that announced the results of the latest clinical studies.<sup>123</sup> Medicare conditioned its expansion of payments for some patients who had not suffered a heart attack on the patient and physician's willingness to become part of registry designed to assist further studies of effectiveness.<sup>124</sup>

There are three ethical and policy questions raised by this linkage of treatment, costs, and increase in professional knowledge through clinical trials. First, a Medicare regulatory rule that links payment to participation in the registry appears unethical. Traditional thinking about access to health care frowns upon this type of "bedside rationing."<sup>125</sup> Second, the potential cost of providing this one device to all at-risk Medicare beneficiaries would require a large share of the entire Medicare budget. In our current political paradigm of "health care cost containment" and "no new taxes," a massive infusion of funds into the Medicare budget is highly unlikely unless some other federal benefit is drastically reduced.<sup>126</sup> Third, once ICDs are installed, we may be creating downstream ethical dilemmas when these devices have to be turned off at the request of terminally ill patients or their surrogates.<sup>127</sup> Our current way of linking the federal public health payment system to the regulation of new devices leads to the possibility that Medicare may pay for the implantation of the newest version of the AbioCor implantable heart in patients who now are defined as "terminal."<sup>128</sup>

A reframing of these questions from the institutional choice perspective argued for here allows us to broaden the context of the debate. Widespread use of ICDs indicates that prevention has become part of the health care delivery system's approach to cardiovascular disease. Further, ICDs are only one of many data points in judging overall reduction of risks of cardiovascular disease. Second, and perhaps most significant, I propose that the over-emphasis on measuring costs ignores the larger systemic issue of developing a method of measuring the

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122. See Wayne Rosamond et al., *Heart Disease and Stroke Statistics—2007 Update: A Report From the American Heart Association Statistics Committee and Stroke Statistics Subcommittee*, 115 CIRCULATION e69, e89 (2007).

123. See Mark B. McClellan & Sean R. Tunis, *Medicare Coverage of ICDs*, 352 NEW ENG. J. MED. 222, 222-24 (Jan. 20, 2005).

124. See *id.*; A. Kadish, *Prophylactic Defibrillator Implantation—Toward an Evidence-Based Approach*, 352 NEW ENG. J. MED. 285, 285-87 (Jan. 20, 2005).

125. See *RESOLVING ETHICAL DILEMMAS: A GUIDE FOR CLINICIANS* 189-195 (3d ed. 2005).

126. Cf. James F. Blumstein & Frank A. Sloan, *Health Care Reform Through Medicaid Managed Care: Tennessee (TennCare) as a Case Study and a Paradigm*, 54 VAND. L. REV. 125 (2000).

127. See Rob Stein, *Devices Can Interfere With Peaceful Death: Implants Repeatedly Shock Hearts Of Patients Who Cannot Be Saved*, WASH. POST, Dec. 16, 2007, at A01.

128. See *AbioCor Heart Moves Closer to Medicare Reimbursement*, J. NEW ENG. TECH., Feb. 4, 2008, available at <http://www.masshightech.com/stories/2008/02/04/daily4-AbioCor-heart-moves-closer-to-Medicare-reimbursement.html> (last visited Nov. 9, 2008).

value to patients. The present methods of measuring effectiveness tell us how much it costs to manufacture, install, and monitor an ICD in a variety of patients with certain types of risks. We do not yet have robust methods of measuring the “value-added” to patients of these innovations in heart technologies and disease management. Were our studies more patient-centered rather than service production centered, our public discourse would be more attuned to the distribution of health benefits.<sup>129</sup> Were we more refined in our analysis of the combined effects of risks factors and inadequate access to health care services in many of our urban communities, we would probably pay more attention to relative lack of progress in health outcomes among inner city dwellers.<sup>130</sup>

Changing our thinking from cost to value to patient requires a three-step process. The first step is to recognize that *health is not a commodity*, and *neither is health care*. The second step is to recognize that costs are important in the type of measurement I have proposed. Value is essentially the cost over a certain period of time. Third, patients and their health providers need information about the effectiveness of both interventions *and* preventive measures, as well as information about available providers, in order to determine which course is best for particular patients. The current system of accounting in health care develops costs and effectiveness measures, but seldom adds the relevant timeframe to the equation.

Essentially, this three-step process reveals that our analysis of the health system needs to be both more disease-specific and more population-specific. Cardiovascular disease treatment and research would have a different set of matrixes than certain kinds of cancers, for instance. Both disease areas deal with risks and prevention, but the generalizing principle for the developments in each area should be “value to patients,” not necessarily “the costs” of producing the treatment. Patients with chronic risks of heart attack may or may not understand the need for ongoing quality improvements in treatments. Given this differential in patient knowledge, the ethics of designing registries might involve a community outreach function or the selection of centers with appropriate diversity among its patient population. Further, the emphasis on value does not mean there will not be competition built into the system.

But rather than compete over costs, the health system should compete over value added to patients, adjusted for their risks. This could mean, for instance, that those providers dealing with those at greater risks of cardiovascular disease could fair better on the measurements than those dealing with lower risk patients. A switch to a value basis of measurement of health outcomes would require a radical reorganization of the payment system for health care where there are

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129. My discussion of “the value to patients” as the center of analysis of the health care system is based on my reading of PORTER & TEISBERG, *supra* note 29.

130. Cf. David Satcher et al., *What If We Were Equal? A Comparison of the Black-White Mortality Gap in 1960 and 2000*, 24 HEALTH AFF. 459 (2005) (describing how the disparities between blacks and others have not changed significantly).

incentives not for “prevention” *per se*, but for “value” added to patients. Whatever the system of paying for health and health care, the system of accountability of the overall system and its component parts must focus on value to patients.

#### CONCLUSION

This analysis encourages us to reject commodity-thinking about public health, health, and health care delivery. The latter may be a service whose outcome is dependent upon both the actions of providers and *clients*. Those clients have various concepts of health and levels of access to health care delivery and public health infrastructure such as parks and safe sidewalks.<sup>131</sup> More important, those clients live and work in diverse communities, whose social, economic, and physical construction may impact the health of their members.<sup>132</sup>

Defining health policy is critical in any context in which we seek to use professional knowledge to move actors within institutional processes of the overall health system, the government, and the market. Lawyers seeking to use their particular skills in this multidisciplinary environment can use comparative institutional analysis to frame the issue of institutional choice. They must determine which of several imperfect institutions—“the markets,” courts, legislative bodies, and regulatory bodies—is the forum in which a particular problem is currently being addressed before they can address the normative and empirical question of whether the current choice is optimal. Most important, comparative institutional analysis should equip lawyers to understand how the legal system operating at various levels of government shapes the living conditions and health of urban populations. It is my hope as a citizen-scholar<sup>133</sup> that such an approach will better enable lawyers to frame the questions from the perspective of those living in the most health risky communities in our cities. This is, after all, what is meant by the phrase, “community participatory action research.”<sup>134</sup>

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131. See, e.g., Barak D. Richman, *supra* note 106.

132. See Nicholas Freudenberg et al., *Beyond Urban Penalty and Urban Sprawl: Back to Living Conditions as the Focus of Urban Health*, 30 J. OF COMMUNITY HEALTH 1 (2005). See also William McGreevey et al., *Propinquity Matters: How Better Health, Urbanization, and Income Grew Together, 1870-2008*, 15 GEO. J. ON POVERTY L. & POL’Y X (2008).

133. See Joseph Goldstein, *Psychoanalysis and Jurisprudence* 77 YALE L. J. 1053—*On the Relevance of Psychoanalytic Theory to Law*, 23 PSYCHOANALYTIC STUD. CHILD 459 (1968) (discussing how legal actors should approach problems in interdisciplinary spaces and encouraging us to distinguish our roles as scholars and as citizens).

134. See GREENWOOD & LEVIN, *supra* note 21.