

1996

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### Recommended Citation

Julie Roin, "The U.S. Response to HIV: Alternate Explanations and the Lessons of 'Success'," 82 Virginia Law Review 1511 (1996).

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## THE U.S. RESPONSE TO HIV: ALTERNATE EXPLANATIONS AND THE LESSONS OF “SUCCESS”

*Julie Roin\**

We should rejoice at the suggestion that the United States has done something right during the AIDS crisis—even if only when judged by the fairly abysmal standards set by other countries. But I am less confident than Professors Trebilcock, Howse and Daniels that this relatively successful performance is attributable to the institutional framework within which the U.S. blood supply function is carried out. Furthermore, to the extent that success is attributable to American institutions, I am afraid that most countries will find the costs of replicating such a structure unacceptable. Indeed, as I hope to explain at the end of this Commentary, the cost may be too high even for the United States to bear.

### I. CONFOUNDING VARIABLES

For several reasons I believe that it is difficult to learn much about the importance of the institutional framework, or to learn it with confidence, from the information about the various blood delivery services that is provided in the paper. A focus on the institutional framework overlooks at least three other factors which may also have influenced the response of each country to the HIV-infected blood crisis. The first, and perhaps most important, confounding variable is salience. In addition, any analysis of the countries' responses should take into account the difficulty of deciding when to invest in rapidly developing technology. A third overlooked variable is the possibility that cultural attitudes towards risk may explain what are, after all, relatively short differentials in the response times of the countries studied. The existence of each of these alternative or supplementary reasons for the varying responses to the HIV crisis complicates any effort to isolate and evaluate the relevance of institutional structure. Each is explored in greater detail below.

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*A. Salience*

Professors Trebilcock, Howse and Daniels note, but for the most part disregard, the confounding variable of salience—the pervasiveness of the underlying HIV infection, and thus the magnitude of the risks faced, in particular countries.<sup>1</sup> This cursory treatment overlooks a factor that on its own provides a compelling explanation for the seven countries' varying responses to the HIV epidemic. In fact, the degree of responsiveness of a country's institutions, as measured in Table 4, correlates at least as well with a country's rate of AIDS cases, shown in Table 2,<sup>2</sup> as it does with any ranking or rating of institutional structures. Professor Glied's comments indicate that a similar correlation existed even within the United States, where hospitals in regions of the country with high AIDS-infection rates allowed directed donations of blood and undertook other precautionary measures before hospitals in regions with lower infection rates.<sup>3</sup> There is, therefore, a serious possibility that the salience factor swamps any institutional factors, and it is easy to imagine that countries with the most cases in the news, or the most celebrities stricken with the disease, would evince the most dramatic responses to the HIV epidemic.<sup>4</sup> If one could separate out the effects of salience (which may be impossible), it seems likely that there would be precious little variation left to be explained by institutional factors. And certainly the causal connection between the salience of HIV and the responsiveness of preventive measures is at least as plausible as that between any of the other factors mentioned in the paper.<sup>5</sup>

It is true that the rate of infection in the surrounding community logically should not have affected the implementation of safety features in all cases, as the magnitude of the risks posed by imported blood products in particular depends on the AIDS-infection rate in the country of those products' origin rather than in the country of use. Therefore, if salience were a good predictor of the response to HIV, one might have expected

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<sup>1</sup> Michael Trebilcock, Robert Howse & Ron Daniels, *Do Institutions Matter? A Comparative Pathology of the HIV-Infected Blood Tragedy*, 82 Va. L. Rev. 1407, 1415-20 (1996).

<sup>2</sup> *Id.* at 1418-19.

<sup>3</sup> Sherry Glied, *Markets Matter: U.S. Responses to the HIV-Infected Blood Tragedy*, 82 Va. L. Rev. 1493, 1501-02 (1996).

<sup>4</sup> The paper itself provides an example of the importance of such factors when it discusses the impact in Australia of the AIDS-related death of three infants. Not until those infants died did the government acknowledge that the blood system was tainted. See Trebilcock, Howse & Daniels, *supra* note 1, at 1478.

<sup>5</sup> Aside from directing attention to the problem, increased salience would also tend to increase the benefits to be derived from undertaking particular precautionary measures, driving down their relative costs. See *infra* Section I.B.

countries importing blood products from countries with high rates of infection to take precautions (at least with respect to the imported blood) at approximately the same time as did the exporting country. In fact, there was no such correspondence.

Although this seems to undermine the explanatory power of salience, there are two ways to account for such discrepancies. One is that the importing country might depend on the exporting country to take the necessary precautions with respect to the blood product that is collected in a high-infection area. The other is that distance, both physical and psychological, from widespread infection necessarily blunts the effect of salience on the level of precaution. Even if the actual risk of infection is the same, both the users and suppliers of blood products are more likely to appreciate (or over-appreciate) this risk if they are in a position to see and possibly treat actual victims stricken by the infectious agent. Intellectual appreciation of a risk lacks the emotional impact provided by physical contact with affected individuals—and, of course, such contact is much more likely to occur in a high-infection area than a low-infection area.

Though the differences in outcome among most countries can be explained as plausibly, or more plausibly, in terms of salience rather than in terms of institutional structure, there is one exception to what is otherwise a general—impressively general—correlation. Switzerland's performance, as measured by the factors outlined in Table 4, is dismal even though it has the second highest rate of AIDS cases per million among the countries considered.<sup>6</sup> There is therefore more room to argue that institutional factors influenced this outcome than in the other jurisdictions studied. And indeed, some features of Switzerland's blood collection and delivery system are unique and could explain its lag in mandating precautionary measures. For example, the overlap in the powers of the federal and cantonal governments over public health issues created confusion as to the locus of regulatory authority over blood products and undoubtedly impeded effective responses to the crisis.

However, this limited (and hardly surprising) message about institutional structure fails to carry the burden placed on it by the authors of the paper. It does not necessarily refute the "dogma in much contemporary policy literature—the notion that governmental, and particularly regulatory performance can generally be improved through devolution of

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<sup>6</sup> Though there was some suggestion at the conference that the salience factor may have remained low despite the high infection rate because the overwhelming majority of affected individuals were drug addicts, a group viewed as socially marginal at best, I am leery of placing much weight on this argument. The primary victims of AIDS in the United States also have been members of marginalized groups—homosexuals, intravenous drug users, certain categories of immigrants, and more recently, the black urban poor.

power and responsibility to lower levels of government” as clearly as the authors would like it to.<sup>7</sup> Rather, one wonders if the response in Switzerland would have been different if the locus of regulatory authority had clearly been allocated to the cantonal authorities. The Swiss experience may in fact show only that *incomplete* devolution of power is unwise, as it may have been the confusion rather than the degree of centralization (or devolution) that caused the relatively ineffective prevention of blood-borne HIV transmission in Switzerland that is noted in the paper.

*B. Relationship Between the Cost and Timing of Precaution*

Underlying Professors Trebilcock, Howse and Daniels’ conclusions is the assumption that the faster the reaction to a medical crisis, the better, and the paper is explicit about its *ex post* rather than *ex ante* perspective. In retrospect, it was clearly true with respect to the particular precautionary measures studied in this paper that faster implementation would have been better. However, speed is not always advantageous. In some cases, lagged imitation may be preferable to speedy action. Accordingly, another explanation for some of the inter-country distinctions may have been the result of honest differences of opinion as to whether waiting for further improvements in medical knowledge or technology made either medical or financial sense.

Many of the measures undertaken to prevent the spread of HIV through the blood supply involved incurring high fixed or up-front costs.<sup>8</sup> Instituting a screening process in the blood donation sector entails political and economic costs that do not depend much on the percentage of potential donors with various risk factors; the cost is in the asking and testing, and these costs vary more with the number of donors than with their relative risks. Indeed, some costs will drop with greater risks because the screening process may end once the donor informs the interviewer of a single risk factor. Likewise the decision to instruct local collectors to screen has decisional and political costs—but these too are largely fixed. Heat-treatment (and perhaps antibody screening) also costs the same for infected as for uninfected units of blood. Though it may well be, as the paper contends, that relatively early on in the crisis, the benefits in fact outweighed the costs of these precautionary measures, even in countries with very low infection rates, that fact may not have been obvious to the decision makers in those countries. But as underlying infection rates increase, the precautionary costs would remain the same while the benefits obtained from them would increase, making it

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<sup>7</sup> Trebilcock, Howse & Daniels, *supra* note 1, at 1482.

<sup>8</sup> If “fixed” is too inexact a term, then we might at least agree that these costs do not vary much with changes in the underlying rate of infection.

harder for decision-makers to overlook or misinterpret this cost-benefit analysis.

There are also circumstances where expenditures even on precautions which seem to survive a cost-benefit analysis may be unwise. The choice is not always between making a particular investment and doing nothing; sometimes there is a third choice of delay in order to make an investment in a predictably improved version of the earlier investment. The second or third mover may have the advantage of being able to learn from the experiences of the first mover—and may occasionally learn to do nothing. Not only may delay result in a wiser investment of resources down the road, it may sometimes be necessary to delay in order to preserve the option of moving to a better precaution any time in the near future. If a precaution requires making a large expenditure, undertaking the precaution at an early stage may foreclose opportunities to participate in later technological improvements because of financial constraints or because the incremental gain from a later switch will fail a cost-benefit test. The losses attributable to delay, or to foregoing the installation of first generation technology, must therefore be weighed against the gains generated through the use of second generation (rather than first generation) technology later in time. This was, apparently, the calculation made by the Federal Aviation Administration (“FAA”) when it decided against requiring airlines to install the first generation of wind shear detection devices<sup>9</sup> (and also some anti-explosive screening devices<sup>10</sup>).

Of course, not every expected technological improvement arrives on schedule or is as improved as was initially projected; in retrospect, the decision to be a follower rather than a leader may turn out to be wrong. However, *ex ante*, a decision to wait before implementing admittedly valuable safety measures may not be irresponsible if the initial cost-benefit justification is slight and the potential for improvements in the

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<sup>9</sup> See Richard Witkin, *F.A.A. Moves To Cut Wind Shift Peril*, N.Y. Times, Dec. 20, 1990, at A28. The FAA granted four airlines two-year exemptions from its requirement that wind-shear detectors be placed on all commercial planes in order to provide incentives for further development of and experimentation with more advanced equipment. It feared that without the exemption, “the manufacturers and petitioners will stop this development [of more advanced equipment], and the benefits associated with development of predictive wind shear systems will be lost.”

<sup>10</sup> See Ron Feemster, *Secure Air Travel Still Eludes U.S.; Lots of Devices Are Being Tested but Their Widespread Use Lags*, Newsday, Oct. 11, 1992, at 109. Three years after the bombing of Pan Am Flight 103, which killed almost 300 people, anti-explosive screening devices were still not required by FAA guidelines or deployed by airlines or airports. According to a spokesman for Air Transport Association of America, explanation for the delay was that “[t]he FAA is not reluctant to tell the airlines to spend money . . . . But they are reluctant to mandate the expenditure of hundreds of millions this year on a machine that is not 100%, when next year there might be one that is.” *Id.*

technology significant. Without knowing more about the sorts of capital investment required to establish heat treatment facilities, for example, it is hard to know whether an expectation of future improvements may have been a factor in the slowness of some countries' blood authorities to take action. And again, the more obvious the cost-benefit justification of the first generation safety device, the less likely it is that delay would seem to be the preferred option.

Professors Trebilcock, Howse and Daniels' paper seeks to deflect this criticism by arguing for an *ex post* perspective, but even on their terms we have no way of evaluating *ex post* the optimal timing of innovations. Moreover, the *ex post* perspective is highly sensitive to the sample that is chosen. The authors of this paper had the advantage of choosing an early innovation that proved worthwhile. But they might have felt quite differently, for example, if the French ELISA test had proved to be superior to the American version. Correcting for the bias inherent in an *ex post* perspective requires either choosing examples the usefulness of which is unknown to the author of the study or choosing many innovations in many fields and assessing more generally the relationship between institutions and *ex post* successes.

### C. Cultural Factors

This reference to the problem of looking at one rather than many public health crises, and in *ex post* fashion, brings me to another topic: the possibility that cultural predilections (such as attitudes toward certain types of risk or toward libertarian values) are more important than institutional factors in determining the rate at which precautions were introduced. It is indeed interesting to compare the rate at which various countries responded to the HIV crisis, but it is somewhat hard to know what to make of this data without comparing it to other potential data points with respect to other public safety issues.

There are a number of situations in which governments may interfere with market behavior in the interests of public health, and there is often great variation among countries in the rate and manner with which such interference has taken place. There are, for example, a host of auto safety measures, some of which involve impositions on individual behavior, the introduction of which can be evaluated in *ex ante* or *ex post* terms in comparison with other countries' performances and in light of differing institutional arrangements for generating safety innovations. Thus, in different years and jurisdictions we find requirements that motorists wear seat belts,<sup>11</sup> shoulder belts, and motorcycle helmets,<sup>12</sup> along

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<sup>11</sup> It is actually rather difficult to know how to compare seat belt requirements across ju-

with speed limits and minimum driving and drinking ages. At the industry level we find requirements as to safety belts again, standards regarding side-impact collisions, and passive-restraint technologies, including, most notably, airbags in new cars.<sup>13</sup> Outside of the automotive context, there are anti-smoking regulations,<sup>14</sup> rules regarding the installation of

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risdictions, since these requirements can vary along a number of dimensions. The Department of Transportation first issued regulations requiring U.S. car manufacturers to equip their vehicles with seat belts in 1967. See *Motor Vehicle Mfrs. Ass'n v. State Farm Mutual Automobile Ins. Co.*, 463 U.S. 29, 33-34 (1983) (noting Department of Transportation Standard 208, 32 Fed. Reg. 2415, issued pursuant to authority granted to the Department by the National Traffic and Motor Vehicle Safety Act of 1966.). However, few drivers or passengers took advantage of seat belts until relatively recently, when, "with strong Federal prodding, all but five states. . . enacted laws requiring the use of seat belts in automobiles." Tamar Lewin, *Seat-Belt Laws Grow*, but by Fits and Starts, N.Y. Times, Aug. 15, 1993, § 1, at 20. By contrast, seat belts were (and remain) much more widely-used in Europe. "Studies find that 95 percent of drivers in Great Britain and Germany wear seat belts, and about 90 percent of drivers in Finland do. In Australia and Canada, about 90 percent also wear their belts, but in the United States, only about 66 percent belt up." Ron Kotulak & Jon Van, *Discoveries: Seatbelts Save Lives Only If You Use Them*, Chi. Trib., Jan. 15, 1995, at 2. Part of the difference is attributed to the fact that mandatory seat belt laws were enacted much earlier in many European countries. Karl Gerlinger, *The Case for Seat Belts—Now*, The Record (Northern N.J.), Oct. 1, 1990 at B8. Further, until recently, U.S. manufacturers lagged behind foreign manufacturers in seat-belt design. See Michael deCourcy Hinds, *Some Seat Belts Found Inferior (or Lethal)*, N.Y. Times, Oct. 22, 1988, at 52.

<sup>12</sup> By 1993, "all but three states require[d] at least some motorcycle riders to wear helmets." Lewin, *supra* note 11, at 20.

<sup>13</sup> Federal regulations promulgated in 1987 provided for the phased-in implementation of a passive restraint requirement for the front outboard seats in passenger cars, beginning with cars produced for the 1987 model year and with full implementation of the requirement for all passenger cars manufactured after September 1, 1989. Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 52 Fed. Reg. 10,096 (1987) (codified at 49 C.F.R. § 571.208). Regulations were again promulgated in 1993, requiring a similar phase-in of mandatory driver and passenger side air bags beginning September 1, 1996, with full implementation for all passenger cars manufactured on or after September 1, 1997 (i.e., for the 1988 model year). Federal Motor Vehicle Safety Standards; Occupant Crash Protection, 58 Fed. Reg. 46,551 (1993) (codified at 49 C.F.R. § 571.208).

By contrast, European countries have yet to require such restraints. See Evelyn Iritani, *Smoothing the Road for Car Sales Worldwide; Manufacturing: Countries' Varying Standards Are Costly for Auto Makers*. U.S., Europe Address Problem in a New Pact, L.A. Times, Apr. 18, 1996, ("The United States is the only country that requires air bags. In Europe, where more than 90% of the passengers wear seat belts, there is no air bag requirement."). However, both European and Japanese car manufacturers are experimenting with improved versions of airbag technology (especially side airbags) because of strong consumer interest in such safety devices. See Jim Mateja, *What's Up Next in Air-Bag Technology*, Chi. Trib., May 9, 1993, § 17, at 1, 7.

<sup>14</sup> See Joshua A. Lerner, Note, *Snuffing Out a National Symbol What the United States Can Learn From France's New No-Smoking Law*, 4 Ind. Int'l & Comp. L. Rev. 165 (1993) (comparing the approaches of France and the United States to anti-smoking legislation).



wind-shear detection devices on commercial airplanes, gun control laws, drug licensing standards . . . and I could go on, but I won't. The point is that if it turns out that the United States leads the other countries studied in the implementation of these safety measures as well, the significance of its lead (which actually isn't that great) in the HIV scenario diminishes. People in the United States may just tolerate (or demand) greater and faster government implementation of safety precautions. By contrast, if the United States generally trails the other countries, or if the pattern of relative development accords with the institutional patterns discerned in Professors Trebilcock, Howse and Daniels' paper—their thesis is accordingly advanced.

My intuition is that the authors face an uphill battle, as there is some indication that the United States evinces just such readiness to accept or even expect government safety regulations regardless of the institutional framework through which they are imposed. In the case of airbags, for example, the United States required them early (and *ex post*, looks terrific<sup>15</sup>), but this was a highly centralized decision. The United States was also quite early to implement anti-smoking regulations, but here most of the decisions were quite decentralized.<sup>16</sup> This single comparison shows

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<sup>15</sup> Actually, how terrific it looks depends on which statistics one reads. Though it is clear that airbags can and do save the lives of many individuals who are involved in auto accidents, recent evidence suggests that the presence of airbags increases the rate at which such accidents occur. The two effects tend to cancel each other out, leading to no net change in auto-related deaths. See Steven Peterson, George Hoffer and Edward Millner, *Are Drivers of Air-Bag-Equipped Cars More Aggressive? A Test of the Offsetting Behavior Hypothesis*, 38 *J.L. & Econ.* 251, 262 (1995) ("We find that risk to drivers of cars equipped with air bags in single car crashes *is not* diminished, that the percentage of occupants killed in single car air bag crashes *is* unusually high, and that drivers of air-bag-equipped cars initiate an unusually large percentage of such crashes.").

<sup>16</sup> Like the seat belt regulations, see *supra* note 11, anti-smoking regulations vary along a number of dimensions. They range from restrictions on advertising and mandatory health warnings on packages to limitations on smoking in public areas and private workplaces. See Ruth Roemer, *Legislative action to combat the world tobacco epidemic* xi (2d ed. 1193). In the 1980s, the United States was regarded as having a stronger, more comprehensive anti-smoking policy than the countries of Europe. See Ben Dobbin, *Smoking Barriers Rising in Europe*, *The Bergen Record*, Jan. 17, 1988, at note 14 (quoting Dr. Marc Danzon of the World Health Organization). This reputation was achieved despite a near-absence of federal legislation; anti-smoking initiatives were largely the province of state and local governmental entities. See Lerner, *supra* note 14, at 176-87 (chronology of state laws restricting smoking); Roemer, *supra*, at 14 ("In the USA, 43 of the 50 states and the District of Columbia have acted to restrict smoking in some manner in public places . . . . As of 1989, about 400 city and county ordinances in the USA restrict smoking in public places.") (citation omitted). Although increasing numbers of countries have enacted national anti-smoking legislation, see Roemer, *supra*, at 97 ("The number of countries or territories in which smoking in public places is controlled by legislation rose from 47 in 1986 to 90 in 1991."), the United States continues to rely largely on state and local

that it will, in short, be no small task to link success and courage in regulation with institutional arrangements.

I do not mean to imply that cross-cultural or cross-national studies are inherently useless because the effects of local differences always drown out the effect of more generalized institutional factors. However, in this particular context, the timing differences tended to be relatively minor (though this is of course small consolation to the affected individuals), making the relative contribution of the confounding variables I have explored more important. Moreover, as the authors themselves admit, many of the institutional forms they discuss have both advantages and disadvantages, making it hard to predict whether any given form will be preferable in a particular context—or whether such a preference will be sustained when transferred to even a slightly different context.<sup>17</sup> One of the lessons to be gleaned from the extensive literature on public choice is that all institutional structures have flaws and that there is, therefore, no reason to believe that any such structure will consistently outperform other structures. Some structures may be particularly well-suited to particular contexts while others are particularly ill-suited to such contexts, but over the course of many cases, none of the options will appear to offer systematic advantages.<sup>18</sup>

## II. THE NOT-SO-HIDDEN COSTS UNDERLYING THE AMERICAN “SUCCESS” STORY

Let me end with the point I alluded to in the beginning—that to the extent there is a structural or institutional component to the variation in national responses to the AIDS crisis and the threat to the blood supply, and especially to the relative success of the United States’ handling of the issue, replicating that component in other countries may impose unacceptable costs. The paper concludes that “[a] second important policy

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anti-smoking measures. See Lerner, *supra* note 14, at 194 (“The federal government appears willing to allow state and local governments to lead the battle against smoking in public places and in the workplace.”).

<sup>17</sup> The institutional lessons will be of little use if they cannot be generalized across health-related issues, for example, since it is unlikely that separate institutions will be established for overseeing blood banking practices, pharmaceutical regulation, medical device regulation, etc. Indeed, if such differentiation were to take place, it would no doubt be criticized as leading to confused and overlapping areas of authority.

<sup>18</sup> See, e.g., Saul Levmore, *Parliamentary Law, Majority Decisionmaking & the Voting Paradox*, 75 *Va. L. Rev.* 971, 1044 (1989) (“The central message of basic collective choice theory is, after all, that there will be some problem with every decisionmaking process.”); *id.* at 1035-39 (explaining flaws and advantages of various forms of plurality voting). See also Daniel A. Farber, *Democracy and Disgust: Reflections on Public Choice*, 65 *Chi.-Kent L. Rev.* 161 (1989) (discussing some implications of arbitrariness in decisionmaking structures).

implication suggested by the comparative experience reviewed in this paper is that governments or their agencies perform better as overseers of the quality of the blood system if their functions are limited and clear, and relatively autonomous from general political decision-making.<sup>19</sup>

It would be hard to disagree with that. But the question facing institutional designers and analysts is not whether one would want a perfect technocrat, nor whether the functions of an administrative agency should be "limited and clear and relatively autonomous from general political decision-making," but how one gets to that desirable state. It turns out to be remarkably hard in most contexts; ironically, the reason this beneficial state may exist in the regulatory structure surrounding the blood industry in the United States may be due to a feature of the general health care system that many observers find abhorrent, the absence of universal, government-financed health care.

As the paper notes, a government's involvement in the funding and delivery of health care tends to complicate regulatory incentives. Immediate budget constraints can impede the exercise of good judgment about long-term interests;<sup>20</sup> the sheer size of the expenditures involved leads to attempts to get "more bang for the buck" by intertwining health and national economic policy. The authors suggest that restructuring government subsidies "to the demand side, e.g. through augmentation of hospital budgets" would eliminate some of these perverse effects.<sup>21</sup> However, the experience in the United States with such "demand side" subsidies has shown that they have their own pernicious side-effects. In particular, as Professor Elhauge's paper (among others) lays out, such subsidies have a tendency to encourage medical innovations that are not cost-effective. When people are spending money that is not their own, they

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<sup>19</sup> Trebilcock, Howse & Daniels, *supra* note 1, at 1486.

<sup>20</sup> Moreover, the regulatory question becomes more difficult (both substantively and politically) if the health authorities are working under a budget cap, so that additional expenditures on one component of health care require offsetting budget cuts in another component. Then the issue that must be faced is whether the medical (and financial) advantages created by the additional expenditure will outweigh the medical (and financial) disadvantages caused by offsetting budget cuts. If, for example, the additional costs of heat-treated blood must be paid for by reducing the funds allocated for kidney dialysis, one has to compare the benefits to hemophiliacs and other blood-users against the losses that will be suffered by those with kidney disease. Although in an ideal world, a government would increase its caps to allow the provision of every cost-justified medical innovation, in the real world it is unrealistic to expect a government that has chosen to police against excessive medical spending by imposing spending caps to do so. After all, one of the justifications for adopting such caps in the first place may be suspicion of the government's ability to judge which medical innovations and services are in fact cost-justified.

<sup>21</sup> Trebilcock, Howse & Daniels, *supra* note 1, at 1486.

tend to demand high-cost medical services of marginal medical benefit.<sup>22</sup> The predictable result is uncontrolled, and uncontrollable, medical spending. It is for this reason that no government has been willing to implement a nationally-financed universal health insurance scheme on a fee-for-service basis, without also providing for some control over total expenditures or direct limits on service usage. Indeed, one of the barriers to the adoption of universal health care in the United States is fear of the budgetary effects of uncontrollable medical spending—an all-too-likely scenario given the U.S. government's inability to come up with a politically acceptable method for "rationing" care, as demonstrated through its implementation of the Medicare and Medicaid programs.<sup>23</sup>

The absence of a national, universal health care system of course has its own costs, not least being the fact that millions of Americans (nearly 40 million at last count<sup>24</sup>) have no health insurance at all, while millions

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<sup>22</sup> See, e.g., Einer Elhauge, *The Limited Potential of Technology Assessment*, 82 Va. L. Rev. 1525, 1562-63 (1996); Alain C. Enthoven and Sara J. Singer, *Market-Based Reform: What to Regulate and by Whom*, 14 Health Aff. 105, 113 (1995) (asserting that tax-exclusion of employer-paid benefits "has encouraged employees to spend more on health care than they would if they were fully responsible for marginal costs"); David M. Cutler, *Cutting Costs and Improving Health: Making Reform Work*, 14 Health Aff. 161, 163 (1995) (ascribing high health care costs to the disconnect between cost and benefit that arises when patients pay little of their health care costs); Daniel Yankelovich, *The Debate That Wasn't: The Public and the Clinton Plan*, 14 Health Aff. 7, 17-19 (1995) (linking the failure to achieve health care reform to the unwillingness or inability of health care consumers—citizens—correctly to evaluate costs and benefits of technologies for which they are not paying); Jack A. Meyer & Rudolph G. Penner, *Impact of National Health Insurance Proposals on the Budget in National Health Insurance: What Now, What Later, What Never?*, 11, 13 (Mark V. Pauly ed., 1980) (citing empirical evidence of the phenomenon). But see Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 Yale J. on Reg. 455, 477 (1994) (questioning "equation of high technology with high growth in costs and waste at a fundamental level.").

<sup>23</sup> See Victor R. Fuchs, *The Future of Health Policy 209-12* (1993) (discussing methods of cost control in a system of universal care); Theodore R. Marmor, Judith Feder & John Holahan, *Introduction*, *National Health Insurance: Conflicting Goals and Policy Choices* 11 (Judith Feder, John Holahan, and Theodore R. Marmor eds., 1980) (noting that "the cost issue dominates the debate on the desirability of greater government intervention in the health sector"); Kennard N. Friedman, *Solidarity and Self-Governance: What Americans Still Could Learn From Germany's National Health Insurance Program*, 13 *Wis. Int'l L.J.* 245, 245 (1994) (asserting that fears of increased cost and decreased quality, based on two decades of experience with attempts at reform, scuttled Clinton health care reform). But see Theodore R. Marmor & Jonathan Oberlander, *A Citizen's Guide to the Healthcare Reform Debate*, 11 *Yale J. on Reg.* 495, 504 (1994) (arguing that Medicare's expenditures grew quickly only "before government officials made cost control in Medicare a priority" and that Medicare expenditures "have increased less rapidly over the past decade than average medical costs.").

<sup>24</sup> See Jay A. Soled, *Taxation of Employer-Provided Health Coverage: Inclusion, Tim-*

more are underinsured. However, those who have private insurance (and particularly those who have insurance that pays claims under a fee-for-service arrangement), can exert a considerable amount of control over health care decisions.<sup>25</sup> And as Professor Glied's comments show, they used this control to speed the implementation of various precautionary measures.<sup>26</sup> Indeed, in many regions of the United States, changes in blood banking practices preceded the imposition of governmental regulations as a result of competitive pressures.<sup>27</sup> And once these changes were implemented for the benefit of some consumers, economies of scale and administration led to their universal provision. In retrospect, of course, the responsiveness of the system to consumer pressure in this situation turned out to be a good thing; however, the same imperative drives the gross over-provision of cardiac by-pass operations,<sup>28</sup> MRIs for minor injuries,<sup>29</sup> and a host of non-cost-effective practices.<sup>30</sup> And, of course, the more unnecessary procedures are performed, the higher the cost of private insurance—driving more people out of the insurance market. In sum, the substitution of consumer judgment for governmental regulation is not an unalloyed good, and on balance, it may be bad.

Moreover, there is no guarantee that the absence of government funding necessarily leads to the provision of relatively disinterested (i.e. public-regarding) oversight. A second obstacle to honest brokering is industry capture of the regulatory agency or the Congressional committee overseeing that agency. If the stakes are big enough, the financial consequences serious enough, and the industry concentrated enough, a regulatory agency will find itself sometimes hobbled by, and sometimes acting in concert with, the industry it is supposed to be overseeing.<sup>31</sup> The tortu-

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ing, and Policy Issues, 15 Va. Tax Rev. 447, 486 n.176 (1996) (38.9 million, according to information abstracted from March 1993 census data).

<sup>25</sup> Whether they exercise this control in an intelligent fashion is another question entirely. See Mashaw & Marmor, *supra* note 22, at 460 (providing explanations for consumers' inability to police inefficiencies in medical care).

<sup>26</sup> Glied, *supra* note 3, at 1501-03.

<sup>27</sup> *Id.*

<sup>28</sup> See Constance Monroe Winslow, Jacqueline B. Kosecoff, Mark Chassin, David E. Kanouse, and Robert H. Brook, The Appropriateness of Performing Coronary Artery Bypass Surgery, 260 JAMA 505, 508 (1988) (reporting results of a retrospective study of coronary artery bypass surgery showing that "[o]verall, 30% of the patients . . . underwent surgery for equivocal reasons and 14% for reasons judged to be inappropriate.").

<sup>29</sup> See Mashaw & Marmor, *supra* note 22, at 476-77 (asserting that the relatively high number of MRI machines in the state of California has caused "supply-induced demand" such that one study showed "fully one-third of the MRI scans requested, . . . were judged inappropriate.").

<sup>30</sup> See *supra* note 22.

<sup>31</sup> This phenomenon has sometimes been referred to as "industry capture," suggesting some distortion of the regulatory scheme by improper industry influence. However, a

ous path to the introduction of airbags in this country is indicative of the delays that may be foisted upon even a relatively disinterested agency by what turned out in the end to be an unwise interest group.<sup>32</sup> And even if an agency is able to resist direct pressure from an interest group, it is often incapable of fending off congressional actions taken at the behest of an organized industry.<sup>33</sup> At the very least, such pressure delays agency actions, as the agency is forced exhaustively to document each factual conclusion as well as each judgment, and frequently to defend each in lengthy court proceedings. While the result may (or may not) be more accurate or rational decision-making, the postponement of decisions exacts an offsetting cost, as Professors Trebilcock, Howse and Daniels so amply demonstrate. There is a point at which checks and balances—whether institutionalized through intragovernmental controls or informally imposed by industry participation—can lead to paralysis rather than progress. Ironically, the rather anarchic and chaotic nature of funding for health care (and blood supplies in particular) in the United States may have prevented the formation of interest groups capable of exerting the pressure necessary to influence the regulatory process ad-

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more complete perspective would have to account for the fact that many agencies were established precisely to give a voice to specific industries or economic interests, in a form of “clientele government” that equally results in industry capture, but with a different starting point. See Glen O. Robinson, *American Bureaucracy: Public Choice and Public Law 13-14* (1991) (describing the elevation of the Department of Agriculture to a Cabinet-level agency as “the model for ‘representative’ bureaucracy designed to serve the distinctive interests of particular interest groups.”).

<sup>32</sup> See *Motor Vehicle Mfrs. Ass’n v. State Farm Mut. Automobile Ins. Co.*, 463 U.S. 29, 34-40 (1983) (explaining the history of passive restraint regulation in the United States).

<sup>33</sup> For example, when industry failed to stop the Federal Trade Commission from initiating a rulemaking proceeding aimed at extending the application of the FTC’s so-called “unfairness” doctrine to commercial advertising, it successfully lobbied Congress for a legislative moratorium on such rulemaking proceedings. The moratorium prevented the agency from implementing such a rule. See Glen O. Robinson, *Commentary on “Administrative Arrangements and the Political Control of Agencies”: Political Uses of Structure and Process*, 75 Va. L. Rev. 483, 490 (1989). Similarly, when the Treasury Department decided in 1975 to promulgate regulations providing for the taxation of “certain fringe benefits about which it had previously made no clear policy choice,” lobbyists convinced Congress to impose a legislative moratorium on the issuance of fringe benefit regulations. Congress did not remove the moratorium until it enacted comprehensive fringe benefit legislation in 1984. Karla W. Simon, *Fringe Benefits and Tax Reform: Historical Blunders and a Proposal for Structural Change*, 36 U. Fla. L. Rev. 871, 879 n.14 (1984). See also Samuel P. Hays, *The Future of Environmental Regulation*, 15 J.L. & Com. 549, 567-68 (1996) (“Within that federal context a pattern has emerged: the Congress authorizes administrative agencies to act; objection to agency decisions arise and the issue is taken to the courts; objection arises to the court decisions and then one goes either to the executive branch to get an executive fix or back to the legislature for a legislative fix.”).

versely. Given the pitfalls of industry capture, it would be interesting to see how well the FDA's regulation of drugs produced by major pharmaceutical companies compares to the haphazard and decentralized oversight of blood products.

#### CONCLUSION

This analysis of the institutional focus of Professors Trebilcock, Howse and Daniels is not meant to deny the importance of institutional factors per se. However, in light of the alternative explanations offered in this Commentary for some of the variation in performance by the seven countries studied in their paper, it seems that the authors may have overplayed their hand. Their analysis overlooks the important variable of salience, the very real tendency of ex post analysis to obscure the ex ante relevance of perceived potential for future development of more effective and/or cost-effective precautions and cultural factors such as toleration of risk or regulation. Professors Trebilcock, Howse and Daniels conclude that the institutional arrangements in the United States account for the comparative responsiveness of the United States to the HIV crisis. But this Commentary has also demonstrated that the relative success of the U.S. response to the AIDS crisis in the blood-banking system may have been the outgrowth of some of the least desirable features of its health care financing system (if the current patchwork of funding sources can be dignified with that name). Furthermore, it would not be a necessary outgrowth of those features, so that even a country willing to accept the accompanying problems with such a system would not be guaranteed similarly favorable results in subsequent crises. In short, an attempt to reap the institutional lessons of this particular scenario could as easily be a high-cost recipe for future disasters as a shortcut to success.