

# The Erosion of Individual Autonomy in Medical Decisionmaking: Of the FDA and IRBs

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## INTRODUCTION

**WHY HEALTH LAW?** In this Essay, I shall examine the institutional pressures on individual autonomy that have been created by two major forces in modern medicine: the Food and Drug Administration, which operates at the federal level, and the many Institutional Review Boards that operate in universities to regulate biomedical research. As a prelude, however, the creation of the Linda and Timothy O’Neill Institute for National and Global Health Law offers a suitable occasion to reflect on the status of health law, both national and global, as an intellectual discipline. In some sense, that large question looks otiose given the paramount importance of health issues everywhere in the world.<sup>1</sup> There is widespread agreement that the health of any individual is crucial to his or her ability to lead a good life: health matters as much, if not more, than wealth, as the recent happiness studies tend to suggest.<sup>2</sup> Those measures that advance the health of individuals are therefore to be welcomed, while those that

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1. For one impassioned view, see Lawrence O. Gostin, *Meeting the Survival Needs of the World’s Least Healthy People: A Proposed Model for Global Health Governance*, 298 JAMA 225, 225–26 (2007).

2. For different views on this relationship, compare RICHARD LAYARD, *HAPPINESS: LESSONS FROM A NEW SCIENCE* (2005), tending to take an interventionist stance, with HELEN JOHNS & PAUL ORMEROD, *HAPPINESS, ECONOMICS AND PUBLIC POLICY* 20–22 (2007), offering a critique of Layard and others.

place their health in jeopardy are to be deplored.

Of course, no one claims that health is the absolute first best good: it has to compete with other goods that people desire at an individual or a collective level. But no matter how those trade-offs are made, there are none, regardless of political or intellectual points of view, that treat the good health of people as an outcome that social policy should avoid. Hence the debate switches to the highly contentious questions of means. What are the best ways to achieve health, and what sacrifices are justified? On these vital questions there is no shortage of approaches. Historically, charitable activities have often centered on providing health care assistance to those who were in need.<sup>3</sup> By the same token, there has never been, nor will be, a consistent charitable movement to supply fine wines to aspiring connoisseurs. In modern days, the impulse for charitable work has not disappeared, but has been augmented (and sometimes displaced) by government expenditures on health care, which consume an ever expanding fraction of national and global wealth.<sup>4</sup> As a lawyer and sometime economist, I believe that there is much to be said for the theory of revealed preference.<sup>5</sup> Our preferences, both individual and collective, reveal an ever-greater commitment to expenditures on health care. This commitment expresses itself in both sensible and unwise ways. The work of the O'Neill Institute is only the latest manifestation of this concern, and I hope that it does well in sorting out the multifaceted problems of health care.

Yet, this question still remains: how does the ever-greater commitment to health care translate itself into an academic discipline? On this point, the grounds for skepticism should, I think, be addressed. In a provocative essay directed to matters of cyberspace, Judge Frank Easterbrook asked this simple question: we have horses, but do we, or should we, have a separate academic discipline for “The Law of the Horse”?<sup>6</sup> My experience with this question predates the Easterbrook article. Years ago, when I interviewed a Rhodes Scholarship candidate, she indicated that she wanted to work with horses and thought that she should go to the University of Louisville because it indeed had a course on the law of the horse. My answer was not that there was no law of the horse, but that she should not pick a law school based on that offering, even if she were 100% sure that horse law was what she wanted to do. I have no idea what happened next.

Be that as it may, Easterbrook's answer to that question, which has been

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3. See, e.g., ROBERT H. BREMMER, *AMERICAN PHILANTHROPY* 43 (2d ed. 1988) (noting that in nearly every American community, citizens contributed to the founding and support of hospitals).

4. See Christian Hagist & Laurence J. Kotlikoff, *Who's Going Broke? Comparing Healthcare Costs in Ten OECD Countries* 3 (Nat'l Bureau of Econ. Research, Working Paper No. 11833, 2005).

5. For the origin of this theory, which states simply that, “[b]y comparing the costs of different combinations of goods at different relative price situations, we can infer whether a given batch of goods is preferred to another batch,” see Paul A. Samuelson, *Consumption Theory in Terms of Revealed Preference*, 15 *ECONOMICA* 243 (1948).

6. Frank H. Easterbrook, *Cyberspace and the Law of the Horse*, 1996 U. CHI. LEGAL F. 207, 207–08.

doubted,<sup>7</sup> is in the negative: we do not have a law of the horse, and we should not have a law of the horse.<sup>8</sup> Rather, we have a set of broad doctrinal areas, including property, contracts, torts, taxation, and the like, all of which are designed to govern the protection, use, and disposition of valuable assets, whether human, physical, or intangible. Horses, like cows and patents, are assets with value in the economic system, such that proper legal study analyzes the way in which various bodies of law either impede or advance the understanding of how horses, or anything else, should be treated. Easterbrook's implication, which does not seem to have been borne out perfectly in practice, was that there should be no distinctive law of cyberspace, but that legal rules for cyberspace should always be folded back into the basic legal categories.<sup>9</sup>

The fair extension of this position is that health law may suffer much the same fate as "cyberspace law." There is the law of contracts, torts, property, and crime, but there is no law of health as such, and it would be foolish to study the problems of health care as a separate academic field *or* branch of law *or* branch of legal theory. Such approaches will likely result in a fragmentation of health care from the larger and more uniform bodies of legal theory that apply everywhere else.

One possible way to read this indictment is that the creation of the O'Neill Institute should be dismissed as an expensive intellectual category error. Its function is to create or foster a branch of law that should never be created in the first place. This objection should not be treated lightly, but nonetheless I am relieved on this occasion to report (as a sometime teacher of health law) that

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7. Mark A. Hall, *The History and Future of Health Care Law: An Essential View*, 41 WAKE FOREST L. REV. 347, 355 n. 41 (2006); Mark A. Hall, *The Legal and Historical Foundations of Patients as Medical Consumers*, 96 GEO. L.J. 583, 584 n.4 (2008).

8. See Easterbrook, *supra* note 6, at 207–08.

9. See *id.* at 208. This topic is in fact extremely important and figures prominently in the decision of the California Supreme Court, which rejected my effort, as an amicus curiae lawyer to argue for close system-wide analogies between cyberspace and real space. The gist of the argument was that the common spaces—highways, for example—had the same role to play in cyberspace as they do in real space, as links among private sites, replete with their own addresses. See Brief for California Employment Law Council et al. as Amici Curiae Supporting Respondent at 34, *Intel Corp. v. Hamidi*, 71 P.3d 296 (Cal. 2003) (No. S103781), [http://www.nam.org/s\\_nam/bin.asp?CID=382&DID=225161&DOC=FILE.PDF](http://www.nam.org/s_nam/bin.asp?CID=382&DID=225161&DOC=FILE.PDF); see also *Hamidi*, 71 P.3d at 309–11 (declining to adopt a rule treating computer servers as real property for the purpose of trespass law). For an insistence that cyberspace is a misleading metaphor, see Dan L. Burk, *The Trouble with Trespass*, 4 J. SMALL & EMERGING BUS. L. 27, 39 (2000) (arguing that common law actions such as trespass to chattels are not appropriate tools for confronting unauthorized uses of computer networks); Dan Hunter, *Cyberspace as Place and the Tragedy of the Digital Anticommons*, 91 CAL. L. REV. 439, 472–500 (2003) (suggesting that the term "cyberspace" encourages lawyers to improperly equate electronic trespasses with trespasses to real property). For answers, see Richard A. Epstein, *Intel v. Hamidi: The Role of Self-Help in Cyberspace?*, 1 J.L. ECON. & POL'Y 147, 159–66 (2005) (writing that physical metaphors for networks have gained popularity based on their accurate reflection of the environment); David McGowan, *The Trespass Trouble and the Metaphor Muddle*, 1 J.L. ECON. & POL'Y 109 (2005) (contending that complaints about the "cyberspace" metaphor ignore the reasoning that underlies relevant judicial decisions). The moral of this debate is that one can disagree with Easterbrook on the grand question and still insist on the transference of insights in particular cases.

Easterbrook's point is not so much wrong as it is overdrawn. It may well be true that some scholars—and I often (but not always) fall in this group—look at all current controversies through the lens of the standard and enduring categories of the law.<sup>10</sup> It hardly follows, however, that what is good advice to some scholars, even most of the time, is good advice for all scholars, all of the time.

The key insight on this point, as on so many others, concerns the importance of *decentralization* in the structure of academic disciplines.<sup>11</sup> Much of the legal curriculum has in fact been profitably organized along lines different from those which Easterbrook suggests. Even if the law of the horse is not (except in Louisville) a useful category for analysis, the same conclusion does not hold for other areas. The study of land development and finance, for example, works very well in the opposite way even though “land” itself need not be dubbed a legal category with greater dignity than the horse. But if one asks the question of how a developer puts a deal together, then the doctrinal information standing alone is not sufficient because it misses the essential features of the larger environment. First, it tends not to take into account how different doctrinal bodies of law interact with each other: why, for example, the tax treatment of the depreciation of property purchased with borrowed capital inclines parties to adopt a limited partnership mode of doing business. Second, it tends to miss the real institutional flavor, as private deals constantly butt heads with local land-use planning boards, whose decisions are in turn subject to constitutional challenges for both procedural and substantive reasons. One cannot do such complex interactive work without knowledge of both doctrine and institutions. But that sensible point is not so much an objection as it is an observation: we teach contracts, property, and torts first, and then only after that do we teach the interactive disciplines. However, as a matter of scholarship, we do not have to follow that strict lexical order. Rather, intellectually, scholars move on all fronts simultaneously, and rely on a market division of labor to decide which person adopts what academic strategy on what question. There is, in short, no need for one national agenda to organize research in any discipline.

These observations about real estate markets apply with equal, if not greater, force to health care. Once again, any analyst must know the basic building blocks before attempting to unpack the integrative mysteries of the field. But, as with land use, health care law can allow for—indeed require—multiple approaches, whereby each scholar brings the distinctive skills that he or she possesses to the table. Those who are doctrinal in orientation can look at particular issues of health care through the lens of the case law—the study of medical malpractice can be understood as a conflict between contract and tort approaches<sup>12</sup>—or it can be asked how the doctrine of proximate causation

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10. See, e.g., Richard A. Epstein, *SIMPLE RULES FOR A COMPLEX WORLD* (1995).

11. See Friedrich Hayek, *The Uses of Knowledge in Society*, 35 *AM. ECON. REV.* 519, 524–26 (1945).

12. I have long stood in favor of the contract approach. See Richard A. Epstein, *Medical Malpractice: The Case for Contract*, 1 *AM. B. FOUND. RES. J.* 87, 94–96 (1976) (calling for “greater respect for private initiative and control” in medical malpractice law).

applies to medical injuries. But this hardly exhausts the relevant set of questions, which also includes inquiries into the way in which tort law interacts with the direct schemes of regulation for patient care that are either adopted internally by hospitals and practice groups or imposed externally by licensing systems and direct regulation of medical care. Studying the pieces without understanding the whole cannot solve all these problems.<sup>13</sup>

The force of these general observations is borne out by the range of topics included in this Symposium. An important example is the Supreme Court's recent blockbuster decision in *Massachusetts v. EPA*,<sup>14</sup> which addresses complex issues related to global warming.<sup>15</sup> The problem itself requires an understanding of multiple fields, from climatology to administrative law. The question of pollution has since the earliest times been the target of the law of nuisance, both public and private. As early as 1536, common law courts had to figure out where the private right of action left off and where the direct form of administrative remedy took over.<sup>16</sup> It is well understood that tort remedies function fitfully at best in a situation where the sources of pollution are manifold and its targets are spread across the globe.<sup>17</sup> No lawyer could hope to determine the impact that various precautions will have on overall warming relative to their cost by looking solely at doctrinal categories without some critical understanding of the underlying science. The problem has, moreover, clear public health implications, for, if temperatures change, then the mix of flora and fauna will change in consequence.<sup>18</sup> Tropical diseases will spread north into populations ill-equipped to handle them. Averaging out the pluses and minuses from any shift presents daunting challenges, but, in the end, the one model that will not work for understanding these problems is the austere model that looks solely at the doctrinal issues at hand.

Apart from these global externalities, of increased urgency nowadays, a second issue that concerns access to health care is the distribution of health care resources both within and across legal systems. In a limited sense, it is always

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13. See Kathryn Zeiler, *Turning from Damage Caps to Information Disclosure: An Alternative to Tort Reform*, 5 YALE J. HEALTH POL'Y L. & ETHICS 385, 398 (2005) (concluding holistic understanding of medical law necessary because "patchwork" reforms may have negative effects on health care markets).

14. 127 S. Ct. 1438 (2007).

15. Brief of Petitioners, *Mass. v. EPA*, 127 S. Ct. 1438 (2007) (No. 05-1120).

16. Anonymous, Y.B. 27 Hen. 8, fol. 27, Mich., pl. 10 (1536), reprinted in RICHARD A. EPSTEIN, *CASES AND MATERIALS ON TORTS* 639, 639-40 (8th ed. 2004).

17. Cf. Arnold W. Reitze, Jr., *A Century of Air Pollution Control Law: What's Worked; What's Failed; What Might Work*, 21 ENVTL. L. 1549, 1564-65, 1567-69 (1991) (arguing that damages from tort actions will be neither large enough nor paid frequently enough to influence the behavior of polluters).

18. See Chris D. Thomas et al., *Extinction Risk from Climate Change*, 427 NATURE 145, 146 (2004) (projecting effects of climate change on plant and animal populations).

proper to say that health care is special.<sup>19</sup> One must recognize that people of all political persuasions will be comfortable with greater disparities in wealth or luxury goods than in health care, which is why the redistributive impulse is strongest in this area whether one speaks of private charity or government intervention. On this issue, I believe that it is quite proper to favor a larger private and a smaller public effort on the simple ground that people who dole out their own money are likely to take greater care to see that it is well spent, so that \$1 in private aid is likely, at a guess, to go further than \$10 in public support. But these issues raise the same type of questions as before. The resolution of difficult empirical issues depends on an appreciation not only of particular doctrines, but of the interactive doctrinal and institutional framework. Thus on the major substantive issues, the O'Neill Center can beat back any criticism that treats its formation as wholly misguided. There are no external or structural limitations on what it can, with hard work and good leadership, achieve.

## I. AUTONOMY IN LIFE AND IN MEDICINE

Now that I have broached the topics of externalities and access, I shall also address a third theme in the health care debate that generates a fair amount of attention. It is the question of the role of autonomy in dealing with health care issues. I will show how tackling this issue requires the successful interaction of the conceptual and institutional considerations I noted above. Here it is wise to start with a conceptual analysis of autonomy to show, however briefly, the institutional pressures that have led to an unfortunate transformation of its meaning: a transformation that accounts in large measure for an unwelcome expansion of the role of government in dealing with health care issues.

### A. AGGRESSION AND AUTONOMY

The choice of definition is crucial for the ultimate shape of the legal doctrine. As I understand the principle of autonomy, it is a principle of self-rule or self-determination whereby each person is regarded as the sole and exclusive owner of his or her own person. In its initial sense, there is some temptation to say that the ability of self-rule means that each person should be able to do whatever he or she wills with his or her own body. Yet a moment's reflection should show that this position is clearly overwrought and is in need of serious modification, both within the health care arena and beyond it.

The initial problem with this unrefined conception is that it does not distinguish between aggression and autonomy. The belief in self-rule should never be allowed to create a system which allows each person to disregard the consequences of his or her actions on other people. Killing, stealing, and maiming

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19. For the ways in which it is not, see Richard A. Epstein, *Why Is Health Care Special?*, 40 U. KAN. L. REV. 307, 324 (1992), suggesting, for example, that health care is not special because it is subject to the "laws of economics."

may be expressions of individual will, but they are surely limited by the autonomy claims of other individuals who seek to resist these various incursions. One way to understand this point helps put the battle over definitions in perspective: let us assume that as a first approximation each person is entitled to do with his or her own person whatever he sees fit, so that there are no constraints on human behavior in, as it were, the state of nature. Liberty and license are, in this state of the world, the same. The ability of the strongest to prevail over the weakest creates political instability that in the end works to the benefit of no one. As a political matter, the easiest way to resolve this instability is to reject the state of nature that would be created even if the correct definition of individual autonomy allowed for unlimited aggression. Our reasons here are both intuitive and instrumental: making this definition of autonomy the linchpin of our system would lead to consequences that no one would care to champion. The refusal to accept this definition shows, I think, that all of us are at bottom closet consequentialists. We may speak of autonomy as though it were a self-evident good, but then we reject any conception of autonomy that exposes everyone to perpetual conflict.

At this point there is a fork in the road, and fortunately, in practice it does not matter which path we take. The first approach is to embed our consequentialist judgments into the definition of autonomy, and claim that the unbridled use of one's natural faculties is not what we mean by autonomy at all. Autonomy just means the ability to use one's body and one's own natural faculties in ways that do not infringe on the autonomy, or the like liberty, of others. Liberty and license are not the same thing after all. The second approach does not tarry over the battle of definitions, and simply applies the good social contract logic. Even if the first definition of autonomy came down on tablets at Mt. Sinai, we can do better if all individuals agree to abandon it.<sup>20</sup> The key move is to accept a mutual renunciation of force whereby, reciprocally, each respects the like bodily integrity of others. It is a testament to the extent of the social gains from this approach that we do not so much as pause when considering this shift, but instead just denounce the no-holds-barred definition of autonomy as a linguistic mistake.

This bit of social contract theory has its own hypothetical element. Perforce, it recognizes that an infinite set of voluntary exchanges among unrelated individuals could never yield the desired result. Hence the ideal solution is imposed from without on the ground that the mutual cessation of force yields a higher level of welfare than people can achieve uniformly if social institutions had to respect our prior definition of autonomy. In fact, we are so confident that this new state of the world is better than the old one, that in common discourse we simply suppress the initial definition and start with this revised definition that recognizes limitations on our ability to deal with others. Of course, we

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20. For a discussion of how these two definitions interact, see Richard A. Epstein, *Liberty Versus Property? Cracks in the Foundations of Copyright Law*, 42 SAN DIEGO L. REV. 1 (2005).

recognize that individual autonomy under this revised definition need not be the final resting place for social deliberation. Claims of individual autonomy do not rule out all forms of taxation, especially if the surrender of some degree of autonomous social control allows us to be more secure in our person. But here is not the place to dwell on those complications.<sup>21</sup> Without question there is no rational person—hence the appeal of rational choice theory—who prefers the initial definition of autonomy to the revised version. Everyone understands at a gut level that introducing some measure of interpersonal security advances the cause of individual liberty.

#### B. TWO COMPONENTS OF AUTONOMY: REJECTION VERSUS ACCEPTANCE OF TREATMENT

As should be evident, this revised account of autonomy gives much stronger weight to defensive autonomy, whereby no one is able to invade the space of another person without his consent:

Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages . . . . This is true, except in cases of emergency where the patient is unconscious, and where it is necessary to operate before consent can be obtained.<sup>22</sup>

This phrase, “right to determine what shall be done with his own body,” contains two different components, which in fact receive quite different treatments in the law, and it is critical to break them apart. The first part, and the focal point of Cardozo’s remarks, is the right to *reject* treatment directed to improve one’s health: the law of battery usually punishes the physician who invades the patient’s body without consent. In this regard, autonomous decisions receive extensive protection as the organizing principle of health care law. The autonomy principle sets up a barrier to the forced treatment by strangers, even if actuated by the noblest of motives. You may persuade me that I should accept a certain treatment, but you cannot compel me to take it against my own better, or even worse, judgment. There are of course cases, as noted, dealing with emergency situations, when this autonomy principle has to be overridden for the benefit of the patient who does not have the capacity to accept or reject treatment. The principle here is an old one, where the autonomy principle is set aside in those cases where high transactions costs block all voluntary transactions, even those needed life-or-death transactions, which well-nigh uniformly work to the advantage of the sick or injured party.

This compromise with the autonomy principle, however, takes place with

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21. For my approach to them, see Richard A. Epstein, *One Step Beyond Nozick's Minimal State: The Role of Forced Exchanges in Political Theory*, 22 *SOC. PHIL. & POL'Y* 286 (2005).

22. See *Schloendorff v. Soc'y of N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914).

genuine reluctance, for the first effort is to find some family proxy to make the decision rather than to entrust it to the physician or other health care provider in the first instance. The simple explanation is that any conflicts of interest are likely to be less acute if one spouse takes care of another, or if parents take care of children, than if physicians are empowered in the first instance to make these judgments. There is a larger community of interest within families, so that proxy consent is likely to prove more reliable, on average.

This ability to reject treatment operates in modest tension with claims for modest paternalism on the ground that health, not autonomy, is the paramount social end.<sup>23</sup> The paternalism argument in this context says that claims of autonomy should be limited by a concern for the health of the individual. After all, there are other cases in which the state requires people to do such things as wear seatbelts or helmets on public highways. Nonetheless these are not clear cases of paternal regulation. The state is the owner of the highway and its motivations may not be paternalistic if it imposes these restrictions so as to protect other highway users from the heavy expense of tort litigation. Alternatively, these measures might be defended as a means to reduce the need for public funds to take care of serious head injuries, since the state should be allowed to reduce the probability of occurrence of those adverse outcomes against which it is now required to insure. There is certainly some element of truth in these last two arguments, but at the same time, it would be hard to gainsay the modest level of paternalism associated with helmet and seatbelt regulation. But note that while they may condition the ability of an individual to engage in certain activities on public roads, these regulations are far less intrusive than the physical invasions associated with surgery. Cases of compulsory vaccination—which raise difficult issues—are not quite paternalistic because they could easily be justified to prevent the spread of harm to others on some principle of herd immunity: vaccinate too small a fraction of the population and everyone could get sick.<sup>24</sup> In this way, coercion is used to control the free riders. So at root the principle in *Schloendorff* holds fast in the cases to which it was originally directed. We do not accept paternalist overrides to individual choices in dealing with individual invasive procedures.

In general, the use of defensive autonomy in medical areas seems to be the

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23. See E-mail from Lawrence O. Gostin, Associate Dean, Linda D. and Timothy J. O'Neill Professor of Global Health Law, Georgetown University Law Center, to author (July 2, 2007) (on file with author) ("It is true that both forms of defensive autonomy [acceptance and rejection of treatment] are self-regarding, but it does not take account of arguments for paternalism. When the state requires people to wear seatbelts or helmets . . . it is technically imposing a state requirement on an unwilling individual, even though the real harm is to oneself . . . [H]ealth may be primary, or at least equally important in the balance.").

24. On the constitutionality of these programs, see *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), which was not quite a compulsory vaccination statute because the payment required for noncompliance was \$5.00. For my commentary on the case, see Richard A. Epstein, *In Defense of the "Old" Public Health: The Legal Framework for the Regulation of Public Health*, 69 *BROOK. L. REV.* 1421, 1452–55 (2004).

first priority. But it can be objected that excessive attention to autonomy necessarily compromises the valid social interest in the good health of all members of society. In practice, the tension between these two objectives is more apparent than real, for we are likely to get better medical outcomes by (collectively) allowing individuals to make self-regarding decisions than by forcing them to take into account the welfare of other individuals, even those close to them. Ordinary people are sufficiently socialized that they do not make their treatment decisions in a vacuum. They will take into account family consequences even if they will not take into account the welfare of people with whom they do not have close attachments, and even in this context, improved health for individuals will have systematic positive consequences for unrelated persons. Legal autonomy does not translate into social isolation. It only allows the autonomous individual to choose on whom to rely in making decisions.

One manifestation of this right to reject treatment is the rise of the doctrine of informed consent over the past forty years.<sup>25</sup> Prior to that time, it was common for physicians to elicit from patients some sense of their preferences before making key medical choices for patients. But today the locus of decision-making power has shifted, so that it lies with the patient to obtain the medical information to guide his or her preferences on what procedures to adopt, what risks to accept, and what pain to endure in the face of medical adversity. The implication is that the consent to treatment is negated if the information needed to provide consent is not complete, such that (with some doctrinal complications) unwanted surgical treatment becomes an assault.<sup>26</sup> The rule itself is best understood as a sticky default rule because individuals can waive the right to make that choice by making clear their intention to abide by the treatment choices of their physicians.<sup>27</sup> The hard question in most of these circumstances is what kinds of informed consent individuals must have to waive, as it were, the physician's duty to disclose, for there is little question that waiver forms are routinely attacked, with, as one might expect, mixed results.<sup>28</sup>

In dealing with this form of individual autonomy, however, the largest challenge to the informed consent doctrine lies in applying it to patients of limited competence. No one routinely doubts the individual competence of ordinary people as they go about their daily business of buying food, renting apartments, or going on vacation. The intrusive nature of any government intervention is enormous and the likelihood that it will generate any positive

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25. For general discussion, see *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

26. See, for discussion of this issue, and the rival negligence theories, *id.* at 787–92. For a more modern account, extending the disclosure duty to chiropractors, see *Hannemann v. Boyson*, 698 N.W.2d 714 (Wis. 2005).

27. For a discussion of the limitations on a patient's ability to waive his or her right to informed consent, see Donald G. Hagman, *The Medical Patient's Right To Know: Report on a Medical-Legal-Ethical, Empirical Study*, 17 UCLA L. REV. 758, 785 (1970).

28. For example, the waiver form was overridden in *Obstetrics & Gynecologists Ltd. v. Pepper*, 693 P.2d 1259 (Nev. 1985), but was accepted in *Hoofnel v. Segal*, 199 S.W.3d 147, 150–51 (Ky. 2006).

return is slight. But that robust presumption of individual competence is untenable in many medical settings, where individuals with diminished physical strength and mental acuity are called upon to make some of the most difficult choices of their lives. Satisfying informational demands is no easy matter. Ironically, our social commitment to defensive autonomy is strongest when that principle is most likely to fail.

The issues of competence also loom large with the second side of individual autonomy, namely the right to *accept* risky medical treatments. As a first approximation, one should think that the two questions were opposite sides of the same coin. If so, then the individuals who have a well-nigh absolute right to turn treatment away should have the similar right to accept it if they think, all told, that the risks in question are worth running in light of the benefits that they hope to obtain. To be sure, the same duties of informed consent could easily carry over to this second context, which leaves individuals in the position to make an authoritative choice, but only after they consider the relevant information. As before, there could well be a resort to family proxies in those cases where the individual is too young, too old, or too infirm to make the necessary decisions.

To my mind, the two-way toggle on individual autonomy makes good sense in medical contexts. We are no longer worried about the prospect that individuals will be conscripted into medical trials against their will. But by the same token, it is surely a big deal to tell individuals that treatments they wish to undergo are to be denied to them on the ground that someone else thinks that it is unwise for them to undergo these treatments. Nonetheless, the single most conspicuous feature about the right to *accept* treatment is that it is now, everywhere, hedged in by administrative procedures that look on first—and second—view to be consistent with the principle of individual self-determination that lies behind the autonomy rule. The position was clearly stated, but not defended, by George Annas: “Patients in the United States have always had a right to refuse any medical treatment, but we have never had a right to demand mistreatment, inappropriate treatment, or even investigational or experimental interventions.”<sup>29</sup> Annas’s remarks were made in an explicit constitutional context, which I shall discuss presently, but wholly apart from the Constitution, there is a large policy debate on the question of whether the right to refuse and the right to receive medical treatment should be treated as two sides of the same coin, as I believe, or as two different coins, as Annas asserts.

To understand this bifurcation on the autonomy issue, it is necessary to place the issue in some larger perspective. This autonomy right is closely tied with the usual conceptions that people have of freedom of association, by which is meant not only the right not to associate with those whom you choose not to, but also the right to associate with those with whom you choose to. I am aware of no

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29. George J. Annas, *Cancer and the Constitution—Choice at Life’s End*, 357 *NEW ENG. J. MED.* 408, 410 (2007).

strong theory of freedom that treats either half of the right as sufficient without regard to the other. To be sure, the claims for freedom of association may be overcome in some contexts by competing social considerations, most of which involve the asserted monopoly power of public utilities who are under a correlative duty to supply standardized services to all comers within the service area at “reasonable and nondiscriminatory prices.”<sup>30</sup> However, those complexities do not come to bear on health treatment cases, so the question remains: why should one half of the autonomy claim be unfettered while the other is wholly subject to constraints of regulation? Nonetheless, the distinction between patients’ rights to *accept* treatment or *reject* it is the mainstay of the modern American law that shapes the role of the Food and Drug Administration (FDA). This distinction also affects the role of Institutional Review Boards (IRBs). I shall be brief, for I have written about these issues in greater detail elsewhere.<sup>31</sup>

*The FDA.* Let me start with the FDA because of its extensive power. Under current American law, no individual is entitled to use any drug for treatment unless it has been approved by the FDA for sale and distribution.<sup>32</sup> As the rule is currently stated, we live in a kind of limbo. Once the drug is released to the market for one purpose, it may be used on the market for any other purpose for which it has *not* received FDA approval because the FDA is generally said not to have the power to regulate the practice of medicine.<sup>33</sup> The governing statute, the Federal Food, Drug, and Cosmetic Act, provides that the FDA has no authority to “limit or interfere with the authority of a health care practitioner to prescribe” any medication that has received FDA approval in the ordinary course of the physician-patient relationship.<sup>34</sup> These so-called “off-label” uses are extremely common, especially in high-risk situations, such as the treatment of advanced cancers.<sup>35</sup> The system for use under the FDA requires a particular drug to go through exhaustive clinical trials before it is released to the market at all.<sup>36</sup> The method of analysis is said by many to be a form of “evidence-based”

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30. See Richard A. Epstein, *Takings, Commons, and Associations: Why the Telecommunications Act of 1996 Misfired*, 22 YALE J. ON REG. 315, 337–39 (2005).

31. See Richard A. Epstein, *Defanging IRBs: Replacing Coercion with Information*, 101 NW. U. L. REV. 735 (2007) [hereinafter Epstein, *Defanging*]; Richard A. Epstein, *Regulatory Paternalism in the Market for Drugs: Lessons from Vioxx and Celebrex*, 5 YALE J. HEALTH POL’Y L. & ETHICS 741 (2005).

32. See 21 U.S.C. § 355(a) (2000).

33. See William L. Christopher, *Off-Label Drug Prescription: Filling the Regulatory Vacuum*, 48 FOOD & DRUG L.J. 247, 248 n.6, 250–54 (1993).

34. 21 U.S.C. § 396 (2000).

35. See generally Sandra H. Johnson, *Polluting Medical Judgment? False Assumptions in the Pursuit of False Claims for Off-Label Prescribing*, 9 MINN. J. L. SCI. & TECH. (forthcoming) (manuscript at 1, available at <http://ssrn.com/abstract=999418>) (“Some estimates, however, indicate that over half of the prescription medications provided to patients in the U.S. may be prescribed for a purpose, in a higher or lower dose, over a longer period of time, or for a population (such as children) different from that for which the drug has been approved.”).

36. See 21 U.S.C. § 355(d) (2000), which in speaking of the evidence needed to secure drug approval, states:

medicine,<sup>37</sup> which is quite in vogue in the FDA.<sup>38</sup> The analysis is supposed to weigh the costs and benefits of the proposed drug or medical device and then make an informed decision on behalf of the public, whose members the FDA is under a fiduciary duty to protect.<sup>39</sup> The praise that is heaped on clinical trials as a means to ferret out the truth about drug use is widespread. In his critical review of my book, *Overdose*,<sup>40</sup> Arnold Relman writes:

Clinical trials were a major contribution to the development of modern medicine. They changed the basis for the use of drugs from something akin to hearsay and witchcraft to something much closer to science. They made possible most of the advances in drug therapy that have revolutionized the treatment of so many diseases over the past half-century.<sup>41</sup>

But once the drug reaches the market, the law allows the physician to prescribe the drug for these off-label uses, yet by the same token prohibits the drug company from promoting the drug for that illegal purpose, and, more critically, from warning about any negative side effects, lest the warning be understood as an implied authorization for use of the drug in question. The FDA in its own pronouncements justifies this position by offering the following reasons:

Permitting Sponsors to Promote Off-Label Uses: Would diminish or eliminate incentive to study the use and obtain definitive data[;] Could result in harm to patients from unstudied uses that actually lead to bad results, or that are merely ineffective[;] Would diminish the use of evidence-based medicine[;] [C]ould ultimately erode the efficacy standard.<sup>42</sup>

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(d) the term ‘substantial evidence’ means evidence consisting of adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved, on the basis of which it could fairly and responsibly be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

37. David L. Sackett et. al., *Evidence Based Medicine: What It Is and What It Isn't*, 312 BRIT. MED. J. 71, 71 (1996). “Evidence based medicine is the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” *Id.*

38. See generally U.S. FOOD & DRUG ADMIN., GUIDANCE FOR INDUSTRY AND FDA: INTERIM EVIDENCE-BASED RANKING SYSTEM FOR SCIENTIFIC DATA (2003), available at <http://www.cfsan.fda.gov/dms/hclmgu4.html>.

39. U.S. FOOD & DRUG ADMIN., MANAGING THE RISKS FROM MEDICAL PRODUCT USE: CREATING A RISK MANAGEMENT FRAMEWORK 16, 20–21, 23–24 (1999), available at <http://www.fda.gov/oc/tfrm/riskmanagement.pdf>.

40. RICHARD A. EPSTEIN, *OVERDOSE* (2006).

41. See Arnold S. Relman, *To Lose Trust, Every Day*, NEW REPUBLIC, July 23, 2007, at 36, 40 (book review).

42. Reasons for FDA Policies on Off-Label Uses, <http://www.fda.gov/cder/present/diamontreal/regappr/tsld006.htm> (last visited Aug. 21, 2007).

It is of course very difficult to get any systematic evidence on either the cost or benefit side of these off-label uses, given that they operate in a legal gray zone. But we do know something about the logic that leads to their extensive use, which explains the collision course between the immediate need for individual choice and the languid processes required by evidence-based medicine. Physicians in the field who have patients with terminal conditions do not have the luxury of waiting for definitive clinical tests to make their decisions today. By the time these results come out, the patient could easily be dead. So physicians do the rational thing, which is to be aware of all the risks that the FDA mentions, and then seek to find that treatment cost, based on information known at the time, which has the highest expected value. Their particular choices are not meant, nor should they be construed, to be an attack on clinical trials as such. We can assume that clinical trials supply better information, and that the same people who opt for off-label uses take into account the information that is available from clinical trials. Yet by the same token, we should realize that information that is better in principle is not available to everyone, so that choices have to be made without delay on the strength of the available evidence.

Faced with these immovable constraints, what physicians do daily is to extrapolate from known to unknown situations by making intelligent guesses. If a given drug works well for a breast cancer, it may be tried on a colon cancer for which it has not been approved, so long as there looks to be some cellular or chemical similarity between the two types of tumors. What is there to lose by taking this risk when other known measures have already failed? In essence, individual physicians build on what is already known and hope that their decisions have a positive expected value for their patients. In so doing, they act how surgeons, who operate largely out of the FDA orbit, have acted for decades, bringing with their decentralized innovation a wealth of advances that parallel (if they do not exceed) those made with drugs. Quite simply, here, necessity is the mother of invention, so trained professionals work by improvisation and intuition only to try to rationalize their behavior later. It is important to understand that, whether we look at the issue from the point of view of health or autonomy, the people in the field have it right. The demands of evidence-based medicine instruct physicians and patients alike to do *nothing* unless the evidence crosses a high bar. There is no reason to believe that this approach, which demands passivity in the face of risk, maximizes the expected value to a patient under uncertainty. Rather, by making the best the enemy of the good, it holds that all increases in expected value that are less than the threshold must be disregarded.

At the same time, the FDA's apparent hope that its nonpromotion norm will induce companies to conduct clinical trials is a pipe dream. In practice, I have heard of only one such study being undertaken, involving the drug Neurontin, which did seek and obtain FDA approval for its use in treating shingles, in part because it was able to gain access to the off-label market (which, ironically,

many of the advocates for further clinical trials want to restrict).<sup>43</sup> But the conditions that make this happen are not likely to occur frequently. From the point of view of a pharmaceutical company, what is there to be gained by running a battery of trials that will cost millions to perform? At best, it only confirms that the drug could be taken. At worst, the test might not be definitive enough and the FDA will use its high standards to block its usage—a point on which the law is surely unclear. And once the trial is run, the drug is likely to have little or no remaining exclusive patent life. Thus, generic substitutes will be able to capture too much of the market for the enterprise to be worthwhile without some very strong new patent protection, which is difficult to achieve with respect to specific uses of compounds already in the public domain.

Of equal importance is the question of what patients would enroll in a trial if offered. The physician will say that the drug has, to his or her best knowledge, a higher expected value than any other treatment. To go into the clinical trial, even if one is just about to start, is to reduce the chances of getting the condition by, say, fifty percent, where the alternative is a therapy that is known not to work—assuming that the trial would take place in time to allow for participation. And in most cases, these trials are closed or subject to enrollment delays, so that numerous trials are of limited value at best.<sup>44</sup> Hence, the expected outcome is to see the informal methods of information dissemination take over relative to the formal ones for drugs on the market. One consequence of this is to make it more unlikely that drug companies will fund the costs of clinical trials for new drugs. Patients that have more off-label uses to choose from will on average be less willing to participate in the trials. There is no doubt that the gold standard of evidence-based medicine is in danger of unraveling. The hard question is whether this development is a bad thing. My own sense is probably not: thousands of physicians are not likely to be wrong in their individual willingness to try these therapies on patients, who in the exercise of their individual autonomy, choose to run the appropriate risks, notwithstanding the real dangers of incompetence and even possible fraud.

In light of these observations, I draw the inference that the FDA should ease its controls on the initial use of the product and encourage the further sharing of information in order to help speed up the process whereby more and better drugs are brought into the market. Stated otherwise, the existence of this off-label market is, to me, strong evidence that the entire system of direct regulation is misguided from its inception. Except in extreme cases—in other

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43. My thanks to Sandra Johnson for the reference. For the site, see About Pain After Shingles, [http://www.neurontin.com/pain\\_after\\_shingles/](http://www.neurontin.com/pain_after_shingles/) (last visited Aug. 21, 2007). For an argument against expanding off-label usage, see generally J. Boos, Editorial, *Off Label Use—Label Off Use?*, 14 ANNALS ONCOLOGY 1 (2003).

44. Linda Marsa, *Clinical Trials Are Suffering; Suspicious of Medical Research, Volunteers Spurn Tests of Possibly Lifesaving Advances*, L.A. TIMES, Dec. 2, 2002, pt. 6, at 1 (noting that “[i]n 2001, 86% of all clinical trials didn’t meet enrollment goals, causing delays of up to a year, up from 80% in 1999”).

words, with drugs that offer benefits to no one—the FDA should get out of the banning business and stay in the warning business. The former requires it to make judgments about risks and benefits in a global fashion, without knowledge of the circumstances in individual cases. Everyone knows that absolute safety is unattainable, and that side effects, sometimes known and sometimes not, are an inevitable by-product of potent drugs. Just where the risks turn too high as opposed to too low is something of a mystery—one which is not likely to be solved by the FDA, which is under its own pressures to filter out drugs with visible dangers, even if it means blocking drugs that have great promise.

Warnings work better than bans in large part because the FDA, fortunately, does not have a monopoly over what information can be offered by whom. Many of the critical questions on drug use are those which concern unanticipated drug interactions, most of which are reported on private sites that operate independently of the FDA.<sup>45</sup> This private market for information arises precisely because the information is so valuable and because there is a lack of confidence in official FDA publications, which on occasion require warnings so severe that one wonders who should be so foolish to take any drug at all.

There are, however, situations where this approach is not possible—namely, those cases where a desired experimental treatment requires the use of a drug that has *not* reached the market for any use. In these circumstances, the question is often whether the FDA will in its wisdom grant a compassionate use exemption for certain people in dire straits. Simply putting the question into this form shows just how deeply and powerfully the government has inserted itself into the lives of ordinary citizens regarding their life and death decisions. Citizens, as autonomous individuals, should be free to make these decisions for themselves. It is, therefore, worthwhile to note that the decision of the Court of Appeals for the District of Columbia in *Abigail Alliance v. Eschenbach*<sup>46</sup> has placed this issue in the constitutional crosshairs and has provoked, to say the least, a powerful reaction by the champions of the FDA-dominated system of drug approval.<sup>47</sup>

In *Abigail Alliance*, the Alliance sought to enjoin the FDA from continuing to enforce its policy barring the sale of new drugs that the FDA had determined, after Phase I trials on human beings, were sufficiently safe for more extensive human testing.<sup>48</sup> In the opening round of the case, Judge Rogers, with Judge Ginsburg in tow, held over the dissent of Judge Griffith that any individual who is in a desperate state has a constitutional right to obtain an experimental drug

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45. Typing “drug interactions” into Google yields multiple sites, including [www.drugdigest.org](http://www.drugdigest.org) and [www.drugs.com](http://www.drugs.com).

46. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc*, 495 F.3d 695 (D.C. Cir. 2007).

47. See *Abigail Alliance*, 445 F.3d at 486–91 (Griffith, J., dissenting) (expressing arguments in favor of FDA regulation).

48. *Id.* at 472 (majority opinion).

that has passed Phase I clinical trials.<sup>49</sup> The argument took the form that an individual has a “liberty” interest under the Due Process Clause of the Fifth Amendment that is protected against government intrusion and can only be limited to advance a narrowly tailored compelling government interest in health and safety.<sup>50</sup> Clearly, Judge Rogers used this language intentionally to subject the FDA’s power to strict judicial scrutiny. Her opinion surveys all the cases that found “fundamental liberty interests” that receive Due Process protection.<sup>51</sup> Yet Judge Rogers’s opinion denying rehearing in the case is even clearer. It concludes with a quotation of the language from *Schloendorff*, referred to above, that these cases now rise from common law to constitutional status.<sup>52</sup>

There are obvious difficulties with this constitutional argument, given the huge deference that our Supreme Court has traditionally given to (at least some) legislative and administrative judgments on matters pertaining to health and safety—including decisions of the FDA. Indeed, the panel decision was not long for this world; for when the case was heard en banc, Judge Griffith prevailed, as the rest of the D.C. Circuit agreed that the individual liberty interest was not strong enough to carry the day, leaving Judges Rogers and Ginsburg as the lone dissenters.<sup>53</sup> For Griffith, the point of departure was the earlier Supreme Court decision in *Washington v. Glucksberg*,<sup>54</sup> where the

49. *Id.* at 486.

50. *See id.*

51. *See id.* at 475–87.

52. Judge Rogers states:

In a long line of cases, we have held that, in addition to the specific freedoms protected by the Bill of Rights, the “liberty” specially protected by the Due Process Clause includes the rights to marry, to have children, to direct the education and upbringing of one’s children, to marital privacy, to use contraception, to bodily integrity, and to abortion. We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment.

We see no reason to retreat from the analysis set forth in *Abigail Alliance* [445 F.3d 470]. Alliance members who are terminally ill and who lack government-approved treatment options have a due process interest in self-determination that protects their pursuit of promising new medications to save their lives.

. . . As their lives hang in the balance, they ask “that the decision to assume . . . known or unknown risks be left to the terminally ill patient and not to the FDA.” So described, this right to self-determination is so fundamental that it is no wonder that no federal law has needed to articulate its precise boundaries. A unanimous declaration sent to England’s King George III more than two centuries ago noted that the “unalienable Rights” of “Life, Liberty and the pursuit of Happiness” were “self-evident.” Justice Cardozo found no difficulty applying this principle in the celebrated case of [*Schloendorff*], where he noted that “[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body.”

*Abigail Alliance*, 469 F.3d at 136–37 (citations omitted). The analysis is the same whether these interests are protected under the Fifth Amendment (against the federal government) or the Fourteenth Amendment (against the states).

53. *Abigail Alliance for Better Access to Developmental Drugs v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc).

54. 521 U.S. 702 (1997). See also the companion case of *Vacco v. Quill*, 521 U.S. 793, 807–09 (1997).

Supreme Court offered this test for what counts as a liberty interest:

[W]e have regularly observed that the Due Process Clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed. Second, we have required in substantive-due-process cases a careful description of the asserted fundamental liberty interest.<sup>55</sup>

To Griffith, all the asserted analogies based on self-defense, private necessity, and rescue were quite beside the point, which in a sense they are, as the autonomy interest in these cases covers only a small part of the complex doctrine that has emerged fitfully in all these cases. When set against the inexorable expansion of the FDA's powers over the past century, it is hard to make these cases go under law. For example, the Supreme Court's 1979 decision that sustained the FDA's ability to ban laetrile was decided strictly on statutory grounds and did not contain the words "due process" or "liberty."<sup>56</sup> That tradition continued here as Judge Griffith concluded: "Our Nation's history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology, and are entitled to deference in doing so."<sup>57</sup> But, in a sense, he gave the game away when he cites as his authority for this proposition, the confused opinion of Justice Harlan in *Jacobson v. Massachusetts*,<sup>58</sup> which dealt with the question of compulsory vaccination, where the question of contagious diseases, wholly absent here, lurks in the background. There is much, then, to be said for the Rogers en banc dissent, which accused the court of confusing the question of whether there is a strong liberty interest—a matter Rogers regarded as simple—with the subsequent question of whether there was some state justification for limiting its exercise.<sup>59</sup>

All of this is water over the dam unless, which I regard as unlikely, the Supreme Court will once again enter the fray. If it showed not the slightest bit of concern for the plight of individuals who were denied medical marijuana in *Gonzales v. Raich*,<sup>60</sup> it is unlikely to draw attention to itself here. Nonetheless, this renewed celebration of state power should be met with a certain degree of regret. The autonomy interests loom much larger in the medical context, for example, than they do in matters of self-defense, where the rights of other

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55. *Glucksberg*, 521 U.S. at 720–21 (citations and internal quotation marks omitted).

56. "The Federal Food, Drug, and Cosmetic Act makes no special provision for drugs used to treat terminally ill patients. By its terms, § 505 of the Act requires premarketing approval for 'any new drug' unless it is intended solely for investigative use or is exempt under one of the Act's grandfather provisions." *United States v. Rutherford*, 442 U.S. 544, 551 (1979).

57. *Abigail Alliance*, 495 F.3d at 713.

58. 197 U.S. 11, 30 (1905).

59. *Abigail Alliance*, 495 F.3d at 714 (Rogers, J., dissenting).

60. 545 U.S. 1 (2005), duly cited in *Abigail Alliance*, 445 F.3d at 493.

individuals are necessarily involved. Writing before the en banc decision, George Annas suggested that the matter is controlled by the flat refusal of the Supreme Court to allow the autonomy argument to support the case for assisted suicide.<sup>61</sup> That is an aggressive reading of cases that can be distinguished on the ground that the state interest in the prevention of suicide or homicide (whether or not murder) is a lot stronger than the state's right to prevent people from using whatever means at their disposal to protect, not end, their own life. In the end, therefore, a good libertarian, like me, has no difficulty in sustaining the constitutional challenge to the FDA's authority.

Unfortunately, libertarian views are not in vogue on either the left or right of the constitutional spectrum these days, so the long history of FDA regulation has given it immunity against any and all constitutional attack. The defeat for autonomy claims in *Abigail Alliance* does not end, the debate, for the political and philosophical debate is not resolved by a constitutional decision that has deference written all over it. Right now, the debate will not end for the Alliance has renewed its call to liberalize the FDA's approach on this point, free of all constitutional complications.<sup>62</sup> For these purposes, I shall assume the constitutional issue has died an undeserved death and concentrate on the substantive merits of the reform proposal that has been proposed and embodied in the form of Senate Bill 1956,<sup>63</sup> which has as its major function the liberalization of the rules allowing access to drugs within clinical trial. As is par for the course, the bill does not simply state that any person can take any drug at any time so long as he is warned of the risk. Rather, the compromise position offers expedited access for drugs in clinical trials, but only to those patients who have "exhausted all treatment options approved . . . for the condition or the disease."<sup>64</sup> In essence, the autonomy claim is allowed to prevail only after some stringent test for necessity is first met. Hence, in these cases, the statute would allow for limited approval by looking at "preliminary evidence that the product may be effective" and by resorting to "case histories, information about the pharmacological mechanism of action, data from animal and computer models, comparison with historical data, or other preliminary information."<sup>65</sup> Thereafter Tier II approval will turn on the presentation of data that shows that the drug "has an effect on a clinical endpoint or on a surrogate endpoint or biomarker that is reasonably likely to predict clinical benefit."<sup>66</sup> Greater distribution of drugs is then allowed under Tier III for drugs that meet existing regulations.

It is clear that the structure of this bill is meant to compromise between the

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61. Annas, *supra* note 29, at 410; *see also* Washington v. Glucksberg, 521 U.S. 702 (1997); *Vacco v. Quill*, 521 U.S. 793 (1997).

62. Ronald L. Trowbridge & Steven Walker, *The FDA's Deadly Track Record*, WALL ST. J., Aug. 14, 2007, at A17 (urging passage of legislation now before Congress).

63. S. 1956, 109th Cong. (2005).

64. *Id.* at 7.

65. *Id.* at 4-5.

66. *Id.* at 9.

demands for individual access and the demands for public protection. Ironically, it gives less choice to the individual patient than the rule announced in *Abigail Alliance*, and thus, by virtue of its proposed moderation, will be pummeled from both sides. As might be expected, the division of opinion concerning this bill is profound.<sup>67</sup> The experts in clinical trials adhere passionately to the scientific model of evidence-based medicine. They point out with great energy and specific examples the high risks associated with this treatment, making the claim that a rush to legalize drugs that have passed Phase I clinical trials is likely to do more harm than good. They continue to insist that the controlled randomized trials should be the gold standard for clinical work.<sup>68</sup>

In making these strong claims, however, it looks as though they have not made a controlled randomized analysis of their own work. It is easy to point to particular cases in which a fuller trial has indicated the imprudence of resorting to certain kinds of therapies. But a fuller analysis would also have to include those cases in which the gold-standard approach *confirmed* the informal field judgment but nonetheless delayed the delivery of the treatment to the market. It would also have to examine the level of acceptance of any treatment exposed by randomized trials. It really matters whether the treatment in question received enthusiastic or cautious endorsement before the fuller information came out. All of this is *not* to urge a *ban* on clinical trials. It is instead a reminder that all methodologies have their own shortfalls, such that it becomes a mistake to dwell on the error of false positives to the exclusion of false negatives.

In addition, the opponents of the new legislation are uneasy that individual patients will be required to sign waivers for liability and to pay for the drugs in question as the *quid pro quo* for obtaining use of experimental treatments as a matter of right. I regard this objection as close to frivolous, for the conditions are wholly acceptable. The use of waivers should be the rule across the board in all drug cases because the freedom of contract regime is the only one that can cope with the necessary risk of experimental treatments. Also, the opponents of the legislation believe that the new legislation will invite the use of new therapies whose risks clearly outweigh their benefits and will frustrate the operation of clinical trials by leading individuals to circumvent the overall process in favor of direct access to the experimental drugs of their choice.<sup>69</sup> Let me turn briefly to both points.

First, I have no doubts that most experimental treatments will fail and some will turn out to be harmful. That is the nature of drug innovation. But the question to ask is whether this objection ought to be dispositive. For a variety of

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67. Compare Susan Okie, *Access Before Approval—A Right To Take Experimental Drugs?*, 355 N. ENG. J. MED. 437, 437–40 (2006), with Society for Clinical Trials Board of Directors, *The Society for Clinical Trials Opposes US Legislation To Permit Marketing of Unproven Medical Therapies for Seriously Ill Patients*, 3 CLINICAL TRIALS 154 (2006) [hereinafter Society for Clinical Trials].

68. Society for Clinical Trials, *supra* note 67, at 154. The Society for Clinical Trials opposes U.S. legislation, like S. 1956, that permits marketing of unproven medical therapies for seriously ill patients.

69. See Okie, *supra* note 67, at 437.

reasons, the answer to that question is no. The first point is to ask, what is lost by an erroneous decision to take a useless or harmful drug? In most of these instances, the answer is very little because the patient's expected life is short in any event. Yet by the same token, if the drug is successful the upside gain (for people with very bad conditions) is much more substantial than the downside, so the expected value calculations are not all that obvious. A high probability of a small loss is not necessarily greater or smaller than a low probability of a great gain. In addition, the choice to use any toxic chemical is never made by patients alone, and the information supplied by physicians could improve the odds even if it does not supply the information that could be derived from a completed clinical trial—when this patient could already be dead. The difficulty, therefore, with the establishment opposition to the proposed initiative is that it is too confident on its answer to the question: what is the expected value of experimental treatment? The difficulty of these calculations should remind us once again to focus on the *prior* question raised by the autonomy issue: *who* should decide whether it is worth running the high risks of experimental treatment in the absence of reliable, or even definitive, clinical trials?

The second objection to the autonomy-based version of choice posits the existence of an important prisoner's dilemma game. The argument here is that all patients are better off as a group if the randomized clinical trial is performed, which cannot happen if individual defection from the clinical trial system is allowed as a matter of right. There is always some force to collective action arguments for the provision of public goods. But we should be aware of the limited appeal of these collective action arguments. In this context, there is surely nothing that compels any one to join a clinical trial, even if there is no alternative treatment. Yet if the prisoner dilemma argument were persuasive, then participation for the greater good could certainly be required. The usual answer to that question is that you could perhaps pay individuals either in cash or in kind to participate in these studies. However, compulsion is not an attractive option because the autonomy principle continues to demonstrate real traction when the rejection of treatment is an issue. If so, then cutting off nonparticipation alternatives that would otherwise be available smacks of a second-tier form of compulsion that should be greeted with some suspicion. Finally, it is worth noting that Abigail Burroughs (whose father founded the Alliance) was not even eligible for participation in the basic clinical trial because she had presented the right form of tumor in the wrong place.<sup>70</sup> Clearly, any concern with the integrity of clinical trials should never place limitations on those persons who are not allowed to participate in them. I conclude, therefore, that the monolithic establishment may well be right on cautioning about the

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70. Sue Kovach, *The Abigail Alliance: Motivated by Tragic Circumstances, Families Battle an Uncaring Bureaucracy*, LIFE EXTENSION, Sept. 2007, at 25, 26–27 (2007), available at <http://abigail-alliance.org/LEMSEP07pAbigailLR.pdf>. Though the drug at issue, Erbitux, was thought to be an effective treatment for the squamous cell carcinoma of the neck and lungs from which Abigail Burroughs suffered, the relevant clinical trial was open only to colon cancer patients. *Id.* at 27.

need to encourage participation in these trials, but that it is wrong to assume that state compulsion should be used to limit personal choice. The autonomy rights should be afforded the same level of respect in cases that request treatment as those which reject it. Even if health is the ostensible end, there is no reason to think that the FDA can calculate the odds better than individual patients armed with physician advice.

## II. INSTITUTIONAL REVIEW BOARDS

The debate over experimental treatment is now being fought out in a second forum, which deals with the status of Institutional Review Boards. These are boards that are internal to various research institutions, and their mission is to supply an adequate set of reviews to see that experimental studies undertaken within the home institution meet sufficient standards of human protection.<sup>71</sup> In one sense, these IRBs look consistent with the general ideal of individual autonomy. Broadly understood, that principle not only allows individual patients to decide whether to accept or reject medical treatment, but it also allows physicians and their home institutions to decide whether to offer or decline to offer the treatment or regimen in question. In effect, the principle of autonomy is not unique to medical decisions by patients but sets the boundary lines for all human interaction, within and across firms as well.

Nonetheless, the model of universal autonomy does not clearly apply to IRBs because their use is often driven by federal regulation that is partly connected to the provision of grant money for the conduct of research.<sup>72</sup> There is also a real sense that IRBs are put into place in order to resist the dangers of potential tort actions because the principle of freedom of contract often does not supply a strong (or even any) defense for the medical institution if its behaviors are challenged in court in the event of an adverse outcome. I shall not dwell on these two points here, although they are of immense importance, but shall instead make one simple point about how the manipulation of the principle of individual autonomy helps speed the path toward greater government regulation.

I refer here to the *Belmont Commission Report*.<sup>73</sup> This report, which has had immense influence in the field, is a remarkable document which starts off with a paean to individual autonomy. Yet by the time it is finished, it ends up with paving the way for the creation of centralized planning boards with complete

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71. See 21 C.F.R. § 56.111 (2006).

72. See 21 C.F.R. § 56.120 (2006).

73. NAT'L COMM'N FOR THE PROT. OF HUMAN SUBJECTS OF BIOMEDICAL & BEHAVIORAL RESEARCH, THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (1979), available at <http://ohsr.od.nih.gov/guidelines/belmont.html> [hereinafter BELMONT REPORT]. The title comes from the name of the conference center at which the relevant deliberations were held. For the influential predecessor, see generally Henry K. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966).

authority to make decisions on what studies may be conducted and how.<sup>74</sup> No one today can offer or participate in a study that does not meet IRB guidelines. The key question to ask is how the *Report* makes its amazing u-turn. It does so in a number of ways. The first step is legitimate: the *Report* notes that autonomy is not an ideal device when compromised by imperfect information. “In most cases of research involving human subjects, respect for persons *demand*s that subjects enter into the research voluntarily and with adequate information.”<sup>75</sup> The sensible response to this problem is to generate more information, not to hinder both researchers and patients with additional procedural obstacles on choice. Unfortunately, the *Belmont Report* chooses the latter approach. The *Report* invokes an off-kilter account of individual beneficence to bridge the gap: “beneficence . . . cover[s] acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (1) do not harm and (2) maximize possible benefits and minimize possible harms.”<sup>76</sup> Note the fatal shift. The first definition of “active goodness” or benevolence, acting from a good will, is all that any dictionary definition will tolerate.<sup>77</sup> But in the *Report* beneficence includes the ability to make decisions for others by means of a cost/benefit analysis and deprive individuals of the right to make it for themselves.

This switch in the meaning of beneficence thus gives rise to the opening wedge for the creation of these IRBs, which tend to develop the same behavioral characteristics as the FDA. Their incentive is to avoid visible failures that could bring discredit to the institution. They do not feel the same heat from any losses that occur from the failure to endorse the research. Their private interest, which is at cross-currents with the social one, is to slow down the pace of work lest any mistake be made that could reflect badly on the home institution. The level of intrusion has given rise to howls of deserved protest insofar as the IRBs have themselves intruded into various social science forms of research.<sup>78</sup> The

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74. In describing its “basic ethical principles,” the *Report* states that individuals should be treated as autonomous agents; however, the report goes on to argue that the FDA should endorse guidelines for institutional review boards that grant them broad powers to evaluate research in terms of informed consent, risks vs. benefits, and selection of subjects. *Id.* The report does not in so many words talk about centralized planning, but the understated recommendation that one of its charges was to “develop guidelines which should be followed to ensure research is conducted in accordance” with basic ethical principles,” has had just this effect. No one can choose to participate in a research program that has not received IRB approval.

75. BELMONT REPORT, *supra* note 73 (emphasis added). I add the emphasis to showing the creeping authoritarian nature of the *Report*.

76. *Id.*

77. See, e.g., FUNK & WAGNALLS, NEW COMPREHENSIVE INTERNATIONAL DICTIONARY OF THE ENGLISH LANGUAGE 130 (encyclopedic ed. 1982).

78. The most vocal leader has been Philip Hamburger. See Philip Hamburger, *Getting Permission*, 101 NW. U. L. REV. 405 (2007); Philip Hamburger, *The New Censorship: Institutional Review Boards*, 2004 SUP. CT. REV. 271.

issue is in closer equipoise with respect to the biological sciences where the informational gaps are more acute. But the level of institutional coercion has still gone too far, which has led me to suggest that we adopt a different approach to the matter, which is to use the IRB process as a bulletin board, not a barricade.<sup>79</sup> The IRB can demand any scientist to report on their activities. Once that information is supplied, the IRB has, say, ninety days on which to comment on the proposal. Both the proposal and the comments are then placed on a web site for open commentary, to which the IRB can contribute, after which the program can go forward with full protection as modified. Information is the right antidote to lack of information. The shift in power to third parties shows once again that individual autonomy has been effectively blocked when it comes to the acceptance of medical forms of treatment. The same excessive devotion to paternalism in the face of incompetence, and the same insistence for evidence-based medicine in the face of genuine uncertainties, has led to excessive control over cutting edge research.

#### CONCLUSION

I hope that the arguments contained in this Essay have proved one point: any study of health issues must combine the analytical with the empirical. When that is done it should yield the familiar conclusion, which is that excessive regulation, not under-regulation, poses the greatest threats to the modern provision of health care. It may seem odd to reflect on a point that seems to be the truth. In many cases the choice of remedy is at least as important as the identification of the grounds for government intervention. In this regard, it should be clear that I part company with the FDA and the many defenders of evidence-based science. They go for the ban. I go for the warning. The difference is palpable. The former transfers power to the state. The latter keeps it in the hands of the individual, where the principle of individual autonomy rightly places it. The people who are competent enough to reject treatment are competent enough to accept it.

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79. See Epstein, *Defanging*, *supra* note 31.