A View from the Trenches

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I have spent the past two years representing the plaintiffs in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, and so it will surprise no one that I agree with Professor Hill's bottom-line conclusions—that there is a fundamental right to make medical treatment decisions free from unwarranted state interference, that the Supreme Court has already recognized that right on several occasions, and that the jurisprudence in this area is nonetheless quite seriously confused and inconsistent. For example: the Supreme Court has recognized that even fairly healthy patients have a fundamental right to refuse life-sustaining treatment (including nutrition and hydration) and die, despite our society's strong preference that they instead choose to live. The D.C. Circuit held in *Abigail Alliance* that a terminally ill patient with no other options has no right to make the opposite choice: to assume some risks and possible suffering in a good-faith effort to fight for his life by the only means available. As Professor Hill notes, five Justices appeared to assume in *Washington v. Glucksberg*[1] that the Due Process Clause may protect a right to palliative pain treatment, even if it might shorten the patient's life. The D.C. Circuit held in *Abigail Alliance* that there is no right to *potentially life-saving* medical treatment, precisely because the FDA fears the treatment might instead shorten the patient's life. And, finally, a woman dying on an operating table has a settled fundamental right to have her doctor administer medical treatment believed to be necessary to save her life but that is otherwise unlawful—if that treatment happens to be a late-term abortion. The D.C. Circuit has now held that she has no such right if the treatment is an investigational cancer vaccine that could harm no one but (possibly) herself. My own view is that the law cannot possibly remain in this state; it turns the traditional values that the Due Process Clause is supposed to reflect upside down.

Since recounting the many issues on which I agree with Professor Hill would make for a dull Comment, I'd like to highlight two potentially significant points on which I disagree. First, I think the article does not take seriously enough the potential distinction between laws genuinely protecting the *public* health and those invading purely private medical decisions. Of course Professor Hill's project is largely descriptive, and it is certainly true

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1. 521 U.S. 702 (1997).

that the modern cases she discusses do not take such distinctions seriously either. The Tenth Circuit in *Rutherford v. United States*[2] saw little if any difference between the plaintiff who refused smallpox vaccination in *Jacobson v. Massachusetts*[3] and terminally ill patients who simply wanted to take Laetrile. But I do not take Professor Hill's project to be *purely* descriptive, and I think the difference is apparent, or at least ought to be, despite what the modern courts have (thus far) said.

As Professor Hill explains, *Jacobson* essentially affirmed an application of the common law police power. And the classic articulation of that power from the nineteenth-century cases and treatises is that it permits the state to constrain the liberty of individuals so far as necessary to permit a like enjoyment of liberty by others.[4]

That is essentially an articulation of John Stuart Mill's principle that state power can be employed only to prevent harm to others. As a genuine statement of the common law, Mill's principle is, of course, overstated. It seems particularly so to modern audiences, which (given how preoccupied constitutional law has been with sexual conduct in our time) tend to associate Mill's harm principle with a repudiation of traditional morals legislation. But prior to the twentieth century, morals offenses *were* generally regarded as inflicting a kind of public harm or offense against the community.[5] And even if the harm principle breaks down as an accurate guide to traditional law in the area of morals legislation, that does not necessarily make it worthless or incoherent *outside* of that somewhat unique context. When it comes to purely paternalistic legislation that involves neither traditional morality nor attempts to "adjust[] the benefits and burdens of economic life"[6] (now off-limits to constitutional law by consensus because of *Lochner*), I see no reason not to take seriously the language in the old cases limiting the police

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2. 616 F.2d 455 (10th Cir. 1980).

3. 197 U.S. 11 (1905).

4. *See, e.g.*, CHRISTOPHER G. TIEDEMAN, A TREATISE ON THE LIMITATIONS OF THE POLICE POWER IN THE UNITED STATES 1–2 (St. Louis, F.H. Thomas Law Book Co. 1886) ("The conservation of private rights is attained by the imposition of a wholesome restraint upon their exercise, such a restraint as will prevent the infliction of injury upon others in the enjoyment of them. . . . The power of the government to enforce this restraint is called police power."); *id.* at 4 ("Any law which goes beyond that principle, which undertakes to abolish rights, the exercise of which does not involve an infringement of the rights of others, or to limit the exercise of rights beyond what is necessary to provide for the public welfare and the general security, cannot be included in the police power of government."); THOMAS M. COOLEY, A TREATISE ON THE CONSTITUTIONAL LIMITATIONS WHICH REST UPON THE LEGISLATIVE POWER OF THE UNITED STATES OF THE AMERICAN UNION 572 (Boston, Little, Brown, and Co. 1868) (noting that the police power permits regulation "to preserve the public order and to prevent offenses against the State, but also to . . . insure to each the uninterrupted enjoyment of his own so far as it is reasonably consistent with a like enjoyment of rights by others").

5. *See, e.g.*, COOLEY, *supra* note 4, at 596 ("The preservation of the public morals is peculiarly subject to legislative supervision . . . .").

6. Penn Cent. Transp. Co. v. City of New York, 438 U.S. 104, 124 (1978).

power to laws that protect *the public*. As Professor Hill notes in a footnote, Tiedeman's treatise articulates a right to autonomy in *private* medical treatment decisions whenever "reputable and intelligent members of the profession disagree"[7] that is strikingly similar to what the Supreme Court articulated in *Stenberg v. Carhart*[8] more than a century later.

I therefore cannot agree with Professor Hill's brief assertion that "[m]ost likely, the concepts of externalities, public good, and harm to others are ultimately far too vague and malleable to be of much help in explaining the two separate lines of cases."[9] Of course in skilled hands all distinctions can be bent somewhat. But the difference between *Jacobson* and *Abigail Alliance* is, I submit, safe from even the most skillful sophistry. The plaintiff in *Jacobson* claimed a right to refuse vaccination from the most contagious and lethal disease in human history. His refusal, if permitted on any kind of scale, could have doomed many of his fellow citizens to death. The Supreme Court in *Jacobson* thus correctly invoked the "principle of self-defense" and "paramount necessity."[10] Following Blackstone, the Framers called the natural right of self-preservation "the first law of nature," and in a real sense the community in *Jacobson* was exercising its right of self-preservation against a grave external threat.[11]

In *Abigail Alliance*, by contrast, the issue is whether terminally ill patients (generally cancer patients) that have exhausted all the remaining approved treatment options will be allowed to take investigational medications that the FDA itself has approved for substantial human clinical trials. Unlike in *Jacobson*, the right of self-defense or self-preservation cuts only the patient's way. I therefore think there is a very profitable distinction to be drawn between legislation that genuinely relates to the "public health" or "public welfare," in the sense that the old common law police power cases actually meant, and legislation that denies individual freedom in medical treatment decisions for reasons that can only be understood as paternalistic. It is hard to prove up such a distinction by reference to the results of the old cases (although their rhetoric is supportive) because eighteenth- and nineteenth-century legislatures simply did not invade medical freedom on paternalistic grounds. Before the Food, Drug, and Cosmetic Act in 1938, the

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7. TIEDEMAN, *supra* note 4, at 205.

8. 530 U.S. 914 (2000).

9. B. Jessie Hill, *The Constitutional Right to Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEXAS L. REV. 277, 327 (2007).

10. *Jacobson*, 197 U.S. at 27.

11. *See, e.g.*, Samuel Adams, *The Rights of the Colonists: The Report of the Committee of Correspondence to the Boston Town Meeting*, 7 OLD SOUTH LEAFLETS 417 (No. 173) (Burt Franklin 1970) (1772) ("Among the natural rights of the Colonists are these: First, a right to life; Secondly, to liberty; Thirdly, to property; together with the right to support and defend them in the best manner they can. These are evident branches of, rather than deductions from, the duty of self-preservation, commonly called the first law of nature.").

only drug regulation in the United States was concerned with adulteration—i.e., ensuring that the contents of a preparation were fully and accurately labeled so that doctors and patients could be sure of what they had.[12] And the modern cases generally do not grapple with such distinctions because we have become overly comfortable (at least in some areas) with the idea that government is entitled to protect people from themselves. But the distinction nonetheless makes a lot of sense, and I don't think it is nearly as "vague" or "malleable" as Professor Hill suggests.[13]

Even if the distinction does prove malleable, and in practice permits more of what might otherwise appear to be purely paternalistic interference than I now suspect, I believe the exercise of forcing the government to articulate truly public justifications for interfering with private medical decisions would be very interesting and productive. Sometimes they will be transparently flimsy. And sometimes those attempts at a non-paternalistic explanation will reveal motivations that we simply are not prepared to accept as legitimate. If readers will forgive a digression, I believe *Abigail Alliance* illustrates both points. The only genuine *public health* justification the government has offered in *Abigail Alliance* is that if drugs currently in Phase 2 or Phase 3 clinical trials are made more widely available then enrollment in clinical trials may suffer. But the plaintiffs in *Abigail Alliance* have repeatedly conceded that the right they seek would apply only to patients who are unable to participate in the trials. And in any event the number of patients dying of cancer every year (approximately 500,000) completely dwarfs the number of available spots in clinical trials. Abigail Alliance was formed to advocate for patients who fought hard for the few and coveted spots in cancer trials, so to deny them access on the accusation that they are somehow trying to avoid the trials is simply Orwellian. Even if in particular cases there could be problems with cheating or patients making themselves deliberately ineligible, surely narrowly tailored regulations could be crafted to address those issues.

Although the FDA and most of its apologists (like Susan Okie, whom Professor Hill cites on this point) are too savvy to admit it explicitly, their real fear is that terminally ill patients given access to Phase 2 or Phase 3 drugs could be dissuaded from signing up to take *even more-untested and potentially dangerous drugs still at Phase 1*. The American Society of Clinical Oncology put this particular potato squarely on the fork in an amicus brief:

> The individuals for whom the Abigail Alliance purports to advocate—terminally ill patients without treatment options—are

12. *See, e.g.*, COOLEY, *supra* note 4, at 595 (acknowledging that the police power extends to "the sale of poisonous drugs, *unless labeled*").

13. Hill, *supra* note 9, at 327.

> precisely the sort of patients who would be good candidates for a Phase I trial. But the fact that some degree of regulatory approval is accorded a post-phase I drug may make it a more attractive alternative than participation in the next phase I trial, where the actual treatment to be received may be somewhat uncertain.[14]

To my way of thinking that is chillingly unethical. At a minimum it proves the need for heightened scrutiny in these cases. The FDA cannot plausibly contend that it is necessary to sacrifice an individual patient's best chance at life to further the progress of science, and at the same time, that its decisions do not involve fundamental rights.

My second friendly disagreement with Professor Hill relates to her assumption that the basic question in this area is whether to trust judges or legislatures on issues of medical or scientific fact. She concludes that "legislatures are particularly ill suited"[15] to such questions and that judicial deference "may be inappropriate when pure questions of medical and scientific fact are involved."[16] I don't disagree, and that is a reasonable framing of the issues at stake in the two *Carhart* "partial-birth abortion" cases. But I think she misapprehends where the real action is likely to be in coming years and where the realistic opportunities for judicial resistance to government interference with medicine really lie.

First of all, the disputes between the patients and the government in these cases are not always just, or even principally, about scientific questions. As Professor Hill notes at the very end of her article, the FDA's official position on the treatments at issue in *Abigail Alliance* is that the scientific evidence for both safety and efficacy is inconclusive—but is promising enough that substantial human trials are justified and ethical, and that the patients who enroll in those trials can sensibly give informed consent. Beyond that, the FDA is sensibly agnostic. And so, for the most part, are the patients and their doctors. There are sometimes genuine scientific disagreements, and sometimes the FDA is just looking at a different scientific question than the individuals. (The early evidence for Erbitux in head and neck cancer, which Abigail had, was extremely promising—but at that point the FDA, and the trials, were simply focused on the much more numerous colon-cancer patients). But at least as often the real disagreement is not over how to interpret the evidence from a particular clinical trial, but instead over what that uncertainty means in the context of the life and treatment of a particular individual patient. That is often largely a philosophical question, not a medical or scientific one. Are the last days of a person's life

14. Brief for the American Society of Clinical Oncology et al. as *Amici Curiae* in Support of Appellees at 19, *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc) (No. 04-5350).

15. Hill, *supra* note 9, at 282.

16. *Id.* at 329.

better spent in perhaps painful struggle against nearly impossible odds, but with the conviction that she is doing everything possible? Or is it instead better or more noble to accept one's fate and spend the final days saying goodbye? In his concurrence in *Washington v. Glucksberg*,[17] Justice Stevens quoted a passage from Ronald Dworkin's book *Life's Dominion* that I think captures the right response to such questions perfectly: "Whether it is in someone's best interests that his life end in one way rather than another depends on so much else that is special about him—about the shape and character of his life and his own sense of his integrity and critical interests—that no uniform collective decision can possibly hope to serve everyone even decently."[18]

Understood that way, the real issue in cases like *Abigail Alliance* is not whether to trust judges or legislators on issues of medical fact, but instead whether to trust patients or government officials about how much risk it makes sense for a particular patient to take—or, put differently, whether to trust judges or legislators on where to draw the line between autonomy and paternalism in the face of scientific uncertainty. Professor Hill seems to regard "values judgments" like these as a particularly legislative prerogative.[19] My own view is that in areas as personal and profoundly important as medical treatment, such judgments are fair game for constitutional law. Despite the present enthusiasm for majoritarianism, the whole point of constitutional rights (and of substantive due process in particular) was supposed to be defining and protecting a sphere of private liberty that is immune from legislative interference.

Professor Hill's juxtaposition of judicial and legislative competencies also largely ignores a third possibility, which looms large in this area. The vast majority of interference with private medical decisions in our society is perpetrated by the Food and Drug Administration, and while the agency operates under congressional charter its substantive decisions are not really attributable to the particular competencies of Congress. Truly legislative findings of medical fact are extremely rare events, and tend to happen only in contexts (like "partial-birth" abortion, the Terri Schiavo fiasco, or the Controlled Substances Act) that are particularly highly charged politically. Professor Hill is surely right to assume that a justifiable suspicion of Congress's "findings" about intact D&X abortion explains in part the Court's reluctance to defer to those findings in the *Carhart* cases. As Professor Hill notes, the FDA's independence from politics can be overstated; its long refusal to approve RU-486, for example, is impossible to understand except in political terms. But at least in most cases the agency's motives are not transparently partisan.

17. 521 U.S. 702, 747 (1997).

18. RONALD DWORKIN, LIFE'S DOMINION 213 (1993).

19. Hill, *supra* note 9, at 334.

If there is a wave of litigation coming over the right to autonomy in medical treatment decisions (Professor Hill's formulation) or "medical self-defense" (Professor Volokh's), it is therefore likely to involve a perceived clash of competencies between the courts and the FDA, not Congress or state legislatures. And an independent and nominally "expert" agency can plausibly claim some of the particular competencies that Professor Hill ascribes to both judges and legislators. Certainly I think judges are going to be very reluctant to second-guess the FDA's statistical evaluation of the results of particular clinical trials, which is one of the reasons that we framed the *Abigail Alliance* case to essentially accept all of the FDA's scientific judgments and instead challenge its resolution of the fundamental *values* questions noted above.

I think that if patients are going to win the kinds of cases that Professor Hill envisions, they are going to have to break past judges' initial inclination to defer to the FDA on scientific questions. Doing so will be far harder than it was in the *Carhart* cases because judges will not suspect ulterior political motives. But in my opinion close scrutiny of the FDA's actual scientific competence is both appropriate and essential. Courts are accustomed to speaking of "expert" agencies in the context of *Chevron* deference. It certainly is fair to assume that Congress trusts the competence of agencies that it has entrusted with the administration of particular programs, and since *Chevron* is all about statutory interpretation, that inference about what Congress probably would have wanted is more or less a show-stopper. But when the issue becomes the *constitutional* rights of an individual, the supposedly "expert" status of the agency ought to be proved, not presumed. And the FDA's own Science Board recently issued a report that concluded: (1) "the Agency suffers from serious scientific deficiencies and is not positioned to meet current or emerging regulatory responsibilities";[20] (2) "[w]hile the world of drug discovery and development has undergone revolutionary change—shifting from cellular to molecular and gene-based approaches—FDA's evaluation methods have remained largely unchanged over the last half century";[21] and (3) "[r]apid changes in biological sciences and bioinformatics are exceeding the capacity of current FDA science capabilities to keep pace and adequately support the Agency's safety mission."[22] As science races into a new era of genetic and personalized medicine, the flaws and limitations of the decade-long multi-phase clinical trial process the FDA has demanded for the past half-century will become increasingly apparent, and the fiction that the FDA represents the pinnacle of medical understanding will further unravel. I believe we will see increasing stridency from patients

20. SCIENCE AND TECHNOLOGY SUBCOMMITTEE OF THE FDA SCIENCE BOARD, FDA SCIENCE AND MISSION AT RISK 2 (2007).

21. *Id.* at 3.

22. *Id.* at 24.

who are unwilling to allow unaccountable and congenitally cautious FDA bureaucrats to determine the course of their own medical care.

I think constitutional law has a role to play in that confrontation if Congress continues to sit on the sidelines—although of course I wish that Congress would stop abdicating its own proper role in the protection of constitutional rights to the courts. It is, frankly, untenable and shocking that constitutional law currently grants far greater protection to an individual's choice between various abortion methods than to an individual's right to decide for herself whether to fight for her own life on the frontiers of modern science when no other options remain. I cited Professor Hill's article to the Supreme Court in the certiorari petition in *Abigail Alliance*, including her observation that the Court's precedents suffer from a "glaring doctrinal inconsistency."[23] Apparently the Court is not yet ready to resolve that inconsistency because it recently denied review. But cases like *Abigail Alliance* have been bubbling up regularly ever since the FDA was first given authority to interfere with private medical treatment decisions and will continue to do so until the Court resolves these obvious tensions.

23. Hill, *supra* note 9, at 283.