

2009

Constitutional Flaw?

Carl E. Schneider

University of Michigan Law School, carlschn@umich.edu

Available at: <https://repository.law.umich.edu/articles/1952>

Follow this and additional works at: <https://repository.law.umich.edu/articles>

 Part of the [Constitutional Law Commons](#), [Food and Drug Law Commons](#), and the [Health Law and Policy Commons](#)

Recommended Citation

Schneider, Carl E. "Constitutional Flaw?" *Hastings Center Rep.* 39, no. 4 (2009): 9-10

This Response or Comment is brought to you for free and open access by the Faculty Scholarship at University of Michigan Law School Scholarship Repository. It has been accepted for inclusion in Articles by an authorized administrator of University of Michigan Law School Scholarship Repository. For more information, please contact mlaw.repository@umich.edu.

Constitutional Flaw?

by Carl E. Schneider

Do terminally ill patients have a constitutional right “to decide, without FDA interference, whether to assume the risks of using potentially life-saving investigational drugs that the FDA has yet to approve for commercial marketing, but that the FDA has determined, after Phase I clinical human trials, are safe enough for further testing”? In *Abigail Alliance for Better Access to Developmental Drugs v. McClellan*, the United States District Court for the District of Columbia said “no.”¹ In *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, a panel (three judges) of the United States Court of Appeals for the District of Columbia Circuit said “yes” (with one dissent).² But when the full appeals court reconsidered the panel’s decision, it said “no” (with two dissents).³

Where in the Constitution might such a right be found? If anywhere, in the fifth amendment’s due process clause: “No person shall be . . . deprived of life, liberty, or property, without due process of law.” This clause might seem only to impose *procedural* limits on how the government may take your life, liberty, or property. Nevertheless, twice in American history the Supreme Court has believed that the clause imposes *substantive* as well as procedural limits—that the clause limits *what* government may do as well as *how* it may do it.

The first period of “substantive due process” was the opening decades of the twentieth century, when the Court announced a person’s right “to his person-

al liberty, . . . to enter into those contracts . . . which may seem to him appropriate.” For example, New York sought to protect bakers’ lungs by forbidding their employers to make them work more than sixty hours a week. The Court thought the statute “an unreasonable, unnecessary, and arbitrary interference with the right of the individual to his personal liberty” because bakers are “equal in intelligence and capacity to men in other trades” and can “assert their rights and care for themselves without the protecting arm of the state, interfering with their independence of judgment and of action. They are in no sense wards of the state.”⁴

The second period of substantive due process began roughly with *Roe v. Wade* and continues today.⁵ The scope of today’s clause is cloudy and controversial, but on one view it embodies a right to make important intimate decisions, like choices about abortion, contraception, marrying, and raising children.

Both versions of substantive due process protect individual autonomy as contemporaneously understood. But most law limits someone’s autonomy in some way. Is most law really made unconstitutional by this expansive interpretation of the due process clause?

Of course not. For one thing, government may infringe any constitutional right with adequate justification. As Justice Holmes famously said, “The most stringent protection of free speech would not protect a man falsely shouting fire in a theater and causing a panic.” But infringements of constitu-

tional rights must generally meet a forbidding standard of justification. Can the Court really subject all legislation to that high standard?

Of course not. So the Court (somewhat erratically) uses a sorting device. When the government infringes a “fundamental” right, it must meet an onerous standard of justification—the infringement must be “necessary” to serve a “compelling state interest.” Where the right is not fundamental, the government need only show that its infringement is “rationally related” to a “legitimate state interest.” These terms are marvelously vague, but they are almost (in the law’s cant) “outcome determinative.” In practice, the government can rarely show a compelling state interest and can almost always show a legitimate state interest.

What makes a right “fundamental”? In *Washington v. Glucksberg* (the assisted-suicide case), the Court said that first it “carefully” defines the right.⁶ Second, it asks whether the right is “‘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.’”

So is the *Abigail Alliance* right “fundamental”? The Food, Drug and Cosmetic Act requires that the FDA approve new drugs, ordinarily in three phases. “A Phase I study usually consists of twenty to eighty subjects and is ‘designed to determine the metabolism and pharmacologic actions of the [new] drug in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.’”⁷ The *Abigail Alliance*—“an organization of terminally ill patients and their supporters”—sought access to developmental drugs by making the constitutional claim we began with.

The appeals court (rather skeptically) “assume[d] *arguendo* that the Alliance’s description of its asserted right would satisfy *Glucksberg*’s ‘careful description’ requirement.” The court then addressed the Alliance’s “history and tradition” argument. First, it evaluated “the Alliance’s claim . . . that ‘common law and historical American practices have tradi-

tionally trusted individual doctors and their patients with almost complete autonomy to evaluate the efficacy of medical treatments.” The court said that even if drug *efficacy* had not historically been regulated, drug *safety* had been. Furthermore, in 1962 the FDCA was amended “to explicitly require that the FDA only approve drugs deemed effective,” and even before that “at least some drug regulation . . . addressed efficacy.”

The court then examined the Alliance’s argument that the FDCA is “inconsistent with the way that our legal tradition treats persons in all other life-threatening situations. . . . Specifically, the Alliance argues that three doctrines—(1) the doctrine of necessity; (2) the tort of intentional interference with rescue; and (3) the right to self-defense—each support the recognition of a right to self-preservation.” The court briskly found these (somewhat obscure) doctrines inapposite. In sum, the right the Alliance asserted was not “fundamental.”

Because the right was not fundamental, the FDA only had to meet the low standard of justification. No problem:

[P]rior to distribution of a drug outside of controlled studies, the Government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of such a drug. We therefore hold that the FDA’s policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.

The dissent was angry, even (by judicial standards) nasty. It contended that the “carefully defined” right was not the one the court had attributed to the Alliance but rather the right to attempt to preserve one’s own life. The dissent not only described a history and tradition of respecting that right; it almost implied that the “history and tradition” test was supererogatory because the right had a basis in the actual words of the Constitution, and indeed in the due process

clause itself: “No person shall be . . . deprived of *life*, liberty, or property, without due process of law.”

In some ways, the dissent has the better of the argument. It *is*

startling that the oft-limited rights to marry, to fornicate, to have children, to control the education and upbringing of children, to perform varied sexual acts in private, and to control one’s own body even if it results in one’s own death or the death of a fetus have all been deemed fundamental rights covered, although not always protected, by the Due Process Clause, but the right to try to save one’s life is left out in the cold despite its textual anchor in the right to life.

Furthermore, preventing patients from deciding what risks to take *is* hard to reconcile with the standard precept that patients have a right to evaluate medical risks for themselves.

Yet what should we make of a constitutional test which is so wondrously manipulable? For example, much turns on how broadly you define your right. The right of terminally ill people to (possibly) lifesaving drugs that have survived a phase I trial looks little like the kind of claim constitutions are written to secure, while the right to protect one’s life goes to the very reason governments are created. Similarly, a right to commit suicide crumbles against centuries of the canon ‘gainst self-slaughter, but a right to decide when your life is worth living resonates with much that makes us cherish autonomy. No wonder the *Abigail Alliance* majority said, “As such rights are not set forth in the language of the Constitution, the Supreme Court has cautioned against expanding the substantive rights protected by the Due Process Clause ‘because guideposts for responsible decisionmaking in this unchartered area are scarce and opened.’”

Whatever one thinks of this classic jurisprudential controversy, one should be relieved that the dissent lost. Had it prevailed, courts would have been launched into work dangerously beyond their competence. For instance, how can judges—who have little science and less

medicine—evaluate the FDA’s decisions about new drugs? As Rebecca Dresser observed in her acute analysis of the panel’s decision, that court’s understanding was

deficient in several ways. The majority seems to assume that most drugs that get through phase I testing will eventually be approved because their expected benefits will outweigh harms. The judges also seem to assume that phase I testing, which primarily examines safety, yields high-quality data on effectiveness. They seem to assume, too, that data from twenty to eighty people can supply sufficient evidence for patients and doctors to make informed decisions about new agents.⁸

This is not to say that the FDA’s rules for approving new drugs are ideal or even sound. A considerable and forceful literature criticizes them, and the FDA itself has proposed changes.⁹ But the best cure for regulatory error is rarely another layer of regulation. Balancing the risks against the benefits of approving a new drug quickly is an impossible job. If the FDA—with its expertise and experience—is getting it wrong, why would the United States District Court for the District of Columbia—with neither expertise nor experience nor, for that matter, useful constitutional guidance—do better?

1. 2004 WL 3777340 (2004).

2. 445 F3d 470 (2006). Both McClellan and von Eschenbach were sued in their capacity as FDA commissioners.

3. 495 F3d 695 (2007).

4. *Lochner v. New York*, 198 US 45 (1905).

5. 410 US 113 (1973).

6. 521 US 702 (1997).

7. All quotations are from the third *Abigail Alliance* decision unless otherwise identified.

8. R. Dresser, “Investigational Drugs and the Constitution,” *Hastings Center Report* 36, no. 6 (2006): 9-10.

9. *Expanded Access to Investigational Drugs for Treatment Use (FDA Proposed Rule)*, 71 Fed Reg 75147 (December 14, 2006).