

Controversial Medical Treatment and the Right to Health Care

BY JOHN A. ROBERTSON

People have long argued that health care is a basic right that the government is obligated to provide. Our constitutional system, however, is notoriously lax in recognizing positive rights to state-funded resources. As a result, health care coverage for the more than forty million uninsured remains hostage to politics and the political process.

A less sweeping approach would talk about health care as a negative right. A negative right to health care means the right of a patient and doctor to pursue a course of treatment of their choosing without interference by the government. While a far cry from a positive right to universal coverage, a negative right is not to be sneered at. Such a right anchors a woman's use of abortion and contraception, and underlies the great deference ordinarily accorded doctors and patients to pursue medical care. A negative right to health care may also play a role in disputes about access to new medical and alternative treatments.

Because conflicts over negative rights to health care have usually been settled in the policy or legislative arena, it is of more than passing interest that a prestigious fed-

eral appeals court has now staked out a role for the courts by holding that constitutional rights to life and liberty protect such rights.¹ Although such a right is not absolute and may be limited by compelling state interests, the constitutional principle recognized is a significant one. If upheld on appeal, the principle underlying *Abigail Alliance for Improved Access to Treatment v. von Eschenbach* will require the government to show that there is a substantial, narrowly tailored justification for restricting patient and physician choice about disputed therapies in many different areas, including access to new cancer drugs, embryonic stem cell therapies, and organ transplants.

Access to Drugs in Phase II Trials

The case arose out of a long campaign by several groups, including both free market business interests and patient advocates, to loosen the Food and Drug Administration's rules for approving new drugs. The steady drumbeat of criticism and the activist efforts of AIDS advocacy groups did lead in the late 1980s to major changes in FDA policy. There is now a fast-track procedure for drugs that show early promise and clear authority for compassionate use exceptions for phase III drugs.²

Yet this new flexibility has not quieted all attacks. The father of a young woman who had died from cancer after being denied access to the then-experimental cancer drug Erbitux founded the Abigail Alliance for Better Access to Developmental Drugs in memory of his daughter.³ Along with the Washington Legal Foundation, a conservative public interest law firm, it formally petitioned the FDA to allow cancer patients to use any drugs that had been approved for phase II clinical trials. When the petition was turned down, the two groups sued, claiming that FDA rules violated their constitutional right to health care.

The federal district court dismissed their complaint on the ground that there was no such right. In a novel move, the Court of Appeals for the District of Columbia, widely viewed as the most important court outside of the Supreme Court, reversed and remanded the case to the

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lower court to hear evidence as to whether the government could show a narrowly tailored, compelling need to deny cancer patients access outside a study to phase II drugs. The government has appealed the decision. While no final determination of the plaintiffs' claims is expected soon, the principle unleashed has potentially wide application in other areas of medicine. [See also Rebecca Dresser's discussion in *At Law*, in this issue, for further analysis of the case.]

Both liberals and conservatives have criticized the decision. Liberals dislike it because it appears to constrain the FDA from preventing unsafe, ineffective drugs from reaching the market, thus exposing end-stage cancer patients to exploitation by unscrupulous sellers.⁴ Judicial conservatives, on the other hand, decry the role of judges in invalidating legislation on the basis of an unspecified "right to life." Only free market conservatives and some cancer advocacy groups are pleased with the outcome.

Novel but Cogent

To evaluate the decision and its importance, we must first be clear about what the court has done and why. The right that the court recognized, while potentially broad in scope, is only a presumptive one. In practice its reach will depend on the strength of governmental interests to restrict patient access to phase I drugs. With the court unlikely to reach a final decision soon, sounding the death knell for safety and efficacy standards for approval of new drugs is premature.

Nor should we assume because of its novelty that the decision was not based on cogent reasoning from constitutional text and precedent. The Fifth and Fourteenth Amendments to the Constitution specifically protect against deprivation of "life . . . or liberty without due process of law." The Supreme Court has a long tradition of using those clauses to protect activities deemed fundamental to a person's life or identity. It has held that decisions of whether to bear or beget children, to marry, to raise a family, to refuse essential medical treatment, or to live with extended family members are so fundamental that they can be restricted only upon a showing of compelling need. But life itself and some minimum degree of health and functional ability are necessary for the exercise of any protected right. It would be strange if specific rights were protected, but not the more general negative right to life and health on which their exercise depends.⁵

Such a conclusion is also supported by a legal tradition of lawful self-defense and Supreme Court precedents about the importance of protecting life over claims to end it. The appeals court contrasted the long tradition of common law rights of self-defense and the use of another's property to save a life with more recent regulation of drugs and medical practice.⁶ It noted, for example, that the FDA's efficacy standards for marketing new drugs did not exist until the Kefauver amendments of 1962. Even now a physician may prescribe drugs "off-label" for uses for which the drugs have not been tested or approved.

Of special importance to the court's outcome were the Supreme Court decisions in the *Cruzan* and *Glucksberg* cases dealing with the limits of personal and family autonomy at the end of life. Both upheld the state's interest in protecting life as a reason for rejecting a family's decision to end life support on a vegetative patient in the former case, and rejecting a competent patient's right to assisted suicide in the latter. If the interest in extending life outweighs the interest in ending it, then extending life should also take precedence over automatic deferral to any regulatory action that shortens it.

Resistance to *Abigail Alliance* flows in part from misunderstanding the right at issue—for example, confusing it with a positive right to medical care, or not recognizing that the right is only presumptive and may be limited for compelling reasons. For judicial conservatives the decision is also controversial because it lacks a more specific provenance for the right articulated. Current debates over the role of judges in invalidating legislation turn on whether there is a need for evidence that the enactors intended to create the claimed right. One side thinks that deriving rights from basic principles, such as due process, is acceptable, while the other side harbors strong antipathy to such practices on both methodological and institutional grounds.

This divide is nicely captured in the majority and dissenting opinions in *Abigail Alliance*. Each draws on the standard arguments about the need for specificity in original intent versus the appropriateness of deriving rights from open-ended textual clauses. Each also draws on institutional arguments for permitting or limiting judicial review of legislation. While the majority held that courts may invalidate legislation that trenches on fundamental rights without adequate justification, the dissent believed that legislatures and agencies are better equipped institutionally than courts to supervise the regulation of medical and drug practice.

The *Abigail Alliance* decision was 2-1, and there is no guarantee that the current Supreme Court would uphold such a claim. In the meantime, lower courts will split on whether they recognize the presumptive negative right to medical care found in *Abigail Alliance*; and, if they do recognize it, on whether they will find the asserted state interests sufficiently compelling and closely tailored to justify the intrusion. Whatever the eventual outcome, *Abigail Alliance* will influence the tactics of groups battling over governmental regulation of controversial treatments. It will also make judges more active participants in resolving such disputes. The reach of the constitutional principle recognized in *Abigail* depends heavily on the facts, however. It will protect patient and physician choice in some areas, but perhaps in fewer areas than critics have thought.

Access to Unapproved Cancer Drugs

The plaintiffs in *Abigail Alliance* spoke for patients with advanced cancer who had run out of options for treatment; the cancer had returned or metastasized, and no other chemotherapy or biologic was deemed appropriate. But many

drugs and treatments for cancer, particularly targeted and molecularly based therapies, are in the research and development pipeline. Some of those agents will eventually prove safe and effective for patients, as occurred with the drug at issue in *Abigail Alliance*. Many current cancer patients will not live long enough to benefit from that research if they must wait for FDA approval, but could benefit from drugs currently in phase II trials. With so few options available, why should a patient be denied investigational drugs outside of phase II studies if the drug maker and patient's physician are willing to provide them?

Note that this claim is much less extreme than the claim made by proponents of laetrile, an extract of almonds and apricot pits thought in the late 1970s to be useful in fighting cancer. The claim is not that because patients are terminally ill they should be free to consult unlicensed practitioners or use any substance without any regard to safety, as laetrile proponents argued.⁷ Rather, the *Abigail Alliance* plaintiffs assert a right to use, outside the study process, drugs that have passed phase I safety review and been approved for phase II review of efficacy.

The resolution of this question—both at the policy and constitutional level—will depend on balancing the risks of phase II drugs and the patient's interest in obtaining possibly beneficial therapy. The FDA's multistep drug approval process is the result of fifty years of struggle between industry and regulators to promote the best interests of patients.⁸ FDA regulatory approval does slow access to new drugs and, like most bureaucratic systems, has not always worked as efficiently as it should. As recognized across the world, however, some premarket drug approval process is needed to protect patients. Indeed, many would argue that the FDA is now approving drugs too quickly and should demand even stronger evidence of safety and efficacy before allowing new drugs on the market.

In light of the need for some regulatory structure for new drugs, one might question whether cancer patients—or indeed any patient group—should have a right to unapproved drugs merely because the drugs have passed the first stages of clinical review. Phase I clinical trials do not occur unless there is adequate preclinical data from laboratory and animal studies to justify giving it to a small group of humans to test safety. If administration in varying doses does not cause major safety issues, the drug or biologic might then be approved for phase II studies on a larger number of patients for both safety and efficacy. Volunteers for phase II trials are hoping for a

benefit that cannot be guaranteed, and they face safety risks in seeking it. Yet a substantial percentage of phase II drugs make it to phase III, and an even larger percentage of those are approved.⁹

A frequent theme in criticism of the *Abigail Alliance* decision is the likelihood that it will undermine the FDA's process for vetting new drugs before allowing them into the marketplace. This will lead to even fewer patients in clinical trials and less need to apply demanding standards to new drugs to protect patients, to the detriment of patients and the health care system generally. It is assumed that the safety gain to future patients justifies the denial of whatever benefits early access might bring to patients.

But this assumption gives too little weight to the patient's interest and too much to the feared effect of a phase II compassionate use program. Cancer patients have a strong interest in access to new drugs that might extend life, even if only for a few months. Yes, people with advanced cancer are desperate for ways to cure or extend their lives, but their decision to use new treatments is not in itself irrational or a sign of magical thinking. If they are competent enough to accept the use of phase I and phase II drugs in a research setting, it is unclear why they should not be able to do so in a nonresearch setting under a physician's supervision.

When a patient has so much at stake, it is not improper to ask the FDA to show convincing reasons for denying informed patients that option—for not permitting a compassionate use program for earlier access to drugs in clinical trials.

Critics of the *Abigail Alliance* decision who fear its consequences for the drug regulatory system appear also to have overestimated the extent to which an unregulated market in such drugs would develop. Few companies conducting phase II studies are equipped on supply or logistical grounds to make them available to all who would want them, much less to train physicians and nurses how best to use them. If they do make them available, they may face legal risks for bad outcomes.¹⁰ Reports of effects in nontrial uses could also muddy the data from phase II studies and thus delay the drug approval they seek. Selling drugs outside phase II trials will simply not be a viable business model for most companies. With insurance not covering use of unapproved drugs, demand will be limited to those few who can pay and can find a drug company willing to provide the drug outside a study. The threat to patients from untested drugs and to the overall regulatory system is much less than critics of the decision have shown.¹¹

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Medical Marijuana

The negative right to medical care recognized in *Abigail Alliance* could boost the claims of individuals seeking to use marijuana for symptoms that they say are not treatable in other ways. Long used as a folk remedy, any medicinal use of marijuana was cut off by the 1937 Marihuana Tax Act, a prohibition reenacted in different form in the Controlled Substances Act of 1970.¹² Under the CSA, marijuana is a schedule I substance with no accepted medical use and thus cannot be prescribed or used for medical reasons. Twelve states have made medical use of marijuana legal, but the federal government retains authority to enforce the CSA's ban on all use of marijuana. In 2005 the Supreme Court held that Congress had authority under the interstate commerce clause to regulate marijuana legally grown and used within state boundaries for medical reasons.¹³ But it did not address the question of whether the federal law violated the plaintiff's right to medical care.

Angel Raich, the woman who had brought the unsuccessful commerce clause challenge, is now pursuing a claim that the CSA violates her right to medical treatment.¹⁴ She suffers from wasting disease and presented medical testimony that only smoked marijuana stimulates her appetite sufficiently to enable her to live free of pain. Others have claimed that smoked marijuana is essential for control of nausea from cancer chemotherapy and treatment of glaucoma.

The principle recognized in *Abigail Alliance* would support Angel Raich's claim of a negative right to medical care to extend life and relieve pain. If the court so holds, the government will have to show that there are equally good alternative ways to treat the illness or symptoms at issue or that allowing medical use of marijuana will so undercut enforcement of the marijuana laws that denying medical use is justified. Even if Ms. Raich and similarly situated plaintiffs are successful in their individual claims, the federal government may continue to contest them, thus greatly limiting the number of patients who will be able to use schedule I controlled substances for medical reasons.

Embryonic Stem Cell Treatments

The ability to culture embryonic stem (ES) cells in the laboratory has opened the door to new avenues of research and therapy for many diseases. Current controversies focus on the use of leftover or created embryos in research. Scientists

are still a long way from being able to direct ES cells to differentiate into the precursor cells or other tissue needed to treat disease, but they are making progress. Phase I clinical trials may well occur within the next year or two. If ES cell-based therapies become an important part of the medical armamentarium, much of the opposition to their use could wither away. Or perhaps, since moral objection to any destruction of embryos is so deeply entrenched in the right-to-life movement, strong resistance to any use of ES cell-derived therapies will persist.¹⁵

One strategy of opponents will be to oppose government funding of ES cell-based treatments under Medicare and Medicaid, as they have done since 1976 with abortion.¹⁶ Opponents may also seek laws that prohibit the use of ES cell-based therapies or the precursor steps necessary to develop them. Several states now criminally ban research with embryos, and seven states make it a crime to create embryos by methods, such as nuclear transfer, that may be essential for creating useful ES cell-based treatments. Many members of Congress would support a federal criminal ban as well.

Suppose, then, that state or federal law prohibits the use of an ES cell-derived therapy essential for life or health. A patient with no viable therapeutic alternative could challenge the law as unconstitutional under the principle recognized in *Abigail Alliance*. Since safety and efficacy are valid governmental concerns, the therapy would have to meet the same regulatory standards that drugs for cancer and other diseases must. But opposition to ES cells is based on moral concerns about embryos, not the need to protect patients from dangerous or untested therapies. Whether the patient would win the suit would depend on whether the state could protect embryos at the expense of the patient's life or liberty.¹⁷

The most relevant precedents suggest that protecting embryos would not be a sufficient justification. Embryos are undifferentiated cells not yet implanted in a uterus. Under *Roe v. Wade*, a woman is free to end any unwanted pregnancy as long as the fetus is not yet viable, and even then may do so when necessary to protect her life or health.¹⁸ If the state cannot protect fetuses at the price of a woman's life or health or even her procreative choice, it should also lack the power to protect the earlier stage embryos that would be used to derive ES cell therapies.

A reversal of *Roe* could change the calculus in several ways. If *Roe* were reversed on the grounds that no right of procreative privacy can be found in the Constitution, it could call

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into question the creation of other unenumerated constitutional rights, such as the negative right to medical treatment recognized in *Abigail Alliance*. Alternatively, the Court could reverse *Roe* on the grounds that the state is free to protect fetal life at the expense of reproductive choice. Reversal on those grounds, however, would not mean that abortions necessary to protect a woman's life or health could also be banned. Nor would it mean that the government has the power to protect embryos not implanted in the uterus at the expense of a person's life or health.

The claim that harm to embryos is more important than harm to patients is even harder to sustain when one recalls that no state limits the current IVF practice of creating many more embryos than will be implanted, with the eventual discard of the excess likely. It is arbitrary to allow infertility patients to create and discard embryos, but not patients and doctors who need them to treat disease and other conditions. Laws limiting the number of embryos created, transferred, frozen, or discarded, as exist in Germany and Italy, are unlikely to be enacted in the United States. If they were, they would be subject to constitutional attack as an interference with the right of infertile couples to procreate.¹⁹ As applied to ES cell-based treatments, then, the right to medical treatment recognized in *Abigail Alliance* could have real bite, even if *Roe* is reversed.

Paying for Organs

Organ transplantation is usually the most desirable therapy for persons with end-stage organ failure. Altruistic donation has been the mainstay of the system, both for cadaveric and live donors. The National Organ Transplantation Act (NOTA) makes it a federal crime to pay "valuable consideration" for organ donation, as do laws in several states.²⁰ As a result, there are long waiting lists for transplantable organs. If people could sell their own organs, however, then perhaps at least the waiting lists for kidneys could be shortened, since it is possible to lose a kidney without adverse health consequences.

The broader principle recognized in *Abigail Alliance* provides a person who is unable to get a kidney altruistically but who could obtain one if donors were paid with grounds to challenge NOTA as an unconstitutional interference with his or her right to life or health. In such a case, the law banning payment would block a person's ability to obtain the most effective treatment, just as if kidney transplants were themselves made illegal. With dialysis as a backup, the right to life may not be directly implicated. But the health advantages make transplant so clearly preferable to dialysis that denying paid access to donor organs could be viewed as interfering with the negative right to health care.

Recognition of a negative right to health care would then shift the burden to the government to show that banning payments to kidney donors is narrowly tailored to serve compelling interests. The policy here is both paternalistic and moralistic. It aims to protect donors from the financial temp-

to undergo major surgery for the benefit of another. Although not directly coercive, such payments are likely to exploit the financial need of poor persons, and they could quickly create a global market in kidneys. Many commentators also think a ban on organ sales serves the compelling need of preventing the commodification of organs and persons. Others argue that a regulated system of paid donors could eliminate the worse abuses and lead to a much greater supply of kidneys for transplant.²¹

The question of paying people to provide tissue or body parts is highly contested in several areas of medicine beyond organ sales. Free market libertarians and some liberal reformers favor relaxing such bans, while other liberals, the religious right, and conservatives oppose it. The field is marked by great inconsistency. Payments are legally made to research subjects, to surrogate mothers, and to women who donate eggs to infertile couples, but not to women who donate eggs to researchers.

A suit arguing that NOTA violates the patient's right to medical care would put judges in the position of deciding which values should have a higher priority. If the negative right to health care is fundamental, then moral objections alone would ordinarily not be a sufficient basis for infringement. Other concerns, however, go beyond moralisms to the health effects on donors. One will need a much finer-grained analysis of the competing interests to determine where the proper constitutional balance lies. Indeed, the complexity of the judgment suggests that courts might not be best situated to settle such a complicated policy issue. If so, the negative right to treatment will have little reach in organ transplant policy.

A New Legal Landscape?

If the *Abigail Alliance* decision is upheld and its reasoning adopted by other courts, the courts will become more active players in battles over governmental regulation of both current and emerging medical treatments. A more robust judicial role will increase litigation and have other costs. But it could force regulators to rethink the balance of burdens and benefits in many policies, thus helping patients get life-extending medical treatments that are now blocked by administrative and political intransigence. Whether few or many patients are ultimately affected will depend on the pace of science and the willingness of courts to recognize a negative right to noninterference with medical decisions that protect life and health.

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6. *Abigail Alliance*, 18-25.
7. *United States v. Rutherford*, 442 U.S. 544 (1979).
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11. B.J. Madden, "Breaking the FDA Monopoly," *Regulation* (Summer 2004): 64-66.
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13. *Gonzalez v. Raich*, 125 S.Ct. 2195 (2005).
14. *Raich v. Gonzalez*, 9th Cir. No. 03-15481 (remand from the United States Supreme Court).
15. Robertson, "Embryo Culture and the Culture of Life."
16. *Harris v. McCrae*, 448 U.S. 297 (1980).
17. Robertson, "Embryo Culture and the Culture of Life."
18. 410 U.S. 113 (1973).
19. Robertson, "Embryo Culture and the Culture of Life."
20. 42 U.S.C.A. #1320b-8; 42 U.S.C.A. #274.
21. S.J. Dubner and S.D. Levitt, "Flesh Trade: Why Not Let People Sell Their Organs," *New York Times Magazine*, July 9, 2006, pp. 20-21.