D.C. Circuit Reconsiders Whether Individuals Have a Constitutional Right to Investigational Drugs

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On Thursday, March 1, the U.S. Court of Appeals for the D.C. Circuit conducted an en banc rehearing of the case of Abigail Alliance v. Eschenbach. The case is significant both in terms of the constitutional question presented, and in terms of the broader policy question presented: whether terminally ill patients possess a substantive due process right to access potentially life-saving drugs when no alternative treatment is available. Specifically, a nonprofit group named Abigail Alliance sought to enjoin the Food and Drug Administration (“FDA”) “from continuing to enforce a policy barring the sale of new drugs” that have only passed Phase I testing.

Under FDA regulations, new drugs must undergo three phases of clinical trials before they can receive FDA approval and enter the stream of commerce. Phase I testing involves tests on 20-80 subjects to assess toxicity and side effects, as well as to gather some early evidence on efficacy. Phase II testing involves larger clinical trials of up to several hundred subjects targeted at assessing efficacy primarily, and also to examine side-effects and risks associated with the drug. Phase III testing employs even larger trials, often on thousands of subjects, and is initiated only after earlier testing suggests efficacy. The purpose of Phase III testing is to “gather the additional information about effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug.” Abigail petitioned the FDA to amend its regulations as to permit new drugs that have passed Phase I testing to be made available to terminally ill patients for whom no alternative treatment is available. The FDA rejected the Alliance’s proposal, and this litigation ensued.

In assessing this case and its implications, the first order of business is to understand that ethical rights and constitutional rights, while often intertwined, are not equivalent. That is, even if one were to agree with the Alliance that terminally ill patients who lack alternatives have a philosophical right to access investigational new drugs that have not passed Phase II and Phase III testing, it does not follow that the Constitution guarantees that right. Simply put, whether the Constitution ought to protect that right is not the same question as whether it does protect that right. Of course, the converse is also valid:

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1 445 F.3d 470 (D.C. Cir. 2006), reh’g en banc granted, judgment vacated.
2 Id. at 472.
3 Id.
4 Id. at 473; see 21 C.F.R. § 312.21(a)-(c) (2006).
5 See 21 C.F.R. § 312.21(c) (2006).
6 This is not to suggest any kind of artificial distinction between a substantive due process analysis and the importance of policy considerations. Policy considerations are obviously significant in any substantive due process assessment. The point here is simply to suggest that the doctrinal analysis is not merely a policy analysis.
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Does the Constitution protect the right? As numerous commentators have observed, much of the action in a substantive due process analysis turns on how broadly or narrowly the right in question is defined. One would correctly surmise, for example, that the result in Lawrence v. Texas would differ if the question presented was phrased as “whether the Constitution protects the right of adult, consenting males to engage in sodomy in their home” than if it was phrased as “whether the Constitution protects the right of consenting adults to engage in sexual intercourse in private.” The same dynamic is evident in the Abigail decision. The majority decision states that

The question presented by the Alliance’s complaint is whether the Due Process Clause protects the right of terminally ill patients to make an informed decision that may prolong life, specifically by use of potentially life-saving new 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 on a substantial number of human beings.

Note that the specific question presented is phrased in exceedingly broad terms: “whether the Due Process Clause protects the right of terminally ill patients to make an informed decision that may prolong life.” Only after the right is framed in this expansive sense does the majority add the qualifying adverbial phrase. Similarly, later in the opinion the majority phrases the right in question as a “substantive due process right of access to potentially life-saving treatment.” Given that the more broadly the right is defined, the more likely it enjoys constitutional protection, it is not surprising that the majority was ultimately persuaded by Abigail’s argument and reversed the district court’s grant of the FDA’s motion to dismiss.

The second question, regarding the policy implications raised by the case, is potentially further reaching in scope. Even if the dissent is correct that the Constitution does not protect the asserted right to potentially life-saving medications, whether Congress or the FDA should take action to amend the policy precluding the dispensation of the medications at issue is a different question.

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7 See Erwin Chemerinsky, CONSTITUTIONAL LAW: PRINCIPLES & POLICIES 765 (2d ed. 2002) (explaining that “[a]t a sufficiently general level of abstraction, any liberty can be justified as consistent with the nation’s traditions. At a very specific level of abstraction, few nontextual rights would be justified”); Roger Craig Green, Note, Interest Definition in Equal Protection: A Study of Judicial Technique, 108 YALE L.J. 439, 455 (1998).
9 Abigail Alliance, 445 F.3d at 478.
10 See note 7 supra and accompanying text.
11 Abigail Alliance, 445 F.3d. at 486.
12 Id. at 487 (Griffith, J., dissenting).
The ethical issues at the heart of this question are among the most difficult in research ethics. On the one hand, it would seem difficult to inform desperately ill, suffering patients that what they perceive as one of their last hopes for cure or even simple therapy is unavailable to them because it has not passed Phase II and Phase III clinical trials. In his dissent, Judge Griffith accuses the majority of “making its own judgment about the medical benefits and risks of providing experimental drugs to terminally ill patients.”

However, this seems somewhat inaccurate, as the majority’s decision does not necessitate such a calculus, but rather implies that the patients suing through the Alliance have the right to assume whatever risks flow from taking drugs that have not passed Phase II or Phase III clinical trials.

On the other hand, the likelihood that the patients seeking the medications are desperate may itself suggest some reasons to be cautious in allowing access to such medications before their risks are even known. The sad story of the use of autologous bone marrow transplants combined with high dose chemotherapy in patients with end-stage breast cancer offers a paradigm case of the risks of providing potentially life-saving but experimental treatment to desperate, terminally ill patients. The women who underwent the procedure, some of whom successfully sued their insurers to compel them to cover its costs, likely suffered and perhaps even died prematurely in undergoing an experimental regimen that later proved to be nonefficacious for breast cancer. This case, as well as the Abigail Alliance case, demonstrates the difficult value conflict policymakers face between a terminally ill patient’s autonomous preference to bear the risks of potentially life-saving experimental medications and the state’s interest in protecting vulnerable persons from harm in the course of research.

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13 Id. at 498.

14 Indeed, where the risks of the drugs are unknown, a basic requirement of informed consent in clinical research – that the subject be informed of all known risks – seems almost inapplicable. See, e.g., George J. Annas, Faith (Healing), Hope, and Charity at the FDA: The Politics of AIDS Drug Trials, 34 VILL. L. REV. 771, 792 (1989) (arguing that true autonomous consent is impossible where clinical trials have not yet produced “adequate and accurate information upon which to base decisions”).


16 Id.