CONSTITUTIONAL LAW — SUBSTANTIVE DUE PROCESS — EN BANC D.C. CIRCUIT REJECTS FUNDAMENTAL RIGHT TO EXPERIMENTAL MEDICATIONS. — *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

In deciding substantive due process cases, courts often rest legal analysis on scientific assertions by the parties. When those scientific assertions are made by agencies, courts may use the doctrines of administrative law in their assessments. Recently, in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*,[1] the en banc D.C. Circuit held that terminally ill patients have no fundamental right to obtain medications still undergoing the testing required by the Food and Drug Administration (FDA). In reaching this decision, the court relied on the FDA's judgment that the medications at issue were neither safe nor effective to preclude the use of common law doctrines such as necessity and self-defense as support for the asserted right. The court, however, failed to subject that scientific judgment to any independent scrutiny. It should have instead separated the FDA's loose combination of legal interpretation and factual findings and applied the corresponding standards of review, although the findings would nevertheless have been likely to stand.

The Abigail Alliance for Better Access to Developmental Drugs (the Alliance) is a nonprofit organization that seeks to increase the availability of experimental medications to the terminally ill.[2] Under the Food, Drug, and Cosmetic Act[3] (FDCA), FDA regulations require three or four stages of clinical testing before a drug can be sold to the public.[4] In early 2003, the Alliance submitted a proposal to the FDA that suggested making drugs available to the terminally ill for purchase after the earliest stage of testing.[5] When the FDA rejected this proposal, the Alliance filed suit seeking to enjoin FDA administrators from enforcing the ban on sale of unapproved drugs against certain terminally ill individuals.[6]

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[1] 495 F.3d 695 (D.C. Cir. 2007) (en banc), *cert. denied*, 128 S. Ct. 1069 (2008).

[2] Abigail Alliance for Better Access to Developmental Drugs v. McClellan, No. 03-1601 (RMU), 2004 WL 3777340, at *1 (D.D.C. Aug. 30, 2004).

[3] 21 U.S.C.A. §§ 301–399 (West 2000 & Supp. 2007). In particular, 21 U.S.C. § 355(i)(1) (2000 & Supp. V 2005) gives the FDA authority to allow investigation of the "safety and effectiveness" of unapproved drugs.

[4] The first stage (Phase 1) is the initial administration of the drug to humans and is primarily focused on whether the drug is safe enough to continue human testing. *Abigail Alliance*, 495 F.3d at 698. Further stages involve larger clinical trials that evaluate the drug's effectiveness and gather further safety information. *Id.*

[5] *See id.* at 699.

[6] *See Abigail Alliance*, 2004 WL 3777340, at *2.

The Alliance claimed that the FDA's ban[7] violated its members' privacy rights, liberty rights, and due process right to life.[8] The FDA moved to dismiss, arguing that no constitutional right of access to experimental drugs exists.[9] The district court granted the motion, holding that neither the Supreme Court nor the D.C. Circuit had ever recognized a fundamental right to receive medical treatment and that the Alliance's analogies to due process rights like the right to *refuse* medical treatment were too strained.[10] The court further held that the FDA's ban was sufficiently related to its legitimate interest in protecting public health to survive rational basis scrutiny.[11]

A panel of the D.C. Circuit reversed and remanded in a 2–1 split.[12] Applying the test that the Supreme Court articulated in *Washington v. Glucksberg*[13] to examine whether the "right of control over one's body"[14] was "deeply rooted in [American] history and tradition,"[15] the majority found that the liberty interest asserted by the Alliance, encompassing the rights of self-defense and self-preservation, was deeply rooted in common law.[16] In contrast, the court noted, there was no tradition of drug regulation at all in America until 1906, and no governmental review of medication safety until 1938, a tradition insufficient to overturn the longer-standing right of self-preservation.[17] The court also noted that the Supreme Court had implied due process protection for a right to refuse lifesaving treatment, and the court used a similar analysis to conclude that the Due Process Clause protects the liberty interest asserted by the Alliance.[18] It therefore remanded the case to the district court for a strict scrutiny analysis of the FDA's policies.[19] In dissent, Judge Griffith argued strongly for the importance of the current regulatory structure and the right of the political branches to resolve the scientific and moral debates inherent in the Alliance's proposal.[20] He similarly applied the *Glucksberg* test, but noted that

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[7] The FDA permits limited experimental drug access through a small, heavily regulated compassionate use program; the Alliance argued that this mechanism was insufficient. *Abigail Alliance*, 495 F.3d at 698–99.

[8] *See Abigail Alliance*, 2004 WL 3777340, at *2.

[9] *Id.*

[10] *Id.* at *9–11.

[11] *Id.* at *11–12.

[12] Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006). Judge Rogers wrote for the panel, joined by Chief Judge Ginsburg.

[13] 521 U.S. 702 (1997).

[14] *Abigail Alliance*, 445 F.3d at 480.

[15] *Id.* at 476 (quoting Washington v. Glucksberg, 521 U.S. 702, 721 (1997)) (internal quotation marks omitted).

[16] *Id.*

[17] *Id.* at 481–83.

[18] *See id.* at 484 (citing Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990)).

[19] *See id.* at 486.

[20] *See id.* at 487–88 (Griffith, J., dissenting).

Glucksberg "prohibits [a court] from creating new substantive due process rights by inference."[21] Although he accepted that the interests cited by the majority, such as necessity, were longstanding common law traditions, he argued that they were insufficient to establish a fundamental constitutional right.[22] The government petitioned for rehearing en banc, which was granted.

The en banc D.C. Circuit vacated the panel's opinion and affirmed the judgment of the district court. In an opinion written by Judge Griffith,[23] the court held that there was no fundamental right of access to experimental drugs for the terminally ill.[24] Turning first to the history of American pharmaceutical regulation, the court found that, although regulation of drugs for efficacy is recent, the country had long regulated drugs for safety.[25] The court suggested that, because the FDA was regulating safety as well as efficacy in post–Phase I trials, the regulations were consistent with this historical tradition.[26] It stated, moreover, that a lack of historical regulation did not create a fundamental right to be free from such regulation and therefore the recent genesis of the government's efficacy regulation did not indicate a fundamental right to access inefficacious drugs.[27]

The court next examined the Alliance's arguments that the common law doctrines of necessity, intentional interference with rescue, and self-defense supported both a broad right to self-preservation and the narrower right of the terminally ill to buy experimental drugs. The court disposed of the necessity argument with *United States v. Oakland Cannabis Buyers' Cooperative*,[28] which it understood to hold that a legislative enactment like the FDCA can limit or eliminate the necessity defense.[29] Because the tort of intentional interference with rescue requires the aid interfered with to be necessary, the court refused to apply it, noting that "an ineffective and unsafe drug" is not "neces-

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[21] *Id.* at 491.

[22] *See id.* at 491–93.

[23] Judge Griffith was joined by Judges Sentelle, Henderson, Randolph, Tatel, Garland, Brown, and Kavanaugh.

[24] *Abigail Alliance*, 495 F.3d at 697. In making this determination, the court accepted, arguendo, that the Alliance's description of the right was sufficiently precise to meet *Glucksberg*'s careful description requirement. *See Abigail Alliance*, 495 F.3d at 702. The court framed the question as "whether terminally ill patients have a fundamental right to experimental drugs that have passed Phase I clinical testing." *Id.* at 701. However, it expressed doubt in a footnote that such a right could ever be recognized, given its reliance on the FDA's regulatory structure. *Id.* at 702 n.6.

[25] *See id.* at 703–04. The court dated the beginning of safety regulation to a 1736 Virginia law prohibiting the unnecessary dispensation of medications. *Id.*

[26] *Id.* at 706.

[27] *See id.* at 706–07. The court attributed the dearth of historical regulation for drug efficacy until 1962 to a lack of scientific and medical expertise. *See id.* at 706 & n.12.

[28] 532 U.S. 483 (2001).

[29] *See Abigail Alliance*, 495 F.3d at 708.

sary."[30] The analogy to self-defense also failed, the court stated, because self-defense allows only the use of reasonable force to defend oneself, and terminally ill patients were not using reasonable force "when they [took] unproven and possibly unsafe drugs."[31] The court then discussed Supreme Court jurisprudence that suggested the Court disfavored challenges to federal food and drug laws brought in similar circumstances.[32] Finally, the court applied rational basis scrutiny to the FDA's regulation and found that it was reasonably related to the government's interest in ensuring patient safety.[33]

Judge Rogers dissented.[34] Calling the court's opinion "a stunning misunderstanding of the stakes,"[35] Judge Rogers suggested that the right being asserted was not the majority's narrowly defined right of access to drugs, but rather the right to attempt to preserve one's life.[36] Judge Rogers found recognition of the right to self-preservation as early as the 1760s, as well as in twentieth-century judicial decisions.[37] She then endorsed the Alliance's common law arguments, emphasizing that using the doctrine of necessity as a historical basis for a fundamental right did not require constitutionalizing the doctrine itself.[38] In addition, she noted that although the use of an experimental drug might not be sufficient to save a patient's life, it was a necessary step in the attempt.[39] Judge Rogers then attacked the majority's historical analysis, arguing that safety regulation was not analogous to efficacy regulation and that even the latter currently left important aspects of patient access to drugs unregulated.[40] Finally, Judge Rogers argued that the right to preserve one's life is implicit in the concept of ordered

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[30] *Id.* at 708 & n.15.

[31] *Id.* at 710.

[32] *Id.* at 710 (citing Gonzales v. Raich, 545 U.S. 1 (2005) (upholding the federal government's ability to ban marijuana use, even for local medical purposes); United States v. Rutherford, 442 U.S. 544 (1979) (holding that the FDCA prevents terminally ill patients from obtaining unapproved drugs)).

[33] *Id.* at 712–13.

[34] *Id.* at 714 (Rogers, J., dissenting). Chief Judge Ginsburg joined the dissent.

[35] *Id.*

[36] *See id.* at 715.

[37] *Id.* at 717.

[38] *Id.* at 718 (citing Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 278 (1990)) (analogizing to the *Cruzan* Court's use of the tort of battery to support a constitutional right to refuse lifesaving treatment).

[39] *Id.* at 719. Judge Rogers went on to analogize the right to access potentially life-saving medications to the Supreme Court's decisions holding that states must provide exceptions to abortion bans when necessary for the mother's health. *Id.* at 720–21 (citing Roe v. Wade, 410 U.S. 113 (1973)).

[40] *Id.* at 723–26. Judge Rogers pointed out that the FDA has not historically regulated physicians, who may prescribe drugs to patients for a use other than that for which the FDA has deemed the drug safe and effective. *Id.* at 725–26.

liberty, another prong of the *Glucksberg* test.[41] Therefore, she proposed a remand for strict scrutiny.[42]

In determining whether the Constitution protects a fundamental right to access experimental medications, the majority of the en banc court took at face value the arguments of the FDA that such drugs are potentially unsafe and often ineffective.[43] The assertion that experimental medications are unsafe is a concatenation of a legal decision and a factual decision: it presumes a legal interpretation of the word "safe" that sets a scientific standard and a factual finding that post–Phase 1 drugs do not meet this standard. Although the Alliance did not ask for review of the FDA's findings on safety, the arguments of both parties with respect to substantive due process rested on different conceptions of when a drug could be considered "safe." Therefore, the court should have evaluated separately the legal and scientific findings on which its substantive due process analysis relied, subjecting the different findings to judicial review using standard administrative law doctrines.

Courts have differed in their willingness to examine closely scientific conclusions of legislatures and agencies implicating restrictions on fundamental rights. The court's failure in *Abigail Alliance* to question the FDA's assertions represents one approach — that of extreme deference.[44] In contrast, the Supreme Court's decision in *Stenberg v. Carhart*[45] delved at length into whether a ban on the dilation and extraction abortion procedure would create a health risk for pregnant women.[46] Rather than accept Nebraska's assurances that the procedure was never medically necessary, the Court conducted its own factual review of the record and concluded that the weight of medical evidence was against the state's position.[47] The Court struck a middle ground when revisiting the question in *Gonzales v. Carhart*,[48] giving

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41 *Id.* at 727.

42 *See id.* at 728.

43 *See id.* at 703, 705–06 (majority opinion). In its brief on rehearing, the agency argued that "[t]he fact that a clinical trial is allowed to proceed from Phase 1 to subsequent phases does not represent a judgment by the FDA that the investigational drug is either safe or effective for use in treating diseases." Corrected *En Banc* Brief for the Appellees at 5, *Abigail Alliance*, 495 F.3d 695 (No. 04-5350), 2007 WL 415084. The court adopted this assertion nearly verbatim. *Abigail Alliance*, 495 F.3d at 706. The court noted that it did not address the question of "whether access to medicine might ever implicate fundamental rights," indicating that the FDA's characterization of Phase 1 drugs did in fact limit the court's inquiry. *Id.* at 701.

44 The Supreme Court expressed similar deference in *United States v. Oakland Cannabis Buyers' Cooperative*, 532 U.S. 483 (2001), refusing to examine Congress's judgment that "marijuana has 'no currently accepted medical use' at all." *Id.* at 491 (quoting 21 U.S.C. § 812 (2000)).

45 530 U.S. 914 (2000).

46 *See id.* at 931–38.

47 *See id.* at 932.

48 127 S. Ct. 1610 (2007).

deference to congressional medical findings but not making those findings dispositive of the constitutional question.[49]

The abortion ban cases are not perfectly analogous to *Abigail Alliance* because they involved scientific judgments made by legislatures rather than administrative agencies. Professor B. Jessie Hill argues that legislative factfinding, particularly on medical matters like those at issue in *Abigail Alliance*, is often substantially flawed, as legislatures have no special factfinding expertise. Consequently, she argues, courts should engage in searching *Stenberg*-like examination of restrictions on medical treatment by legislatures.[50] Agencies, on the other hand, possess "a superior degree of technical competence,"[51] presumably producing more reliable results. Nevertheless, agencies do sometimes alter their scientific findings based on political influence.[52] In dealing with agency findings, courts must attempt to strike an appropriate balance between recognizing agencies' expertise and institutional competency and acknowledging that they are nonetheless subject to political pressure that affects even non-normative, fact-based decisions. Courts have not often spoken on what the appropriate standard for judicial oversight in a substantive due process case would be, as it is rarely an agency that reaches the scientific conclusions at issue in these cases.[53] But since the same goal, balancing deference to agency competence while preventing overly politicized decisionmaking, has also informed courts' administrative law decisions, those decisions can be used as a guide to the manner in which agency scientific conclusions in substantive due process cases should be treated.

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[49] *Id.* at 1637; *see also* B. Jessie Hill, *The Constitutional Right To Make Medical Treatment Decisions: A Tale of Two Doctrines*, 86 TEX. L. REV. 277, 321–22 (2007).

[50] *See* Hill, *supra* note 49, at 334–41.

[51] Cass R. Sunstein & Adrian Vermeule, *Interpretation and Institutions*, 101 MICH. L. REV. 885, 928 (2003).

[52] *See, e.g.*, Cornelia Dean, *At a Scientific Gathering, U.S. Policies Are Lamented*, N.Y. TIMES, Feb. 19, 2006, § 1, at 28. A cautionary tale can be seen in the FDA approval process of the "abortion drug" RU-486, which was deemed unsafe and fraudulent by the administration of the first President Bush but solicited for expedited approval by the administration of President Clinton. *See* Lars Noah, *A Miscarriage in the Drug Approval Process?: Mifepristone Embroils the FDA in Abortion Politics*, 36 WAKE FOREST L. REV. 571, 576–81 (2001). Similar political influence can be seen in the FDA's approval process for over-the-counter use of the Plan B emergency contraceptive. *See* Gillian E. Metzger, *Abortion, Equality, and Administrative Regulation*, 56 EMORY L.J. 865, 879–82 (2007). *See generally* Tummino v. von Eschenbach, 427 F. Supp. 2d 212 (E.D.N.Y. 2006).

[53] Hill, *supra* note 49, at 345. Courts have, however, sometimes addressed situations in which nonscientific agency determinations of fact have implicated constitutional rights, and have employed a searching standard of factual review. *See, e.g.*, Quaker Action Group v. Hickel, 421 F.2d 1111, 1114, 1117–18 (D.C. Cir. 1969) (reviewing the Department of the Interior's decision to deny permits to protests near the White House based on its expertise in protecting the President, and concluding that the importance of First Amendment considerations precluded the court from accepting the agency's factual allegations).

In evaluating the Alliance's substantive due process claims, the court should have first reviewed the FDA's contested conclusion that post–Phase I drugs "ha[ve] not been shown to be safe and effective and may well be neither,"[54] a conclusion that formed the basis for both the court's analysis of the history of drug safety regulation and its rejection of common law analogies involving the saving of lives.[55] Although both sides agreed that the safety of the drugs had not been sufficiently proven to market them to the general public, they disagreed on whether the same standards of safety should apply to terminally ill patients.[56] Reviewing such a finding requires two steps: an inquiry into the FDA's legal interpretation of "safe" and an inquiry into the factual finding that post–Phase I drugs do not meet that interpretation. Judicial review of agencies' legal interpretations of statutory terms is governed by the *Chevron*[57] doctrine; factual findings that were not made in on-the-record proceedings, as in *Abigail Alliance*, are reviewed to determine if they are arbitrary and capricious or an abuse of discretion.[58] Although both standards are deferential to agency expertise — *Chevron* allows agencies to interpret ambiguous statutory terms in any "permissible" way,[59] and the abuse of discretion standard[60] similarly does not allow a court to substitute its judgment for that of an agency[61] — they involve a review that is more searching than the unquestioning deference that the court displayed in *Abigail Alliance*.

Even had the court engaged in the proposed level of independent review, however, the FDA's conclusion about the drugs' safety would likely have survived. The court would first have needed to apply

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[54] Corrected *En Banc* Brief for the Appellees, *supra* note 43, at 41. The FDA rejected the Alliance's initial proposal in a letter that constituted the agency's only "finding" on the question of the drugs' safety. The proposal was rejected on the ground that the plan's "lower standard of evidence" for access to medications would impede the "obtain[ing] [of] sufficient data to provide a reasonable expectation of benefit and lack of excessive harm." Letter from Peter J. Pitts, Assoc. Comm'r for External Relations, Dep't of Health and Human Servs., to Frank Burroughs, President, and Steven T. Walker, FDA Advisor, Abigail Alliance for Better Access to Developmental Drugs 4 (Apr. 25, 2003), *in* Defendant's Motion to Dismiss or in the Alternative for Summary Judgment, Attachment 1, Abigail Alliance for Better Access to Developmental Drugs v. McClellan, No. 03-1601, 2004 WL 3777340 (D.D.C. Aug. 30, 2004).

[55] *See Abigail Alliance*, 495 F.3d at 705–06, 708–10.

[56] *Compare* Brief of Appellants at 43–46, Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach, 445 F.3d 470 (D.C. Cir. 2006) (No. 04-5350), 2005 WL 1826286 (arguing that some safeguards should be relaxed for terminally ill patients due to their short life expectancy), *with* Corrected *En Banc* Brief for the Appellees, *supra* note 43, at 56–57 (arguing that safety standards are equally meaningful to the terminally ill).

[57] Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc., 467 U.S. 837 (1984).

[58] *See* PETER L. STRAUSS ET AL., GELLHORN AND BYSE'S ADMINISTRATIVE LAW 970, 1033–34 (rev. 10th ed. 2003).

[59] *See Chevron*, 467 U.S. at 843.

[60] 5 U.S.C. § 706(2)(A) (2000).

[61] *See* AFL-CIO v. OSHA, 965 F.2d 962, 970 (11th Cir. 1992) (holding that arbitrary and capricious review is "more deferential" to agencies than the substantial evidence standard).

Chevron in order to determine whether the agency's legal interpretation of the FDCA — that the standard of drug safety for the terminally ill is the same as that for the general population — was permissible.[62] The Supreme Court held in *United States v. Rutherford*[63] that "[f]or the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit."[64] Although *Rutherford* is potentially distinguishable both because it dealt with a drug that had not received any imprimatur of safety from the FDA (unlike post–Phase 1 drugs) and because it was a pre-*Chevron* decision, the situations are sufficiently similar that the court would have likely applied it to find that the FDA's interpretation of the statute was permissible. If the legal question of what is "safe" had been answered by reference to the general public, then the FDA's standard factual threshold for safety — passing Phase 3 testing — would have applied, a standard that the experimental drugs in question would clearly not have met. Even so, this consideration might have affected the court's thinking on the common law analysis; drugs that are not safe in the sense of satisfying the FDA's regulations may nonetheless be safe enough to be "necessary."

Abigail Alliance serves as an important reminder that what may seem like purely legal discussion in a judicial opinion, particularly on a scientific matter, often rests on agency assertions that intricately combine legal interpretation of statutory standards with the agency's factual determinations. It is important in substantive due process cases that those presuppositions be evaluated for validity in a manner that both respects and critically examines their origins. The court's acceptance of the FDA's assertions was incorrect, and the D.C. Circuit missed the opportunity to clarify what standard of review should apply to agency findings combining fact, policy, and law in a substantive due process case. Future courts should look to administrative law doctrine to make this decision and avoid *Abigail Alliance*'s mistakes.

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[62] *See Chevron*, 467 U.S. at 843. It could be argued that the FDA's findings in *Abigail Alliance* might not be entitled to full *Chevron* deference. Under *United States v. Mead*, 533 U.S. 218 (2001), agency findings are generally entitled to *Chevron* deference only when they are reached via a somewhat formal proceeding, particularly a notice-and-comment rulemaking or a formal adjudication. *See id.* at 230; Alan B. Morrison, *Agencies Are Just Like Legislatures and Courts — Except When They're Not*, 59 ADMIN. L. REV. 79, 118 (2007). The letter in which this finding was originally contained seems far more analogous to the opinion letter in *Mead*, which was not granted *Chevron* deference, than to the more formal proceedings. In this case, it would merit only limited deference due solely to the agency's specialized expertise. *Mead*, 533 U.S. at 234 (citing Skidmore v. Swift & Co., 323 U.S. 134, 139 (1944)).

[63] 442 U.S. 544 (1979).

[64] *Id.* at 555–56.