CLIENT ALERT

ROPES & GRAY

HEALTH CARE/LIFE SCIENCES May 15, 2006

Abigail Alliance for Better Access to Developmental Drugs v. Food and Drug Administration: Broadened Access to Early Phase Investigational New Drugs for Terminally Ill Patients

On May 2, 2006, a three-judge panel of the United States Court of Appeals for the District of Columbia Circuit ("D.C. Circuit") resurrected a lawsuit filed by the Abigail Alliance for Better Access to Developmental Drugs ("Abigail Alliance"), on behalf of terminally ill patients, against the Food and Drug Administration ("FDA"); the case had been dismissed by the United States District Court for the District of Columbia ("District Court") in August 2004 for failure to state a claim. In a 2-1 opinion, a majority of the D.C. Circuit endorsed Abigail Alliance's position that constitutional due process rights include the right of terminally ill patients, acting on a physician's advice, to obtain potentially life-saving medication when no alternative FDA-approved treatment is available. The dissent argued that the majority's "creation of a new fundamental right" to procure and use experimental drugs "raises a number of vexing questions."

District Court Ruling

FDA's longstanding regulations generally require three discrete phases of testing on humans before an investigational new drug can receive full approval and enter the market. FDA has acknowledged that successful completion of the initial phase of human testing ("Phase I") means an investigational new drug is sufficiently safe for further human testing but not yet proven safe and effective for approval and marketing. In July 2003, Abigail Alliance, a patient advocacy group, filed a lawsuit in the District Court alleging that enforcement of these regulations violates the constitutional privacy and liberty rights of terminally ill patients and their constitutional guarantee against deprivation of life without due process. On August 30, 2004, the District Court granted FDA's motion to dismiss the case. The District Court found that there is no constitutional right of access to unapproved drugs and refused to create a new constitutional right without clear guidance from the U.S. Constitution or Supreme Court precedent.

D.C. Circuit Decision

On appeal, the majority of the D.C. Circuit relied on principles set forth by the Supreme Court, in *Washington v. Glucksberg*, 521 U.S. 702 (1997) and *Cruzan v. Dir., Mo. Department of Health*, 497 U.S. 261 (1990), to analyze Abigail Alliance's claim that a fundamental right had been violated. The *Glucksberg* approach allows a court to infer a fundamental right from U.S. history and legal tradition, even if not expressly provided by law. Such an inference, however, requires a court to articulate a "careful description of the fundamental liberty interest," and to find that the fundamental right asserted is "objectively, 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 it were sacrificed."

Consistent with *Glucksberg*, the majority found that Abigail Alliance had carefully described the right at issue as follows: the right of a mentally competent, terminally ill adult patient to access potentially life-saving post-Phase I investigational new drugs, upon a doctor's advice, when no alternative treatment approved by the government is available, even where that medication carries risks for the patient. In addition, the majority cited the long-standing tradition of the right to "self-preservation" and examined U.S. history, legal traditions, and practices relating to access to new drugs, which it characterized as a "history of liberty from governmental interference," as the basis for concluding that the government has not blocked access to new drugs throughout the greater part of U.S. history.

The majority also relied on *Cruzan*, which held that an individual has a due process right to refuse life-sustaining medical treatment. According to the majority, Abigail Alliance's claim, by inference, implicates a similar right - the right to access potentially life-sustaining medication where there are no alternative government-approved treatment options. In both instances, the court found, the key is the patient's right to make the decision free from government interference. As such, the majority concluded that, if there is a protected liberty interest in self-determination that includes a right to refuse life-sustaining treatment, then the same liberty interest must include the complementary right of access to potentially life-sustaining medication. Therefore, the majority remanded the case to the District Court with instructions to assess whether FDA's policy, under a heightened scrutiny standard, is narrowly tailored to serve a compelling governmental interest.

Potential Implications

In the original complaint, Abigail Alliance alleged that non-commercial options - such as participation in clinical trials - provide relief only to a small number of terminally ill patients. Abigail Alliance also asserted that FDA's "compassionate use" programs, which permit drug companies voluntarily to provide new drugs at cost during the pre-approval period, are available only to a fraction of those in desperate need. However, unlimited access by terminally ill patients to experimental drugs may pose some very serious commercial and public health concerns. FDA's current system attempts to balance the competing interests of patients, public health, and science to avoid harm to individuals while advancing scientific discovery. Possible ramifications of this decision include obstruction of drug development by creating disincentives for patients to enroll in clinical trials.(the experimental drugs being readily available even outside of clinical trials). Pharmaceutical companies developing drugs may have liability concerns if their drugs are more widely taken before having been approved by the FDA as safe and effective. Further, patients who have received experimental drugs in clinical trials and who believe that they have experienced some improvement have advocated for continued access to these drugs even after the trials have ended. Such a demand was recently litigated, and denied in March 2006 by the Sixth Circuit Court of Appeals, in a case in which research subjects in a clinical trial of a Parkinson's drug had sought an order compelling Amgen to continue providing the drug even after the trial closed. Some in the pharmaceutical industry have feared that the weakening of the FDA regulatory structure, and increased rights of access to investigational drugs, ultimately could make it more difficult for industry to deny access in circumstances such as those of the Amgen case.

What's Next: Possible Expanded Access to Experimental Drugs

On the legislative front, Senator Sam Brownback (R-Kan.), introduced legislation last year that would require FDA to create a three-tiered approval system to expand access of experimental drugs for patients with serious or life-threatening conditions and diseases. The bill, S.B. 1956, was referred to committee in November 2005. In March 2006, Ropes & Gray assisted the American Society of Clinical Oncology ("ASCO"), the leading professional organization representing oncologists, in its submission, together with the National Coalition for Cancer Survivorship , of a Citizen Petition to FDA requesting the issuance of industry guidance on procedures and standards for initiating an expanded

access program for unapproved drugs. This Petition therefore is pending before the FDA even as the implications of the Abigail decision are being sorted out.

In a recent statement, an FDA spokeswoman commented: "We remain sympathetic to the desire of terminally ill patients to get access to experimental treatments when they have exhausted other therapeutic options, and have a number of new efforts under way inside the FDA to improve how we make investigational drugs available through expanded access programs. We plan to have much more to say about this soon." Currently, FDA has said that it is studying the opinion and consulting with the Department of Justice on its next steps. FDA could choose to ask for the full D.C. Circuit to rehear the case or could seek review before the Supreme Court. If FDA does not request a rehearing or further review, the case returns to the District Court. FDA has reportedly created an internal task force and may be issuing proposed regulations to address issues surrounding access to experimental drugs.

Contact Information

If you would like to discuss these recent developments or learn more about these issues, feel free to contact Ropes & Gray.

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