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### **FDLI Publishes White Paper on Access to Unapproved Drugs**

Should terminally ill patients be allowed access to drugs not approved by the Food and Drug Administration?

That is the question being heard today by the U.S. Court of Appeals for the District of Columbia and the focus of a new White Paper published by the Food and Drug Law Institute (FDLI).

The White Paper, *Whose Life Is It, Anyway? Abigail Alliance at the Crossroads*, was released in conjunction with FDLI's watershed Colloquium, *Whose Life Is It, Anyway?*, in Washington, D.C. Feb. 27, 2007. The sold-out meeting, the first in a series of colloquia to be sponsored by FDLI, discussed the complexities of access to experimental drugs and the colliding impact of constitutional rights, FDA regulations and liability implications affecting health care, the pharmaceutical industry and, most importantly, the patient. "We heard passionate points of view on how to reform the current system. We look forward to sponsoring similar meetings that could lead to the constructive development of law fueled by the accelerating pace of the new science and technological innovations," said FDLI President and CEO James Kelly.

The appeals court is holding a rehearing *en banc* on its May 2006 ruling in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach* that terminally ill, mentally competent adults, with no reasonable alternative to government-approved treatment options, have a constitutional right to access potentially life-saving drugs. The decision struck an unprecedented blow against the drug approval system, according to FDA, and the Supreme Court may eventually decide the matter.

The White Paper includes articles by:

**Scott Ballenger**, a partner at Latham & Watkins LLP, who represents Abigail Alliance;  
**Arthur Caplan**, chair of the Department of Medical Ethics and director of the Center for Bioethics at the University of Pennsylvania;

**Richard Cooper**, a partner at Williams & Connolly, and former FDA chief counsel;

**Mark D. Gately**, a partner at Hogan & Hartson, who was lead counsel in *Abney v. Amgen Inc.* and *Suthers v. Amgen*.

**Scott Gottlieb**, resident fellow at American Enterprise Institute, and former deputy commissioner for medical and scientific Affairs at FDA;

**Francis Palumbo**, professor and executive director of the University of Maryland School of Pharmacy Center on Drugs and Public Policy; and

**David C. Welch**, founder of 38 Lemon ([www.38lemon.com](http://www.38lemon.com)), an organization promoting brain cancer awareness from a patient's perspective.

For more information, visit the FDLI website, [www.fdi.org](http://www.fdi.org) or contact Michael Levin-Epstein, Editor-in-Chief, FDLI, (202) 222-0897; [mdl@fdli.org](mailto:mdl@fdli.org).

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Founded in 1949, FDLI publishes the award-winning, peer-reviewed *Food and Drug Law Journal*; the bimonthly magazine *Update*; *FDA Directory*; and dozens of books and publications for attorneys, regulatory affairs practitioners, scientists, health care professionals, government employees and marketers in the food and drug field.