

**FOR IMMEDIATE RELEASE**  
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**FOOD AND DRUG LAW INSTITUTE SPONSORS NATIONAL COLLOQUIUM  
ON ACCESS TO UNAPPROVED DRUGS**

*Landmark Meeting Feb. 27, 2007 — Whose Life Is It, Anyway? — To Address Impact of Abigail Alliance Case*

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

That is the question a panel of experts will discuss and debate at a landmark Colloquium, *Whose Life Is It, Anyway?*, sponsored by the Food and Drug Law Institute (FDLI), Feb. 27, 2007, in Washington, D.C.

This meeting is the first in a series of colloquia to be sponsored by FDLI in upcoming months. Under its new strategic direction, FDLI is committed to using the Colloquium series as a neutral forum to address the legal, regulatory, policy and practical implications of technological innovations affecting the food and drug industry.

In May 2006, in *Abigail Alliance for Better Access to Developmental Drugs v. von Eschenbach*, the U.S. Court of Appeals for the District of Columbia ruled 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. Eventually, the Supreme Court may decide the case, but already pharmaceutical manufacturers, physicians, government regulators, health care providers and patients are feeling its potential impact.

The Colloquium will include interactive audience and panel discussions on several important aspects of the decision, including constitutionality, scope, FDA responsibility, ethical considerations, impact on clinical trials, and liability and enforcement. It will address these specific issues:

- \* Does FDA's mission to regulate drugs for the public safety and health supersede patient access to drugs?
- \* Should terminally ill patients have access to any experimental drug?
- \* Should children with life-threatening illnesses or mentally ill adults also have access to experimental drugs?
- \* Will providing access to unapproved drugs hinder the drug development process?

\* Will manufacturers have increased liability as the result of the *Abigail Alliance* decision?

\* How will this decision affect clinical trials?

\* In the end, are patients better or worse off as a result of this decision?

A distinguished panel of experts will come together to discuss these far-reaching issues, including:

\* **Scott Gottlieb**, Deputy Commissioner for Policy, Food and Drug Administration;

\* **Richard Cooper**, Partner, Williams & Connolly; Former General Counsel, Food and Drug Administration;

\* **Arthur Caplan**, Director, Center for Bioethics, University of Pennsylvania;

\* **Frank Palumbo**, Director, Center for Drugs and Public Policy, University of Maryland School of Pharmacy

\* **Susan Okie**, Contributor, *New England Journal of Medicine*

\* **Scott Ballenger**, Principal, Trial Acceleration Institute, Inc.

\* **Mark Gately**, Partner, Hogan & Hartson

\* **David Welch**, 38 Lemon

Early Bird registration (through Dec. 22, 2006) is \$295 for FDLI members. Attendance is limited to the first 75 paid registrants. All registrants will receive a copy of FDLI Colloquium Series White Paper #1: *Whose Life Is It, Anyway? Abigail Alliance at the Crossroads*. The White Paper also will be available for purchase after the Colloquium for those unable to attend the meeting.

To register, visit <http://fdli.org> or call (800) 956-6923 or (202) 371-1420.

*Media:* To register, or to find out more about the conference, contact Michael Levin-Epstein, Editor-in-Chief, FDLI, (202) 222-0897; 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.