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**System for Gaining Access to Unapproved Drugs Flawed,  
Conclude Expert Panelists at FDLI's Colloquium Series #2**

The current system in the United States for gaining access to experimental drugs is flawed, but finding feasible solutions to the problem is extremely difficult and complex. That is the key conclusion reached at the Food and Drug Law Institute's (FDLI's) Colloquium Series #2, *From Abigail to Penelope: Individual to Corporate Rights*, presented to more than 50 drug industry professionals June 28, 2007, in Washington, D.C.

The colloquium explored several critical issues involved in access to unapproved drugs for patients who have exhausted traditional alternatives, including:

- > Do pharmaceutical manufacturers have any responsibility to provide experimental drugs to terminally ill patients, even when all risks are assumed?
- > What issues and concerns are the most prominent factors in making access requests and decisions?

The colloquium focused on the situation presented by a young girl, Penelope, profiled on the front page of *The Wall St. Journal* of May 1: Fighting for her life, Penelope sought access to an unapproved drug. FDA had no objections, but the pharmaceutical manufacturer and its venture capitalist backer declined to provide the drug despite pleas by family, influential friends and politicians.

Here's what the panel of experts had to say about the Penelope situation:

- > Janet Woodcock, MD, Deputy Commissioner and Chief Medical Officer at the Food and Drug Administration, said that FDA was concerned about the impact that access would have on the clinical trials process, but that the agency already had programs in place to facilitate compassionate use of drugs for seriously ill patients.
- > Scott Ballenger, a partner at Latham & Watkins in Washington, D.C., and lead attorney in the *Abigail Alliance* case, argued that seriously ill patients should be given the choice of whether to take an unapproved drug that already has undergone preliminary clinical trials.
- > D. Bruce Burlington, MD, Executive Vice President of Business Practices and Compliance at Wyeth Pharmaceuticals, noted that pharmaceutical firms are justifiably concerned that permitting patients access to experimental drugs may jeopardize the approval process and ultimately result in denying access to the largest cohort of needy individuals.
- > John Crowley, President and Chief Executive Officer at Amicus Therapeutics, asserted that many biotechnology and pharmaceutical companies were not aggressive enough in doing what was in the best interest of seriously ill patients.
- > Philip Katz, a partner at Hogan & Hartson in Washington, D.C., said that the law needs to be used more effectively to bring order to the confusion surrounding access to unapproved drugs.

> Jonathan Moreno, an ethics professor at the University of Pennsylvania, argued that dispassionate medical experts may be the best decision-makers regarding access to unapproved drugs.

FDLI has produced a complete transcript of Colloquium #2, *From Abigail to Penelope: Individual to Corporate Rights*, which is available for \$49.

To obtain a copy of the transcript, visit <http://fdli.org> or call (800) 956-6923 or (202) 371-1420.

*Media:* For more information about the Colloquium Series, 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.