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FDA Primed to Help Dying Patients Gain Easier Access to Unapproved Drugs

In 2007, terminally ill patients are expected to gain expanded access to unapproved medications. As soon as its proposed guidelines become final later this year, the Food and Drug Administration (FDA) will proactively assist physicians in getting experimental drugs in the hands of their dying patients, the Food and Drug Law Institute (FDLI) has learned.

FDA is taking action on the controversial issue of access to unapproved drugs as the landmark case of *Abigail Alliance v. von Eschenbach* heads toward a possible showdown in the U.S. Supreme Court, notes the article published in the *FDLI Insider* column on the FDLI website (www.fdpi.org). On March 1, the U.S. Court of Appeals for the District of Columbia will hear FDA's rehearing petition on its May 2006 ruling that terminally ill patients have a constitutionally based right to access to experimental drugs not fully approved by the agency.

Six months after the ruling by the three-judge appeals court panel, FDA published a proposal for "significant regulatory changes" to expand access to unapproved drugs. The agency is currently evaluating public comment on those guidelines and is not expected to issue final rules for several months. However, after FDA publishes those final rules, it is committed to making sure that physicians who want to get unapproved medications for their patients have all the information they need to process their applications, FDA spokeswoman Susan Cruzan tells FDLI. "We plan to do a number of educational/outreach [efforts]," Cruzan explains. "We also plan to engage external constituents [and] help identify the information needs and the target audiences as we develop this effort."

Although patients will be able to apply through their physicians for expanded access to unapproved drugs, FDA has no authority to compel them to do so, emphasizes Cruzan. "As the preamble to the proposed rule says, 'FDA cannot compel a drug manufacturer to provide access to investigational drugs for treatment use.'" Whether pharmaceutical firms make such medications available will be their decision, Cruzan explains.

No matter what happens with the final FDA rule and the *Abigail Alliance* case, the decades-long debate over expanded access is not likely to end soon, the article concludes. The Food and Drug Law Institute will sponsor a Colloquium on Access to Unapproved Drugs, *Whose Life Is It, Anyway?*, Feb. 27, 2007, in Washington, D.C. For more information on the Colloquium, visit FDLI's home page, www.fdpi.org.)

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.