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The Food and Drug Law Institute's *Food and Drug Policy Forum* Discusses Orange Book's Regulation of "Skinny Labeled" Generic Drugs

"Is it time for FDA to revise its Orange Book rules to deal with "skinny labeled" generic drugs?" That's the timely topic addressed by the latest issue of FDLI's Food and Drug Policy Forum (Volume 1, Number 19, October 12, 2011).

Written by Terry Mahn, Managing Principal at Fish and Richardson, in Washington, D.C., the article concludes that federally driven therapeutic equivalence policies are long overdue for reform.

In an upcoming case before the Supreme Court, *Caraco v. Novo Nordisk*, the Court will, for the first time, focus its attention on the role of the Orange Book in the cost and delivery of national healthcare. Mahn argues that the Court will discover how FDA, in an effort to promote generic drug substitution on a national scale, has turned the Orange Book into a vehicle that can distort pioneer patent rights and put patient safety needlessly at risk.

Mahn argues that if drug discoveries "go generic" too quickly the process for developing pioneer drug will break down, new drug investments will dry up and, ultimately, the public health will suffer. Mahn recommends that FDA create and maintain a database providing information on generic label carve-outs so the public can determine if a generic drug has been approved as "use equivalent" to the pioneer drug; consider labeling changes for "skinny-labeled" generics; add "use equivalency codes" to the Orange Book; and create a second carve-out option for "skinny-labeled" generics to address patent concerns.

FDLI's Food and Drug Policy Forum is a concise (approximately 10 pages), twice-a-month, peer-reviewed, digital publication on current food and drug policy topics. Posed in the form of a question, each issue provides subscribers and purchasers with pertinent background information, relevant research, a discussion of central issues, relevant resources and policy recommendations. The views, opinions and statements expressed in the Policy Forum are those of the authors. The Food and Drug Law Institute neither contributes to nor endorses Policy Forum articles. As a nonprofit 501 (c) (3) organization, FDLI does not engage in advocacy activities.

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