

Calif. Appeals Panel Revives Suits Over Diabetes Drugs

By **Emily Field**

Law360 (November 7, 2018, 9:58 PM EST) -- A California appeals court revived claims Tuesday that Merck & Co. and other diabetes drugmakers failed to warn about their drugs' pancreatic cancer risks, finding a lower court erred in not considering scientific evidence the U.S. Food and Drug Administration hadn't evaluated.

A unanimous state appeals panel, in an unpublished opinion, said that a lower court misinterpreted the U.S. Supreme Court's ruling in [Buckman Co. v. Plaintiffs' Legal Committee](#) , which bars state law tort claims that are predicated on alleged violations of the Food, Drug, and Cosmetic Act. The state appeals court agreed with a Ninth Circuit decision that revived litigation in federal court over similar claims that the class of diabetes drugs, incretin-based drugs, did not have warnings that they increase the risk of pancreatic cancer.

Like the judge in the federal litigation, the lower state judge had found that the claims were preempted by the high court's [Wyeth v. Levine](#)  decision because the undisputed evidence showed the FDA would not have allowed a pancreatic cancer warning.

According to the opinion, the state judge and the California federal judge held joint hearings on the companies' motions for summary judgment in the state and federal litigation. A week after U.S. District Judge Anthony J. Battaglia dismissed the claims in the federal litigation, Judge William Highberger dismissed the roughly 300 claims in Los Angeles County Superior Court, the panel said.

Like the federal MDL, the state court suits are aimed at a class of Type 2 diabetes drugs known as incretin mimetics that have been under regulatory scrutiny since academic researchers suggested in early 2013 that they may lead to an increased risk of pancreatitis and precancerous changes in the pancreas. But the FDA and the European Medicines Agency found no firm evidence that the drugs are connected to pancreas problems, according to a study released in February 2014.

The companies, including Eli Lilly & Co., AstraZeneca's now-defunct Amylin Pharmaceuticals unit and Novo Nordisk Inc., conceded that the Buckman ruling doesn't apply to state law claims that a drugmaker failed to warn about its product's risk, but argued that it still barred taking into account any evidence that manufacturers are alleged to have misrepresented or intentionally withheld from the FDA.

"We reject this argument," the panel said. "First, only a portion of plaintiffs' 'new safety evidence' consists of information that defendants allegedly had in their possession, but failed to disclose, or otherwise misrepresented, to the FDA."

The consumers haven't alleged that the companies played a part in withholding evidence, such as a report by Canadian health authorities, the panel said. Instead, they claim that if a drug manufacturer had included the new information in an application to change a drug's labeling, it might change the FDA's viewpoint on the risk of pancreatic cancer.

"In light of the [Ninth] Circuit's reversal of Judge Battaglia's order, which the state court judge virtually adopted verbatim, this reversal of the state court preemption decision was expected," Hunter J. Shkolnik of Napoli Shkolnik PLLC, counsel for the patients, told Law360 on Wednesday.

"Both the federal court and state court rulings were improper, and now these families will be able to pursue their cases."

"Merck believes that additional discovery will only further establish the already clear evidence that the FDA would not permit Merck and other manufacturers of incretin-based therapies to add a warning concerning pancreatic cancer to the labels for these medications," a company spokeswoman told Law360 on Wednesday. "We remain fully committed to defending these cases."

"AstraZeneca believes that all applicable laws were followed and that the allegations are without merit," a company spokeswoman told Law360 on Wednesday.

"Novo Nordisk is deeply committed to safety, with a long history in developing innovative and important medicines for patients with diabetes," a company spokesman told Law360 on Wednesday. "We are disappointed by the California Court of Appeal's ruling, and will continue to vigorously defend the company against the plaintiffs' claims."

Representatives for the remaining companies didn't immediately respond to requests for comment on Wednesday.

The consumers are represented by Hunter J. Shkolnik and Jennifer R. Liakos of Napoli Shkolnik PLLC, Thomas V. Girardi and V. Andre Sherman of Girardi & Keese, and Elizabeth L. Crooke and Brian D. Depew of Engstrom Lipscomb & Lack.

Amylin Pharmaceuticals LLC is represented by Richard B. Goetz, Amy J. Laurendeau and Houman Ehsan of O'Melveny & Myers LLP.

Merck & Co. is represented by Stephen D. Raber, Douglas R. Marvin, F. Lane Heard III and Kannon K. Shanmugam of Williams & Connolly LLP.

Eli Lilly & Co. is represented by Kenneth J. King, Barry H. Boise, Aline Fairweather of Pepper Hamilton LLP, and David E. Stanley of Reed Smith LLP.

Novo Nordisk Inc. is represented by Loren H. Brown, Raymond M. Williams and Stanley J. Panikowski of DLA Piper.

The case is *Rotondo v. Amylin Pharmaceuticals et al.*, case number B275314, in the California Court of Appeals for the Second Appellate District, Division Seven.

--Editing by Jay Jackson Jr.