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Incretin Mimetics Cases See Signs of New Life on Appeal

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As we have previously reported, safety concerns regarding incretin mimetics (such as Byetta, Januvia/Janumet and Victoza), led to more than a thousand lawsuits being filed across the country.

Reports suggest that people taking the medications for the treatment of Type 2 diabetes may be at an increased risk of developing pancreatic cancer.

In August 2013, those lawsuits were consolidated in a Multi-District Litigation (MDL), before Judge Anthony J. Battaglia, in the United States District Court for the Southern District of California. The litigation suffered an unexpected setback when, in November 2015, the trial court granted summary judgment, essentially dismissing the claims.

One of the primary bases for that ruling, in very basic terms, was that the trial court found that the plaintiffs' claims were "preempted," because the courts should not be able to second guess the agency in charge of regulating how drugs should be labeled (the Food and Drug Administration or FDA).

The trial court basically ruled that, since it would have been the FDA's job to require or approve a change in the labeling of these drugs to warn of a connection to pancreatic cancer, the plaintiffs would be prohibited from pursuing their claims in court - regardless of whether the drug makers had hidden information from, or misrepresented information to, the FDA. So, because the FDA did not require, and would not have allowed, such warnings on the drug label, the claims for failure to warn were dismissed.

That, and other issues, were appealed, and in December 2017, the United States Court of Appeals for the Ninth Circuit reversed the trial court's decision.

The appellate court essentially found that the trial court should have considered and permitted further discovery on the information provided to and reviewed by the FDA, including any newly discovered or withheld information concerning the growing concerns over the link between the drugs and pancreatic cancer.

This information was crucial to determining whether the FDA would have required changing the warnings on the drug, and should have been considered before the trial court dismissed the plaintiffs' failure to warn claims.

Based on this latest ruling, the incretin mimetics pancreatic cancer claims are expected to proceed forward in the MDL. A status conference is currently scheduled for the end of February to discuss the next steps in the litigation.

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