In re: Genentech Herceptin Multidistrict Litigation, 960 F.3d 1210 (10th Cir. 2020)

Topics Covered: Drug Price Transparency

Outcome: Very Favorable

Issue

The issue in this appeal was whether federal laws preempt state laws that would otherwise hold Genentech liable for its sale of the drug Herceptin in amounts less than that shown on the vials in which the drug is sold.

AMA Interest

The AMA supports drug pricing transparency.

Case Summary

Genentech, a California company, invented, manufactured and distributed Herceptin, a biologic product used to treat breast cancer. The drug was sold primarily (perhaps exclusively) to cancer treatment providers, rather than to patients. The Federal Food and Drug Administration (FDA) closely monitors the production and sale of Herceptin, including labelling of the drug vials.

On September 25, 1988, the FDA approved the sale of Herceptin in vials labelled as holding 440 mg. of the drug. However, the FDA found that complexities in the manufacturing of Herceptin required some leeway in the exact amount of drug held in each vial. Thus, the FDA approval covered a variance (either more or less) of up to 35 mg. of drug per 440 mg. vial.

In the first 20 years of its sale, a majority of the Herceptin batches would equal or exceed 440 mg. per vial. However, the proportion of batches containing at least 440 mg. dropped below 50% by 2009, and it has never exceeded 50% since. Always, though, Herceptin sales met the minimum 405 mg. threshold.

Several class actions were filed against Genentech by oncologists, oncological practices, and other health care providers (such as state government institutions) who purchased Herceptin. The lead suit was filed in Oklahoma, and the other suits have been consolidated into the Oklahoma case in a multidistrict litigation proceeding.

The claim, in essence, is that Genentech sells Herceptin in vials labelled as containing 440 milliliters, but in fact these vials generally contain smaller amounts of the drug. Although the drugs were sold within the FDA's allowed variations, those variations were meant to accommodate uncertainties in the manufacturing process. They were not a blanket license to mislead purchasers. Genentech is simply taking advantage of a now-obsolete latitude in the original FDA approval, so it can systematically shortchange its customers. Suit is based on violations of California law.

Genentech's defense is that the Federal Food, Drug, and Cosmetic Act (FDCA) preempts the California law on which the lawsuits are based. It contends that the FDA closely regulates the manufacture of Herceptin, and the drugs it sold came within the FDA's approved 35 mg./vial variances. In light of the federal laws, only the FDA is authorized to take action against Genentech for mislabeling.

The trial court accepted Genentech's argument and granted summary judgment in its favor and against the plaintiffs. The plaintiffs appealed to the Tenth Circuit, which reversed the grant of summary judgment. The Tenth Circuit largely followed the arguments of the Litigation Center *amicus* brief.

Litigation Center Involvement

The Litigation Center, through the AMA and the Oklahoma State Medical Association, filed an *amicus* brief in the Tenth Circuit to support the plaintiffs.

United States Court of Appeals for the Tenth Circuit brief