

United Therapeutics Beats HHS' Discount-Dodging Claims

By **Andrew Karpan**

Law360 (November 10, 2021, 10:06 PM EST) -- A federal judge in Washington, D.C., has ruled that the federal government can't go after United Therapeutics and Novartis over their marketing policies limiting the number of drugs sold as part of a federal drug discount program for low-income patients, a decision that departs from recent rulings against other pharmaceutical companies.

U.S. District Judge Dabney Friedrich found that the U.S. Department of Health and Human Services overreached when the agency tried to stop United Therapeutics and Novartis from restricting the discounts that the companies are supposed to provide pharmacies under the Public Health Service Act's 340B program.

"The plain language, purpose, and structure of the statute do not prohibit the manufacturers from imposing any conditions on their offers of 340B-priced drugs to covered entities," Judge Friedrich said in a Nov. 5 ruling, emphasizing that the companies should be able to impose some conditions on those sales.

The 340B Drug Pricing Program requires drugmakers to discount thousands of medications for hospitals that serve low-income neighborhoods. To limit the amount of drugs it sold under the program, Novartis began imposing geographic restrictions on which orders the company would fill, while United Therapeutics adopted slightly different limits on those orders.

The companies then filed suit after receiving letters from the HHS that indicated that those policies resulted in overcharges that violated the terms of the program. Filed in May and June of this year, their lawsuits joined those of other large drugmakers in the barrage of litigation over the rule that have hit federal courts around the country.

In fact, Judge Friedrich's decision came down the same day that New Jersey's chief federal judge, U.S. District Judge Freda Wolfson, issued a 122-page ruling that agreed with the federal government that policies by two other drugmakers — Sanofi-Aventis US LLC and Novo Nordisk Inc. — ran afoul of the language of the 340B program. Citing, however, the "complex 340B landscape," Judge Wolfson ordered HHS to rethink those notices with respect to the program's scope.

Judge Friedrich took this idea even further and wrote that the agency needed to start entirely from scratch if it wanted to prevent drug companies from curbing discounts on the drugs it sold under the program.

"Any future enforcement action must rest on a new statutory provision, a new legislative rule, or a well-developed legal theory that Section 340B precludes the specific conditions at issue here," she wrote.

Unlike the New Jersey court, Judge Friedrich had declined to opine on whether the companies were evading the law.

"The court expresses no view as to whether any other legal theory — such as one based on the structure of Section 340B — rules out the plaintiffs' specific conditions," she wrote.

Late last month, a federal judge in Indiana ruled that the 340B statute did prevent manufacturers from conditioning their offers, in a decision for Eli Lilly's challenge of the same rule. The federal government brought the Indiana judge's ruling to Judge Friedrich's attention early last week, and pointed to "its clear holding that [Health Resources and Services Administration]'s statutory interpretation is correct."

But Judge Friedrich wrote that she did not find the Indiana judge's ruling "persuasive" either.

The structure of the anti-fraud provisions that were written into the original law, she wrote, "suggests that Congress did not intend Section 340B's purpose to be pursued at all costs."

Judge Friedrich, a Trump appointee, also found earlier this year that the federal government's eviction moratorium had overstepped its authority.

Counsel for the companies and the federal government did not respond to requests for comment.

United Therapeutics is represented by Phil Perry, Andrew Prins, Christopher Schott, Cherish Drain, Greg in den Berken and Jamie Deal of Latham & Watkins LLP.

Novartis is represented by Catherine E. Stetson, Susan M. Cook and Harrison Gray Kilgore of Hogan Lovells.

U.S. Department of Health and Human Services Secretary Xavier Becerra and the federal agencies are represented by Deputy Assistant Attorney General Brian D. Netter, Michelle R. Bennett, Rachael. L. Westmoreland, Kate Talmor and Jody Lowenstein.

The cases are Novartis Pharmaceuticals Corp. vs. Diana Espinosa and United Therapeutics Corp. vs. Diana Espinosa, case numbers 1:21-cv-01479 and 1:21-cv-01686, both in the U.S. District Court for the District of Columbia.

--Additional reporting by Adam Lidgett and Jeannie O'Sullivan. Editing by Dave Trumbore.