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CLIENT ALERT

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District Court Rules Pharmaceutical Manufacturers Are Not Required to Discount Orphan Drugs - Regardless of the Condition Being Treated - for Certain 340B Eligible Health Care Entities

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HHS' rule requiring pharmaceutical manufacturers to discount orphan drugs when they were used to treat non-rare diseases was inconsistent with Congress' intent to exclude all orphan drugs from the 340B discount program for certain health care facilities newly eligible under the ACA, with no exceptions based on the purpose of treatment.

On October 14, 2015, a federal district court vacated a Department of Health and Human Services (HHS) rule requiring pharmaceutical manufacturers to apply the 340B program discount to orphan drugs if they were being used to treat non-rare diseases. The court found that HHS' rule impermissibly narrowed the scope of Congress' exclusion of orphan drugs from mandatory discounts for certain 340B program entities. As a result, manufacturers will no longer have to discount orphan drugs — regardless of how they are used — for a number of 340B entities.

Promoting Development of Medications to Treat Rare Diseases

The Orphan Drug Act (ODA), enacted in 1983, promotes the development of medications used to treat rare diseases. The ODA defines rare diseases as diseases that affect fewer than 200,000 persons in the United States or diseases that affect more than 200,000 persons, but for which there is no reasonable expectation that the cost of developing a drug for the disease and making it available in the United States will be recovered from U.S. sales. The ODA creates incentives to promote orphan drug development, including a seven-year market exclusivity period during which no other drugs can be licensed or approved for the orphan condition; a tax credit to offset clinical development expenses; research grants; and exemptions from fees otherwise applicable to new drug applications.

Although the orphan drug designation is most often granted to medications indicated to treat rare diseases, physicians may also use orphan drugs to treat non-rare diseases. A drug can be designated an orphan drug even if it is approved to treat a different, non-rare disease in addition to a rare disease. Orphan drugs must still meet the usual regulatory requirements for Food and Drug Administration marketing approval.

Medication Discounts for 340B Entities

The 340B program, established under section 340B of the Public Health Services Act, requires pharmaceutical manufacturers to discount drugs to eligible health care facilities. Under the Patient Protection and Affordable Care Act of 2010 (ACA), Congress expanded the types of entities eligible for 340B discounts. In an amendment to the ACA, Congress also excluded orphan drugs from the mandatory discounts for a number of these newly eligible entities. The statutory scheme sets ceilings on manufacturer drug prices for medications sold to specified health care entities. The ceiling price can be up to 50 percent lower than the non-340B price.[1] Starting with the Veterans Health Care Act of 1992, Congress required manufacturers to discount medications to any entity covered by the 340B program. Orphan drugs were not excluded from these required discounts for the entities originally covered by the Veterans Health Care Act.

The ACA significantly expanded the list of entities eligible for the 340B program, with the number of participating hospitals tripling since 2004.[2] In the Health Care and Education Reconciliation Act, an amendment to the ACA, Congress excluded orphan drugs from the list of 340B discounted medications for these newly eligible 340B entities.

Court Finds that HHS Narrowed the Orphan Drug Discount Exclusion Beyond Congress' Intent

HHS has twice tried to narrow the orphan drug exclusion to apply only when orphan drugs are being used to treat rare diseases. On May 23, 2014, the U.S. District Court for the District of Columbia vacated HHS' first July 2013 rule attempting to narrow the exclusion, deciding that HHS lacked the statutory rule-making authority. On October 14, 2015, the same court vacated HHS' substantively identical second rule, promulgated in July 2014.[3] The court ruled that HHS' exclusion was inconsistent with the statutory language establishing the 340B discount program and contrary to what Congress intended when it established the exception for orphan drugs.

HHS' position has been that the ACA's 340B orphan drug exclusion applied only when orphan drugs were "used for the rare condition or disease for which the drug was designated."[4] HHS has also taken steps to enforce its rules, including sending letters to pharmaceutical manufacturers advising them of their failure to comply, publishing online lists of those manufacturers out of compliance and requiring refunds of discounts not provided.

In its October 14, 2015 opinion, the U.S. District Court for the District of Columbia found that HHS' rule requiring pharmaceutical manufacturers to discount orphan drugs when they were used to treat non-rare diseases was inconsistent with Congress' intent to exclude all orphan drugs from the 340B discount program for certain health care facilities newly eligible under the ACA, with no exceptions based on the purpose of treatment.

Endnotes

1. *See* Gov't Accountability Office, GAO-11-836, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,* 2 (2011).

2. *Id.* at 20.

3. *Pharm. Research & Mfrs. of Am. v. U.S. Dep't of Health & Human Servs*., No 1:14-CV-01685 (D. D.C. Oct. 14, 2015).

4. *See* Availability of Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program, 79 Fed. Reg. 42,801, 685 (July 23, 2014).