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in the news

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Recent 340B Orphan Drug Decision May Have Widespread Implications

In this Issue:

On May 23, 2014, the U.S. District Court for the District of Columbia ruled in favor of the Pharmaceutical Research and Manufacturers of America ("PhRMA") by invalidating the "orphan drug rule." Generally, the orphan drug rule allows rural referral centers, sole community hospitals, critical access hospitals and free-standing cancer hospitals to purchase certain "orphan drugs" that are used for "non-orphan" conditions at 340B Program prices. The Department of Health and Human Services had finalized this rule in 2013 as part of its efforts to bring clarity to the 340B Program. This decision calls into question HHS's rulemaking authority with respect to the 340B Program, and has created an atmosphere of regulatory uncertainty for providers and pharmaceutical manufacturers alike just as HHS was expected to release its sweeping "mega-reg" for the 340B Program.

Orphan Drug Rule Background

The Affordable Care Act extended participation in the 340B Program to critical access hospitals, rural referral centers, sole community hospitals, free-standing cancer hospitals and children's hospitals. Congress recognized that providing 340B Program discounts on all outpatient drugs purchased by these newly eligible entities could adversely affect the desire and ability of pharmaceutical manufacturers to develop orphan drugs. Generally, orphan drugs are developed to treat rare diseases or conditions that affect fewer than 200,000 people. Congress balanced its desire to extend the benefits of the 340B Program to these newly eligible entities against its concern for stymieing the development of orphan drugs by denying 340B Program pricing to certain of these newly eligible entities for drugs "designated by the

Secretary under section 526 of the Federal Food, Drug and Cosmetic Act for a rare disease or condition."

In response to market confusion regarding the scope of this exclusion, HHS proposed the orphan drug rule in May 2011. The orphan drug rule prohibits rural referral centers, sole community hospitals, critical access hospitals and free-standing cancer hospitals from obtaining 340B Program pricing on an "orphan drug" when the drug was used for the disease or condition for which the drug received its orphan designation. However, these newly eligible entities could receive 340B Program discounts on the drugs when used for "non-orphan" conditions. The regulation also requires these entities to have an auditable tracking mechanism to evidence that 340B Program pricing was not applied when those drugs were dispensed for orphan conditions. HHS finalized the orphan drug rule over the objections of PhRMA on July 23, 2013, making it effective as of October 1, 2013. HHS's regulation is available here.

PhRMA Sues to Block the Orphan Drug Rule

On September 27, 2013, PhRMA filed suit to block HHS from implementing the orphan drug rule. PhRMA argued that HHS did not have the statutory authority to issue the orphan drug rule, and that HHS's interpretation contravened the plain meaning of the statute. PhRMA maintained that Congress had excluded orphan drugs from 340B Program pricing for these newly eligible entities regardless of whether the drugs were prescribed for non-orphan conditions.

District Court Says HHS Overstepped Its Authority and Invalidates Orphan Drug Rule

While the Court found that HHS's regulation was "the most reasonable way of administering the statute," it concluded that "Congress [had] not given HHS the broad rulemaking authority to do so…" The Court construed HHS's rulemaking authority narrowly by finding that Congress had granted HHS the power to issue regulations in only three areas: (1) establishing an administrative dispute resolution process, (2) calculating ceiling prices, and (3) imposing civil monetary penalties. The Court's decision left open the possibility of additional briefing on whether the orphan drug rule was merely interpretive and, as such, a permissible use of regulatory power.

The immediate result of this decision is that rural referral centers, sole community hospitals, critical access hospitals and cancer hospitals may no longer purchase orphan drugs at 340B Program discounts under any circumstance. Drug manufacturers will likely stop offering 340B pricing on orphan drugs to these newly eligible entities in light of this ruling.

The full text of the Opinion is available here.

Implications on the "Mega-Reg"

The Court's decision applies only to HHS's authority to issue the orphan drug rule, but the wide-ranging nature of the decision creates an atmosphere of uncertainty for covered entities and drug manufacturers. The Court calls into question whether HHS has the authority to issue other regulations implementing the 340B program, including the widely anticipated "mega-reg." Observers had expected the mega-reg to offer greater clarity, certainty and oversight for the 340B Program by redefining eligible patients, imposing new compliance requirements for contract pharmacy arrangements, revisiting hospital eligibility criteria and addressing participation by off-site hospital facilities. Pharmaceutical manufacturers and providers could now challenge provisions of the mega-reg that they dislike by arguing these rules fall outside the scope of HHS's authority as interpreted by the Court. The Office of Management and Budget is currently reviewing the mega-reg and, before the orphan drug ruling, its release had been anticipated this June.

HHS's Next Steps

Procedurally, in response to the Court's May 23, 2014 Order, HHS could choose to pursue an interlocutory appeal to the United States Court of Appeals for the District of Columbia Circuit. Unless certain post-Order motions were filed, such an appeal would have to be filed no later than sixty (60) days from the date of the Order, or by July 22, 2014. Thereafter, HHS also has the option of filing a motion to stay the permanent injunction pending any appeal, first with the United States District Court for District of Columbia and, failing relief there, with the United States Court of Appeals for the District of Columbia Circuit.

Separately, if HHS chooses to submit further briefing on the interpretive-rule question left open for resolution by the Order, it must do so under the terms of the Order no later than June 13, 2014. Response and reply briefs would likely be permitted thereafter.

HHS has not yet indicated how it will respond (if at all) to the ruling.

Industry Reactions

The American Hospital Association ("AHA") and Safety Net Hospitals for Pharmaceutical Access ("SNHPA"), among others, have issued statements in response to the District of Columbia Circuit Court's ruling. AHA's statement is available here; SNHPA's statement is available here.

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