D.C. District Court Vacates 340B Orphan Drug Rule

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On July 23, 2013, the U.S. Department of Health and Human Services (HHS) issued its so-called Orphan Drug Rule. This rule allowed critical access hospitals, sole community hospitals, rural referral centers, and cancer hospitals participating in the 340B Federal Drug Pricing Program (340B Program) to purchase orphan drugs, if used to treat non-orphan conditions, at discounted 340B prices. As further discussed below, the Orphan Drug Rule has been recently vacated by the by the U.S. District Court for the District of Columbia in *Pharmaceutical Research & Manufacturers of America v. HHS*.

As noted by the Court, the drug Prozac has orphan drug designation from the Food and Drug Administration for the treatment of autism and body dysmorphia in children, as well as a non-orphan indication for treating depression. Under the Orphan Drug Rule, critical access hospitals, sole community hospitals, rural referral centers, and cancer hospitals could obtain Prozac, when used for the treatment of depression (a non-orphan use), at 340B prices. According to HHS, the Orphan Drug Rule has reflected the agency's attempt to balance the Congressional intent to lower drug costs for these providers with the preservation of incentives for drug manufacturers to develop orphan drugs. However, several stakeholders, including the trade group, Pharmaceutical Research & Manufacturers of America (PhRMA), questioned the authority of the agency to promulgate the rule.

In September 2013, PhRMA brought suit against HHS challenging the validity of the Orphan Drug Rule, claiming that the rule was in contradiction to the underlying statutory language for the 340B Program. On May 23, 2014, in *PhRMA v. HHS*, the Court agreed with PhRMA, issuing a Memorandum Opinion that vacated the Orphan Drug Rule. In holding that HHS had exceeded the scope of its statutory authority, the Court noted that the agency's legislative authority to implement rules arising under Section 340B of the Public Health Service Act was limited by Congress to (1) establishing an administrative dispute resolution process, (2) issuing regulations on the methodology used for calculating ceiling prices, and (3) the imposition of monetary civil sanctions. In contrast, the Court noted that the Congressional intent to provide financial incentives to manufacturers for the development of orphan drugs was unambiguous.

Since the Orphan Drug Rule became effective on October 1, 2013, the impact of the Court's decision on prior purchases of orphan drugs at 340B pricing is as yet unknown. Because the Orphan Drug Rule made hospital providers responsible for maintaining auditable records to demonstrate compliance with the terms of the rule, the Court's decision opens up the possibility of future audits by HHS (through the Health Resources and Services Administration or HRSA), as well as by pharmaceutical manufacturers, to seek repayment for any inappropriate purchases of orphan drugs through the 340B program.

In addition, the Court's criticism focused on the agency's improper exercise of its legislative rule-making authority but subtly suggested that the agency may have greater leeway when adopting interpretive rules, such as guidance documents, related to the 340B program. Thus, it will be interesting to see what effect this court decision may have on future attempts at 340B rulemaking, including the much-anticipated comprehensive 340B proposed rules (which have been expected to be released this month).

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