House Bill Would Narrow 340B Orphan Drug Exception

Neil W. Hoffman, Ph.D. and Alexander B. Foster

A recently proposed House bill entitled The *Closing Loopholes for Orphan Drugs Act* would narrow the exception for orphan drugs under the federal 340B Drug Pricing Program. Representative Peter Welch (D-VT) introduced the bill on June 13, 2017[1] in order to "close a loophole" that permits drug companies to deny discounts to certain covered entities for all use of orphan drugs.

The bill is the most recent in a string of events related to the orphan drug exception. The Patient Protection and Affordable Care Act of 2010 (PPACA), as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA), revised the 340B statute to add the following provider types as 340B covered entities: children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals.[2] However, with the exception of children's hospitals all of these newly eligible covered entities were excluded from access to discount pricing under the 340B program for orphan drugs used to treat rare diseases or conditions. As amended by HCERA and Section 204 of the Medicare and Medicaid Extenders Act of 2010, section 340B(e) of the PHSA currently sets forth this orphan drug exception as follows:

> EXCLUSION OF ORPHAN DRUGS FOR CERTAIN COVERED ENTITIES—For covered entities described in subparagraph (M) (other than a children's hospital described in subparagraph (M)), (N), or (O) of subsection (a)(4), the term "covered outpatient drug" shall not include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition.

In May 2011, the U.S. Department of Health and Human Services (HHS) issued a proposed rule to implement the orphan drug exception such that the exception would apply only to orphan drugs used for the orphan indication. Since that time, HHS, pharmaceutical manufacturers, and covered entities have been arguing over the scope of the orphan drug exception.[3] For example, on October 9, 2014, the Pharmaceutical Research & Manufacturers of America (PhRMA) challenged HHS's interpretive rule (limiting the exception to use of the orphan drug for the orphan indication) by filing suit with the U.S. district court in D.C. In its complaint,[4] PhRMA argued that the statutory text of the 340B orphan drug exception is self-executing and that the exception is based on the designation of the orphan drug and not limited by the drug's use. On October 14, 2015, the district court found in favor of PhRMA by granting its motion for summary judgment, concluding, among other things, that HHS's interpretive rule contravenes the plain language of the underlying statute.

The bill introduced by Representative Welch would accomplish by statute what HHS has been unable to do through rule-making. The bill would modify Section 340B(e) of the PHSA (42 U.S.C. § 256b(e)) as follows:

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1 For the text of the House bill, see https://www.congress.gov/bill/115th-congress/house-bill/2889/text.

2 For additional background, see http://www.agg.com/files/Publication/f54cdd7a-7d89-48b7-bdf6-f23950bbcb1e/Presentation/PublicationAttachment/c5758b0d-3117-44b7-a535-dccd35130c6d/Hoffman-District-Court-in-DC-Vacates-HHS-Interpretive-Rule.pdf.

3 See, e.g., *PhRMA v. HHS*, Complaint, Civil Action No. 14-1685 (D.D.C. Oct. 9, 2014).

4 *Id.*

include a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act for a rare disease or condition *when transferred, prescribed, sold, or otherwise used for the rare condition or disease for which such drug is so designated*. [Emphasis supplied.]

The bill, cosponsored by Representative Gregg Harper (R-MS), was referred to the House Energy and Commerce Committee. If the bill moves forward, expect this already hotly debated topic to again capture the attention of interested parties.

Authors and Contributors

Neil W. Hoffman, Ph.D
Partner, Atlanta Office
404.873.8594
neil.hoffman@agg.com

Alexander B. Foster
Associate, Atlanta Office
404.873.8598
alex.foster@agg.com

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Atlanta Office
171 17th Street, NW
Suite 2100
Atlanta, GA 30363

Washington, DC Office
1775 Pennsylvania Avenue, NW
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