

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA**

PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES, *et*
al.,

Defendants.

Civil Action No. 1:13-cv-1501-RC

DEFENDANT’S RESPONSE TO THE COURT’S MAY 23, 2014, ORDER

On May 23, 2014, the Court issued an Order and Memorandum Opinion granting plaintiff’s motion for summary judgment and denying defendant United States Department of Health and Human Services’ (“HHS’s”) motion to dismiss or, in the alternative, for summary judgment. The Court held that HHS did not have the rulemaking authority to issue, as a legislative rule, its new regulation addressing the treatment of orphan-designated drugs under the Section 340B Program. *See* 42 U.S.C. § 256b(e). The Court accordingly issued a permanent injunction vacating the regulation. However, the Court declined to rule on whether the new rule could be upheld as an interpretive rule but invited HHS to submit further briefing by June 13, 2014, should it wish to pursue the interpretive-rule theory.

HHS respectfully declines the Court’s invitation to submit further briefing defending the challenged regulation as an interpretive rule. HHS is currently evaluating

its options as to how to respond to the Court’s decision, including whether to appeal and/or whether to propound an interpretive rule or other type of interpretive guidance that would set forth HHS’s interpretation of 42 U.S.C. § 256b(e). HHS does not interpret the Court’s decision as precluding it from issuing an interpretive rule or other type of interpretive guidance, even if that rule or guidance sets forth the same interpretation previously embodied in the challenged regulation. *See, e.g., Kelley v. EPA*, 15 F.3d 1100, 1108-09 (D.C. Cir. 1994) (holding that regulation was not valid as a legislative rule and did not qualify as an interpretive rule, but remanding for the agency to “try again”); *CERCLA Enforcement Against Lenders and Government Entities That Acquire Property Involuntarily*, 60 Fed. Reg. 63,517, 63,518 (Dec. 11, 1995) (stating, in wake of *Kelley*, the agencies’ intentions to follow the provisions of the invalidated regulation “as enforcement policy”).

Respectfully submitted,

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Dated: June 12, 2014