UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA,	:		
Plaintiff,	:	Civil Action No.:	13-1501 (RC)
v.	:	Re Document No.:	48
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*	:		
Defendants.	:		

ORDER

ENTERING FINAL JUDGMENT

The plaintiff, Pharmaceutical Research and Manufacturers of America ("PhRMA"), initially challenged a final rule promulgated by the Health Resources and Services Administration ("HRSA") and the U.S. Department of Health and Human Services ("HHS") that interpreted and implemented part of the 340B Orphan Drug Program of the Public Health Service Act ("PHSA"), 42 U.S.C. § 256b(e). *See* Exclusion of Orphan Drugs for Certain Covered Entities Under 340B Program, 78 Fed. Reg. 44,016 (July 23, 2013); *see also* Compl. ¶ 1, ECF No. 1. That rule was codified in the Code of Federal Regulations at 42 C.F.R. § 10.21. The plaintiff's complaint clearly and unequivocally challenged the final rule promulgated by HHS and HRSA in 42 C.F.R. § 10.21. *See generally* Compl.

On May 23, 2014, this Court vacated that final rule, on the grounds that HHS lacked the substantive rulemaking authority to implement the rule in the first instance. *See* Mem. Op. 27, ECF No. 43; *see also* Order, ECF No. 42 ("It is hereby ORDERED that the final rule, 42 C.F.R. § 10.21 is VACATED."). Though the Court vacated the final legislative rule, it invited the

parties to submit supplemental briefs on whether the legislative rule could survive as an interpretive rule. *See* Order 1. HHS declined that invitation, while it evaluated "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)." *See* Notice 1–2, ECF No. 45.

Though HHS declined to brief the issue, from May 23, 2014 until July 21, 2014, HHS continued to promulgate the final rule as a quasi-interpretive rule. *See* Pl.'s Ex. 1, ECF No. 47-1 (June 19, 2014) (print out of HRSA's website saying that "the Court did not invalidate HRSA's interpretation of the statute. HHS/HRSA continues to stand by the interpretation described in its published final rule, which allows the 340B covered entities affected by the orphan drug exclusion to purchase orphan drugs at 340B prices when orphan drugs are used for any indication other than treating the rare disease or condition for which the drug received an orphan designation."). The plaintiff responded by asking this Court to "either order additional briefing on whether the Final Rule survives as an interpretive rule or enter a judgment vacating the Final Rule because (i) HHS lacks substantive rulemaking authority under § 256b(e) and (ii) the Final Rule is incapable of surviving as an interpretive rule." *See* Pl.'s Resp. 5, ECF No. 47 (June 19, 2014).

On July 21, 2014, however, HHS issued a notice of availability of an interpretive rule. *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 (July 21, 2014), *available at* www.hrsa.gov/opa/programrequirements/interpretiverule/. The interpretive rule "interprets section 340B(e) of the Public Health Service Act as excluding drugs with an orphan designation only when those drugs are transferred, prescribed, sold, or otherwise used for the

rare condition or disease for which the drug was designated under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA). Section 340B(e) does not exclude drugs that are transferred, prescribed, sold, or otherwise used for conditions or diseases other than for which the drug was designated under section 526 of the FFDCA." *See* Interpretive Rule: Implementation of the Exclusion of Orphan Drugs for Certain Covered Entities Under the 340B Program at 6–7.

PhRMA argues that this interpretive rule is "materially identical to the vacated and unauthorized Final Rule," because it "adopts the *same* interpretation of 'covered outpatient drug' and imposes the *same* compliance obligations as the vacated Final Rule." *See* Pl.'s Supp. Mem. 2, ECF No. 52 (July 21, 2014) (emphasis in original). PhRMA accordingly asks the Court to either order additional briefing on whether the interpretive rule is valid, or to vacate the Final Rule—which the Court has already done.

Meanwhile, HHS explains that it "chose not to defend its prior issuance, 78 Fed. Reg. 44,016 (July 23, 2013), as an interpretive rule" because "HRSA reasonably concluded that defending that document on such grounds was inadvisable because it was so clearly framed in terms of legislative rulemaking. So as to avoid confusion as to the effect of its guidance, therefore, *HRSA reasonably chose to issue a new document couched as an interpretive rule*." *See* Defs.' Supp. Mem. Reply 3–4, ECF No. 53 (July 24, 2014) (emphasis added). PhRMA's final plea again asks this Court to either invalidate HHS's now-interpretive rule, or order an expedited briefing schedule on whether the interpretive rule survives. *See* Pl.'s Reply 3, ECF No. 54 (July 25, 2014).

As set forth above, PhRMA's Complaint originally challenged the final rule promulgated by HHS/HRSA regarding the Orphan Drug exclusion under the 340B Program, 42 C.F.R. §

10.21. On May 23, 2014, the Court vacated that final rule, and as of July 21, 2014, HHS and HRSA no longer defend that final rule in any form—either as a legislative rule or as a quasi-interpretive rule. And HHS and HRSA have since taken new agency action—implementing an interpretive rule—that was not the subject of this lawsuit. The plaintiff is free to challenge that interpretive rule, but such a challenge is beyond the scope of the instant action.

Accordingly, pursuant to Federal Rule of Civil Procedure 54, JUDGMENT IS ENTERED in favor of the plaintiff in this case, as set forth in the Court's Memorandum Opinion and Order. *See* ECF Nos. 42 & 43. This is a final, appealable order. *See* Fed. R. App. P. 4(a).

SO ORDERED.

Dated: August 27, 2014

RUDOLPH CONTRERAS
United States District Judge