

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF INDIANA  
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, et al.	)	
	)	
Plaintiffs,	)	
	)	
v.	)	No. 1:21-cv-00081-SEB-MJD
	)	
UNITED STATES DEPARTMENT OF	)	
HEALTH AND HUMAN SERVICES, et al.	)	
	)	
Defendants.	)	

**AMENDED PARTIAL FINAL JUDGMENT<sup>1</sup>**

The Court, having this day granted summary judgment in favor of Plaintiffs on Counts III and XII, and in favor of Defendants on Counts X, XI, and XIII, finds, pursuant to Federal Rule of Civil Procedure 54(b), that there is no just reason for delay. The Court therefore hereby enters partial final judgment in favor of Defendants and against Plaintiffs on Counts X, XI, and XIII, and in favor of Plaintiffs and against Defendants on Counts III and XII.

Accordingly, the Court enters declaratory judgment as follows:

- (1) HHS's General Counsel's December 30, 2020 Advisory Opinion is arbitrary and capricious under 5 U.S.C. § 706;
- (2) HRSA's May 17, 2021 Enforcement Letter is arbitrary and capricious under 5 U.S.C. § 706;

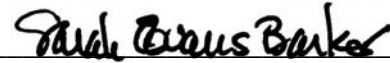
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<sup>1</sup> Pursuant to the Seventh Circuit's April 8, 2022 directive [Dkt. 155], we are entering this amended judgment "declaring specifically and separately the respective rights of the parties," *nunc pro tunc* to October 29, 2021.

- (3) HRSA's May 17, 2021 Enforcement Letter does not violate the notice-and-comment requirements of 5 U.S.C. § 553;
- (4) HRSA's May 17, 2021 Enforcement Letter does not exceed statutory authority under 5 U.S.C. § 706 because 42 U.S.C. § 256b, correctly construed, does not permit drug manufacturers, such as Plaintiffs, to impose unilateral extra-statutory restrictions on their offer to sell 340B drugs to covered entities utilizing multiple contract pharmacy arrangements;
- (5) HRSA's May 17, 2021 Enforcement Letter is not a taking under the Fifth Amendment's Takings Clause; and
- (6) HRSA's May 17, 2021 Enforcement Letter is not an unconstitutional condition on the receipt of benefits.

HHS's General Counsel's December 30, 2020 Advisory Opinion and HRSA's May 17, 2021 Enforcement Letter are hereby SET ASIDE and VACATED, and HRSA's May 17, 2021 Enforcement Letter is REMANDED for further action as Defendants may determine consistent with these rulings.

Date: 4/14/2022



SARAH EVANS BARKER, JUDGE  
United States District Court  
Southern District of Indiana

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