UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

WELLNESS PHARMACY, INC., *et al.*	)	
	)	
Plaintiffs,	)	
	)	
v.	)	Civil Action No. 1:20-cv-03082 (CRC)
	)	
XAVIER BECERRA, *et al*.	)	
	)	
Defendants.	)	
	)	

STATUS REPORT

Defendants, Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services ("HHS"); Robert Califf, in his official capacity as Commissioner of Food and Drugs;[1] and the Food and Drug Administration ("FDA"), by and through their undersigned counsel, respectfully submit this status report in accordance with the Court's Minute Order of November 29, 2021. Defendants report the following:

1. Defendants intend to engage in notice-and-comment rulemaking to implement certain provisions of 21 U.S.C. § 353a(b)(3)(B). Defendants are preparing a Notice of Proposed Rulemaking ("NPRM") that will set out definitions applicable to both the provisions of § 353a(b)(3)(B)(i) (the Standard Memorandum of Understanding ("Standard MOU")) and § 353a(b)(3)(B)(ii) (the five percent limit) and may codify

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Robert Califf, M.D. (in his official capacity as the Commissioner of Food and Drugs) is automatically substituted as a Defendant for former Acting Commissioner Janet Woodcock, M.D.

provisions of the Standard MOU. It will also include other provisions related to the five percent limit applicable to drugs compounded in States that do not sign the Standard MOU. Generally, the process to prepare and publish an NPRM, receive and review public comments, and revise and finalize the rule can take several years.

2. Defendants previously announced that they would exercise enforcement discretion over the five percent limit until October 2022. Defendants intend to extend this exercise of enforcement discretion for the duration of the rulemaking process, and will publish an announcement in the Federal Register before the current term of enforcement discretion expires.

3. As part of the NPRM, Defendants are preparing a preliminary economic analysis of impact, which will include analysis under the Regulatory Flexibility Act. The NPRM will include either an initial regulatory flexibility analysis, *see* 5 U.S.C. § 603, or a certification that the rule will not "have a significant economic impact on a substantial number of small entities[,]" *see* 5 U.S.C. § 605(b).

4. Defendants will revise the Standard MOU in accordance with any changes developed through the rulemaking process. Defendants consider the Standard MOU that was published on October 27, 2020 to be suspended. While the Standard MOU is suspended, Defendants do not expect signatories to collect or report any information pursuant to its provisions, and Defendants will not enter into new agreements with States based on the Standard MOU during the rulemaking process. FDA is communicating its intention to undertake rulemaking and the suspended status of the October 2020 Standard MOU by public announcement and through direct communication with stakeholders, including State Boards of Pharmacy.

5. Prior to filing this report, Defendants met and conferred with Plaintiffs regarding Defendants' intention to engage in rulemaking. The parties are continuing to confer about next steps in the litigation. Thus, the parties respectfully request the opportunity to inform the Court of their intentions regarding this matter by March 22, 2022.

Dated: February 22, 2022

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Respectfully submitted,

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