

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

_____	)	
ADHERIS, INC.,	)	
	)	
Plaintiff,	)	
	)	No. 13-cv-01342-EGS
v.	)	
	)	
KATHLEEN SEBELIUS, <i>et al.</i> ,	)	
	)	
Defendants.	)	
_____	)	

**JOINT MOTION TO SUSPEND SCHEDULE  
ON PLAINTIFF’S MOTION FOR PRELIMINARY INJUNCTION**

Plaintiff Adheris, Inc., and defendants Kathleen Sebelius, Secretary of Health and Human Services (“Secretary”), and the Department of Health and Human Services (“HHS”) respectfully move to suspend the current schedule for submission of briefs or authorities and for consideration of plaintiff’s pending Motion for Preliminary Injunction, in light of recent developments that have obviated any need for the parties to provide further briefing on, or for the Court to resolve, plaintiff’s motion prior to September 23, 2013. The basis for this motion is as follows:

1. In this action, plaintiff challenges a Final Rule issued by defendants on January 25, 2013, as it pertains to the use or disclosure of protected health information to provide remunerated refill reminders or other communications about a drug or biologic currently being prescribed to an individual. *See* Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules; Final

Rule, 78 Fed. Reg. 5566, 5592-97, 5696 (Jan. 25, 2013) (“Final Rule”) (codified at 45 C.F.R. § 164.501).

2. On September 5, 2013, contemporaneous with the filing of this lawsuit, plaintiff filed a Motion for Preliminary Injunction, seeking to enjoin defendants from enforcing the remunerated refill reminder restrictions, “insofar as those restrictions require patient authorization for, or limit the compensation a covered entity or business associate may receive for, providing refill reminders and other communications about a drug or biologic currently being prescribed for an individual when the communication is funded by the manufacturer of the drug or biologic.” Pl.’s Mtn. for Prelim. Inj. at 1, ECF No. 3. Plaintiff requested a ruling on its Motion by September 23, 2013, the deadline set by the Secretary for compliance with the Final Rule.

3. On September 9, 2013, the first business day following plaintiff’s service of its Motion for Preliminary Injunction, the Court held a telephonic conference call with the parties to discuss scheduling. The Court entered a schedule that would allow the motion to be fully heard and decided in advance of September 23, 2013. Under that schedule, defendant’s opposition to the Motion for Preliminary Injunction (together with relevant portions of the administrative record) must be filed by noon on Friday, September 13, 2013; plaintiff’s reply must be filed by noon on Sunday, September 15, 2013; and a hearing is scheduled for September 19, 2013 at 10:00 a.m. In addition, plaintiff is required to file a motion to file a document under seal, and to submit copies of its prior filings and related points and authorities, by noon today.

4. Following that telephonic status conference, undersigned counsel for defendants was informed that HHS intends to issue further guidance concerning the

provision challenged by plaintiff in this litigation. The guidance will pertain to the financial remuneration that would be considered “reasonable” for providing refill reminders or other communications about a drug or biologic currently being prescribed to an individual. HHS expects to issue such guidance by September 23, 2013.

5. In order to avoid the need for the Court to rule on plaintiff’s Motion for Preliminary Injunction before the forthcoming guidance has been issued and fully considered by plaintiff, the Secretary has decided, as an exercise of her discretion, not to enforce the restrictions on remunerated refill reminders and other communications about drugs and biologics (as set forth in 45 C.F.R. § 164.501) for a period of 45 days following the announced compliance date, or until November 7, 2013.

6. In light of the foregoing, the parties agree that it would be appropriate to defer briefing on plaintiff’s Motion for Preliminary Injunction until after the Secretary’s guidance has been issued, at which time the parties will be in a better position to evaluate the precise legal issues, if any, that remain to be litigated in this case. “The interest of judicial economy and avoiding unnecessary litigation” counsel against proceeding with the current schedule for briefing and consideration of plaintiff’s challenge to the refill reminder regulation, while the agency is in the process of issuing guidance as to its interpretation of that regulation. *See Abdulla Thani Faris Al-Anazi v. Bush*, 370 F. Supp. 2d 188, 199 (D.D.C. 2005).

7. The parties therefore respectfully request that the Court suspend the current schedule for submission of briefs and authorities and for consideration of plaintiff’s Motion for Preliminary Injunction. In addition, they propose to file a status

report on or before September 27, 2013, setting forth a proposal for any further briefing in this matter.

Dated: September 11, 2013

/s/ Joseph Guerra  
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Respectfully submitted,

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