IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ADHERIS, INC.,
One Van de Graaff Drive
Burlington, Massachusetts 08103,

Plaintiff,

v.

KATHLEEN SEBELIUS,
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201,

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
200 Independence Avenue, S.W.
Washington, DC 20201,

Defendants.

Case No. _____

COMPLAINT FOR DECLARATORY, INJUNCTIVE, AND OTHER RELIEF

Plaintiff Adheris, Inc. ("Adheris"), brings this Complaint against Defendants the Department of Health and Human Services and the Honorable Kathleen Sebelius in her official capacity as Secretary of the Department of Health and Human Services (collectively, "HHS").

INTRODUCTION

1. Adheris seeks injunctive and declaratory relief prohibiting Defendants from enforcing an unconstitutional rule restricting Adheris from sending truthful and socially beneficial communications that encourage people to take their medications as prescribed by their treating physicians. *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 (Jan. 25, 2013) (the "Omnibus Final Rule").

2. Defendants' Omnibus Final Rule is contrary to law and to constitutional right. This unlawful rule has already caused harm to Adheris's core business and, unless enjoined, the Omnibus Final Rule will inflict irreparable harm on that core business.

THE PARTIES

3. Plaintiff Adheris is a subsidiary of inVentiv Health, Inc., and has its principal place of business at One Van de Graaff Drive, Burlington, Massachusetts 08103.

4. Defendant United States Department of Health and Human Services (HHS), which has its principal office at 200 Independence Avenue, S.W., Washington, D.C. 20201, is a federal agency headquartered in the District of Columbia.

5. Defendant Kathleen Sebelius is the Secretary of the Department of Health and Human Services, and is sued here in her official capacity. As Secretary, Ms. Sebelius has ultimate responsibility for the activities of the Department, including those actions complained of herein. Secretary Sebelius maintains an office at 200 Independence Avenue, S.W., Washington, D.C. 20201.

JURISDICTION AND VENUE

6. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1331.

7. This Court has the authority to grant the relief requested by Adheris under the Administrative Procedure Act, 5 U.S.C. §§ 701-706, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(e) because at least one defendant in this action resides in this judicial district, and because a substantial part of the events giving rise to Adheris's claims occurred in this judicial district.

BACKGROUND

I. Adheris's Services

9. Adheris was formed in 1993 with the goal of helping patients follow their medication therapy as prescribed by their doctors.

10. A significant number of patients do not take their prescribed medication at all, or fail to take it properly or for the full period prescribed. Fifteen to thirty percent of patients never fill their first prescription for a chronic disease therapy. Of those who fill their first prescription, thirty percent will typically drop off their prescription regimen within the first 30 days, and sixty percent of patients will typically drop off their regimen within 180 days.

11. Nonadherence to prescription regimens and related suboptimal medication practices have been estimated by credible sources to cost up to $290 billion per year in avoidable medical costs in the United States, with $100 billion in costs for excess hospitalizations alone. These failures can also be life-threatening for patients, leading to an estimated 89,000 premature deaths every year just for nonadherence to hypertension medication.

12. Adheris provides a refill reminder service and other adherence messaging services. Adheris develops and reviews the content of these communications.

13. Adheris's refill reminder program is focused on chronic diseases such as heart disease, osteoperosis, depression, asthma, and diabetes, where medication therapy adherence makes a significant difference.

14. Adheris provides its refill reminder and adherence message services only to those pharmacies or pharmacy chains that have affirmatively chosen to participate and which have executed an appropriate contract with Adheris.

15. Adheris has contracts with 38 pharmacy chains.

16. When patients fill a prescription at a participating pharmacy, the pharmacy sends Adheris the patients' prescription record. Based on that prescription information, Adheris arranges a series of letters to the patients encouraging adherence to the regimen prescribed by their doctors.

17. Within approximately a week after the pharmacy dispenses the prescription, Adheris sends the patient a welcome letter on the pharmacy's letterhead, including educational information about the medication, safety information, positive reinforcement to stay on therapy, and a direction to follow the treating physician's advice.

18. The educational information included in Adheris's letters may consist of a description of the drug prescribed, the dosage prescribed, and a description of the conditions the drug is commonly prescribed to treat. The letters also provide safety information, such as how to take the drug properly, allergy and side effect information, and instructions to obtain medical help if certain side effects occur. The letters encourage patients to take the medication as prescribed and explain the consequences of stopping the regimen prematurely.

19. Adheris then sends patients a reminder to refill the prescription five to seven days before the refill is due; that reminder contains educational and safety materials similar to those sent in the initial letter. If the prescription is not refilled, patients are sent an urgent reminder to complete the refill seven to ten days after the missed refill.

20. The overwhelming majority of Adheris's letters serve only to reinforce the treating health care practitioner's prescription, and do not encourage patients to switch drugs or to take alternative or adjunctive therapies.

21. Adheris's programs have a verifiably significant impact on the percentage of patients still complying with their prescribed regimens at the end of a program period. Adheris

has conducted controlled and randomized tests of the effectiveness of its programs, and these studies have found that patients in its programs are 2 to 7 percent more likely to be on their therapy at the end of the program period.

22. This increase in prescription adherence translates into a significant public health benefit. The Congressional Budget Office estimates that a 1% increase in prescription refills in the United States would cause Medicare's spending on medical services to fall by one-fifth of one percent. This translates into more than a billion dollars in annual Medicare cost savings for each 1% increase in prescription refills. *See* CBO, *Offsetting Effects of Prescription Drug Use On Medicare's Spending for Medical Services* (Nov. 2012), *available at* http://www.cbo.gov/sites/default/files/cbofiles/attachments/43741-MedicalOffsets-11-29-12.pdf. Several additional studies also support the significance and potential cost savings of adherence programs.

23. These findings are consistent with adherence-promotion activities by the Center for Medicare and Medicaid Services (CMS), a component of HHS. For example, entities that offer Medicare Part D prescription drug plans must have medication therapy management programs "to increase adherence to prescription medications," 42 U.S.C. § 1395w–104(c)(2)(C), and these programs "may include . . . medication refill reminders." *Id.* § 1395w–104(c)(2)(B)(ii). CMS requires medication therapy management programs for the same chronic diseases for which Adheris provides refill reminders and adherence messages. *See* CMS, *2012 Medicare Part D Medication Therapy Management (MTM) Programs* at 3-4 (Nov. 12, 2012), *available at* http://www.cms.gov/Medicare/Prescription-Drug-Coverage/ PrescriptionDrug CovContra/Downloads/CY2012-MTM-Fact-Sheet.pdf.

24. Pharmaceutical companies sponsor the refill reminders and other adherence messages that Adheris sends on behalf of pharmacies. The pharmaceutical companies send the

payment for the mailings directly to Adheris, which collects the funds as an agent for the pharmacies. Adheris then sends the funds to the pharmacies, retaining a portion as compensation for its services, including its services developing the content of the mailings.

25. In 2012, Adheris derived total revenues of $49 million from its refill reminder and adherence message services, which together account for more than 90% of Adheris's total revenues.

26. The letters sent by Adheris clearly identify the entity that sponsors the communication. The letters are printed on the participating pharmacy's letterhead and contain a disclosure that the pharmacy was reimbursed for sending the letter by a named pharmaceutical company. The letters also prominently display opt-out information if patients do not wish to receive further mailings.

27. For every pharmacy that contracts for Adheris programs, Adheris enters into a Business Associate Agreement that requires it to protect the privacy and security of patients' protected health information (PHI) in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-191, 110 Stat. 1936 (1996).

28. In providing its services, Adheris does not disclose protected health information to pharmaceutical manufacturers.

29. Adheris has established strict technical and organizational security and quality control protocols, at great expense, to ensure that PHI is safeguarded consistent with its statutory and contractual obligations. The costs for this security include extra hardware and software costs, detailed analysis of potential information security risks, the development of written documentation of plans to address these risks, the implementation of appropriate controls, the external validation of the successful implementation of such controls, and rigorous programs to

maintain the effectiveness of these protections, such as through software updates, ongoing employee training, and continual assessment of new risks. This equipment also involves the normal costs of operation, including depreciation, maintenance, electricity, insurance, associated property taxes, and the costs for secure physical space.

30. Adheris also has complex quality control systems to ensure that each adherence letter is sent to the appropriate person and relates to the appropriate disease and treatment.

II. The HITECH Act and HHS's Omnibus Final Rule

31. HIPAA generally requires a covered entity, such as a pharmacy, to obtain an individual's authorization before using or disclosing the individual's PHI for marketing purposes. *See* 45 C.F.R. § 164.508(a)(3). Such patient authorizations must be received in advance, in a separate writing that has specific regulator-prescribed elements, and if the covered entity requests the authorization, the patient must be given a copy of such authorization. Moreover, such authorizations must be tracked so they can be revoked at a later date. However, covered entities may generally use PHI without patient authorization for treatment, payment, or healthcare operations purposes. *Id.* § 164.502(a)(1)(ii).

32. For years, HHS took the position that communications by health care providers, including pharmacies, to patients about health-related products or services were not "marketing" for purposes of HIPAA and were instead "treatment" communications not subject to the patient authorization requirement. Such communications were excluded from the definition of marketing, and deemed "treatment" communications, even if they were subsidized by a third party, such as a pharmaceutical manufacturer. *See, e.g.*, HHS, Standards for Privacy of Individually Identifiable Health Information; Final Rule, 67 Fed. Reg. 53187 (Aug. 14, 2002) ;

HHS, *HIPAA Frequent Questions, FAQ 285* (created Dec. 20, 2002), http://www.hhs.gov/ocr/privacy/hipaa/faq/marketing/285.html (last accessed Aug. 14, 2013).

33. In 2009, Congress passed the Health Information Technology for Economic and Clinical Health Act (the "HITECH" Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. No. 111-5, 123 Stat. 226; 123 Stat. 467 (codified at 42 U.S.C. §§300jj *et seq.*; §§17901 *et. seq.*) (Feb. 17, 2009).

34. One provision of the HITECH Act, codified at 42 U.S.C. § 17936, addresses when subsidized communications about a health-related product or service fall outside the scope of the "health care operations" exception of HIPAA and require patient authorization.

35. In proposing rules to implement this provision, HHS concluded that it was "unclear whether Congress intended . . . all subsidized communications about products and services, *including treatment communications*," to be treated as "marketing." Modifications to the HIPAA Privacy, Security, and Enforcement Rules Under the HITECH Act; Proposed Rule, 75 Fed. Reg. 40868, 40885-86 (Jul. 14, 2010) (emphasis added); *see also* HHS, 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, 5593 (Jan. 25, 2013) (explaining rationale for 2010 proposed rules). Accordingly, HHS proposed to continue to allow subsidized treatment communications, provided that the recipient of the communication received notice and an opportunity to opt out of receiving such communications. 78 Fed. Reg. at 5593 (explaining, in 2013, the 2010 proposal).

36. In the Omnibus Final Rule that it published on January 25, 2013, however, HHS took a different position. The final regulations define "marketing" as "a communication about a product or service that encourages recipients of the communication to purchase or use the

product or service," then except from this definition, *inter alia*, communications made for "treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication." 45 C.F.R. § 164.501 (defining "marketing"). "Financial remuneration," in turn, means "direct or indirect payment from or on behalf of a third party whose product or service is being described. Direct or indirect payment does not include any payment for treatment of an individual." *Id.*

37. In the preamble to the Omnibus Final Rule, HHS explained that its new regulations required "authorization for all treatment and health care operations communications where the covered entity receives financial remuneration for making the communications from a third party whose product or service is being marketed." 78 Fed. Reg. at 5595. HHS stated that the authorization requirement also applies where a business associate (such as Adheris), rather than a covered entity, "receives financial remuneration from a third party in exchange for making a communication about a product or service." *Id.*

38. The HITECH Act provides that where a subsidized communication "describes only a drug or biologic that is currently being prescribed for the recipient of the communication," that communication may still be considered a health care operation for purposes of HIPAA if, among other things, "any payment received by such covered entity in exchange for making [the] communication . . . is reasonable in amount." 42 U.S.C. § 17396(a)(2)(A)(ii). The HITECH Act further provides that "the term 'reasonable in amount' shall have the meaning given such term by the Secretary [of HHS] by regulation." *Id.* § 17396(a)(3).

39. In the final regulations, HHS excepted from the definition of "marketing" those communications made "[t]o provide refill reminders or otherwise communicate about a drug or biologic that is currently being prescribed for the individual," but "only if any financial

remuneration received by the covered entity in exchange for making the communication is reasonably related to the covered entity's cost of making the communication." 45 C.F.R. § 164.501 (defining "marketing").

40. In the Omnibus Final Rule, HHS explained that this provision permits remuneration "which cover[s] only the costs of labor, supplies, and postage to make the communication," or in other words "only the pharmacy's cost of drafting, printing, and mailing the refill reminders." 78 Fed. Reg. at 5597. The Omnibus Final Rule further states that "[w]here the financial remuneration a covered entity receives in exchange for making a [refill reminder] communication generates a profit or includes payment for other costs, such financial remuneration would run afoul of the Act's 'reasonable in amount' language." *Id.*

III. The Impact of the Omnibus Final Rule on Adheris

41. Because it interprets the HITECH Act to require patient authorization for subsidized treatment communications (such as the refill reminders and adherence communications that Adheris provides) and severely limits the "reasonable in amount" cost exception to this requirement, the Omnibus Final Rule is having a materially adverse effect on Adheris, and threatens the continued operation of its core refill reminder and adherence business.

42. As noted above, Adheris expends a significant amount of money to securely obtain, process, and store the PHI it uses to send the reminders. The costs of these complex information systems and related infrastructure greatly exceed the costs of "drafting, printing, and mailing" refill reminders.

43. Adheris's customers read the Omnibus Final Rule to mean that Adheris's refill reminder service, which uses PHI, cannot be conducted without patient authorization, which is not economically feasible to obtain. These customers fear that, without patient authorization,

their use of Adheris's service could expose them to legal penalties and sanctions and reputational harms for unauthorized use or disclosure of PHI under HIPAA.

44. A major pharmacy chain stopped contracting for most new programs with Adheris in March of 2013, and in July 2013 this chain notified Adheris that it would not continue with its current programs beyond August 31, 2013 due to the Omnibus Final Rule. Likewise, substantially all of the pharmaceutical manufacturers that have contracts with Adheris have communicated that the Omnibus Final Rule has caused them to re-evaluate their existing contracts and programs with Adheris and that they will be terminating their existing contracts and programs with Adheris imminently unless HHS clarifies that refill reminder programs sponsored by pharmaceutical manufacturers and administered at a profit by Business Associates such as Adheris are permissible under the Omnibus Final Rule.

45. As large pharmacy contracts are cancelled, and as pharmaceutical manufacturers reallocate their budgets away from refill reminders, the continued existence of Adheris's core business of providing written adherence communications is threatened. In light of the substantial technology and other costs needed to operate that business, Adheris would not have the level of sales necessary to continue this core business (from which it derives over 90% of its revenues) should any other significant pharmacy or pharmaceutical partners make good on their promises to cancel their contracts.

46. Any attempt to measure the harms that the Omnibus Final Rule is inflicting, and will continue to inflict, on Adheris would be extremely difficult to quantify.

CLAIMS FOR RELIEF

COUNT I
For Declaratory and Injunctive Relief Based Upon Violation of the First Amendment (5 U.S.C. §§ 701-706)

47. Adheris incorporates by reference the allegations set forth in the prior paragraphs above, as if fully set forth herein.

48. HHS's Omnibus Final Rule is subject to judicial review because it is a final agency action within the meaning of 5 U.S.C. § 704.

49. Under 5 U.S.C. § 706, a "reviewing court shall. . . hold unlawful and set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" or "contrary to constitutional right, power, privilege, or immunity."

50. HHS's Omnibus Final Rule is not in accordance with law and is contrary to constitutional right because its restrictions on refill reminders and adherence communications violate the First Amendment.

51. Adheris's refill reminder and adherence communications are protected speech under the First Amendment. Indeed, Adheris's speech is properly viewed as non-commercial, and thus entitled to the highest level of First Amendment protection. But even if viewed as commercial, Adheris's speech enjoys substantial First Amendment protection.

52. The Omnibus Final Rule places content- and speaker-based burdens on Adheris's protected speech. The Omnibus Final Rule is content-based because its restrictions on refill reminders and adherence communications apply only to communications that "encourage individuals to purchase or use a third party's product or service." 78 Fed. Reg. at 5596. The Omnibus Final Rule is speaker-based because it discriminates against speakers who communicate in exchange for payment from "a third party whose product or service is being

described." 45 C.F.R. § 164.501. HHS itself has explained that the restrictions of the Omnibus Final Rule are triggered only where financial remuneration is provided in exchange for making the communication from or on behalf of the entity whose product or service is being described, and that identical speech funded by anyone other than the manufacturer of a product or provider of a service is permissible without individual authorization. *Id.* at 5593. These content- and speaker-based restrictions have already had a serious chilling effect on Adheris's refill reminders and adherence communications.

53. Because Adheris's speech is properly characterized as non-commercial speech for First Amendment purposes, the content- and speaker-based burdens that the Omnibus Final Rule imposes on that speech are constitutionally impermissible.

54. Even if Adheris's speech is deemed commercial speech, the content- and speaker-based burdens that the Omnibus Final Rule imposes are subject to heightened scrutiny. *Sorrell v. IMS Health, Inc.*, 131 S. Ct. 2653 (2011). The Omnibus Final Rule fails heightened scrutiny because its restrictions on refill reminders and adherence communications do not directly advance a substantial government interest in a proportional manner.

55. In promulgating the Omnibus Final Rule, HHS identified no harms or dangers posed by refill reminders or adherence communications. Indeed, the communications promote patient health and reduce health costs, and HHS itself has promoted such communications in other contexts.

56. The Omnibus Final Rule also does not directly advance a substantial governmental interest because, among other reasons, of the inconsistencies in its requirements. It treats identical speech differently depending upon who compensates the speaker for the speech

and whether the speaker derives a profit for that speech. The different treatment for this identical speech is based on impermissible hostility to the financial motivation underlying the speech.

57. The Omnibus Final Rule also does not directly advance a substantial governmental interest because, among other reasons, it does not advance any legitimate privacy interests.

58. The Omnibus Final Rule also does not directly advance any legitimate governmental interests in a proportional manner. Instead, the Omnibus Final Rule restricts more speech than necessary by, *inter alia*, requiring patients affirmatively to opt-in to refill reminder and adherence communications, rather than using less restrictive means such as patient opt-outs or disclosure requirements.

59. Accordingly, Adheris is entitled to a declaration that those aspects of the Final Omnibus Rule restricting refill reminders and adherence communications are unconstitutional and an order enjoining HHS from enforcing those aspects of the Rule.

COUNT II
For Declaratory and Injunctive Relief Based Upon Violation of the Administrative Procedure Act
(5 U.S.C. §§ 701-706)

60. Adheris incorporates by reference the allegations set forth in the prior paragraphs above, as if fully set forth herein.

61. The Omnibus Final Rule is "not in accordance with law," 5 U.S.C. § 706, for the alternative reason that HHS improperly interpreted the HITECH Act.

62. The HITECH Act, properly construed, does not limit the pre-existing ability of health care providers to make "treatment" communications that are funded by pharmaceutical manufacturers. Instead, it only limits their ability to make "health care operations"

communications when funded by pharmaceutical manufacturers. 42 U.S.C. § 17936(a)(1). As HHS has previously recognized, refill reminders and adherence communications are "treatment" communications, not "health care operations" communications, when made by health care providers such as pharmacies, and their business associates, such as Adheris. 67 Fed. Reg. 53187. The HITECH Act does not change the pre-existing definition of "treatment."

63. HHS was obligated to adopt this interpretation of the HITECH Act in order to avoid the clear First Amendment violation caused by its alternate interpretation in the Omnibus Final Rule.

64. Accordingly, Adheris is entitled to a declaration that those aspects of the Final Omnibus Rule restricting refill reminders and adherence communications are not in accordance with law and an order enjoining HHS from enforcing those aspects of the Rule.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully prays that this Court:

A. Issue an Order granting injunctive relief in favor of Adheris and against Defendants that prohibits Defendants from enforcing the marketing restrictions set forth in the definition of "marketing" in 45 CFR § 164.501 insofar as they 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.

B. Declare that the marketing restrictions set forth in the definition of "marketing" in 45 CFR § 164.501 are unlawful insofar as they 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.

Dated: September 5, 2013

Respectfully Submitted,

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