

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN )  
PHYSICIANS & SURGEONS, INC. )  
1601 N. Tucson Blvd., Suite 9 )  
Tucson, AZ 85716, )  
Plaintiff, )  
v. )  
U.S. DEPARTMENT OF HEALTH & )  
HUMAN SERVICES, )  
200 Independence Avenue, SW )  
Washington, DC 20201, )  
and )  
MICHAEL O. LEAVITT, )  
SECRETARY OF HEALTH & )  
HUMAN SERVICES, )  
200 Independence Avenue, SW )  
Washington, DC 20201, )  
in his official and individual capacities, )  
Defendants. )

Civil Action No. \_\_\_\_\_

**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

Plaintiff Association of American Physicians and Surgeons, Inc. (“AAPS”) seeks declaratory and injunctive relief based on the following allegations.

**NATURE OF THE ACTION**

1. AAPS brings this action to compel the federal Defendants to comply with the Federal Advisory Committee Act, 5 U.S.C. App. 2 (“FACA”), and other applicable laws in connection with the American Health Information Community (“AHIC”) and related health information technology (“Health IT”) initiatives launched by Defendant U.S. Department of Health and Human Services (“HHS”) and Defendant Leavitt, the Secretary of HHS.

2. As set forth more fully below in Paragraph 101, AAPS seeks the following declaratory and injunctive relief:

(a) That AHIC violates FACA both because the panel is not fairly balanced and because Defendants have an undue influence over it;

(b) That Defendants lack authority to circumvent FACA by creating other “public-private partnerships” and non-FACA consensus panels through contract, or otherwise, outside the FACA process;

(c) That AHIC subcommittees comprised of both AHIC members and AHIC nonmembers are wholly new FACA advisory committees, for which Defendants must comply (but have not complied) with all FACA requirements; and

(d) That neither Defendants nor AHIC can use or even obtain workproduct from any consensus panel or public-private partnership created or maintained without full FACA compliance.

In sum, Defendants lawfully may carry out only the specific authorities that the Congress has delegated to them; they must do so without circumventing either the substance or the procedures of the congressional delegation; and Congress (not Defendants) has the authority to make laws.

3. As used in this Complaint, the following terms have the indicated meanings:

(a) The term “consensus panel” means a group of persons (whether convened under FACA or not) that, if established or utilized by a federal officer or agency, would be subject to FACA;

(b) The term “contractual panel” means a consensus panel established or continued pursuant to contract by a federal officer or agency, which expressly includes *inter alia* the “Contractual Panels” identified in Paragraph 67;

(c) The term “federal member” means a member of a consensus panel who is fulltime or permanent parttime federal employee or officer;

(d) The term “public-sector member” means a member of a consensus panel who is a federal member or represents and/or is employed by a state or local public entity;

(e) The term “non-federal member” means a member of a consensus panel who is not a federal member; and

(f) The term “private-sector member” means a member of a consensus panel who is not a public-sector member.

### **PARTIES**

4. Plaintiff AAPS is a not-for-profit membership organization, incorporated under the laws of Indiana and headquartered in Tucson, Arizona. AAPS’ members include thousands of physicians nationwide in all practices and specialties, but primarily in small and solo practices. AAPS was founded in 1943 to preserve the practice of private medicine, ethical medicine, and the patient-physician relationship. On behalf of its members and their patients (who overwhelmingly wish their medical record to remain confidential and available only to treating clinicians), AAPS opposes efforts to coerce or mandate the profession to adopt Health IT solutions that open medical care to third-party monitoring and rationing.

5. Headquartered in the District of Columbia, Defendant HHS is an executive department of the United States government.

6. Defendant Leavitt is the Secretary of Health and Human Services and maintains an office in the District of Columbia. Defendant Leavitt is sued in his official capacity and also in his individual capacity for actions taken, threatened, or unlawfully not taken under color of legal authority by him and by those under his control. Defendant Leavitt is not sued in his individual capacity for monetary or punitive damages.

## FEDERAL ADVISORY COMMITTEE ACT

7. Prospective FACA committee members (and the organizations that they may represent) covet and highly esteem appointment to FACA advisory committees, both for the recognition and prestige that appointment bestows and for the opportunity it provides to represent their views and peers and to participate in the formation of policies that affect them. A properly selected advisory committee provides the government valuable advice for policy decisions. Even if an agency already has concluded how to address a particular matter and convenes a biased advisory committee merely to validate that prior conclusion, that advisory committee would provide political legitimacy for those policy decisions, in the absence of oversight such as congressional or judicial review.

8. Congress enacted FACA to open to public scrutiny the giving of government advice, to limit wasteful expenditures, and to avoid the preparation and dissemination of biased proposals under the false or misleading veneer of an “expert panel.” Because it also wanted to curb the proliferation of advisory committees, Congress expressly found that “new advisory committees should be established only when they are determined to be essential.” FACA §2(b)(2).

9. FACA §3(2) defines “advisory committee” to mean “any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as ‘committee’),... established or utilized by one or more agencies,... in the interest of obtaining advice or recommendations for... one or more agencies or officers of the Federal Government.” FACA committee members are “officers” of the Federal government as that term is used in FACA §3(2). FACA §3(2)(i)

exempts from FACA those advisory committees that are composed wholly of full-time, or permanent part-time, officers or employees of the federal government.

10. As here relevant, FACA applies *directly* only to advisory committees “established or utilized” by one or more Executive-Branch agency “in the interest of obtaining advice or recommendations for... one or more agencies or officers of the Federal Government.” FACA §3(2). FACA also applies *indirectly* to occupy the field of Executive-Branch agencies’ authority to convene – by request, by contract, or otherwise – a consensus panel, in the absence of one FACA’s enumerated exemptions or some other authorizing statute. Both the Senate and House identified the Advisory Council on Federal Reports (an industry advisory group, organized *at the request* of the Office of Management and Budget, that provided information to the Executive Branch) as an example of activity *prohibited* by FACA, and the Conference Committee did not alter the House or Senate bills in any way that undercut that prohibition.

11. In creating an advisory committee, a federal Executive-Branch agency must (*e.g.*, by regulation, by charter) *inter alia* do the following: (1) ensure that the advisory committee has a “clearly defined purpose;” (2) require the advisory committee’s membership “to be fairly balanced in terms of the points of view represented;” and (3) include “appropriate provisions to assure that the [committee’s] advice and recommendations... will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee’s independent judgment.” FACA §5(b)(1)-(3), (c).

12. FACA §10(a)(1) requires that advisory-committee meetings be open to the public, and FACA §10(a)(3) requires that advisory committees permit the interested public to attend, to appear before, and to file statements with any advisory committee. FACA §10(b) requires that the agency grant the public access to inspect and copy the records, reports, transcripts, minutes,

appendixes, working papers, drafts, studies, agenda, or other documents made available to or prepared for or by the advisory committee.

13. Congress intended FACA §5(b)(2)'s balance requirement to ensure that persons or groups directly affected by an advisory committee's work would have some representation on the committee, with the balance requirement applying to both viewpoint (*e.g.*, pro-privacy versus pro-biosurveillance) and function (*e.g.*, practicing physician versus payer organization). FACA §5(b)(3)'s undue-influence provision works in conjunction with FACA §5(b)(2)'s balance requirement to ensure unbiased workproduct, based on the advisory committee's independent deliberations. Congress intended FACA §5's "balance" and FACA §10's "openness" requirements as "strong safeguard[s] of the public interest." H.R. Rep. No. 92-1017, *reprinted in Fed. Advisory Comm. Act (Pub. L. 92-463), Source Book: Legislative History, Texts, and Other Documents*, at 280 (Cong. Res. Serv. 1978).

14. FACA §9(a)(2) prohibits Executive-Branch agencies' establishing an advisory committee absent a "determin[ation] as a matter of formal record, by the head of the agency... with timely notice published in the *Federal Register*, [that the advisory committee is] in the public interest in connection with the performance of duties imposed on that agency by law." FACA §9(c) prohibits an Executive-Branch agency's advisory committee from meeting or taking any action without first filing a charter with the agency head and the standing congressional committees with legislative jurisdiction over the agency. The charter must specify *inter alia* the committee's designation, objectives and scope, duties, the period of time necessary to carry out its purposes, the agency or officer to whom the committee reports, and the number and frequency of committee meetings. FACA §9(c)(A)-(J).

15. FACA §14(b)(1) requires a renewed advisory committee to file a charter pursuant to FACA §9(c), and FACA §14(b)(3) prohibits a renewed advisory committee's taking any action (other than preparing and filing its charter) prior to the date that the renewed charter is filed pursuant to FACA §9(c).

16. FACA requires Executive-Branch agencies to maintain a designated official to attend each meeting of the advisory committee, who is "authorized, whenever he determines it to be in the public interest, to adjourn any... meeting" of the advisory committee. FACA §10(e).

### **VENUE**

17. Pursuant to 28 U.S.C. §1391(e), venue is proper in the District of Columbia, where Defendants are headquartered. Under the Administrative Procedure Act, 5 U.S.C. §§551-706 ("APA"), venue is proper in any court of competent jurisdiction. 5 U.S.C. §703.

### **JURISDICTION**

18. This case arises out of Defendants' ongoing violation of FACA and the APA and, therefore, raises federal questions over which this Court has jurisdiction pursuant to: 28 U.S.C. §§1331, 1361, 1651(a); the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended); D.C. Code §11-501, and this Court's equity jurisdiction.

19. To the extent that this action presents non-federal or common-law issues outside the jurisdictional bases in Paragraph 18, this Court has jurisdiction under 28 U.S.C. §1367(a).

### **JUSTICIABILITY**

20. Paragraphs 21 through 40, *infra*, provide AAPS's initial proffer on this action's justiciability, which AAPS will supplement in defense of any motion to dismiss. Exhibit 1 is incorporated herein by reference.

## **Standing**

21. Because Defendants' Health IT initiatives seek to build the infrastructure and record that Defendants need to alter fundamentally the practice of medicine, AAPS's members are persons affected by the Defendants' Health IT initiatives for purposes of the protections that FACA's balance, undue-influence, and openness provisions provide the public.

22. As set forth in Paragraphs 49-53 and 54-55, *infra*, respectively, Defendants established AHIC without complying with FACA's balance and undue-influence requirements.

23. If this Court grants the relief requested in Paragraph 101, AAPS members would seek to participate on a reconstituted AHIC, and AAPS also would nominate eminent non-members with relevant expertise (*e.g.*, antitrust, small-business, technology, and privacy issues) who share AAPS's views. If Defendants reconstituted a FACA-compliant AHIC, AAPS's members, AAPS's proposed non-member experts, and other parties representing similar views and functions would have a significantly greater opportunity to obtain an AHIC appointment, thereby significantly increasing the likelihood of unbiased AHIC workproduct.

24. If Defendants reconstituted the Contractual Panels (as defined in Paragraphs 3 and 67) as FACA-compliant advisory committees, AAPS members would seek to participate on the reconstituted committees, and AAPS also would nominate eminent non-members with relevant expertise (*e.g.*, antitrust, small-business, technology, and privacy issues) who share AAPS's views. If Defendants reconstituted the Contractual Panels as FACA-compliant committees, AAPS's members, AAPS's proposed non-member experts, and other parties representing similar views and functions would have a significantly greater opportunity to obtain appointment to such committees, thereby significantly increasing the likelihood of unbiased workproduct from such committees and facilitating oversight by AAPS and the Congress.

25. If this Court grants the relief requested in Paragraph 101, AAPS members (including AAPS members who did not seek to participate on AHIC) would seek to participate on AHIC subcommittees, and AAPS also would nominate eminent non-members with relevant expertise (*e.g.*, antitrust, small-business, technology, and privacy issues) who share AAPS's views. If Defendants establish FACA-compliant AHIC subcommittees, AAPS's members, AAPS's proposed non-member experts, and other parties representing similar views and functions would have a significantly greater opportunity to obtain an appointment to AHIC subcommittees, thereby significantly increasing the likelihood of unbiased workproduct from AHIC subcommittees.

26. Because AAPS advocates in administrative, legislative, and public-policy arenas on behalf of its members (and their patients), AAPS is an intended beneficiary of FACA's protection of the public interest, including facilitated oversight of advisory committees, elimination of unnecessary, duplicative, and overlapping advisory committees, and protection from biased advisory-committee reports (*e.g.*, those that result from committees that lack the required balance and those over which the appointing authority has an undue influence).

27. Physicians and surgeons have standing to protect the patient-physician relationship – including a patient's interests in privacy and nondisclosure of his or her medical information – on their own behalf and on behalf of their patients.

28. On behalf of its members (and their patients), AAPS intends to challenge and/or to advocate against efforts to mandate or coerce adoption of Defendants' Health IT policies, including proceedings under the rulemaking and petition processes contemplated by 5 U.S.C. §553, the congressional review process contemplated by 5 U.S.C. §§801-808, and the First Amendment.

29. The declaratory and injunctive relief requested in Paragraph 101 will provide legal bases – *i.e.*, what the D.C. Circuit has called “ammunition” – for AAPS to challenge Defendants’ Health IT initiatives, including enjoining Defendants from using (or declaring the unfitness for use of) workproduct from AHIC (including any AHIC subcommittees) and the Contractual Panels. The declaratory and injunctive relief requested in Paragraph 101 will ensure Defendants’ consideration of relevant issues – including negative impacts of Defendants’ Health IT initiatives – in the reports and deliberations of the various advisory committees, as Defendants may reconstitute them after this Court grants the requested relief.

30. By operating the Contractual Panels outside the FACA oversight process, Defendants have denied AAPS and the Congress the benefits that FACA bestowed on both the affected public and the Congress, thereby inflicting both procedural and substantive injuries in the denial of *inter alia* facilitated oversight, the opportunity to participate, participation, balanced panels, and information. *See, e.g.*, Ex. 1, ¶3. Defendants have no authority to circumvent FACA by contract (*i.e.*, a contract that successfully creates a consensus panel outside of FACA is nonetheless *ultra vires*).

31. Although Defendants apparently intend to operate the AHIC subcommittees in compliance with FACA’s openness requirements, Defendants failed to convene the AHIC subcommittees in compliance with FACA’s requirements for convening a FACA advisory committee (*e.g.*, findings on the essentiality for the subcommittees as distinct FACA advisory committees, the preparation and filing of a charter and the requisite determinations, prior notice in the *Federal Register* of the formation). In doing so, Defendants have denied AAPS and the Congress the benefits that FACA bestows on both the affected public and the Congress, thereby

inflicting both procedural and substantive injuries in the denial of *inter alia* the opportunity to participate, participation, balanced panels, and information. *See, e.g.*, Ex. 1, ¶3.

32. Defendants expressly intend to use the federal government’s “market power” as a health-care payer to impose or coerce Health IT on the medical profession and patients as soon as possible, and their initiatives will impose financial burdens on AAPS members (*e.g.*, purchasing and training on new systems). By design, Defendants’ Health IT initiatives seek to accelerate the imposition of these burdens on AAPS members, sooner than the market otherwise would develop formal or informal industry standards for Health IT. All AAPS members have standing to avoid the financial burden of additional requirements. In particular, AAPS members who either would retire or forgo Health-IT-mandated forms of medical practice have standing to challenge Defendants’ rush to judgment to accelerate the imposition of Health IT.

33. The relief requested in Paragraph 101 will redress AAPS’s injuries by requiring Defendants to cease operation of FACA-noncompliant consensus panels and not to reconstitute those consensus panels except in compliance with FACA and this Court’s ordered relief.

34. Prudentially, as members of the public directly affected by Defendants’ FACA violations and their Health IT initiatives, AAPS and its members are FACA’s intended beneficiaries and thus their injuries fall within FACA’s zone of interests. In addition, as to FACA’s protection of congressional interests (*e.g.*, facilitated congressional oversight), AAPS and its members have interests congruent to those of the Congress, and thus are suitable challengers to enforce the congressional interests.

35. In addition to having standing to defend its own interests from injury, AAPS is a proper party to protect its members’ interests from injury because its members have standing, AAPS’s opposition to Defendants’ Health IT initiatives is germane to AAPS’s purpose (*see*

Paragraph 4, *supra*), and the purely legal questions presented by the requested non-monetary, equitable and declaratory relief do not require the participation of individual members.

### **Sovereign Immunity**

36. The APA waives sovereign immunity for actions against the United States, its instrumentalities, and officers for non-monetary relief and for the entry of judgments and decrees against the United States in such actions. 5 U.S.C. §702.

37. With Defendant Leavitt named and served in his official and individual capacities, sovereign immunity does not shield Defendant Leavitt's *ultra vires* actions. Further, mandamus claims against a named federal officer do not require a waiver of sovereign immunity. Finally, this Court possesses equity jurisdiction over federal officers derived both from the Court's enabling legislation and from the historic equity jurisdiction of Maryland courts over Maryland officers, prior to Maryland's ceding the District of Columbia as a federal enclave.

### **Adequacy of Alternate Remedies**

38. This action is not barred by the APA's "adequate-remedy bar," 5 U.S.C. §704, or analogous equitable doctrines because FACA does not provide an alternate legal remedy for violations of the requirements of balanced advisory panels, free from undue influence, and FACA's other procedural and substantive protections.

39. Because this Court has jurisdiction as a threshold matter, the Declaratory Judgment Act, 28 U.S.C. §§2201-2202, provides this Court the power to "declare the rights and other legal relations of any interested party..., whether or not further relief is or could be sought." 28 U.S.C. §2201; *accord* FED. R. CIV. P. 57 advisory committee note ("the fact that another remedy would be equally effective affords no ground for declining declaratory relief").

40. Although AAPS may have an action at law against the federal Defendants' unlawful Health IT policies when Defendants finalize those policies, a subsequent legal action does not terminate an extant equitable action that predates the accrual of the legal action.

#### **NEED FOR INJUNCTIVE RELIEF**

41. Otherwise-irreparable injury and the lack of an adequate legal remedy justify injunctive relief. In addition to the declaratory relief requested in Paragraph 101, *infra*, AAPS requires injunctive relief because (a) the maintenance of AHIC (including its subcommittees) and the Contractual Panels in violation of FACA constitutes irreparable injury, which declaratory relief alone will neither prevent nor fully redress; (b) as set forth in Paragraph 38, *supra*, AAPS lacks an alternate remedy against Defendants' FACA violations.

#### **HEALTH INFORMATION TECHNOLOGY INITIATIVES**

42. On April 27, 2004, the President gave a prepared speech on the need for Health IT (<http://www.whitehouse.gov/news/releases/2004/04/print/20040427-5.html>) and issued Executive Order 13,335, 69 Fed. Reg. 24,059 (Apr. 30, 2004) ("EO 13,335") for the stated purpose of providing leadership for the development and nationwide implementation of an interoperable health information technology infrastructure. EO 13,335 also directs HHS to establish the office (with sufficient staff) of the National Health Information Technology Coordinator ("National Coordinator").

43. Less than two weeks later, on May 6, 2004, the then-Secretary of HHS appointed David J. Brailer, M.D., Ph.D., to serve as National Coordinator. Less than two and half months later, on July 21, 2004, the National Coordinator released a report entitled *The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care – Framework for Strategic Action*, which outlined various goals and strategies for Health IT

adoption. This *Framework* document proposed a Health Information Technology Leadership Panel (“HIT Leadership Panel”) to examine the importance of investing in Health IT and the respective major roles of government and the private sector necessary for widespread implementation.

44. In August 2004, Defendant HHS retained The Lewin Group, a consulting firm, to convene the HIT Leadership Panel and to report on its findings. The HIT Leadership Panel consisted of senior executives of the FedEx Corporation, General Motors, International Paper, Johnson Controls, Target Corporation, Pepsico, Procter & Gamble, Wells Fargo, and Wal-Mart Stores, Inc. All of the foregoing are major corporations, and none of the foregoing represent the interests of practicing physicians and surgeons or their patients. In March 2005, the HIT Leadership Panel final report was issued.

#### **American Health Information Community**

45. On July 14, 2005, Defendants announced in the *Federal Register* the formation of AHIC and the availability of a draft AHIC charter, with a final charter to be filed with the Congress within 15 days. 70 Fed. Reg. 40,703 (2005).

46. In conjunction with AHIC’s charter, Defendant Leavitt determined as follows:

I determine, after appropriate consultation between this Department and General Services Administration, that formation of the American Health Information Community is in the public interest in connection with the performance of duties imposed on the Department by law, and that such duties can best be performed through the advice and counsel of such a group.

I deem that it is not feasible for the Department or any of its existing committees to perform these duties, and that a satisfactory plan for appropriate balance of committee membership has been submitted.

Defendants appended the foregoing determination to the AHIC charter. Ex. 1, ¶7.

47. Neither Defendant HHS nor Defendant Leavitt (or his predecessors) have publicly promulgated guidance on advisory committees pursuant to FACA §8(a). Defendant HHS maintains an internet site of certain policies, which at all times prior to the filing of this lawsuit did not include FACA policies pursuant to FACA §8(a). On information and belief, formed after reasonable inquiry, which likely could be proved by discovery, Defendants maintain a 2003 revised edition entitled *Federal Advisory Committee Management Handbook* on their intranet (*i.e.*, in a publicly inaccessible location). Defendant HHS refused to provide a copy of this document without a Freedom of Information Act request. *See* Ex. 1, ¶¶5-6. AAPS has no knowledge of the contents of this *Handbook*.

48. Defendants have scheduled AHIC meetings in Washington, DC, at Defendant HHS's headquarters, according to the following schedule: October 7, 2005; November 29, 2005; Jan 17, 2006; March 7, 2006; April 25, 2006; June 13, 2006; August 1, 2006; September 12, 2006; October 31, 2006; and December 5, 2006. The first three meetings have taken place, as scheduled, in Defendant HHS's headquarters in Washington, DC.

49. During the first AHIC meeting, Defendant Leavitt said "I don't think there is a person who sits at this table who has not given speeches about the promise of health IT. Probably dozens of them, many of you hundreds of them." Similarly, during the first AHIC meeting, the National Coordinator remarked that his time at HHS has been a "wonderful experience from the perspective of just how resonant health information technology is with people in the United States." By contrast, to the extent that patients will lack control over third parties' access to their health records, the experience of AAPS and its members indicates that people and clinicians in the United States consider Defendants' Health IT agenda frightening. That no-one on AHIC

challenged the National Coordinator's position, then or later, further demonstrates how cloistered the AHIC membership are from the views of the public and medical profession.

50. The ostensible representative of practicing physicians (Doug Henley, Executive Director of the American Academy of Family Physicians ("AAFP")) also serves on the Certification Commission for Health Information Technology. The AAFP colleague who represented him at the second AHIC meeting, David Kibbe, is the Director of AAFP's Center for Health Information Technology. In short, with regard to practicing physicians, Defendants have turned to an organization deeply committed to the goals of Defendants' Health IT initiatives and thus not representative of practicing physicians generally and *a fortiori* not representative of small- and solo-practice physicians.

51. The ostensible representative of patients and consumers (Nancy Davenport-Ennis of The Patient Advocate Foundation) comes from a group that focuses on patients with chronic, life-threatening, and debilitating conditions (83% of whom have cancer), which does not represent the typical medical patient's or consumer's views, including in particular typical medical patients' and consumers' views on the privacy of their medical information (*i.e.*, their desire to limit disclosure to treating clinicians).

52. In the instances where AHIC deliberations have faulted practicing physicians for failing to adopt technology (*e.g.*, e-prescriptions, electronic records), no AHIC member defended practicing physicians' interests. Similarly, during the public-participation section at AHIC's first meeting, AAPS's public affairs counsel, Kathryn Serkes, posed privacy- and openness-related questions (namely, which AHIC member is the designated privacy expert and what circumstances does AHIC foresee that would justify secret, non-public meetings). The National Coordinator (then the acting AHIC chair) indicated that he would have answers to her questions

posted as part of the minutes of the proceedings. At its second AHIC meeting (Nov. 29, 2005), AHIC approved the minutes for the October 7, 2005, meeting, which do not answer AAPS's questions.

53. In sum, Defendants have selected a panel of "yes-men" and "yes-women" already committed to the Defendants' agenda. Further, AHIC lacks the balance that representatives of small practices and general consumer/patients would provide. Finally, as constituted, AHIC is unwilling even to address publicly posed questions that challenge the Defendants' agenda.

54. Defendant Leavitt is the appointing authority, chairs AHIC, is the agency head who will receive and act on AHIC advice, and (like the seven other federal AHIC members) serves at the pleasure of the President who launched the Health IT initiative in April 2004.

55. In addition to selecting an unbalanced panel favorable to his agenda, Defendant Leavitt chairs AHIC and the federal members hold a near majority of votes. Further, Defendant Leavitt does not operate AHIC as an advisory committee with independent judgment. At the first AHIC meeting, Defendant Leavitt said:

I'd like to speak frankly about how the influence of this group actually converts to action. The community is a federal advisory committee.... That is the form of collaboration that was available to us. It may not be ideal, but it nevertheless is quite workable. I will, of course, need to maintain the autonomy of the office that I have sworn to uphold. But I'd like to make clear that it's my intention to weigh very heavily the advice that I receive here. It will, of course, need to be converted to action, and I want to make clear to you that [I] intend, as secretary, to act. And by act, I mean to imply that there are certain regulatory authorities and capacities that as Secretary of Health and Human Services, I have to be able to implement in a broad sector of the healthcare industry, because of my relationship with the payers, meaning Medicare and Medicaid and the Indian Health Service and FDA and others, certain directions. There are others at this table who have similar capacities. The Department of Defense, the Department of -- Veteran's Administration, at the Department of Commerce, in the form of NIST.

...

... I want to move with a Model of Consensus. Let's talk about what consensus is. To me, consensus is not unanimous agreement. We likely won't reach unanimous agreement on everything. I intend to manage our group, as Chairman, in a way that will determine when we are, for the most part, in agreement. Because this is advice to the Secretary, we're able to do that. The measure of our success will be that, at certain points along the way, we're going to reach Milestones of Conclusion. And when we reach those Milestones of Conclusion, if as the Chairman, I have bypassed dissent too many times, it's going to manifest itself because the majority of this group isn't going to agree. And if that's the case, then it will be clear to me that I have not managed that part of the process adequately and will have to recalibrate. But my purpose isn't to sit around and have a lot of votes. We will vote when I need to have a point validated and to understand with certainty whether or not we're on track.

56. The private-sector and nonfederal public-sector AHIC members are special-purpose (*i.e.*, non-permanent and part-time) federal officers within the meaning of FACA. The federal AHIC members are federal officers within the meaning of FACA.

57. Defendants have announced their intention to create AHIC subcommittees, chaired by AHIC members (usually with one non-federal member and one federal member as co-chairs) and to fill these subcommittees with those who sought or were nominated for appointment to the original 17-member AHIC (*see* Paragraph 45, *supra*). Defendants have convened four such subcommittees (Consumer Empowerment, Chronic Care, Electronic Health Records, and Biosurveillance), comprised of both AHIC members and AHIC nonmembers, without first complying with FACA's requirements for forming an advisory committee. Notwithstanding that Defendants deem these subcommittees or workgroups of AHIC, they have an independent need to comply with all of FACA's procedural and substantive requirements.

58. According to the agenda circulated at its inaugural January 30, 2006, meeting, the Consumer Empowerment subcommittee plans to meet throughout 2006, to make

recommendations to AHIC during that period, and to present a final report to AHIC members at AHIC's December 5, 2006 meeting. Ex. 1, ¶9.

59. According to the agenda circulated at its inaugural January 31, 2006, meeting, the Electronic Health Records subcommittee plans to meet throughout 2006, to make recommendations to AHIC during that period, and to present a final report to AHIC members at AHIC's December 5, 2006 meeting. Ex. 1, ¶10.

60. According to the agenda circulated at its inaugural February 1, 2006, meeting, the Chronic Care subcommittee plans to meet throughout 2006, to make recommendations to AHIC during that period, and to present a final report to AHIC members at AHIC's December 5, 2006 meeting. Ex. 1, ¶11.

61. According to the agenda circulated at its inaugural February 2, 2006, meeting, the Biosurveillance subcommittee plans to meet throughout 2006, to make recommendations to AHIC during that period, and to present a final report to AHIC members at AHIC's December 5, 2006 meeting. Ex. 1, ¶12.

### **Related Health IT Initiatives**

62. In 1944, Congress established the National Committee on Vital and Health Statistics ("NCVHS"), an advisory committee that Defendant HHS and its predecessors have renewed periodically. *See* Ch. 373, §306 (1944) (*codified as amended at* 42 U.S.C. §242k). Notwithstanding that the charter on Defendant HHS's website expired on January 16, 2006, Ex. 1, ¶13, a notice dated January 24, 2006, in the *Federal Register* on February 3, 2006, announced a series of three NCVHS meetings scheduled for February 21 through 23, 2006. 71 Fed. Reg. 5849 (2006). NCVHS maintains four active subcommittees: National Health Information Infrastructure; Populations; Privacy and Confidentiality; and Standards and Security. NCVHS

has two inactive subcommittees: Computer-Based Patient Records; and Health Statistics for the 21st Century. The Subcommittee on Standards and Security has responsibility for any follow-up work for Computer-Based Patient Records, and the Subcommittee on Populations has responsibility for any follow-up work for Health Statistics for the 21st Century. As indicated by NCVHS's charter, its subcommittees, their charges, and 42 U.S.C. §242k, NCVHS's mission overlaps significantly with AHIC's charter and mission. Ex. 1, ¶13.

63. By contract with the George Washington University on or about October 6, 2005, Defendant HHS through the National Coordinator entered a public-private partnership for the Health IT Adoption Initiative ("HIT Adoption Initiative"). Key components of the HIT Adoption Initiative include convening an "expert consensus panel," developing and publicizing "consensus-panel-driven guidelines" for EHR adoption measurement, and synthesizing multiple EHR adoption measurements into an Annual Report on the overall state of EHR adoption. The HIT Adoption Initiative "team" includes federal members representing Defendants and the National Coordinator. *See, e.g.,* Ex. 1, ¶14.

64. By contract with RTI International on or about October 6, 2005, Defendant HHS established the National Health Information Security and Privacy Collaboration ("HISPC"), a public-private partnership consisting of a multi-disciplinary team of experts and the National Governor's Association ("NGA"). HISPC will work with approximately 40 states or territorial governments to assess and develop plans to address variations in organization-level business policies and state laws that affect privacy and security practices which may pose challenges to interoperable health information exchange. Employees representing Defendant HHS and its National Coordinator have participated and will participate in HISPC. *See, e.g.,* Ex. 1, ¶15.

65. The George Washington University, RTI International, and the National Governor's Association maintain offices in the District of Columbia. *See* Ex. 1, ¶¶16-18.

66. The Lewin Group maintains offices in Falls Church, Virginia. Although AAPS does not seek relief against The Lewin Group and considers this Court's jurisdiction over it irrelevant to this action, AAPS alleges that, on information and belief, which likely could be proved with the opportunity for discovery, The Lewin Group has contacts with the District of Columbia sufficient for this Court to assert jurisdiction over The Lewin Group in the event that Defendants allege that The Lewin Group is a necessary party to this action.

67. As used in this Complaint, "Contractual Panel" includes the HIT Leadership Panel, the HIT Adoption Initiative, the HIT Adoption Initiative's Expert Consensus Panel, the HISPC, and any other consensus panel that the Defendants or their agents form by contract to address issues related to Health IT.

### **LEGAL BACKGROUND**

#### **Executive and Agency Authority under Constitution**

68. Under the U.S. Constitution, Congress is the Legislative Branch and enacts laws, and the Executive Branch sees that those laws are faithfully executed. Through that process, the United States has created Executive-Branch administrative agencies, such as Defendant HHS. As creatures of statute, such agencies have only the powers and authorities vested in them by enabling legislation, and all actions in excess of those powers and authorities are *ultra vires* and impermissible. While the Executive Branch (including its administrative agencies) may ask the Congress to provide new authorities, Executive-Branch agencies lawfully cannot acquire through unilateral action any powers and authorities not expressly conferred.

## **Prohibition against Unauthorized Agency Propaganda**

69. For more than forty years, Congress annually has prohibited the use of appropriated funds for “publicity or propaganda.” For fiscal 2006, the provision reads: “No part of any appropriation contained in this or any other Act shall be used *directly or indirectly, including by private contractor*, for publicity or propaganda purposes within the United States not heretofore authorized by the Congress.” Pub. L. No. 109-115, §824, 119 Stat 2396, 2501 (Nov. 30, 2005) (emphasis added). The 109<sup>th</sup> Congress added the direct-indirect and contractor restrictions to the section previously in place. *See, e.g.*, Pub. L. No. 108-447, §624, 118 Stat. 2809, 3278 (Dec. 8, 2004) (“No part of any appropriation contained in this or any other Act shall be used for publicity or propaganda purposes within the United States not heretofore authorized by the Congress”); Pub. L. No. 108-199, §624, 118 Stat. 3, 355 (Jan. 23, 2004) (same); Pub. L. No. 108-7, §626, 117 Stat. 11, 470 (Feb. 20, 2003) (same).

70. An agency’s authority first to prepare and then to disseminate particular information and the information’s status as misleading are two factors that distinguish lawfully disseminated agency information from “propaganda.” Because AHIC represents an unbalanced advisory committee over which Defendants HHS and Leavitt have undue influence (thereby precluding AHIC’s independent judgment), AHIC is *ultra vires* Defendants’ authority. Similarly, because FACA occupies the field of Executive-Branch agencies’ consensus-panel deliberations, the Contractual Panels are *ultra vires* Defendants’ authority. Finally, the AHIC subcommittees convened without FACA compliance are *ultra vires* Defendants’ authority. In all three instances, the FACA violations render the committees’ workproduct the “propaganda” of Defendants HHS and Leavitt, outside Defendants’ authority either to prepare or to disseminate.

71. Defendant HHS and other Executive-Branch agencies have a pattern and practice of disseminating propaganda to support their initiatives, including the use of contractors to create misleading information (*i.e.*, the aspect of the propaganda prohibition expressly tightened by §824 of Pub. L. No. 109-115).

### **Defendants' Authority to Adopt or Impose Health IT Standards**

72. The express authority of Defendants HHS and Leavitt for Health IT initiatives lies in the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (“MMA”), and the fiscal-year 2006 appropriation for HHS, Pub. L. No. 109-149, 119 Stat. 2833 (Dec. 30, 2005). Congress did not enact Pub. L. No. 109-149 as a retroactive statute in any respect that is material to Defendants’ authority for Health IT initiatives.

73. MMA §649 requires defendant HHS to undertake a “pay-for-performance demonstration program with physicians to meet the needs of eligible beneficiaries through the adoption and use of health information technology” for three years at “no more than 4 sites.” Pub. L. No. 108-173, §649(1), (2), (3), 117 Stat. at 2329-31.

74. MMA §1012 requires defendant HHS to convene the Commission on Systemic Interoperability (“CSI”), with CSI’s issuing its final report no later than October 31, 2005. Pub. L. No. 108-173, §1012, 117 Stat. at 2435-37.

75. In its fiscal-year 2006 appropriation for Defendant HHS, Congress appropriated for the National Coordinator certain sums for “expenses necessary..., including grants, contracts and cooperative agreements for the development and advancement of an interoperable national health information technology infrastructure.” Pub. L. No. 109-149, tit. II, 119 Stat. at 2857. Such “necessary-expense” appropriations do not authorize Defendants to violate any otherwise-

applicable statute in executing the appropriation. *See, e.g.*, U.S. General Accounting Office, *Principles of Federal Appropriations Law*, vol. I, at 4-27 to 4-29 (3<sup>rd</sup> ed. 2004).

76. In its fiscal-year 2006 appropriation for Defendant HHS, Congress placed a \$50M ceiling on expenditures for the “development of scientific evidence that supports the implementation and evaluation of health care information technology systems.” Pub. L. No. 109-149, tit. II, 119 Stat. at 2851. The term “scientific evidence” does not include advisory committee reports or deliberations, standards, or other activities material to this action.

77. In its fiscal-year 2006 appropriation for Defendant HHS, Congress prohibited use of appropriated funds in any activity related to activity designed to influence state or federal legislation:

No part of any appropriation contained in this Act shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

Pub. L. No. 109-149, §503(b), 119 Stat. at 2878.

### **Privacy of Patients’ Health Information**

78. In a Gallup Poll conducted in August 2000, the public overwhelmingly opposed access to their medical records without the patient’s prior consent. According to the Gallup Poll, seventy eight percent (78%) of respondents said that it is very important that no one have access to their medical information without their permission. The opposition was even higher for “government agencies” (92%) and “insurance companies” (82%) and slightly lower for “local and state health departments” (71%). The Gallup Poll had a three-percent margin of sampling error. The Gallup Poll accurately reflects public sentiment on Defendants’ goals of making personal health information available to third-party governmental and payer organizations.

79. The AHIC charter specifically requires that “[a]t least one member shall be an expert on matters pertaining to privacy and security protections of individually identifiable health information.” As set forth in Paragraph 52, Defendants and their agents have declined to identify such a member.

### **Views and Functions to Balance Reconstituted Committees**

80. FACA originated in guidelines issued by the Department of Justice in 1950 for the operation of federal advisory committees to forestall their facilitation of anticompetitive behavior when industry leaders gathered together with Government approval. *See* Hearings on WOC's [Without Compensation Government employees] and Government Advisory Groups before the Antitrust Subcommittee of the House Committee on the Judiciary, 84th Cong., 1st Sess., pt. 1, at 586-87 (1955) (reprinting guidelines). Further, notwithstanding Defendant Leavitt's frequently stated goal to impose standards through the federal government's market power, the antitrust laws appear not to authorize suit directly against the federal Defendants, and the *Noerr-Pennington* doctrine appears to immunize third parties' anticompetitive actions first to influence and then to comply with the federal Defendants' unlawful Health IT policies. Nonetheless, legislation requiring the consideration of the “public interest” has been held to include a consideration of anticompetitive effects. Further, the Regulatory Flexibility Act, 5 U.S.C. §§601-612, requires consideration of regulatory impacts on small entities when agencies adopt certain regulations. Any advisory committee convened to address Health IT generally (as distinct from those convened to address only narrow technical issues under a particular Health IT topic) must include practicing physicians presenting both large and small practices.

81. The public's overarching concern with electronic medical records is maintaining privacy of individuals' medical records against third parties other than treating clinicians. Any

advisory committee convened to address Health IT generally (as distinct from those convened to address only narrow technical issues under a particular Health IT topic) must include members who represent patient privacy views.

### **Judicial Review of *Ultra Vires* Actions**

82. As a matter of historical fact, at the time that the states ratified the U.S. Constitution, the equitable, judge-made doctrine allowing use of the sovereign's courts in the name of the sovereign to order the sovereign's officers to account for their conduct (*i.e.*, the rule of law) was as least as firmly established and as much a part of the legal system as the judge-made doctrine of sovereign immunity. Congress has not passed any applicable law that limits this Court's jurisdiction to entertain an equity action against Defendant Leavitt's *ultra vires* acts.

### **COUNT I AHIC VIOLATES FACA'S BALANCE AND UNDUE-INFLUENCE REQUIREMENTS**

83. Plaintiff incorporates Paragraphs 1 through 82 as if fully set forth herein.

84. As created by Defendants, AHIC lacks balanced membership and provides Defendants an undue influence over AHIC deliberations, in violation of FACA §5(b)(2)-(3), (c). Defendants' conclusory determination that "that a satisfactory plan for appropriate balance of committee membership has been submitted" provides no basis for a reviewing court to uphold Defendants' formation of AHIC as complying with FACA.

85. For the foregoing reasons, Defendants' creating AHIC was, and Defendants' maintaining AHIC is, arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, and without observance of procedure required by law.

**COUNT II**  
**CONTRACTUAL PANELS VIOLATE FACA AND ARE *ULTRA VIRES***

86. Plaintiff incorporates Paragraphs 1 through 82 and Paragraphs 83 through 85 as if fully set forth herein.

87. In causing the Contractual Panels to be formed without complying with FACA, Defendants both directly violated FACA and indirectly violated FACA by acting *ultra vires* their authority, which requires Defendants to convene only FACA-complaint consensus panels. Even if a court held FACA not to apply to a contracted-for consensus panel, such an entity nonetheless is *ultra vires* Defendants' authority because Congress intended FACA to occupy the field of agencies' creation of consensus panels (*i.e.*, the successful circumvention of FACA is nonetheless unlawful).

88. For the foregoing reasons, Defendants' creating the Contractual Panels by contract without ensuring FACA compliance was, and maintaining the Contractual Panels is, arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, and without observance of procedure required by law.

**COUNT III**  
**AHIC SUBCOMMITTEES MUST COMPLY WITH FACA**

89. Plaintiff incorporates Paragraphs 1 through 82, Paragraphs 83 through 85, and Paragraphs 86 through 88 as if fully set forth herein.

90. Before Defendants can convene an AHIC subcommittee comprised of both AHIC members and AHIC nonmembers, Defendants must comply with all FACA requirements for creating a new FACA advisory committee (*e.g.*, preparing and filing a charter, notice in the *Federal Register*). In convening the Consumer Empowerment, Chronic Care, Electronic Health Records, and Biosurveillance subcommittees, Defendants violated FACA by failing to do so.

91. For the foregoing reasons, Defendants' creation and maintenance of the foregoing AHIC subcommittees and any AHIC subcommittees created without full FACA compliance was and is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, and without observance of procedure required by law.

**COUNT IV**  
**AHIC CHARTER AND DETERMINATION VIOLATE FACA**

92. Plaintiff incorporates Paragraphs 1 through 82, Paragraphs 83 through 85, Paragraphs 86 through 88, and Paragraphs 89 through 91 as if fully set forth herein.

93. Defendant Leavitt's AHIC determinations concerning the public interest, Defendants' duties, and the ability of other groups to perform AHIC's functions (Paragraph 46, *supra*) are too conclusory to withstand judicial review. Particularly given the raft of Contractual Panels, AHIC subcommittees, CIS, NCVHS, and competing private-sector Health IT bodies, the determinations fail the statutory requirement that new advisory committees be essential and fail even to identify the relevant duties or duty-imposing laws to which AHIC allegedly relates. Moreover, if Defendants proceed without a new charter for each AHIC subcommittee, the AHIC charter fails adequately to describe AHIC, as expanded by the subcommittees.

94. For the foregoing reasons, the AHIC charter and Defendants' determinations regarding AHIC are arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, and without observance of procedure required by law.

**COUNT V**  
**AHIC VIOLATES AHIC CHARTER**

95. Plaintiff incorporates Paragraphs 1 through 82, Paragraphs 83 through 85, Paragraphs 86 through 88, Paragraphs 89 through 91, and Paragraphs 92 through 94 as if fully set forth herein.

96. In violation of its charter, AHIC does not include “[a]t least one member [who is] an expert on matters pertaining to privacy and security protections of individually identifiable health information.”

97. For the foregoing reasons, Defendants’ creation and maintenance of AHIC as presently constituted violates the AHIC charter and was and is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, and without observance of procedure required by law.

**COUNT VI  
MAINTENANCE OF NCVHS BEYOND ITS TERMINATION DATE VIOLATES FACA**

98. Plaintiff incorporates Paragraphs 1 through 82, Paragraphs 83 through 85, Paragraphs 86 through 88, Paragraphs 89 through 91, Paragraphs 92 through 94, and Paragraphs 95 through 97 as if fully set forth herein.

99. In violation of FACA §14(b)(3), NCVHS continued after the expiration of its charter, took various staff-, subcommittee-, and committee-level actions, noticed future meetings, and apparently intends to hold such future meetings.

100. For the foregoing reasons, Defendants’ maintenance of NCVHS beyond its termination date without first preparing and filing a renewed NCVHS charter violates FACA and is arbitrary, capricious, an abuse of discretion, not otherwise in accordance with the law, and without observance of procedure required by law.

**PRAYER FOR RELIEF**

101. WHEREFORE, AAPS respectfully asks this Court to grant the following relief:

A. Pursuant to 5 U.S.C. §706, 28 U.S.C. §§1331, 1361, 1367(a), 1651(a), 2201-2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C.

Code §11-501, Fed. R. Civ. Proc. 57, and this Court's equitable powers, a Declaratory Judgment that:

- (i) Defendants lack the authority to convene consensus panels – by any means, including contract, request, or otherwise – except in compliance with FACA;
- (ii) AHIC violates FACA's balance and undue-influence provisions;
- (iii) The Contractual Panels violate FACA and are *ultra vires* Defendants' authority;
- (iv) Defendants formed the AHIC subcommittees without complying with FACA;
- (v) Defendants violated FACA by continuing NCVHS after the expiration of its charter;
- (vi) Workproduct from AHIC, AHIC subcommittees formed without full FACA compliance, and the Contractual Panels is invalid for all regulatory purposes;
- (vii) Workproduct from the AHIC subcommittees and the Contractual Panels cannot lawfully be presented to the federal officers serving on AHIC until after Defendants cure all FACA violations and comply with the relief that this Court orders in this action; and
- (viii) It violates FACA and exceeds Defendants' authority to operate a consensus panel either without initially preparing and filing a FACA charter or, if an existing charter is vacated or terminates, without first preparing and filing a new charter.

B. Pursuant to 5 U.S.C. §706, 28 U.S.C. §§1331, 1361, 1367(a), 1651(a), 2202, the Acts of March 3, 1863, 12 Stat. 762, and June 25, 1936, 49 Stat. 1921 (as amended), D.C. Code §11-501, and this Court's equitable powers, an Order providing that

- (i) Defendants are enjoined from continuing AHIC and from reconstituting AHIC without fully complying with FACA and the relief that this Court orders;

- (ii) To the extent that AHIC continues, Defendants are enjoined from convening or maintaining AHIC subcommittees (unless comprised solely of AHIC members) without first complying with all FACA requirements (*e.g.*, noticing a charter in the *Federal Register*, making the requisite FACA determinations, and filing the charter with Congress);
- (iii) Defendants are enjoined from using contracted-for panels to circumvent FACA;
- (iv) If Defendants reconstitute AHIC (including any of its subcommittees), any determinations regarding the public interest and essentiality of AHIC (or any relevant subcommittee) must specifically address the existence of the various other overlapping consensus panels and private-sector equivalents;
- (v) If Defendants reconstitute NCVHS (including any of its subcommittees), any determinations regarding the public interest and essentiality of NCVHS (or any relevant subcommittee) must specifically address the existence of the various other overlapping consensus panels and private-sector equivalents;
- (vi) Defendants and their agents are enjoined from obtaining or using workproduct from AHIC (unless Defendants cure all FACA violations), AHIC subcommittees formed without FACA compliance, and the Contractual Panels;
- (vii) AHIC, its members, and its staff are enjoined from obtaining or using workproduct from AHIC subcommittees formed without FACA compliance or from the Contractual Panels;
- (viii) Defendants and their agents are enjoined from using any materials created by the Contractual Panels with appropriated funds to influence state or federal legislation or appropriations;

- (ix) If Defendants reconstitute any previously FACA non-compliant advisory committee or consensus panel as a FACA-compliant advisory committee, Defendants shall include at least one non-federal member of opposing or alternate views for each non-federal member from the previous advisory committee or consensus panel who serves on the reconstituted panel; and
  - (x) The AHIC charter and accompanying determination are vacated.
- C. Pursuant to 28 U.S.C. §2412 and any other applicable provisions of law or equity, award AAPS its costs, including attorneys fees.
- D. Such other relief as may be just and proper.

Dated: February 23, 2006

Respectfully submitted,

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(<http://www.whitehouse.gov/news/releases/2004/04/print/20040427-5.html>), saved it to portable document format, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append the speech to the pleadings.

5. On several occasions in January 2006, I searched the *Federal Register* online for guidance on advisory committees issued pursuant to FACA §8(a) by the Department of Health & Human Services (“HHS”) and its predecessor. HHS maintains an internet site of policies (<http://www.hhs.gov/policies/index.shtml>), which does not include FACA policies. On information and belief, formed after reasonable inquiry, which likely could be proved by discovery, HHS maintains a 2003 revised edition entitled *Federal Advisory Committee Management Handbook* on its intranet (*i.e.*, in a publicly inaccessible location).

6. On January 18, 2006, on behalf of AAPS, I had a telephone conversation with HHS’s Ms. Debbie Grant. In that call, I asked whether HHS or its predecessor had prepared any guidance pursuant to FACA §8(a), and she advised me of the foregoing *Handbook*, which I requested her to provide to me. By return telephone call on January 20, 2006, Ms. Grant indicated that her supervisor had told her that she could not provide a copy of the *Handbook* without a Freedom of Information Act request. Neither I nor (to the best of my knowledge) AAPS has any knowledge of what the *Handbook* contains. Indeed, prior to January 18, 2006, neither I nor (to the best of my knowledge) AAPS had any knowledge that the *Handbook* existed. On information and belief, formed after reasonable inquiry, which likely could be proved by discovery, Ms. Grant is the HHS staff contact person for FACA issues.

7. On February 22, 2006, I downloaded the AHIC charter and accompanying determinations from HHS’s website (<http://www.hhs.gov/healthit/ahiccharter.pdf>), saved it, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not

append it to the pleadings.

8. Where the complaint in the above-captioned action makes allegations concerning actions taken and statements made during AHIC meetings, those allegations are based on the minutes, transcripts, and online video broadcasts linked from HHS's AHIC website (<http://www.hhs.gov/healthit/ahic.html>), which I have downloaded and/or viewed in pertinent part. These materials include the following for the AHIC meeting on October 7, 2005:

<http://www.hhs.gov/healthit/documents/October29thTranscript.pdf>;

<http://www.hhs.gov/healthit/documents/AHICminutes.pdf>;

<http://www.hhs.gov/healthit/documents/October72005.ram>;

and the following for the AHIC meeting on November 29, 2005:

<http://www.hhs.gov/healthit/documents/November29thTranscript.pdf>;

<http://www.hhs.gov/healthit/documents/AHIC112905MeetingReport.pdf>;

<http://www.hhs.gov/healthit/documents/hhs112905a.ram>;

and the following for the AHIC meeting on January 17, 2006:

<http://www.hhs.gov/healthit/documents/TranscriptJan1706.pdf>;

<http://www.hhs.gov/healthit/documents/MeetingMinutes060117.pdf>;

<http://www.hhs.gov/healthit/documents/January172006.ram>.

We can produce the relevant evidence if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append it to the pleadings.

9. On February 22, 2006, I downloaded the agenda circulated at the inaugural January 30, 2006, meeting of AHIC's Consumer Empowerment subcommittee from HHS's website (<http://www.hhs.gov/healthit/documents/CE.pdf>), saved it, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append it to the

pleadings.

10. On February 22, 2006, I downloaded the agenda circulated at the inaugural January 31, 2006, meeting of AHIC's Electronic Health Records subcommittee from HHS's website (<http://www.hhs.gov/healthit/documents/EHR.pdf>), saved it, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append it to the pleadings.

11. On February 22, 2006, I downloaded the agenda circulated at the inaugural February 1, 2006, meeting of AHIC's Chronic Care subcommittee from HHS's website (<http://www.hhs.gov/healthit/documents/Chronic.pdf>), saved it, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append it to the pleadings.

12. On February 22, 2006, I downloaded the agenda circulated at the inaugural February 2, 2006, meeting of AHIC's Biosurveillance subcommittee from HHS's website (<http://www.hhs.gov/healthit/documents/Bio.pdf>), saved it, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append it to the pleadings.

13. On February 21, 2006, I downloaded the charter dated January 13, 2004, and expiring January 16, 2006, for the National Committee on Vital and Health Statistics ("NCVHS") from HHS's website (<http://www.ncvhs.hhs.gov/charter06.pdf>), saved it, and can produce it if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append the charter to the pleadings. At the same time, I downloaded the charges of each of the NCVHS subcommittees from the same website (<http://www.ncvhs.hhs.gov/popschrg.htm>, <http://www.ncvhs.hhs.gov/nhichrg.htm>, <http://www.ncvhs.hhs.gov/privchrg.htm>, <http://www.ncvhs.hhs.gov/stdschrg.htm>, <http://www.ncvhs.hhs.gov/2kchrg.htm>, <http://www.ncvhs.hhs.gov/cprchrg.htm>), saved them to portable document format, and can

produce them if requested to do so. Pursuant to Local Rule LCvR 5.1(g), however, we do not append the subcommittee charges to the pleadings.

14. On February 22, 2006, I downloaded the “project team” page from the website of Health Information Technology Adoption Initiative (<http://hitadoption.org/index.php?p=team>), saved it to portable document format, and can produce it if requested to do so. This page indicates that the “project team” includes Richard Singerman, Ph.D., and Karen Bell, M.D., of HHS in addition to various private institutional and individual members from academia. Pursuant to Local Rule LCvR 5.1(g), however, we do not append this evidence to the pleadings.

15. The meeting minutes to the January 17, 2006, AHIC meeting cite Dr. Scott Young, the director of the health information technology “portfolio” at HHS’s Agency for Healthcare Research and Quality, for the proposition that “[National Health Information Security and Privacy Collaboration (“HISPC”)]... will include membership from state governments, the federal government, and leaders from key non-governmental organizations. The purpose of HISPC will be to maximize knowledge exchange and identify common solutions. HISPC will seek consensus-based solutions and implementation plans through a public, community-based model.”

16. On February 22, 2006, I visited the website of RTI International, Inc. (<http://www.rti.org>), which indicates that it maintains an office at One Metro Center, 701 13th Street, N.W., Suite 750, Washington, DC 20005-3962.

17. On February 22, 2006, I visited the website of the George Washington University (<http://www.gwu.edu>), which indicates that it maintains an office at 2121 Eye Street, N.W. Washington, D.C. 20052.

18. On February 22, 2006, I visited the website of the National Governors

Association (<http://www.nga.org>), which indicates that it maintains an office at Hall of the States, 444 N. Capitol St., Washington, D.C. 20001-1512.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 23<sup>rd</sup> day of February, 2006.

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Lawrence J. Joseph