

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ASSOCIATION OF AMERICAN)	
PHYSICIANS & SURGEONS,)	
Plaintiff,)	
)	
v.)	Civil Action No. 06-0319-ESH
)	
U.S. DEPARTMENT OF HEALTH &)	
HUMAN SERVICES, <i>et al.</i> ,)	
Defendants.)	

DECLARATION OF JANE M. ORIENT, M.D.

I, Jane M. Orient, M.D., hereby declare and state as follows:

1. I am over 18 years of age, and I am not a party to this action. I reside in Tucson, Arizona. I am the Executive Director of the Association of American Physicians and Surgeons, Inc. (“AAPS”), a position I have held for over 15 years. During my tenure as Executive Director, I also have concurrently been an AAPS member.

2. AAPS, a non-profit organization founded in 1943, is dedicated to protecting private medicine, ethical medicine, and the patient-physician relationship. Through thousands of member physicians and surgeons, AAPS represents virtually all medical specialties nationwide, primarily in small and solo practices.

3. AAPS receives no government funding and has negligible unrelated business income. Instead, AAPS is funded almost entirely by member dues, reflecting its representation of its members and their patients, in contrast with many other medical organizations.

Education and Experience

4. In 1974, I received my M.D. degree from Columbia University, College of Physicians & Surgeons.

5. I am an internist and have been in solo private practice since 1981. Before opening my practice, I was full-time faculty at the University of Arizona College of Medicine

(“UACM”) and a staff physician at the Veterans Administration Medical Center in Tucson. I have remained a Clinical Lecturer in Internal Medicine with UACM. In addition, I serve as the Director of Continuing Medical Education at Carondelet St. Joseph’s Hospital in Tucson.

6. I have published more than 100 articles on medicine, including many in peer-reviewed journals. I frequently speak and write about issues relating to the practice of private medicine, the interests of patients, the privacy of medical records, and electronic medical records.

7. I am the author of Jane M. Orient, *Sapira’s Art and Science of Bedside Diagnosis* (Lippincott, Williams & Wilkins 2d ed. 2000) and (3d ed. 2005), a textbook of clinical examination for medical students. Record-keeping and the diagnostic thought process are integral parts of this book.

8. At UACM, I participated in the first controlled study on the use of practice guidelines by physician extenders, employing checklists designed for computerized data entry (*i.e.*, the type of research in which the computerized patient record might be used). We reported our research in Orient J, Kettel L, Sox H, *et al.* “The Effects of Algorithms on Care in a Nurse Practitioner Clinic,” *Clinical Research* 28:33A, 1980; Orient J, Kettel L, Sox HC Jr., Sox C, Brown B Jr., Berggren H, Woods A. “Can Algorithms Change Ambulatory Care Costs or Efficacy?” in *Primary Care Research* in 1980 ed. by Lipkin M Jr. and White KL, Rockefeller Foundation, 1981; and Orient JM, Kettel LJ, Sox HC Jr., Sox CH, Berggren HJ, Woods AH, Brown BW, Lebowitz M. “The Effects of Algorithms on the Cost and Quality of Patient Care,” *Medical Care* 21:157-167, 1983.

Opposition to Health IT Policies

9. 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 information technology (“Health IT”) solutions that open medical care to third-party monitoring and rationing.

10. Portrayed in the most positive light possible, the results of the study described in Paragraph 8, *supra*, were decidedly equivocal. No salutary effects were definitely attributable to the evidence-based guidelines, data collection devices, or computerized monitoring of the process of care. There was a decrease in the number of diagnostic tests ordered (for both appropriate and inappropriate tests), but other facts could explain the difference: a research assistant followed the nurse practitioners and timed them with a stopwatch; every chart was closely monitored; and the nurse practitioners knew they were supposed to order fewer tests. The study also showed some potential hazards: inaccurate or even dishonest record-keeping; and the denial of beneficial care in order to avoid receiving an “error statement.”

11. One of the most serious problems with the computerized record is that it can stand in the way of medical reasoning. The electronic checklist might be suitable for the medical student, who is just learning to take a history and perform a physical examination. But to the sophisticated clinician, constraining the record into a computer straitjacket is not just a thief of time. It alters and impairs the entire diagnostic process. The good clinician’s interview and examination is a complex, highly individualized process of hypothesis testing. It is interactive and iterative. Every patient, every clinician, every problem is unique; yet there are patterns, and the clinical expert is highly skilled at pattern recognition. The computerized checklist has both

too much and too little: too many irrelevancies, too few special questions or tests for the unusual diagnosis or presentation.

12. Another serious problem is that one tends to get more of what one measures. If physicians are judged by given criteria (*e.g.*, the percentage of patients who have C-sections, or blood transfusions, or aspirin after a heart attack, or a beta blocker in the intensive care unit), they will treat patients with one eye on their own clinical profiles.

13. Counsel has provided me with a summary of a Gallup Poll conducted in August 2000, and the summary indicates that 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 access by "government agencies" (92%) and "insurance companies" (82%) and slightly lower for access by "local and state health departments" (71%). The summary indicates that the Gallup Poll had a margin of sampling error of plus or minus three percent. From my perspective as a physician in private practice and as a speaker on privacy topics, the foregoing polling results continue accurately to reflect public sentiment on making personal health information available to third-party governmental and payer organizations.

Economic Interest

14. The computerized medical record will be very expensive to implement (*e.g.*, purchasing new hardware and software, training and retaining staff or contractors), to the disadvantage of small practices. In fact, the overhead is likely to be unaffordable for many, particularly at the small and solo practice level prevalent among AAPS's members. If a government-imposed Health IT regime becomes mandated for medical care for patients enrolled

in federal programs (*e.g.*, Medicare, Medicaid), the mandate's attendant costs and burdens will drive many AAPS members from performing work in those areas.

15. Many AAPS members depend on patients enrolled in federal programs for a substantial share of their revenue. For that reason, Secretary Leavitt's stated goal as part of the American Health Information Community ("AHIC") meetings of using federal market power to impose Health IT on the medical profession and patients threatens significant economic injury to AAPS members. Video of AHIC Meeting, at 1:08 of 3:53:08 (Oct. 7, 2005). Similarly, National Coordinator Brailer's suggestions to present standards generated by HHS contractor panels to AHIC for approval (followed by HHS's incorporating them by reference into regulations) as well as to use AHIC to vet "voluntary consensus standards" under the National Technology and Transfer Act for incorporation into federal procurement standards (*i.e.*, without a rulemaking) also threatens injury to AAPS members. Video of AHIC Meeting, at 3:44 to 3:46 of 3:53:08 (Oct. 7, 2005). The foregoing video is located at <http://www.hhs.gov/healthit/documents/October72005.ram>.

16. Hospital policies concerning the use of Health IT and other issues directly affect AAPS members. Many physicians, including myself, rely on hospital privileges to maintain their practices, and hospital policies control the relationship between the hospital and the physician. If HHS succeeds in using its market power to change third-party hospitals' Health IT policies, the change will directly affect physicians, including AAPS members, in their practice of medicine.

Participation and Advocacy

17. If the Court ordered HHS to reconstitute AHIC, the AHIC subcommittees, and/or HHS's contractual consensus panels to comply with FACA, I would seek to participate on the resulting panel(s), particularly to represent the interests of private practitioners and the privacy

of their patients. In addition, AAPS would seek to sponsor both other AAPS members and non-members with relevant expertise (*e.g.*, antitrust, small-business, technology, and privacy issues) who share AAPS's views.

18. Similarly, AAPS will seek to place members and non-members who share AAPS's views on future HHS advisory committees. To do so, AAPS relies on FACA's chartering process. As revealed by the AHIC subcommittee and non-FACA contract panels in the above-captioned litigation, HHS policies that circumvent the FACA chartering process impair AAPS's ability to participate in these processes.

19. As part of its mission, AAPS monitors HHS regulatory actions that could affect AAPS members' practices and their patients' privacy. As part of that process, AAPS monitors HHS's regulatory developments and its advisory panels. To do so, AAPS staff obtains advance materials on advisory panels directly from HHS websites, from AAPS's consultants, and from "list-serve" emails directly from HHS. In the case of HHS's contract-based consensual panels, failure to provide such information impairs AAPS's ability to monitor the actions of such contract-based panels.

20. AAPS advocates in administrative, legislative, and public-policy arenas on behalf of its members (and their patients) and benefits from FACA's public protections, including its facilitated oversight of advisory committees and its elimination of unnecessary, duplicative, and overlapping advisory committees. In the case of HHS's numerous Health IT advisory committees and non-FACA consensus panels, the number of committees (and their duplication and overlap) impair and make more expensive AAPS's ability to monitor HHS's activities on health topics critical to AAPS members' livelihoods and AAPS's mission. AAPS's public relations counsel (Kathryn Serkes) regularly attends and reports on meetings of the National

Committee on Vital and Health Statistics and AHIC. The overlapping jurisdiction and duplication between the various Health IT panels increase the burden and expense of monitoring these panels.

21. On behalf of its members (and their patients), AAPS intends to challenge and to advocate against HHS's 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. Because advisory panels create the basis on which HHS has stated its intent to take regulatory actions, AAPS must monitor and challenge the record as HHS creates it.

22. Because of how HHS threatens to use overlapping and interlocking Health IT panels, it is even more imperative than usual for AAPS to challenge HHS's record. By way of specific example, as indicated in Paragraph 15, *supra*, in a candid acknowledgment of HHS's intent for Health IT, the National Coordinator (Dr. Brailer) indicated HHS's intent to use AHIC to facilitate adopting Health IT standards and policies with limited or no future rulemakings.

23. I have personal knowledge of the foregoing declarations and am competent to testify thereto at trial.

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 11th day of July, 2006.

/signed/ Jane M. Orient
Jane M. Orient, M.D.