

# Letter to HHS Secretary Thompson on HIPAA Privacy Regulations and Research

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August 14, 2001

The Honorable Tommy G. Thompson  
Secretary of Health and Human Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Mr. Secretary:

The undersigned individuals and organizations represent America's leading research universities, medical schools, teaching and community hospitals, scientific societies, and health care analysts, as well as the pharmaceutical research, medical device, and biotechnology firms that produce new medical products and therapies. We write to voice our shared concern that the Department's final rule, "Standards for Privacy of Individually Identifiable Health Information," unless substantially amended, will harm patients and scientific innovation by creating significant obstacles to the conduct of biomedical, epidemiologic, health services, and other research.

The academic and industry research communities believe that the rule's restrictions on the use and disclosure of protected health information for research purposes and limits on the retention of research data will seriously impair our ability to conduct clinical trials, clinico-pathological studies of the natural history and therapeutic responsiveness of disease, epidemiologic and health outcome studies, and genetic research. The Department's recently issued (7/06/01) guidance, intended to provide technical assistance with implementation of the privacy regulation, does not address this or the majority of the other concerns that research organizations have raised about the rule's impact.

Our concerns, along with a range of proposed modifications to address the rule's impediments to research, were detailed in the

many letters that we severally submitted to the Department during the comment periods on the proposed and final rules, and in subsequent communications. With this letter we hope to alert the Department to the growing consensus within the research community that the rule must be amended as quickly as possible, to avoid the inevitable harm that will result when covered entities and research companies in private industry begin their implementation efforts.

As researchers and representatives of research organizations, we recognize that safeguards for privacy and confidentiality are profoundly important to research participants. We commend the Department's commitment to protecting health information privacy, and we share the goal of ensuring the protection of privacy in research. We believe nonetheless that the privacy rule can be - and must be - amended to better serve the public interest in sustaining the research enterprise. We are eager to assist the Department in its efforts to accomplish this objective.

Sincerely,

AdvaMed, Advanced Medical Technology Association  
American Medical Group Association  
Association of Academic Health Centers  
Association of American Medical Colleges  
Association of American Universities  
BIO, Biotechnology Industry Organization  
California Healthcare Institute  
Council on Governmental Relations  
Federation of American Societies for Experimental Biology  
Healthcare Leadership Council  
Lasker /Funding First  
Pharmaceutical Research and Manufacturers of America  
Society for Epidemiologic Research  
Task Force on Informed Consent Issues in Psychiatric Genetics (US) of the International Society of Psychiatric Genetics

cc: The Hon. Mitchell E. Daniels, Director, Office of Management and Budget Members of the 107th Congress

Replies to the endorsing organizations may be addressed care of David Korn, MD and Roger Meyer, MD, Association of American Medical Colleges, 2450 N St. NW, Washington, DC, 20037.