



## INTERNATIONAL SOCIETY *for* PHARMACOEPIDEMIOLOGY

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October 20, 2011

The Honorable Kathleen Sebelius  
Secretary of Health and Human Services  
200 Independence Avenue, SW  
Washington, D.C. 202001

Dear Madam Secretary:

The International Society for Pharmacoepidemiology (ISPE) is very pleased to have the opportunity to offer our perspectives and suggestions, and submits for your consideration a set of recommendations relative to the Department's recent Advance Notice of Proposed Rulemaking (ANPRM) entitled "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators" and that appeared in the Federal Register 76, 143:44512, 2011. We have filed these comments on [regulations.gov](http://regulations.gov) as well.

ISPE is an international, nonprofit, professional membership organization dedicated to promoting the health of the public by advancing pharmacoepidemiology, the science that applies epidemiological approaches to studying the use, effectiveness, values and safety of pharmaceuticals. ISPE is firmly committed to providing an unbiased scientific forum for the views of all parties with interests in drug, biologics, and devices development, delivery, use, costs and value, adverse and beneficial effects, and therapeutic risk management.

Moreover, the Society provides an international forum for the open exchange of scientific information among academia, government, and industry and for the development of policy. ISPE is a provider of education and an advocate for the fields of pharmacoepidemiology and therapeutic risk management. The Society's more than 1,000 members represent 45 countries. ISPE members work in academic institutions, the pharmaceutical industry, government agencies, and non-profit and for-profit private organizations. ISPE members are researchers with background and training in epidemiology, biostatistics, medicine, public health, nursing, pharmacology, pharmacy, law, and health economics. Our comments are based on a careful review of the document by the Public Policy Committee as well as by the Society's membership including ISPE Fellows, Past Presidents, members of the Board of Directors, Executive Committee, and the membership-at-large. Due to the development process of the draft documents in which many ISPE members from academia, research centers and regulatory bodies were involved, comments may also have been sent directly by individual members and may duplicate some of the comments in this document.

We thank the Office of the Secretary for allowing us the opportunity to comment on this document. ISPE welcomes any future dialogue.

Sincerely,

Public Policy Committee  
Board of Directors  
International Society for Pharmacoepidemiology (ISPE)