



Federation of American Societies for Experimental Biology

---Quality Life Through Research---

Member Societies

- The American Physiological Society
- American Society for Biochemistry and Molecular Biology
- American Society for Pharmacology and Experimental Therapeutics
- American Society for Investigative Pathology
- American Society for Nutrition
- The American Association of Immunologists
- American Association of Anatomists
- The Protein Society
- Society for Developmental Biology
- American Peptide Society
- Association of Biomolecular Resource Facilities
- The American Society for Bone and Mineral Research
- American Society for Clinical Investigation
- Society for the Study of Reproduction
- Teratology Society
- The Endocrine Society
- The American Society of Human Genetics
- Society for Gynecologic Investigation
- Environmental Mutagen Society
- International Society for Computational Biology
- American College of Sports Medicine

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Dear Dr. Zarin:

On behalf of the Federation of American Societies for Experimental Biology (FASEB), I am writing to express interest in the implementation of Title VIII of the *Food and Drug Administration Amendments Act of 2007* (P.L. 110-85), which expands the clinical trials registry databank. Registering clinical trials provides important trial information to scientists and the patient community, helping to guide future research, assist patients in making decisions about trial participation and treatment options, and increase public trust in the clinical trials process. This Title is, therefore, of considerable relevance to FASEB, a consortium of 21 biomedical research societies representing over 80,000 basic and clinical investigators.

FASEB appreciates the challenges the National Library of Medicine (NLM) faces in expanding the trials registry to incorporate additional trial types and a results database that accurately reflects trial outcomes, facilitates access to and interpretation of trial data, and enables researchers to meet reporting requirements with minimum difficulty. One section of the legislation that stands out to us is the provision preventing the posting of clinical trial information for device trials that have not been cleared or approved. There is no such delay in posting data elements related to drug trials, and FASEB sees no reason to impose one for device trials. Indeed, doing so limits the transparency of trials, prevents patients and researchers from making timely use of trial information, and may have a negative impact on investigators' ability to publish trial data in light of registration requirements imposed by journal editors. We hope it will ultimately be possible to implement a policy that makes this information publicly available. In the meantime, we would appreciate any information you may have regarding the intended purpose of this requirement.

Thank you in advance for considering our comments. We look forward to additional opportunities to correspond with NLM on this issue, and we hope you will consider FASEB and the biomedical researchers we represent to be a resource as the new policy unfolds.

Sincerely,

Robert E. Palazzo, Ph.D.
 FASEB President

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