



November 1, 2005

Division of Dockets Management (HFA-305)
Docket No. 2005N-0404
Food & Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Via electronic mail

On behalf of The American Society for Reproductive Medicine (ASRM), we appreciate the opportunity to submit comments in response to the October 7, 2005 *Federal Register* Solicitation of Public Review and Comment on Research Protocol: Gonadotropin-releasing Hormone Agonist Test in Disorders in Puberty [Docket No. 2005N-0404].

The American Society for Reproductive Medicine, founded in 1944, is an organization of approximately 8,500 physicians, researchers, nurses, technicians, and other professionals dedicated to advancing knowledge and expertise in reproductive biology and medicine.

The protocol being considered by the Subcommittee has been sent by the University of Chicago Institutional Review Board (IRB) to OHRP for 407 review and is authored by Robert L. Rosenfield, M.D., a pediatric endocrinologist. It compares the sleep-related luteinizing hormone (LH) increase at puberty compared to the gonadotropin and sex steroid response to a gonadotropin releasing hormone agonist (leuprolide) test of pituitary-gonadal function. We understand there are concerns about whether the protocol would represent a “minor increase over minimal risk in healthy children and therefore be subject to a 407 review by the OHRP.

Our organization is not familiar with the specific protocol being used in this study, however we do feel strongly that it can be important to obtain data from “healthy” children and adolescents in order to improve our evaluation and treatment of young patients with hormonal problems. Without data from a “normal” population it may be difficult if not impossible, to ascertain the safety and efficacy of some medications and treatments. We think it is possible to move this vital research forward and to set up appropriate safeguards to protect the youngsters who might involved in these studies. We feel that some diagnostic tests and use of some pharmaceutical products are not “minor increases over minimal risks” and therefore should not require review by a 407 panel.

We appreciate the opportunity to comment on this important matter in the docket.

Sincerely,

Joe Sanfilippo MD
President.

Robert W. Rebar, MD
Executive Director

