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Guidelines for the Clinical Testing of Male Contraceptive Drugs

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The development of male contraceptive drugs is of great scientific importance for andrologists as well as being of vital world interest. The American Society of Andrology, therefore, welcomed the opportunity to work closely with the Division of Metabolism and Endocrine Drug Products of the Food and Drug Administration (FDA) in formulating appropriate guidelines for clinical testing of male contraceptive drugs. During the past year, a committee of the Society consisting of Drs. Nancy Alexander, Andrzej Bartke, Glenn R. Cunningham, Richard M. Harrison, Thomas J. Lobi, Howard R. Nankin, D. J. Patanelli, C. Alvin Paulsen, Eugenia Rosemberg, Richard J. Sherins, Emil Steinberger, Ronald S. Swerdloff, and myself has reviewed and commented on proposed guidelines as they have been drafted by the FDA.

Although some members of the committee have individual reservations on some items, there is general agreement that the guidelines as presented here are a viable and useful approach to a complex area of clinical investigation. However, the final responsibility for the guidelines properly remains with the Food and Drug Administration. Further experience will indicate whether additional modifications will be necessary. We are pleased that the Society has been privileged to play a role in this process.

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