WHO Supported Symposium
Hormonal Male Contraception: A Critical Update

Chairs: Jolanta Slowikowska-Hilczer (Poland) & Frederick Wu (United Kingdom)

Speakers: Douglas Colvard (USA) and Ronald Swerdloff (USA)

Panel Discussion: Frederic Wu (Chair), Diana Blithe (USA), Douglas Colvard (USA), Robert McLachlan (Australia), Ronald Swerdloff (USA).

The session was well attended with over 100 people in the room with two competing sessions. There were excellent response and discussion from the audience during the panel discussion period. Dr. Wu introduced the session indicating there will be a panel discussion after the presentation to discuss critical issues related to the development of a male hormonal contraceptive.

The chairs then introduced Dr. Colvar who described the WHO-Contraceptive Research and Development Program (CONRAD) supported multicentre study to investigate the contraceptive efficacy of a combination of testosterone undecanoate (1000 mg every 8 weeks) administered intramuscularly together with norethisterone enanthate (200 mg every 8 weeks). 320 participants enrolled, 96.8% of those who completed the 6 months suppression and entered efficacy study (n=274), 109 completed efficacy because the study was prematurely stopped by the WHO based on increased adverse events relating mood changes that the WHO deemed that enrolment and further injections should be stopped. This decision was made despite excellent efficacy data and a recommendation of the Study Data and Safety Monitoring Board to continue the study. The contraceptive failure rate was 1.6% which was comparable to hormonal long acting methods for women. 96.4% of the subjects recovered within 52 weeks after stopping the injections.

Dr. Swerdloff followed by a review of the current state of male hormonal contraceptive development and noted that multiple studies conducted by the pharmaceutical industry and non-government organizations indicated that about 50% of men welcomed a male contraceptive and that females would trust their partners to use the male contraception. He also described that current studies on different routes
of administration of the hormones and a new androgen are being investigated by the National Institute of Child Health and Human Development (NICHD) as well as non-hormonal methods that will be discussed in another symposium.

The discussion focused on

1. Why industry is not enthusiastic about hormonal male contraception development? Economic versus efficacy; a new male method may decrease the market share of female methods; liability in case of contraceptive failure; industry has their focus on cardiovascular disease and cancer therapy

2. Why funding agencies are not more enthusiastic about supporting hormonal male contraception research? Funding is low for medical research because of economic downturn, but NICHD in the United States is expanding the clinical trial centers for male contraception to outside the United States

3. What are the main obstacles and opportunities for further male hormonal contraceptive research? Lack of industry support and a product may have to be taken to phase 3 development before industry may be interested.

4. What is the likely acceptability of hormonal male contraception for men and for women? Appears to be acceptable to both men and women from international surveys

5. Is there a realistic chance for hormonal male contraception to become an accepted method of family planning? The general response of the panel is yes but a product needs to be forthcoming soon.

6. What are the most realistic alternatives to hormonal methods for male contraception? None at the present, there are leads but none in near clinical trials stage.