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Position Statement on Prion Proteins

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CFAS position statement on the possible clinical significance of prion proteins in urinary-derived human menopausal gonadotropins and human chorionic gonadotropin:

Recent data published by van Dorsselaer et al indicate that urinary gonadotropins including, urinary-derived human chorionic gonadotropin, may contain normal prion proteins. Such proteins are often found in the urine of most healthy individuals. Abnormal prion proteins, in contrast, are not usually found in the urine of otherwise healthy individuals. The abnormal prion proteins have been implicated in certain neurological disorders, specifically Creutzfeldt-Jakob Disease (CJD). This is the human equivalent of "mad cow disease". It is important to note that van Dorsselaer et al did not find any abnormal prion proteins in the urinary gonadotropins. The concern raised by the authors is that they suggest that the abnormal prion proteins could at some time contaminate urinary gonadotropins. Based upon the authors' research as well as that of others, this has never occurred. Moreover, van Dorsselaer et al acknowledge that there are no known cases of CJD associated with the use of urinary-derived human gonadotropins including FSH/LH or chorionic gonadotropins preparations. The authors conclude that with the availability of recombinant gonadotropins, the risk of prion contamination might be reduced even further. The study considers an important issue since the use of urinary gonadotropins is global.

The CFAS has reviewed the study published by van Dorsselaer et al and find the data intriguing. However, the concern raised by the authors is not substantiated by clinical evidence as no cause and effect relationship has ever been demonstrated. The question of the clinical significance of these observations remains unanswered. Regardless, the CFAS is continuing to review this data and as well as other literature pertaining to this issue. Over the next few weeks we hope to offer more extensive comments on the safety of urinary hMG.

At this point in time, the CFAS can conclude:

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Urinary gonadotropins may contain normal prion proteins. Presently, there appears to be no clinical consequence to this observation.

Urinary hMGs have been available for over 50 years and used by millions of women worldwide. To date and to the best of our knowledge, there has never been a case of a prion-associated disease such as CJD reported in a woman previously exposed to urinary gonadotropins.

Prions may be easily transmitted via an intra-muscular injection. The current urinary gonadotropin preparations however, are most often injected by the subcutaneous route. We are unaware of any risk of prion transmission following a subcutaneous injection.

Based upon current knowledge and literature, there appears to be no confirmed clinical differences in the safety or efficacy among the currently available urinary gonadotropins compared to the newer recombinant gonadotropin products. The CFAS remains committed to protecting the safety and welfare of our patients. With that in mind, we shall continue to monitor the medical literature and await further evaluation by world experts in this field as the data are further scrutinized.