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RED HOT MAMAS

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*Menopause Management Education Programs and Services*

July 13, 2000

Dockets Management Branch (HFA-305)  
U. S. Department of Health and Human Services  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, Maryland 20852

Reference: **SEXUAL DYSFUNCTION GUIDELINES FOR INDUSTRY**

As a women's healthcare advocate and founder of PRIME PLUS/Red Hot Mamas® Menopause Management Education Programs, which have been offered throughout the United States since 1991, I am deeply concerned over your Sexual Dysfunction Guidelines for Industry on the clinical development of drug products for treatment.

First, I must preface that tens of thousands of women have attended our programs over the years. Each one of our programs, which are conducted through hospitals, health maintenance organizations and physician group practices, devotes at least one program per year to female sexuality.

In addition, over the years we have both formally and informally collected data on the sexual concerns of mid-life women. I should note that the average age of women attending our programs is nearly 52 and the majority have been in long-term relationships.

Karen L. Giblin  
President

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Their overwhelming sexual concern is that of adequate desire or interest. In fact, in a study I recently conducted with Philip Sarrel, M.D., of Yale University School of Medicine, "Helping Women Function Sexually After Menopause – A Survey to Determine Women's Needs and Their Positive and Negative Experiences with Healthcare Providers", of 258 peri-menopausal and post-menopausal women who were attending PRIME PLUS programs at selected sites in the United States, eight out of ten respondents listed the lack of desire as their greatest concern.

In another study we recently conducted of 2,200 physicians, menopausal women and partners, with Harris Poll, nearly one-half of the OB/GYN's and Primary Care physicians surveyed, indicated that nearly half of their menopausal patients suffer from a loss of sexual desire. Concerns about sexual performance/outcomes (climaxes) are hardly mentioned by this population.

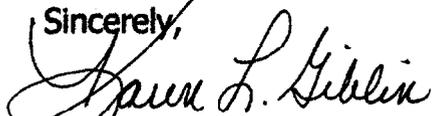
Undoubtedly, a similar survey of twenty, or thirty-something year olds would likely generate vastly different results. But for the mid-life women, suffering a decrease in desire is the salient issue; continuing to comfortably perform what many probably still consider to be a "marital responsibility" is, by far, more important to them than achieving heightened outcomes.

Therefore, in regards to the design of clinical studies in this area, and certainly as they pertain to mid-life women, there should be more focus on pleasure and far less focus on orgasmic outcomes. I must reiterate on behalf of the thousands of women who have attended our programs, and who have participated in our studies, their chief concern is not their lack of orgasms, but it is the loss of sexual desire. Measuring the number of orgasms definitely would not address their needs.

In closing, I would be happy to provide the research studies mentioned herein, and/or respond to any questions you wish to submit to me.

Thank you for your continuing interest and support of all aspects of women's healthcare.

Sincerely,



Karen L. Giblin  
President  
Prime Plus, Inc.



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