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Dockets Management Branch (HFA-305)
Food and Drug Administration
5600 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Over-the-Counter Vaginal Contraceptive Drug Products Containing Nonoxynol 9; Required Labeling [Docket No. 80N-0280]

The American College of Obstetricians and Gynecologists, representing 45,000 obstetrician–gynecologists and other clinicians, is pleased to offer comments on the proposed rule "Over-the-Counter Vaginal Contraceptive Drug Products Containing Nonoxynol 9; Required Labeling" (68 Federal Register 2254-2262). We support efforts aimed at increasing the availability of effective contraceptives and encourage the accurate labeling of contraceptive products to assist women in choosing the contraceptive method that is best for them.

General Comments

In general, we find that this proposed rule is very thoughtfully presented and represents an accurate synopsis of the existing data relating to the use and safety of nonoxynol-9 (N-9). The interpretation of the data relating to the lack of protection from sexually transmitted diseases (STDs), including human immunodeficiency virus (HIV), is excellent and well supported by the data. The most controversial issue is the definition of what level of use constitutes a "safe" level, but the definition used in the proposed rule (once daily or less frequently) appears to be reasonable. This frequency of use should be described in every reference to "frequent use."

The proposed rule appears to focus on the use of spermicides containing N-9 in conjunction with male condoms. Many male condoms are treated with N-9, and the rule does not address the use of these products. The WHO/CONRAD Technical Consultation on Nonoxynol-9 (cited as reference 31 in the proposed rule) recommends that these condoms not be promoted but that their use is better than no condom use at all. A spermicide is also a necessary part of the contraceptive regimen for women who use other

barrier methods, such as diaphragms and cervical caps. If there is evidence regarding the safety of N-9 with these methods, it would be useful to add it. We encourage further research regarding all these uses of N-9.

Questions to Be Addressed

1. Do the proposed warnings...adequately convey the safety concerns to consumers?
The "Ask a doctor before use if you have" warning is unclear in comparison with the similar section of the labeling ("Studies have raised safety concerns...") and should be clarified. The labeling, but not the "Ask a doctor" warning, specifies frequent use as a reason to consult a physician. "Unprotected sex" should be defined throughout the warnings and labeling; does it mean sex without a condom (male or female?), or sex without any form of birth control? Also, since these products are labeled for vaginal use only, it may be more accurate to refer to "unprotected vaginal intercourse." As is proposed for the labeling, the warning should state "Ask a doctor or other health professional for your best birth control and methods to prevent STDs." Finally, it is unclear what the consumer is to do before she is able to consult a doctor: Avoid sexual intercourse? Use alternative methods of birth control?

6. Is a package insert the best way to provide additional information to consumers or should this information appear on the outer carton?
We recommend that the necessary information appear in both places in order to warn consumers most effectively. A woman's ability to choose the most appropriate contraceptive is compromised if she cannot review important information until after she has purchased the product. For this reason, the message proposed for inclusion in the product labeling regarding condom use ("Correct use of a latex condom with every sexual act will help reduce the risk of getting the AIDS virus (HIV) and other STDs") should appear on the carton as well.

7. Are the proposed statements for the package insert appropriate?
As noted in comments on Question 1, certain areas of the labeling require clarification: what is meant by "unprotected sex," should the labeling address frequent users, and what is a consumer to do before she consults a physician? The statement in the labeling "Studies have raised safety concerns..." should read "If you use these products more often than once a day and/or have ..."

Conclusion

The American College of Obstetricians and Gynecologists supports adding a warning to the labeling of vaginal contraceptive products containing N-9 regarding their lack of STD protection and their risk for increasing vaginal irritation with use more often than once a day. We recommend that additional research on vaginal microbicides focus on the effects of N-9 when used in treated male condoms or in conjunction with other barrier methods. We appreciate the opportunity to share our comments on this important issue.

Sincerely,

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