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News & Commentary

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Comment. This is an extremely large observational study that presents levels of breast cancer risk associated with ET/EPT that are similar to those reported by the WHI and as predicted in the Collaborative Group on Hormonal Factors in Breast Cancer study. [Lancet 1997] As mentioned by the above reviewers, it implicates an expanded number of ET/EPT products and routes of administration.

Acting as the devil's advocate, it should be emphasized that this is an observational study with large potential areas for error. The major weakness of this study is that it is a snapshot of hormone therapy use taken at the time of the women's entry into the study, which was at the time of their 3-year mammogram. No further information was gleaned from the women regarding subsequent changes in hormone therapy use, such as whether they terminated use or changed the dose or route. Also, the patient-provided data at entry showed a 96% agreement with the actual prescription written by their physician. The 4% variance, although it seems small, is of some concern given the narrow difference in relative risks and the large number of study participants. This is essentially a weakness of any observational study—even if the prescription is filled, there is inadequate evidence that it is actually taken. Finally, the authors report that current use of hormone therapy at baseline increased the risk of breast cancer, although the relative risk was not as large as for disease incidence. They were not able to come up with reliable estimates of mortality attributable to breast cancer.

In conclusion, the Million Women Study can be accepted only as an observational study providing confirmation of a small increase in the

absolute risk for breast cancer in women on hormone therapy. The suggestion that these results apply to products beyond those tested in the WHI supports the NAMS 2002 Advisory Panel on Postmenopausal Hormone Therapy statement that although it is not possible to make general conclusions about all members of the estrogen and progestogen families, "an improved benefit-risk profile of other EPT agents cannot be assumed."

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Comment. The 1,084,110 participants (mean age 55.9 years) in this ambitious, prospective cohort study represent a quarter of the population of British women aged 50 to 64 years. The results are in harmony with the findings from the Women's Health Initiative (mean age 63.3 years). The present study goes further in generalizing the risk of breast cancer with hormone use to other forms of estrogen and progestogen as well as to other regimens. It also predicts greater mortality associated with breast cancer that occurs in hormone users as opposed to nonusers. Many other interesting observations can be found in the paper, including an association of tibolone with breast cancer and a discussion of differences between the occurrence of breast and endometrial cancer according to hormone regimen. I highly recommend this thought-

provoking article to all who are interested in the topic.

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These news items with expert commentary come from the First-to-Know® program offered to members of The North American Menopause Society (NAMS) by broadcast e-mail within days after publication of the studies. The items are then posted on the NAMS Web site (www.menopause.org). You can receive this valuable resource via e-mail by joining NAMS on the Web site or by calling 440/442-7550.

Description of the levels of evidence

Level I: Properly randomized, controlled trial.

Level II-1: Well-designed controlled trial but without randomization.

Level II-2: Well-designed cohort or case-control analytic study, preferably from more than one center or research group.

Level II-3: Multiple time series with or without the intervention (eg, cross-sectional and uncontrolled investigational studies); uncontrolled experiments with dramatic results could also be regarded as this type of evidence.

Level III: Opinions of respected authorities that are based on clinical experience; descriptive studies and case reports; reports from expert committees.