Conclusion: The incidence of nausea and edema occurring in these women during 25th to 42d months of medication is slightly less than that reported by the same group during the first 2 years. After 24 months, the incidence appears to stabilize. No patients in the study group dropped out for these reasons.

[Figures in percent]

	Class I	Class II	Class III	Classes IV–V
At 25 months	79.1 (5,208/6,583)	20.4 (1,343/6,583)	0.4 (26/6,583)	0.1 (6/6,583)
At 30 months	87.0 (2,090/2,402)	12.5 (300/2,402)	0.3 (8/2,402)	0.2 (4/2,402)
At 36 months	79.9 (1,094/1,369)	20.1 (275/1,369)	0	0
At 42 months	88 (88/100)	12 (12/100)	0	0

CERVICAL CYTOLOGY

At the time of enrollment, 6,583/11,711 women had recorded Pap smears.

Conclusion: The incidence of abnormal cytology was low in those women examined, and was not observed to increase with continued use (25–42 months).

THROMBOPHLEBITIS

This study was not designed to provide a comparative incidence of thrombophlebitis. Such an investigation would require more detailed follow-up examinations than were feasible in order to establish (1) a positive diagnosis of the condition, (2) the existence of recognized contributing causes, and (3) whether the patient was hospitalized. Satisfying these criteria is necessary to provide any meaningful comparison with the only reliable base-line incidence data for this disorder which is limited to idiopathic, hospitalized cases.

However, in an effort to provide a rough check on thromboembolic incidence, the women were asked, "Have you had thrombophlebitis?" at the time they were enrolled in the study (25th month of medication), and at each subsequent six-month visit. All those answering "yes" to this question are presently being followed-up to verify the diagnosis and hospitalization. When completed, this data will be analyzed electronically to provide a comparison with the exact population-at-risk at the time of *each* occurrence. The resulting incidence rate will then be released.

Of interest is the fact that 116 of the 11,711 women enrolled reported a prior history of thrombophlebitis; during the first two years of medication 8 reported a recurrence and continued uneventfully on the medication. A total of 58 occurrences (new and recurrent) were reported during the 29,124 woman-years of exposure, resulting in a crude incidence rate of 2 per 1,000 woman-years.

This crude rate based on unverified patient-response will undoubtedly be significantly reduced by verification with each woman's personal physician, and classification as hospitalized and non-hospitalized cases. The crude rate does, however, closely correspond to those comparable estimates of thrombophlebitis rates which include both hospitalized and non-hospitalized cases.*

Conclusion: The crude reported incidence of thrombophlebitis in women who have been taking an oral contraceptive (norethynodrel with mestranol) for two years or longer appears to approximate that in the untreated population.

* Health Insurance Plan of New York: 1.97 cases/1,000 enrollees, both sexes, age 15–44 years.
Morbidity Statistics in General Practice (England): 2.4 cases/1,000 non-pregnant women 15–44 years.