

ethnic groups in clinic and private practice to confirm the efficacy, safety and acceptability of this dosage form. At the end of the third quarter of 1963, 2,946 women had participated in Enovid-E trials for from one to forty-six cycles for a total of 33,416 cycles, as indicated in Tables I and II.

In no instance did pregnancy occur during cyclic administration^{1, 2, 4, 6, 15-24} of Enovid-E when taken as directed. A substantial number of these women were well into their third year of continuous cyclic medication with Enovid-E by the third quarter of 1963.

No serious manifestations of toxicity have been observed in any of these women, and normal or pretreatment physiologic

TABLE I. NUMBER OF WOMEN IN CLINICAL STUDIES TAKING ENOVID-E ACCORDING TO CYCLES OF USE

Clinical Groups	1st-5th	6th-11th	12th-17th	18th-23rd	24th-29th	30th-36th	Over
Wiseman ⁵ (Slough, England)	782	364	241	134	56	12	7
Binks ⁶ (Australia)	64	47	23	18	13	11	9
Wisdom ⁷ (London)	235	209	182	123	47	2	—
Chinnatamby ⁸ (Ceylon)	673	139	48	—	—	—	—
Satterthwaite ⁹ (Humacao, P.R.)	94	75	55	41	30	12	10
Comparative Study ¹⁰	198	164	112	78	31	—	—
Tyler ¹¹ (Los Angeles)	106	101	83	73	35	4	3
García and Pincus ^{12*} (San Juan, P.R.)	413	291	204	168	102	56	48
Flowers ¹³ (Chapel Hill, N.C.)	245	214	130	76	37	1	—
Burket ¹⁴ (Cincinnati, Ohio)	136	113	95	37	11	—	—
	2,946	1,717	1,173	748	362	98	77

The above tabulation shows that at least 362 women were in the third year or more of medication with Enovid-E.

*In this study 234 women received other dosage forms of Enovid before taking Enovid-E for from one to fifty-six cycles and 118 of this group were in their fourth year or more of medication with Enovid and Enovid-E at the end of April 1963.