

tion of material already submitted to FDA. This total, I am told, is at considerable variance with the number of deaths presented to the Advisory Committee by FDA.

4. The expressed desire of cooperation in carrying out the provisions of statutes and regulations should be accepted. It may be that enforcement will be easiest and most complete when the industry participates in policing itself. The medical personnel, recruitable by FDA and the medical departments of the manufacturers, will be improved by cooperation. This will permit the insinuation of scientific activity into the usual expending or receiving effects of the required "police activity."

Report of Deaths in Patients Taking Oral Contraceptives

A series of tables is appended to the report which lists the 110 deaths found in the files of the manufacturers. The tables also show a second listing of 65 deaths judged to be due to "idiopathic pulmonary embolus." These 65 deaths were from the total of 75 deaths caused by pulmonary embolization. For the following reasons 10 deaths were deleted:

- Rheumatic heart disease with valvulitis.
- Pancreatitis, hypertension, and renal disease.
- Thrombophlebitis in a previous pregnancy (three patients).
- Thrombophlebitis 3 months before therapy.
- Postoperative cholecystectomy.
- Postoperative hysterectomy (two patients).
- Postoperative radical mastectomy.

The collected data were abstracted onto 80-column punchcards which have been turned over to the Committee. The coding was performed in accordance with the attached code sheet. The IBM facilities of the Downstate Medical Center were employed to prepare the punchcards and to sort them for the preparation of the tabulations.

It is not possible to draw statistically valid con-

clusions regarding deaths in association with the taking of oral contraceptives. There is no reason to believe that these reported deaths are either a complete or an incomplete recording. They are more likely to be incomplete. The fact that most of the deaths occurred within the first 4 months of administration may reflect the larger number of patients taking the drug for this period of time as opposed to any later time period. It may reflect the fact that if a patient dies after taking a drug for a short period of time, it is more likely to be associated as a possible causative factor and reported. It may reflect the impression of the physician that the drug taken for a long period of time is not likely to have an etiologic relationship with a death. It may even be that a drug taken for a long period of time is ignored in getting a medical history.

Another unusual finding is that over 80 percent of the deaths were known to have been submitted to autopsy. This suggests that the association with the oral contraceptives may be an after thought suggested by the pathologic findings.

I surely agree with the position taken by the Committee members who feel that the present study has added little to our knowledge of the relationship of oral contraceptives to death in the population at risk. I have detailed the type of data needed to cast light on the presence or absence of such relationship.

I wish to thank the Advisory Committee for having given me the opportunity to carry out the investigation. The medical departments of the pharmaceutical manufacturers were forthright and cooperative and they made copies of reports available and in some cases prepared special tabulations and listings. The study could not have been completed or even begun without the approval and support of the Commissioner and his staff. It was a rewarding experience for your reporter.

Respectfully submitted,

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Oral Contraceptive—Death Report

1	1. Searle	2-3	Case number	12-13	Age at death
	2. Ortho	4-8	Manufacturers identification number	14	Race
	3. Upjohn				0—White
	4. Parke Davis	9	Month of death		1—Negro
	5. Mead Johnson	10-11	Year of death		2—Yellow
	6. Eli Lilly				3—Unknown
	7. Syntex				