

FOOD AND DRUG ADMINISTRATION

OBSTETRICS & GYNECOLOGY

ADVISORY COMMITTEE

FIFTH MEETING

JANUARY 16, 1967

CRYSTAL PLAZA BUILDING # 5

ROOM 1114

2211 JEFFERSON DAVIS HIGHWAY

ARLINGTON, VIRGINIA

AGENDA

Opening Remarks: Dr. Louis M. Hellman, Chairman  
Dr. Herbert L. Ley, Director, Bureau of Medicine

1. The Development of Food and Drug Laws and Regulations  
William W. Goodrich
  - A. Drugs
  - B. Devices
2. Present Use and New Developments in the Field of Intra-uterine  
Contraceptive Devices - Dr. Sheldon Segal
3. Quality Control of Intra-uterine Devices  
Dr. John Mc Shefferty  
Director of Pharmaceutical Development,  
Ortho Pharmaceutical Corporation
4. Results of Clinical Experience with Intra-uterine Devices  
Dr. Christopher Tietze
5. Follow-up On the Report On the Oral Contraceptives  
Dr. E. M. Ortiz
6. CONCLUSIONS AND RECOMMENDATIONS - Dr. Louis M. Hellman

Dr. Segal continued his presentation stating that there are various recommendations as to the time of insertion.

- 1) Relationship to the last parturition. There tends to be a higher expulsion rate if inserted immediately post delivery. After 72 hours post-partum there is better retention, while after 96 hours the expulsion rate is similar to that seen 6 weeks post-partum.
- 2) Relationship to the last menstruation. There seems to be no effect on uterine activity. The advantages of insertion immediately after the menses are:
  - a) Less dilation of the cervix is required.
  - b) There is less bleeding.
  - c) There is practically no chance of insertion in a gravid uterus.
- 3) Insertion after incomplete abortion. There seems to be no apparent increase in pelvic inflammatory disease if the device is inserted immediately post abortion.

Dr. Segal then discussed some side effects:

- 1) Bleeding is probably the most common side effect. When encountered immediately after insertion this is probably traumatic. There is no apparent explanation for the latent bleeding encountered.
- 2) Possibility of carcinogenic potential. The study currently under way in Barbados is up to 30,000 women years of use. This may yield some figures as to cervical dysplasia and possibly carcinoma. No study currently in progress will give figures regarding endometrial carcinoma.
- 3) Pelvic inflammatory disease. The Barbados study will provide this information.

#### CLINICAL ASPECTS:

Dr. Tietze mentioned the incidence of ectopic pregnancies with intrauterine devices. He stated that intrauterine devices prevent uterine and ectopic pregnancies but seem to be more efficacious in the prevention of uterine pregnancies than ectopic pregnancies. Dr. Tietze then presented a cumulative report of clinical data obtained under the auspices of the Population Council on users of intrauterine devices. The data presented is contained in the Seventh Progress Report of the Cooperative Statistical Program for the Evaluation of Intrauterine Devices dated September 30, 1966 and published elsewhere.

#### FOLLOW-UP ON ORAL CONTRACEPTIVE REPORT:

Dr. Ley then presented to the Committee a progress report on the ten recommendations contained in the report on oral contraceptives.

- I. The pilot study at Johns Hopkins is currently being expanded.

- II. The study at the University of Pittsburgh is to be terminated in March of 1967. Currently negotiations are in progress with Kaiser to expand the present contract to include study of oral contraceptives. Dr. Corfman stated that Dr. Segal and he will hold a meeting with members of the Kaiser Permanente group since the FDA apparently cannot fund a contract this fiscal year.
- III. Action taken same as #II.
- IV. Surveillance has been strengthened by (1) organizing a Task Force on Adverse Reactions under the direction of Dr. Ruskin (2) Soliciting requests from potential users of information so as to provide a better service (3) revision of the standard form 1639.
- V. FDA adverse reactions reporting program has been reviewed by a staff member from NIH.
- VI. At a meeting in October of 1966 this question was discussed with the manufacturers.
- VII. This function is more suited for NIH.
- VIII. Uniform labeling for oral contraceptives has been developed.
- IX. The time limitations have been discontinued under revised labeling.
- X. Applications for lower dosage compounds are being evaluated and their processing expedited.

Dr. Hellman appointed several Task Forces. They are to meet separately and furnish a report at the next meeting of the Committee, which will be held in May of 1966. The task forces will be constituted as follows:

1. Utility, Effectiveness and Safety
  - Dr. Tietze (c)
  - Dr. Sartwell
  - Dr. Kohl
2. Pelvic Inflammatory Disease
  - Dr. Scott (C)
  - Dr. Delfs
  - Dr. Masi
3. Histopathologic Effects
  - Dr. Hertz (C)
  - Dr. Carrington
  - Dr. Adamsons
4. Biological Action
  - Dr. Segal (C)
  - Dr. Corfman
5. Legislative Recommendations
  - Dr. Fuller (C)
  - Dr. Hellman
  - Dr. Eastman

Respectfully Submitted,  
E. M. Ortiz, M.D.  
Executive Secretary

