

The Drug Efficacy Study

1966-1969

[The following description was adapted from former Division of Medical Sciences Chairman R. Keith Cannan's history of the DES, published in the May 1968 NAS News Report]

The Drug Efficacy Study of the National Research Council's Division of Medical Sciences, which was tasked with evaluating the medical effectiveness of 3,000-4,000 drugs introduced between 1938 and 1962, was undertaken in April 1966 at the request of the Food & Drug Administration (FDA) and its then-new Commissioner James L. Goddard. The stimulus to the study was the 1962 Kefauver-Harris Amendment to the Food Drug & Cosmetic Act of 1938. The Amendment required that in addition to being proven to be safe, drugs must be shown to be effective in regard to the therapeutic claims made for them.

Guidelines for the conduct of the study were developed by a Policy Advisory Committee (PAC), the membership of which derived from academic and professional medicine and its major specialties, as well as from pharmacology, industry, and medical sociology. The actual work of drug evaluation was assigned to 180 specialists assembled into thirty panels covering the main categories of drug applications. The panels sought evidence of drug efficacy from four main sources: 1) Briefs submitted by the sponsor of the drug; 2) additional evidence directly solicited from the sponsor; 3) the files of the FDA; and 4) pertinent medical literature brought in by the panelists. Each claim for a drug was subjected to a separate evaluation leading to a decision as to the drug's efficacy, thus compelling the panels to make literally tens of thousands of such decisions. The panels then submitted the reports of their evaluations to the PAC, which in turn transmitted the reports to the FDA. A final report was issued by the DES in 1969; in addition, the panels' reports were published verbatim in the Federal Register after they were received by the FDA.

The records of the Drug Efficacy Study contain correspondence, reports, meeting minutes, press clippings, and other records documenting the activities of the DES. The papers originated in the offices of the DES and the Division of Medical Sciences. The size of the collection is approximately 3.5 linear feet, spanning the dates of 1963-1974 with the bulk of the collection dating from 1966-1969.

SERIES 1: DRUG EFFICACY STUDY (DES)

- Ad hoc Committee on Drug Efficacy Review: Meeting: 20 Apr 1966
- Agreement on Transmittal of New Drug Applications from FDA to NAS: 1966
- Aid to FDA in Implementing Recommendations: 1967-1968
- Beginning of Program: 1966
- Categorization of Drugs: Aug 1966
- Chronology: 1968
- Committees
 - Drug Categorization: 1966
- Conferences
 - On Guidelines
 - Assembly of Organizational Delegates: Proceedings: 1966
 - Report of Pharmaceutical Manufacturers Association (PMA): 1966
 - General: 1966

- For Drugs Ranked “Effective, But”: 5 Apr 1971
- Contract: 1966-1968
- Critiques of DES by Executive Secretaries: 1966-1968
- “Drug Efficacy Study of the NAS-NRC”
 - Smith R G [History of DES]: 1968
- End of Program: 1969
- FDA Interim Index to Evaluations Published in Federal Register for NAS-NRC Reviewed Prescription Drugs: 1974
- General Statements: 1967-1968
- Guidelines: 1966
 - General: 1966-1967
- Ineffective Drugs
 - Roster: 1969-1972
- Information Exchanges
 - Veterinary Drug Study: 1966-1968
- Information Releases by FDA: 1967-1968
- Invitations to Panel Members to Testify in Legal Proceedings
 - 1970
 - US Vitamin v Finch: 1969
 - Bentyl: 1968
- Meetings
 - Listings: 1966-1968
 - Staff Meetings: 1966-1968
- Memoranda
 - Executive Secretaries: 1966-1968
 - Panel Chairmen & Members: 1966-1968
 - Policy Advisory Committee (PAC): 1966-1968
- Organizing Committee: 1966
- Policies
 - Panel Members Testifying in Legal Proceedings: 1968
- Problems
 - Clarification of “Effective But” Ranking: 1971-1972
 - Meeting: 5 Apr 1971
 - Memorandum to Panel Chairmen: Jan 1971
 - Legal Status of Package Inserts [Modell Editorial “FDA Censorship”]: 1967
 - Therapeutic Equivalence of Generic Drugs: 1967-1969
- Progress Reports: 1966-1969
- Reporting Forms: 1966
- Retention of Records: 1967-1968
- Special Statements: 1967-1968
- Speeches on History & Work of DES by Cannan Gilman & Trexler: 1966-1968
- Structure: 1966-1969
- General: 1966-1974

SERIES 2: DES PANELS

- Administrative Procedures: 1966-1967

- Allergy
 - Meetings: 1966-1968
 - Membership: 1966
 - General: 1966-1969
- Anesthesia
 - Membership: 1966
 - General: 1966-1969
- Anti-Infectives
 - (I): 1966-1969
 - (II): Consultants: 1967
 - (II): General: 1966-1968
 - (III): Membership: 1966
 - (III): General: 1966-1969
 - (IV): 1966-1969
 - (V): 1966-1968
 - Membership: 1966-1967
- Antineoplastic
 - Membership: 1966
 - General: 1966-1968
- Anti-Parasitic
 - Membership: 1966
 - General: 1966-1968
- Cardiovascular
 - (I): Membership: 1966-1967
 - (I): General: 1966-1968
 - (II): Membership: 1967
 - (II): General: 1967-1969
- Chairmen
 - Rosters: 1966-1968
 - Meetings: First: 9 Sep 1966
- Consultants
 - Surgery: 1967
 - Urology: 1967-1969
- Dentistry
 - Membership: 1966
 - General: 1966-1969
- Dermatology
 - (I): Membership: 1966-1969
 - (I): General: 1966-1969
 - (II): Membership: 1966-1967
 - (II): General: 1966-1969
 - (III): Membership: 1967
 - (III): General: 1967-1969
- Diagnostic Agents
 - Membership: 1966
 - General: 1966-1968
- Endocrine Disturbances

- Membership: 1966
 - General: 1966-1968
- Executive Secretaries: 1966-1968
- Fluid & Electrolyte Imbalance
 - Membership: 1966-1967
 - General: 1966-1968
- Gastroenterology
 - (I): Membership: 1966
 - (I): General: 1966-1969
 - (II): Membership: 1966-1967
 - (II): General: 1966-1968
- Hematology
 - Membership: 1966
 - General: 1966-1969
- Interviews with Chairmen: 1967
- Meetings
 - Listings: 1966-1968
- Membership
 - Comments on DES Experience: 1969
 - Comments on Topics for Final Report: 1969
 - Excerpts: 1969
 - End of Term Letters: 1969
 - Nominations
 - By Panel Chairmen: 1966
 - Of Chairmen by Professional & Scientific Societies: 1966
 - Release of Names of Panel Members to Congress: 1968
 - General: 1966-1969
- Metabolic
 - Membership: 1966
 - General: 1966-1968
- Neurological
 - Membership: 1966-1967
 - General: 1966-1969
- Ophthalmology
 - Membership: 1966
 - General: 1966-1968
- Psychiatric
 - Consultants: 1967-1968
 - Membership: 1966-1967
 - General: 1966-1971
- Relief of Pain
 - Membership: 1966-1967
 - General: 1966-1968
- Reproductive System
 - Membership: 1966
 - General: 1966-1968
- Respiratory Disturbances

- Membership: 1966-1967
 - General: 1966-1968
- Rheumatic Diseases
 - Consultants: 1967
 - Membership: 1966
 - General: 1966-1969
- Surgery
 - Establishment: 1967
 - Membership: 1967-1968
 - General: 1967-1969
- General: 1966-1967

SERIES 3: DES POLICY ADVISORY COMMITTEE (PAC)

- Executive Committee
 - Briefing for Pharmaceutical Manufacturers Association on Status of Drug Efficacy Study: 31 Oct 1967
 - Meeting to Consider Classification of Anti-Infective Combination Drugs: 24 May 1968
 - Meeting with Representatives of FDA: 30 Nov 1967
- Meetings
 - Joint with Panel Chairmen: 17 May 1967
 - With FDA on Interpretation of DES Reports: 23 Jan 1969
 - Fourth: 6 Mar 1969
 - Third: 27 Mar 1968
 - Second: 12 Jan 1967
 - First [DES Meeting with Representatives of FDA]: 16 Dec 1966
- Membership
 - Appointments: 1966-1968
 - General: 1966-1967
- Resolution on Publications by Panel Members: 1968
- General: 1966-1968

SERIES 4: DES REPORTS

- Categorization of Final Reports: 1968
- Final: 1969
 - Distribution: 1969
 - Preparation: 1968-1969
 - Transmittal to Panel Members: 1969
 - General: 1968-1970
- Reevaluation of Drugs Ranked "Effective But"
 - Allergy: 1971
 - Anesthesia: 1971
 - Anti-Infective: 1971
 - Antineoplastic: 1971
 - Antiparasitic: 1971
 - Cardiovascular: 1971

- Dentistry: 1971
- Fluid & Electrolyte Imbalance: 1971
- Gastroenterological: 1971
- Hematologic: 1971
- Metabolic: 1971
- Neurological: 1971
- Ophthalmologic: 1971
- Relief of Pain: 1971
- Reproductive System: 1971
- Respiratory Disturbances: 1971
- Rheumatic Diseases: 1971
- Surgery: 1971
- General: 1971
- Release: 1967-1968
- Submissions
 - 1-6: 1968
 - 7-10: 1968
 - 11-15: 1968
 - 16-19: 1968
 - 20-25: 1968-1969
- Summaries: 1968
- White Papers
 - Anti-Infective Combinations: 1968-1969
- General: 1967-1968

SERIES 5: DES NAME FILES

- Cannan R K [Special Assistant to NAS President]: 1963-1968
- De Haen P [Drugs in Use Index Card System]: 1964-1967
- Gilman A [PAC Exec Com Member]: 1967-1968
- Goddard J L [FDA Commissioner]: 1966-1968
- Middleton W S [DES Chairman]
 - 1966-1968
 - Drug Research Board (DRB) Correspondence: 1963-1965
- Seevers M: 1967
- Shirkey H C [PAC Member]: 1966-1969
- Smith R G [FDA Liaison to NAS]: 1966-1968

SERIES 6: PRESS COVERAGE

- Press Coverage
 - News Articles: 1966-1969
 - General: 1967-1970