

Frances Oldham Kelsey Papers

A Finding Aid to the Collection in the
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Prepared by T. Michael Womack with the
assistance of Sherralyn McCoy



Manuscript Division, Library of
Congress

Washington, D.C.

2009

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Collection Summary

Title: Frances Oldham Kelsey Papers

Span Dates: 1913-1998

Bulk Dates: (bulk 1960-1990)

ID No.: MSS84006

Creator: Kelsey, Frances Oldham, 1914-

Extent: 12,000 items; 35 containers; 13.8 linear feet

Language: Collection material in English

Repository: Manuscript Division, Library of Congress, Washington, D.C.

Abstract: Pharmacologist and government official. Correspondence, memoranda, reports, press releases, proceedings, research files, speeches, statements, studies, articles, biographical material, draft of a book, and other papers documenting Kelsey's career, particularly as a researcher and regulator investigating new drugs at the United States Food and Drug Administration.

Selected Search Terms

The following terms have been used to index the description of this collection in the Library's online catalog. They are grouped by name of person or organization, by subject or location, and by occupation and listed alphabetically therein.

People

Geiling, E. M. K. (Eugene Maximilian Karl), 1891-

Kelsey, F. E. (Fremont Ellis)

Kelsey, Frances Oldham, 1914-

Organizations

American Medical Association.

United States. Food and Drug Administration.

United States. Food and Drug Administration. Division of Scientific Investigations.

Subjects

Civil service--Awards--United States.

Drugs--Law and legislation--United States.

Drugs--Testing--United States.

Medicine, Eclectic.

Pharmaceutical policy--United States.

Pharmacology.

Quacks and quackery.

Thalidomide.

Occupations

Pharmacologists.

Public officials.

Administrative Information

Provenance

The papers of Frances Oldham Kelsey, pharmacologist and government official, were transferred to the Library of Congress in 1997 by the Food and Drug Administration under the instructions of Kelsey.

Processing History

The papers of Frances Oldham Kelsey were arranged and described in 1998. The register was revised in 2009.

Transfers

Sound recordings have been transferred to the Motion Picture, Broadcasting, and Recorded Sound Division where they are identified as part of the Frances Oldham Kelsey Papers.

Copyright Status

The status of copyright in the unpublished writings of Frances Oldham Kelsey is governed by the Copyright Law of the United States (Title 17, U.S.C.).

Access and Restrictions

Restrictions apply governing the use, photoduplication, or publication of items in this collection. Consult reference staff in the Manuscript Division for information concerning these restrictions. In addition, many collections are stored off-site and advance notice is needed to retrieve these items for research use.

Preferred Citation

Researchers wishing to cite this collection should include the following information: Container number, Frances Oldham Kelsey Papers, Manuscript Division, Library of Congress, Washington, D.C.

Biographical Note

<i>Date</i>	<i>Event</i>
1914, July 24	Born, Cobble Hill, Vancouver Island, British Columbia, Canada
1934	B.Sc., McGill University, Montreal, Quebec, Canada
1935	M.Sc., McGill University, Montreal, Quebec, Canada
1938	Ph.D., University of Chicago, Chicago, Ill.
1938-1950	Instructor and assistant professor of pharmacology, University of Chicago, Chicago, Ill.
1943	Married Fremont Ellis Kelsey
1950	M.D., University of Chicago, Chicago, Ill.
1950-1952	Editorial associate, American Medical Association, Chicago, Ill.
1953-1954	Intern, Sacred Heart Hospital, Yankton, S.D.
1954-1957	Associate professor of pharmacology, University of South Dakota, Vermillion, S.D.
1956	Became United States citizen
1957-1960	General practitioner, Vermillion, S.D.

1960	Published with F. E. Kelsey and E. M. K. Geiling <i>Essentials of Pharmacology</i> . Philadelphia: Lippincott
1960-1963	Medical officer, Bureau of Medicine, United States Food and Drug Administration
1962	Recipient, President's Award for Distinguished Federal Civilian Service for refusal to approve commercial distribution of thalidomide in the United States
1963-1966	Medical officer, Investigational Drug Branch, Division of New Drugs, Bureau of Medicine, United States Food and Drug Administration
1966-1967	Director, Division of Oncology and Radiopharmaceutical Drug Products, Office of New Drugs, Bureau of Medicine, United States Food and Drug Administration
1967-1968	Assistant to the director for Scientific Investigations, Bureau of Medicine, United States Food and Drug Administration
1968-1971	Director, Division of Scientific Investigations, Office of Medical Support, Bureau of Medicine, United States Food and Drug Administration
1971-1977	Director, Scientific Investigations Staff, Office of Scientific Evaluation, Bureau of Drugs, United States Food and Drug Administration
1977-1982	Director, Division of Scientific Investigations, Office of Scientific Evaluation, Bureau of Drugs, United States Food and Drug Administration
1982-1987	Director, Division of Scientific Investigations, Office of Compliance, Center for Drugs and Biologics, United States Food and Drug Administration
1987-1995	Director, Division of Scientific Investigations, Office of Compliance, Center for Drug Evaluation and Research, United States Food and Drug Administration
1995-	Deputy for Scientific and Medical Affairs, United States Food and Drug Administration
2005	Retired from United States Food and Drug Administration

Scope and Content Note

The papers of Frances Oldham Kelsey (1914-) span the years 1913-1998, with the bulk of the items concentrated in the period between 1960 and 1990. The collection includes Kelsey's files created during her work as a pharmacologist and public official and consists of three series: [Office File](#), [Speeches and Writings File](#), and [Research File](#). Included in the papers are biographical material, correspondence, memoranda, speeches, editorials, background information and chapter drafts for a book, reports and statements, studies, press releases, newspaper and magazine clippings, reprints of articles, proceedings of hearings, research files, and other material pertaining to Kelsey's career as a researcher and regulator of investigational new drugs at the United States Food and Drug Administration (FDA).

The [Office File](#) consists of general correspondence and other material of an administrative nature documenting Kelsey's activities at the FDA primarily during the 1960s. The file of biographical material in particular contains information regarding Kelsey's receipt of the President's Award for Distinguished Federal Civilian Service in 1962 for her refusal to approve the commercial distribution of thalidomide in the United States. Following the thalidomide controversy, Kelsey was much sought after as a public speaker. Correspondence regarding invitations to speak documents her numerous engagements. Kelsey's work as an investigator is reflected by her office memoranda and by memoranda for the record which summarize her participation in conferences, interviews, telephone conversations, and other interactions. Detailed trip reports chronicle her participation in national and international conferences on pharmacology and related fields.

The historical file in the series consists of photocopies of memoranda written between 1994 and 1997 by Kelsey during the process of transferring her files to John Swann, historian at the FDA, where the collection was originally housed. Scattered throughout the papers attached to the respective item or items described, the original memoranda range in length from a sentence to three pages and describe single items as well as whole batches of material. By bringing the photocopies of the memoranda together into one location, the historical file constitutes a collection of Kelsey's reflections on her long career at the FDA. It provides valuable information on current scientific research and development, the discovery of new drugs and therapies and their effects, prominent individuals in the field, controversies within the pharmaceutical industry as well as the FDA, and day-to-day issues encountered at the workplace.

The [Speeches and Writings File](#) consists primarily of interviews, speeches, background information and chapter drafts for a book, editorials, and articles by others. Kelsey's activity as a public speaker over a thirty-year period is chronicled in the speeches file. During the early 1960s, she frequently spoke on the drug thalidomide. Other topics include promising new cures for diseases, quack remedies, and the tension between the desire of pharmaceutical companies to release new drugs on the market as quickly as possible and the regulatory mechanism of the FDA in demanding stringent drug testing. *Essentials of Pharmacology*, coauthored with E. M. K. Geiling and F. E. Kelsey, her husband, is represented by numerous folders of background information and drafts of chapters eight and nine. The editorials file consists primarily of brief scientific articles written by Kelsey while an editorial associate with the American Medical Association in Chicago during the early 1950s.

The [Research File](#) constitutes the largest section of material in the collection. Many of the files reflect Kelsey's research on various new drugs undergoing the regulatory process for FDA approval, such as Avazyme, Bamfolin, Daroil, Fluorouracil, Librium, Parotin, Ritalin, Triparanol, and Vesprin. Kelsey's participation on numerous committees is also documented. The computerization of scientific information during the early 1960s is reflected in the files on the National Library of Medicine and Arthur D. Little, Inc., regarding its proposal to establish an integrated agency-wide scientific information system. The material on DES (diethylstilbestrol), DMSO (dimethyl sulfoxide), and thalidomide is quite extensive and reflects the considerable attention given these controversial drugs by Kelsey. The subject of quackery appears throughout the Research File. Controversies in the field of new drug research are reflected in the files on Emanuel Revici concerning selenium diethyl dithiocarbonate (SDD) as a treatment for cancer, on William K. Summers's promotion of tetrahydroaminoacridine (THA) (Tacrine) as a treatment for Alzheimer's disease, and on Henry Turkel's request for approval of "U" series drugs as a treatment for cancer.

Folders under the heading investigational new drugs (INDs) relate to congressional legislation primarily resulting from Senator Estes Kefauver's investigations in the early 1960s. Files on congressional hearings feature the involvement of various congressional committees in reviewing and overseeing the Food and Drug Administration in its capacity as guarantor of the purity and efficacy of the nation's drugs. These files reflect the growing change in public attitude regarding the ethics of drug testing on selected sections of the population who often had little or no control over their involvement in new drug trials which could frequently prove life-threatening. Subject

studies in vulnerable populations constitute a large section of material in the series. The testee categories include fetuses, infants, children, geriatrics, prisoners, and women of childbearing potential. The Kelsey Papers also contain numerous reports documenting studies and research which had significant effects upon the drug regulatory process in the United States during the second half of the twentieth century

Arrangement of the Papers

This collection is arranged in three series:

- [Office File, 1960-1997](#)
- [Speeches and Writings File, 1913-1993](#)
- [Research File, 1917-1998](#)

Description of Series

<i>Container</i>	<i>Series</i>
BOX 1-4	<u>Office File, 1960-1997</u> Biographical material, correspondence, memoranda, a file of memoranda for the record describing portions of the collection, and trip reports. Arranged alphabetically by type of material and thereunder chronologically.
BOX 4-10	<u>Speeches and Writings File, 1913-1993</u> Interviews, speeches, background information, drafts of a book, editorials, and miscellaneous writings by Kelsey and others. Arranged alphabetically by type of material and thereunder chronologically.
BOX 11-35	<u>Research File, 1917-1998</u> Correspondence, memoranda, reports, statements, studies, proposals, reviews, guidelines, reprints of articles, newspaper and magazine clippings, press releases, testimonies, minutes, and printed matter. Arranged alphabetically by subject, name of individual or organization, or type of material and thereunder chronologically.

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