

## Appendix

### Chronology of Court battles, 1970-1984

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| 1970 | November   | Committee on the Care of Diabetic (CCD) formed   |
| 1971 | June       | FDA outlines labeling changes for sulfonylureas (Food and Drug Admin, 1971)  |
| 1971 | October 7  | CCD petitions FDA commissioner to rescind proposed label change  |
| 1972 | May        | FDA reaffirms position on proposed labeling change (Food and Drug, Admin 1972)   |
| 1972 | June 5     | FDA commissioner denies CCD 7 October 1971 request to rescind proposed label change  |
| 1972 | July 13    | CCD requests evidentiary hearing before FDA commissioner on proposed labeling changes (Food and Drug Admin 1975)   |
| 1972 | August 3   | Commissioner of FDA denies 13 July 1972 CCD request for evidentiary hearing (US Court of Appeals 1973)   |
| 1972 | August 11  | CCD argues to have the FDA enjoined from implementing labeling change before the United States District Court for the District of Massachusetts (US Court of Appeals 1973)                                       |
| 1972 | August 30  | Request to have the FDA enjoined from making labeling change denied by Judge Campbell of the United States District Court for the District of Massachusetts (Food and Drug Admin 1975, US Court of Appeals 1973) |
| 1972 | October 17 | Second motion for injunction against label change filed by CCD in the United States District Court for the District of Massachusetts (US Court of Appeals 1973)  |
| 1972 | November 3 | Temporary injunction order granted by Judge Murray of the United States District Court for the District of Massachusetts (US Court of Appeals 1973)  |
| 1972 | November 7 | Preliminary injunction against proposed label change granted by United States District Court for the District of Massachusetts (Food and Drug Admin 1975)  |
| 1973 | July 31    | Preliminary injunction vacated by Judge Coffin of the United States Court of Appeals for the First Circuit. Case sent back to FDA for further deliberations (Food and Drug Admin 1975, US Court of Appeals 1973) |

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| 1973 | October      | FDA hearing on labeling of oral agents (Food and Drug Admin 1975)   |
| 1974 | February     | FDA circulates proposed labeling revision (Food and Drug Admin 1975)  |
| 1974 | March-April  | FDA holds meeting on proposed label change, then postpones action on change until report of Biometrics Committee (Food and Drug Admin 1975)   |
| 1974 | Sept 18-20   | Testimony taken concerning use of oral hypoglycemic agents before the United States Senate Select Committee on Small Business, Monopoly Subcommittee (US Senate Select Comm 1974)   |
| 1975 | January 31   | Additional testimony concerning use of oral hypoglycemic agents before the United States Senate Select Committee on Small Business, Monopoly Subcommittee (US Senate Select Comm 1975)  |
| 1975 | July 9, 10   | Additional testimony concerning use of oral hypoglycemic agents before the United States Senate Select Committee on Small Business, Monopoly Subcommittee (US Senate Select Comm 1975)  |
| 1975 | September 30 | CCD files suit against David Mathews, Secretary of Health, Education, and Welfare, et al., for access to UGDP raw data under the Freedom of Information Act (FOIA) in the United States District Court for the District of Columbia (US District Court NY 1975) |
| 1975 | October 14   | Ciba-Geigy files suit against David Mathews, Secretary of Health, Education, and Welfare, et al., for access to UGDP raw data under the FOIA in the United States District Court for the Southern District of New York (US District Court NY 1975)              |
| 1975 | December     | FDA announces intent to audit UGDP results  |
| 1976 | February 5   | United States District Court for the District of Columbia rules UGDP raw data not subject to FOIA (US District Court 1976)  |
| 1976 | February 25  | CCD files appeal of February 5 decision in United States Court of Appeals for the District of Columbia Circuit (US Supreme Court 1978)  |
| 1976 | October      | FDA Endocrinology and Metabolism Advisory Committee recommends removal of phenformin from market (Food and Drug Admin 1977a)  |

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| 1977 | March 8      | United States District Court for the Southern District of New York rejects Ciba-Geigy request for UGDP raw data (US District Court NY 1977)  |
| 1977 | April 22     | Health Research Group (HRG) of Washington, DC, petitions Secretary of HEW to suspend phenformin from market under imminent hazard provision of law (Food and Drug Admin 1977a)   |
| 1977 | May 6        | FDA begins formal proceedings to remove phenformin from market (Food and Drug Admin 1977a)   |
| 1977 | May 13       | FDA holds public hearing on petition of HRG (Food and Drug Admin 1977a)  |
| 1977 | July 25      | Secretary of HEW announces decision to suspend New Drug Applications (NDAs) for phenformin in 90 days (Food and Drug Admin 1977b)  |
| 1977 | August       | CCD requests that United States District Court for the District of Columbia issue an injunction against HEW order to suspend NDAs for phenformin†  |
| 1977 | September 20 | FDA audit report ( <a href="https://www.trialsmeinertsway.com/PDFs/UGDP/Doc_27_UGDP%20Audit%20September%202020%201977.pdf">trialsmeinertsway.com/PDFs/UGDP/Doc_27_UGDP%20Audit%20September%202020%201977.pdf</a> )                                       |
| 1977 | October 21   | CCD request to United States District Court for the District of Columbia for injunction against HEW order to suspend NDAs for phenformin denied†   |
| 1977 | October 23   | NDAs for phenformin suspended by Secretary of HEW under imminent hazard provision of law (Food and Drug Admin 1977c)   |
| 1978 | January      | Appeal of October 21, 1977 court ruling filed by the CCD in United States Court of Appeals for the District of Columbia Circuit  |
| 1978 | July 11      | Judges Leventhal and MacKinnon of the United States Court of Appeals for the District of Columbia Circuit rule that public does not have right to UGDP raw data under the FOIA. Judge Bazelon dissents (US Court of Appeals 1978, US Supreme Court 1978) |
| 1978 | July 25      | CCD petitions United States Court of Appeals for the District of Columbia Circuit for rehearing on July 11 ruling (US Supreme Court 1978)  |
| 1978 | October 17   | Petition for rehearing at the United States Court of Appeals for the District of Columbia Circuit denied (US Supreme Court 1978)   |
| 1978 | November 14  | Results of FDA audit of UGDP announced (Food and Drug Admin 1978)  |
| 1978 | November 15  | FDA Commissioner orders phenformin withdrawn from market (US Supreme Court 1980)   |

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| 1979 | January 15 | CCD petitions the United States Supreme Court for writ of certiorari to the United States Court of Appeals for the District of Columbia Circuit (US Supreme Court 1978) |
| 1979 | April 10   | Appeal of October 21, 1977 ruling denied†   |
| 1979 | May 14     | Writ of certiorari granted  |
| 1979 | October 31 | UGDP case of Forsham et al., versus Harris et al., argued before the United States Supreme Court (US Supreme Court 1980)  |
| 1980 | March 3    | United States Supreme Court holds that HEW need not produce UGDP raw data; 7 to 2 decision (US Supreme Court 1980)  |
| 1984 | March 16   | Revised label for sulfonylurea class of drugs released (Food and Drug Admin, 1984a, 1984b, 1984c)   |

†Personal communications with Robert F Bradley, Joslin Diabetes Center, Boston (1st chair of the CCD).