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CLOSED, TYPE-I

# U.S. District Court District of Columbia (Washington, DC) CIVIL DOCKET FOR CASE #: 1:96-cv-01650-JR

PUBLIC CITIZEN HEAL. v. FDA Assigned to: Judge James Robertson

Demand: \$0

Cause: 05:552 Freedom of Information Act

Date Filed: 07/16/1996 Date Terminated: 12/22/1997

Jury Demand: None

Nature of Suit: 895 Freedom of

Information Act

Jurisdiction: U.S. Government Defendant

#### **Plaintiff**

PUBLIC CITIZEN HEALTH RESEARCH GROUP represented by Lucinda A Sikes

PUBLIC CITIZEN LITIGATION

**GROUP** 

1600 20th Street, NW

Washington, DC 20009-1001

(202) 588–1000 LEAD ATTORNEY

ATTORNEY TO BE NOTICED

V.

#### **Defendant**

FOOD & DRUG ADMINISTRATION

represented by Suzanne Claire Nyland

U.S. ATTORNEY'S OFFICE Judiciary Center Building 555 Fourth Street, NW Washington, DC 20530

(202) 252–6751

Email: <a href="mailto:suzanne.c.nyland@usdoj.gov">suzanne.c.nyland@usdoj.gov</a>

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V.

**Intervenor Defendant** 

BRISTOL-MYERS SQUIBB COMPANY

represented by Michael Darnell Petty

KING & SPALDING LLP 1700 Pennsylvania Avenue, NW

Suite 200

Washington, DC 20006 (202) 626–5619

Fax: (805) 499–8011 Email: mpetty@amgen.com

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Date Filed	#	Docket Text
07/16/1996	1	COMPLAINT filed by plaintiff PUBLIC CITIZEN HEAL. (JMF) (Entered: 07/17/1996)
07/16/1996		SUMMONS (3) issued to federal party(s) federal defendant FDA, and non-parties: U.S. Attorney and U.S. Attorney General. (JMF) (Entered: 07/17/1996)
07/23/1996	2	ATTORNEY APPEARANCE for federal defendant FDA by Suzanne Claire Nyland (dbw) (Entered: 07/25/1996)
07/23/1996	3	RETURN OF SERVICE/AFFIDAVIT of summons and complaint executed on 7/19/96 upon federal defendant FDA (JMF) (Entered: 07/26/1996)
07/23/1996	4	RETURN OF SERVICE/AFFIDAVIT of summons and complaint executed upon U.S. Attorney General on 7/18/96 (JMF) Modified on 07/26/1996 (Entered: 07/26/1996)
07/23/1996	5	RETURN OF SERVICE/AFFIDAVIT of summons and complaint executed upon U.S. Attorney on 7/16/96 (JMF) Modified on 07/26/1996 (Entered: 07/26/1996)
08/15/1996	6	ANSWER TO COMPLAINT [1–1] by federal defendant FDA . (JMF) (Entered: 08/16/1996)
09/11/1996	7	MEET AND CONFER STATEMENT/REPORT PURSUANT TO L.R. 206(d) filed by plaintiff PUBLIC CITIZEN HEAL., federal defendant FDA . (JMF) (Entered: 09/12/1996)
09/13/1996	8	NOTICE OF FILING by plaintiff PUBLIC CITIZEN HEAL., federal defendant FDA of Rule 206(d) order (JMF) (Entered: 09/17/1996)
09/16/1996	9	ORDER by Judge James Robertson : dispositive motions due $10/11/96$ ; response to dispositive motions due $11/8/96$ ; reply to dispositive motions due $12/6/96$ ; cross motions due $11/8/96$ ; response to cross motions due $12/6/96$ ; reply to cross motions due $1/2/97$ ; , and motion hearing set for $9:30\ 1/27/97$ ; (N) (jeb) (Entered: $09/17/1996$ )
09/20/1996	10	MOTION filed for BRISTOL–MYERS SQUIBB to intervene as party defendant EXHIBIT (Answer) (jeb) (Entered: 09/24/1996)
09/24/1996	11	ORDER by Judge James Robertson: granting motion for BRISTOL-MYERS SQUIBB to intervene as party defendant [10–1] (N) (jeb) (Entered: 09/24/1996)
09/24/1996	12	ANSWER TO COMPLAINT [1–1] by intervenor–defendant BRISTOL–MYERS SQUIBB . (jeb) (Entered: 09/24/1996)
10/11/1996	13	MOTION filed by federal defendant FDA for summary judgment; exhibits (1) (JMF) (Entered: 10/15/1996)
10/11/1996	14	MOTION filed by intervenor–defendant BRISTOL–MYERS SQUIBB for summary judgment (JMF) (Entered: 10/16/1996)
10/16/1996	15	ATTORNEY APPEARANCE for intervenor–defendant BRISTOL–MYERS SQUIBB by Terry S. Coleman (JMF) (Entered: 10/17/1996)
10/21/1996	16	NOTICE OF FILING by federal defendant FDA of exhibits and slip opinion as exhibits A and B referenced in the declaration of Carolann W. Hoten, which declaration was filed in support of the FDA's motion for summary judgment on October 11, 1996 (JMF) (Entered: 10/22/1996)
11/08/1996	17	CROSS MOTIONS by plaintiff PUBLIC CITIZEN HEAL. for summary judgment; exhibits (5) (JMF) (Entered: 11/12/1996)
11/08/1996	18	RESPONSE by plaintiff PUBLIC CITIZEN HEAL. to motion for summary judgment [13–1] by FDA and motion for summary judgment [14–1] by BRISTOL–MYERS SQUIBB; declarations (1) (JMF) (Entered: 11/12/1996)
11/15/1996	19	ATTORNEY APPEARANCE for intervenor–defendant BRISTOL–MYERS SQUIBB by Michael D. Petty (JMF) (Entered: 11/18/1996)
12/06/1996	20	MEMORANDUM by intervenor–defendant BRISTOL–MYERS SQUIBB in opposition to cross motion for summary judgment [17–1] by PUBLIC CITIZEN
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		HEAL. (adc) (Entered: 12/09/1996)
12/06/1996	22	MOTION (Consent) filed by federal defendant FDA to extend time to 12/9/96 within which to file its reply to plaintiff's opposition to defendant's motion for summary judgment and opposition to plaintiff's motion for summary judgment (adc) (Entered: 12/09/1996)
12/09/1996	21	REPLY by intervenor–defendant BRISTOL–MYERS SQUIBB to response to motion for summary judgment [18–1] by PUBLIC CITIZEN HEAL (adc) (Entered: 12/09/1996)
12/09/1996	23	RESPONSE by federal defendant FDA in opposition to cross motion for summary judgment [17–1] by PUBLIC CITIZEN HEAL (JMF) (Entered: 12/10/1996)
12/09/1996	24	REPLY by federal defendant FDA to plaintiff's opposition to motion for summary judgment [13–1] (JMF) (Entered: 12/10/1996)
12/10/1996	25	ORDER by Judge James Robertson: granting motion to extend time to 12/9/96 within which to file its reply to plaintiff's opposition to defendant's motion for summary judgment and opposition to plaintiff's motion for summary judgment [22–1] by FDA (N) (jeb) (Entered: 12/10/1996)
01/02/1997	26	REPLY MEMORANDUM by plaintiff PUBLIC CITIZEN HEAL. in support of cross motion for summary judgment [17–1]; exhibits (5) (JMF) (Entered: 01/06/1997)
01/23/1997	27	MOTION filed by federal defendant FDA for leave to file response to plaintiff's reply memorandum in support of plaintiff's cross-motion for summary judgment , and to reschedule oral argument on cross-motions for summary judgment (JMF) (Entered: 01/24/1997)
01/23/1997	28	MEMORANDUM by plaintiff PUBLIC CITIZEN HEAL. in opposition to motion for leave to file response to plaintiff's reply memorandum in support of plaintiff's cross—motion for summary judgment [27–1] and, motion to reschedule oral argument on cross—motions for summary judgment [27–2] by FDA (JMF) (Entered: 01/24/1997)
01/24/1997	29	ORDER by Judge James Robertson: denying motion for leave to file response to plaintiff's reply memorandum in support of plaintiff's cross—motion for summary judgment [27–1] and denying motion to reschedule oral argument on cross—motions for summary judgment [27–2] by FDA (N) (JMF) (Entered: 01/24/1997)
01/27/1997		MOTION HEARING before Judge James Robertson taken under advisement by PUBLIC CITIZEN HEAL. cross motion for summary judgment [17–1]; taken under advisement by FDA motion for summary judgment [13–1]; taken under advisement by BRISTOL–MYERS SQUIBB motion for summary judgment [14–1] Reporter: Vicky Stallsworth (jeb) (Entered: 01/27/1997)
01/31/1997	30	SUPPLEMENTAL MEMORANDUM by federal defendant FDA in response to plaintiff's reply to defendant's opposition to plaintiff's cross motion for summary judgment [17–1] by PUBLIC CITIZEN HEAL. (JMF) (Entered: 02/03/1997)
01/31/1997	31	NOTICE OF FILING by intervenor–defendant BRISTOL–MYERS SQUIBB of post–hearing memorandum (JMF) (Entered: 02/03/1997)
02/25/1997	32	MEMORANDUM OPINION by Judge James Robertson (N) (jeb) (Entered: 02/25/1997)
02/25/1997	33	ORDER by Judge James Robertson: directing the defendant FDA submit a copy of the protocol in question for in camera review due by 3/6/97; directing that the intervenor defendant Bristol Myers Squibb may file an additional memorandum ex parte under seal. (N) (jeb) Modified on 04/16/1997 (Entered: 02/25/1997)
03/06/1997	34	NOTICE OF FILING by federal defendant FDA of submission of protocol for in camera review (JMF) (Entered: 03/07/1997)
03/12/1997	35	NOTICE OF FILING by intervenor–defendant BRISTOL–MYERS SQUIBB of submission of Protocol and memorandum for in camera review for the postmarketing study of Glucophage (JMF) (Entered: 03/13/1997)

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03/18/1997	36	MEMORANDUM by Judge James Robertson accepting from parties any recommendations of candiates for appointment of expert, and any objections no later than 3/28/97 (dcn) (Entered: 03/19/1997)
03/28/1997	37	JOINT MOTION by plaintiff PUBLIC CITIZEN HEAL., intervenor–defendant BRISTOL–MYERS SQUIBB to extend time to 4/7/97 to file recommendations of candidates for court appointment of expert to assist the court in resolving the technical issue (JMF) (Entered: 04/01/1997)
04/03/1997	38	ORDER by Judge James Robertson: granting joint motion to extend time to 4/7/97 to file recommendations of candidates for court appointment of expert to assist the court in resolving the technical issue [37–1] by BRISTOL–MYERS SQUIBB, PUBLIC CITIZEN HEAL. (N) (jeb) (Entered: 04/03/1997)
04/07/1997	39	RECOMMENDATION by plaintiff PUBLIC CITIZEN HEAL. for appointment as expert; exhibits (2) (JMF) (Entered: 04/08/1997)
04/07/1997	40	RECOMMENDATION by intervenor–defendant BRISTOL–MYERS SQUIBB of candidates for court–appointed expert to assist the court's review of the postmarketing Final Protocol for Glucophage; exhibits (4) (JMF) Modified on 04/08/1997 (Entered: 04/08/1997)
05/23/1997	41	ORDER by Judge James Robertson: appointing Dr. Oscar Crofford and Dr. Stanley Edlavitch expert witnesses in this case, subject only to their consenting to the act; directing the experts' report(s) be filed with the Court due by 6/30/97 (N) (jeb) (Entered: 05/23/1997)
06/11/1997	42	ORDER by Judge James Robertson: setting forth procedures for providing copies of public record to Dr. Oscar Crawford and Dr. Stanley Edlavitch; directing the parties to submit protective order governing Dr. Crawford's and Dr. Edlavitch's handing of the BMS Final Protocol and memorandum (N) (jeb) (Entered: 06/11/1997)
06/27/1997	43	PROTECTIVE ORDER by Judge James Robertson; setting forth procedures for handling confidential material; allowing designated material to be filed under seal. (N) (gew) (Entered: 07/03/1997)
07/15/1997	44	NOTICE OF FILING by intervenor–defendant BRISTOL–MYERS SQUIBB of sealed documents (JMF) (Entered: 07/16/1997)
11/03/1997	45	ORDER by Judge James Robertson: granting cross motion for summary judgment [17–1] by PUBLIC CITIZEN HEAL., denying motion for summary judgment [13–1] by FDA, denying motion for summary judgment [14–1] by BRISTOL–MYERS SQUIBB; directing that the Final Protocol for the post–marketing study of Glucophage be released in its entirety to the plaintiffs. (N) (jeb) (Entered: 11/04/1997)
11/24/1997	46	MOTION filed by federal defendant FDA for order directing plaintiff to file declaration and other documents supporting its claim for attorneys' fees (JMF) (Entered: 11/25/1997)
11/26/1997	47	ORDER by Judge James Robertson: granting motion for order directing plaintiff to file declaration and other documents supporting its claim for attorneys' fees [46–1] by FDA; directing the defendant FDA to file its opposition to plaintiff's motion for attorney's fees no later than ten days after service of plaintiff's documentation supporting its request for fees. (N) (jeb) (Entered: 11/26/1997)
12/04/1997	48	APPLICATION by plaintiff PUBLIC CITIZEN HEAL. for attorney fees; exhibits (2) (JMF) (Entered: 12/05/1997)
12/22/1997	49	STIPULATED ORDER by Judge James Robertson: dismissing complaint [1–1] with prejudice; defendant FDA agrees to pay plaintiff the sum of Nineteen Thousand Seven Hundred and Fourteen Dollars and Fifty Cents (\$19,714.50) in full anad complete settlement and release of any and all claims plaintiff has or may have for attorneys' fees and costs incurred in this case, said payment to be made by check payable to Public Citizen Litigation Group; in exchange for the payment referenced, plaintiff agrees to release any and all claims against defendant FDA, the U.S. Dept. of Justice, and the U.S. for attorneys' fees and costs incurred by plaintiff in this matter; neither this agreement, nor the payment referenced, shall constitute an admission by defendant FDA, the U.S. Dept. of Justice, the U.S. or defendant—intervenor Bristol—Myers that

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		plaintiff "substantially prevailed" in this case, or that plaintiff is entitled to recover any attorneys' fees and costs in this case. (N) (mlp) (Entered: 12/22/1997)
01/21/1998	50	NOTICE OF FILING by intervenor–defendant BRISTOL–MYERS SQUIBB of memorandum sent requesting fee information from Dr. Stanley Edlavitch (JMF) (Entered: 01/22/1998)
03/16/1998	51	STIPULATION & ORDER by Judge James Robertson: regarding the payment of the fees of the court–appointed experts (N) (jeb) (Entered: 03/16/1998)