

**U.S. District Court
District of Columbia (Washington, DC)
CIVIL DOCKET FOR CASE #: 1:23-cv-03675-JMC**

INFORMED CONSENT ACTION NETWORK v. FOOD AND DRUG ADMINISTRATION et al
Assigned to: Judge Jia M. Cobb
Cause: 05:552 Freedom of Information Act

Date Filed: 12/10/2023
Jury Demand: None
Nature of Suit: 895 Freedom of Information Act
Jurisdiction: U.S. Government Defendant

Plaintiff

INFORMED CONSENT ACTION NETWORK

represented by **Richard Scott Pietrowski**
SIRI & GLIMSTAD LLP
4780 I-55 North
Suite 100
Jackson, MS 39211
601-274-4252
Fax: 646-417-5967
Email: spietrowski@sirillp.com
PRO HAC VICE
ATTORNEY TO BE NOTICED

Elizabeth Ann Brehm
SIRI & GLIMSTAD LLP
745 Fifth Avenue
Suite 500
New York, NY 10151
888-747-4529
Fax: 646-417-5967
Email: ebrehm@sirillp.com
ATTORNEY TO BE NOTICED

V.

Defendant

FOOD AND DRUG ADMINISTRATION

represented by **Dedra Seibel Curteman**
DOJ-USAO
US Attorney's Office, Civil Division
601 D Street, NW
Washington, DC 20530
(202) 252-2550
Email: dedra.curteman@usdoj.gov
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Defendant

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

represented by **Dedra Seibel Curteman**
(See above for address)
LEAD ATTORNEY
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
12/10/2023	<u>1</u>	COMPLAINT against All Defendants (Filing fee \$ 405 receipt number ADCDC-10547851) filed by INFORMED CONSENT ACTION NETWORK. (Attachments: # <u>1</u> Exhibit 1, # <u>2</u> Exhibit 2, # <u>3</u> Exhibit 3, # <u>4</u> Civil Cover Sheet, # <u>5</u> Summons to FDA, # <u>6</u> Summons to HHS, # <u>7</u> Summons to USAG, # <u>8</u> Summons to USAO)(Brehm, Elizabeth) (Entered: 12/10/2023)

12/10/2023	<u>2</u>	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by INFORMED CONSENT ACTION NETWORK (Brehm, Elizabeth) (Entered: 12/10/2023)
12/11/2023		Case Assigned to Judge Jia M. Cobb. (zrtw) (Entered: 12/11/2023)
12/11/2023	<u>3</u>	SUMMONS (4) Issued Electronically as to FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, U.S. Attorney and U.S. Attorney General (Attachments: # <u>1</u> Notice and Consent)(zrtw) (Entered: 12/11/2023)
12/16/2023	<u>4</u>	MOTION for Leave to Appear Pro Hac Vice :Attorney Name– R. Scott Pietrowski, Filing fee \$ 100, receipt number ADCDC–10564370. Fee Status: Fee Paid. by INFORMED CONSENT ACTION NETWORK. (Brehm, Elizabeth) (Entered: 12/16/2023)
12/19/2023		MINUTE ORDER granting <u>4</u> Motion for Leave to Appear Pro Hac Vice: Attorney R. Scott Pietrowski is hereby admitted pro hac vice to appear in this matter. Counsel should register for e-filing via PACER and file a notice of appearance pursuant to LCvR 83.6(a). Click for instructions. Signed by Judge Jia M. Cobb on December 19, 2023. (lcjmc2) (Entered: 12/19/2023)
12/19/2023	<u>5</u>	NOTICE of Appearance by Richard Scott Pietrowski on behalf of INFORMED CONSENT ACTION NETWORK (Pietrowski, Richard) (Entered: 12/19/2023)
12/20/2023	<u>6</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. FOOD AND DRUG ADMINISTRATION served on 12/18/2023 (Brehm, Elizabeth) (Entered: 12/20/2023)
12/20/2023	<u>7</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES served on 12/15/2023 (Brehm, Elizabeth) (Entered: 12/20/2023)
12/20/2023	<u>8</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 12/19/2023. (Brehm, Elizabeth) (Entered: 12/20/2023)
12/20/2023	<u>9</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 12/11/2023. Answer due for ALL FEDERAL DEFENDANTS by 1/10/2024. (Brehm, Elizabeth) (Entered: 12/20/2023)
01/03/2024	<u>10</u>	NOTICE of Appearance by Dedra Seibel Curteman on behalf of All Defendants (Curteman, Dedra) (Entered: 01/03/2024)
01/03/2024	<u>11</u>	Consent MOTION for Extension of Time to File Answer re <u>1</u> Complaint, by FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # <u>1</u> Text of Proposed Order)(Curteman, Dedra) (Entered: 01/03/2024)
01/04/2024		MINUTE ORDER granting <u>11</u> Motion for Extension: Having considered the motion, and for good cause shown, the Court hereby GRANTS the motion. It is further ORDERED that Defendant shall respond to the complaint in this action by February 9, 2024. Signed by Judge Jia M. Cobb on January 4, 2024. (lcjmc2) (Entered: 01/04/2024)
02/09/2024	<u>12</u>	ANSWER to Complaint by FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES.(Curteman, Dedra) (Entered: 02/09/2024)
02/12/2024		MINUTE ORDER: The Court ORDERS that the Parties confer and submit a joint proposed schedule for further proceedings, which shall include a proposed schedule for the processing and release of responsive records or for briefing dispositive motions, by February 26, 2024. Signed by Judge Jia M. Cobb on February 12, 2024. (lcjmc2) (Entered: 02/12/2024)
02/20/2024	<u>13</u>	MOTION to Stay by FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # <u>1</u> Declaration, # <u>2</u> Text of Proposed Order)(Curteman, Dedra) (Entered: 02/20/2024)

02/26/2024	<u>14</u>	Joint STATUS REPORT by FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Curteman, Dedra) (Entered: 02/26/2024)
03/05/2024	<u>15</u>	RESPONSE re <u>13</u> MOTION to Stay filed by INFORMED CONSENT ACTION NETWORK. (Attachments: # <u>1</u> Text of Proposed Order)(Pietrowski, Richard) (Entered: 03/05/2024)
03/12/2024	<u>16</u>	REPLY to opposition to motion re <u>13</u> MOTION to Stay filed by FOOD AND DRUG ADMINISTRATION, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES. (Attachments: # <u>1</u> Attachment A)(Curteman, Dedra) (Entered: 03/12/2024)
09/04/2024		<p>MINUTE ORDER: The Court ORDERS that <u>13</u> Defendants' Motion to Stay is GRANTED in part and DENIED in part: for the reasons stated below, this matter shall be stayed for approximately six months until and including March 4, 2025. It is further ORDERED that the parties shall file a joint status report on or before March 4, 2025, stating their positions on whether the stay should be lifted and, if so, proposing a schedule for further proceedings. If circumstances change while the case is stayed that warrant lifting the stay or otherwise affect the posture of this case, the parties may file a joint status report.</p> <p>FOIA provides that agencies shall make requested records "promptly available," 5 U.S.C. § 552(a)(3)(A), but "[i]f the Government can show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, the court may retain jurisdiction and allow the agency additional time to complete its review of the records," <i>id.</i> § 552(a)(6)(C)(i). An agency may obtain a stay of proceedings if it "is deluged with a volume of requests for information vastly in excess of that anticipated by Congress, when the existing resources are inadequate to deal with the volume of such requests within the time limits of subsection (6)(A), and when the agency can show that it 'is exercising due diligence' in processing the requests." <i>Open America v. Watergate Special Prosecution Force</i>, 547 F.2d 605, 616 (D.C. Cir. 1976). Here, the FDA has shown both exceptional circumstances and due diligence justifying an <i>Open America</i> stay.</p> <p>Turning first to exceptional circumstances: Plaintiff requests records from FDA's Center for Biologics Evaluation and Research ("CBER"). But CBER has been ordered by another court to produce "approximately 5.7 million pages of COVID-19 vaccine records in a compressed timeframe." <u>13</u> at 7-8; <i>see Pub. Health & Med. Pros. for Transparency v. FDA</i>, No. 21-CV-1058 (N.D. Tex.) ("<i>PHMPT I</i>"); <i>Pub. Health & Med. Pros. for Transparency v. FDA</i>, No. 22-CV-0915 (N.D. Tex.) ("<i>PHMPT II</i>"). "The unprecedented rate at which the PHMPT orders require the FDA to produce records is exceptional, and it is, if anything more overwhelming than the extraordinary increase in FOIA workloads that past decisions have found sufficient to warrant stays." <i>Child.'s Health Def. v. FDA</i>, No. 23-CV-220, 2024 WL 147851, at *3 (D.D.C. Jan. 12, 2024) (collecting cases).</p> <p>The FDA must also demonstrate due diligence. The agency states that it has "a multi-track process for handling FOIA requests... and requests in each queue are generally assigned to reviewers for processing on a first-in, first-out basis," and that it "has undertaken immediate and aggressive efforts to hire additional staff and contractors, seek funding, and reorganize its resources." <u>13</u> at 12-13. "Both the onboarding and reassignment of new staff, as well as the first-in, first-out multi-track system for processing requests have been found sufficient to establish due diligence in other cases... and are sufficient here." <i>Child.'s Health Def.</i>, 2024 WL 147851, at *3.</p> <p>Because the FDA has demonstrated both exceptional circumstances and due diligence, an <i>Open America</i> stay is warranted here. However, the Court is sensitive to Plaintiff's concern that staying this case for 18 months, as FDA requests, could "render[] the [requested] data completely stale by the time it ever sees the light of day." <u>15</u> at 2. The Court also notes that some other courts in this district faced with similar requests for an 18-month stay have instead imposed – at least initially – a six-month stay. <i>See Child.'s Health Def.</i>, 2024 WL 147851, at *5 (staying case for six months); <i>Child.'s Health Def. v. Ctrs. for Disease Control & Prevention</i>, No. 23-CV-00431, 2024 WL 3521593, at *6 (D.D.C. July 24, 2024) (staying case for six months); May 24, 2024</p>

Minute Entry, *Informed Consent Action Network v. FDA*, No. 23-CV-219 (staying case for six months). *But see* Oct. 13, 2023 Order, *Wright v. Dept of Health & Hum. Servs.*, No. 22-CV-1378 (granting unopposed motion for 18-month stay); Dec. 13, 2023 Minute Order, *Child.'s Health Def. v. FDA*, No. 23-CV-2316 (staying case for 18 months). The Court therefore finds it appropriate to impose a six-month stay at this time. Signed by Judge Jia M. Cobb on September 4, 2024. (lcjmc2) Modified docket text on 9/4/2024 (zed). (Entered: 09/04/2024)