

**U.S. District Court**  
**District of Columbia (Washington, DC)**  
**CIVIL DOCKET FOR CASE #: 1:23-cv-02316-LLA**

CHILDREN'S HEALTH DEFENSE v. FOOD AND DRUG  
ADMINISTRATION  
Assigned to: Judge Loren L. AliKhan  
Cause: 05:552 Freedom of Information Act

Date Filed: 08/10/2023  
Jury Demand: None  
Nature of Suit: 895 Freedom of  
Information Act  
Jurisdiction: U.S. Government Defendant

**Plaintiff****CHILDREN'S HEALTH DEFENSE**

represented by **Risa Evans**  
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V.

**Defendant****FOOD AND DRUG  
ADMINISTRATION**

represented by **Brian J. Levy**  
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Date Filed	#	Docket Text
08/10/2023	<u>1</u>	COMPLAINT against FOOD AND DRUG ADMINISTRATION ( Filing fee \$ 402 receipt number BDCDC-10266256) filed by CHILDREN'S HEALTH DEFENSE. (Attachments: # <u>1</u> Exhibit, # <u>2</u> Summons Request for Summons to Issue, # <u>3</u> Summons Request for Summons to Issue as to US Attorney's Office, # <u>4</u> Summons Request for Summons to Issue, # <u>5</u> Civil Cover Sheet)(Flores, Ray) (Entered: 08/10/2023)
08/10/2023	<u>2</u>	ENTERED IN ERROR.....LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by CHILDREN'S HEALTH DEFENSE (Flores, Ray) Modified on 8/16/2023 (zljn). (Entered: 08/10/2023)
08/10/2023		NOTICE OF ERROR re <u>1</u> Complaint; emailed to raylflores2@msn.com, cc'd 0 associated attorneys -- The PDF file you docketed contained errors: 1. Noncompliance with LCvR 5.1(c). Please file an errata correcting the initiating pleading to include the name & full residence address of each party using the event Errata., 2. Missing 26.1 Disclosure(s). Please submit using the event LCvR 26.1 Certificate of Disclosure-Corporate Affiliations/Financial Interests., 3. You submitted a Certificate of disclosure of corporate affiliations and financial interests, but the

		document attached to the entry is a Civil Cover Sheet., 4. <b>COMPLIANCE DEADLINE is by close of business today. This case will not proceed any further until all errors are satisfied.</b> (zljn, ) (Entered: 08/10/2023)
08/10/2023	<u>3</u>	LCvR 26.1 CERTIFICATE OF DISCLOSURE of Corporate Affiliations and Financial Interests by CHILDREN'S HEALTH DEFENSE (Flores, Ray) (Entered: 08/10/2023)
08/10/2023	<u>4</u>	ERRATA <i>Complaint</i> by CHILDREN'S HEALTH DEFENSE. (Flores, Ray) (Entered: 08/10/2023)
08/10/2023		Case Assigned to Judge Timothy J. Kelly. (zljn) (Entered: 08/10/2023)
08/10/2023	<u>5</u>	SUMMONS (3) Issued Electronically as to FOOD AND DRUG ADMINISTRATION, U.S. Attorney and U.S. Attorney General (Attachments: # <u>1</u> Notice and Consent)(zljn) (Entered: 08/10/2023)
08/17/2023	<u>6</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed on United States Attorney General. Date of Service Upon United States Attorney General 8.17.2023. (Flores, Ray) (Entered: 08/17/2023)
08/17/2023	<u>7</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed as to the United States Attorney. Date of Service Upon United States Attorney on 8/17/2023. Answer due for ALL FEDERAL DEFENDANTS by 9/16/2023. (Flores, Ray) (Entered: 08/17/2023)
08/17/2023	<u>8</u>	RETURN OF SERVICE/AFFIDAVIT of Summons and Complaint Executed. FOOD AND DRUG ADMINISTRATION served on 8/17/2023 (Flores, Ray) (Entered: 08/17/2023)
09/18/2023	<u>9</u>	NOTICE of Appearance by Brian J. Levy on behalf of FOOD AND DRUG ADMINISTRATION (Levy, Brian) (Entered: 09/18/2023)
09/18/2023	<u>10</u>	ANSWER to Complaint by FOOD AND DRUG ADMINISTRATION.(Levy, Brian) (Entered: 09/18/2023)
09/19/2023		MINUTE ORDER: Before the Court are a complaint and an answer. It is hereby ORDERED that the parties shall meet, confer, and file a joint proposed schedule for briefing by October 16, 2023. Signed by Judge Timothy J. Kelly on 9/19/2023. (lctjk1) (Entered: 09/19/2023)
10/12/2023	<u>11</u>	MOTION to Stay by FOOD AND DRUG ADMINISTRATION. (Attachments: # <u>1</u> Memorandum in Support, # <u>2</u> Declaration, # <u>3</u> Exhibit Attachment to Declaration, # <u>4</u> Text of Proposed Order)(Levy, Brian) (Entered: 10/12/2023)
10/16/2023	<u>12</u>	Joint STATUS REPORT <i>FILED</i> by CHILDREN'S HEALTH DEFENSE. (Flores, Ray) (Entered: 10/16/2023)
10/17/2023		MINUTE ORDER: Upon consideration of the parties' <u>12</u> Joint Status Report regarding Defendant's <u>11</u> Motion to Stay, it is hereby ORDERED that Plaintiff shall file any opposition by November 13, 2023, and Defendant shall file any reply by November 29, 2023. Signed by Judge Timothy J. Kelly on 10/17/2023. (lctjk1) (Entered: 10/17/2023)
11/13/2023	<u>13</u>	Memorandum in opposition to re <u>11</u> Motion to Stay filed by CHILDREN'S HEALTH DEFENSE. (Evans, Risa) (Entered: 11/13/2023)
11/29/2023	<u>14</u>	REPLY to opposition to motion re <u>11</u> MOTION to Stay filed by FOOD AND DRUG ADMINISTRATION. (Attachments: # <u>1</u> Exhibit, # <u>2</u> Declaration, # <u>3</u> Declaration)(Levy, Brian) (Entered: 11/29/2023)
12/13/2023		MINUTE ORDER granting the FDA's <u>11</u> motion for an 18-month stay of proceedings. 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). Accordingly, the District of Columbia Circuit has recognized that 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

		<p>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. The FDA was ordered by another court to produce 5.7 million pages of records at an unprecedented rate which, this month, picks up to 180,000 records per month. <i>See</i> ECF No. 11-2 &amp;para 26; <i>Pub. Health &amp; Med. Pros. for Transparency (PHMPT) v. FDA</i>, No. 21-cv-1058, ECF No. 35 (N.D. Tex.); <i>PHMPT v. FDA</i>, No. 22-cv-915, ECF Nos. 31, 38 (N.D. Tex.). Despite the agency's efforts to hire and train additional personnel to respond to the <i>PHMPT</i> requests, it has been unable to scale up its FOIA capabilities at the speed necessary to handle the volume of other requests, ECF No. 11-2 &amp;para&amp;para 24-25, 28-30, and "it is not the role of the judiciary to question how executive agencies request and allocate resources, absent some compelling evidence of purposeful conduct," <i>Democracy Forward Found. v. DOJ</i>, 354 F. Supp. 3d 55, 62 (D.D.C. 2018). The FDA has exercised due diligence in responding to Plaintiff's request, which, though mired behind several hundred other requests in the "complex requests" queue, will be resolved on a first-in, first-out basis. ECF No. 11-2 &amp;para&amp;para 11-12; ECF No. 14-2 &amp;para 11; <i>see Open America</i>, 547 F.2d at 613; <i>Appleton v. FDA</i>, 254 F. Supp. 2d 6, 10 (D.D.C. 2003) (concluding that "defendants have demonstrated good-faith efforts and due diligence in processing the plaintiff's request on a first-in, first-out basis"). Other courts to be confronted with the same question have come to the same conclusion. <i>Informed Consent Action Network v. FDA</i>, No. 23-cv-219 (RBW), ECF No. 27 (D.D.C. Nov. 11, 2023) (granting FDA an 18-month <i>Open America</i> stay in light of the expedited production schedule in the <i>PHMPT</i> litigations). And it bears note: any pending deadlines in this case will be vacated, but Plaintiff will not lose its place in the queue, and the FDA will continue to process requests in the order received. ECF No. 14-2 &amp;para 12. Accordingly, the <u>11</u> motion is GRANTED. It is further ORDERED that this case is STAYED until further order of the Court. It is further ORDERED that Defendant shall file a status report by June 13, 2024, updating the Court on the status of this case and any continued need for a stay of proceedings, and Plaintiff may file any response to that report by June 20, 2024. Signed by Judge Timothy J. Kelly on 12/13/2023. (lctjk1) (Entered: 12/13/2023)</p>
12/13/2023		Case Stayed. (zkh) (Entered: 12/13/2023)
12/14/2023		Case directly reassigned to Judge Loren L. AliKhan. Judge Timothy J. Kelly is no longer assigned to the case. (tj) (Entered: 12/14/2023)
04/17/2024	<u>15</u>	ENTERED IN ERROR.....Memorandum in opposition to re <u>11</u> Motion to Stay filed by CHILDREN'S HEALTH DEFENSE. (Flores, Ray) Modified on 4/17/2024, Counsel will refile. (mg). (Entered: 04/17/2024)
06/13/2024	<u>16</u>	ENTERED IN ERROR.....STATUS REPORT by FOOD AND DRUG ADMINISTRATION. (Attachments: # <u>1</u> Text of Proposed Order)(Levy, Brian) Modified on 6/13/2024, refiled at docket entry <u>17</u> (mg). (Entered: 06/13/2024)
06/13/2024	<u>17</u>	STATUS REPORT by FOOD AND DRUG ADMINISTRATION. (Attachments: # <u>1</u> Text of Proposed Order)(Levy, Brian) (Entered: 06/13/2024)
06/20/2024	<u>18</u>	RESPONSE re <u>17</u> Status Report filed by CHILDREN'S HEALTH DEFENSE. (Attachments: # <u>1</u> Text of Proposed Order Plaintiff's Proposed Order)(Evans, Risa) Modified to add link on 6/20/2024 (znmw). (Entered: 06/20/2024)
07/18/2024		<p>MINUTE ORDER: Upon consideration of Defendant's Status Report <u>17</u> and Plaintiff's Response <u>18</u>, it is hereby ORDERED that the current stay shall remain in place until further order of the court. Defendant continues to show exceptional circumstances exist and that the agency is exercising due diligence in responding to the request, 5 U.S.C. § 552(a)(6)(C)(i), because the original circumstances necessitating the stay have not changed substantially and Defendant has shown due diligence by hiring five additional full-time employees, ECF No. 17, at 2, <i>see Open Am. v. Watergate Special Prosecution Force</i>, 547 F.2d 605, 612-13, 616 (D.C. Cir. 1976).</p> <p>It is further ORDERED that Defendant shall file a status report by December 13, 2024, updating the court on the status of this case, and Plaintiff may file a response to that report by December 20, 2024. Signed by Judge Loren L. AliKhan on 07/18/2024.</p>

		(lc1a2) (Entered: 07/18/2024)
07/24/2024		Case Stayed. Set/Reset Deadlines/Hearings: Defendant's Status Report due by 12/13/2024. Response due by 12/20/2024. (zcdw) (Entered: 07/24/2024)