UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TREATMENT ACTION GROUP and GLOBAL HEALTH JUSTICE PARTNERSHIP, Plaintiff, v. FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendant.	No. 15-cv-976 (VAB)

RULING ON MOTION TO STAY, PARTIAL MOTION FOR SUMMARY JUDGMENT, AND CROSS-MOTION FOR PARTIAL SUMMARY JUDGMENT

Plaintiffs Treatment Action Group ("TAG") and the Global Health Justice Partnership ("GHJP") bring this action against The Food and Drug Administration ("FDA") and its parent agency, the Department of Health and Human Services ("HHS") under the Freedom of Information Act ("FOIA") 5 U.S.C. § 552 *et seq.*, seeking the production of clinical trial data and communications regarding clinical trial design and the FDA approval process relating to two Hepatitis C virus ("HCV") drugs, Sovaldi and Harvoni. ECF No. 1.

Defendants filed a motion to stay this action to allow Defendants 14 months to process Plaintiff's FOIA request in accordance with the FDA's typical first-in, first-out multi-track processing system. ECF No. 16. TAG and GHJP move for partial summary judgment regarding their entitlement to expedited processing under 5 U.S.C. § 552(a)(6)(E) and for the denial of the Defendants' motion to stay. ECF No. 19. Defendants have filed a cross-motion for summary judgment, arguing that the Plaintiffs are not entitled to expedited processing. ECF No. 37.

For the reasons stated herein, Defendants' motion to stay this action is **DENIED**. Plaintiffs' motion for summary judgment regarding their entitlement to expedited processing is also **DENIED** and Defendants' cross-motion for summary judgment on the expedited processing issue is **GRANTED**.

Nevertheless, given that Defendants have stated that the FDA is currently processing the Plaintiffs' FOIA request, consistent with the applicable law, the Court orders the FDA to immediately produce all responsive records that have been gathered so far and to report back to the Court by October 21, 2016 regarding responsive records that have yet to be produced and when the Plaintiffs could expect to receive any documents outstanding as of October 21.

I. STATEMENT OF FACTS

TAG is an independent AIDS research and policy think tank seeking better treatment options for HIV-related diseases. FOIA Request at 5, ECF No. 19-2. GHJP is a nonprofit initiative of Yale Law School and Yale School of Public Health dedicated to facilitating open science, community engagement, and public health. *Id.* The FDA is responsible for ensuring that drugs marketed to the public are safe and effective. Pl.'s Local Rule 56(a)(1) Statement ¶ 38, ECF No. 19-30.

The FDA approved Sovaldi and Harvoni after the drugs received Priority Review under the Breakthrough Therapy Designation Program. Pl.'s Local Rule 56(a)(1) Statement ¶ 55. Solvadi (sofosbuvir) and Harvoni (sofosburvir/ledipasvir) are drugs used in the treatment of HCV. FOIA Request at 1, ECF No. 19-2. The FDA approved Sovaldi in December 2013. *Id.* Harvoni was approved more recently, in October 2014. FDA, *FDA Approves First Combination Pill to Treat Hepatitis C*, (Oct. 10, 2014), http://www.fdagov/NewsEvents/Newsroom/PressAnnouncements/ucm418365.htm.

The FDA subsequently revised the warning labels for both drugs based on previously unknown interactions with the antiarrhythmia medication amiodarone. Pl.'s Local Rule 56(a)(1) Statement ¶ 58. An estimated 3.2 million people in the USA are infected with HCV. FOIA Request at 1, ECF No. 19-2. Both Sovaldi and Harvoni are expensive, with a typical 12-week course of Sovaldi costing $84,000 and a 12-week course of Harvoni costing $94,500. *Id.*

A. Plaintiff's FOIA Request

On December 17, 2015, TAG and GHJP submitted a FOIA request by letter to the FDA and HHS seeking records related to the FDA's approval of Sovaldi and Harvoni. Pl.'s Local Rule 56(a)(1) Statement ¶ 18. The eight categories of information requested included: all data submitted to the FDA as part of the New Drug Application ("NDA") for Sovaldi and Harvoni including but not limited to patient-level safety and efficacy data, all correspondence between the Defendants and the companies developing the drugs relating to any aspect of the FDA approval process, and any other raw clinical trial data regarding the drugs. *Id.* ¶¶ 19-20. Plaintiffs requested expedited processing under 5 U.S.C. § 552(a)(6)(E), a public interest fee waiver for duplication fees under 5 U.S.C. § 552(a)(4)(A)(iii), and a fee limitation under 5 U.S.C. § 552(a)(4)(A)(ii)(II). *Id.* ¶¶ 22-24.

On December 22, 2014, Sara Kotler, the Acting Director of the FDA's Division of Freedom of Information, denied Plaintiffs' request for expedited processing. Kotler Letter, ECF No. 19-4. Ms. Kotler's letter indicated that the Plaintiffs had "not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual " or "an urgency to inform the public concerning actual or alleged Federal Government Activity." *Id.* The letter did not inform Plaintiffs of when they could expect a response to their request, instead it stated that the FDA would "process [the] request in the order in which it was received." *Id.*

On January 26, 2015, Plaintiffs filed an administrative appeal of the denial of their request for expedited processing and what they allege to be the constructive denial of their request for the eight categories of records by letter to the Deputy Agency Chief Freedom of Information Officer in HHS's Office of the Assistant Secretary for Public Affairs. Pl.'s Local Rule 56(a)(1) Statement ¶¶ 28-29. Plaintiffs received a January 29, 2015 letter from HHS's Division of FOIA Services acknowledging receipt of the administrative appeal. *Id.* ¶¶ 30-31.

On February 19, 2015, Catherine Teti, the Executive Officer and Deputy Agency Chief FOIA Officer in the HHS's Office of the Assistant Secretary for Public Affairs, sent a letter to Plaintiffs affirming the denial of their request for expedited processing. Pl.'s Local Rule 56(a)(1) Statement ¶ 32. Ms. Teti's letter explained that Plaintiffs had failed to show a "compelling need" that justified expedited processing pursuant to 21 C.F.R. § 20.44(a), whether by showing that a "failure to obtain records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual" or that Plaintiffs were "person[s] primarily engaged in disseminating information" and that there was "a demonstrated urgency to inform the public concerning actual or alleged Federal Government activity." Teti Letter at 1-2, ECF No. 19-8. Ms. Teti's letter also explained that the Plaintiffs' FOIA requests had been placed in the "complex queue" of the FDA's Center for Drug Evaluation and Research, with an expected processing time of 18 to 24 months.[1] *Id.* at 3.

On April 1, 2015, Plaintiffs sent another letter to the Defendants, requesting the reconsideration of the denial of their Administrative Appeal. Pl.'s Local Rule 56(a)(1) Statement ¶ 35. Defendants did not respond to this request. *Id.* ¶ 36. On June 25, 2015, Plaintiffs filed their complaint in this case. ECF No. 1. Defendants' filed their motion for a stay on November

[1] Under this timeline, the Defendants expected to respond to the Plaintiffs' FOIA request sometime between August 2016 and February 2017.

12, 2015, requesting a 14-month stay to allow Defendants to process Plaintiffs' request in accordance with the FDA's first-in, first-out multi-track processing system.[2] ECF No. 16.

Plaintiffs moved for partial summary judgment regarding their entitlement to expedited processing on December 7, 2015. ECF No. 19. Defendants filed a cross-motion for partial summary judgment on January 29, 2016, arguing that Plaintiffs are not, in fact, entitled to expedited processing. ECF No. 37. Plaintiffs moved for leave to file supplemental materials on August 12, 2016. ECF No. 56. Defendants filed a response to this motion on August 28, 2016, and represent that Plaintiff's request is now at the top of the queue. ECF No. 61 at 3 n.5, ECF No. 61-1. Defendants represent that, because of the breadth of Plaintiffs' FOIA request and the time required to review and redact potentially relevant documents, the full response will now be provided to Plaintiffs by March 31, 2017.[3] Philips Decl. ¶¶ 7-10, ECF No. 61-1.

B. FDA FOIA Processing

The Division of Information and Disclosure Policy ("DIDP") within the FDA's Center for Drug Evaluation and Research ("CDER") is the branch of the FDA processing the Plaintiffs' FOIA request. Def.'s Motion for Stay at 2, ECF No. 16. Between 2012 and 2014, DIDP received the following numbers of requests each year: 2012 (2,364), 2013 (2,868), 2014 (3,017). Sager Decl. at 12, ECF No. 16-1. DIDP processed approximately 3,122 requests in 2014, 105 more than it received. *Id.* at 7. In relation to its motion to stay filed in November 2015, the Defendants indicated that DIDP received 2,522 FOIA requests between January 1, 2015 and September 30, 2015. *Id.* at 12. In that same period, DIDP processed 2,507 requests, only 115

[2] Under this timeline, the Defendants expected to respond to the Plaintiffs' FOIA request around January 12, 2017, within the range of the original estimate in Ms. Teti's letter. Oral argument for these motions occurred on September 9, 2016.

[3] Defendants represent that "at least 8,000 electronic files and 4,600 documents, which range in length from one page to 500 pages each" will need to be reviewed to complete a response to Plaintiffs' request. Philips Decl. ¶ 7, ECF No. 61-1.

less than it received. *Id.* at 7. As of September 30, 2015, DIDP had a backlog of 600 FOIA requests. *Id.* Between 2012 and 2014, DIDP's backlog has been at the following sizes: 2012 (777), 2013 (690), 2014 (585). *Id.* at 12. A comparison of the increase in DIDP FOIA requests between 2012 and 2014 and the decrease in DIDP's backlog is as follows. Between 2012 and 2014, DIDP received 28% more requests in 2014 than in 2012. *Id.* at 12. During this period, DIDP also reduced its backlog by 24%.[4] *See id.*

In addition to FOIA requests, DIDP also responds to document requests from Congress, the United States Government Accountability Office ("GAO"), and various other governmental agencies, including foreign, state, local, and other U.S. federal agencies. Sager Decl. at 7. Defendants report that these requests require the "attention of up to three DIDP employees," who are then unable to devote their time to FOIA requests. *Id.* at 8. The DIDP also faces additional burdens related to productions arising out of litigation. *Id.* at 8-9. It is also under additional information production obligations imposed by the Food and Drug Administration Amendments Act of 2006 ("FDAAA"). *Id.* at 9-10. Defendants do not offer any quantitative measures of the resources taken up by litigation-related or FDAAA-related obligations.

As for agency resources, DIDP had 18 full-time employees in 2002, 25 full-time employees in 2003, and it currently has 40 full-time employees and one additional full time contractor. Sager Decl. at 16. The FDA had 33 full-time employees and two full-time contractors in 2009. *See Buc v. Food & Drug Admin*, 762 F. Supp. 2d 62, 72 (D.D.C. 2011). DIDP has also implemented organizational changes intended to increase efficiency by creating new "non-supervisory team lead positions" to focus on "ways to improve production and increase the quality of work of the team." Sager Decl. at 17. Before these changes, each

[4] Defendants do not provide this figure, but it can be calculated based on the provided data.

supervisor reviewed the work of 10-15 people, but with the new team lead positions, one person manages the work of every five to six people. *Id.*

II. STANDARD

Where an agency denies a request or affirms a denial of a request for expedited processing under FOIA, the decision to deny such a request is "subject to judicial review . . . based on the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii). District courts have "jurisdiction to enjoin the agency from withholding agency records and to order the production of any agency records improperly withheld" and make such determinations de novo. 5 U.S.C. § 552(a)(4)(B); *see also Bloomberg, L.P. v. United States Food & Drug Admin.*, 500 F. Supp. 2d 371, 374 (S.D.N.Y. 2007) ("The Court reviews agency decisions, including those regarding expedited processing of FOIA requests, de novo.") While the burden is on the agency to sustain its action in cases involving the improper withholding of records under claimed FOIA exemptions, 5 U.S.C. § 552(a)(4)(B), the requestor has the burden to "demonstrate[] a compelling need" for expedited processing. 5 U.S.C. § 552(a)(6)(E)(i); *see also Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 122 (D.D.C. 2013) (explaining that "[t]he requestor bears the burden of proof" in expedited processing cases).

The Court will grant a motion for summary judgment if it determines that there is no genuine dispute of material fact and the movant is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). The moving party bears the burden of showing that no genuine dispute of material fact exists. *Carlton v. Mystic Transp., Inc.*, 202 F.3d 129, 133 (2d Cir. 2000). "A dispute regarding a material fact is genuine if the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Williams v. Utica Coll. Of Syracuse Univ.*, 453 F.3d 112, 116 (2d Cir. 2006) (quoting *Stuart v. Am. Cyanamic Co.*, 158 F.3d 622, 626 (2d Cir. 1998)).

The substantive law governing the case identifies which facts are material, and "only disputes over facts that might affect the outcome of the suit under the governing law will properly preclude the entry of summary judgment." *Boubolis v. Transp. Workers Union of Am.*, 442 F.3d 55, 59 (2d Cir. 2006) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986)). When reviewing the record on a motion for summary judgment, the Court must "assess the record in the light most favorable to the non-movant" and "draw all reasonable inferences in its favor." *Weinstock v. Columbia Univ.*, 224 F.3d 33, 41 (2d Cir. 2000).

III. DISCUSSION

As an initial matter, the Court notes that FOIA limits its review of "[a]gency action to deny or affirm denial of a request for expedited processing" to "the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii). Courts have, at times, considered evidence from outside the record that was before the agency when reviewing denials of expedited processing. *See Landmark Legal Found. v. E.P.A.*, 910 F. Supp. 2d 270, 277 (D.D.C. 2012) (finding that "FOIA does not limit a Court's equitable powers" to consider new justifications related to a proposed rule that plaintiff could not have raised before the agency because the rule was proposed only after plaintiff made initial FOIA request); *Bloomberg*, 500 F. Supp. 2d at 377-78 (considering article that was cited in defendant's brief but was not in the agency record when analyzing plaintiff's entitlement to expedited processing).[5] The statute makes clear, however, that the Court is not required to do so. As the Defendants also move for an *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir. 1976) stay,

[5] Plaintiffs, in their reply to Defendants' Response to Plaintiffs' Motion for Leave to File Supplemental Materials, also cite to *Elec. Frontier Found. v. Dep't of Justice*, 57 F. Supp. 3d 54 (D.D.C. 2014) and *Am. Civil Liberties Union v. U.S. Dep't of Homeland Sec.*, 810 F. Supp. 2d 267 (D.D.C. 2011), but these cases discuss situations where the agency proactively chose to reconsider initial denials of requests for expedited processing without court intervention, potentially allowing for expansion of the agency record after the agency's initial denial. ECF No. 62. This has not occurred here.

evidence from outside the agency record regarding "extraordinary need" may also be considered, because even if an agency has shown due diligence that warrants such a stay, extraordinary need may nonetheless justify the denial of the stay. *Bloomberg*, 500 F.Supp.2d at 376.

Because the Court **DENIES** Defendants' motion for stay, for the reasons outlined below, without reaching the question of whether "extraordinary need" exists that could justify the denial of an *Open America* stay, and because of the explicit limitations of the statute, the Court declines to consider evidence from outside of the record before Defendants at the time of their denial of Plaintiffs' request for expedited processing and their denial of Plaintiffs' administrative appeal. The record is therefore limited to the contents of the letters exchanged between Plaintiffs and Defendants beginning with the Plaintiffs' December 17, 2015 FOIA request and ending with Ms. Teti's letter, dated February 19, 2015, rejecting the Plaintiffs' administrative appeal of the denial of their request for expedited processing. Plaintiffs' motion for summary judgment with regards to their entitlement to expedited processing is **DENIED** and the Defendants' cross-motion for summary judgment is **GRANTED** as to the Plaintiffs' lack of entitlement to expedited processing.

A. Mootness

In light of Defendants' representation that Plaintiffs' FOIA request has reached the top of the queue and that CDER has already begun processing the request, there is a question of whether the pending motions in this case are now moot. For the reasons below, the Court finds that the motions are not moot.

Insofar as Plaintiffs' initial motion for summary judgment on the expedited processing issue merely requested that the Court "order FDA immediately to process Plaintiffs' request," the fact that CDER has begun searching for documents responsive to the request to prepare a

response could moot the motion. Pl.'s Br. at 3, ECF No. 19-1. Plaintiffs' reply brief, however, also requests that, in light of the entrance of Gilead Sciences to this case as an intervening party, ECF No. 39, the Court "order the immediate processing of a representative sample of the requested records, and direct the parties to agree upon a schedule to present the legal issues [regarding Defendants' and Gilead's objections to releasing certain requested records under the 'business confidentiality' exception] for prompt resolution by the Court." Pl.'s Reply Br. at 3, ECF No. 42. Because Plaintiffs remain unsatisfied with Defendants' proposed schedule of production and seek additional relief from the Court, in addition to an order that Defendants' immediately begin processing their FOIA requests, the motion for stay and the motions for summary judgment regarding expedited processing are not moot.[6]

The case law supports the conclusion that the motions in this case are not moot. Under FOIA, a district court "shall not have jurisdiction to review an agency denial of expedited processing . . . after the agency has provided a complete response to the request." 5 U.S.C. § 552(a)(6)(E)(iv). Even an agency's partial production of documents in response to a FOIA request for expedited processing does not, therefore, "negate the court's ability to review the agency's determination unless and until that response is 'complete,'" and until the agency's response is complete, the court retains the ability to review "the substantive merits of the

[6] Because the Court denies Plaintiffs' motion for expedited processing, there is no need to reach the issue of what Plaintiffs would be entitled to if the Court found that their requests warranted expedited processing. The Court notes, however, that, under FOIA, expedited processing likely does not require an agency to produce documents by a firm deadline. Courts have found that the time limits in FOIA are deadlines for agencies to provide letter responses giving notice to requestors of the agency's planned course of action, which is what Defendants did in a timely fashion in this case. *See Daily Caller v. U.S. Dep't of State*, 152 F. Supp. 3d 1, 10 (D.D.C. 2015) ("As an initial matter, the agency is plainly correct that FOIA does not require production of all responsive, non-exempt documents within twenty days of receiving a request."); *NAACP Legal Def. & Educ. Fund, Inc. v. U.S. Dep't of Hous. & Urban Dev.*, No. 07-CIV-3378 (GEL), 2007 WL 4233008, at *7 (S.D.N.Y. Nov. 30, 2007) ("An agency is not required to substantively respond to a FOIA request within ten days when a requester files an expedited request-all the agency must do in such a situation is decide whether to process the request 'as soon as practicable,' and provide notice of that decision to the requester within ten days.").

agency's disclosure." *NAACP Legal Def. & Educ. Fund, Inc. v. U.S. Dep't of Hous. & Urban Dev.*, No. 07-CV-3378 (GEL), 2007 WL 4233008, at *6 (S.D.N.Y. Nov. 30, 2007) (reviewing case where plaintiff requested expedited processing but parties then agreed to schedule for release of documents and continued to litigate issue of whether defendants properly withheld one portion of requested records under deliberative process privilege).

Many courts also recognize an "authority to impose concrete deadlines on agencies that delay the processing of requests meriting expedition." *Elec. Privacy Info. Ctr. v. Dep't of Justice*, 416 F. Supp. 2d 30, 38 (D.D.C. 2006). This precedent further suggests that a plaintiff's request for expedited processing cannot be moot until all records have been produced. As a general matter, FOIA also "imposes no limits on courts' equitable powers in enforcing its terms." *Payne Enterprises, Inc. v. United States*, 837 F.2d 486, 494 (D.C. Cir. 1988) (citing *Renegotiation Bd. v. Bannercraft Clothing Co.*, 415 U.S. 1, 19-20 (1974)). Furthermore, with the 1996 Electronic Freedom of Information Act Amendments that added the expedited processing provisions, FOIA "envisions the courts playing an important role in guaranteeing that agencies comply with its terms." *NAACP*, 2007 WL 4233008 at *7 (quoting *Elec. Privacy Info. Ctr.*, 416 F. Supp. 2d at 37).

B. Entitlement to Expedited Processing

FOIA provides that every agency "shall promulgate regulations . . . providing for expedited processing of requests for records" both "in cases in which the person requesting the records demonstrates a compelling need" and other cases determined by each agency. 5 U.S.C. § 552(a)(6)(E)(i). Responses to requests for expedited processing must typically be made within 10 days after such requests, and there must be "expeditious consideration of administrative appeals" of determinations regarding such requests. 5 U.S.C. § 552(a)(6)(E)(ii). The Court's

review of "[a]gency action to deny or affirm denial of a request for expedited processing" is limited to "the record before the agency at the time of the determination." 5 U.S.C. § 552(a)(6)(E)(iii).

Both FOIA and the FDA's regulations provide for expedited processing when the requester demonstrates a compelling need because either (1) "[a] failure to obtain requested records on an expedited basis could reasonably be expected to pose an imminent threat to the life or physical safety of an individual" or (2) "[w]ith respect to a request made by a person primarily engaged in disseminating information," there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 21 C.F.R. § 20.44(a); *see also* 5 U.S.C. § 552(a)(6)(E)(v). Based on the legislative history, the D.C. Circuit has held that "the specified categories for compelling need are intended to be narrowly applied." *Al-Fayed v. C.I.A.*, 254 F.3d 300, 310 (D.C. Cir. 2001) (discussing legislative history of the 1996 Electronic Freedom of Information Act Amendments that added the expedited processing provision to FOIA). Cases discussing FOIA expedited processing typically focus on the second type of compelling need, involving a request by a "person primarily engaged in disseminating information" when there is a demonstrated urgency to inform the public. *See Bloomberg, L.P.*, 500 F. Supp. 2d at 377 (analyzing plaintiff's request for expedited processing in context of need or urgency to inform the public); *see also Al-Fayed*, 254 F.3d at 309 ("Plaintiffs claim 'compelling need' only under the second branch.").

1. Imminent Threat to the Life or Safety of an Individual

Under FDA regulations, a FOIA request for expedited processing on the basis of an imminent threat to an individual's life or safety "must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or

other authorized representative." 21 C.F.R. § 20.44(b). The requestor also "must demonstrate a reasonable basis for concluding" that failure to obtain such records quickly "could reasonably be expected to pose a specific and identifiable imminent threat" to that individual's life or safety. 21 C.F.R. § 20.44(a).[7]

The parties cite no case law discussing requests for expedited processing on the basis of an imminent threat to an individual's life or safety. The Court has only been able to identify two arguably relevant cases, both of which discuss danger faced by one specific individual. *See Exner v. F.B.I.*, 443 F. Supp. 1349, 1353 (S.D. Cal. 1978), *aff'd sub nom. Exner v. Fed. Bureau of Investigation*, 612 F.2d 1202 (9th Cir. 1980) (discussing attorney's fees for plaintiff who made FOIA request from the FBI because she felt she was in "grave personal danger" after FBI file discussing her "alleged personal relationships with organized crime figures, two of whom had been murdered" was leaked); *Cleaver v. Kelley*, 427 F. Supp. 80, 81 (D.D.C. 1976) (finding that "exceptional need or urgency" justified placing plaintiff's request "ahead of all other requests received prior" because the FBI likely possessed information related to its "covert activities" against plaintiff and the Black Panther Party that would be relevant to plaintiff's defense of a murder case against him that "could mean his loss of freedom or life"). While these cases predate the FOIA provisions that provide for expedited processing, they give guidance regarding the types of threats to an individual's life or safety that could be relevant to the Court's analysis.

[7] Plaintiffs' brief argues that they "cannot be required to satisfy the additional requirements that FDA purports to impose by regulation," citing to *Al-Fayed*. Pl.'s Memo. of Law at 18, ECF No. 19-1. The cited portion of the case merely holds that agencies, such as the FDA, are not entitled to *Chevron* deference on their interpretations of FOIA. *Al-Fayed*, 254 F.3d at 307 ("Indeed, it is precisely because FOIA's terms apply government-wide that we generally decline to accord deference to agency interpretations of the statute, as we would otherwise do under *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984).") The absence of *Chevron* deference means only that the Court is free to interpret the underlying statute consistent with the general rules of statutory construction, rather than be bound by a "reasonable interpretation made by the administrator of an agency." *Chevron*, 467 U.S. at 844

In light of the FDA regulation and what little case law exists regarding the imminent threat to life or safety type of compelling need, the Court finds that the Plaintiffs are unable to show a sufficient basis for expedited processing on these grounds. According to the Plaintiff's own briefs, the threat to life or safety that, in their view, justifies a grant of expedited processing, involves the "[m]ore than 250,000 patients [that] may receive Sovaldi and Harvoni in 2015." Pl.'s Br. at 17. Plaintiffs describe a problem that could affect the general HCV-affected public. Thus, Plaintiffs can only potentially support a case for expedited processing on the grounds of urgent need to inform the public. Their briefs also do not contain any allegations regarding specific types of medical problems, whether side effects or drug interactions, caused or exacerbated by Sovaldi or Harvoni and that could result in harm to specific subsets of patients or be immediately solved by access to the requested information.[8] This absence further demonstrates that no reasonable jury could find that Plaintiffs can show the need for expedited processing on the grounds of imminent threat to the life or safety of an individual.

2. Need to Inform the Public

a. Primarily Engaged in the Dissemination of Information

To prevail in its request for expedited processing under the urgent need to inform the public type of compelling need, a plaintiff must first be a "person primarily engaged in disseminating information. 21 C.F.R. § 20.44(a); *see also* 5 U.S.C. § 552(a)(6)(E)(v). While courts regularly find that "reporters and members of the media qualify" as "persons primarily engaged in information dissemination," courts "must be cautious in deeming non-media

[8] To the contrary, a representative of one Plaintiff, GHJP, even told the Wall Street Journal that the Plaintiffs did not make the FOIA request at issue "because we think there's some horrible side effect lurking in the data" and that Plaintiffs acknowledged that "[m]aybe there's nothing new," they just believed "we have a right to see what's there." Def.'s Ex. 2 Att. 1, ECF No. 37-5. While this document is outside the agency record, it does add weight to this Court's conclusion regarding this point.

organizations" as being such persons because the legislative history dictates that compelling need must be narrowly construed. *Landmark,* 910 F. Supp. 2d at 275-76.

Courts generally only find that a plaintiff is primarily engaged in information dissemination if information dissemination is the primary activity of the organization, to the exclusion of other main activities. *Compare Landmark,* 910 F. Supp. 2d at 276 (concluding that plaintiff's claim that "among its primary activities is to disseminate to the public about the conduct of governmental agencies" in context of a mission also involving the investigation and litigation of government wrongdoing was "not sufficient to show that [plaintiff] is primarily, and not just incidentally, engaged in information dissemination"); *with Leadership Conference on Civil Rights v. Gonzales*, 404 F. Supp. 2d 246, 260 (D.D.C. 2005) (determining that plaintiff is primarily engaged in disseminating information where its "mission is to serve as the site of record for relevant and up-to-the minute civil rights news and information"); *compare Am. Civil Liberties Union of N. California v. Dep't of Justice*, No. C 04-4447 PJH, 2005 WL 588354, at *14 (N.D. Cal. Mar. 11, 2005) (finding that the ACLU of Northern California does not qualify because information dissemination is not its sole primary purpose) *with Am. Civil Liberties Union of N. California v. U.S. Dep't of Def.*, No. C 06-01698 WHA, 2006 WL 1469418, at *6 (approving expedited processing in case where ACLU was co-plaintiff with a local newspaper). In short, the court should not "allow nearly any organization with a website, newsletter, or other information distribution channel to qualify as primarily engaged in disseminating information." *Landmark*, 910 F. Supp. 2d at 276. It is also not enough that a "plaintiff has been the object of media attention, and has at times provided information to the media." *Tripp v. Dep't of Def.*, 193 F. Supp. 2d 229, 241 (D.D.C. 2002).

Of the documents in the agency record, only the Plaintiffs' initial FOIA request letter contains information regarding TAG and GHJP and their respective missions. FOIA Request at 5, ECF No. 19-2. TAG is described as "an independent AIDS research and policy think tank dedicated to fighting for better treatment, vaccines, and cures for HIV-related diseases." *Id.* The description mentions that TAG's Hepatitis/HIV Project "collaborates with activists, community members, scientists, governments, and drug companies to make safer, more effective, and less toxic treatment for viral hepatitis available." *Id.* The Hepatitis/HIV Project has three separate missions: (1) to ensure that research on viral hepatitis is well-designed, (2) to provide "accurate and timely information" about hepatitis treatment "to people living with HIV and viral hepatitis, treatment activists, health care providers, advocates, educators, people working in harm reduction, and drug treatment program staff," and (3) to ensure that all co-infected patients have access to "safe and effective treatment for HIV and viral hepatitis." *Id.* GHJP is described as "a science-based, nonprofit initiative" that is "dedicated to promoting improvements in health systems and health justice" with a primary objective of facilitating "open science, community engagement, and public health." *Id.* GHJP also works with Yale Medical School's Open Data Access Project to provide public access to clinical trial data for researchers. *Id.* at 5-6.

Based on the information in the agency record, neither TAG nor GHJP qualify as organizations primarily engaged in disseminating information. TAG is described as being dedicated, first and foremost, to a general mission of improving treatment options for HIV and HIV-related diseases. FOIA Request at 5, ECF No. 19-2. Its Hepatitis/HIV Project is described as having three missions, only one of which focuses on disseminating information, and only to a subset of the public, those "living with HIV and viral hepatitis" and activists, health care providers, and others working with such patients. *Id.* GHJP, meanwhile, is described as having

the broad goal of "promoting improvements in health systems and health justice" with an interest in facilitating "open science, community engagement, and public health." *Id.* GHJP collaborates with an Open Data Access Project, but based on the agency record, this is only a part of GHJP's mission, and the extent to which GHJP contributes to Yale Medical School's Open Data Access Project is unclear. Plaintiffs cannot, therefore, show that either TAG or GHJP is "primarily, and not just incidentally, engaged in information dissemination." *Landmark*, 910 F. Supp. 2d at 276.

b. Urgency to Inform the Public

In considering the need for expedited processing in relation to urgency to inform the public, courts must consider at least the following factors: " (1) 'whether the request concerns a matter of exigency to the American public; (2) whether the consequences of delaying a response would compromise a significant recognized interest; and (3) whether the request concerns federal government activity.'" *Bloomberg*, 500 F. Supp. 2d at 377 (quoting *Al-Fayed*, 254 F.3d at 310). Neither claiming that requested information will benefit the general "health and wellbeing of the public" nor citing "[t]he public's right to know" is sufficient to show that a matter is of exigency to the American public. *Landmark*, 910 F.Supp.2d at 276-77. Instead, to show that a request concerns a matter of exigency to the American public and that there is a resulting urgency to inform the public, a requestor should be able to show that records are "the subject of a currently unfolding [news] story." *Al-Fayed*, 254 F.3d at 310.

To receive expedited processing, the requestor must show that the request concerns a "breaking news story of general public interest," rather than one that only concerns a specialized audience. *Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 123 (D.D.C. 2013) (rejecting expedited processing of FOIA request concerning a topic discussed only in articles posted "on a specialized blog dedicated to the Foreign Service" that was read by "several thousand people").

There should also be widespread and intense media interest in the subject matter of the request in the time period immediately prior to when the request was made. *Id.* at 123-24 ("Plaintiffs' submission of one article, a series of posts on a specialized blog, and plaintiff Truthout's representation that it 'intends' to publish a story do not come close to demonstrating a comparable level of media interest."); *Gerstein v. C.I.A.*, No. C-06-4643 MMC, 2006 WL 3462658, at *5 (N.D. Cal. Nov. 29, 2006) (granting plaintiff's motion for summary judgment regarding entitlement to expedited processing where plaintiff submitted a "search of the Nexis database conducted on March 11, 2006 [that] identified 977 news reports in the previous 90 days" that were relevant to his request); *Am. Civil Liberties Union of N. California v. U.S. Dep't of Def.*, 2006 WL 1469418 at *6 ("There had been at least fifty-three separate articles on the TALON program in the fifty-two days immediately prior to the FOIA requests. . . . In the ten days leading up to the requests, there were at least fourteen articles. In the four days preceding the request, there were at least five."); *but see Bloomberg*, 500 F. Supp. 2d at 378 (finding expedited need warranted though record before agency cited only one relevant May 14, 2006 article in case where plaintiff made initial request in February 2006 and appealed the constructive denial of the request in April 2006). The request should also concern recent events as of the time the plaintiffs made their FOIA request. *Wadelton*, 941 F.Supp.2d at 123 (finding that "fact that OIG conducted an investigation in 2010 certainly does not give rise to any sense of urgency" in FOIA case commencing in 2013); *Tripp*, 193 F. Supp. 2d at 242 ("Furthermore, there is no 'urgent need' for this information. The events at issue occurred over three years ago.") (internal citations omitted).

The record before the agency does not support a reasonable showing that the clinical trial data and other information surrounding the approval of Sovaldi and Harvoni is a matter of

exigency to the American public. Only two submissions by Plaintiffs are part of the agency record: (1) the December 17, 2014 letter making the initial expedited processing request and (2) the January 26, 2015 letter appealing the denial of the expedited processing request.

The December 17, 2014 letter cites to only one 2014 academic journal article and seven news articles specifically discussing Sovaldi and Harvoni, which were published between December 30, 2013 and September 16, 2014. Expedited FOIA Request at 1-7, Pl.'s Ex. A, ECF No. 19-2. The January 26, 2015 letter cites to only three news articles specifically discussing Sovaldi and Harvoni, all of which were published in the period between January 8, 2015 and January 21, 2015. FOIA Appeal at 1-2, Pl.'s Ex. D, ECF No. 19-5. The Court concludes that no reasonable jury could find this record sufficient to support a finding that Plaintiffs' request concerns a matter of public exigency, which under the case law, must involve a breaking news story that is the subject of intense media interest. The seven news articles cited in the Plaintiffs' initial request were published in a roughly one-year period prior to the Plaintiffs' December 2014 request, which does not amount to exigent public interest in the subject matter of their request. While the three articles cited in Plaintiffs' January 2015 appeal were from the period immediately leading into the appeal, three articles alone are insufficient to show public exigency. Furthermore, the Plaintiffs' request ultimately concerns the FDA approval of Sovaldi and Harvoni, events which took place in December 2013 and October 2014, respectively. By the time the Plaintiffs made their initial request for expedited processing in December 2014, there was no longer any sense of urgency or urgent need to inform the public regarding the FDA's actions from two months to a year before the Plaintiffs made their initial request.

C. FOIA Motion to Stay

1. Requirements for an *Open America* Stay

FOIA typically requires agencies to determine whether to respond to a document request within 20 working days. 5 U.S.C. § 552(a)(6)(A)(i). The agency is also obligated to "immediately notify" the requestor of its "determination and the reasons therefore," the requestor's right "to seek assistance from the FOIA Public Liaison of the agency," and if the agency has made an adverse determination, "the right of such person to appeal to the head of the agency." 5 U.S.C. § 552(a)(6)(A)(i). To meet this deadline, an agency's "'determination' does not require actual *production* of the records . . . at the exact same time that the 'determination' is communicated to the requester" because "a distinction exists between a 'determination' and subsequent production." *Citizens for Responsibility & Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180, 188 (D.C. Cir. 2013) (emphasis in original). An agency may need additional time to physically redact, duplicate, or assemble documents it has "gathered and decided to produce" and must do so and produce documents "promptly." *Id.* at 189.

In "unusual circumstances" including "the need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records which are demanded in a single request," the deadline "may be extended by written notice to the person making such request," but the extension may not be "for more than ten working days." 5 U.S.C. § 552(a)(6)(B). Once the agency has provided written notice of an extension, then "if the request cannot be processed within the [30 total working days provided by 5 U.S.C. § 552(a)(6)(A) and (B)]," the agency shall notify the requestor and provide them with "an opportunity to limit the scope of the request so that it may be processed within that time limit or an opportunity to arrange with the agency an alternative time frame for processing the request or a modified request." 5 U.S.C. §

552(a)(6)(B). A requestor's refusal to "reasonably modify the request or arrange such an alternative time frame shall be considered as a factor in determining whether exceptional circumstances exist" to justify a stay under 5 U.S.C. § 552(a)(6)(C). 5 U.S.C. § 552(a)(6)(B).[9] "If 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." 5 U.S.C. § 552(a)(6)(C)(i).

Courts may grant an agency a stay of litigation in exceptional circumstances, as provided in *Open America v. Watergate Special Prosecution Force*, 547 F.2d 605 (D.C. Cir.1976). To show that exceptional circumstances exist, the agency must show that "(1) [it] is deluged with an volume of requests for information on a level unanticipated by Congress; (2) existing agency resources are inadequate to deal with the volume of requests within the time limits established;" and (3) "the agency can show that it is exercising due diligence in processing the requests." *Bloomberg*, 500 F. Supp. 2d at 374 (internal citations omitted) (referring to *Open America*, 547 F.2d at 616). Various factors "outside [of] the raw volume of outstanding requests may be relevant," including "an agency's efforts to reduce the number of pending requests," the "size and complexity of other requests processed by the agency," and "the number of requests . . . by

[9] The D.C. Circuit summarizes the requirements of the deadlines set in 5 U.S.C. § 552(a)(6) and the consequences when an agency fails to meet the deadlines as such: "An agency usually has 20 working days to make a 'determination' with adequate specificity, such that any withholding can be appealed administratively. 5 U.S.C. § 552(a)(6)(A)(i). An agency can extend that 20–working–day timeline to 30 working days if unusual circumstances delay the agency's ability to search for, collect, examine, and consult about the responsive documents. *Id.* § 552(a)(6)(B). Beyond those 30 working days, an agency may still need more time to respond to a particularly burdensome request. If so, the administrative exhaustion requirement will not apply. But in such exceptional circumstances, the agency may continue to process the request, and the court (if suit has been filed) will supervise the agency's ongoing progress, ensuring that the agency continues to exercise due diligence in processing the request. Id. § 552(a)(6)(C). If the agency does not adhere to FOIA's explicit timelines, the 'penalty' is that the agency cannot rely on the administrative exhaustion requirement to keep cases from getting into court. This scheme provides an incentive for agencies to move quickly but recognizes that agencies may not always be able to adhere to the timelines that trigger the exhaustion requirement." *Citizens for Responsibility & Ethics in Washington v. Fed. Election Comm'n*, 711 F.3d 180, 189 (D.C. Cir. 2013).

courts or administrative tribunals." *Buc v. Food & Drug Admin.*, 762 F. Supp. 2d 62, 66 (D.D.C. 2011), as amended (Feb. 24, 2011).

"[D]elays that result from a predictable agency workload of requests" cannot form the basis for showing a volume of requests unanticipated by Congress. *Buc*, 762 F.Supp.2d at 66 (internal quotation marks omitted). "[A]llowing a mere showing of a normal backlog of requests to constitute 'exceptional circumstances' would render the concept and its underlying Congressional intent meaningless." *Bloomberg*, 500 F. Supp. 2d at 375. Instead, an agency must make a specific showing that the number or type of FOIA requests "have become increasingly or unexpectedly more complex as of late." *Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp. 2d 55, 60 (D.D.C. 2008) (holding that agency had not shown sufficient increase in workload to establish exceptional circumstances).

A showing that the agency is significantly understaffed could allow a court to find that agency resources are inadequate to process FOIA requests within the statutory time limits. *Elec. Frontier Found. v. Dep't of Justice*, 517 F. Supp. 2d 111, 115-16 (D.D.C. 2007) (allowing a stay where the agency remained "115 positions under its funded staffing level" and would "not be able to hire any new employees in the immediate future due to a federal government hiring freeze"). An agency will not, however, be able to show that its resources are inadequate to deal with information requests under FOIA's time limits if it is both faced with a predictable volume of requests while also having access to an increasing number of employees to process requests. *Buc*, 762 F. Supp. 2d at 72 (rejecting FDA's argument that it has inadequate resources when it faced a predictable and declining volume of FOIA requests and had added new staff members and anticipated adding even more staff to the department processing FOIA requests).

An agency may show "due diligence" by "complying with all lawful demands under FOIA in as short a time as is possible by assigning all requests on a first-in, first-out basis." *Fisher v. F.B.I.*, 94 F. Supp. 2d 213, 217 (D. Conn. 2000) (internal quotation marks omitted); *see also Gov't Accountability Project*, 568 F. Supp. 2d at 59. Courts generally require that an agency using a first-in, first-out process also make an additional showing that it has "made reasonable progress in reducing its backlog of pending requests." *Gov't Accountability Project*, 568 F. Supp. 2d at 59. It is not enough for an agency to simply show a decline in the number of pending FOIA requests. Instead, the agency should be able to prove that a decrease in the agency's backlog is "attributable to the measures Defendants have undertaken." *Id.* at 63; *Buc*, 762 F.Supp.2d at 70-71 (explaining that FDA had not shown due diligence when it could not show that its efforts reduced the volume of incoming requests and decrease in backlog also correlated with decrease in volume of requests with a difference of only 4%). Additionally, if the agency's actions "suggest a pattern of unresponsiveness, delays, and indecision" with regards to the specific FOIA request at issue, the Court may find "an absence of due diligence." *Bloomberg*, 500 F.Supp.2d at 376 (finding lack of due diligence when FDA requested a 20 month stay after responding to plaintiff's request for expedited processing a month late, failed to respond to the plaintiff's appeal of that denial, and failed to respond to the plaintiff's underlying FOIA request until after plaintiff filed complaint with the court). Even a showing of due diligence, however, potentially "fails if extraordinary need is demonstrated." *Id.*

District courts in the Second and D.C. Circuits have repeatedly found that the FDA and its related agencies are unable to show that they are deluged with a volume of requests unanticipated by Congress because, even if the agencies receive thousands of FOIA requests each year, the number of new requests was on a noticeable downward trend. *Buc*, 762 F.Supp.2d

at 68 ("Simply by way of example, according to the FDA's own figures, the number of requests received by the DIDP dropped from 5,310 in 2003 to 1,756 in 2009, a decline of 3,554 – or 66.9%."); *Gov't Accountability Project*, 568 F. Supp. 2d at 61-63 (noting that even if the agencies established that their workloads also included non-FOIA requests for information by Congress, related to litigation, or for FDAAA compliance, these developments were part of a "predictable agency workload of requests"); *Bloomberg*, 500 F. Supp. 2d at 374–75 (finding that the FDA's evidence "is reflective, not of an unpredicted spike in requests, but rather of a manageable workload flow encountered in the due course of FOIA processing"). Only one court has granted the FDA and related agencies an *Open America* stay in the period between 2005 and the present, but only because the requestor "provided nothing but speculation and innuendo about the FDA's failure to timely respond to its requests." *CareToLive v. U.S. Food & Drug Admin.*, No. 2:08-CV-005, 2008 WL 2201973, at *2 (S.D. Ohio May 22, 2008). Previously, the D.C. District Court last granted the FDA a stay in 2003, noting that the FDA had acted with due diligence in reducing its backlog from 16,704 in 1998 to 14,193 by the end of 2001. *Appleton v. F.D.A.*, 254 F. Supp. 2d 6, 8-9 (D.D.C. 2003).

An agency requesting an *Open America* stay faces a high burden. First, it must show that it is deluged with a volume of FOIA requests "on a level unanticipated by Congress." *Bloomberg, L.P.*, 500 F. Supp. 2d at 374. The Court notes that, unlike in 2007, 2008, and 2011 when courts rejected the FDA's requests for a stay, the DIDP now appears to be facing a consistent increase in the number of new FOIA requests each year for the period between 2012 and 2014.[10] Sager Decl. at 12. Nonetheless, this increasing volume of requests, with 3,017 received in 2014, is considerably less than the 5,310 new DIDP FOIA requests received in 2003,

[10] The FDA has not provided information regarding the number of new DIDP FOIA requests for 2010 and 2011, and Plaintiffs were unable identify and provide information for those year. Melnyk Decl. at 2-3, ECF No. 19-29.

when the D.C. District Court last granted the FDA an *Open America* stay in *Appleton*, 254 F. Supp. 2d at 8-9. Melynck Decl. at 2, ECF No. 19-29. The FDA cannot, therefore, show that it faces a volume of requests unanticipated by Congress, one that significantly exceeds the "predictable agency workload" for the FDA. *Buc*, 762 F.Supp.2d at 66. While the Court acknowledges that raw numbers alone may not provide a complete picture of the DIDP's workload, given that many of their FOIA requests, including Plaintiffs', may be complex multi-part requests requiring review of tens of thousands of pages of documents, the FDA only provides two examples of specific time-intensive searches as evidence. Sager Decl. at 6-7. This showing is insufficient to establish that all or most DIDP FOIA requests "have become increasingly or unexpectedly more complex as of late." *Gov't Accountability Project*, 568 F. Supp. 2d at 60.

Defendants must also show that "existing agency resources are inadequate" to deal with the volume of requests within FOIA's time limits. *Bloomberg*, 500 F. Supp. 2d at 374. In terms of human resources, the DIDP has had the benefit of an increased number of full-time employees, with seven more full-time employees in September 2015 than it had in 2009. Sager Decl. at 16; *Buc*, 762 F. Supp. 2d at 72. The FDA also reports that DIDP has implemented organizational changes that increase the efficiency of the DIDP's processing of information requests. Sager Decl. at 17. Because the DIDP is both dealing with a predictable workload and not significantly understaffed, the Court finds that the FDA is unable to show that its existing resources are inadequate, one of the necessary factors for obtaining an *Open America* stay.

As the Defendants cannot show the first two factors required to obtain a stay, there is no need for the Court to reach the issue of whether the agency has shown due diligence in processing its FOIA requests. *Bloomberg*, 500 F. Supp. 2d at 374. The Court notes that, in

contrast with the circumstances in *Buc* and *Bloomberg*, the DIDP is now reducing its backlog despite simultaneously receiving an increased number of requests, having received 28% more requests in 2014 than in 2012 while still reducing its backlog by 24% in the same period. *Compare* Sager Decl. at 12 *with Bloomberg*, 500 F.Supp. 2d at 375-76 (finding that DIDP's backlog decreased by approximately 37% while its FOIA requests decreased by "the same amount, approximately one-third or greater"); *Buc*, 762 F.Supp.2d at 70-71 (explaining that decrease in FDA FOIA backlog correlated with decrease in volume of requests with a difference of 4%). The Court declines to decide whether this is sufficient to show that the FDA is acting with due diligence.

2. Remedy for Denial of *Open America* Stay

When an *Open America* stay is denied, the Court may order the agency "to process Plaintiff's FOIA request and release the documents on a rolling basis" and require the agency to file a status report with the court regarding the status of the request and expected processing timelines. *Gov't Accountability Project*, 568 F. Supp. 2d at 64 (discussing case where plaintiffs requested data from two specific clinical trials of Cipro). The Court may also order the agency to "begin processing Plaintiffs' FOIA requests immediately," "promptly produce any responsive documents on a rolling basis," and set a deadline for the completion of production. *Buc*, 762 F. Supp. 2d at 73 (applying remedy to case where plaintiff made several separate FOIA requests including one for FDA health hazard evaluations of Zicam nasal cold remedy, one for documents related to a specific Compliance Policy Guide, one for documents related to a specific Drug Safety Oversight Board Meeting, one for documents related to a specific FDA press conference, and one for documents and records related to the statements a FDA employee made during a specific telephone call that included plaintiff). The court could also order the parties to submit a

case management plan in light of the denial of the stay and, if the parties are unable to agree, order that the agency produce documents by a certain deadline. *See Bloomberg*, 500 F. Supp. 2d at 378-79 (giving agency a "75-day period within which the Government is to produce the requested disclosures" subject to a potential "extension not to exceed fifteen days" subject to good faith effort by agency to comply in case involving plaintiff request for correspondence of one specific FDA employee with different drug companies regarding a link between suicidal thoughts and Neurontin, Topamax, Lyrica, and other anti-epileptic drugs).

Plaintiffs requested that the Court order the FDA to immediately process their request. Pl.'s Br. at 3, ECF No. 19-1. The Court notes that Plaintiffs' FOIA request, which appears to include essentially all clinical trial data related to the approval of Sovaldi and Harvoni in addition to all communications between the Defendants and the companies developing the drugs, is considerably broader than those at issue in *Buc*, *Bloomberg*, or *Gov't Accountability Project*. Under the updated timeline Defendants provided in their August 28, 2016 response to Plaintiffs' motion for leave to file supplemental materials, the Plaintiffs' request is at the top of CDER's FOIA request queue and CDER has, accordingly, begun searching for documents relevant to Plaintiffs' FOIA request. ECF No. 61-1.

Defendants represent that, because of the complexity of Plaintiffs' request and the quantity of documents CDER will need to review and potentially redact, a full response to Plaintiffs' request will be made by March 31, 2017. ECF No. 61-1. In light of these circumstances, the Plaintiffs' request to be moved to the top of the queue is moot. The Court does not believe that ordering Defendants to produce all documents by a certain date is warranted. Instead, the Court orders the FDA to immediately produce all responsive records gathered so far and report back to the Court by October 21, 2016 as to the responsive records yet

to be produced and when the Plaintiffs could expect to receive any documents outstanding as of October 21.

IV. CONCLUSION

For all of the foregoing reasons, Defendants' motion to stay is **DENIED**. Plaintiffs' motion for summary judgment regarding their entitlement to expedited processing is also **DENIED** and Defendants' cross-motion for summary judgment on the expedited processing issue is **GRANTED**.

Given that Defendants have stated that the FDA is currently processing the Plaintiffs' FOIA request, the Court orders the FDA to immediately produce all responsive records that have been gathered so far and to report back to the Court by October 21, 2016 as to responsive records that have yet to be produced and when the Plaintiffs could expect to receive any documents outstanding as of October 21. A telephonic status conference has been scheduled for October 21, 2016 for the parties to discuss the status of document production with the Court.

SO ORDERED at Bridgeport, Connecticut, this 20th day of September, 2016.

/s/ Victor A. Bolden
Victor A. Bolden
United States District Judge