UNITED STATES DISTRICT COURT
DISTRICT OF CONNECTICUT

TREATMENT ACTION GROUP and GLOBAL HEALTH JUSTICE PARTNERSHIP, Plaintiffs, v. FOOD AND DRUG ADMINISTRATION and DEPARTMENT OF HEALTH AND HUMAN SERVICES, Defendants.	Case No. 15-CV-00976 (VAB) ECF Case February 19, 2016

PLAINTIFFS' OPPOSITION TO DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT ON EXPEDITED PROCESSING, REPLY IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT ON EXPEDITED PROCESSING, AND SUR-REPLY IN OPPOSITION TO DEFENDANTS' MOTION FOR A STAY

Jonathan Manes, ct29574
David A. Schulz
Amanda Lynch, Law Student Intern
Yurij Melnyk, Law Student Intern
Nora Niedzielski-Eichner, Law Student Intern, Application Pending
Ben Picozzi, Law Student Intern
MEDIA FREEDOM AND INFORMATION ACCESS CLINIC, YALE LAW SCHOOL
P.O. Box 208215
New Haven, CT 06520
Tel: (203) 432-9387
Fax: (203) 432-3034
jonathan.manes@yale.edu
dschulz@lskslaw.com
amanda.lynch@clinics.yale.edu
yurij.melnyk@clinics.yale.edu
nora.niedzielski-eichner@clinics.yale.edu
ben.picozzi @clinics.yale.edu

Counsel for the Plaintiffs

ORAL ARGUMENT REQUESTED

TABLE OF CONTENTS

PRELIMINARY STATEMENT

FDA's posturing makes plain it has no interest in facilitating the scientific review of the clinical trial data at the heart of this litigation, despite both its statutory obligation and the public interest. Disclosure of these data is needed to answer important questions about the safety and efficacy of Sovaldi and Harvoni—drugs that are being sold for $1,000 per pill to treat a mass HCV epidemic that affects more people than HIV/AIDS. The societal cost has already been enormous, and will continue to grow as millions of people are prescribed these drugs. While the health benefits may also be enormous, when drugs this costly are prescribed on this scale, rare toxicities can impact thousands of lives, and drug resistance can lead to treatment failure that wastes millions of dollars. Open, scientific review of the trial data can identify and minimize these risks, but this cannot occur while FDA withholds critical data from qualified researchers.

Access to clinical trial data is most urgently needed for drugs that win expedited approval on the basis of limited test data. Uncontested scientific studies have documented an increase in post-approval drug safety and efficacy concerns since FDA began expedited approvals, including cases where fatal risks were not identified because the clinical trial data were misreported or improperly analyzed. Against this background of concern about FDA's expedited approval process, questions surrounding the safety and efficacy of the widely distributed new drugs Sovaldi and Harvoni create a particular need for immediate, independent scientific analysis of the clinical trial data. For example, the potentially fatal drug-drug interaction between Sovaldi and amiodarone was not discovered until after approval.

Instead of acknowledging the obvious public importance of prompt access to the clinical trial data, FDA's latest submission continues on a path of obstruction and delay that it has needlessly and improperly pursued since Plaintiffs first submitted their simple request for access to the data 14 months ago. In fighting to further delay processing Plaintiffs' FOIA request, FDA

offers up entirely new reasons for its foot-dragging and advances meritless form-over-substance legal arguments. Its effort is entirely misdirected because Plaintiffs' request easily satisfies the statutory standard for expedited consideration. As organizations dedicated to public education, Plaintiffs are regularly engaged in disseminating information to the public, and as the numerous newspaper and journal articles in the record demonstrate, the safety and efficacy of Sovaldi and Harvoni are undeniably matters of public concern. Given the public's compelling need for, and interest in, further analysis of the clinical trial data, expedited processing should readily have been granted.

Nor is a stay of proceedings justified. FOIA allows agencies to obtain a stay only in "exceptional circumstances." But for nearly a decade, perhaps more, FDA has routinely required FOIA requesters to wait two-years before even providing an initial response. This constitutes a systematic denial of FOIA's mandate for prompt disclosure—the statute requires disclosure *in 20 business days*. FDA cannot seriously contend that this regular, longstanding, and ongoing violation of FOIA deadlines is an "exceptional circumstance."

FDA's delay is particularly egregious given the importance of its responsibilities to oversee the safety and efficacy of drugs, medical devices, and other matters of life and death. As it stands, FDA's seriously delinquent FOIA responses frustrate the important work of researchers, physician-scientists, and others who need crucial information that only FDA possesses. This Court should not grant a stay, which would effectively endorse FDA's delays and give the agency permission to perpetuate its pattern of noncompliance in this case. Until FDA actually brings it FOIA process in line with the law, requesters must have recourse to the courts to secure timely access to information.

With the entrance into the case of Gilead Sciences, the manufacturer of Sovaldi and Harvoni, all of the parties are in place to immediately begin adjudicating purported concerns of "business confidentiality," which FDA and Gilead have both said they will interpose as objections to the release of any clinical trial data and other basic scientific information Plaintiffs seek to make public. Plaintiffs have previously offered to litigate a representative sample of the information at issue in order to resolve this dispute with minimal burden on the agency. FDA's refusal even to entertain this orderly and efficient approach further bespeaks a strategy of non-compliance and delay.

Given the urgent need for access to the clinical test data at stake here, this Court should deny any stay, 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 in this case for prompt resolution by the Court. There is no good reason the parties should not be required to move quickly to brief their core dispute: whether FDA has the legal authority to refuse to make public the data needed for the scientific community to analyze the safety and efficacy of drugs that FDA has approved in an expedited fashion and that will be distributed on a massive scale at a massive cost over the next few years.

FACTUAL BACKGROUND

Throughout the administrative process and this litigation, FDA has repeatedly postponed consideration of the merits of Plaintiffs' arguments. On December 17, 2014, Plaintiffs Treatment Action Group ("TAG") and Global Health Justice Partnership ("GHJP") submitted identical FOIA requests to FDA and HHS, seeking access to eight categories of information relating to Sovaldi and Harvoni and asking the agencies to expedite processing. Local Rule 56(a)1 Statement ¶ 18, ECF No. 19-30 ("Pls.' Rule 56(a)1 Statement"); Pls.' Mem. Opp. Defs.' Mot. for Stay & Supp. Pls.' Cross-Mot. for Expedited Processing ("Pls.' Mem.") Ex. A, ECF No. 19-2.

Plaintiffs' requests described in detail the nature of their work and the pressing concerns underlying the need for the requested information. *See* Pls.' Mem. Ex. A. Yet, FDA summarily denied expedited processing, stating simply that TAG and GHJP 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." Pls.' Rule 56(a)1 Statement ¶ 26; Pls.' Mem. Ex. C, ECF No. 19-4.

Plaintiffs administratively appealed FDA's conclusory denial. Pls.' Rule 56(a)1 Statement ¶¶ 28-29; Pls.' Mem. Ex. D, ECF No. 19-5. FDA persisted in its refusal to grant expedited processing, offering certain reasons for its denial for the first time. Pls.' Mem. Ex. G, ECF No. 19-8. FDA cited regulations it considered determinative and asserted that Plaintiffs had "not provided sufficient information to support a determination" that (1) they were "primarily engaged in disseminating information" and (2) there existed an urgent need for the information requested. Pls.' Mem. Ex. G, ECF No. 19-8.

In an effort to move this matter forward, on April 1, 2015, Plaintiffs submitted a letter to FDA supplementing the record to address the supposed evidentiary deficiencies in their original FOIA request and appeal. Pls.' Rule 56(a)1 Statement ¶ 35. That letter provided substantial evidence responding to each of the objections raised in FDA's denial of the administrative appeal. Pls.' Rule 56(a)1 Statement ¶ 35. Plaintiffs asked the agency to reconsider its decision in light of this additional evidence. Pls.' Rule 56(a)1 Statement ¶ 5. FDA responded two days later, but only to refuse to consider the additional evidence. Defs.' Rule 56(a)1 Statement ¶¶ 14-15, ECF No. 37-2; Defs.' Mem. Opp. Pls.' Mot. for Partial Summ. J. on Expedited Processing Cause of Action, Cross-Mot. for Partial Summ. J. on Expedited Processing Issue & Reply Further Supp. Mot. for Stay 12-14 ("Defs.' Mem.") Ex. 1, Attach. 1, ECF No. 37-4. FDA did not engage with

or address the copious additional evidence before it demonstrating a clear entitlement to expedited processing of the request. FDA's April 3, 2015 letter simply advised Plaintiffs to litigate if they did not want to wait the 18-24 months FDA had earlier advised Plaintiffs it would take to process their request.[1] Pls.' Mem. Ex. G at 3, ECF No. 19-8. FDA's attempt to stay this litigation is thus only the latest example of FDA's eagerness to delay.

On January 25, 2016, Gilead Sciences, the company that manufactures Sovaldi and Harvoni, moved to intervene in this case, *see* Gilead's Unopposed Mot. for Leave to Intervene, ECF No. 29, and this Court granted that motion, *see* Order Granting Mot. to Intervene, ECF No. 39. Gilead based its intervention on its asserted need to oppose the disclosure of clinical trial data and other scientific documents as "business confidential" information.[2] *See* Gilead's Mem. Supp. Mot. for Leave to Intervene, ECF No. 29-1. There are now parties on both sides prepared to litigate the merits.

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO EXPEDITED PROCESSING.

Plaintiffs are entitled to expedited processing because it is imperative that scientists and researchers obtain access to clinical trial data about Sovaldi and Harvoni as soon as possible. Without this data, researchers are not able to resolve questions about how these extremely expensive drugs are being rationed, nor are they able to address outstanding concerns about the

[1] Due to a filing error, Plaintiffs' counsel was unaware of the FDA's April 3, 2015 letter until January 22, 2016. Plaintiffs had proceeded to litigate under the impression that FDA had not responded at all to the request for reconsideration.

[2] FDA recently litigated and lost this very argument against disclosure in another FOIA case where it opposed release of clinical trial data about another drug manufactured by Gilead. *See* Order Re: Def.'s Mot. for Summ. J. Mot., *AIDS Healthcare Foundation v. U.S. Good & Drug. Admin.*, No. Cv 11-07925 MMM (JEMx) (N.D. Cal. Aug. 6, 2013).

drugs' effectiveness in various subpopulations. Currently available information cannot address these unresolved and pressing questions.

As explained in Plaintiffs' motion for partial summary judgment, Plaintiffs easily meet both expedited processing standards set out by FOIA. Pls.' Mem. 10-18. Specifically, (1) Plaintiffs are "primarily engaged in disseminating information," and there is an "urgency to inform the public concerning actual or alleged Federal Government activity;" and (2) "failure to obtain requested records on an expedited basis under this paragraph could reasonably be expected to pose an imminent threat to the life or physical safety of an individual." 5 U.S.C. § 552(a)(6)(E)(v)(I)-(II). If TAG or GHJP satisfy either one of these standards, expedited processing should be granted.

In opposition, FDA attempts to justify—for the first time—its conclusory denial of Plaintiffs' request for expedited processing, relying on lengthy declarations adducing facts and rationales not offered during the agency proceedings. Even if FDA's belated justifications are properly considered by the Court, they fail to meet Plaintiffs' arguments and obfuscate the central fact that disclosure of the information sought here is a matter of pressing concern to the public, and rightfully so. Expedited treatment is fully warranted, and FDA's attempt to put this litigation on hold for 14 more months should be flatly rejected.

A. Plaintiffs Are Primarily Engaged in Disseminating Information.

TAG and GHJP are both "primarily engaged in disseminating information." 5 U.S.C. § 552(A)(6)(E)(v)(II); 21 C.F.R. § 20.44.[3] FDA seeks to avoid this conclusion by arguing that because the stated "missions" of TAG and GHJP are to improve public health and achieve

[3] Further, as Plaintiffs have already argued, to the extent FDA's regulations contract FOIA's definition of compelling need, they are invalid. *See* Pls.' Mem. 12-13; 5 U.S.C. § 552(a)(6)(E)(i)(II); *Al-Fayed v. C.I.A.*, 254 F.3d 300, 307 (D.C. Cir. 2001).

related policy goals—rather than to disseminate information—they cannot be "*primarily* engaged in disseminating information." Defs.' Mem. 12-14. This argument willfully misunderstands how TAG and GHJP work and contorts the applicable legal standard.[4]

The primary means by which TAG and GHJP achieve their public health and educational "missions" is by researching and disseminating accurate and timely information to the public in a variety of ways, including by publishing reports for general and specialized audiences, hosting conferences, compiling fact sheets and training manuals for public consumption, and sharing information with the press. Pls.' Rule 56(a)1 Statement ¶¶ 1-17; Pls.' Mem. 11-13; Ex. A, at 5-6; Ex. H, at 2-4, ECF No. 19-9.[5]

FDA's argument thus appears to amount to the claim that, unless a requester disseminates information for its own sake, it is disqualified from obtaining expedited processing under this prong of the test. Defs.' Mem. 12-14. This position is inconsistent with the plain text of the statute, which requires only that a requester be "primarily *engaged* in disseminating information," not that its primary mission or objective be to disseminate information. 5 U.S.C. § 552(a)(6)(E)(v)(II).[6]

---

[4] Defendants assert that the D.C. Circuit has held that the burden is on the requester to establish a compelling need exists. *See.* Defs.' Mem. 9-10; *Al-Fayed*, 254 F.3d at 305 n.4. The Second Circuit has not considered this question, and district courts in this circuit have not found it necessary or helpful to specify who bears the burden on this issue once in litigation. *See, e.g.*, *Bloomberg L.P. v. U.S. Food & Drug Admin.*, 500 F. Supp. 2d 371, 374 (S.D.N.Y. 2007).

[5] FDA asserts that media interest in GHJP's efforts is beside the point. Defs.' Mem. 14. This is transparently wrong. The media interest in GHJP arises precisely because GHJP disseminates important information to the public. For example, the recent *New York Times* article about GHJP covers a report it published. Coverage of GHJP's publications in a newspaper of record only underscores the broad audience its publications can reach. *See* Pls.' Mem. Ex. O, ECF No. 19-16.

[6] Indeed, the FOIA statute separately defines "representative of the news media" in the fee waiver context as "any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience." 5 U.S.C. § 552(4)(A)(ii). Ordinary canons of statutory construction

FDA's position is also contrary to case law, which rejects FDA's conflation of an organization's "mission" with the primary means (i.e., dissemination of information) that it uses to achieve that mission. Defs.' Mem. 13-14. FDA points to two cases in which courts held that public interest law firms were not "primarily engaged in disseminating information" and argues they should govern the expedited processing inquiry here. *See* Defs.' Mem. 13-14 (citing *Landmark Legal Found. v. EPA*, 910 F. Supp. 2d 270 (D.D.C. 2012); *Am. Civil Liberties Union of N. Cal. v. Dep't of Justice*, No. 04-4447 PJH, 2005 WL 588354, at *8, 14 (N.D. Cal. Mar. 11, 2005)). But both of the organizations involved in those cases—the American Civil Liberties Union and the Landmark Legal Foundation—achieved their objectives primarily by bringing legal challenges in court, not by disseminating information. Those organizations share little in common with TAG and GHJP, which conduct and publish research to educate and advocate on issues affecting public health. Pls.' Rule 56(a)1 Statement ¶¶ 1-17; Pls.' Mem. 11-13; Ex. A, at 5-6; Ex. H, at 2-4. Neither Plaintiff is a law firm or regularly engaged in litigation, and FDA's attempt to liken Plaintiffs to these public interest law firms fails.

Instead, TAG and GHJP's efforts are entirely focused on education and advocacy, both activities that consist of disseminating information. TAG and GHJP thus resemble the Leadership Conference on Civil Rights and the Electronic Privacy Information Center (EPIC), policy organizations that likewise disseminate information in order to further their missions. Courts have recognized that both of these organizations are "primarily engaged in disseminating information." *Leadership Conference on Civil Rights v. Gonzalez,* 404 F. Supp. 2d 246 (D.D.C. 2005); *Am. Civil Liberties Union v. U.S. Dep't of Justice*, 321 F. Supp. 2d 24, 29 n.5 (D.D.C.

---

presume that Congress intends different words to have different meanings, *see Keene Corp. v. United States*, 508 U.S. 200, 208 (1993), and the ordinary meaning of "primarily engaged in disseminating information" is broader than "representative of the news media." *Cf. Am. Civil Liberties Union*, 321 F. Supp. 2d at 29 n.5.

2004). In *Leadership Conference*, for example, the Court credited that the organization disseminated information "to educate the public, promote effective civil rights laws, and ensure their enforcement." *Id.* at 260. Like the Leadership Conference and EPIC, TAG and GHJP are nonpartisan organizations that disseminate information in service of their missions. Further, like the Leadership Conference, TAG seeks to serve as a "site of record" for information and analysis of developments relevant to HIV and HCV treatment. Pls.' Mem. Ex. H, at 3-4.[7] Because disseminating information to advance their missions is "the *main activity*" engaged in by TAG and GHJP, they readily satisfy the first prong of the test for expedited processing. *Landmark Legal Found.*, 910 F. Supp. 2d at 276

B. <u>There Is an Urgent Need for the Requested Information.</u>

Plaintiffs should be granted expedited treatment because information about Sovaldi and Harvoni is urgently needed to allow scientists, researchers, and patient advocates to independently review the cost-effectiveness, safety, and efficacy of these drugs, and to contest the policies that have been adopted to determine who has access to them. *See* Pls.' Mem. 13-17.[8] As the FDA well knows, and as documented in numerous publications presented to it by Plaintiffs, the requested information "concerns a matter of current exigency to the American public" and "delaying a response would compromise a significant recognized interest." *Al-Fayed*, 254 F.3d at 310; *Bloomberg*, 500 F. Supp. 2d at 377.

---

[7] To grant expedited processing, this Court need only find that one of the two plaintiff organizations is primarily engaged in disseminating information. *Am. Civil Liberties Union v. U.S. Dep't of Justice*, 321 F. Supp. 2d 24, 29 n.5 (D.D.C. 2004).

[8] FDA contends that Sovaldi and Harvoni have undergone "independent" review, because FDA reviewed the drugs during the approval process. *See* Defs.' Mem. 20 n.16. FDA's semantic quibble is disingenuous. "Independent" review, as used in Plaintiffs' request, and by the many scientists concerned with the adequacy of the FDA's review process, refers to analysis performed by the broader scientific community, not only by the regulators, manufacturers, or small group of scientists appointed to FDA advisory committees. *See, e.g.*, Pls.' Mem. 14.

1. Delaying public access to the requested information would compromise significant public interests.

HCV is a chronic disease that affects millions of people in the United States. Pls.' Rule 56(a)1 Statement ¶ 50. Hundreds of thousands of patients have already been treated with these drugs, at extraordinary cost. Pls.' Rule 56(a)1 Statement ¶¶ 51, 53. Many hundreds of thousands more will be treated, placing an extraordinary fiscal burden on state insurers. Pls.' Rule 56(a)1 Statement ¶¶ 52, 64-66. In addition, ever greater numbers of the public, both domestically and internationally, will be treated with drugs whose safety and efficacy in specific populations has never been fully evaluated. *See* Pls.' Rule 56(a)1 Statement ¶¶ 48-70; Pls.' Mem. 4-5, 14-17.[9] These concerns implicate the public's concrete interests in ensuring that patients receive treatments that are safe and effective for the purposes for which they are prescribed, and in determining that rationing of access to these extraordinarily costly treatments is based on an accurate understanding of the drugs' costs and benefits. These public concerns unquestionably are significant.

There are significant unanswered questions about the safety and efficacy of Sovaldi and Harvoni. For instance, FDA offers no meaningful response to studies demonstrating resistance to ledipasvir, one of the drugs in Harvoni. *See* Pls.' Mem. 5. These studies suggest that Sovaldi and Harvoni may not be as effective for HCV patients of certain racial or ethnic groups. Pls.' Rule 56(a)1 Statement ¶¶ 60-63. For example, in a clinical trial of HIV/HCV coinfected patients, all ten individuals who were not cured with Harvoni were African American. Pls.' Rule 56(a)1 Statement ¶ 63. Additionally, studies find that some individuals are resistant to NS5A inhibitors

[9] FDA stresses that this standard "requires that 'a reasonable person might conclude that the consequences of delaying a response to a FOIA request would compromise a significant recognized interest.'" Defs.' Mem. 26 (citing *Al-Fayed*, 254 F.3d at 310). Plaintiffs' evidence supporting the need for disclosure, which includes several publications in leading medical journals, demonstrates that these concerns are reasonable. *See infra* at 17-18.

such as ledipasvir, an active ingredient in Harvoni. Pls.' Rule 56(a)1 Statement ¶ 60; Pls.' Mem. Ex. S at 5-6. Some HCV mutations render NS5A inhibitors ineffective. Pls.' Rule 56(a)1 Statement ¶ 61; Pls.' Mem. Ex. S at 2. FDA boasts that the agency "independently analyzed the raw clinical data for safety and efficacy," Defs.' Mem. 8, but the evidence FDA has made available provides no means to validate these conclusions and identify which mutations make the drugs less effective.

In addition, FDA's own post-approval actions underscore the urgent need for independent scientists and researchers to have access to the requested clinical trial data. As FDA acknowledges, *see* Defs.' Mem. 19, the agency revised Sovaldi and Harvoni's warning labels in response to drug interactions that were not discovered during the expedited review process. Pls.' Rule 56(a)1 Statement ¶ 58.[10] And researchers have reported severe bradyarrhythmia in patients treated with Sovaldi and Harvoni. Pls.' Rule 56(a)1 Statement ¶ 59.

Access to the clinical trial data could allow researchers to validate these ongoing concerns and also to discover other problems that may be lurking in the data. Indeed, despite FDA's protestation that its Fast Track, Breakthrough Therapy, and Priority Review designations are no less rigorous than its ordinary approval process, scientists have shown that drugs approved under these programs are more likely to be withdrawn than other drugs. Pls.' Rule 56(a)1

[10] FDA contends that revisions to Sovaldi and Harvoni's labeling was "based on post-marketing reports" and therefore could not have been discovered through analysis of the clinical trial data subject to Plaintiffs' request. Defs.' Mem. 19. But this does not follow. There may well have been evidence in the raw clinical trial data that would have indicated a risk of bradyarrhythmia or related issues earlier, before the drug was marketed. Notably, FDA does not assert that it reviewed the clinical trial data for such evidence. Moreover, even assuming *arguendo* that the requested data includes no episodes of bradyarrhythmia, analysis of the underlying data might still discover defects in trial design or procedure. Plaintiffs' point is that the discovery of these risks post-marketing underscores the need to obtain disclosure of all the pre-marketing data. In addition, the post-marketing discovery of these events suggests that FDA's pre-marketing review may not be as robust or unquestionable as it suggests. *See* Pls.' Mem. 4-5.

Statement ¶ 56; Pls.' Mem. Ex. A, at 2 n.6. The speedy approval of Sovaldi and Harvoni therefore underscores the need for outside scientists to be able to review the raw data.

The importance of prompt access to clinical trial data in this case is illustrated vividly by the experience with other drugs, where public access to this data helped (or could have helped) identify deficiencies in the initial government review. In several high-profile cases, including those involving Avandia, Paxil, Tamiflu, and Vioxx, independent analysis of clinical trial data identified—or could have identified—defects that FDA's own analysis of the data did not find. Pls.' Rule 56(a)1 Statement ¶¶ 43-47.[11] In the case of Vioxx, independent researchers found that the manufacturer had significantly understated the drugs' cardiovascular risks, which killed thousands of patients treated with the drug. *See* Pls.' Rule 56(a)1 Statement ¶ 45. And in the case of Paxil, researchers found that the drug's efficacy was overstated. Pls.' Rule 56(a)1 Statement ¶ 44. As this experience demonstrates, access to data bears on questions of life or death.

The high prices of Sovaldi and Harvoni, and the massive scale on which they are already being used, only reinforce the importance of prompt access to the clinical trial data. The prices of these drugs continue to prevent patients from accessing these medicines, and at least half of states currently restrict access to these drugs. Pls.' Rule 56(a)1 Statement ¶ 66-67. In making the inevitable rationing decisions, fully informed and careful analysis of the trial data is needed to know which patients will most benefit from the drugs, and how to optimize treatment outcomes in patients less likely to be cured, such as people with genotype 1a, cirrhosis, and a high hepatitis

[11] This analysis of clinical trial data continues to yield results. Two studies in the *British Medical Journal*, published in September 2015 and January 2016, use clinical trial data to reevaluate the claims made for Paxil and other antidepressants. Joanna Le Noury et al., *Restoring Study 329: Efficacy and Harms of Paroxetine and Imipramine in Treatment of Major Depression in Adolescence*, 351 Brit. Med. J. (2015); Tarang Sharma, *Suicidality and Aggression During Antidepressant Treatment: Systematic Review and Meta-Analyses Based on Clinical Study Reports*, 352 Brit. Med. J. (2016). Both studies conclude that the drugs were less effective and more harmful than the manufacturers' original analysis of that data found.

C viral load. These analyses cannot currently be undertaken because FDA is refusing to release clinical trial data needed to do so. Pls.' Rule 56(a)1 Statement ¶ 64.

The urgency of these concerns has not abated since Plaintiffs filed their requests. In just the past month, the Senate Finance Committee has completed an investigation into the drugs' pricing. Pls.' Rule 56(a)1 Statement ¶ 73. Its report highlights concerns about drug rationing and notes that the high price of the drugs is directly linked to their perceived efficacy, not their actual production costs. *See* Staffs of Ranking Mem. Ron Wyden & Comm. Mem. Charles E. Grassley, 114th Cong., *The Price of Sovaldi and Its Impact on the U.S. Health Care System* 45 (Comm. Print Dec. 2015) (finding that in choosing Sovaldi's price, Gilead believed that the drug's effectiveness "was ample justification for increased pricing"), attached hereto as Exhibit A ("Pls.' Opp. Ex. A").

Relying principally on *Landmark Legal Foundation*, FDA argues that such concerns about health and economic wellbeing are not cognizable interests that warrant expedited processing. Defs.' Mem. 26 (citing *Landmark Legal Found.*, 910 F. Supp. 2d at 277). But in that case—unlike this one—the plaintiff stated only a generalized interest shared by the public. By contrast, Plaintiffs here identify specific groups of individuals who will be harmed by delaying public access to the requested information, namely, the hundreds of thousands of patients who will be treated with Sovaldi and Harvoni during the period of time in which Plaintiffs' unprocessed request sits at the FDA, as well as insurance claimants and individuals dependent on state authorities for healthcare whose access has been improperly rationed. *See* Pls.' Rule 56(a)1 Statement ¶ 52; Pls.' Mem. 4-6, 14-15; *supra* at 10-13. As FDA concedes in its discussion of *Bloomberg*, 500 F. Supp. 2d 371, "a reasonable expectation" that the requested information "might lead to a greater understanding" of a "potential association" between a drug and a

negative health outcome is a cognizable interest that satisfies the standard for compelling need. *See* Defs.' Mem. 27-28.[12]

FDA also argues that in order to state a cognizable interest, Plaintiffs must "identif[y] a specific point in time at which the information they seek will no longer be valuable in evaluating FDA's approval of these drugs." Defs.' Mem. 28. That rule might make sense in the cases FDA cites, where the requested information's value is attached to the expiration of a particular statutory provision. *See Leadership Conference on Civil Rights*, 404 F. Supp. 2d at 260; *Am. Civil Liberties Union*, 321 F. Supp. 2d at 29. But it makes no sense here, where the value of the information *increases* over time. In this case, the requested clinical trial data is needed today, to evaluate risks and allocation decisions for hundreds of thousands of patients being prescribed Sovaldi and Harvoni. *See* Pls.' Rule 56(a)1 Statement ¶ 51. That information is also needed tomorrow, and the next day, and in a year, when those drugs have been prescribed to hundreds of thousands more. *See* Pls.' Rule 56(a)1 Statement ¶ 52.[13] Patients receiving treatment now and in the future should have the full benefit of data produced from trials on patients before. In the absence of access, future patients are, in effect, subjected to unnecessary risks and substantial sums may be spent providing the drugs to individuals for whom it has no effect. In these circumstances, FDA cannot plausibly argue that there is no cognizable interest in prompt release of the information.

---

[12] FDA attempts to distinguish *Bloomberg* on the grounds that in that case, there was a "reasonable" chance plaintiffs' request would reveal significant information regarding drug safety. Defs.' Mem. 27. However, again, FDA's basis for this distinction rests on the naked assertion that "the clinical data submitted during the approval process for Sovaldi and Harvoni supports those drugs' safety and efficacy." Defs.' Mem. 27-28. The evidence in this case belies that assertion. *See supra* at 10-13.

[13] FDA's argument that "Plaintiffs' urgency claims are belied by their delay in making their FOIA request," Defs.' Mem. 28, is also meritless. As this case demonstrates, the public's urgent need for clinical trial data can in fact *grow* as time passes and more patients are treated.

2. The requested information is a matter of current exigency to the public.

Seeking to sidestep the importance of disclosing the information requested, FDA argues that the numerous news and journal articles submitted in support of expedited processing do not establish a matter of "current exigency" to the public because they are too general, too few, too specialized, or irrelevant. Defs.' Mem. 15-25. FDA's arguments are entirely misdirected.

In this case, the record speaks for itself. Plaintiffs have submitted more than 20 news and journal articles, discussing the safety, efficacy, and cost of Sovaldi and Harvoni, all of which were published no earlier than 1 year before the filing of Plaintiffs' FOIA request. These include articles published in the *Atlantic*, *Bloomberg*, *Health Affairs*, *Journal of the American Medical Association*, *New York Times*, *National Public Radio*, *New England Journal of Medicine*, *Reuters*, *USA Today*, *Wall Street Journal*, and *Washington Post*. Pls.' Mem. Ex. A, at 1 nn.2-3, 2 n.6, 4 n.9, 5 nn.11-13; Ex. D, at 2 nn.2-3; Ex. H, at 5 n.21, 6 n.29-33; 7 n.35-36; Ex. R, ECF No. 19-19; Ex. S, ECF No. 19-20; Ex. T, ECF No. 19-21; Ex. U, ECF No. 19-22. Collectively, these sources demonstrate a public interest in the drugs that is not confined to narrow interest groups, but transcends political and professional boundaries.

Widespread public concerns regarding Sovaldi and Harvoni have also led the Senate Finance Committee to undertake an extraordinary investigation into the drugs' pricing. *See* Pls.' Rule 56(a)1 Statement ¶ 73; Pls.' Mem. 16. The Committee's report found that "in pricing its line of HCV drugs Gilead may have underestimated the warnings of patient groups, insurers, health care providers, and other organizations about the potential impact that price would have on access. Such warnings were made not only through the media, but directly to company officials, both in private correspondence and various public forums." Pls.' Opp. Ex. A, at 3. FDA's conclusion that there is no public interest in the requested information contradicts Congress's own findings regarding this issue.

The very scope of the public attention on these drugs refutes FDA's claims that granting expedited processing in this case would mean that "any request for documents related to a drug reviewed under one of FDA's expedited programs would receive such treatment." Defs.' Mem. 20. Tellingly, while FDA approved 27 drugs in 2014 "under one or more of the agency's expedited programs," *see* Defs.' Mem. 20 n.17, the agency provides no evidence of public interest in the safety, efficacy, or cost-effectiveness of these drugs approaching anything like the interest in Sovaldi and Harvoni, *see supra* at 10-13.

FDA contends that the numerous news articles submitted only demonstrate public interest in "general topics," not the "*specific* subject of Plaintiffs' FOIA request." Defs.' Mem. 17. But the articles Plaintiffs cite demonstrate public interest in exactly the questions that can only be answered by public disclosure of the clinical trial data and other information sought by Plaintiffs. The information will enable independent analysis of the drugs' safety and efficacy. Moreover, the drugs' high prices have led to significant rationing of access. *See* Pls.' Rule 56(a)1 Statement ¶¶ 65-66; Pls.' Mem. 15; *see also* Pls.' Opp. Ex. A, at 45. The cases on which FDA relies to discredit the relevance of the news reports on these drugs are readily distinguishable. In those cases, the plaintiffs either sought information related to specific government programs based on public interest in topics related to *other* government activities, *see Elec. Privacy Info. Ctr. v. Dep't of Defense*, 355 F. Supp. 2d 98, 102 (D.D.C. 2004); *Am. Civil Liberties Union of N. Cal. v. Dep't of Justice*, No. C 04-4447 PJH, 2005 WL 588354, at *14 (N.D. Cal. Mar. 11, 2005), or provided no evidence of public interest at all, *see Al-Fayed*, 254 F.3d at 310-11.[14]

[14] In *Electronic Privacy Information Center*, the plaintiffs sought information related to a specific Department of Defense data mining program, but provided no evidence of public interest in that program. 355 F. Supp. 2d at 102. Likewise, in *American Civil Liberties Union of Northern California*, the plaintiffs sought information related to the Department of Justice's Joint Terrorism Task Force in Northern California, but only submitted articles that focused on other

FDA's contention that the total volume of cited articles is too small to establish a matter of current exigency to the American public, *see* Defs.' Mem. 24-25, also misses the mark. None of the cases FDA cites creates a bright-line rule regarding the volume of articles needed to establish exigency. *See* Defs.' Mem. 24-25. By contrast, in *Bloomberg*, the Southern District of New York held that a current exigency existed based on a single national news report combined with the "importance of public knowledge of the potential association between certain anti-epileptic drugs and suicide-related adverse events." 500 F. Supp. 2d at 378.

Startlingly, FDA attempts to exclude medical journals from consideration, on the grounds that they serve professional or international audiences. This argument, which seeks to dismiss the importance of the leading medical journals in the world, is particularly surprising coming from the agency tasked with safeguarding public health and, presumably, reviewing the medical literature. FDA's argument radically understates the public impact of these journals. For example, the *Journal of the American Medical Association* (*JAMA*), the source of four of the articles cited in Plaintiffs' request, *see* Pls.' Mem. Ex. A, at 1 n.4, 2 nn.5-6, has an online circulation of 1.2 million and a print circulation of 320 thousand. *See* About JAMA, J. Am. Med. Ass'n (Feb. 2016), http://jama.jamanetwork.com/public/About.aspx.[15] Further, *JAMA*'s impact far exceeds its readership. *JAMA*'s website receives over 16 million visits per year, and the

---

topics and only contained "generalized references" to the task force. 2005 WL588354, at *14. And in *Al-Fayed*, the plaintiffs sought information related to allegations that "Mohamed Al Fayed was the victim of an attempted fraud," arguing that the government's refusal to prosecute the perpetrators was evidence of public interest. 254 F.3d at 310. However, they provided no evidence of "any news reports on the subject of the United States Attorney's alleged refusal to prosecute, other than reports on the press conference plaintiffs held to announce the filing of their complaint." *Id.* at 311.

[15] For comparison, the *New York Times* has a total online and print circulation of between 2.2 and 2.6 million. Chris O'Shea, *NY Times Circulation Increases*, Adweek (May 1, 2015), http://www.adweek.com/fishbowlny/ny-times-circulation-increases/341204.

Journal actively promotes its articles with mainstream journalists. *See id*. Moreover, the mainstream press regularly reports on findings in publications like the *New England Journal of Medicine* and other leading medical journals; their impact on mainstream discourse is undeniable. FDA's effort to liken them to technical publications of interest only to a small, specialized audience cannot be credited.[16]

Desperate to support a patently incorrect position, FDA points to an out-of-court statement by one Plaintiff representative that "[t]here is no smoking gun," arguing that this means Plaintiffs "agree with FDA's conclusions to approve Sovaldi and Harvoni." Defs.' Mem. 22. FDA confuses the nature of Plaintiffs' concerns. Whether FDA was correct to approve Sovaldi and Harvoni is beside the point; the question is whether Sovaldi and Harvoni are appropriately labeled, and effectively being made available to the proper populations given the evidence that can only be gleaned by further analysis of the clinical test data. FDA omits the portion of the quotation that actually makes this very point, noting that "the drug was studied for a certain set of patients and is being used for a wider set of patients." *See* Defs.' Mem. Ex. 2, Attach. 1 at 2, ECF No. 37-5. FDA also overlooks that the publication of this statement in the *Wall Street Journal* belies its claim that there is no "mainstream" media coverage of the subject matter of Plaintiffs' FOIA request. Plainly, there is. *See also* Defs.' Mem. 18, 20, 24-25.

[16] Citing *Wadelton v. Dep't of State*, 941 F. Supp. 2d 120, 123 (D.D.C. 2013), FDA contends that medical journals "are not mainstream press outlets and, instead, target a narrow population, *i.e.*, medical professionals, and, thus, cannot demonstrate current interest on the part of the larger American public." Defs.' Mem. 18. However, *Wadelton* does not support the broad proposition that journal articles can never be considered. In that case, the court held that the plaintiff's evidence, consisting in part of articles published on a "specialized blog dedicated to the Foreign Service" and "*read by 'several thousand people*'" was insufficient to demonstrate exigency. 941 F. Supp. 2d at 123 (emphasis added). As noted, the readership of the medical journals at issue in this case is orders of magnitude greater than the blog at issue in *Wadelton*.

Finally, FDA argues that concerns about Sovaldi and Harvoni's prices and domestic and international distribution are irrelevant because they are unrelated to the subject of Plaintiffs' request. Defs.' Mem. 22-24. But, as Plaintiffs have noted, foreign countries often rely on the FDA's review in making their own approval decisions. Pls.' Rule 56(a)1 Statement ¶¶ 68-70. Yet, the drugs' effectiveness in treating foreign population is questionable precisely because the clinical trials submitted to the FDA may not have adequately tested genetic variations of the virus prominent abroad, or potential resistance among unstudied groups of people. Pls.' Rule 56(a)1 Statement ¶ 69; Pls.' Mem. 15.

Thus, FDA's attempts to demonstrate that the requested information is not a matter of current exigency to the public are meritless.

3. Public and scientific concerns with Sovaldi and Harvoni's safety, efficacy, and cost-effectiveness are not speculative or conjectural.

Contrary to FDA's contention that concerns over Sovaldi and Harvoni's safety, efficacy, and cost-effectiveness are based on "speculation" and "conjecture," Defs.' Mem. 20, serious questions exist with respect to each of these issues. As discussed above, *supra* at 10-11, studies suggest that Sovaldi and Harvoni's effectiveness may vary across patient groups. Pls.' Rule 56(a)1 Statement ¶¶ 60-63. FDA has revised the drugs' warning labels. Pls.' Rule 56(a)1 Statement ¶ 58. And researchers have reported severe adverse events in patients treated with sofosbuvir, an active ingredient present in the drugs. Pls.' Rule 56(a)1 Statement ¶ 59.

FDA insists that "none of FDA's expedited programs alter the statutory standards for drug approval," and that, in the case of Priority Review, "FDA directs additional resources and manpower to the application's review so that the agency can complete its normal, rigorous review within the target review period." Defs.' Mem. 5-6. However, as the studies that Plaintiffs cited to the FDA demonstrate, FDA's expedited review may not be equally effective

notwithstanding the agency's efforts. According to peer-reviewed studies, drugs like Sovaldi and Harvoni that are approved under the FDA's expedited review programs are less likely to be safe than those subject to regular review. Pls.' Rule 56(a)1 Statement ¶ 56; Pls.' Mem. 4-5 & Ex. A, at 2 n.6.

Additionally, FDA argues that its decision to approve Harvoni for an 8-week treatment plan for non-cirrhotic patients with low pre-treatment viral load was consistent with the sponsor's request. *See* Defs.' Mem. 21. However, this argument elides the lack of data supporting this decision. Even assuming that the approved treatment plan was consistent with the sponsor's request, the ION-3 Trial that formed the basis for that decision relied on a post-hoc analysis of the data, a methodology that masks differences in Harvoni's efficacy across subpopulations. *See* Pls.' Rule 56(a)1 Statement ¶ 57; Pls.' Mem. 5. While the sponsor's researchers have since attempted to demonstrate that subgroup differences do not exist with respect to a limited number of patient characteristics, *see* Kris V. Kowdley et al., Correspondence, *Analysis of Subgroup Differences in the ION-3 Trial of Ledipasvir-Sofosbuvir in Chronic Hepatitis C Infection*, 2 Open F. Infectious Disease, Spr. 2015, attached hereto as Exhibit B, they nevertheless concede that "given the few number of failures overall, post hoc analysis is not a substitute for real-world data derived from thousands of patients, which will ultimately determine the patient subpopulation in whom 8 weeks of treatment is the optimal duration," *id*. at 1.

Apart from these concerns regarding Sovaldi and Harvoni's safety and efficacy, FDA downplays the effects of the drugs' prices on patient access. *See* Defs.' Mem. 23 n.20. But, as discussed, state agencies and other insurers have rationed access to these drugs, and disclosing clinical trial data would allow the public to assess whether such rationing is being made on a

scientifically sound basis, preventing certain populations from receiving treatment. Pls.' Rule 56(a)1 Statement ¶¶ 64, 66-67; Pls. Mem.' 15. Tellingly, FDA argues that insurers would not necessarily respond to the scientific evidence, but it does not dispute that the information is needed for the purpose of determining whether people are being denied treatment based on faulty assumptions that they would not benefit. *See* Defs.' Mem. 23 n.20.[17] It cannot be the case that to obtain expedited treatment a requester must somehow prove that policymakers will choose to act upon the information that is obtained. Expedited processing is thus warranted simply because the information sought is of current exigency to the public.

C. Failure To Obtain the Requested Documents Could Reasonably Be Expected To Affect the Life or Physical Safety of an Individual.

Plaintiffs are also entitled to expedited processing on the separate and independent statutory basis that "failure to obtain requested records . . . could reasonably be expected to pose an imminent threat to the life or physical safety of an individual." 5 U.S.C. § 552(a)(6)(E)(v)(I). Without access to the requested information, physicians may continue to prescribe Sovaldi and Harvoni to patients for whom the drugs are unsafe or ineffective, and insurers may continue to ration access, denying treatment to those who might benefit. Pls.' Mem. 17-18; *supra* at 10-13.

FDA's counterarguments break no new ground. Instead, FDA again repeats its contentions that Plaintiffs' arguments for granting expedited processing—the need to determine Sovaldi and Harvoni's safety, efficacy, and cost-effectiveness—do not "identify a significant recognized interest that will be compromised by a delayed response to their FOIA request" or are "purely speculative." Defs.' Mem. 30. As explained above, these contentions ignore the ongoing

[17] FDA argues that the release of the requested information will not affect state insurers' decisions to withhold access because those insurers "mak[e] judgments based on policy or moral concerns," which "are not necessarily influenced by science." Defs.' Mem. 23 n.20. But access to the clinical testing data would prevent those insurers from using uncertainty as a shield. *See* Pls.' Mem. 15.

harms caused by the public's inability to independently evaluate the clinical trial data that supported these drugs' approval, *see supra* at 10-13, and should be rejected.

Moreover, FDA has effectively abandoned the rationale that it put forward in denying Plaintiffs' administrative appeal. *See* Defs.' Mem. 30 n.22. In that decision, FDA relied on its own FOIA regulations that require requesters to show that failure to disclose would threaten the life or safety of a "specific individual" and that the request is made by a "family member, medical or health care professional, or other authorized representative" of that individual. Pls.' Mem. Ex. G, at 2 (citing 21 C.F.R. § 20.44(a)(1)). FDA denied Plaintiffs' administrative appeal, in part, on the basis of these two requirements, which are not found in the FOIA statute. *See* 5 U.S.C. § 552(a)(6)(E)(v)(I). The agency now abandons that rationale, disclaiming any reliance on its regulation whatsoever. [18]

But on judicial review, FDA can only rely on the reasons for denial that it offered at the administrative level. *See infra* at 27-28. This Court should not credit FDA's belated attempt to argue that Plaintiffs do not meet the less stringent statutory standard. In any case, because failure to expedite this case could indeed be expected to affect the life or safety of an individual—many individuals, in fact—this Court should grant expedited processing on this basis as well.

D. The Court Should Reject FDA's Efforts To Manipulate the Record.

In an attempt to distract from the merits of Plaintiffs' arguments, FDA advances two inconsistent evidentiary points. On the one hand, FDA asserts that Plaintiffs' April 1, 2015 letter and FDA's April 3, 2015 response fall outside the administrative record and should therefore be

[18] FDA asserts that those regulations are lawful, but provides no explanation whatsoever for why that might be so. *See* Defs.' Mem. 30 n.22. This is because the regulations are in fact unlawful. The statute imposes neither of the requirements found in the regulations. *See* 5 U.S.C. § 552(a)(6)(E)(v)(I). FDA's unilateral attempt to impose additional requirements that narrow the scope of expedited processing exceeds its authority. *See Al-Fayed*, 254 F.3d at 307; Pls.' Mem. 18.

disregarded on judicial review.[19] Defs.' Mem. 10. On the other hand, FDA seeks to put into evidence declarations that introduce new facts and rationales purportedly justifying their denial of Plaintiffs' request for expedited processing. Defs.' Rule 56(a)1 Statement ¶¶ 16-17, 19-72; Defs.' Mem. 4-9, 19-23, 27; Ex. 2, ECF No. 37-5; Ex. 3, ECF No. 37-6. In doing so, FDA effectively takes the position that an agency may hide the true basis for its decision until it denies an administrative appeal and then refuse to consider evidence submitted to address its concerns, while at the same time preserving its own ability to dramatically supplement the record on judicial review. This approach is patently unfair and this Court should reject it.

The Court should find that Plaintiffs' April 1, 2015 letter supplementing the administrative record was before the agency and is properly considered by this Court. It should also find that FDA's denial of expedited processing must stand or fall based solely on the reasons it gave at the administrative stage.

1. Plaintiffs have adduced a proper record for judicial review.

Contrary to FDA's assertion, Plaintiffs' April 1, 2015 letter was properly before the FDA

[19] FDA contends that Plaintiffs' statements in support of their expedited processing claim—contained in the FOIA request, administrative appeal, and April 1, 2015 letter to the FDA—were not submitted in admissible form, in violation of Local Rule 56(a)3. FDA appears to simply misunderstand the Court's rules. Plaintiffs placed the entire administrative record before the Court in accordance with this Court's individual rules of practice, which do not require use of a separate attorney's affidavit authenticating exhibits. *See Pre-Trial Preferences for Hon. Victor A. Bolden*, U.S. District Ct. for District Conn. *available at* http://www.ctd.uscourts.gov/content/victor-bolden (last visited Feb. 19, 2016). Because the primary question for the Court at this stage is whether FDA properly applied the expedited processing standard to the record before it, plaintiffs do not believe it is necessary or even appropriate to submit affidavits or other extrinsic evidence to prove the truth of the facts in the administrative record. *See* 5 U.S.C. § 552(a)(6)(E)(iii); *Delta Air Lines, Inc. v. Exp.-Imp. Bank of United States*, 85 F. Supp. 3d 436, 446 (D.D.C. 2015) (noting in the APA context that analogous Federal Rule of Civil Procedure 56(c) does not apply "because of the limited role of a court in reviewing the administrative record"). Of course, if the Court disagrees, Plaintiffs stand ready to submit such evidence and would request an opportunity to do so before the Court rules on the merits of the expedited processing issue.

and is part of the administrative record here. In addition, it is appropriate for the Court to consider certain additional evidence that arose after this lawsuit was filed, as an exercise of the Court's equitable discretion.[20]

The April 1, 2015 letter was a proper response to supposed deficiencies that FDA raised for the first time in denying Plaintiffs' administrative appeal. It is the agency's responsibility to craft a denial letter that is "reasonably calculated to put the requester on notice as to the deficiencies in the requester's case." *Friends of Coast Fork v. U.S. Dep't of Interior*, 110 F.3d 53, 55 (9th Cir. 1997); *Judicial Watch, Inc. v. Gen. Servs. Admin.*, No. Civ. A. 98-2223(RMU), 2000 WL 35538030, at *5 (D.D.C. Sept. 25, 2000). FDA failed to meet this standard in summarily denying the expedited processing claim contained in Plaintiffs' FOIA request. Pls.'

[20] Specifically, Plaintiffs ask that this Court consider the following exhibits submitted in support of Plaintiffs' expedited processing claim: Exhibit O, ECF No. 19-16 (Sheri Fink, *Ebola Crisis Passes, but Questions on Quarantine Persist*, N.Y. Times (Dec. 2, 2015) (covering release of GHJP report on Ebola quarantine practices)); Exhibit P, ECF No. 19-17 (Jon N. Jureidini et al., *Clinical Trials and Drug Promotion: Selective Reporting of Study 329*, 20 Int'l J. Risk & Safety Med. 73 (2008) (discussing selective reporting of clinical trial data)); Exhibit Q, ECF No. 19-18 (Harlan Krumholz et al., *What Have We Learnt from Vioxx?*, 334 Brit. Med. J. 120 (2007) (discussing lessons learned from Vioxx case)); Exhibit R, ECF No. 19-19 (Hélène Fontaine, Bradyarrhythmias Associated with Sofosbuvir Treatment, 373 New Eng. J. Med. 1886 (2015) (reporting adverse events of bradyarrythmia caused by sofosbuvir)); Exhibit S, ECF No. 19-20 (Chistoph Sarrazin, *The Importance of Resistance to Direct Antiviral Drugs in HCV Infection in Clinical Practice*, J. Hepatology (forthcoming 2015) (describing sofosbuvir resistance)); Exhibit T, ECF No. 19-21 (Susanna Naggie et al., *Ledipasvir and Sofosbuvir for HCV in Patients Coinfected with HIV-1*, 703 New Eng. J. Med. 705 (discussing sofosbuvir/ledipasvir use in HIV co-infected patients)); and Exhibit U, ECF No. 19-22 (Olga Khazan, The True Cost of an Expensive Medication, Atlantic, Sept. 25, 2015 (discussing cost and rationing of Sovaldi and Harvoni)).

Each of these exhibits (with the exception of Exhibits P and Q) puts forward developments that occurred subsequent to the filing of Plaintiffs' requests that further underscore the urgency of the requests and the validity of the underlying concerns. Plaintiffs have also submitted certain evidence in opposition to Defendants' Rule 56(a)1 statement. *See* Pls.' Rule 56(a)2 Statement, attached hereto as Exhibit C. It is appropriate for the Court to exercise its discretion to consider all of these materials. *See Landmark Legal Found.*, 910 F. Supp. 2d at 277 (considering as a matter of equitable discretion requester's additional justifications supporting the urgency of its request).

Rule 56(a)1 Statement ¶¶ 25-26; Pls.' Mem. 7; Ex. C, ECF No. 19-4. Plaintiffs submitted an administrative appeal, and, in response, HHS offered new justifications for denying Plaintiffs' claim, citing regulations it believed Plaintiffs had not satisfied and asserting for the first time that Plaintiffs had not shown they were primarily engaged in disseminating information. Pls.' Rule 56(a)1 Statement ¶¶ 32-33; Pls.' Mem. 7; Ex. G. Once put on notice of the alleged deficiencies in their request, Plaintiffs submitted a letter amply justifying their entitlement to expedited processing. Rather than engaging seriously with that letter and reconsidering its prior determination, HHS merely reiterated its invitation to litigate. Defs.' Rule 56(a)1 Statement ¶¶ 14-15; Ex. 1, Attach. 1, ECF No. 37-4.

FDA makes much of the fact that its regulations do not provide for reconsideration, but it is equally true that nothing in the FOIA statute or the relevant regulations forbids it, and agencies appear to regularly engage in the practice. *See* 5 U.S.C. § 552; 45 C.F.R. § 5.34; *see also, e.g.*, *Am. Civil Liberties Union v. U.S. Dep't of Homeland Security*, 810 F. Supp. 2d 267, 270-71 (D.D.C. 2011) (in which the agency assessed an organization's request for reconsideration having already denied its administrative appeal). Moreover, FDA's refusal to consider additional evidence in the circumstances here does not comport with the purpose of administrative exhaustion, which is to give the agency "an opportunity to correct its own mistakes with respect to the programs it administers before it is haled into federal court." *Woodford v. Ngo*, 548 U.S. 81, 89 (2006) (quoting *McCarthy v. Madigan*, 503 U.S. 140, 145 (1992)). Instead of taking the opportunity to reconsider and potentially correct mistakes, FDA argues, in effect, that it may manipulate the administrative process in such a way as to deprive a FOIA requester of any opportunity to address the merits of FDA's objections. This is both unfair and inefficient. As the

Supreme Court has observed, "Claims generally can be resolved much more quickly and economically in proceedings before an agency than in litigation in federal court." *Id.*

Even if Plaintiffs' April 1, 2015 letter was not part of the administrative record, this Court could still consider it. "[B]ecause FOIA does not limit a Court's equitable powers," a Court may consider evidence submitted outside the administrative record in reviewing de novo a requester's expedited processing claims. *Landmark Legal Found.*, 910 F. Supp. 2d at 277. Plaintiffs' expedited processing arguments were put before the agency, and there is no reason for this Court to refuse to consider them now.

2. Expedited processing cannot be denied on the basis that certain administrative submissions were not certified.

FDA asserts that Plaintiffs have forfeited their expedited processing argument because they did not include certifications in their original request and administrative appeal, as provided by statute. Defs.' Mem. 11. This argument fails, for three reasons. First, FDA may not now rely on this justification, having not advanced it at any point during the administrative process. "[O]n judicial review, the agency must stand on whatever reasons for denial it gave in the administrative proceeding." *Friends of Coast Fork*, 110 F.3d at 55; *see also, e.g.*, *Eakin v. U.S. Dep't of Defense*, No. SA-10-CV-0784 FB NN, 2011 WL 5925570, at *8 (W.D. Tex. Nov. 28, 2011); *Manley v. Dep't of Navy*, No. 1:07-CV-721, 2008 WL 4326448, at *2 (S.D. Ohio Sept. 22, 2008). Second, Plaintiffs cured this defect by certifying the April 1, 2015 letter they submitted to the FDA. That letter also explicitly certified to the truth of the statements in Plaintiffs' original request and appeal. Pls.' Mem. Ex. H, at 9. Third, courts have considered claims for expedited processing even if the certification is missing. For instance, in *Tripp v. Department of Defense*, the only case FDA cites to support their argument on this point, the court noted that the agency did not raise the plaintiffs' failure to certify as grounds for denying their

request for expedited processing and proceeded to "address the substance of the parties' arguments." 193 F. Supp. 2d 229, 241 (D.D.C. 2002). For all of these reasons, the Court should not accept FDA's belated attempt to deny expedited processing on a technicality.

3. FDA has improperly submitted additional facts and justifications for denying expedited processing.

This Court should likewise reject FDA's attempt to bolster its determination with extra-record evidence advancing additional justifications for its decision to deny expedited treatment. When the record on judicial review is constrained by statute, as it is here, agencies are limited to defending the reasons they advanced at the administrative level. 5 U.S.C. § 552(a)(6)(E)(iii); *Forest Watch v. U.S. Forest Serv.*, 410 F.3d 115, 119 (2d Cir. 2005). Agencies can only introduce new evidence, if at all, in order to "illuminat[e] the original record." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 82 (2d Cir. 2006); *see also Judicial Watch*, 2000 WL 35538030, at *4 ("[T]he court may not consider new reasons by the agency that were not advanced in its denial letter.").

Here, FDA provides additional declarations replete with extra-record evidence to oppose Plaintiffs' expedited processing claim. *See* Decl. Laurie Himebaugh, Defs.' Mem. Ex. 2, ECF No. 37-5 ("Himebaugh Decl."); Decl. Debra B. Birnkrant, Defs.' Mem. Ex. 3 ("Birnkrant Decl."). FDA nowhere indicates that the facts adduced in these declarations were actually part of the agency's original decision-making process. *See* Himebaugh Decl. ¶¶ 1-2; Birnkrant Decl. ¶¶ 1-8. And, indeed, much of the evidence provided has no plausible bearing on the original decision. It is improperly introduced here in a belated effort to respond to Plaintiffs' arguments or cast aspersions on Plaintiffs themselves. *See, e.g.*, Birnkrant Decl. ¶ 32; Defs.' Rule 56(a)1 Statement ¶¶ 69-70 (asserting that FDA has no concerns regarding the evidence supporting the drugs' approval, safety, or efficacy); Birnkrant Decl. ¶ 30; Defs.' Rule 56(a)1 Statement ¶ 65

(pointing out that Plaintiffs did not participate in a public meeting); Himebaugh Dec. Attach. 1 (introducing a June 2015 *Wall Street Journal* article containing a quote from Gregg Gonsalves). This Court should therefore disregard the new facts and rationales advanced in the Birnkrant and Himenbaugh declarations.

II. DEFENDANTS ARE NOT ENTITLED TO A STAY OF PROCEEDINGS.

In FOIA cases, stays are extraordinary remedies, awarded only in "exceptional circumstances" in order to accommodate an agency that finds its FOIA office in unforeseeably dire straits. Pls.' Mem. 19-20. FDA asks this Court, in effect, to allow this exception to swallow the rule. Nothing in FDA's reply establishes that it is entitled to a stay. To the contrary, FDA's belated effort to supplement the record with copious additional evidence only underscores the weakness of its position and the lengths to which it must go to obfuscate the one central fact: for years, FDA has systematically violated FOIA's guarantee of prompt disclosure.[21]

[21] Upon reply, FDA introduces new evidence regarding DIDP's past FOIA workload and methods of calculating that workload, staffing changes and hiring methods, evolving criteria for assigning FOIA requests to its "Complex Track," and various other matters. *See* Supp. Decl. Nancy B. Sager ("Supp. Sager Decl."). Accordingly, Plaintiffs request the Court's leave to file this Sur-reply to respond to this abundance of new facts. Courts in the Second Circuit and the District of Connecticut have held that parties may move for leave to file a sur-reply in these circumstances. *See, e.g.*, *Bayway Ref. Co. v. Oxygenated Mktg. & Trading A.G.*, 215 F.3d 219, 227 (2d Cir. 2000) ("Where new evidence is presented in a party's reply brief or affidavit in further support of its summary judgment motion, the district court should permit the nonmoving party to respond to the new matters prior to disposition of the motion." (quoting *Litton Indus., Inc. v. Lehman Bros. Kuhn Loeb Inc.*, 767 F.Supp. 1220, 1235 (S.D.N.Y. 1991))); *Travelers Indem. Co. v. Excalibur Reins. Corp.*, No. 3:11-CV-1209, 2013 WL 4012795, at *3 (D. Conn. Aug. 5, 2013) ("When new evidence appears in opposition papers, the non-moving party should seek leave, or may receive the Court's sua sponte permission, to file a sur-reply to address those new issues." (citing *Guadagni v. N.Y. City Transit Auth.*, 387 Fed. App'x 124, 125 (2d Cir. 2010); *Goins v. JBC & Assocs.*, 352 F. Supp. 2d 262, 270 n.3 (D. Conn. 2005)). Indeed, parties ought to move for leave to file a sur-reply in response to new evidence and arguments. *See, e.g.*, *Guadagni*, 387 Fed. App'x at 125-26 (stating that the plaintiff should have moved for leave to file a sur-reply in response to "new material," including new facts and arguments, introduced on reply).

FOIA mandates that agencies respond to requests within twenty days. 5 U.S.C. § 552(a)(6)(A). FDA seeks a stay that will grant it *two years* to provide an initial response. Defs.' Mot. for Stay 11. This two-year delay is no "exceptional circumstance." In fact, a two-year response time has been the status quo at FDA for nearly 10 years, if not more. *Infra* at 32-34. Courts have repeatedly denied FDA's requests to endorse this flagrant violation of FOIA's mandate of timely disclosure. Pls.' Mem. 21. In this case, FDA makes the same arguments that failed before, asserting that it faces an "unexpected" workload of "complex" cases and has been increasing its staffing and reducing its backlog. But all of these supposed efforts have amounted to nothing at all for FOIA requesters. Individuals seeking information from FDA still must wait two years even to obtain a response, just as they did when FDA was denied stays in 2007, 2008, and 2011.

This state of affairs is unacceptable with respect to any agency. It is particularly unacceptable with respect to an agency that has a responsibility to protect the health and safety of Americans. The purpose of judicial review in FOIA cases is to hold agencies to the obligations imposed upon them by Congress. FDA has shown no exceptional reasons why it should be allowed to evade the law's command of prompt disclosure. If this Court grants a stay it would, in effect, endorse FDA's serially delinquent FOIA practice and bless the status quo. Denying a stay merely requires FDA to abide by those obligations to the public that Congress has imposed upon all governmental agencies.

A. Exceptional Circumstances Justifying a Prolonged Stay of Proceedings Do Not Exist.

FDA's own declarations belie the notion that its Division of Information Disclosure and Policy ("DIDP") now faces exceptional circumstances. Since at least 2007, FDA has pressed almost exactly the same arguments regarding DIDP's workload that it puts forward now. Pls.'

Mem. 20-22. DIDP has had more than 8 years to adjust and adapt, yet FDA still claims that the various obligations of that office constitute "exceptional circumstances." Defs.' Mem. 31-32. The argument cannot withstand scrutiny. The elements of DIDP's workload FDA seeks to highlight are routine and have been so for years.

In addition, FDA's selective citation and presentation of data regarding DIDP's FOIA workload fails to demonstrate that DIDP is faced with exceptional circumstances. FDA initially sought a stay based on data from 2012-2014. Defs.' Mot. for Stay & Mem. Supp. Thereof 12-13, ECF No. 16; Decl. Nancy B. Sager ¶ 22, ECF No. 16-1. In opposition, Plaintiffs pointed out that declarations FDA had filed in earlier cases seeking stays demonstrated that FDA has in fact been facing the same, supposedly "exceptional" circumstances for years. Pls.' Mem. 20-22. On reply, apparently recognizing that its initial arguments were inadequate, FDA has introduced additional data—and "corrected" data it submitted to courts in prior litigation—to bolster its position. *See* Supp. Sager Decl. But even the expanded data cannot satisfy FDA's burden. This Court should reject FDA's arguments as insufficient and deny a stay of proceedings.

1. DIDP's workload is not exceptional.

FDA cannot identify any aspects of its workload that are presently "exceptional." For instance, FDA makes much of DIDP's obligations under the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 ("FDAAA"), going so far as to claim that Plaintiffs "ignored" this burden. Defs.' Mem. 32. But as Plaintiffs previously argued, FDA has made nearly identical assertions regarding its FDAAA workload in three recent FOIA cases. And in each of those cases, the court rejected FDA's arguments. *See* Pls.' Mem. 20-22. Indeed, in *Buc v. U.S. Food & Drug Admin.*, the most recent of those cases, FDA itself "concede[d] that it ha[d] largely resolved many of the implementation issues associated with FDAAA-related disclosure obligations." 762 F. Supp. 2d 62, 69-70 (D.D.C. 2011). In any event,

the court in *Buc* explicitly rejected the notion that FDAAA, and other statutory obligations that have not been "'newly' imposed," are evidence of exceptional circumstances. *Id*. Almost ten years later, FDA's arguments are even less plausible. DIDP's apparently-continuing struggle to fulfill its statutory obligations cannot excuse FDA's delinquent FOIA processing time and serve as a basis for a stay.

Unable to point to new or exceptional burdens, FDA places great weight on *CareToLive v. U.S. Food & Drug Admin.*, No. 2:08-CV-00005, 2008 WL 2201973 (S.D. Ohio, May 22, 2008), an outlier where the agency successfully obtained a stay. *See, e.g.*, Defs.' Mem. 34. But as Plaintiffs previously demonstrated—and FDA has ignored—FDA's motion to stay in that case was essentially unopposed. Pls.' Mem. 32. Indeed, the plaintiff in that case offered "nothing but speculation and innuendo" and "utterly failed" to respond "in any way" to FDA's assertions. *CareToLive*, 2008 WL 2201973, at *2, 4.

More importantly, courts *denied* FDA a stay in three other FOIA cases, decided contemporaneously with *CareToLive*, in which there *was* meaningful opposition. *See Buc*, 762 F. Supp. 2d at 66-73; *Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp 2d 55, 59-64 (D.D.C. 2008); *Bloomberg*, 500 F. Supp. 2d at 374-76; *see also* Pls.' Mem. 21-24, 27-28. In those cases, the reviewing courts did not, as FDA asserts, decline to give FDA's declarations a "presumption of good faith." Defs.' Mem. 37. Instead, those three decisions weighed plaintiffs' arguments against FDA's assertions—the very same ones offered here—and found those assertions wanting. This Court should do the same.

Additionally, FDA seeks to massage the new data introduced on reply regarding DIDP's incoming requests and backlog in an attempt to show that DIDP's workload is exceptional. *See* Defs.' Mem. 33-35. But FDA's own declarations concede that DIDP has faced only a recent

"*steady* increase" of requests, Defs.' Mem. 31 (emphasis added), rather than the unanticipated "deluge" of requests that is required to obtain a stay, *Fiduccia v. U.S. Dep't of Justice*, 185 F.3d 1035, 1041-42 (9th Cir. 1999). [22]

Finally, FDA reasserts that DIDP faces increasingly complex requests, but provides no data to substantiate that assertion. Defs.' Mem. 33. Despite submitting a seventeen-page declaration on reply, FDA has not given an account of even a single "existing request that has overwhelmed its resources and staff." *Bloomberg*, 500 F. Supp. 2d at 375. As in *Buc*, FDA's declarations in this case fail to provide sufficient "evidence in the record to draw any concrete or meaningful conclusions as to" the complexity of the requests faced by DIDP. *Buc*, 762 F. Supp. 2d at 68. Rather, FDA asserts broad trends in the types of requests faced by DIDP unsupported by any concrete measurement. Defs.' Mem. 33-34. Following *Buc*, this Court should hold that FDA's unspecific, "blanket" statements about the supposed complexity of the requests it has received do not demonstrate "exceptional" circumstances that could justify the extraordinary relief of a stay of proceedings. 762 F. Supp. 2d at 68.

2. DIDP has not made reasonable progress in reducing its backlog.

FDA asks this Court to endorse a standard two-year waiting period for FOIA requestors that appears to have remained unchanged for a decade. Defs.' Mot. for Stay 1, 20. Despite all of

[22] In order to try to show an upward trend in requests, FDA arbitrarily begins measuring the percent change in requests faced by DIDP in 2012. These three years of data emphasized on reply are hardly more statistically representative than the two offered initially. *See* Defs.' Mem. 31; Sager Decl. ¶ 22. The broader trend—dating back more than a decade—is of greatly decreased number of FOIA requests. Supp. Sager Decl. ¶ 5. Elsewhere, FDA looks back to 2003 to describe the size of its backlog, because in that instance widening the lens serves FDA's interest in magnifying the apparent reduction in that backlog. Defs.' Mem. 35.

Of course, all of these statistical tricks serve merely to hide the fact that FOIA requesters seeking information from the FDA still must wait two years to get a response to their requests. This was true ten years ago, and it remains true today. A reduced number of FOIA requests in FDA's backlog means nothing if the requesters must wait just as long as ever to receive a response.

FDA's relative reductions and claimed gains in efficiency, *see* Supp. Sager Decl. ¶ 10, FOIA requestors have nothing to show for FDA's supposed improvements, *see* Pls.' Mem. 3-6. Just as it has done four previous times in the past ten years, FDA asks this Court to give it two years to provide an initial response to a FOIA request.[23] It strains belief to call such consistent and extensive delay "progress."

Furthermore, FDA offers no data to controvert Plaintiffs' analysis of DIDP's reduced efficiency and the drastic difference in backlog reduction from 2003-2009 and 2012-2014. Pls.' Mem. 29-31. Indeed, FDA's own statistics demonstrate that the pace of DIDP's backlog reduction has slowed. Defs.' Mem. 35-36. Plaintiffs' analysis further confirms that FDA's purported progress is illusory and is consistent with the unchanging length of time FDA requires FOIA requesters to wait before their requests are processed. DIDP has been aware of systemic problems since 2003 and claims that the raw number of requests in their backlog has decreased. Supp. Sager Decl. ¶¶ 8, 14-15. Therefore, it must be the case that DIDP's remaining requests are processed more and more slowly, forcing FOIA requestors to continue to endure the same, overlong waits for any kind of response.

FDA makes much of DIDP's improvements with regards to requests in its "simple track," but is silent regarding changes in DIDP's response times to complex requests, which is to say,

[23] In each of its most recent FOIA cases, FDA has requested stays allowing it about two years to respond to plaintiffs' requests. *See Buc*, 762 F. Supp. 2d at 63-64 & n.1 (request submitted October 22, 2009; stay requested until "early September 2011"); *Gov't Accountability Project*, 568 F. Supp. 2d at 57-58 (request submitted June 27, 2007; stay requested until June 2009); *CareToLive*, 2008 WL 2201973, at *1-2 & n.3 (request submitted August 15 but received September 11, 2007; stay requested until October 18, 2009); *Bloomberg*, 500 F. Supp. 2d at 372-73 (request submitted February 2, 2006, and received February 28, 2006; stay requested until August 2008).

any request requiring more than cursory review. Sager Decl. ¶ 29(b).[24] FDA gives no indication that DIDP's changes in procedure or reduction in backlog have improved its ability to process supposedly "complex" request, like the one here.

Ironically, the declaration FDA's submitted on reply touts DIDP's efforts a decade ago to reduce DIDP's FOIA backlog by negotiating with requesters. Supp. Sager Decl. ¶ 15(b). To judge from the FDA's posture in the present case, DIDP has abandoned or limited that practice. Indeed, FDA has refused even to entertain Plaintiffs' proposal that DIDP process a small slice of the requested data now, so that the parties can get on with the business of litigating whether FDA and Gilead may properly withhold that information. Pls.' Mem. 8-9. Because FDA has not made "reasonable progress" in reducing its backlog and wait times, FDA is not entitled to a stay that would halt all progress in this case.

3. DIDP has adequate resources.

FDA admits that DIDP's resources are "ever-increasing." Sager Decl. ¶ 30. It cannot therefore contend that it does not have "adequate resources" and that its extraordinary delay should be accommodated on this basis. FDA has not "describe[d] a situation in which DIDP's staffing levels have dropped precipitously at the same time as the agency has faced an increased workload." *Gov't Accountability Project*, 568 F. Supp. 2d at 62. Indeed, since 2009, DIDP's staff

[24] As FDA acknowledges, any request that requires more than three hours' work will be shunted to the "complex" queue, where it will idle for two years. Supp. Sager Decl. ¶ 13(d). This means that a requester will be thwarted if she seeks any documents that might conceivably require redaction, or which could require any amount of internal consultation. The upshot is that if a requester seeks anything remotely controversial, they will be systematically stymied by the FDA. This status quo plainly subverts FOIA's mandate to open government activity to public scrutiny.

has increased by 21 percent, closely tracking the increase in requests received during that time. Supp. Sager Decl. ¶ 11.[25]

FDA argues that this Court should consider DIDP's non-FOIA-related disclosure efforts in order to determine whether it has "adequate resources." Defs.' Mem. 38 n.28.[26] But to hold that DIDP has inadequate resources because it dedicates resources to non-FOIA disclosure efforts would be perverse. FDA has a *statutory obligation* to respond to requests under FOIA within twenty business days. 5 U.S.C. § 552(a)(6)(A). DIDP cannot unilaterally determine that there are other, superior means by which it may disclose information and thereby elude its duty to respond to FOIA requests within the mandated length of time. Indeed, endorsing FDA's approach would, in effect, allow FDA to put all "complex" requests on the backburner, thereby frustrating disclosure of precisely the information that FDA would prefer not to disclose proactively. FDA's attempts to justify a fourteen-month stay by reference to burdens of its own making should be denied.

B. FDA's Failure To Respond to Plaintiffs' Request with Due Diligence Defeats Its Request for a Stay of Proceedings

FDA is not entitled to a stay for the further reason that it has not responded to Plaintiffs' request with "due diligence." FDA would have Plaintiffs—and this Court—wait for 14 months before even beginning to litigate potential withholdings. But FDA has already stated it plans to oppose disclosure of "much, if not all, of the information" Plaintiffs have requested under FOIA

[25] Like FDA's decision to measure the change in requests from 2012 and change in backlog from 2003, FDA's choice to point to the change in DIDP's staff since 2009 is entirely arbitrary. *Supra* at 32 n.22.

[26] FDA suggests that the court in *Electronic Privacy Information Center* supports this contention. *See* Defs.' Mem. 38 n.28. However, the court's decision in that case only recognized the extraordinary burdens on the FBI immediately after the September 11 terrorist attacks. No. 02-CV-0063, 2005 U.S. Dist. LEXIS 18876 (D.D.C. Aug. 31, 2005).

Exemption 4. Answer 11, ECF No. 13. Indeed, Gilead, the manufacturer of the drugs in question, has intervened precisely in order to assert the confidentiality of the requested information. Gilead Sciences' Mot. Intervene; Gilead Sciences' Mem. Supp. Mot. Intervene 6, 8. FDA has refused to proceed to orderly litigation of those issues now—for example, by processing a representative sample of the key types of documents in question, as Plaintiffs have suggested. Pls.' Mem. 8-9.

Furthermore, because Plaintiffs have demonstrated a compelling and extraordinary need for the information requested, FDA's first-in first-out system cannot in any case establish its due diligence in responding to Plaintiffs' request. *Supra* at 32-34; *see also Bloomberg*, 500 F. Supp. 2d at 376. Such compelling need further establishes that prioritizing Plaintiffs' request would not be "unfair to other requestors." Defs.' Mem. 39; *see also* Pls.' Mem. 26-27.

In addition, FDA's reliance on DIDP's non-FOIA "measures" to establish its due diligence is misplaced. Defs.' Mem. 39 n.31. FOIA requires that an agency demonstrate due diligence in responding to "the request" at issue in the case. 5 U.S.C. 552(a)(6)(C)(i); *Gov't Accountability Project*, 568 F. Supp. 2d at 64 (scrutinizing "[d]efendants' conduct in responding to [plaintiffs'] FOIA request, as opposed to FOIA requests in general"). Measures such as proactive postings and organizational adjustments are not directed at Plaintiffs' request in particular and are thus wholly irrelevant to the question of due diligence. FDA offers no evidence to suggest otherwise, and there is none.

FDA simply has not demonstrated any of the statutory requirements for being granted a stay. FDA attempts to cast its routine and long-held obligations as "exceptional" and finds progress where there is only stagnation. Even where the other parties stand ready to proceed and FDA has itself contemplated the merits of this case, FDA seeks to justify continued delay. FDA contends that unless it obtains a stay, plaintiffs will "jump the queue" Defs.' Mem. 39. But

denying FDA a stay here would not give Plaintiffs any special treatment. Rather, it would enforce FOIA's deadlines upon a serially delinquent agency. Conversely, granting FDA the stay it seeks would endorse the agency's delinquency and deprive FOIA requesters of the only remedy that FOIA provides against its systematic, unlawful delay: judicial review. This Court should deny FDA's motion to stay these proceedings.

CONCLUSION

For these reasons, Plaintiffs' cross-motion for expedited processing should be granted, FDA's cross-motion opposing expedited processing should be denied, and FDA's motion to stay proceedings through December 2016 should also be denied.

Respectfully submitted,

MEDIA FREEDOM AND INFORMATION ACCESS CLINIC, YALE LAW SCHOOL[27]

By: /s/ Jonathan M. Manes
Jonathan M. Manes, ct29574
Amanda Lynch, Law Student Intern
Yurij Melnyk, Law Student Intern
Nora Niedzielski-Eichner, Law Student Intern, Application Pending
Ben Picozzi, Law Student Intern
P.O. Box 208215
New Haven, CT 06520-8215
Tel: (203) 432-9387
Fax: (203) 432-3034
jonathan.manes@yale.edu
dschulz@lskslaw.com
amanda.lynch@clinics.yale.edu
yurij.melnyk@clinics.yale.edu
nora.niedzielski-eichner@clinics.yale.edu
ben.picozzi @clinics.yale.edu

David A. Schulz
321 West 44th Street, Suite 1000
New York, NY 10036
Tel: (212) 850-6100
Fax: (212) 850-6299
dschulz@lskslaw.com

Counsel for the Plaintiffs

Dated: February 19, 2016
New Haven, CT

[27] This memorandum has been prepared by the Media Freedom and Information Access Clinic, a program of the Abrams Institute for Freedom of Expression at Yale Law School. Nothing in this memorandum should be construed to represent the official views of the law school.

CERTIFICATE OF SERVICE

I certify that on February 19, 2016, this Memorandum was filed with the Clerk of the Court using the Court's CM/ECF docketing system, which will mail a copy of all counsel of record capable of receiving electronic pleadings. Parties may access this filing through that system.

/s/ Jonathan M. Manes
Jonathan M. Manes, ct29574