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 December 7, 2015

PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT ON THEIR CLAIM FOR EXPEDITED PROCESSING

Pursuant to Federal Rule of Civil Procedure 56, Plaintiffs Treatment Action Group ("TAG") and Global Health Justice Partnership ("GHJP") respectfully move for partial summary judgment on their claim that they are entitled to expedited processing of their Freedom of Information Act request by Defendants. The reasons for granting this motion are set forth in the accompanying Memorandum of Law and attachments.

Respectfully submitted,

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Dated: December 7, 2015
New Haven, Connecticut

ORAL ARGUMENT REQUESTED

CERTIFICATE OF SERVICE

I certify that on December 7, 2015, this Motion 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.

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MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR STAY AND IN SUPPORT OF PLAINTIFFS' CROSS-MOTION FOR EXPEDITED PROCESSING

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PRELIMINARY STATEMENT

Plaintiffs Treatment Action Group ("TAG") and Global Health Justice Partnership ("GHJP") filed this action under the Freedom of Information Act, 5 U.S.C. § 552 ("FOIA") to compel the Food and Drug Administration ("FDA") and its parent agency, the Department of Health and Human Services ("HHS"), to disclose clinical test data and other information submitted to FDA during its recent approval of two drugs used to treat hepatitis C ("HCV"), Sovaldi and Harvoni.

Plaintiffs seek the underlying trial data for Sovaldi and Harvoni in order to permit independent scientific scrutiny of the safety and efficacy of these drugs, which is otherwise impossible. Access to the data regarding these drugs is especially important for a number of reasons. First, FDA approved these drugs through an accelerated process, known as the "Breakthrough Therapy" designation program, which permits expedited clinical testing and, therefore, increases concerns regarding oversights and errors in the approval process. Scientists have questioned whether the size of clinical trial groups for both Sovaldi and Harvoni were sufficient to demonstrate their safety and efficacy. Second, a huge number of patients have been prescribed these two drugs in a very short time period. About 210,000 patients have taken Sovaldi and Harvoni already, and that number is expected to reach 250,000 by the end of the year. When a drug is prescribed so widely, so quickly, it is imperative that scientists and doctors have access to as much data as possible about its effect. Third, the drugs are extremely expensive and, as a result, state insurers have rationed treatment in various ways among the Hepatitis C-infected population, which includes many vulnerable individuals struggling with HIV or substance abuse disorders. These restrictions are not currently evidence based. Access to the underlying data would allow such decisions to be based on science, rather than on speculation or prejudice.

Recent public health catastrophes highlight the importance of releasing the raw clinical data. FDA approved Merck's Vioxx on the basis of clinical trial data that was, as usual, kept hidden from the public. Years later, it became clear that the drug was associated with thousands of heart attacks and strokes. When the raw clinical data was eventually released, independent third parties determined that FDA's review missed problems that were evident in the data, and that scientists could have foretold the cardiovascular risks years earlier—*and* have potentially saved thousands of lives—if they had had access to the data sooner.

For the same reasons, there is a compelling need for the data Plaintiffs seek about Sovaldi and Harvoni. Yet FDA has now moved for a 14-month stay of all proceedings in this case, which follows the 11 months that FDA has not apparently taken any action on the request except to deny Plaintiffs' application for expedited treatment. Moreover, FDA has indicated that it plans to assert various exemptions over the material sought, so the 14-month stay would be but a prelude to protracted litigation over the lawfulness of FDA's withholding. FDA has also refused to take up Plaintiffs' offer to negotiate a case management plan that would move this matter along in a reasonable and expeditious manner.

Plaintiffs are entitled to expedited processing—and the motion for a stay must be denied—due to the urgent public health and safety interests in the material sought. A stay is also inappropriate because defendants cannot establish that FDA's FOIA operation faces "exceptional circumstances," nor can they establish that FDA has processed the request with "due diligence."

Granting FDA the lengthy stay that they seek here would simply reward FDA's delinquent performance in responding to FOIA requests. It would send an unmistakable signal to other individuals seeking all but the most basic information from the FDA that, unless they are willing to wait years in order to get a response, they might as well not bother. Given FDA's

crucial responsibility for safeguarding public health, and given FOIA's clear mandate of prompt agency disclosure, this Court should deny the stay and order FDA immediately to process Plaintiffs' request.

FACTUAL BACKGROUND

I. PROMPT DISCLOSURE OF CLINICAL TRIAL RECORDS IS NECESSARY TO ENSURE THE SAFETY AND EFFICACY OF NEWLY-APPROVED DRUGS.

FDA has a crucially important mission: to ensure that drugs marketed to the public are safe and effective. Local Rule 56(a)1 Statement ¶ 38 ("SOF"). It carries out this mission by requiring the sponsor of new drug to conduct clinical trials and to submit the results of those trials to FDA for review. SOF ¶ 39. Once approved, FDA releases summary reports regarding these trials, but the underlying raw data from the studies are not shared with the public, and neither are the detailed protocols regarding the design of the clinical trials. SOF ¶ 40. Without this information, outside scientists, researchers, and public health professionals cannot independently assess the adequacy and reliability of the studies upon which FDA's approval of a new drug is based. SOF ¶ 41. Nor can they review FDA's performance in approving the design of the studies and reviewing their results. SOF ¶ 41. Without access to the underlying data, errors, omissions, and obfuscations in the studies cannot be unearthed, and may only come to light years later when reports of adverse events among patients pile up. *See* SOF ¶¶ 42-47.

In order to protect public safety and health, it is therefore necessary to have public access to raw clinical trial data and related information. The data underlying the approval allows for third-party oversight; doctors, scientists, and other medical professionals may examine the rigor of the original clinical trials and have a starting point to conduct trials of their own.

Recent experience with two drugs—Paxil and Vioxx—demonstrates the critical importance of prompt disclosure of raw clinical data. *See* SOF ¶¶ 44-45. Both drugs had caused a

number of adverse effects in patients, effects that had been overlooked due to poor clinical trial design. GlaxoSmithKline and Merck, the pharmaceutical companies that produced the drugs, respectively, released the clinical trial information after litigation. Upon the release, independent researchers discovered that GlaxoSmithKline had selectively published trial data and consequently had overstated Paxil's efficacy. SOF ¶ 44. For Vioxx, researchers determined Merck understated the drug's cardiovascular risks. SOF ¶ 45. Independent scrutiny may thus prevent public health and safety catastrophes before they happen. SOF ¶¶ 42-47. Without access to the underlying clinical trial data, it is impossible to tell if there are problems lurking, undiscovered, in the clinical trials. SOF ¶ 41.

II. PROMPT DISCLOSURE OF CLINICAL TRIAL RECORDS REGARDING SOVALDI AND HARVONI IS PARTICULARLY IMPORTANT.

The need for disclosure of underlying clinical trial records is especially pressing for Sovaldi and Harvoni, two revolutionary treatments for HCV that attack the virus in new ways and promise a cure, rather than just a treatment. On December 6, 2013 and on October 14, 2014, FDA approved, respectively, two new drug applications ("NDA") through its "Breakthrough-Therapy" designation program: NDA No. N204671 for sofosbuvir—marketed as Sovaldi—and NDA No. N205824 for sofosbuvir/ledipasvir—marketed as Harvoni. SOF ¶ 55. This accelerated program allowed for both drugs to be more rapidly available to individuals suffering from HCV. *See* SOF ¶ 55. Approximately 3.2 million people in the United States are infected with the virus. SOF ¶ 50.

The rapid release of these two drugs has raised a number of pressing public health concerns. There is significant concern that the clinical trials submitted to FDA under the "Breakthrough Therapy" designation sacrifice safety for expediency. SOF ¶ 56. As a result, drugs approved through such means have historically been more likely to be later withdrawn

than drugs that have not. SOF ¶ 56. Recent FDA actions also suggest a need for more careful scrutiny with respect to Sovaldi and Harvoni in particular. After the drugs' release, FDA revised warning labels to reflect previously unknown interactions with the antiarrhythmia medication amiodarone. SOF ¶ 58. Moreover, researchers have reported severe events of severe bradyarrhythmia in patients treated with sofosbuvir, an active ingredient in Sovaldi and Harvoni, and warned that the drug is potentially cardio-toxic. SOF ¶ 69. And FDA approved a shorter treatment plan for non-cirrhotic patients with a low viral load based on a post-hoc review of the data, raising concerns of the approval's legitimacy. SOF ¶ 57.

There are already indications that the accelerated approval process may have led FDA to overlook problems lurking in the raw clinical trial data for Sovaldi and Harvoni. For instance, FDA may have overlooked resistance to the drugs in certain key subpopulations. A large number of individuals have a predisposed resistance to NS5A inhibitors, such as ledipasvir, one of the active ingredients in Harvoni. SOF ¶ 60. Certain mutations in HCV can render NS5A inhibitors totally ineffectual. SOF ¶ 61. And researchers have noted that little is known about patients infected with variants of the virus other than Genotype 1, one of six distinct HCV variants. SOF ¶ 62. Furthermore, in a clinical trial of HIV/HCV coinfected patients, all ten individuals who were not cured with Harvoni were African American. SOF ¶ 64. Given these drugs may be less effective for individuals from certain racial and ethnic groups, data from clinical trials are crucial for determining the root cause of inefficacy, and for determining whether other subpopulations may likewise see no benefit, or increased risk.

These concerns are only made more pressing by the inordinately high cost of the drugs. Initially, the cost for a full course of Solvadi and Harvoni was $84,000 and $96,000, respectively—$1,000 per pill. SOF ¶ 53. This high cost burdens state insurers who cover more

than half of those infected with HCV and forces them to ration treatment to only certain segments of the HCV population—withholding it from high prevalence populations. SOF ¶¶ 66-67. State Medicaid programs have denied access on a variety of potentially arbitrary—or even prejudicial—grounds. For example, at least half of state programs have devised policies restricting access to Sovaldi and Harvoni to patients who have already suffered liver damage and who have not abstained from alcohol or other drugs. SOF ¶¶ 67. Access to the underlying data would allow researchers to determine whether these and other rationing decisions are justified. SOF ¶ 65. Absent access to this information, life-saving HCV treatments will continue to be withheld without a sound evidentiary basis. ¶¶ 65-67.

III. PLAINTIFFS HAVE REQUESTED RECORDS ESSENTIAL TO DETERMINING THE SAFETY AND EFFICACY OF SOVALDI AND HARVONI.

On December 17, 2014, the Treatment Action Group ("TAG") and the Global Health Justice Partnership ("GHJP") submitted identical FOIA requests to FDA and its parent organization, the Department of Health and Human Services ("HHS"). SOF ¶ 18; Letter from Tracy Swan et al. to Dep't of Heath & Human Servs. & U.S. Food & Drug Admin. 3 (Dec. 17, 2014) (attached hereto as "Ex. A"). The request sought eight categories of information. SOF ¶¶ 19-20. Generally, Plaintiffs seek the following documents: (1) application materials related the NDA and "Breakthrough" designation, (2) materials detailing clinical trial designs, (3) the raw data from such clinical trials, and (4) communications between Gilead and FDA concerning clinical trials. SOF ¶¶ 19-20. Given the important issues described above, and the fact that physicians continue to prescribe Sovaldi and Harvoni to tens of thousands of patients, Plaintiffs sought expedited processing for the raw clinical trial data. SOF ¶ 22. Further, Plaintiffs requested the data in its native electronic format so that researchers could easily utilize the information in assessing the safety and efficacy of the drugs. SOF ¶ 21.

IV. FDA HAS UNREASONABLY DELAYED PROCESSING OF PLAINTIFFS' REQUESTS, DESPITE PLAINTIFFS' GOOD FAITH EFFORTS TO NEGOTIATE A PROCESSING SCHEDULE.

At every stage, FDA has delayed the processing of this time-sensitive request and has rebuffed Plaintiffs' good faith efforts to negotiate a reasonable plan to move at least parts of this case forward expeditiously. Defendants initially denied Plaintiffs' request for expedited processing of their FOIA request on December 22, 2014, providing no reason for the denial but instead citing the statute without explanation. SOF ¶¶ 25-26; Letter from Sarah Kotler to Meredith Berger 1 (Dec. 22, 2014) (attached hereto as "Ex. C"). Defendants did not at that time indicate when they would begin to process the request. *See* SOF ¶ 26. By January 8, 2014, defendants had failed to respond to the request within the twenty-business days required of even non-expedited requests. SOF ¶ 27; 5 U.S.C. § 552 (a)(6)(A)(ii).

On January 26, 2015, Plaintiffs filed a timely administrative appeal from both the denial of expedited processing and the constructive denial of the initial request. SOF ¶ 28; Letter from Tracy Swan et al. to U.S. Dep't of Health & Human Servs. (Jan. 26, 2015) (attached hereto as "Ex. D"). Defendants responded with a letter on February 19, 2015, and shifted from their original explanation. Defendants denied the appeal on the grounds that the request had been placed in the "complex queue" and that Plaintiffs' had failed to provide "sufficient information" to demonstrate a "compelling need" for the information. SOF ¶¶ 32-33; Letter from Catherine Teti to Meredith Berger 2 (Feb. 19, 2015) (attached hereto as "Ex. G"). The letter indicated that FDA would need up to 24 months in order to respond to the request. SOF ¶ 34.

While the denial of Plaintiffs' appeal was nearly as conclusory as the initial denial, it at least indicated which prerequisites for expedited treatment FDA believed Plaintiffs had not satisfied. In response, TAG and GHJP sought reconsideration of the denial of expedited

treatment and supplemented the administrative record with additional evidence meant to address the supposed deficiencies identified in FDA's denial of Plaintiffs' appeal. SOF ¶ 35; Letter from Tracy Swan et al. to Sarah Kotler & Catherine Teti (Apr. 1, 2015) (attached hereto as "Ex. H"). In particular, the letter, dated April 1, 2015, provided further evidence and details establishing that TAG and GHJP are organizations primarily engaged in disseminating information to the general public; that an urgency to inform the public exists; and that disclosure is necessary to address an imminent threat to life and safety. SOF ¶ 35. Plaintiffs sent the letter to both FDA FOIA office and appellate authority, specifically seeking reconsideration of the denial of expedited processing. Plaintiffs did not receive any response. SOF ¶ 36. Unwilling to wait up to 2 years simply to receive a substantive response to their FOIA request despite the urgent public need for the information sought, Plaintiffs filed suit to enforce the request on June 25, 2015. SOF ¶ 36.

Since this litigation commenced, FDA has continued to delay and has rebuffed efforts to resolve this dispute in a reasonable and expeditious manner. In August, FDA requested an extension of their time to answer the Complaint. *See* Mot. for an Extension of Time, ECF. No. 10. Plaintiffs agreed with the understanding that FDA would meet with them soon after filing the Answer in order to discuss a case management plan. SOF ¶ 75. In response to a request from counsel at FDA at that time, Plaintiffs' counsel provided an overview of the information Plaintiffs sought and, in response, FDA indicated it would confirm a date for a meeting. SOF ¶ 75.

Plaintiffs heard nothing from FDA thereafter. Four weeks after the Answer was filed, Plaintiffs' counsel contacted Defendants' counsel on October 24, 2015, seeking again to establish a time to discuss the future progress of the case. SOF ¶ 76. Plaintiffs reiterated this

request twelve days later on November 5, 2015. Defendants rejected all of the times that Plaintiff proposed for a meeting and never proposed any times of their own. SOF ¶¶ 77-78. Instead, on November 12, 2015—the day that FDA filed the present motion to stay—Defendants' counsel notified Plaintiffs that the motion to stay would be filed imminently. SOF ¶ 79.

On that day, Plaintiffs' counsel finally was able to speak with FDA's counsel. In the course of the conversation, Plaintiffs proposed to negotiate a reasonable schedule that would avoid unnecessary litigation over a stay. Specifically, Plaintiffs proposed that FDA could commence processing a subset of the information sought sooner than others, perhaps focusing first on the raw clinical trial data. FDA stated—as it has now reiterated, *see* Decl. of Nancy B. Sager ¶¶ 37-38, ECF No. 16-1 ("Sager Decl.")—that it anticipated withholding much of the information requested under FOIA's exemption for confidential commercial information, 5 U.S.C. § 552(b)(4). SOF ¶ 80. Plaintiffs explained that precisely for that reason, they would prefer to negotiate a schedule that would enable the parties to litigate these likely claims of exemptions at an early date, rather than delay those inevitable legal disputes for well over a year while the entire case was stayed. FDA refused to engage in any such negotiations. SOF ¶ 80. Instead, FDA filed the present motion that same day. SOF ¶ 81.

Plaintiffs ask the Court to order FDA promptly to respond to Plaintiffs' request, disclosing any non-exempt material and stating its basis for refusing to produce the rest. As noted, FDA has indicated that it plans to invoke exemptions to refuse to produce the information sought. In light of the pressing public health and safety implications of denying disclosure, this Court should require the parties to reach the merits of those issues as soon as possible. Indeed, FDA has recently litigated and lost its claim that essentially the same kind of clinical trial data is exempt under FOIA. *See* Order Re: Def.'s Mot. for Summ. J., *AIDS Healthcare Found. v. U.S.*

Food & Drug Admin., No. CV 11-07925 MMM (JEMx) (C.D. Cal. Aug. 6, 2013), ECF No. 60. If the agency persists in pressing the same arguments here, as it has indicated it will, Plaintiffs respectfully submit that no legitimate interest is served by delaying adjudication of those issues until 2017, at the earliest. To the contrary, the life and safety of HCV patients demands the most expeditious resolution of this lawsuit.

ARGUMENT

I. PLAINTIFFS ARE ENTITLED TO EXPEDITED PROCESSING.

FOIA requires agencies to make "records promptly available," 5 U.S.C. § 552(a)(3)(A), and to "determine within 20 days . . . whether to comply with such request." 5 U.S.C. § 552(a)(6)(A)(i). A requestor is entitled to even faster treatment—known as "expedited processing"—if the requestor "demonstrates a compelling need" for the requested materials. 5 U.S.C. § 552(A)(6)(E)(iii). Compelling need exists if (1) the requester is a "person primarily engaged in disseminating information" and an "urgency to inform the public concerning actual or alleged Federal Government activity" exists; or (2) "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." 5 U.S.C. § 552(A)(6)(E)(v).

An agency's decision to deny expedited processing is subject to judicial review. 5 U.S.C. § 552(a)(6)(E)(iii). The reviewing court "shall determine the matter de novo," and the agency bears the "burden" of "sustain[ing] its action." 5 U.S.C. § 552(a)(4)(B); *Al-Fayed v. C.I.A.*, 254 F.3d 300, 304 (D.C. Cir. 2001).

TAG and GHJP are entitled to expedited processing. They are "primarily engaged in disseminating information" and, given the urgent public health and safety implications of the information sought, there is both an "urgency to inform the public" and a risk of "imminent

threat to the life or physical safety." 5 U.S.C. § 552(A)(6)(E)(v).

A. Plaintiffs Are Public Health Policy Organizations Whose Primary Mission Is Public Education and Disseminating Information to the Public.

Both TAG and GHJP are "primarily engaged in disseminating information." 5 U.S.C. § 552(A)(6)(E)(v). TAG is an independent AIDS research and policy think tank dedicated to fighting for better treatment, vaccines, and cures for HIV-related diseases. SOF ¶ 2. To fulfill its mission, TAG publishes training manuals and other documents to provide accurate and timely information about hepatitis prevention, care, and treatment is available 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. SOF ¶¶ 3-8. Additionally, TAG hosts public conferences and publishes additional information for public consumption on its websites. SOF ¶ 7. TAG's work receives broad public attention and has been the subject of an Academy-Award-nominated documentary film, *How to Survive a Plague*. SOF ¶ 8.

Similarly, GHJP's primary objectives are to facilitate open science, community engagement, and public health. SOF ¶ 11. GHJP is an initiative of the Yale Law School and Yale School of Public Health. SOF ¶ 9. GHJP regularly publishes policy papers directed to the general public. SOF ¶¶ 12-15. And GHJP's faculty directors publish academic and public interest articles discussing public health issues, their research, and access to medicines. SOF ¶ 16. GHJP makes this information publically available on its website and has received significant media attention for its work in major publications like the *New York Times*. SOF ¶¶ 13, 17; Sheri Fink, *Ebola Crisis Passes, but Questions on Quarantine Persist*, N.Y. Times (Dec. 2, 2015), http://www.nytimes.com/2015/12/03/health/ebola-crisis-passes-but-questions-on-quarantines-persist.html (attached hereto as "Ex. O"). Thus, TAG and GHJP are not meaningfully distinguishable from other policy organizations found to be "primarily engaged in disseminating

information." *See, e.g.*, *Leadership Conference on Civil Rights v. Gonzalez*, 404 F. Supp. 2d 246, 251 n.2, 259-60 (D.D.C. 2005) ("nonpartisan coalition" formed "to promote enactment and enforcement of effective civil rights legislation and policy" qualifies as a "person primarily engaged in disseminating information").

FDA has improperly denied that Plaintiffs meet this requirement. FDA first noted its disagreement that TAG and GHJP were primarily engaged in disseminating information in its decision on Plaintiff's administrative appeal. SOF ¶ 33. In that decision, FDA summarily concluded that TAG and GHJP were not primarily engaged in disseminating information because FDA's regulations require requestors to show that they "primarily engaged in disseminating information *to the general public not merely a narrow interest group*." Ex. G, at 2 (quoting 20 C.F.R. § 20.44(c)) (emphasis added).[1]

FDA's conclusion is erroneous for two reasons. First, as shown above, TAG and GHJP disseminate information the general public, not narrow interest groups. TAG and GHJP publish their reports online for public consumption and target a broad range of audiences, including physicians, patients, lawyers, and other constituencies. SOF ¶¶ 1-17. These activities are consistent with those of other organizations found to be engaged in disseminating information to the public. *See Leadership Conference on Civil Rights*, 404 F. Supp. 2d at 251 n.2, 259-60.

Second, even if TAG and GHJP were primarily engaged in disseminating information to "interest groups," the statute does not impose this limitation. *See* 5 U.S.C. § 552(A)(6)(E)(v). FDA's regulations are unlawful to the extent that they purport limit expedited processing to

[1] FDA's memorandum repeats its conclusion that GHJP and TAG are not persons "primarily engaged in disseminating information," but FDA continues to provide no explanation for this conclusion. Defs.' Mot. for Stay and Mem. in Supp. Thereof 20 n.11, ECF No. 16 ("Defs.' Mot. for Stay").

requestors who do not disseminate information to interest groups. The statute's language authorizes agencies to expand access to expedited processing, but not to contract access beneath the statutory minimum. *See* 5 U.S.C. § 552(A)(6)(E)(i) (requiring agencies to grant expedited processing "in cases in which the person requesting the records demonstrates a compelling need; *and* in other cases determined by the agency" (emphasis added)). While an agency may "issue regulations setting forth the procedures by which it will make expedition determinations," it may not "offer its own definition of 'compelling need.' That term is defined by FOIA itself, and because the definition applies across the government, district courts may not defer to any individual agency's effort to elaborate upon that definition—whether through case-specific determinations or through regulations." *Al-Fayed*, 254 F.3d at 307.

B. There Is an Urgent Need for the Requested Information To Permit Independent Review of Questions Regarding the Safety and Efficacy of Sovaldi and Harvoni.

Plaintiffs also satisfy the other requirements for expedited processing because there is an "urgency to inform the public," 5 U.S.C. § 552(A)(6)(E)(i), and the requested information "has a particular value that will be lost if not obtained and disseminated quickly," 21 C.F.R. § 20.44(c). In determining whether there is an "urgency to inform," courts must consider "(1) whether the request concerns a matter of current 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." *Al-Fayed*, 254 F.3d at 310; *Bloomberg L.P. v. U.S. Food & Drug Admin.*, 500 F. Supp. 2d 371, 376-77 (S.D.N.Y. 2007).

Applying these factors, the Southern District of New York has recognized that the public has an urgent need to independently analyze data submitted to FDA by drug manufacturers, including raw data. In *Bloomberg L.P. v. U.S. Food & Drug Administration*, the court granted

the plaintiffs' motion for expedited processing of their request for data submitted by manufacturers to FDA regarding the possible relationship between anti-epileptic drugs and suicidal thoughts. *Id.* at 376-78. The court rejected FDA's contention that the public's knowledge of its inquiry into this relationship did not eliminate the public's urged need for the requested information. *Id.* at 377-78. Further, the court explained that the public's alleged "inability" to understand the raw clinical data did not "lessen[]" this urgency. *Id.* at 378. The same reasoning applies to the data that Plaintiffs' seek here.

FDA does not appear to dispute the third factor for "urgency to inform"—whether the request concerns federal government activity. *See* SOF ¶¶ 26, 33. The other two factors are easily satisfied.

The first factor, whether the request concerns a matter of current exigency, is satisfied for at least four reasons. First, public access to the requested information is crucial in order to permit scientists, physicians, public health professionals, and others to determine whether FDA is properly discharging its core mission of determining, in a timely fashion, whether pharmaceuticals are safe and effective. SOF ¶ 49; *supra* pp. 5-6. Approximately 140,000 patients have been treated with Sovaldi and Harvoni, and this number may increase to 250,000 in 2015. SOF ¶¶ 51-52. Independent analysis is essential identifying important information not uncovered by manufacturers or regulators. SOF ¶¶ 42-47. FDA has already revised the warning labels of these drugs. SOF ¶ 58. Further, FDA approved Sovaldi and Harvoni on an accelerated timeline and with smaller clinical studies than usual, increasing the likelihood of error during the approval process. SOF ¶¶ 55-63. Thus, prompt disclosure of the requested information is needed to ensure that FDA has not sacrificed public health in order to accelerate approval of the drugs.

Second, the public's need for the request information is especially exigent given the high

cost and number of patients treated with these drugs. *Supra* pp. 6-7. A twelve-week course of Sovaldi initially costed $84,000, and a twelve-week course of Harvoni began at $94,500. SOF ¶ 53. However, because of these high costs, state agencies and other insurers have imposed access restrictions, preventing certain populations from receiving treatment. SOF ¶¶ 66-68. In the absence of public access to clinical trial data, these restrictions have not been based on any credible scientific evidence. SOF ¶ 53. In the absence of disclosure, thousands of individuals may be denied access to the drugs on the basis of questionable assumptions about who would not benefit from treatment. SOF ¶ 66-67. Disclosure of the requested information would allow the public to verify whether Sovaldi and Harvoni's prices are justified given their benefits. SOF ¶ 65.

Third, public access to the requested information has international ramifications because FDA approval influences treatment options in other nations—once approved, many other countries follow FDA's lead. SOF ¶ 68. Delaying access to the requested information prevents scientists and other members of the public from independently assessing whether Sovaldi and Harvoni are appropriate for all global populations on which the drug is likely to be used. SOF ¶ 68. The manufacturer has announced distribution agreements for Sovaldi and Harvoni with 91 developing countries, where the HCV-infected population is greater than 100 million. SOF ¶ 70. However, genetic differences among patients and in the virus itself expose populations treated in these countries to risks that may go undetected in the absence of independent testing. For example, the manufacturer plans to make Sovaldi available in countries where most of the infected population is infected with genotypes uncommon on the United States and that have undergone limited testing. SOF ¶ 69. Denying access to the underlying information that plaintiffs seek prevents scientists from properly assessing the scope of this problem.

Fourth, there has been substantial media attention on Sovaldi and Harvoni, underscoring the significant public concern with these drugs. In determining whether a request involves a matter of public exigency, courts have routinely looked to the existence of media reports and other evidence of public interest. *See Gerstein v. C.I.A.*, No. C-06-4643 MMC, 2006 WL 3462658, at *6 (N.D. Cal. Nov. 29, 2006) (granting expedited processing where requested information was "not only newsworthy, but was the subject of an ongoing national debate"); *Am. Civil Liberties Union of N. Cal. v. U.S. Dep't of Defense*, No. C 06-01698 WHA, 2006 WL 1469418, at *7 (N.D. Cal. May 5, 2006) ("[E]xtensive media interest usually is a fact supporting not negating urgency in the processing of FOIA request." (emphasis removed)); *Leadership Conference on Civil Rights*, 404 F. Supp. 2d at 260 (granting expedited processing where administrative record was "full of news reports and magazine articles" about the government activity at issue). Here, the administrative record contains numerous media reports expressing concerns regarding the safety, efficacy, and cost-effectiveness of Sovaldi and Harvoni and the ethical and public health implications of restrictions on patient access. SOF ¶¶ 71-72. Furthermore, public concerns have led the Senate Finance Committee to investigate the drugs' prices. SOF ¶ 73. Thus, consistent with other cases in which courts have granted requests for expedited processing, this case involves information subject of lively public debate.

The second factor for determining "urgency to inform"—whether the consequences of delaying the request would compromise a significant recognized interest—is satisfied for similar reasons. As argued above, delay would prevent the public from independently investigating FDA's approval of Sovaldi and Harvoni, and would expose members of the public to greater health risks because of likely inadequacies in this process and because of uncertainties surrounding the drugs. *Supra* pp. 6-7, 15-16. Further, delay would impede ongoing public

debates about Sovaldi and Harvoni. *Supra* p. 16. Each of these interests is sufficient to satisfy the requirements for expedited processing. *See Bloomberg*, 500 F. Supp. 2d at 378 (urgency to inform existed where FDA's failure to disclose clinical data received from drug manufacturer would result in "harm to the health of the public" based on use of the drug at issue); *Leadership Conference on Civil Rights*, 404 F. Supp. 2d at 260 (urgency to inform existed where DOJ's failure to disclose communications records would "advance the current debate" about federal elections).

Again, FDA failed to provide a reasoned basis for its finding that the requested information is not urgently needed. FDA's denial of Plaintiffs' request merely asserted, without explanation, that the Request does not "demonstrat[e] that there exists an urgency to inform the public concerning actual or alleged Federal Government activity." SOF ¶ 26. FDA's Denial of Administrative Appeal repeats this conclusion without further analysis. SOF ¶ 33; *see also* Defs.' Mot. for Stay and Mem. in Supp. Thereof 19-20, ECF No. 16 ("Defs.' Mot. for Stay"). FDA's conclusory denial of expedited processing simply ignores the overwhelming evidence demonstrating the urgent need for prompt disclosure of the information sought. The Court should order FDA to expedite processing of the request.

C. Plaintiffs Are Entitled to Expedited Processing Because Delay Could Reasonably Be Expected To Pose an Imminent Threat to Life or Safety of an Individual.

GHJP and TAG's request should also be granted expedited processing because FDA's failure to promptly disclose the requested information "could reasonably be expected to pose an imminent threat to the life or safety of an individual," which is a distinct basis for establishing "compelling need" under FOIA. 5 U.S.C. § 552(A)(6)(E)(v)(I). More than 250,000 patients may receive Sovaldi and Harvoni in 2015. SOF ¶ 52. These two drugs were approved on an

accelerated timeline, and are being prescribed to treat some genotypes and for certain patient subpopulations after small and nonrepresentative clinical trials. SOF ¶ 55-63, 68-70; *supra* pp. 5-6, 15-16. Without access to the requested information, practitioners will continue to prescribe Sovaldi and Harvoni without adequately understanding the possible adverse health consequences of these decisions, and states and other insurers will continue to deny access based on incomplete information regarding the drugs' cost effectiveness. SOF ¶¶ 49, 64; *supra* pp. 5-7, 15-16. In short, in the absence of independent review of the clinical information that Plaintiffs' seek, individuals who should receive this life-saving treatment will not; and individuals who should not receive it will.

Notwithstanding this evidence, FDA's has failed to provide any proper grounds for denying expedited processing under this alternate definition of compelling need. FDA's Denial of Administrative Appeal relied on FDA's regulations, which unlawfully contract the statutory entitlement to expedited processing by requiring requesters to show that failure to disclose requested information would threaten the life or safety of a "specific individual," and that the request be made by a "family member, medical or health care professional, or other authorized representative" of that individual. Ex. G, at 2 (citing 21 C.F.R. § 20.44(b)). These regulations radically narrow the statutory standard by limiting both the nature of the threat for which expedited processing is warranted and the range of requesters who can obtain expediting processing on this basis. Plaintiffs cannot be required to satisfy the additional requirements that FDA purports to impose by regulation. *See Al-Fayed*, 254 F.3d at 307. And Plaintiffs meet the standard enacted by the statute, because failure to disclose presents an imminent risk to life or safety of an individual. Expedited processing should be granted on this basis too.

II. DEFENDANTS ARE NOT ENTITLED TO A STAY OF PROCEEDINGS

The court should deny FDA's request for a "14-month stay" because FDA has failed to make the showings FOIA requires for a grant of a stay of proceedings. Defs.' Mot. for Stay 1. A court may stay proceedings to "allow the agency additional time to complete its review of the records" and respond to a FOIA request only where "exceptional circumstances" exist and the agency exercises "due diligence in responding to the request." 5 U.S.C. § 552(a)(6)(C)(i). FDA has done none of these things. Because FDA cannot meet the high bar for obtaining a stay, its motion should be denied.

A. No Exceptional Circumstances Exist To Warrant a Stay

No "exceptional circumstances" exist in this case to justify a stay. 5 U.S.C. § 552(a)(6)(C)(i). The statute specifically provides that delays resulting "from a predictable workload of agency requests" do not constitute exceptional circumstances "unless the agency demonstrates reasonable progress in reducing its backlog of pending requests." 5 U.S.C. § 552(a)(6)(C)(ii). Accordingly, courts have found exceptional circumstances only where an agency is "deluged" with unanticipated requests and its resources are inadequate to respond in a timely fashion. *Fiduccia v. U.S. Dep't of Justice*, 185 F.3d 1035, 1041-42 (9th Cir. 1999); *see also Buc v. U.S. Food & Drug Admin.*, 762 F. Supp. 2d 62, 70-73 (D.D.C. 2011); *Bloomberg*, 500 F. Supp. 2d at 374-75; *Edmonds v. Fed. Bureau of Investigation*, No. Civ. A. 02-1294, 2002 WL 32539613 at 1 (D.D.C. Dec. 3, 2002). Further, the complexity of an agency's requests is not enough to establish exceptional circumstances. Rather, the agency must show that "incoming requests have, on average, become significantly and unexpectedly more complex as of late." *Buc*, 762 F. Supp. 2d at 68; *see also Gov't Accountability Project v. U.S. Dep't of Health &*

Human Servs., 568 F. Supp. 2d 55, 60 (D.D.C. 2008). FDA fails to make any of these showings.[2]

1. FDA's Workload Is Unexceptional.

DIDP's workload does not meet the statute's standards for a stay, which are truly demanding. For instance, *Open America v. Special Watergate Prosecution Force*, 547 F. 2d 605 (D.C. Cir. 1976), the first case granting a stay in FOIA litigation, involved an agency that was faced with "an unforeseen 3,000 percent increase in FOIA requests in one year," H.R. Rep. No. 104-795, at 24 (1996). By contrast, a "slight upward creep in caseload" is "unexceptional" and does not warrant a stay. *See Fiduccia*, 185 F.3d at 1042. FDA alleges only a slight, short-term uptick in requests—amounting to only approximately 300 additional requests per year, where DIDP annually processes thousands—and a supposed "upward trend" in the number of FOIA requests received by DIDP. Sager Decl. ¶ 22. This is not the sort of wild fluctuation or "unanticipated deluge" necessary to establish "exceptional circumstances." *Buc*, 762 F. Supp. 2d at 69. This is especially clear because DIDP received roughly the same absolute number of requests in 2006-2008, when two stays were denied, as it did in 2012-2014, the only years for which FDA offers data in this case. *See* Sager Decl. ¶ 22; Decl. of Yurij Melnyk ¶ 5 (attached hereto as "Ex. BB") ("Melnyk Decl."); *Buc*, 762 F. Supp. 2d at 67-68; *Gov't Accountability Project*, 568 F. Supp. 2d at 59-60; *Bloomberg*, 500 F. Supp. 2d at 374-75.

In *Buc*, *Government Accountability Project*, and *Bloomberg*, the most recent cases in

[2] Moreover, FDA's submissions focuses entirely on one component, DIDP, to the exclusion of the rest of the FDA. This focus is misplaced. FOIA imposes obligations upon agencies as a whole, not their subcomponents. See 5 U.S.C. § 552. FDA has offered no evidence whatsoever that the "agency" as a whole faces "exceptional circumstances" and that there are not other parts and subdivisions whose FOIA staff might be able to pick up DIDP's slack. To the contrary, FDA acknowledges that DIDP has in the past increased its resources in order to contend with its FOIA workload. *See* Sager Decl. ¶ 30. Granting a stay based only upon the representation of a single subdivision would allow agencies to evade their obligations under FOIA by making improper intra-agency funding and personnel decisions and allocations.

which FDA has moved for a stay, courts repeatedly held that FDA does not face "exceptional circumstances." *Buc*, 762 F. Supp. 2d at 67-70; *Gov't Accountability Project*, 568 F. Supp. 2d at 59-63; *Bloomberg*, 500 F. Supp. 2d at 374-75. In all of these cases, FDA pointed to essentially the same set of facts that it contended justified a stay: that DIDP's FOIA requests constituted about 25 percent of those received by FDA; and that DIDP had to respond to subpoenas, document production for lawsuits, proactive document postings, and document requests from Congress and other governmental entities, as well as implement the disclosure provisions of the Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 ("FDAAA"). *See* Def.'s Mot. for a Stay 14-16, *Buc*, 762 F. Supp. 2d 62 (No. 1:10-cv-00293 (CKK)), ECF No. 7 (attached hereto as "Ex. Y"); Def.'s Mot. for an Open America Stay & Opp'n to Pl.'s Mot. for J. on the Pleadings 9-18, *Gov't Accountability Project*, 568 F. Supp. 2d 55 (Civ. A. No. 07-01702 (CKK)), ECF No. 7 (attached hereto as "Ex. Z"); Mem. in Supp. of Def.'s Mot. for a Stay of Proceedings 7-9, *Bloomberg*, 500 F. Supp. 2d 371 (No. 06-Civ-6552 (VM)), ECF No. 8 (attached hereto as "Ex. AA"). In *Buc*, the District of Columbia noted that FDA presented "strikingly similar" evidence to that offered in *Government Accountability Project*, and rejected FDA's contentions point-by-point. 762 F. Supp. 2d at 67-71. In all three of these cases, the court denied FDA's motion for a stay. *See Buc*, 762 F. Supp. 2d at 73; *Gov't Accountability Project*, 568 F. Supp. 2d at 64; *Bloomberg*, 500 F. Supp. 2d at 379.

FDA presents essentially the same facts in this case as it did in *Buc*, *Government Accountability Project*, and *Bloomberg*, describing DIDP's workload as including "approximately 30% of all FOIA requests submitted to FDA . . . document requests by [governmental entities]. . . document productions in response to FOIA lawsuits, subpoenas, and discovery," and compliance with the FDAAA. Defs.' Mot. for Stay 5-8. The court should follow

those three cases in finding these circumstances unexceptional.

FDA has not presented any meaningful, principled grounds for distinguishing the present case from those in which it has failed to obtain a stay. First, DIDP's current workload of 30 percent of the FDA's FOIA requests is only slightly greater than the figure of 25 percent that failed to convince the court in *Bloomberg*, *Government Accountability Project*, and *Buc*, and is simply not exceptional. In addition, merely pointing to the fact that DIDP handles inquiries from governmental entities, Defs.' Mot. to Stay, 6, does not indicate that the DIDP's workload is overwhelming or unpredictable—and courts have rejected FDA's claims for exactly this reason. *See*, *e.g.*, *Buc*, 762 F. Supp. 2d at 68 ("[E]ven assuming that th[e] aspect of the DIDP's workload [concerning requests from governmental entities] was once unpredictable or unforeseen, it now appears to be routine."); *Gov't Accountability Project*, 568 F. Supp. 2d at 60-62 (noting that DIDP had been facing requests from governmental entities since at least 2004 and that such burdens thus constituted "more of a predictable agency workload than a deluge of unanticipated responsibility").

Furthermore, FDA has made no record at all of what percent of FOIA requests have been routed to the DIDP in years before 2014, nor what percent are routed to other divisions, nor whether DIDP's workload is significantly greater relative to its resources when compared to other divisions, nor whether other divisions may have tasks other than responding to FOIA requests. In the absence of complete data allowing for a meaningful assessment of the DIDP's workload, the percent of FOIA requests routed to that division is not probative of any relevant inquiry, nor is the fact that DIDP responds to document requests by government entities. *See Buc*, 762 F. Supp. 2d at 69 ("FDA neglects to compare the DIDP's present workload with past levels in such a way that would permit the Court to draw any broader conclusions about the

DIDP's workload as it has developed over time."). The narrow set of data cited by FDA is unrepresentative of DIDP's workload, not to mention FDA's workload as a whole (about which FDA has made no representations at all), and is thus doubly inadequate for the showing required by FOIA for a stay.

Second, FDA attempts to show that "DIDP's workload has increased unexpectedly" since FDA's unsuccessful motions for stays in *Government Accountability Project* and *Bloomberg* — FDA does not mention *Buc*—by identifying three complex requests handled by DIDP in September 2015. Defs.' Mot. for Stay 12 n.5. Once again, there is no indication that these three requests are in any way unusual. FDA offers no evidence that DIDP is not faced with similarly complex tasks on a regular basis, nor of the typical number of pages produced in response to a complex request, nor of the typical number of hours of search and review spent on a complex request. Indeed, FDA points to similar requests processed "in the past few months," Sager Decl. ¶ 19, and unsuccessfully pointed to an even more extensive list of complex tasks and requests in *Government Accountability Project*. *See* Ex. Z, at 13-16.

In the same vein, FDA asserts that a "great number" of requests routed to the DIDP "actually contain[] multiple component requests" and that the number of requests routed to the DIDP thus under-represents the division's workload. Defs.' Mot. for Stay 12. Without context, this claim, too, is empty: the mere number of requests routed to the DIDP is relevant only when the change in that number across years is calculated, and the fact that some of these requests are more complex than others does not in any way show that the DIDP's workload is overwhelming. *See also Fiduccia*, 185 F.3d at 1040 (finding no exception circumstances where queue for larger requests "was delayed because of the increased workload of the FBI unit handling FOIA requests, the shortage of personnel, a big case that happened to come along, an increase in

litigation, and a new law giving priority to requests concerning the assassination of President Kennedy"). In fact, FDA has made the same argument in prior cases, using nearly identical language, and it has repeatedly been rejected. In *Government Accountability Project*, the court found that FDA's claim that "many of the [FOIA] requests [that DIDP receives] actually contain multiple individual requests for documents" did not suggest exceptional circumstances. 568 F. Supp. 2d at 60. In *Buc*, the court offered a carefully reasoned rejection of a similar contention, finding that FDA's declarations' "blanket and rather unilluminating" claims—asserting that because many requests are complex, the mere number of requests received does not reflect the true workload—leave the court unable to "draw any meaningful conclusions." 762 F. Supp. 2d at 68. There is no reason to think that FDA's assertion of hidden complexity should lead to a different result in the present case.

Finally, FDA selectively cites its data to argue that specific complex cases are indicative of a general trend of an increase in the number of such cases. Defs.' Mot. for Stay 12 & n.5, 13. Such an argument cannot stand. The total number of complex requests received by the FDA has actually *decreased* by 20 percent since 2012, and has decreased 55 percent since its peak in 2008. Melnyk Decl. ¶¶ 22-23. FDA has altogether failed to demonstrate that "incoming requests have, *on average*, become significantly and unexpectedly more complex as of late." *Buc*, 762 F. Supp. 2d at 68 (emphasis added). As a result, FDA's cursory attempt to distinguish the instant circumstances from those in *Bloomberg* and *Government Accountability Project* must fail because "at best," FDA has provided "ultimately unproven bases for concluding" that it faces exceptional circumstances. *Buc*, 762 F. Supp. 2d at 70.

2. FDA Has Adequate Resources To Respond to the Current Volume of Requests It Faces.

For "exceptional circumstances" to exist, an agency's resources must be "inadequate to

deal with the volume of" requests that it receives. *Open America*, 547 F.2d at 616. FDA has failed to demonstrate that its existing resources are inadequate to deal with a predictable volume of requests (and indeed fails to make any representation about FDA's resources as opposed to those it has allotted to DIDP). Rather, FDA's own statistics demonstrate that DIDP's resources are "ever-increasing." Sager Decl. ¶ 30. Since 2011, DIDP has added seven full-time staff. *See Buc*, 762 F. Supp 2d at 72; Sager Decl. ¶ 30. 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," having described instead a "predictable agency workload of requests." *Gov't Accountability Project*, 568 F. Supp. 2d at 62-63. In *Electronic Privacy Information Center v. Department of Justice*, the court found exceptional circumstances only upon a showing that FBI's FOIA staff took on numerous additional administrative and litigation duties and that FBI's FOIA resources were diverted to counterterrorism operations in the aftermath of September 11, 2001. No. 1:02-cv-00063, 2005 U.S. Dist. LEXIS 18876, at *13-15 (D.D.C Aug. 31, 2005). And even if DIDP's resources were inadequate to the task before it, FDA has offered no reason why there are insufficient resources in the FDA as a whole are inadequate to respond to DIDP's workload. *Supra* p. 21 n.2. DIDP's workload is predictable while their resources are increasing, and the naked statistics FDA offers cannot conceal the fact that these circumstances are in no way exceptional.

B. FDA Has Not Established That It Has Acted with Due Diligence.

FDA argues that it is nevertheless entitled to a stay because DIDP has exercised due diligence in responding to requests and has achieved "reasonable progress," 5 U.S.C. § 552(a)(6)(C)(ii), in reducing its backlog. Defs.' Mot. for Stay 1. FDA cites three facts in support: (1) its adherence to a first-in first-out processing system, Defs.' Mot. For Stay 9; (2) its "two-

pronged strategy" for reducing its backlog, Defs.' Mot for Stay 14; and (3) certain data regarding its FOIA processing over two years, Defs.' Mot. for Stay 14, 16 (citing Sager Decl. ¶ 22). All three arguments fail, and have previously been rejected.

First, DIDP's mere adherence to a first-in first-out processing system is insufficient to demonstrate due diligence because there is an exceptional need for the information Plaintiffs seek. In *Bloomberg*, the court held that "[w]hile a general showing of an agency processing FOIA requests on a first-in, first-out basis, coupled with a multitrack [sic] processing system may be consistent with due diligence in some instances, this determination should not be automatic, and *fails if extraordinary need is demonstrated*." 500 F. Supp. 2d at 376 (emphasis added). As already shown, plaintiffs have an urgent, compelling need for the information sought. *Supra* pp. 14-18.

FDA's argument that granting Plaintiffs' request to be processed out of turn would "unfairly displace other requests" fails on its own terms, because a first-in first-out system is fair only for "requests that are not urgent." Defs.' Mot. for Stay 19 (*quoting Freeman v. U.S. Dep't of Justice*, 822 F. Supp. 1064, 1067 (S.D.N.Y. 1993)). *Freeman* and *Donham v. U.S. Dep't of Energy*, the other case cited in support of adherence to first-in first-out for reasons of fairness, both concerned non-urgent requests. *See Freeman*, 822 F. Supp. at 1065 (recounting no request for expedited processing or attempt to demonstrate compelling need); *Donham*, 192 F. Supp. 2d 877, 880 (S.D. Ill. 2002) (stating that plaintiff only made claim for expedited processing upon filing of action and making no mention of urgency or need of plaintiff's request). These cases are thus inapposite.

FDA's warnings against a "first to sue, first served system" are likewise misplaced where, as here, Plaintiffs have sued to enforce a time-sensitive request that bears upon the health

of tens of thousands of being patients prescribed Sovaldi or Harvoni. Defs.' Mot. for Stay 19 (*quoting Donham*, 192 F. Supp. 2d at 883). Moreover, given the exceedingly small proportion of FOIA requests that enter litigation—and the high costs and difficulty of doing so—the FDA's concern about jumping the queue is misplaced. Defs' Mot. for Stay 18-19. That is especially true where, as here, Plaintiffs have offered to prioritize and sequence processing of the request in a way that would permit speedy resolution of the most urgent aspects of the request, while delaying others. *See supra* pp. 9-10.[3]

Second, FDA's "two-pronged strategy," for reducing its backlog, Defs.' Mot. for Stay 14, does not constitute "reasonable progress." In at least three prior cases, FDA has made very similar or nearly identical claims regarding this "two-pronged strategy." *See* Decl. of Nancy B. Sager in Supp. Def.'s Mot. for a Stay ¶¶ 23-24, *Buc*, 762 F. Supp. 2d 62 (No. 1:10-cv-00293 (CKK)), ECF No. 7-15 (attached hereto as "Ex. V") (using terms nearly identical to those used in this case); Decl. of Nancy B. Sager ¶¶ 26-27, *Gov't Accountability Project*, 568 F. Supp. 2d 55 (Civ. A. No. 07-01702 (CKK)), ECF No. 7-1 (attached hereto as "Ex. W"); Decl. of Nancy B. Sager ¶¶ 28-35, *Bloomberg*, 500 F. Supp. 2d 371 (No. 06-Civ-6552 (VM)), ECF No. 9 (attached hereto as "Ex. X"). In all three of those cases, the court rejected FDA's motion to stay. *See*

[3] FDA relies on *Fisher v. Federal Bureau of Investigation* for the proposition that processing FOIA requests on a first-in first-out bases demonstrates due diligence. Defs.' Mot for Stay 9, 11, 17 (citing *Fisher v. Fed. Bureau of Investigation*, 94 F. Supp. 2d 213 (D. Conn. 2000)). But that case is readily distinguishable. In that case, the court was not faced with a motion for a *stay*, but a motion to *dismiss* in circumstances where the agency had already "produced a majority of the records [sought] before litigation began," and had reviewed and released the remainder of the documents by the time the court issued its opinion. 94 F. Supp. 2d at 217-18. The court discussed the standard for a stay only to dismiss the requestor's argument that the agency's delay amounted to a denial that could still be litigated even after the agency released responsive documents. *Id.* at 217. Here, by contrast, FDA has released not a single document, nor has it even apparently begun its search to identify the set of responsive documents. Moreover, the plaintiff in *Fisher* made no claim of urgency or compelling need. *Fisher*'s facts thus shed no light on those of this case, and its discussion of *Open America* is irrelevant to the present case.

Bloomberg, 500 F. Supp. 2d at 379; *Gov't Accountability Project*, 568 F. Supp. 2d at 64; *Buc*, 762 F. Supp. 2d at 73.

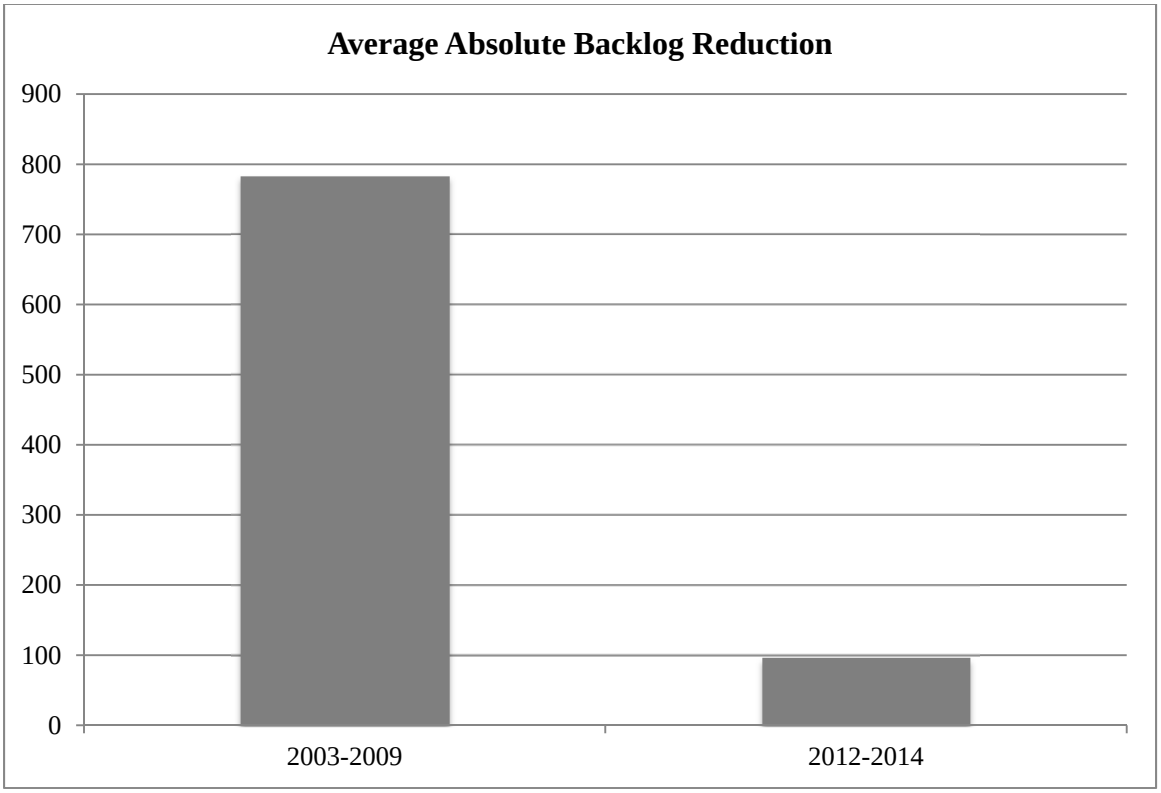
Third, in an attempt to distinguish the present case from those it has previously lost, FDA provides data about DIDP's workload from 2012 to 2014, including the number of new requests received, the number of requests processed, and the number of requests remaining in the backlog. Defs.' Mot for Stay 17; Sager Decl. ¶ 22. As an initial matter, Plaintiffs point out that an analysis of only two years of data is plainly insufficient to show the kind of "progress" necessary to justify a stay. Even if those data did demonstrate drastic progress (and upon careful inspection, it is far from clear that they present any at all), this could be a statistically insignificant blip. The court should not deem FDA to have carried its statutory burden based on only three data points.

Moreover, the data that FDA submits are largely irrelevant to the issue in this case. DIDP has placed plaintiffs' request in the "Complex Track" for FOIA processing. Defs.' Mot. for Stay 2. But the data provided by FDA relates to the backlog of *all* DIDP requests, and FDA provides no specific data for complex requests. Sager Decl. ¶¶ 22, 33. FDA also asserts that it has become increasingly effective in processing simple requests, but this is again irrelevant to its handling of complex requests such as Plaintiffs'. Sager Decl. ¶ 29. Superficially, the data FDA submits shows a 28-percent increase in FOIA requests received, a 13-percent increase in requests processed, and a 32-percent decrease in backlog. Sager Decl. ¶ 22. But as will be demonstrated, a closer inspection of this data and a comparison to an analogous chart presented in *Buc*, Ex. V ¶ 22, makes clear that FDA has not made the reasonable progress the data are meant to show.

While FDA has only submitted data for 2012-2014, Plaintiffs have found access to analogous data for 2003 through 2009 by inspecting the filings in previous cases in which FDA

moved for a stay. Ex. V.[4] Widening the lens to incorporate these additional data points—which were insufficient to justify a stay at the time—demonstrates that FDA's current efforts also fail to demonstrate sufficient "due diligence" to justify a stay.

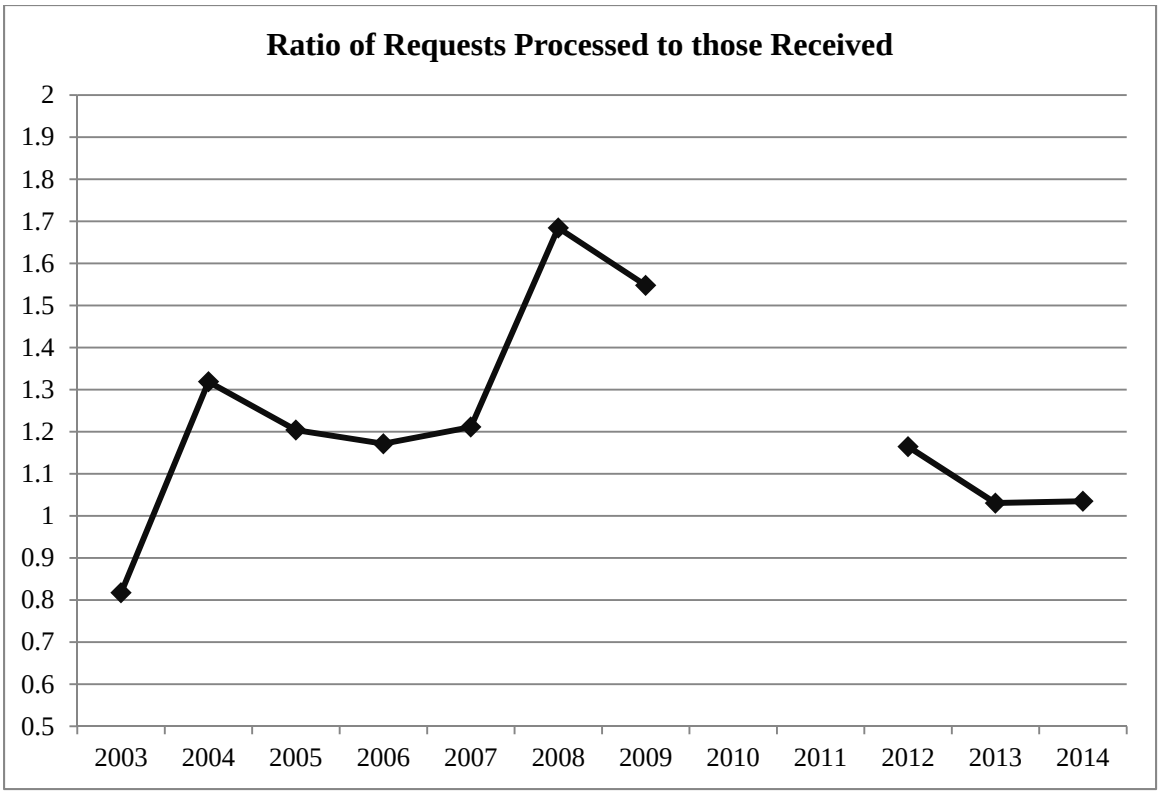
It appears that the past two years are not even an upward blip in DIDP's progress in reducing its backlog: DIDP actually reduced its backlog and processed requests *at a slower rate* in that time than it did between 2003 and 2009. Melnyk Decl. ¶¶ 13-18. Though DIDP's backlog may have decreased in absolute terms between 2012 and 2014, these absolute reductions of 87 and 105 requests pale in comparison to the average yearly reduction of 784 requests between 2003 and 2009. Melnyk Decl. ¶¶ 13-14. The following graph demonstrates the magnitude of this difference:



Melnyk Decl. ¶ 24. In the past two years, DIDP has reduced its backlog by 11 and 15 percent,

[4] FDA does not appear to have publically disclosed data for 2010 and 2011.

while DIDP reduced its backlog by 17 percent on average between 2003 and 2009. Melnyk Decl. ¶¶ 15-16. In addition, DIDP processed 1.16 requests for every new request received in 2012, and 1.03 in 2013 and 2014, but processed on average 1.28 requests for every new request received between 2003 and 2009. Melnyk Decl. ¶¶ 17-18. The following graph demonstrates this decrease in efficiency:



Melnyk Decl. ¶ 25. Even the earlier, superior rates of progress and efficiency were insufficient to merit a finding of "reasonable progress" and a stay of proceedings. *See Buc,* 762 F. Supp. 2d at 70-73. Since that time, DIDP has only become less efficient.

FDA cannot attribute this decrease in efficiency to an increase in average complexity, as it has failed to demonstrate any such increase, *supra* pp. 24-25, and the data thus do not "demonstrate[] reasonable progress in reducing [DIDP's] backlog of pending requests." 5 U.S.C. § 552(a)(6)(C)(ii). If anything, DIDP's effectiveness in reducing its backlog has regressed.

Indeed, the above analysis suggests that FDA has provided data only since 2012 and limited the types of data provided in order to present modest trend lines that are meant to show "reasonable progress," when in fact that progress is slower than before. As the court rejected FDA's arguments of "reasonable progress" in *Buc* in the face of more consistent data and much more drastic reductions, 762 F. Supp. 2d at 70-73, the court should reject the even-weaker versions of those arguments presented here.

Finally, FOIA specifically requires an agency to demonstrate due diligence in responding to "the request" that is the subject of the proceedings in order to obtain a stay. 5 U.S.C. § 552(a)(6)(C)(i); *see also Gov't Accountability Project*, 568 F. Supp. 2d at 64. As previously mentioned, FDA failed to respond to the substance of Plaintiffs' contentions regarding Plaintiffs' entitlement to expedited processing, and instead offered conclusory and shifting justifications for its denial. *Supra* pp. 8-9. Counsel for Defendants also rejected repeated attempts by Plaintiffs' counsel to discuss these proceedings in order to attempt to reach agreement on a reasonable plan to move even part of Plaintiffs' request forward, even though Plaintiffs' counsel had readily cooperated with Defendants' counsel's earlier requests for time and clarification of the request. *Supra* pp. 9-10. FDA's unwillingness to give proper consideration to the urgency of Plaintiffs' Request and its counsel's resistance to any negotiation regarding a case management plan make clear that FDA has not responded to Plaintiffs' Request with due diligence. The court should deny FDA's motion for a stay.

C. Prior Cases in Which FDA Was Grated a Stay Are Obsolete or Irrelevant.

FDA identifies three FOIA cases in which it has been granted a motion for a stay. Defs.' Mot. for Stay 11, 12, 18 (citing *CareToLive v. U.S. Food & Drug Admin.*, No. 2:08-cv-00005, 2008 WL 2201973 (S.D. Ohio, May 22, 2008); *Appleton v. U.S. Food & Drug Admin.*, 254 F.

Supp. 2d 6 (D.D.C. 2003); and *Bower v. U.S. Food & Drug Admin.*, 1:03-cv-00224, 2004 WL 2030377 (D. Maine Aug. 30, 2004)). All are readily distinguishable. *Appleton* and *Bower* were decided more than ten years before Plaintiffs filed their FOIA request, when FDA's FOIA workload and backlog were at their peak. Melnyk Decl. ¶¶ 20-21; Compl. ¶ 6. The statistics cited to support FDA's motions in those cases are obsolete and do not support a finding of exceptional circumstances here. Furthermore, in *Appleton*, the plaintiff made no claim for expedited processing or any special urgency. *Appleton*, 451 F. Supp. 2d at 134-35.

In *CareToLive*, the FDA's factual allegations faced no meaningful opposition. The court adopted FDA's interpretation of its workload, accepting its declarations at face value because the plaintiff offered "nothing but speculation and innuendo" in response. *Id.* at *2. Indeed, the plaintiff in that case filed only a two-page response to the FDA's motion, which the court found "utterly failed" to respond "in any way" to FDA's arguments and assertions, offering only baseless allegations and claims unsupported by the kind of evidence that Plaintiffs offer here. *Id* at *2, 4.

In all of the most recent cases in which plaintiffs have meaningfully challenged FDA's motions for a stay, courts have consistently refused to find exceptional circumstances warranting a stay and any exercise of due diligence. Courts repeatedly found that DIDP's workload is not "vastly in excess of that anticipated by Congress" and that it has failed to make reasonable progress in reducing its backlog. *See Buc*, 762 F. Supp. 2d at 66-73; *Government Accountability Project*, 568 F. Supp at 59-64; *Bloomberg*, 500 F. Supp. 2d at 374-76. This Court should do the same.

CONCLUSION

For these reasons, FDA's motion to stay proceedings should be denied and Plaintiffs' motion for partial summary judgment on their claim for expedited processing should be granted.

Respectfully submitted,

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New Haven, CT

[5] 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.

LIST OF EXHIBITS

Exhibit	Document
A	Letter from Tracy Swan et al. to Dep't of Heath & Human Servs. & U.S. Food & Drug Admin. (Dec. 17, 2014) [FOIA Request]
B	Letter from Pamela A. True to Meredith Berger 1 (Dec. 19, 2014)
C	Letter from Sarah Kotler to Meredith Berger 1 (Dec. 22, 2014) [Denial of Expedited Processing]
D	Letter from Tracy Swan et al. to U.S. Dep't of Health & Human Servs. (Jan. 26, 2015) [Administrative Appeal]
E	Letter from John D. Ivey to Meredith Berger (Jan. 29, 2015)
F	E-mail from Denise Wallace to Amy Kapczynski & Tracy Swan (Jan. 30, 2015)
G	Letter from Catherine Teti to Meredith Berger (Feb. 19, 2015) [Denial of Administrative Appeal]
H	Letter from Tracy Swan et al. to Sarah Kotler & Catherine Teti (Apr. 1, 2015) [Request for Reconsideration]
I	E-mail from Jonathan Manes to Alan Soloway (Aug. 14, 2015)
J	E-mail from Yurij Melnyk to Alan Soloway (Oct. 24, 2015)
K	E-mail from Yurij Melnyk to Alan Soloway (Nov. 5, 2015)
L	E-mail from Alan Soloway to Yurij Melnyk et al. (Nov. 7, 2015)
M	E-mail from Alan Soloway to Yuri Melnyk et al. (Nov. 12, 2015)
N	E-mail from Ben Picozzi to Alan Soloway (Nov. 12, 2015)
O	Sheri Fink, *Ebola Crisis Passes, but Questions on Quarantine Persist*, N.Y. Times (Dec. 2, 2015), http://www.nytimes.com/2015/12/03/health/ebola-crisis-passes-but-questions-on-quarantines-persist.html
P	Jon N. Jureidini et al., *Clinical Trials and Drug Promotion: Selective Reporting of Study 329*, 20 Int'l J. Risk & Safety Med. 73 (2008)
Q	Harlan Krumholz et al., *What Have We Learnt from Vioxx?*, 334 Brit. Med. J. 120, 120-123 (2007)

Exhibit	Document
R	Hélène Fontaine, *Bradyarrhythmias Associated with Sofosbuvir Treatment*, 373 New Eng. J. Med. 1886, 1886-7 (2015)
S	Chistoph Sarrazin, *The Importance of Resistance to Direct Antiviral Drugs in HCV Infection in Clinical Practice*, J. Hepatology (forthcoming 2015)
T	Susanna Naggie et al., *Ledipasvir and Sofosbuvir for HCV in Patients Coinfected with HIV-1*, 703 New Eng. J. Med. 705, 709 (2015)
U	Olga Khazan, *The True Cost of an Expensive Medication*, Atlantic, Sept. 25, 2015, http://www.theatlantic.com/health/archive/2015/09/an-expensive-medications-human-cost/407299
V	Decl. of Nancy B. Sager in Supp. Def.'s Mot. for a Stay, *Buc v. U.S. Food & Drug Admin.*, 762 F. Supp. 2d 62 (D.D.C. 2011) (No. 1:10-cv-00293 (CKK)) (excerpted)
W	Decl. of Nancy B. Sager, *Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp. 2d 55 (D.D.C. 2008) (Civ. A. No. 07-01702 (CKK)) (excerpted)
X	Decl. of Nancy B. Sager, *Bloomberg L.P. v. U.S. Food & Drug Admin*, 500 F. Supp. 2d 371 (S.D.N.Y. 2007) (No. 06-Civ-6552 (VM)) (excerpted)
Y	Def.'s Mot. for a Stay, *Buc v. U.S. Food & Drug Admin.*, 762 F. Supp. 2d 62 (D.D.C. 2011) (No. 1:10-cv-00293 (CKK)) (excerpted)
Z	Def.'s Mot. for an Open America Stay & Opp'n to Pl.'s Mot. for J. on the Pleadings, *Gov't Accountability Project v. U.S. Dep't of Health & Human Servs.*, 568 F. Supp. 2d 55 (D.D.C. 2008) (Civ. A. No. 07-01702 (CKK)) (excerpted)
AA	Mem. in Supp. of Def.'s Mot. for a Stay of Proceedings, *Bloomberg L.P. v. U.S. Food & Drug Admin*, 500 F. Supp. 2d 371 (S.D.N.Y. 2007) (No. 06-Civ-6552 (VM)) (excerpted)
BB	Decl. of Yurij Melnyk (December 7, 2015)

CERTIFICATE OF SERVICE

I certify that on December 7, 2015, 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