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. _____ ECF Case

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

INTRODUCTION

1. The Food and Drug Administration ("FDA") is charged with determining which drugs are safe and effective for public use. The agency makes these determinations based on clinical trial data submitted by drug manufacturers, yet the FDA does not release the raw clinical trial data to the public, even after a drug has been approved and marketed to consumers. Public disclosure of this data—with appropriate redactions to protect patient privacy—is mandated by the Freedom of Information Act and is essential to enable independent review by outside scientists, researchers, public health organizations, patient advocates, and others. This oversight is necessary to ensure that the FDA is fulfilling its core duties of ensuring the safety and efficacy of drugs.

2. Over the past 18 months, the FDA has approved two groundbreaking drugs for the treatment of hepatitis C virus ("HCV"): Sovaldi (sofosbuvir) and Harvoni (sofosbuvir/ledipasvir). The drugs promise not simply better treatment for HCV, but a cure. They

are also enormously costly. Initial pricing for the Sovaldi was $1,000 per pill, and a full course of treatment cost $84,000 and $94,500 for Sovaldi and Harvoni, respectively. Despite the high cost of the drugs and their approval for widespread use, the underlying clinical trial data has not been made available to the public or even to the scientific community.

3. Public access to the raw clinical trial data is necessary so that doctors and patients can make informed treatment decisions and cost-benefit determinations. As it stands now, doctors and patients lack the benefit of any independent assessment of the data that led to the approval of Sovaldi and Harvoni. Moreover, given the high cost of the drugs, state healthcare programs and private insurers need to make difficult decisions about how to prioritize access to the drugs. The drugs have already placed an enormous strain on state budgets, and have led numerous insurers to institute non-evidence based exclusion criteria and other restrictions that inhibit access to these lifesaving medications. It is crucial that policymakers be able to evaluate the cost-effectiveness of these drugs based on the underlying clinical data so that evidence can lead decisions about their availability.

4. Since their approval, hundreds of thousands of patients have been prescribed Sovaldi and Harvoni, and the drugs promise to become the backbone of HCV treatment worldwide. Available data suggest that the drugs have been widely used to treat HCV patients who face variants of the virus or other circumstances that were little-studied during the clinical trials. The adequacy of clinical trials is a particular concern with respect to these drugs because both were approved on an accelerated timeline, under the FDA's "Breakthrough-Therapy" designation program. While the program aims to streamline approval for promising drugs, it may increase the risk that gaps in drug efficacy will go undiscovered, or that side effects or

contraindications will go unnoticed. Independent analysis of patient-level clinical trial data is essential to identify and bring to light unresolved safety and efficacy issues.

5. Because of the importance of public access to clinical trial data in general, and the particular need for disclosure with respect to Sovaldi and Harvoni, plaintiffs Treatment Action Group ("TAG") and the Global Health Justice Partnership ("GHJP") bring this action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.*, to compel the FDA and its parent agency, the Department of Health and Human Services ("HHS"), to release the clinical trial data that was submitted for the two drugs, as well as communications between the FDA and the manufacturer concerning the design of clinical trials, and related information regarding the FDA's approval process.

6. Plaintiffs bring this suit after trying and failing to obtain access to the data voluntarily. On November 18, 2014, TAG and GHJP wrote to the drugs' manufacturer, Gilead Sciences, to ask that it agree to release patient-level clinical trial data. TAG and GHJP received no response. On December 17, 2014, plaintiffs submitted their FOIA requests to the FDA and HHS ("the FOIA Requests") seeking disclosure of the information on an expedited basis. The FDA denied plaintiffs' request for expedited processing and ultimately informed plaintiffs that it would take an estimated 18-24 months to process their request, in clear violation of the statutory deadlines for producing records or justifying their withholding.

7. As a result, plaintiffs bring this lawsuit to obtain timely disclosure of the clinical trial data and related records. Given the significant public health implications of the information sought and the strong public interest in disclosure, plaintiffs seek expeditious treatment of their Complaint pursuant to 28 U.S.C. § 1657. Unless defendants disclose the requested information,

hundreds of thousands more patients will be treated with drugs whose safety, efficacy, and cost-effectiveness cannot be fully studied or understood.

PARTIES

8. Plaintiff Treatment Action Group is an independent, non-profit AIDS research and policy institute dedicated to fighting for better treatment, vaccines, and cures for HIV and common coinfections. TAG's Hepatitis/HIV Project collaborates with activists, community members, scientists, governments, and drug companies to make safer, more effective, and less toxic treatment for HCV available. TAG submitted the FOIA Requests, together with GHJP.

9. Plaintiff Global Health Justice Partnership is an initiative hosted by the Yale Law School and Yale School of Public Health dedicated to generating, compiling, and distributing information about structural influences on global health. As a science-based, non-profit initiative, Global Health Justice Partnership's primary objectives are to facilitate open science, community engagement, and public health, including the availability and efficacy of HCV treatments. GHJP submitted the FOIA Requests, together with TAG.

10. Defendant Food and Drug Administration is a component of HHS. The FDA is responsible, *inter alia*, for regulating the safety, efficacy, and security of drugs and other pharmaceutical products intended for human use. The FDA is also responsible for providing the public with accurate scientific information regarding drugs and other products. The FDA is an agency of the United States within the meaning of 5 U.S.C. § 552(f)(1). The FOIA Requests sought records from the FDA.

11. Defendant Department of Health and Human Services is an agency within the Executive Branch of the United States government. HHS is responsible for managing a wide variety of health and welfare programs, directly and through its components. HHS is an agency

of the United States within the meaning of 5 U.S.C. 552(f)(1). The FOIA Requests sought records from HHS.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action and personal jurisdiction over the defendant pursuant to 5 U.S.C. §§ 552(a)(4)(B) and 552(a)(6)(E)(iii). This Court also has jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 5 U.S.C. §§ 701-06.

13. Venue is proper in the District of Connecticut pursuant to 5 U.S.C. § 552(a)(4)(B) because GHJP's principal place of business is in New Haven, Connecticut.

FACTS

Public Access to Clinical Trial Data

14. The Food, Drug, and Cosmetic Act and Defendant's implementing regulations require new drug applicants to provide "full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use." 21 U.S.C. § 355(b)(1)(A); 21 C.F.R. 314.50.

15. The statistical analysis required to evaluate this data is complex, and internal and external reviews often find evidence of significant health or budgetary implications unnoticed during the initial review.

16. Drug manufacturers design the clinical trials that provide support for their New Drug Applications ("NDAs"). The FDA then reviews the submitted trials for adequacy. The FDA does not, however, release the underlying clinical trial data to the public or the broader research community, even after a drug has been approved for sale to the public.

17. Doctors, public health professionals, and scientists have expressed concern that the FDA may be vulnerable to lobbying by drug manufacturers to accelerate approval for new

drugs. Such concerns are particularly relevant given the revolving door that exists between the FDA and the drug manufacturers it regulates. Greater transparency regarding clinical trial data would improve public confidence in the FDA's decision-making process.

18. Flaws in the design, publication, and analysis of clinical data for new drugs may obscure critical safety and efficacy issues. Drug manufacturers may suppress or de-emphasize negative clinical trials, or alter the parameters of clinical trials to highlight positive results. For instance, researchers found that GlaxosmithKline selectively published clinical trials for the antidepressant Paxil, overstating the drug's efficacy and misleading doctors and patients. Studies that purport to analyze clinical data may contain methodological flaws that can only be uncovered through external scrutiny. For instance, a prominent study analyzing clinical trials for the painkiller VIOXX used a reporting method that significantly understated the drug's effects in increasing risks of heart attacks.

19. Recognizing the public health benefits of independent scrutiny, some drug companies have voluntarily made raw patient-level clinical trial data available to researchers. For example, Johnson & Johnson and Medtronic, Inc. have partnered with the Yale Open Data Access Project to facilitate access to their clinical trial program data. GlaxoSmithKline makes anonymized patient-level data available to researchers on its website. These and other companies now routinely release the type of information plaintiffs seek to obtain through the FOIA Requests.

20. Independent analysis of clinical trial data can uncover important information about drug safety and efficacy not found by manufacturers or regulators during the approval process. For example, as part of a 2004 settlement agreement, GlaxoSmithKline published its clinical trial data in an online registry. A cardiologist subsequently conducted a meta-analysis

and found significant cardiovascular risks associated with Avandia, a diabetes medication. Similarly, an independent post-market study of Merck's popular nonsteroidal anti-inflammatory drug VIOXX revealed that the manufacturer could have identified cardiovascular risks several years before it was pulled off the market. That analysis was also based on clinical trial data released through litigation. Independent scrutiny of clinical trial data can thus accelerate the identification of potential risks to patients.

FDA Approval of Sovaldi and Harvoni

21. On December 6, 2013, Defendant FDA approved NDA No. N204671 for sofosbuvir, marketed as Sovaldi; and on October 10, 2014, Defendant approved NDA No. N205824 for sofosbuvir/ledipasvir, marketed as Harvoni for the treatment of the hepatitis C virus ("HCV").

22. Approximately 3.2 million people are infected with HCV in the United States. Since Sovaldi was approved in December 2013, more than 210,000 HCV patients have been treated with Sovaldi or Harvoni, and the manufacturer estimates that as many as 250,000 patients will be treated with these drugs in 2015.

23. However, Sovaldi and Harvoni's high costs—initially priced at $84,000 and $94,500 for a twelve-week course, respectively—limit access to these drugs. More than half of all HCV patients in the United States are publicly insured, and the cost of these drugs threatens to overwhelm state healthcare budgets. Because of their high cost, healthcare authorities and insurers are rationing access, denying treatment to patients who they deem to be insufficiently sick or who are substance users. It is unclear whether these judgments are based on scientific evidence about the efficacy, safety, or cost-effectiveness of the drugs in these populations.

Access to clinical trial data would allow policymakers to ensure these crucial decisions about treatment access are supported by the best available evidence.

24. Both drug applications were approved after receiving Breakthrough Therapy Designation status pursuant to 21 U.S.C. § 356(a). This designation authorizes the FDA to expedite the development and review of a drug application by "taking steps to ensure that the design of clinical studies is as efficient as practicable." 21 U.S.C. § 356(a)(3)(B)(5).

25. While accelerated approval makes potentially life-saving drugs available to patients more quickly, it also heightens the need for independent scrutiny. Available data suggest the FDA sometimes approves drugs for broad indications based on clinical studies whose populations are too small to adequately demonstrate the drugs' safety and efficacy. Participants in these studies may carry uncommon disease strains or may possess risk profiles not shared by the general population. The health consequences of the FDA's accelerated approval pathway are largely unknown, and there is some evidence suggesting that drugs approved in this manner are more likely than drugs approved with more extensive evidence to later be withdrawn from the market.

26. Public health professionals have already identified potential concerns regarding Sovaldi and Harvoni in particular. For instance, the FDA recently revised the warning labels for the drugs to reflect previously unknown interactions with the antiarrhythmia medication amiodarone. Publicly available records also suggest that the FDA approved a shorter Harvoni treatment course than that proposed by the manufacturer for non-cirrhotic patients with a low viral load, and that the FDA did so on the basis of a post-hoc analysis of data without peer review. Access to the underlying clinical trial data may well reveal other concerns about the safety and efficacy of the drugs, or the basis for the FDA's approved prescribing information.

TAP and GHJP's FOIA Request

27. On December 17, 2014, TAG and GHJP submitted identical FOIA requests by letter to the FDA and HHS seeking eight specific categories of records relating to the FDA's approval of Sovaldi (sofosbuvir) and Harvoni (sofosbuvir/ledipasvir). (A true and correct copy of the Request is annexed hereto as Exhibit A.)

28. Specifically, TAG and GHJP's Requests sought the following eight categories of information:

a. All data submitted in relation to the NDAs for sofosbuvir and the sofosbuvir/ledipasvir combination from the earliest trials onward, including, but not limited to: patient-level safety and efficacy data; case report forms; informed consent forms; adjudication forms; toxicity and dosage information; pharmacology data and formulation; records generated by international experience regarding sofosbuvir.

b. All records submitted in support of any associated accelerated NDAs or supplemental NDAs for these drugs.

c. All study protocols submitted along with the raw pre-market approval and post-market adverse event data for sofosbuvir and the sofosbuvir/ledipasvir combination.

d. All records regarding the Breakthrough Therapy Designation priority review of sofosbuvir and the sofosbuvir/ledipasvir combination.

e. All records related to trials and design of trials for sofosbuvir and the sofosbuvir/ledipasvir combination, whether the trial design was approved or not approved.

f. All correspondence between HHS or FDA and the company or companies developing sofosbuvir and the sofosbuvir/ledipasvir combination, including both Gilead Sciences and Pharmasset, that concern any aspect of the FDA approval process.

g. Any other raw clinical trial data regarding sofosbuvir and the sofosbuvir/ledipasvir combination submitted by Gilead Sciences to the FDA in support of FDA approval.

h. All records, including the Clinical Study Reports, regarding trials of sofosbuvir and the sofosbuvir/ledipasvir combination alone or in

> combination with another drug or drugs (e.g., ribavirin and/or interferon), including, but not limited to, the following trials: SPARE Trial; ELECTRON Trial; FUSION Study; FISSION Study; POSITRON Study; VALENCE Study; NEUTRINO Study; PHOTON-1 Study; ION-1 Study; ION-2 Study; and ION-3 Study.

29. The requests explained that these records were "likely to contribute significantly to public understanding of FDA's operations and activities," and that without these records, clinicians, researchers, and public health advocates would be "unable to determine whether the FDA has properly carried out its responsibility to determine the safety and efficacy of these drugs, or to evaluate the costs and benefits of these drugs when used for the approved indications."

30. Additionally, plaintiffs requested expedited processing of their requests pursuant to 5 U.S.C. § 552(a)(6)(e). Plaintiffs explained that a "compelling need exist[ed]" for the requested information because doctors had already prescribed sofosbuvir and sofosbuvir/ledipasvir to hundreds of thousands of patients and continued to write prescriptions at a rapid rate in the United States and abroad.

31. The Requests asked defendants to produce the requested documents in their native electronic formats with any attached metadata included, provided that the files could be opened using standard commercially available software, or, if the files could not be produced in this manner, in an alternative electronic text-searchable format. The request further asked that the defendants produce databases, spreadsheets, and similar sets of data in .xls or .csv format.

32. Finally, plaintiffs requested a public interest fee waiver for duplication fees pursuant to 5 U.S.C. § 552(a)(4)(A)(iii), because "disclosure of the requested information is in the public interest," and a fee limitation pursuant to 5 U.S.C. § 552(a)(4)(A)(ii)(II), because

GHJP is an "educational institution or a non-commercial scientific institution, operated primarily for scholarly or scientific research."

Defendants' Responses

33. Plaintiffs received a letter dated December 19, 2014, from Pamela A. True, Information Technician at HHS, acknowledging receipt of the requests. (A true and correct copy of this response is annexed hereto as Exhibit B.)

34. Plaintiffs received a letter dated December 22, 2014, from Sarah Kotler, Acting Director in the FDA's Division of Freedom of Information, denying plaintiffs' request for expedited processing. (A true and correct copy of this response is annexed hereto as Exhibit C.)

35. On January 8, 2014, defendants' twenty-business-day window for responding to plaintiffs' FOIA request expired. At the time the window expired, defendants had not responded to plaintiffs' request for the eight categories of records or their request for a public interest fee waiver and limitation of fees.

TAG and GHJP's Administrative Appeal

36. By letter dated January 26, 2015, plaintiffs timely filed an administrative appeal with the Deputy Agency Chief FOI Officer in the Office of the Assistant Secretary for Public Affairs. In that letter, plaintiffs appealed: (1) defendants' denial of their request for expedited processing and (2) defendants' constructive denial of their request for the eight categories of records. (A true and correct copy of this appeal is annexed hereto as Exhibit D.)

37. Plaintiffs received a letter dated January 29, 2015, from John Ivey in HHS's Division of FOIA Services, acknowledging receipt of plaintiffs' administrative appeal. (A true and correct copy of this response is annexed hereto as Exhibit E.)

38. On January 30, 2015, plaintiffs received an email from Denise Wallace, a Senior FOIA Analyst at HHS, again acknowledging receipt of plaintiffs' administrative appeal. Ms. Wallace's email also provided instructions for accessing the NDA approval packages for Sovaldi and Harvoni through the FDA's website. Neither of these publicly available packages, however, contain the patient-level safety and efficacy data or detailed descriptions of clinical studies sought by plaintiffs' FOIA requests. (A true and correct copy of this correspondence is annexed hereto as Exhibit F.)

39. Plaintiffs received a letter dated February 19, 2015, from Catherine Teti, Executive Officer and Deputy Agency Chief FOIA Officer in the HHS's Office of the Assistant Secretary for Public Affairs, denying plaintiffs' request for expedited processing. Ms. Teti's letter stated that plaintiffs' requests did not meet the requirements for expedited processing because plaintiffs did not provide "sufficient evidence" that there was a "compelling need" for the requested information. The letter further stated that plaintiffs' FOIA requests had been placed in the "complex queue" at the FDA's Center for Drug Evaluation and Research, and that the timeframe for responding to requests in this queue is 18 to 24 months. (A true and correct copy of this response is annexed hereto as Exhibit G.)

40. By letter dated April 1, 2015, plaintiffs requested that defendants reconsider their denial of plaintiffs' administrative appeal. The letter explained the compelling need for the requested information and provided additional evidence addressing the alleged deficiencies identified by Ms. Teti's letter. (A true and correct copy of this response is annexed hereto as Exhibit H.)

41. Plaintiffs have yet to receive a response to their April 1, 2015, letter.

42. Defendants have not provided the requested information, nor have they provided a justification for withholding the requested information. Defendants have also failed to address plaintiffs' requests for a fee waiver and fee limitation. Plaintiffs have exhausted their administrative remedies.

FIRST CAUSE OF ACTION
(Failure to expedite Plaintiffs' request)

43. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

44. Defendants' failure to expedite the processing of plaintiffs' request and appeal violates FOIA, 5 U.S.C. § 552(a)(6)(E), and defendants' corresponding regulations.

SECOND CAUSE OF ACTION
(Failure to make reasonable search for records)

45. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

46. Defendants' failure to make a reasonable search for records requested by plaintiffs violates FOIA, 5 U.S.C. § 552(a)(3), and defendants' corresponding regulations.

THIRD CAUSE OF ACTION
(Failure to make records available)

47. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

48. Defendants' failure timely to make available and to release all of the documents requested by plaintiffs violates FOIA, 5 U.S.C. § 552(a)(3)(A), and defendants' corresponding regulations.

FOURTH CAUSE OF ACTION
(Wrongful withholding of records)

49. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

50. Defendants' wrongful withholding of records, or portions thereof, requested by plaintiffs violates FOIA, 5 U.S.C. § 552(a)(3)(A) and 5 U.S.C. § 552(a)(6)(A), and defendants' corresponding regulations.

FIFTH CAUSE OF ACTION
(Failure to grant waiver of fees)

51. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

52. Defendants' failure to grant plaintiffs a waiver of fees violates FOIA, 5 U.S.C. § 552(a)(4)(A)(iii), and defendants' corresponding regulations.

SIXTH CAUSE OF ACTION
(Failure to grant limitation of fees)

53. Plaintiffs repeat, reallege, and incorporate the allegations in the foregoing paragraphs as though fully set forth herein.

54. Defendants' failure to grant a limitation of fees violates FOIA, 5 U.S.C. § 552(a)(4)(A)(ii)(II), and Defendants' corresponding regulations.

RELIEF REQUESTED

WHEREFORE, plaintiffs respectfully pray that this Court:

a. Expedite consideration of this Complaint pursuant to 28 U.S.C. § 1657;

b. Declare that defendants improperly failed to grant expedited consideration to plaintiffs' FOIA Requests and order defendants immediately to conduct and complete a thorough search for all responsive records;

c. Order defendants immediately and expeditiously to provide to plaintiffs copies of the requested records;

d. Order defendants to provide to plaintiffs copies of the records in their native electronic format or other electronic format, as requested;

e. Enjoin defendants from unlawfully withholding records, or portions thereof;

f. Enjoin defendants from assessing any fees against plaintiffs in relation to the processing of the FOIA Requests;

g. Award plaintiffs the costs of this proceeding, including reasonable attorneys' fees and costs, pursuant to 5 U.S.C. § 552(a)(4)(E); and

h. Grant such other and further relief as the Court deems just and proper.

Respectfully submitted,

MEDIA FREEDOM AND INFORMATION ACCESS CLINIC, YALE LAW SCHOOL

By: /s/Jonathan M. Manes

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Counsel for the Plaintiffs

Dated: June 25, 2015
New Haven, Connecticut

EXHIBIT A

December 17, 2014

Department of Health and Human Services
Mary E. Switzer Building, Room 2221
330 C Street, S.W.
Washington, DC 20201
Via Fax: (202) 690-8320

U.S. Food and Drug Administration
5630 Fishers Lane
Room 1035
Rockville, MD 20857
Via Fax: (301) 827-9267

RE: EXPEDITED FREEDOM OF INFORMATION ACT REQUEST

To Whom It May Concern:

This is an expedited request under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, for access to information regarding clinical testing and FDA approval of sofosbuvir, marketed as Sovaldi, and sofosbuvir/ledipasvir, marketed as Harvoni, which are used in the treatment of the Hepatitis C virus ("HCV") infection. This request seeks records held by the Department of Health and Human Services ("HHS") and its component, the Food and Drug Administration ("FDA").

An estimated 3.2 million people are infected with HCV in the United States.[1] New HCV drugs promise unprecedented treatment success at unprecedented cost: a typical twelve-week course of Sovaldi, for example, costs $84,000,[2] while a twelve-week course of Harvoni costs nearly $94,500.[3] Given the cost of treatment and the large population that will likely be prescribed these two drugs, interested parties should be able to evaluate the quality of all evidence submitted to the FDA in support of its approval, compare this evidence to the latest medical literature, and subject the raw data to additional analysis.

Disclosure of the requested information would make valuable knowledge available to interested scientists. There is a growing consensus in the medical community about the importance of open access to clinical trial data for the advancement of science and the public health.[4] Moreover, public access to the raw clinical trial data submitted to the FDA in support of

[1] Viral Hepatitis, *Ctrs. for Disease Control & Prevention*, http://www.cdc.gov/hepatitis/c/cfaq.htm (last updated Dec. 9, 2014).
[2] Richard Knox, $1000 Pill for Hepatitis C Spurs Debate Over Drug Prices, *NPR* (Dec. 30, 2013), http://www.npr.org/blogs/health/2013/12/30/256885858/-1-000-pill-for-hepatitis-c-spurs-debate-over-drug-prices.
[3] Anna Edney, Gilead Wins U.S. Approval for Hepatitis C Combo Pill, *Bloomberg News* (Oct. 11, 2014), http://www.bloomberg.com/news/2014-10-10/gilead-wins-u-s-approval-for-hepatitis-c-combo-pill.html.
[4] *See, e.g.*, Joseph S. Ross & Harlan M. Krumholz, Ushering in a New Era of Open Science Through Data Sharing: The Wall Must Come Down, *JAMA* 2013;309(13): 1355-56; Ben Goldacre & Carl Heneghan, Improving, and

drugs that are ultimately approved is crucial in order to permit scientists, physicians, public health professionals, and others to determine whether the FDA is properly discharging its core mission of determining, in a timely fashion, whether pharmaceuticals are safe and effective. Without the raw data—which is not routinely made public—experts are unable to independently assess and verify the FDA's safety and efficacy determinations.[5]

Independent oversight is especially important in light of available data that suggests the FDA has accelerated its drug approval timeline across the board, and sometimes approves drugs for broad indications based on clinical studies with small sample sizes in an effort to get promising drugs to market quickly. The safety risks of this accelerated approval pathway are still largely unknown, and there is some evidence suggesting that drugs approved in this manner are more likely than drugs approved with more extensive evidence to later be withdrawn from the market.[6] Even in the normal case, the FDA faces very substantial challenges in accurately evaluating the data it receives. The statistical analysis required is complex, and the FDA is both understaffed and under tremendous pressure from pharmaceutical companies, who may gain or lose billions of dollars based upon FDA decisions. It is not uncommon for later reviews of evidence submitted to the FDA, conducted either internally or externally, to turn up evidence that has very significant health and/or budgetary implications.[7] Access to this information will improve public understanding of the FDA approval process, and will shed necessary light on the efficacy and cost-effectiveness of these drugs.

Document Requests

We seek to obtain copies of the following records:[8]

Auditing, Access to Clinical Trial Results, *BMJ* 2014;348:g213 (Jan. 15, 2014). *Cf. AllTrials.net* (Oct. 17, 2014), http://www.alltrials.net/.

[5] *See, e.g.*, Harlan M. Krumholz & Eric D. Peterson, Open Access to Clinical Trials Data, *JAMA* 2014;312(10):1002-1003; Daniel M. Hartung et al., Reporting Discrepancies Between the ClinicalTrials.gov Results Database and Peer-Reviewed Publications, *Ann. Intern. Med.* 2014;160(7):477-83; Peter Lurie & Allison Zieve, Sometimes the Silence Can Be Like the Thunder: Access to Pharmaceutical Data at the FDA, 69 *Law & Contemporary Problems* 85 (2006); Kristin Rising, Peter Bacchetti & Lisa Bero, Reporting Bias in Drug Trials Submitted to the Food and Drug Administration: Review of Publication and Presentation, *PLoS Med.* 5(11):e217 1561 (2008).

[6] Cassie Frank et al., Era of Faster FDA Drug Approval Has Also Seen Increased Black-Box Warnings and Market Withdrawals, 33 *Health Affairs* 1453-1459 (Aug. 2014). *See also* Thomas J. Moore & Curt D. Furberg, Development Times, Clinical Testing, Postmarket Follow-Up, and Safety Risks for the New Drugs Approved by the U.S. Food and Drug Administration, *JAMA Intern Med*. 2014;174(1):90-95 (Jan. 2014); Thomas J. Moore & Curt D. Furberg, The Safety Risks of Innovation: The FDA's Expedited Drug Development Pathway, *JAMA* 2012;308(9):869-870.

[7] *See, e.g.*, *id.*; Pfizer Voluntarily Withdraws Cancer Treatment Mylotarg from U.S. Market, Press Release, *U.S. Food & Drug Admin.* (June 21, 2010), http://www.fda.gov/newsevents/newsroom/pressannouncements/ucm216448.htm; Gardiner Harris, F.D.A. to Restrict Avandia, Citing Heart Risk, *N.Y. Times* (Sept. 23, 2010), http://www.nytimes.com/2010/09/24/health/policy/24avandia.html; Public Health Advisory: Tagaserod Maleate (Marketed as Zelnorm), *U.S. Food & Drug Admin*. (Mar. 30, 2007), http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm051284.htm.

[8] Records include, but are not limited to, electronic files, letters, correspondence, tape recordings, notes, data, memoranda, reports, email, computer source and object code, technical manuals, technical specifications, or any other materials. *See* 5 U.S.C. § 552(f)(2).

1. All data submitted in relation to the new drug application ("NDA") for sofosbuvir and the sofosbuvir/ledipasvir combination from the earliest trials onward, including, but not limited to:
    - patient-level safety and efficacy data;
    - case report forms;
    - informed consent forms;
    - adjudication forms;
    - toxicity and dosage information;
    - pharmacology data and formulation;
    - records generated by international experience regarding sofosbuvir.
2. All records submitted in support of any associated accelerated NDAs or supplemental NDAs for these drugs.
3. All study protocols submitted along with the raw pre-market approval and post-market adverse event data for sofosbuvir and the sofosbuvir/ledipasvir combination.
4. All records regarding the Breakthrough Therapy Designation priority review of sofosbuvir and the sofosbuvir/ledipasvir combination.
5. All records related to trials and design of trials for sofosbuvir and the sofosbuvir/ledipasvir combination, whether the trial design was approved or not approved.
6. All correspondence between HHS or FDA and the company or companies developing sofosbuvir and the sofosbuvir/ledipasvir combination, including both Gilead Sciences and Pharmasset, that concern any aspect of the FDA approval process.
7. Any other raw clinical trial data regarding sofosbuvir and the sofosbuvir/ledipasvir combination submitted by Gilead Sciences to the FDA in support of FDA approval.
8. All records, including the Clinical Study Reports, regarding trials of sofosbuvir and the sofosbuvir/ledipasvir combination alone or in combination with another drug or drugs (e.g., ribavirin and/or interferon), including, but not limited to, the following trials:
    - SPARE Trial;
    - ELECTRON Trial;
    - FUSION Study;
    - FISSION Study;
    - POSITRON Study;
    - VALENCE Study;
    - NEUTRINO Study;
    - PHOTON-1 Study;
    - ION-1 Study;
    - ION-2 Study; and
    - ION-3 Study.

We request that all of these documents be produced in their native electronic formats with any attached metadata included, so long as such electronic files can be opened using standard commercially available software. If the files cannot be produced in this manner, we request that

records be produced in an alternative electronic format that is text-searchable. With respect to databases, spreadsheets or similar organized sets of data, we request that the records be produced in .xls or .csv format. *See* 5 U.S.C. § 552(a)(3)(B).

Fee Waiver Request

A waiver of search and review fees is appropriate here, because disclosure of the requested information is in the public interest under the meaning of 5 U.S.C. § 552(a)(4)(A)(ii)(III) and 45 C.F.R. §§ 5.45(a)(1), (b); and because we do not have any commercial interest in disclosure, 45 C.F.R. §§ 5.45(a)(2), (c).

Disclosure Is in the Public Interest

Disclosure of the requested information is likely to contribute significantly to public understanding of the FDA's operations and activities. 45 C.F.R. § 5.45(b)(1). Specifically, the requested information will "reveal meaningful information" that is "not already public knowledge" about the FDA's drug approval process and the quality of its decision-making as it relates to promising new treatments for the Hepatitis C virus. 45 C.F.R. § 5.45(b)(2). The information sought in this FOIA request is of significant public interest.

The FDA first approved sofosbuvir in December 2013, after receiving Breakthrough Therapy Designation priority review status upon its application in April 2013. Sofosbuvir has received widespread attention as a first-in-kind, "game-changing" drug that is expected to drastically improve the outcome of treatment for adults with chronic HCV infection. At $1,000 per pill, it has also faced controversy for its extraordinary price. This controversy was heightened by Gilead Science's decision not to work jointly with Bristol-Myers Squibb on a highly promising combination of sofosbuvir and daclatasvir, another drug currently under development. The recently approved sofosbuvir/ledipasvir combination offers additional promising benefits at an even steeper price. Given the great significance of sofosbuvir as a first-in-kind drug, the lack of opportunity to study its long-term effects, the centrality of clinical trials to FDA determinations, and expressed interest by clinicians, researchers, and public health advocates to examine the safety and efficacy of sofosbuvir and other HCV drugs, release of the raw clinical trial data would further the public interest. Without full access to this data, interested parties are unable to determine whether the FDA has properly carried out its responsibility to determine the safety and efficacy of these drugs, or to evaluate the costs and benefits of these drugs when used for the approved indications.

Moreover, FDA approval of these drugs has international ramifications. Because the FDA conducts significantly more rigorous review than comparable agencies in other countries, FDA approval influences treatment options in other nations as well. Gilead is making sofosbuvir available in Egypt at a 99% discount from the U.S. price.[9] Approximately 10% of Egypt's population is infected with HCV,[10] and most are infected with Genotype 4, a variant that is

[9] Maggie Fick & Ben Hirschler, Gilead Offers Egypt New Hepatitis C Drug at 99 Percent Discount, *Reuters* (Mar. 21, 2014), http://www.reuters.com/article/2014/03/21/us-hepatitis-egypt-gilead-sciences-idUSBREA2K1VF20140321.

[10] *Id.*

uncommon in the United States and that has undergone limited testing.[11] Gilead has also agreed to license the drug to seven Indian generic drug companies, who will make the full course of treatment available at a similar price.[12] The company is expected to reach deals with other developing nations soon.[13]

Our two organizations, Treatment Action Group and Global Health Justice Partnership, have "the knowledge or expertise . . . necessary to understand the information" sought and are "in the position to contribute to public understanding." 45 C.F.R. § 5.45(b)(3). Treatment Action Group ("TAG") is an independent AIDS research and policy think tank dedicated to fighting for better treatment, vaccines, and cures for HIV-related diseases. TAG's Hepatitis/HIV Project collaborates with activists, community members, scientists, governments, and drug companies to make safer, more effective, and less toxic treatment for viral hepatitis available.[14] Among other things, TAG's Hepatitis/HIV Project works to assure that:

- clinical and operational research on viral hepatitis is efficient, relevant and well-designed;
- 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; and
- all coinfected people have access to safe and effective treatment for HIV and viral hepatitis.

Global Health Justice Partnership ("GHJP") is an initiative of the Yale Law School and Yale School of Public Health dedicated to promoting improvements in health systems and health justice. As a science-based, nonprofit initiative, GHJP's primary objectives are to facilitate open science, community engagement, and public health. One of GHJP's current long-term projects concerns the availability and efficacy of Hepatitis C treatments. In conducting its research and policy projects, GHJP brings together physicians, public health professionals, scientists, and lawyers to work together in an interdisciplinary setting.[15] GHJP has also partnered with the Yale Open Data Access Project at Yale Medical School, an initiative committed to open science and

[11] R.S. Koff, The Efficacy and Safety of Sofosbuvir, a Novel, Oral Nucleotide Ns5B Polymerase Inhibitor, in the Treatment of Chronic Hepatitis C Virus Infection, 39(5) *Alimentary Pharmacology & Therapeutics* 478 (2014), *available at* http://www.medscape.com/viewarticle/820752_5. *See also* Heba Wanis, Egypt Will Not Patent New Hepatitis Drug, *Mada Masr* (May 23, 2014), http://www.madamasr.com/content/egypt-will-not-patent-new-hepatitis-c-drug.

[12] Gardiner Harris, Maker of Costly Hepatitis C Drug Sovaldi Strikes Deal on Generics for Poor Countries, *N.Y. Times* (Sept. 15, 2014), http://www.nytimes.com/2014/09/16/business/international/maker-of-hepatitis-c-drug-strikes-deal-on-generics-for-poor-countries.html.

[13] Ketaki Gokhale & Robert Langreth, Gilead Close to Sending $84,000 Drug to Poor Countries, *Bloomberg* (Sep. 5, 2014), http://www.bloomberg.com/news/2014-09-04/gilead-close-to-sending-84-000-drug-to-poor-countries.html.

[14] See, for example, Treatment Action Group, *Training Manual for Treatment Advocates: Hepatitis C Virus and Coinfection with HIV* (Nov. 2013), http://www.treatmentactiongroup.org/hcv/publications/training-manual-hcv-hiv; *HepCoalition*, www.hepcoalition.org, (last visited Dec. 12, 2014) (a collaboration between Médecins du Monde and TAG, which recently published the report "New Treatments for Hepatitis C Virus: Strategies for Achieving Universal Access").

[15] See, for example, Global Health Justice Project, *Policy Papers*, http://www.yaleghjp.org/#!policy-papers/c13bw (last visited Dec. 12, 2014).

the rigorous and objective evaluation of participant-level clinical research data. This Project has experience hosting large clinical trial datasets and making them accessible to researchers.

Our aim in requesting this information is that its disclosure will "advance the understanding of the general public." 45 C.F.R. § 5.45(b)(3). Through this FOIA request, we hope to be able to facilitate research projects to better determine the benefits and harms of sofosbuvir and to assess the adequacy of the FDA's drug approval process with respect to this drug and others. We also plan to make the information we obtain broadly available to health researchers in order to permit independent evaluation of these and other questions.

The information we are requesting is "not already public knowledge." 45 C.F.R. § 5.45(b)(2). While the FDA routinely makes summaries of clinical trial results available, the raw patient-level data is not readily obtainable. Neither does the FDA provide detailed descriptions of the designs of clinical trials, decisional documents resulting from discussions with drug companies regarding such designs, or other crucial information—such as the manner in which raw data from such trials is processed and adjudicated prior to publication. This FOIA request seeks to shine light on these aspects of the FDA's operations. Accordingly, the public's understanding of the FDA's operations will be "substantially greater as a result of the disclosure." 45 C.F.R. § 5.45(b)(4).

No Commercial Interest in the Information Sought

Neither TAG nor GHJP has any commercial interest in the information sought. 45 C.F.R. § 5.45(a)(2), (c). We are not in the business of developing or selling new drugs, and we do not stand to make a profit from the disclosure of the requested information. We have no commercial interest in these records, but rather we aim to facilitate and conduct rigorous, objective, and fair evaluation of the information sought in furtherance of public knowledge and public health.

For these reasons, a public interest waiver of fees is appropriate here. We therefore respectfully request that all fees related to the search, review, and duplication of the requested records be waived. If the search and review fees will not be waived, we ask that you contact us at the email addresses listed below should the estimated fees resulting from this request exceed $100.

Limitation of Fees

We are also entitled to a limitation of fees because GHJP is an "educational institution or a non-commercial scientific institution, operated primarily for scholarly or scientific research." 45 C.F.R. § 5.41(b); 5 U.S.C. § 552(a)(4)(A)(ii)(II). As already described, GHJP is part of Yale University and is a program jointly administered by Yale Law School and the Yale School of Public Health. It brings together scientists, physicians, lawyers, and others to conduct scholarly and scientific research on issues concerning public health. It therefore falls squarely within the definition above. Moreover, this request is not for commercial use, as already discussed. *See supra*. Thus, in the event that you deny our application for a public interest waiver of all fees, *see supra,* we are nevertheless entitled to a limitation of fees. Specifically, we can only be

charged "reasonable standard charges for document duplication," and may not be charged search fees or any other fees. 5 U.S.C. § 552(a)(4)(A)(ii)(II); 45 C.F.R. § 5.41(b).

Request for Expedited Processing

Expedited processing is appropriate here, under 5 U.S.C. § 552(a)(6)(E) because a compelling need exists for the disclosure of the requested information. Shedding light on the FDA's internal processes more generally is likely to have significant public health benefits, thereby reducing threats to the life or physical safety of all individuals using FDA-approved drugs. For example, in the second quarter of 2014, sales of sofosbuvir reached $3.5 billion in the U.S., with 70,000 people treated so far.[16] More prescriptions are written daily, in the U.S. and, increasingly, abroad. *See supra* (discussing access to the drug in Egypt and India). Clinicians, researchers, and the public at large would benefit from prompt access to this information.

Request for Explanation of Withholdings and Redactions

If this FOIA request is denied in whole or in part, please provide a reasonable description of any withheld materials and a justification for all such withholdings that includes reference to the specific exemptions of FOIA authorizing withholding and specific reasons why such exemptions apply. 45 C.F.R. § 5.33(a). In addition, please release all segregable portions of otherwise exempt material, with redactions if necessary. 5 U.S.C. § 552(b).

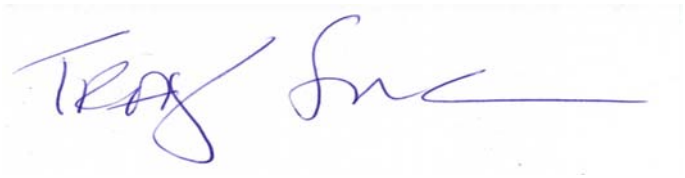
Thank you for your prompt attention to this request. If you have any questions or concerns about what we are seeking, please do not hesitate to contact us at the below email addresses. Pursuant to the applicable FOIA provision and departmental regulations, we expect a response regarding this request within the ten (10) working day time limit set by law. 45 C.F.R. § 5.35(b); 5 U.S.C. § 552(a)(6)(E).

Please direct all records and other correspondence relating to this request to:

Global Health Justice Partnership
Attn: Meredith Berger/Coordinator
Yale Law School
P.O. Box 208215
New Haven, CT 06520
FAX: (203) 436-9397

[16] Andrew Pollack, Gilead's Hepatitis C Drug, Sovaldi, Is on Pace to Become a Blockbuster, *N.Y. Times* (July 23, 2014), http://www.nytimes.com/2014/07/24/business/sales-of-hepatitis-c-drug-sovaldi-soar.html.

Sincerely,



Tracy Swan
Karyn Kaplan
Treatment Action Group
261 Fifth Avenue, Suite 2110
New York, NY 10016-7701
(212) 253-7922
tracy.swan@treatmentactiongroup.org

Amy Kapczynski
Gregg Gonsalves
Global Health Justice Partnership
Yale University
P.O. Box 208215
New Haven, CT 06520
(203) 432-3823
amy.kapczynski@yale.edu

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

GLOBAL HEALTH JUSTICE PARTNERSHIP
MEREDITH BERGER
YALE LAW SCHOOL
PO BOX 208215
NEW HAVEN CT 06520 USA

12/19/2014

In Reply refer to:

2014-9958

Your reference:

Dear Requester:

The Food and Drug Administration (FDA) has received your Freedom of Information Act (FOIA) request for records regarding:
SOVALDI (SOFOSBUVIR) APRVL

We will respond as soon as possible and may charge you a fee for processing your request. If your informational needs change, and you no longer need the requested records, please contact the undersigned to cancel your request, as charges may be incurred once processing of your request has begun. For more information on processing fees, please see http://www.fda.gov/RegulatoryInformation/FOI/FOIAFees/default.htm.

If you have any questions about your request, please call Pamela A. Prue, Information Technician, at (301) 796-8984 or write to us at:

Food and Drug Administration
Division of Freedom of Information
5630 Fishers Lane, Room 1035
Rockville, MD 20857

If you call or write, use the reference number above which will help us to answer your questions more quickly.

Sincerely,

Pamela A. Prue
Information Technician

EXHIBIT C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

DEC 22 2014

Meredith Berger
Global Health Justice Partnership
Yale Law School
P.O. Box 208215
New Haven, CT 06520

In Reply Refer To: 2014-9958

Dear Requester:

This is in response to y our request for expedited processing of your Freedom of Information Act (FOIA) request for information regarding K955168, K000470 and Q131322.

The Electronic Freedom of Information Act (EFOIA) Amendments of 1996 amended the FOIA by adding section (a)(6)(E), 5 U.S.C. 552(a)(6)(E), to require agencies to consider requests for expedited processing and grant them whenever a "compelling need" is shown and in other cases as determined by the agency. The term "compelling need" is defined as (1) involving "an imminent threat to the life or physical safety of an individual," or (2) in the case of a request made by "a person primarily engaged in disseminating information, urgency to inform the public concerning actual or alleged Federal Government activity."

I have determined that your request for expedited processing does not meet the criteria under the FOIA. You have not demonstrated a compelling need that involves an imminent threat to the life or physical safety of an individual. Neither have you demonstrated that there exists an urgency to inform the public concerning actual or alleged Federal Government activity. Therefore, I am denying your request for expedited processing. The responding agency office will process your request in the order in which it was received.

The Department of Health and Human Services' implementing regulations, 45 CFR 5.34, set forth the procedures for you to follow if you decide to appeal this decision not to provide you with the information you requested. Your appeal should be sent within 30 days from the date you receive this letter to the Deputy Agency Chief FOI Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, Parklawn Building, Room 19-01, 5600 Fishers Lane, Rockville, MD 20857.

Sincerely yours,

Sarah Kotler
Acting Director
Division of Freedom of Information

EXHIBIT D

TAG
Treatment Action Group

GLOBAL HEALTH JUSTICE PARTNERSHIP
GHJP

January 26, 2015

Deputy Agency Chief FOI Officer
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Parklawn Building
Room 19-01
5600 Fishers Lane
Rockville, MD 20857

RE: Freedom of Information Act Appeal, Reference Number 2014-9958

Dear Sir or Madam:

We, the Global Health Justice Partnership ("GHJP") and the Treatment Action Group ("TAG"), write to appeal your agency's denial of expedited processing regarding our December 17, 2014 Freedom of Information Act ("FOIA") request, as well as the constructive denial of the substance of that request by the Food and Drug Administration ("FDA").

I. Background

By letter dated December 17, 2014, GHJP and TAG requested from the Department of Health and Human Services ("HHS") and its component, the FDA, copies of its records relating to clinical testing and FDA approval of sofosbuvir, marketed as Sovaldi, and sofosbuvir/ledipasvir, marketed as Harvoni. The FOIA request (attached as Exhibit A) enumerated eight specific categories of records sought and argued that expedited processing was appropriate under 5 U.S.C. § 552(a)(6)(E).

As of today, we have received two letters in response to our request. The first is dated December 19, 2014 and acknowledges receipt of our request (attached as Exhibit B). The second, dated December 22, 2014, is from Sarah Kotler, Acting Director of the FDA Division of Freedom of Information, and denies our request for expedited processing (attached as Exhibit C). We have received no documents from your agency responsive to our request, nor has FDA cited any FOIA exemptions as a basis for refusing to disclose records.[1]

[1] This appeal is timely filed within 30 days of receipt of Ms. Kotler's letter denying our request for expedited processing. We received that letter on January 6, 2015.

II. Basis for Appeal

Pursuant to HHS regulations 45 C.F.R. § 5.34, we hereby appeal FDA's refusal to grant expedited processing. 5 U.S.C. § 552(a)(6)(E) provides that expedited processing of FOIA requests is required when a "compelling need" for the information exists. GHJP and TAG have demonstrated that such a need exists regarding clinical trial data for these two drugs, which are increasingly used to treat the estimated 3.2 million people infected with HCV in the United States.

Given the drugs' accelerated approval timeline and their extraordinary costs—$84,000 and $94,500, respectively—it is important that interested scientists and others promptly be given access to the raw clinical trial data. Access to this data will allow the public to understand the FDA's approval process for these drugs and perform additional statistical analysis to further public health and understanding of the benefits and costs of sofosbuvir and the sofosbuvir/ledipasvir combination. The cost of these drugs has already significantly impacted state budgets[2] and netted Gilead more than $11.4 billion in sales.[3] Additional prescriptions for these two drugs are written daily, both in the United States and abroad. The longer access to raw, patient-level clinical trial data is denied, the more individuals will be affected by any subsequent discovery of gaps in the FDA's expedited approval process or risks associated with these recently approved drugs.[4] There is therefore a "compelling need" to expedite processing of the FOIA request. *See* 5 U.S.C. § 552(a)(6)(E).

We also appeal your agency's constructive denial of our Dec. 17, 2014 request. HHS regulations require prompt action on FOIA requests. *See* 45 C.F.R. § 5.35(b). Under the Freedom of Information Act, documents are required to be produced within 20 days. *See* 5 U.S.C. § 552(a)(6)(A)(i). It is also well-settled that records sought under FOIA may only be withheld "if they fall under an applicable exemption," *Burka v. U.S. Dep't of Health & Human Servs.*, 87 F.3d 508, 515 (D.C. Cir. 1996), in which case the agency must provide both the factual support and "the reasons behind their conclusions in order that they may be challenged by FOIA plaintiffs and reviewed by the courts." *Mead Data Cent., Inc. v. United States Dep't of the Air Force*, 566 F.2d 242, 261 (D.C. Cir. 1977). An agency must demonstrate "by specific and detailed proof that disclosure would defeat, rather than further, the purpose of the FOIA." *Mead Data Cent.*, 566 F.2d at 258 (citation omitted). Any claim of exemption must be supported with "specificity and [in] detail." *Senate of the Commonwealth of Puerto Rico on Behalf of Judiciary Comm. v. United States Dep't of Justice*, 823 F.2d 574, 585 (D.C. Cir. 1987) (alteration in original).

To date, FDA has responded only with the aforementioned letters acknowledging receipt and denying our organizations' request for expedited processing. FDA has not produced any

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[2] *See, e.g.,* Bryan Clark, Idaho Medicaid Wants $6.5M to Treat 50 Patients, *Twin Falls Times-News*, Jan. 21, 2015, http://magicvalley.com/news/local/govt-and-politics/idaho-medicaid-wants-m-to-treat-patients/article_17170107-f9b6-596c-ae16-f293cfabae21.html; David Siders, Hepatitis C Drug's High Cost Hits California Budget, *The Sacramento Bee*, Jan. 16, 2015, http://www.sacbee.com/news/politics-government/article7058828.html.

[3] Patricia Kime, VA, DoD Spend More than $450M on Costly Hepatitis Drug, *USA Today*, Jan. 8, 2015, http://www.usatoday.com/story/news/politics/2015/01/08/government-hepatitis-drug-costs/21462363/.

[4] Requesters also incorporate by reference here all of the arguments and citations offered in their original request, attached as Exhibit A.

documents and has not claimed any exemptions to disclosure. FDA's failure to produce the requested records or to cite specific exemptions to justify its refusal to disclose the records is improper. Federal regulations stipulate that "[i]f we fail to meet the deadlines, you may proceed as if we had denied your request or your appeal." 45 C.F.R. § 5.35(a). FDA's failure to produce the records or claim any exemption is a "constructive denial" of the December 17, 2014 request. We hereby appeal FDA's constructive denial of our request.

III. Request for Relief

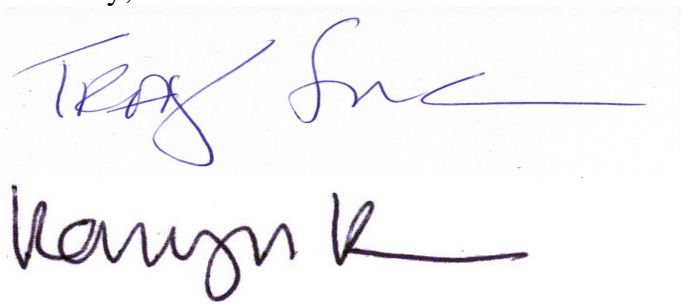
For the foregoing reasons, we submit that GHJP and TAG are entitled to expedited review and that FDA has failed to meet its legal obligation to disclose the records and information requested by GHJP and TAG on December 17, 2014. We respectfully request immediate disclosure of the records requested.

This FOIA request seeks information concerning the business of the government agencies responsible for this nation's public health and safety; the information requested concerns the practices behind government analysis and approval of new drugs that may affect millions of Americans, and the disclosure of this information will shed light on important government activity and allow public oversight. The disclosures requested here would therefore further "the basic purpose of the Freedom of Information Act to open agency action to the light of public scrutiny," and no proper basis exists under FOIA to withhold them. *Dep't of Air Force v. Rose*, 425 U.S. 352, 372 (1976) (quotations omitted); *see also id.* at 381 (emphasizing "the policies underlying the Freedom of Information Act, to open public business to public view").

We trust that we will receive your decision within 20 business days as required by 45 C.F.R. § 5.35(b)(2) and 5 U.S.C § 552(a)(6)(A)(ii). Thank you for your prompt attention to this matter. Please direct all correspondence relating to this request to:

Global Health Justice Partnership
Attn: Meredith Berger/Coordinator
Yale Law School
P.O. Box 208215
New Haven, CT 06520
FAX: (203) 43609397

Sincerely,



Tracy Swan

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Amy Kapczynski
Gregg Gonsalves
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amy.kapczynski@yale.edu

Enclosures: Exhibit A: FOIA Request of December 17, 2014
Exhibit B: December 19, 2014 Letter acknowledging receipt of request
Exhibit C: December 22, 2014 Letter from Sarah Kotler

EXHIBIT E

DEPARTMENT OF HEALTH AND HUMAN SERVICES Program Support Center

Division of FOIA Services
5600 Fishers Lane Rm. 19-01
Rockville MD 20857

Phone: 301- 443-3403
Fax:301- 480-5862

Request Number: PSC - 15-0179 - AA
Date Received: 1/29/2015

January 29, 2015

Meredith Berger
Global Health Justice Partnership - Yale Law School
P.O. Box 208215
New Haven, CT 06520

Dear Requester:

This acknowledges receipt of your administrative appeal received by this office on the date above. Your appeal has been assigned the above-stated case number based on when it was received in this office.

Your letter is summarized below:

Appealing the Food and Drug Administration (FDA) denial of expedited processing and constructive denial of FOIA Request 2014-9958, which sought records related to clinical testing and FDA approval of sofosbuvir, marketed as Sovaldi, and sofosbuvir/ledipasvir, marketed as Harvoni.

The case number of the original request was: 2014-9958

Any questions regarding the status of your appeal should be directed to the Public Health Service (PHS) Freedom of Information (FOI) office.

Please reference this number on your correspondence.

Sincerely Yours,

John D. Ivey -S

Digitally signed by John D. Ivey -S
DN: c=US, o=U.S. Government, ou=HHS, ou=PSC, ou=People, cn=John D. Ivey -S, 0.9.2342.19200300.100.1.1=2001055019
Date: 2015.01.29 16:45:05 -05'00'

Division of FOIA Services

EXHIBIT F

From: "Wallace, Denise (PSC/AOP/FOIA)" <Denise.Wallace@psc.hhs.gov>
Subject: Appeal 15-0179AA FDA 2014-9958
Date: January 30, 2015 2:52:54 PM EST
To: "'amy.kapczynski@yale.edu'" <amy.kapczynski@yale.edu>, "'tracy.swan@treatmentactiongroup.org'" <tracy.swan@treatmentactiongroup.org>

Good Afternoon

My name is Denise Wallace I am currently reviewing Freedom of Information Act appeal you submitted regarding your FOIA request to FDA for records regarding drugs Sovaldi and Harvoni. I just wanted to inform you that you can obtain access to some of the information you requested at Drug@FDA,http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm. In particular, I was able to locate both Sovaldi and Harvoni's NDA approval packages on FDA's webpage. Please see the links below.

http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204671Orig1s000TOC.cfm ;http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205834Orig1s000TOC.cfm

I wanted to provide you with this information for your review, in the meanwhile I will continue to process your FOIA appeal. If you have any questions please do not hesitate to contact me via email or call me at the phone number in my signature block.

Thank you

Denise F. Wallace, J.D.
Senior FOIA Analyst, Freedom of Information Act Services
Program Support Center
U.S. Department of Health and Human Services
5600 Fishers Lane, Room 19-01
Rockville, MD 20857

Office: (301) 443-3403
Fax: (301) 480-5862

EXHIBIT G

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for Public Affairs
Washington, D.C. 20201

February 19, 2015

Appeal No.: 15-0179-AA
FDA File No.: 2014-9958

Meredith Berger
Global Health Justice Partnership and
Treatment Action Group
Yale Law School
P.O. Box 208215
New Haven, Connecticut 06520

Dear Ms. Berger:

I am responding to your letter of January 26, 2015, on behalf of the Global Health Justice Partnership (GHJP) and the Treatment Action Group (TAG), appealing the Food and Drug Administration's (FDA) denial of your expedited processing request and constructive denial of your Freedom of Information Act (FOIA) request. In summary, the request sought expedited processing for information regarding clinical testing and approval of sofosbuvir, marketed as Sovaldi and sofosbuvir/ledipasvir, marketed as Harvoni, which are used to treat the Hepatitis C virus.

Expedited Processing

Under the FOIA, a requester is to be granted expedited processing "in cases in which the person requesting the records demonstrates a "compelling need" and "in other cases determined by the agency."[1] One can show "compelling need" in one of two ways: (1) by establishing that his or her failure to obtain the records quickly "could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;" or, (2) if the requester is a "person primarily engaged in disseminating information," by demonstrating that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists.[2]

FDA's expedited processing regulation provides for the expedited processing of FOIA requests for persons who demonstrate "compelling need," or in other cases as determined by the Agency.[3] Your request and appeal letter asserted that your "compelling need" for expedited processing is based upon possible effects on individuals of discoveries that the release of raw, patient-level clinical data might facilitate and "further[ing] public health and understanding."

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[1] 5 U.S.C. § 552(a)(6)(E)(i).
[2] 5 U.S.C. § 552(a)(6)(E)(v); 21 C.F.R. § 20.44(a).
[3] 21 C.F.R. § 20.44(a).

In order to meet the threshold for the first category of the "compelling need" standard, the request must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or other authorized representative of the individual, and must demonstrate a reasonable basis for concluding that failure to obtain the requested records on an expedited basis could reasonably be expected to pose a specific and identifiable imminent threat to the life or safety of the specific individual. [4]

The appeal notes that GHJP and TAG are requesting the information because the information will allow the public to understand the FDA's approval process for these drugs and GHJP and TAG can perform additional statistical analysis to further public health and understanding of the benefits and costs of sofosbuvir and the sofosbuvir/ledipasvir combination. The appeal does not provide any justification to demonstrate that a failure to obtain the records quickly could reasonably be expected to pose an imminent threat to the life or physical safety of a specific individual. In addition, the GHJP and TAG have not presented any evidence that either organization is the authorized representative of an individual subject to an imminent threat. Thus, for multiple reasons, your request does not qualify for expedited processing under 21 C.F.R. § 20.44(a)(1).

In order to meet the threshold for the second category of the "compelling need" standard, a requester must demonstrate that (l) they are a "person primarily engaged in disseminating information to the general public and not merely to a narrow interest group," (2) there is an "urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly," and (3) "the request for records specifically concerns identifiable operations or activities of the Federal Government."[5]

To qualify for this category of "compelling need," a requester must meet all three of these criteria. You have not provided sufficient information to support a determination that you or your organizations are persons primarily engaged in disseminating information for the general public, nor have you provided sufficient information to support a determination that there is an urgent need for the information and that its particular value will be lost if not obtained and disseminated quickly. Thus, for multiple reasons, your request does not qualify for expedited processing under 21 C.F.R. § 20.44(a)(2).

I have determined that, based on the information above, your request does not qualify for expedited processing.

Constructive Denial

The FOIA contains a general requirement that federal agencies respond to FOIA requests within twenty working days, unless exceptional circumstances exist. With respect to these exceptional circumstances, courts have repeatedly held that when an agency can show (1) a great number of requests and inadequate resources, and (2) good faith and due diligence in complying with requests by processing them in a first-in-first-out basis within tracks, the agency may take longer to process the FOIA request.

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[4] 21 C.F.R. § 20.44(b).
[5] 21 C.F.R. § 20.44(c).

Upon receipt of your FOIA request, FDA assigned the request to the Center for Drug Evaluation and Research (CDER) for processing and response. CDER uses multitrack processing of requests "for records based on the amount of work or time (or both) involved."[6]

Your FOIA request contained eight parts, ranging from (#1) all the data submitted in relation to the NDA for sofosbuvir and the sofosbuvir/ledipasvir combination from the earliest trials onward, including 7 categories of information, to (#5) all records related to trial and design of trials for sofosbuvir and the sofosbuvir/ledipasvir combination, whether the trial design was approved or not approved, to (#8) all records, including the Clinical Study Reports, regarding trials of sofosbuvir and the sofosbuvir/ledipasvir combination alone or in combination with another drug or drugs (e.g., ribavirin and/or interferon); including, but not limited to, eleven trial categories. Upon receipt, CDER placed your eight-part request it in its complex queue, as described in the following paragraph.

Although much of the information contained in the NDA for these drugs is posted on FDA's website,[7] CDER still must search the pre-approval records and documents in the NDA in order to determine whether additional requested records exist and whether they can be released, in full or in part. This requires searching multiple systems that combine electronic and paper records. In addition, searching pre-approval records and documents requires assessing the need for redactions, which can be extensive, in order to protect confidential information, as well as substantive decisions on whether records can be released. Therefore, given the demands of your request, it was placed in CDER's complex queue.

CDER takes its responsibilities for the administration of its FOIA program very seriously. Despite an increase of incoming requests by approximately 18% in 2014, CDER was able to reduce its backlog of pending requests by approximately 12%; from 680 to 599 requests. Additionally, CDER receives the highest number of incoming requests of any FDA component (3,130 requests were received in 2014) and processes the requests it receives on a "first-in-first-out" basis.

In conclusion, I find that GHJP's FOIA request is properly pending in CDER's complex queue and will be processed under its "first-in-first-out" rule within that queue based on the original date of receipt. The timeframe for responding to requests in CDER's complex queue is approximately 18 to 24 months. In order to provide you with additional information while the request is in the queue, on January 30, 2015, the Program Support Center's Freedom of Information Act office sent GHJP and TAG[8] an email providing them with web links to the drug approval packages for sofosbuvir and the sofosbuvir/ledipasvir.

This letter constitutes the final decision of the Department in this matter. If you wish, you may seek judicial review in the district court of the United States in the district in which you reside or

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[6] as authorized by section 552(a)(6)(D)(i) of the FOIA and FDA regulations.

[7] Drug Approval Package, SOVALDI sofosbuvir Tablets, http://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204671Orig1s000TOC.cfm (Jan. 27, 2014); Drug Approval Package, Harvoni (ledipasvir and sofosbuvir) Tablets http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/205834Orig1s000TOC.cfm (Nov. 3, 2014).; Drugs@FDA, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm.

[8] The January 30, 2015, email was addressed to Amy Kapczynski and Tracy Swan from TAG and GHJP.

have your principal place of business, in which the agency records are located, or in the District of Columbia.

The 2007 FOIA amendments created the Office of Government Information Services (OGIS) to offer mediation services to resolve disputes between FOIA requesters and federal agencies as a non-exclusive alternative to litigation. Using OGIS services does not affect your right to pursue litigation. You may contact OGIS in any of the following ways: Telephone: (202) 741-5770; Facsimile: (202) 741-5769; E-mail: ogis@nara.gov; or U.S. Mail at:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road – OGIS
College Park, MD 20740

Sincerely,

Catherine Teti

Catherine Teti
Executive Officer
Deputy Agency Chief FOIA Officer
Office of the Assistant Secretary for Public Affairs

EXHIBIT H

TAG
Treatment Action Group

GLOBAL HEALTH JUSTICE PARTNERSHIP
GHJP

April 1, 2015

Ms. Sarah Kotler
Division of Freedom of Information
U.S. Food and Drug Administration
5630 Fishers Lane
Room 1035
Rockville, MD 20857

Ms. Catherine Teti
Deputy Agency Chief FOIA Officer
Department of Health and Human Services
Parklawn Building
5600 Fishers Lane
Room 19-01
Rockville, MD 20857

RE: Freedom of Information Act Request No. 2014-9958 and Appeal No. 15-0179-AA

Dear Ms. Kotler and Ms. Teti,

We, the Global Health Justice Partnership ("GHJP") and the Treatment Action Group ("TAG") write in response to a February 19, 2015 letter from Catherine Teti in the Office of the Assistant Secretary of Public Affairs at the Department of Health and Human Services ("HHS letter"). The HHS letter, which was issued in response to our administrative appeal, affirmed the Food and Drug Administration's ("FDA") denial of our request for expedited processing regarding our December 17, 2014 Freedom of Information Act ("FOIA") request. The HHS letter also responded to our appeal from the FDA's constructive denial of the substance of that request. The HHS letter stated that a response to our FOIA request will take an estimated 18 to 24 months. The HHS letter, our FOIA request, and our administrative appeal are attached as Exhibits A, B, and C, respectively.

As the HHS letter acknowledges, under FOIA, the FDA is required to grant a request for expedited processing if the requester "demonstrates a compelling need." 5 U.S.C. § 552(A)(6)(E)(i). The requester may demonstrate a "compelling need" by showing either (1) that the requester is a "person primarily engaged in disseminating information" and that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists; or (2) "that 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).

We write to provide further evidence that both of these conditions are met here. In light of this additional evidence, which further addresses the supposed deficiencies identified in the decision denying our administrative appeal, we ask that the FDA reconsider its prior determination and immediately grant expedited processing of our request.

I. The Evidence Demonstrates That Requesters Are Primarily Engaged in Disseminating Information to the General Public and That an Urgency to Inform the Public Exists

Our FOIA request and subsequent appeal show that our request meets the definition of compelling need because we are "primarily engaged in disseminating information," and that an "urgency to inform the public concerning actual or alleged Federal Government activity" exists. 5 U.S.C. § 552(A)(6)(E)(v)(II); 21 C.F.R. § 20.44(c). Per the FDA's regulations, a requester may meet these requirements by showing that (1) "[t]he requester is primarily engaged in disseminating information to the general public and not merely to a narrow interest group;" (2) "[t]here is an urgent need for the requested information and that it has a particular value that will be lost if not obtained and disseminated quickly;" and (3) "[t]he request for records specifically concerns identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c).

The HHS letter summarily concluded that we did not meet the first and second requirements because we had "not provided sufficient information" "to support a determination" that we or our organizations are "persons primarily engaged in disseminating information for the general public," and that "there is an urgent need for the information and that its particular value will be lost if not obtained and disseminated quickly." Ex. A at 2. These findings are inconsistent with the evidence presented in our FOIA request and appeal, which is summarized and supplemented below.

A. Requesters Are Primarily Engaged in Disseminating Information to the General Public

Our FOIA request and appeal, together with the additional evidence provided in this letter, demonstrate that both TAG and GHJP are primarily engaged in disseminating information. Both TAG and GHJP obtain, analyze, and provide information to the general public about the hepatitis C virus ("HCV") and other significant diseases in furtherance of their respective missions.

GHJP is jointly hosted by the Yale Law School and the Yale School of Public Health and is dedicated to generating, compiling, and distributing information about structural influences on global health. Through inter-disciplinary work by students and professionals, GHJP publishes reports, organizes conferences and other events that are open to the public, and exchanges information with partner non-governmental organizations around the world. For example, in February 2015, GHJP released *Ending an Epidemic: Overcoming the Barriers to an HCV-Free Future*, a policy report highlighting the size of the HCV-infected population and the experiences

of individual patients.[1] The report, intended for consumption by the general public and released to the public at large, addresses the same subject matter as our FOIA request: the report assesses the promise of direct-acting antivirals, such as sofosbuvir and sofosbuvir/ledipasvir, and analyzes barriers to effective and affordable treatment. In addition to its work on HCV, GHJP has pursued projects disseminating information to the general public about miners' health in South Africa;[2] Congress's role in eliminating obstetric fistula in Africa;[3] UN accountability for the cholera outbreak following the 2010 Haiti earthquake;[4] and the intersection between human rights, intellectual property law, and access to medicines in the developing world.[5] In addition to policy papers like the HCV report, the GHJP faculty directors also publish both academic and general interest articles discussing public health issues, their research, and access to medicines. [6] GHJP makes these reports, publications, and other information readily accessible to the public on its website.[7] GHJP has also partnered with the Yale Open Data Access Project at the Yale School of Medicine, an initiative that has experience hosting large clinical trial datasets and making them accessible to researchers. The Yale Open Data Access Project is likewise committed to disseminating information to the public in furtherance of its mission of facilitating open science and rigorous, evidence-based review of clinical trial data.

Similarly, TAG's core mission involves disseminating information to the public. For more than two decades, TAG has engaged in public education and activism relating to treatment research for AIDS and other common coinfections, such as HCV. TAG disseminates information through fact sheets,[8] formal reports,[9] blog posts,[10] a newsletter,[11] public activism and

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[1] *Ending an Epidemic: Overcoming the Barriers to an HCV-Free Future*, GLOBAL HEALTH JUSTICE P'SHIP (2015), http://media.wix.com/ugd/148599_3746a108d074493d8fc18ed1f9c262c2.pdf.
[2] *Miners' Health in South Africa*, GLOBAL HEALTH JUSTICE P'SHIP, http://www.yaleghjp.org/#!miners-health-in-southern-afr/c1bm6 (last visited Mar. 18, 2015).
[3] *U.S. Congressional Aid for the Elimination of Obstetric Fistula*, GLOBAL HEALTH JUSTICE P'SHIP, http://www.yaleghjp.org/#!elimination-of-obstetric-fistu/c1xac (last visited Mar. 18, 2015).
[4] *U.N. Accountability for Cholera in Post-Earthquake Haiti*, GLOBAL HEALTH JUSTICE P'SHIP, http://www.yaleghjp.org/#!un-accountability-for-choler/c4qj (last visited Mar. 18, 2015).
[5] *Human Rights, Intellectual Property Law & Access to Medicines*, GLOBAL HEALTH JUSTICE P'SHIP, http://www.yaleghjp.org/#!human-rights-ip-law--a2m/cd86 (last visited Mar. 18, 2015).
[6] *See, e.g.*, *Faculty Research & Writings*, GLOBAL HEALTH JUSTICE P'SHIP, http://www.yaleghjp.org/#!faculty-research-writings/c1xtq (last visited Mar. 18, 2015); Gregg Gonsalves & Peter Staley, *Panic, Paranoia, and Public Health*, 371 NEW ENG. J. MED. 2348 (2014), http://www.nejm.org/doi/full/10.1056/NEJMp1413425; Gregg Gonsalves, *Stop Playing Cowboy on Ebola*, FOREIGN POL'Y, Oct. 28, 2014, http://foreignpolicy.com/2014/10/28/stop-playing-cowboy-on-ebola/; David Singh Grewal & Amy Kapczynski, *Let India Make Cheap Drugs*, N.Y. TIMES, Dec. 11, 2014, http://www.nytimes.com/2014/12/12/opinion/let-india-make-cheap-drugs.html.
[7] GLOBAL HEALTH JUSTICE P'SHIP, http://www.yaleghjp.org/ (last visited Mar. 18, 2015).
[8] *See, e.g.*, *HIV Cure Research Fact Sheet*, TREATMENT ACTION GRP. (Dec. 2014), http://www.treatmentactiongroup.org/cure/fact-sheet; *Fact Sheet: Hepatitis C and the IL28B Gene*, TREATMENT ACTION GRP. (Apr. 2013), http://www.treatmentactiongroup.org/hcv/factsheets/il28b.
[9] *See, e.g.*, *2014 Pipeline Report: Drugs, Diagnostics, Vaccines, Preventative Technologies, Research Toward a Cure, and Immune-Based and Gene Therapies in Development*, TREATMENT ACTION GRP. (2014), http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201407/2014%20Pipeline%20Report%20Full.pdf.
[10] *See, e.g.*, *Basic Science*, TREATMENT ACTION GRP., http://www.treatmentactiongroup.org/basic-science (last visited Mar. 18, 2015).
[11] *See, e.g.*, *Tagline: News on the Fight to End HIV/AIDS, Viral Hepatitis, and Tuberculosis*, TREATMENT ACTION GRP., http://www.treatmentactiongroup.org/tagline (last visited Mar. 18, 2015).

education,[12] and two websites[13] compiling and summarizing other resources like scientific publications[14] and conferences.[15] In 1992, for example, TAG released an influential policy report on government investment in basic science,[16] and their innovative work was featured in the critically acclaimed and Academy-Award-nominated documentary *How to Survive a Plague.*[17] TAG runs a dedicated program that addresses HCV[18] and regularly disseminates information about treatment options and recent developments relating to HCV in particular. For example, TAG's *2014 Pipeline Report* presents recent developments in HIV, HCV, and tuberculosis treatment options.[19] TAG also contributed to and published the *1st Hepatitis C Virus World Community Advisory Board Report*.[20] In 2014, TAG organized the first Hepatitis C Virus World Community Advisory Board meeting with a coalition of activists, many living with HCV and HIV/AIDS, representatives from non-governmental organizations, and regional and global advocacy networks. More generally, TAG is dedicated to disseminating accurate, comprehensive, and actionable information to the broad audience of ordinary citizens, pharmaceutical companies, activists, clinicians, and policymakers its work has historically reached.

B. An Urgent Need for the Requested Information Exists

In addition, contrary to the HHS's and the FDA's determinations, there is an "urgent need for the requested information," and "it has a particular value that will be lost if not obtained and disseminated quickly." 21 C.F.R. § 20.44(c)(2). As the numerous news reports cited below indicate, the requests concern matters of exigency to the American public. These matters include the cost-effectiveness of sofosbuvir and sofosbuvir/ledipasvir, the safety and efficacy of these two drugs across different populations, and the ethical and public health implications of restricting patient access. Unless expedited processing is granted, hundreds of thousands of patients will be administered treatments whose safety and efficacy are still not fully understood,

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[12] *See, e.g.*, HOW TO SURVIVE A PLAGUE (Public Square Films 2012) (highlighting TAG's advocacy efforts in a documentary film).

[13] TAG operates two websites, treatmentactiongroup.org and hepcoalition.org, which it co-hosts with *Médecins du Monde*. TAG's own website provides the informational resources described above, among others, while hepcoalition.org provides HCV treatment and advocacy-related resources and information in six languages. *See* TREATMENT ACTION GRP., http://www.treatmentactiongroup.org (last visited Mar. 18, 2015); HEPCOALITION, http://www.hepcoalition.org (last visited Mar. 18, 2015).

[14] *See Scientific Publications*, TREATMENT ACTION GRP., http://www.treatmentactiongroup.org/CURE/scientific-publications-open-access (last visited Mar. 18, 2015).

[15] *Conferences, Meetings, and Events*, TREATMENT ACTION GRP., http://www.treatmentactiongroup.org/CURE/conferences-meetings-and-events (last visited Mar. 18, 2015).

[16] Gregg Gonsalves & Mark Harrington, *AIDS Research at the NIH: A Critical Review*, TREATMENT ACTION GRP. (1992), http://www.treatmentactiongroup.org/sites/g/files/g450272/f/AIDS%20Research%20at%20the%20NIH%20Part%20I%20Jul%201992.pdf.

[17] HOW TO SURVIVE A PLAGUE, *supra* note 12.

[18] *See Hepatitis/HIV Project*, TREATMENT ACTION GRP., http://www.treatmentactiongroup.org/hcv/description (last visited Mar. 18, 2015).

[19] *2014 Pipeline Report: Drugs, Diagnostics, Vaccines, Preventative Technologies, Research Toward a Cure, and Immune-Based and Gene Therapies in Development*, TREATMENT ACTION GRP. (2014), http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201407/2014%20Pipeline%20Report%20Full.pdf.

[20] *1st Hepatitis C Virus World Community Advisory Board Report*, TREATMENT ACTION GRP. (2015), http://www.treatmentactiongroup.org/sites/g/files/g450272/f/201407/1st%20HCV%20World%20CAB%20Report.pdf.

billions of dollars of public funds will be spent on a drug whose cost-effectiveness remains uncertain, and thousands more may be denied treatment based on an incomplete accounting of the public health risks involved.

First, delaying access to the requested information prevents medical researchers and other members of the public from independently assessing the safety and efficacy of sofosbuvir and sofosbuvir/ledipasvir. These drugs continue to be prescribed at an extremely high rate, both in the United States and in other high-income countries. In 2014 alone, sofosbuvir and sofosbuvir/ledipasvir generated $12.4 billion in sales, with the vast majority of sales occurring in the United States.[21] Gilead, the manufacturer, estimates that as many as 250,000 patients could receive sofosbuvir and sofosbuvir/ledipasvir in 2015.[22] More prescriptions are written every day, and given that both these drugs are widely recommended by the American Association for the Study of Liver Diseases (AASLD),[23] the prescription rate is likely to remain high. As of January 2015, approximately 140,000 of the more than 3 million individuals infected with HCV in the U.S. had been treated using sofosbuvir-based therapy.[24] In addition, this past year, Gilead announced non-exclusive licensing agreements for sofosbuvir and sofosbuvir/ledipasvir for distribution in 91 developing countries, where more than 100 million people are estimated to be living with HCV infection.[25] This enormous population is now being prescribed these drugs at an accelerated pace, largely on the strength of the FDA's evaluation of submitted clinical trial data. As past experience with other drugs demonstrates, independent analysis of this data is essential. In previous cases, independent analysis of clinical trial data has uncovered important information about drugs' safety and efficacy not found by manufacturers or regulators.[26] The FDA has already revised the warning labels for sofosbuvir and sofosbuvir/ledipasvir to take account of previously unknown interactions with the antiarrhythmia medication amiodarone.[27] Publicly available information suggests that the FDA approved, post-hoc and without peer review, a shorter sofosbuvir/ledipasvir treatment course than the manufacturer proposed for a subset of

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[21] Andrew Pollack, *Sales of Sovaldi, New Gilead Hepatitis C Drug, Soar to $10.3 Billion*, N.Y. TIMES, Feb. 3, 2015, http://www.nytimes.com/2015/02/04/business/sales-of-sovaldi-new-gilead-hepatitis-c-drug-soar-to-10-3-billion.html.

[22] *Id.*

[23] *Gilead Quarterly Earnings Slides*, GILEAD SCIENCES, INC., http://investors.gilead.com/phoenix.zhtml?c=69964&p=irol-earnings (last visited Mar. 17, 2015).

[24] *Id.*

[25] *Id.*

[26] As part of a 2004 settlement to a lawsuit filed by New York's attorney general, GlaxoSmithKline agreed to publish all clinical trial data dating back to 2000 in an online registry. Using this newly available data, researchers conducted a meta-analysis that found significant cardiovascular risks in Avandia, a popular diabetes medication. Gardiner Harris, *Diabetes Drug Maker Hid Test Data, Files Indicate*, N.Y. TIMES, July 13, 2010, http://www.nytimes.com/2010/07/13/health/policy/13avandia.html. Similarly, clinical data obtained through freedom of information requests with the European Medicines Agency led researchers to uncover serious efficacy issues and previously unknown adverse effects in Tamiflu, a widely used flu medication. Peter Doshi, Tom Jefferson & Chris Del Mar, *The Imperative to Share Clinical Study Reports: Recommendations from the Tamiflu Experience,* 9 PLOS MED. e1001201 (2012).

[27] *FDA Drug Safety Communication: FDA Warns of Serious Slowing of the Heart Rate when Antiarrhythmic Drug Amiodarone Is Used with Hepatitis C Treatments Containing Sofosbuvir (Harvoni or Sovaldi) in Combination with Another Direct Acting Antiviral Drug*, U.S. FOOD & DRUG ADMIN. (Mar. 24, 2015), http://www.fda.gov/Drugs/DrugSafety/ucm439484.htm.

non-cirrhotic patients with a low viral load.[28] Additionally, there is concern in the medical community that cure rates for sofosbuvir in realistic treatment environments remain lower than reported rates in clinical studies, and that ledipasvir, as an NS5A inhibitor, may breed drug-resistant strains of HCV. Disclosing the requested information will aid researchers in addressing as quickly as possible these unresolved safety and efficacy issues.

Second, delaying access to the requested information prevents states and the public from adequately assessing sofosbuvir and sofosbuvir/ledipasvir's cost-effectiveness. The need for accurate cost-benefit analysis is urgent because these drugs threaten to overwhelm state health budgets. At least half of all 3.2 million HCV patients nationwide are covered by some form of taxpayer-subsidized insurance, and patient demand for sofosbuvir and sofosbuvir/ledipasvir poses an enormous burden to federal and state budgets. In Illinois, for instance, demand for sofosbuvir and sofosbuvir/ledipasvir drove Medicaid spending on HCV in 2014 from $6.7 million to $22 million—a more than 200 percent increase.[29] State prisons, which are required to treat inmates and have very limited means to gain reductions from the retail drug price, face similarly daunting budget pressures.[30] Widespread public concerns about the extraordinary costs of these two drugs have led the Senate Finance Committee to investigate Gilead's pricing policies, as well as whether prices for sofosbuvir and sofosbuvir/ledipasvir reflect a competitive, fair, and transparent marketplace.[31] However, the drugs' cost-effectiveness cannot be fully assessed without more detailed information about the medical efficacy or safety of these drugs. If the release of the requested information is delayed, millions—or billions—of dollars in taxpayer funds and insurance plans will be spent on a drug whose cost-effectiveness and underlying value cannot be fully evaluated by the American public.

Third, delaying access to the requested information deprives states and the public of data relevant to Medicaid policies that affect thousands of HCV patients. Due to cost pressures, at least half of all state Medicaid agencies are devising non-evidence based policies that restrict access to these drugs to a narrow subset of patients who have already suffered severe liver damage and who have abstained from drugs or alcohol.[32] As public debates in New York,[33] Illinois,[34] Oregon,[35] and Texas[36] illustrate, these restrictive access policies are being developed

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[28] *Compare* Ctr. for Drug Evaluation & Research, *Application Number: 205834Orig1s000 Pharmacology Review*, U.S. FOOD & DRUG ADMIN. 14 (2014), *with Harvoni Package Insert*, U.S. FOOD & DRUG ADMIN. (2014), http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205834s000lbl.pdf.

[29] Wes Venteicher, *Medicaid Patients Denied New Hepatitis C Cures*, CHI. TRIB., Nov. 16, 2014, http://www.chicagotribune.com/news/ct-medicaid-hepatitis-met-20141116-story.html.

[30] Margot Sanger-Katz, *Why the Hepatitis Cure Sovaldi Is a Budgetary Disaster for Prisons*, N.Y. TIMES, Aug. 7, 2014, http://www.nytimes.com/2014/08/07/upshot/why-the-hepatitis-cure-sovaldi-is-a-budgetary-disaster-for-prisons.html.

[31] Peter Loftus, *Senate Committee Is Investigating Pricing of Hepatitis C Drug*, WALL ST. J., July 11, 2014, http://www.wsj.com/articles/senate-finance-committee-is-investigating-pricing-of-hepatitis-c-drug-1405109206.

[32] Michelle Andrews, *Hepatitis C Patients May Not Qualify for Pricey Drugs Unless Illness is Advanced*, WASH. POST, Nov. 4, 2014, http://www.washingtonpost.com/national/health-science/hepatitis-c-patients-may-not-qualify-for-pricey-drugs-unless-illness-is-advanced/2014/11/03/6d0646bc-5f71-11e4-9f3a-7e28799e0549_story.html; Chris Kardish, *The Risky Business of Limiting Medicaid Access to Sovaldi*, GOVERNING (Aug. 19, 2014), http://www.governing.com/topics/health-human-services/gov-hepatitis-coverage-solvaldi-lawsuits.html; Venteicher, *supra* note 29.

[33] *Advocates Criticize Plans to Restrict N.Y. Hepatitis C Drugs*, HEP MAGAZINE, Oct. 21, 2014, http://www.hepmag.com/articles/nys_sovaldi_restrictions_2831_26318.shtml.

[34] Venteicher, *supra* note 29.

based on incomplete and contested information about the safety and efficacy of sofosbuvir and sofosbuvir/ledipasvir in certain subpopulations as well as the public health ramifications of rationing access. In the absence of adequate information, New York initially denied treatment to drug and alcohol users based on concerns that substance use would prevent patients from adhering to a treatment regimen;[37] Illinois has denied access to patients who cannot tolerate interferon;[38] and Texas has justified access restrictions by citing an alleged lack of large-scale trials involving low-income individuals, minorities, and substance users.[39] In response, public health experts and activists have suggested that forcing HCV patients to endure additional liver damage could subject them to unpredictable health risks such as liver cancer,[40] questioned the medical rationale for requiring interferon tolerance,[41] and argued that curing people who use drugs could prevent onward transmission of HCV to other individuals.[42]

Prompt access to the requested information will inform these ongoing policy debates. Granular, patient-level clinical data may allow researchers to better evaluate the safety and efficacy of these drugs in minority or substance-using populations. Delaying release of the requested information could lead states to enshrine flawed rationing policies that have life-or-death consequences for hundreds of thousands of HCV patients, who may be forced to endure additional liver damage and other health risks before becoming eligible for treatment. Prompt access to the requested information may also cause states to reconsider policies denying treatment to substance users. In the interim, untreated drug users with HCV—in particular, people who inject drugs—may continue to transmit HCV to others, creating a greater public health risk.

Finally, the HHS letter appeared to accept that our organization's FOIA requests satisfy the third requirement for expedited processing—i.e., that the request concerns "identifiable operations or activities of the Federal Government." 21 C.F.R. § 20.44(c). Analyzing clinical trial data, identifying risks, and approving drugs for use by the American public are among the FDA's core functions. These operations and activities lie at the heart of our organizations' FOIA requests; we wish to make available for independent analysis the clinical trial data submitted to the FDA to ensure the FDA is properly fulfilling its statutory mandate.

II. The Evidence Demonstrates That There Is an Imminent Threat to the Life or Safety of an Individual

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[35] Tara Bannow, *State Oks New Hep C Drug for Medicaid Patients,* THE BEND BULLETIN (Mar. 5, 2015), http://www.bendbulletin.com/health/2919053-151/state-oks-new-hep-c-drug-for-medicaid.
[36] Alexa Ura, *Cost of New Drug Complicates Access for Inmates and the Poor*, N.Y. TIMES, May 24, 2014, http://www.nytimes.com/2014/05/25/us/cost-of-new-drug-complicates-access-for-inmates-and-the-poor.html.
[37] *Hepatitis C Virus Clinical Criteria Update*, N.Y. STATE DEP'T OF HEALTH & STATE UNIV. OF N.Y. (Sept. 18, 2014), http://cdn.hepfree.nyc/wp-content/uploads/sites/57/2014/09/HCV-DAA-Clinical-Criteria-2014_17_09_Final1.pdf; *Medicaid Pharmacy Program Prior Authorization (PA) Update*, N.Y. STATE MEDICAID UPDATE, Oct. 2014, at 9, https://www.health.ny.gov/health_care/medicaid/program/update/2014/oct14_mu.pdf.
[38] Andrew L. Wang, *Illinois Medicaid Restricts Who Can Get Game-Changing Drug,* CRAIN'S CHI. BUS., July 29, 2014, http://www.chicagobusiness.com/article/20140729/NEWS03/140729819/illinois-medicaid-restricts-who-can-get-game-changing-hepatitis-drug.
[39] Kardish, *supra* note 32.
[40] *Id.*
[41] Wang, *supra* note 38.
[42] *Id.*

Furthermore, our FOIA request and subsequent appeal, together with the additional evidence offered in this letter, show that the request meets the alternate definition of "compelling need" because FDA's failure to release the requested pharmaceutical regulatory data related to the FDA's approval of sofosbuvir and sofosbuvir/ledipasvir "could reasonably be expected to pose an imminent threat to the life or safety of an individual." 552(A)(6)(E)(v)(I).

The FDA's failure to promptly disclose the requested information will subject many individuals to imminent threats to life and safety. As discussed above, these two drugs were prescribed to more than 100,000 individuals during their first year on the market, and it is likely that prescriptions will continue at an even higher rate during the next 18-24 months both in the United States and abroad. There are 26-30 million people globally with F3-F4 stage liver disease, and who are therefore most urgently in need of treatment.[43] These two drugs were approved on an accelerated timeline after being given Breakthrough Therapy Designation, and are being prescribed for certain genotypes and for certain patient subpopulations after very small clinical trials. On the basis of these trials, both the AASLD and the Worth Health Organization already recommend sofosbuvir in their treatment guidelines,[44] and sofosbuvir is now considered the backbone of direct-acting antiviral curative treatment. Any safety and efficacy issues discovered after release of the requested information will affect the population that has already been prescribed these drugs. Prompt release of the requested information will minimize the threats posed by these kinds of concerns.

In addition, current and developing state policies selectively deny access to these drugs to certain patients based on incidental factors like liver damage or tolerance of other treatment options, even while the relationship between these variables remains incompletely understood. These policies reflect the currently available information and require some patients to await further liver damage before they can receive treatment. Access to the requested information will shed light on the wisdom of these policies, which effectively determine the trajectory of a patient's treatment. It is urgent that any adjustments to these access policies be made as soon as possible, given the patient lives that hang in the balance.

Under the FOIA statute, this showing is sufficient to establish a "compelling need" for expedited processing. Your letter denied our administrative appeal, however, on the grounds that the FDA's regulations require that the request (1) "must be made by the specific individual who is subject to an imminent threat, or by a family member, medical or health care professional, or other authorized representative of the individual," and (2) "must demonstrate a reasonable basis for concluding that failure to obtain the requested records on an expedited basis could reasonably be expected to pose a specific and identifiable imminent threat to the life or safety of the individual." 21 C.F.R. § 20.44(b). GHJP and TAG pursue their missions by working closely with medical and public health professionals and people living with HCV, and our work—including this FOIA—is done in order to further the interests of individual, identifiable patients. While we

[43] Gottfried Hirnschall, World Health Org., Presentation at 20th Int'l AIDS Conf. (July 21, 2014), http://pag.aids2014.org/session.aspx?s=1050#1.

[44] *Recommendations for Testing, Managing, and Treating Hepatitis C*, AM. ASSOC. FOR STUDY LIVER DISEASES (2015), http://www.hcvguidelines.org/fullreport; *Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection*, WORLD HEALTH ORG. (2014), http://www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/.

bring this request in our own capacities as organizations dedicated to public health, rather than on behalf of a specific individual, we articulate the compelling need for this information based on extensive professional and personal knowledge of individuals whose lives and health are at stake. The information we seek must be produced immediately in order to prevent potential serious and imminent threats to a potentially very large number of people who may be treated with these drugs.

Moreover, the FDA regulations' requirement that the requester be an "authorized representative" of "the individual" whose life or safety is threatened is at odds with the FOIA statute, which neither requires the request to be made by an "authorized representative" nor the threat to life or physical safety to be specific to a particular, identified individual. Instead, FOIA simply provides that a requester may demonstrate compelling need by showing "that 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)(2) (emphases added). While the FDA may expand access to expedited processing by regulation, the agency may not contract that 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)). Your restriction of "compelling need" to particular threatened individuals and their "authorized representatives" denies expedited processing to requesters who, like our organizations, are entitled to expedited processing by statute and are well positioned to disseminate the requested information to—and use information on behalf of—the very individuals and groups that may be directly impacted.

* * *

For the forgoing reasons, we are entitled to expedited processing of our December 17, 2014 FOIA request. In light of the additional evidence and argument presented here, we respectfully request that the FDA reconsider its denial and grant our petition for expedited processing immediately.

The contents of this letter, and of our prior submissions in support of expedited processing, *see* Exhibits B and C, are true and correct to the best of the undersigned individuals' knowledge and belief.

Thank you for your prompt attention to this matter. Please direct all correspondence relating to this request to:

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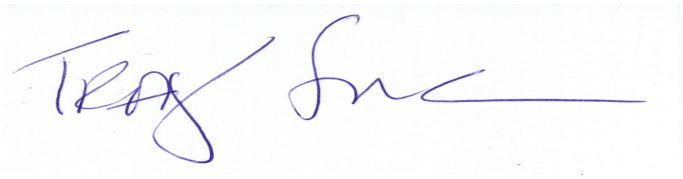
FAX: (203) 43609397

Sincerely,



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Enclosures: Exhibit A: Letter from Catherine Teti, Office of the Assistant Secretary of Public Affairs, Department of Health and Human Services, to Meredith Berger, Coordinator, Global Health Justice Partnership (Feb. 19, 2015);
Exhibit B: FOIA Request No. 2014-9958;
Exhibit C: FOIA Appeal No. 15-0179-AA.

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