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.

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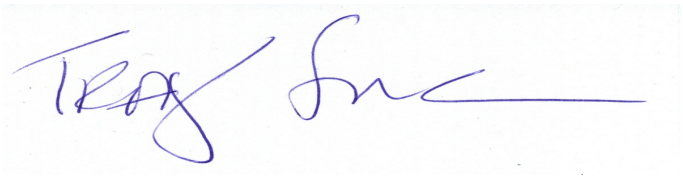
For the forgoing reasons, we are entitled to expedited processing of our December 17, 2014 FOIA request. In light of the additional evidence and argument presented here, we respectfully request that the FDA reconsider its denial and grant our petition for expedited processing immediately.

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:

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