April 1, 2022

From:

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To:

[redacted]
Health Scientist and Opioid Rapid Response Program (ORRP) Lead Coordinator, CDC, Division of Overdose Prevention

Dea[redacted]

It is my understanding that you work within CDC's Center for Injury Prevention and Control, Division of Overdose Prevention, strengthening Federal partnerships and programs to support state and local drug overdose prevention initiatives, with a focus on data use and coordination among public health, law enforcement, criminal justice, and first responders. According to your linkedin profile [redacted], you are an experienced health scientist, that applies theory and practice driven methods to inform overdose prevention program design, outreach, and innovation.

I have read three important publications about the program that you are heading.

1. Responding to Pain Clinic Closures: A GUIDE FOR STATE HEALTH DEPARTMENTS JUNE 2020; ASSOCIATION OF STATE AND TERRITORIAL HEALTH OFFICIALS- This guide is based on a review of the literature and resources available on current practices, including protocols provided by Maryland, Washington state, West Virginia, and expert guidance provided by state representatives, federal partners and organizations who attended ASTHO's Building State Opioid Preparedness meeting in January 2019.
2. OPIOID RAPID RESPONSE PROGRAM Trusted Contacts' Frequently Asked Questions (FAQs)- The document explains that as part of the Opioid Rapid Response Program (ORRP), the Centers for Disease Control and Prevention (CDC) and the Office of Inspector General within the US Department of Health and Human Services (HHS OIG) establish trusted contacts who work within state public health and behavioral health government agencies. This document is intended to explain the role of these trusted contacts and answer frequently asked questions.
3. OPIOID RAPID RESPONSE PROGRAM Background and Description-This document explains Opioid Rapid Response Program (ORRP), an interagency, coordinated federal effort to mitigate drug overdose risk among patients impacted by law enforcement actions that disrupt access to prescription opioids or

medication assisted treatment/medication for opioid use disorder (MAT/MOUD). Overseen by United States Department of Health and Human Services (HHS) Office of the Assistant Secretary for Health (OASH) and coordinated by US Centers for Disease Control and Prevention (CDC) and the Office of the Inspector General within HHS (HHS OIG).

The documents explain that ORRP supports care continuity and risk reduction for patients by coordinating federal law enforcement actions and public health overdose risk mitigation. The documents as a whole presents the context and basis for ORRP. They describe the roles of different federal law enforcement programs in identifying, investigating and prosecuting prescribers and the downstream impact these types of actions can have on people with opioid use disorder or physical dependency. They describe CDC's public health role in addressing the opioid overdose epidemic, including CDC's support for state and local overdose prevention efforts. The documents summarize the ORRP's origin and its specific strategic components, goals, and activities. The documents also describe ORRP "Trusted Contacts". Trusted contacts typically include one individual from the state health department, and another from the state behavioral health or substance abuse services agency, who are entrusted with confidential law enforcement information prior to an action being taken against a prescriber of opioids or medication-assisted treatment/ medication for opioid use disorder (MAT/MOUD). In many cases, trusted contacts are the principal investigators for CDC's Overdose Data to Action (OD2A) Cooperative Agreement and directors of the state agency funded by Substance Abuse and Mental Health Services Administration (SAMHSA). Trusted contacts are contacted by the CDC ORRP team prior to a law enforcement action and are provided with information that can help them assess patient risk and direct resources to mitigate the risk of overdose among patients and others in the community (in cases of diversion).

According to the documents there are Clinic Closure Response Team (CCRT) and Emergency Management Assistance Compact (EMAC) that coordinate continuity of care for vulnerable patients including following a clinic closure, the officer of the local health jurisdiction is the key player to ensure patients are referred to care.

I am currently facing federal felony charges relating to health care fraud and controlled substances in *United States v.* [redacted]. The indictments in this criminal case against myself assert, inter alia, that [redacted] illegally prescribed and distributed various commonly abused opioids (see attached indictment). I am presumed innocent until proven guilty, and have elevated status to obtain information from the ORRP for trial impeachment purposes. The U.S. Department of Justice has the burden of proof, at a jury trial, to prove beyond a reasonable doubt, that each of the criminally indicted physicians actually committed all the elements of the alleged crimes, in the absence of justifications or excuses. The outcome of criminal proceedings for myself would be different without the release of the information from ORRP as

requested in this document. The refusal of the ORRP to release the information would lead to a finding of cumulative error. The ORRP's denial of release of the information requested in an expedited rolling process will be prejudicial to myself in his upcoming criminal trial *United States v.* [redacted]. In this case, the failure of ORRP to release the requested information (also subject to Freedom of Information Act) will reduce the chance of myself to defend each element of the charged crime in *United States v.* [redacted]. The ORRP's error and failure to process my requests for information in an expedited rolling process would not be harmless.

Additionally, the requested information concerning ORRP and ORRP "Trusted Contacts" would be critical to other physicians facing allegations of improper prescribing can alter the outcome of their criminal proceeding by being better informed when taking a plea bargain, proceeding to a jury trial, or if proceeding to trial, deciding on the optimum trial strategy. The lack of production of the requests for information by ORRP in an expedited manner will prejudice criminal defendant physicians in three ways: "oppressive pretrial incarceration, anxiety and concern caused by the delay, and an impaired defense." (*Foster*, 1997 ND 8, ¶ 12, 560 N.W.2d 194). Significant anxiety and concern will be caused to other pain specialists or substance abuse doctors who are uncertain as to the exact proscribed behaviors involving controlled substances in the treatment of patients.

I am formally requesting expedited and rolling disclosure of critical information for criminal trial preparation in *United States v.* [redacted]. A failure by ORRP to release information for my upcoming criminal trial would later be subject to future expedited FOIA disclosure under *Freeman v. Dep't of Justice*, No. 92-0557 (D.D.C. Oct. 2, 1992) ("exceptional circumstances"/"due diligence": vacates, in part, court's May 22, 1992 order; because of the limited scope of plaintiff's FOIA request and because plaintiff has demonstrated that the information will assist him in his defense against state criminal charges for securities fraud where discovery of these records would not be available, orders the defendant to comply with plaintiff's FOIA request by December 31, 1992; and also by that date, to file a Vaughn Index of those documents or document portions for which it invokes exemptions).

Furthermore, my upcoming criminal trial mandates expedited FOIA disclosure under *Brady* [(*Brady v. Maryland*, 373 U.S. 83, 83 S.Ct. 1194, 10 L.Ed.2d 215 (1963)]. The prosecution team in *United States v.* [redacted] must disclose, upon request, evidence that is material either to guilt or to punishment. *Gilliam v. Sec'y for the Dep't of Corrections*, 480 F.3d 1027, 1032 (11th Cir. 2007). Such evidence is material only if "there is a reasonable probability that, had the evidence been disclosed to the defense, the result of the proceeding would have been different." *United States v. Bagley*, 473 U.S. 667, 682, 105 S.Ct. 3375 3383, 87 L.Ed.2d 481 (1985). *Brady* requires disclosure of material impeachment evidence as well as material exculpatory evidence. *Flores v. Satz*, 137 F.3d 1275, 1278 (11th Cir. 1998)." *Mize v. Hall*, 532 F.3d 1184 (11th Cir. 2008).

A Government agency (in this case Center for Disease Control) failure to disclose the requested Brady information that a respondent could have used to conduct an effective cross-examination impairs a respondent's right to confront adverse witnesses. The court noted: "In *Davis v. Alaska*, . . . the Supreme Court held that the denial of the 'right of effective cross-examination' was "constitutional error of the first magnitude" requiring automatic reversal." 719 F.2d, at 1464 (quoting *Davis v. Alaska*, 415 U.S. 308, 318, 94 S.Ct. 1105 1111, 39 L.Ed.2d 347 (1974).

As part of the Opioid Rapid Response Program (ORRP), the **Centers for Disease Control and Prevention (CDC)** and the **Office of Inspector General within the US Department of Health and Human Services (HHS OIG)** establish trusted contacts who work within state public health and behavioral health government agencies. Trusted contacts are contacted by the CDC ORRP team prior to a law enforcement action and are provided with information that can help them assess patient risk and direct resources to mitigate the risk of overdose among patients and others in the community (in cases of diversion). Sensitive information related to the action is shared with trusted contacts only at the request of law enforcement agents. Trusted contacts may take immediate steps to further assess patient risk and prepare to put mitigation measures in place. Examples of actions a state may decide to take include the following:

a) Querying the prescription drug monitoring program (PDMP) database to determine the scope and types of risk (e.g., by identifying numbers of patients' living in surrounding counties and their medications and dosing)

b) Arranging to have on-site support for patients while an action (e.g., an arrest) is taking place (only at the request of law enforcement)

c) Identifying available providers to whom patients can be referred

d) Developing notices with contact numbers for patient referrals

e) Preparing health alert notices for local hospitals/ emergency departments, first responders, and harm reduction organizations

f) Increasing naloxone distribution in the area

g) Accessing care coordinators to help patients navigate options, including offering treatment

h) Contacting local law enforcement to assess current illicit supply risks (e.g., counterfeit pills) and incorporate information into patient or public education

i) Issuing a press release or providing risk reduction information to include in a law enforcement press release

j) Monitoring referrals and patient outcomes

The Overdose Response Strategy (ORS), in which a drug intelligence office and/or a public health analyst is assigned to the state. ORS is a partnership between the Office of National Drug Control Policy and CDC to better share real-time drug seizure data and organize a public health response. Drug intelligence officers (DIOs) and public health analysts (PHAs) who have been trained on ORRP Public Health and Safety Team

(PHAST) is a framework for multi-sector data sharing and coordinated overdose prevention. When multi-sector partners are engaged in ongoing coordination and relationship building, jurisdictions can enhance their situational awareness and optimize response capacity. The ORRP was largely developed through a partnership between CDC, the Office of the Assistant Secretary for Health (OASH), and HHS OIG. Most of the actions to date that have leveraged ORRP have resulted from HHS OIG and/or Drug Enforcement Administration (DEA) investigations. Diversion investigations often target physicians who provide prescriptions to individuals for purposes other than a legitimate medical treatment or outside the scope of legitimate medical practice. Investigations also often involve pharmacies that fill prescriptions despite "red flag" indicators of diversion; pharmacists who falsify records and subsequently sell the drugs; employees who steal from inventory and falsify orders to cover illicit sales; prescription forgers; and individuals who steal from pharmacies, drug distributors, or other DEA registrants. Law enforcement actions that may disrupt prescription supply and impact patients include: a search warrant on a facility where opioid prescribing occurs or MAT/MOUD is provided, provider arrest, DEA registration suspension, DEA registration surrender by a prescriber, Medical license suspension.

I am seeking information from ORRP and ORRP "Trusted Contacts" concerning the efforts made concerning the continuity of care for my chronic pain and substance use disorder patients following my September 25, 2019, arrest. I am seeking all relevant information concerning activation of Primary Components PHASE 1: Pre-Incident Planning; PHASE 2: Immediate Phase (Mobilization through first 24 hours); PHASE 3: Intermediate Phase (Through week one); PHASE 4: Longer-Term Response (Beyond week one) alerting others (e.g., a medical examiner or EMS, or ED provider noticing a surge reporting it) pertaining to my criminal indictment and continuity of care for my chronic pain and substance use disorder patients following my September 25, 2019 arrest. I am seeking the following detailed information:

i. [redacted] ORRP and ORRP "Trusted Contacts" phone tree and contact list; the United States "Trusted Contacts" phone tree and contact list for each of the States

ii. Identification of other stakeholders who may be involved in or affected by my clinics closure including identification of physicians who were willing and able to accept patients taking high doses of opioids

iii. Assessment of the number of pain clinics within [redacted] State and their capacity to accept new patients

iv. Verification of the number of MAT-waivered providers and assess their experience with MAT within Pennsylvania State

v. The location of waivered prescribers and if there was a deficit, considered models of telehealth across [redacted] State

vi. Evaluation of the capacity of local hospitals including management and programs, reimbursement models, EMS volunteer versus paid, and the level of experience of staff within [redacted] State.

vii. A list of available providers in specified areas and if possible, a GIS map of primary care practices linked to Medicaid claims data and the PDMP within [redacted] State

viii. [redacted] State contacts at the relevant office to determine which private insurers are contracted with the provider.

ix. The availability of peer recovery specialists to connect affected patients with continuity of care following my September 25, 2019 arrest. Please release all information concerning referral of my patients to: a) Emergency departments, b) Primary and ambulatory care clinics, c) State medical review board, d) Health systems and quality assurance

x. Assessments of the infrastructure of the [redacted] area, including transportation challenges, prior to my [redacted] arrest

xi. Assessment of needed resources to fill gaps identified by readiness assessment, prior to my [redacted] arrest

xii. [redacted] "Trusted Contacts" who ensured availability and distribution of naloxone to key areas following my [redacted] arrest

xiii [redacted] "Trusted Contacts" who checked availability of hospital beds for treatment and rehabilitation following my [redacted] arrest

xiv. [redacted] Trusted Contacts" who checked capacity of addiction treatment facilities prior to and following my [redacted] arrest

xviii [redacted] Trusted Contacts" who checked capacity of morgues to house fatal overdose victims following my [redacted] arrest

xix. **The dates and names of responsible individuals who posted flyers guiding my patients following my September 25, 2019 arrest**

I am also seeking from ORRP Clinic Closure Response Team Members in [redacted] State and Nationwide including:

1) Local officials (including directors of health and behavioral health, medical epidemiologist)

2) Local public safety officials (fire, EMS, sheriffs, police chiefs)

3) Regional emergency coordinator

4) Opioid task force

5) Office of Drug Control Policy director

6) Drug intelligence officer (from DEA and HIDTA)

7) Health communications director

8) State office of the insurance commissioner, or another similar state body who can determine which private insurers are contracted with the provider

9) Medicaid director

10) Local and state social services officials (including those from child protective services)

11) Other communications directors (from public safety, DOH, mayor's office, governor's office)

12) Attorney general

13) Medical officer

14) Harm reduction lead

15) Career epidemiology field officer

In conclusion ORRP must expeditiously provide me the requested information as I will be unable to recover damages from the Center for Disease Control (CDC), who enjoys sovereign immunity. 5 U.S.C. § 702 (providing for relief "other than money damages"). This renders injuries or harms from ignoring my good faith request "per se" irreparable. See *Feinerman v. Bernardi*, 558 F. Supp. 2d 36, 51 (D.D.C. 2008) (unrecoverable harms are "per se" irreparable); *Smoking Everywhere, Inc. v. FDA*, 680 F. Supp. 2d 62, 77 n.19 (D.D.C. 2010) (similar); see also *Whitman-Walker Clinic, Inc.*, 485 F. Supp. at 64-65 ("'[W]here economic loss will be unrecoverable, such as in a case against a Government defendant where sovereign immunity will bar recovery, economic loss can be irreparable' even if it would not wipe the business out." (quoting *Everglades Harvesting & Hauling, Inc. v. Scalia*, 427 F. Supp. 3d 101, 115 (D.D.C. 2019), and citing additional cases)). In addition to being "beyond remediation," these losses are irreparable because they are "certain and great" for the reasons detailed *supra*. *Whitman-Walker Clinic, Inc.*, 485 F. Supp. 3d at 56 (quoting *Chaplaincy of Full Gospel Churches v. England*, 454 F.3d 290, 297 (D.C. Cir. 2006), and *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)).

CDC harms against myself are "both certain and great; . . . actual and not theoretical and of such imminence that there is a clear and present need for equitable relief." *Olu-Cole v. Haynes Pub. Charter Sch.*, 930 F.3d 519, 529 (D.C. Cir. 2019) "These harms from the forced diversion of resources are similar to those recognized as irreparable harm in other suits," *District of Columbia v. USDA*, 444 F. Supp. 3d 1, 42 (D.D.C. 2020), and they far exceed the showing required here. The United States District Court for the District of Columbia has previously recognized that the ORRP's denial of expedited rolling production of documents (also subject to Freedom of Information Act) would, as previously described by myself, constitute irreparable harm. E.g., *Whitman-Walker Clinic, Inc.*, 485 F. Supp. 3d at 58 ("Because of the significant financial and operational harms the health-provider Plaintiffs will suffer on account of the 2020 Rule—and the consequent, well-established threat to their ability to deliver timely and effective care to their patients—the Court finds that their asserted injuries clear the irreparable-harm threshold."). *Texas Children's Hosp. v. Burwell*, 76 F. Supp. 3d 224 (D.D.C. 2014); see also *League of Women Voters v. Newby*, 838 F.3d 1, 9 (D.C. Cir. 2016) (finding irreparable harm when challenged action "ma[de] it more difficult for [organizations] to accomplish their primary mission").

All in all, myself and other U.S. physicians will suffer unrecoverable future harm which is of such a degree, severity, and 'imminence that there is a clear and present need for equitable relief to prevent' it." Id. (quoting *Wisconsin Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985)). "Courts have also recognized that such

[reputational] harm . . . can constitute irreparable harm sufficient to qualify for a preliminary injunction." *Everglades Harvesting*, 427 F. Supp. 3d at 116.

[redacted] would like to engage in cordial communication with you to ultimately receive the requested information above expeditiously. I seek a response from your office within seven business days. If you decide to ignore my good faith request, a result and consequence of the aforementioned and numerous irreparable injuries, would allow me the subsequent right pursuant to the FOIA Act to receive expedited production of documents from the CDC. I could also enjoin this request to current litigation in [redacted] *v. U.S. Department of Health and Human Services et al.*, [redacted]

Respectfully Submitted,

[redacted]

[redacted]

April 1, 2022