IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TEXAS
AUSTIN DIVISION

INFORMED CONSENT ACTION NETWORK, Plaintiff, v. CENTERS FOR DISEASE CONTROL AND PREVENTION AND HEALTH AND HUMAN SERVICES, Defendants.	Civil Action No. 1:22-cv-481-RP

JOINT STATUS REPORT

The parties respectfully submit the following joint status report pursuant to the Court's Order of October 17, 2022, *see* Text Order.

This case involves a Freedom of Information Act ("FOIA") request that Plaintiff Informed Consent Action Network submitted to the Centers for Disease Control and Prevention ("CDC"). The request seeks all data submitted to the CDC's "v-safe" program, a smartphone-based system that uses text messaging and web-based surveys for personalized and confidential health check-ins with enrolled participants to monitor and assess for potential adverse events following a COVID-19 vaccination.[1] On May 17, 2022, Plaintiff filed this action under FOIA, 5 U.S.C. § 522, seeking to compel CDC to produce non-exempt records responsive to its FOIA request. ECF No. 1. CDC filed an answer to the complaint on June 22, 2022. ECF No. 14.

[1] Centers for Disease Control and Prevention, *v-safe After Vaccination Health Checker* (updated Jan. 20, 2022), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

Plaintiff's Statement

Background

The CDC's Covid-19 vaccine recommendations have been the basis of mandates across this country that have pressed deeply on cherished individual and civil rights. Americans could not, and many still cannot, hold a job, attend school, serve in the military, and otherwise engage in many aspects of everyday life in America unless they complied with the CDC's recommended Covid-19 vaccine regiment to receive numerous injections of this product – a product whose manufacturers have immunity for the injuries they cause under the PREP Act. Central to the CDC's Covid-19 vaccine campaign for Americans was the claim that these products are safe and effective.

And central to supporting the claim that these products are safe and effective is the CDC's premier tracking system for tracking same: its new v-safe platform. The CDC, in dozens of publications, relied on the data from v-safe to argue and support its recommendations regarding Covid-19 vaccination that upended the lives of tens of millions of Americans who refused to comply. The public, and especially these tens of millions of Americans, and the tens of millions more that received this injection relying on the CDC's guidance, have an acute right to see the v-safe data that they paid for through taxes and which underpin the CDC's claims of safety. Especially those fired from their jobs, expelled from school, discharged from the military, thrown out of restaurants, and otherwise excluded from participation in many aspects of everyday and civil life in this country for refusing to follow the CDC's Covid-19 vaccine directives. Those injured by this product similarly should be able to see this data forthwith, including the thousands of individuals who have contacted our law firm with claims of serious injuries from Covid-19 vaccines and the likely far larger group of such individuals that have not contacted our law firm.

Overview of V-Safe Program

The v-safe program has approximately 10 million users. These users were prompted by the v-safe program by text message to fill out a survey after receiving a Covid-19 vaccine. The information collected in these surveys was very limited, consisting of a limited set of check-the-box fields along with free-text fields to provide additional information.

V-safe asked users to complete this survey on the day of injection and for each day for seven days thereafter. On those eight days, it asked users to check one of 18 pre-specified symptoms, mostly minor symptoms considered normal after vaccination (*e.g.*, pain, fatigue, etc.) It does not ask about or have any check-the-box fields for any of the known serious symptoms and effects from Covid-19 vaccines such as myocarditis, pericarditis, Guillain-Barre Syndrome, MIS, seizures, transverse myelitis, etc. V-safe did not ask about these serious issues despite the fact that the CDC specifically identified these as adverse events of special interest in a chart of "Prespecified Medical Conditions" in its protocol for developing v-safe.[2] However, the CDC did include free-text fields, limited to 250 characters each, for users to list other symptoms or reactions they experienced from Covid-19 vaccination, and, hence, this is the only place where serious issues occurring from Covid-19 vaccination would have been recorded. These surveys also asked about whether the user tested positive for Covid-19. Finally, the surveys provided check-the-box fields for whether the user missed school/work, could not perform normal daily activities, or needed medical care (the "health impact questions").

The v-safe system also sent slightly different surveys to users at 2, 3, 4,5 ,6, 12, 24, and 52 weeks after vaccination that again included the check-the-box health impact questions, a question

[2] See page 58 of the CDC v-safe protocol dated January 28, 2021 available at https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-v2-012821.pdf.

concerning whether the user tested positive for Covid-19, and free-text fields for reporting issues the user believes are related to Covid-19 vaccination.

It is worth noting that most of the v-safe users signed up for v-safe between when the first Covid-19 vaccine was released in December 2020 and May 2021, during a period of high enthusiasm to participate in the vaccine program and when few, if any, were being compelled to receive this product. These individuals wanted to participate and were likely less inclined to report issues from these products than the average person who received this product, especially less likely than those who were compelled to receive these products when mandates were eventually enacted.

Check-the-Box Fields

Regarding the check-the-box fields, after a year and a half of demands and litigation, the CDC finally produced what appears to be a significant portion of the check-the-box fields. This consisted of five excel files which likely took the CDC minutes to download and produce. In our last status conference letter, we explained that Plaintiff requested that the CDC produce the birth year of each v-safe user so that the data provided could be assessed by birth cohorts. The CDC has now agreed to provide the birth-year for each participant.

We also had a dispute in our last status letter as to whether the CDC had produced all of the check-the-box data. In that regard, the CDC has since agreed to produce the non-exempt portions of the data generated from the v-safe survey questions by November 16, 2022. There remains, however, a dispute as to whether the CDC has produced all of the data, including check-the-box data, because in a document produced by the CDC in another matter, it appears there is more data the agency may have not produced, including “call center,” “call center pregnancy,” and

"pregnancy" data).[3]

Free-Text Fields

The remaining substantive issue is a dispute regarding production of the data from v-safe's free-text fields.

As it explains below, the CDC will not agree to produce the free-text data nor does it agree to enter into a briefing schedule to adjudicate this issue. Plaintiff's position is that the CDC is required to produce this data and so it seeks a briefing schedule to adjudicate this issue.

The CDC has represented that there are 6.8 million v-safe free-text entries, each limited to 250 characters. The free-text fields contain information on the symptoms and effects experienced after Covid-19 vaccination that is critical, especially given the very limited check-the-box fields v-safe users were provided to report symptoms and health impacts. The CDC clearly saw the importance of gathering information not relegated to check-the-box options. The public has the same interest in seeing and analyzing this data.

The data in these free-text fields are unlikely to contain any personally identifiable information ("PII"). These fields were requesting symptoms and reactions after Covid-19 vaccination and limited these answers to 250 characters. Individuals are unlikely to include their names, phone numbers, or social security numbers in this field, and such text can be readily scanned for such information. Plaintiff does not dispute that this data should be reviewed for personally identifiable information but submits that this review is likely to find little, if any, PII. In that regard, Plaintiff has asked the CDC to review and produce a random sample of a few

[3] *See* https://www.sirillp.com/wp-content/uploads/2022/11/v-safe-page-from-larger-production-12c01263aabee91d2e611a744e8d00a6.pdf. This image shows 7 types of data within the consolidate datasets for v-safe. Five of those have been produced by the agency ("vaccinations," "registrants," "race ethnicity," and two "health-checkin" files). It is unclear whether the other 3 datasets have been produced ("call center," "call center pregnancy," and "pregnancy" data).

hundred free-text fields, but the CDC has thus far refused this simple exercise.

The CDC instead offered Plaintiff a proposal: the agency would review every single one of these 6.8 million free text fields in order to convert them into medical codes (MedDRA codes) and stated it could do same in a few months' time. The process of converting free text fields to medical codes, as proposed by the CDC, is far more complex than reviewing for PII and yet the CDC was willing to perform that more complex task and complete same in a matter of months. It was apparently willing to do this because, even though it would have been more time consuming and complex then simply reviewing for PII, this approach would permit the CDC to hide from the public most of what is actually written in the free-text fields. The CDC is presumably plainly concerned about being transparent with the public because what this data may reveal may run contrary to the recommendations it pushed to deprive people of their jobs, their livelihoods, schooling, military careers, among other harms. It may also potentially reveal data that is contrary to the CDC's claim that there was a low incidence of various serious issues, like tinnitus, myocarditis, and small fiber neuropathy, from this product.

Unlike the CDC's VAERS system, which gathers reports from an unknown number of individuals, the v-safe system has a denominator. The number of v-safe users is known. Hence the v-safe data provides the public the ability to add up the total reports of a given condition and divide by the number of users. That number provides an indication of the true adverse event rate of a given condition form these products. A product the CDC promoted widely to the public. The CDC plainly does not want the public to have that information.

The public also has an acute interest in this data because the CDC publishes dozens of publications and studies using v-safe data to push its agenda on the American public. Yet at the same time, it refuses to release this data despite its claims of transparency. Despite the scientific

community, and independent scientists, clamoring to obtain this data from the CDC to conduct independent analysis. Analysis free from the filter of a federal health agency that has staked its reputation on the success of these products, that has claimed they are safe, and pushed to deprive Americans of the ability to engage in nearly every aspect of American life if they refused these products.

Despite all of this, the CDC claims that due to the purported volume of the entries, these records are not reasonably segregable. This is a frivolous position on which the parties have reached an impasse. Plaintiff therefore believes it is high time this issue be briefed and finally adjudicated. The American public has already waited over 16 months since Plaintiff first requested this information and should not have to wait any longer.

The CDC unsurprisingly seeks to delay briefing because it claims it has not produced all responsive documents. But the failure to produce these documents already rests squarely on the CDC, including the failure to produce all of records timely pursuant to the scheduling order. The scheduling order contemplated that the CDC would release, by September 30, 2022, "a public-use set of data that the agency collected from tens of millions of V-safe participants between December 14, 2020 and July 31, 2022" to exclude only "data derived from fields in the V-safe questionnaires that collect personally identifiable information…or that capture free-text responses that permit a participant to enter personally identifiable information." (Dkt. No. 17.) That the CDC chose to violate the prior scheduling order and fail to produce the remaining check-the-box data, including the survey questions which contain no personally identifiable information, shouldn't buy them more delay in being transparent with the American public. Same with producing the birth year – which, in any event, should take the CDC minutes to download and produce. The CDC's improper withholding cannot possibly be a justification for further delay. If it is permitted to obtain delay

on this basis, then it will have every interest in delaying release of the remaining check-the-box data for as long as possible.

In sum, there has been undue delay in the public's ability to access the free-text field data (a majority of which the CDC has had exclusive access to for over 17 months) and now the agency is taking a frivolous position to continue withholding it. Plaintiff therefore respectfully requests that the Court enter a briefing schedule as follows to address the issue of the free-text fields' data:

Defendant Opening Brief: November 25, 2022

Plaintiff Opposition and Cross-Motion: December 16, 2022

Defendant Opposition and Reply: December 30, 2022

Plaintiff Reply: January 13, 2023

Defendants' Statement

Status of Plaintiff's FOIA request. As Plaintiff indicated above, CDC is currently in the process of producing records in response to Plaintiff's FOIA request. To date, CDC has produced an extensive set of data that the agency collected from over ten million v-safe participants between December 14, 2020, and July 31, 2022. As previously explained, *see* ECF No. 20, CDC withheld from that dataset personally identifiable information (*e.g.*, name, phone number, date of birth) pursuant to 5 U.S.C. § 552(b)(6) (permitting an agency to withhold information about individuals in "personnel and medical files and similar files" when the disclosure of such information "would constitute a clearly unwarranted invasion of personal privacy"). Since the parties' joint status report of October 14, 2022, CDC has informed Plaintiff that it expects to produce additional batches of non-exempt records responsive to Plaintiff's FOIA request. Specifically, CDC intends to produce a batch of records containing data derived from specific feedback-survey questions no later than November 16, 2022. CDC also intends to produce the birth year of v-safe participants,

which the agency originally withheld along with participants' date and month of birth from its first production, and will promptly inform Plaintiff when it expects to make that production.[4]

Defendants' opposition to Plaintiff's proposal. Although production remains ongoing in this FOIA matter, Plaintiff asks the Court to compel Defendants to file a partial motion for summary judgment to address the propriety of some of CDC's withholdings to date. Defendants oppose that request because bifurcated briefing is rare in FOIA cases, and Plaintiff has not provided a justification for it here. It would be premature and inefficient (not to mention highly irregular) for the parties to brief and the Court to address the legality of CDC's withholdings in piecemeal fashion, before the agency has finished responding to Plaintiff's FOIA request. Instead, "the most appropriate time for summary-judgment proceedings" in a FOIA case is "after the final production is delivered." *Republican Nat'l Comm. v. U.S. Dep't of State*, No. 16-486, 2016 WL 9244625, at *1 (D.D.C. Sept. 16, 2016).

This standard practice is standard for a reason. After production is completed, the parties can meet and confer to narrow the issues in need of judicial resolution. The agency can then move for summary judgment on all disputed issues, submitting a *Vaughn* index and a supporting declaration to justify any and all challenged withholdings, and the Court can determine the propriety of those withholdings and any other contested issues on a complete record at one time. Conducting periodic partial-summary-judgment briefing through the course of a FOIA case (as

[4] Plaintiff accuses CDC of failing "to produce all of records [*sic*] timely pursuant to the scheduling order." But under this Court's scheduling order of September 8, 2022, *see* ECF No. 19, CDC was instructed to produce, on or before September 30, 2022, its first batch of non-exempt records responsive to Plaintiff's FOIA request, as described more fully in the parties' status report of August 22, 2022." *Id.* at 2. In that status report, Defendants explained that CDC would produce by the end of September "a public-use set of data that the agency collected from tens of millions of V-safe participants between December 14, 2020, and July 31, 2022," and that that dataset would not include "data derived from fields in the V-safe questionnaires that collect personally identifiable information, including fields that request that a participant enter personally identifiable information . . . or that capture free-text responses that permit a participant to enter personally identifiable information." *See* ECF No. 17 at 2. CDC's first production of responsive, non-exempt records on September 30, 2022, as described in the parties' joint status report of October 14, 2022, *see* ECF No. 20, thus complied with this Court's scheduling order.

Plaintiff proposes) would, on the other hand, require a court to decide issues (*e.g.*, the propriety of an agency's withholdings) that pertain to only a subset of records in piecemeal fashion and before the agency has had the opportunity to fully respond to the FOIA request. Moreover, requiring CDC to brief withholding-related issues while production is ongoing would delay production, as it is the same agency personnel doing both tasks. For these reasons, courts routinely reject such proposals. *See, e.g.*, Order Setting Production Schedule at 4, *Knowledge Ecology Int'l v. U.S. Dep't of Health and Human Servs.*, No. 1:20-cv-02986-KBJ, ECF No. 17 (D.D.C. Feb. 11, 2021) (Brown Jackson, J.) ("[I]t is this Court's practice not to entertain motions for summary judgment in FOIA cases . . . until processing and production of all records at issue in the case are complete[.]") (citation omitted); *Republican Nat'l Comm.*, 2016 WL 9244625, at *1 (Boasberg, J.) (holding that it was "too soon to adjudicate [the agency's] reliance on Exemption 6" based on the subset of produced documents, because it would be problematic to apply a decision to the unprocessed documents and any decision limited to the produced documents "would open the door to burdensome piecemeal litigation"); Order at 2, *Brown v. Dep't of State*, No. 15-cv-1459-CKK (D.D.C. Oct. 31, 2017) (Kollar-Kotelly, J.), ECF No. 36 (denying a plaintiff's attempt to obtain documents more quickly through summary judgment briefing on redactions while productions were ongoing because "Defendant is still in the process of searching for and/or producing documents responsive to Plaintiff's FOIA request and "[r]uling on the appropriateness of Defendant's withholdings based on a small subset of documents that have been withheld thus far, when additional searches and productions are ongoing, would be extremely inefficient"); *Nat. Res. Def. Council v. E.P.A.*, No. 08-1429-PLF, 2009 WL 1767570, at *1 (D.D.C. June 23, 2009) (Friedman, J.) (denying without prejudice a FOIA requestor's motion for summary judgment because "an immediate award of judgment typically is considered premature" prior to completion of the agency's production

obligations); Order at 1, *Am. Oversight v. U.S. Dep't of Treasury*, No. 17-cv-2078 (D.D.C. July 5, 2018) (Walton, J.); Minute Order, *Heritage Found. v. Nat'l Archives & Record Admin*, No. 1:22-cv-2671-JEB (D.D.C. Oct. 28, 2022) (Boasberg, J.).

Plaintiff asks that the Court deviate from this standard practice for litigating FOIA cases simply because it disagrees with Defendants' determination that a subset of records should be withheld pursuant to § 552(b)(6) and are not reasonably segregable, and wishes to obtain these records as soon as possible.[5] But if that was a sufficient reason to require the parties in a FOIA case to conduct multiple rounds of partial summary judgment, that would have become the norm long ago, as virtually every FOIA requester wants the documents it has requested sooner rather than later. Moreover, many FOIA requesters assume (like Plaintiff) that their arguments against an agency's response to a FOIA request are correct—especially before the agency has had the chance to justify its actions in summary-judgment briefing and in an accompanying *Vaughn* index or declaration. Defendants' position that the records at issue here are not reasonably segregable—the issue Plaintiff wants to brief now—is not "frivolous," as Defendants will fully explain at summary judgment.[6]

Defendants' proposal. It is Defendants' position that this case should continue to proceed in the ordinary course for FOIA litigation. After CDC completes production of all non-exempt, responsive records, the parties will meet and confer about Plaintiff's challenges to CDC's response to Plaintiff's FOIA request. Following the parties' meet-and-confer, Defendants will then move

[5] Although Plaintiff suggests that it has "waited over 16 months since [it] first requested" these records, the FOIA request at issue in this litigation was filed in April 2022. *See* Compl. ¶ 23, ECF No. 1.

[6] Plaintiff speculates that "[t]he data in the[] free-text fields are unlikely to contain any personally identifiable information." But according to CDC, these records contain v-safe participants' full names, phone numbers, dates of birth, home addresses, e-mail addresses, prescription lists, medical providers, and other information that—whether on its own or in combination with other available information—could easily be used to identify a participant and connect him or her to private and highly sensitive health information. Similarly, Plaintiff offers no support for its assumption that CDC can "readily scan[] for such information."

for summary judgment on any and all disputed issues.

Defendants submit that the parties and the Court will resolve this case most efficiently by following the standard practice in FOIA litigation, and it is within this Court's inherent authority to "control the disposition of the causes on its docket with economy of time and effort for itself, for counsel, and for litigants." *Landis v. N. Am. Co.*, 299 U.S. 248, 254 (1936). Accordingly, Defendants respectfully request that the Court order the parties to file an additional joint status report on or before December 5, 2022, to provide further information regarding the status of Plaintiff's FOIA request, including CDC's forthcoming production.

Dated: November 4, 2022

Respectfully submitted,

SIRI & GLIMSTAD LLP

/s/ Aaron Siri
Aaron Siri, NY Bar No. 4321790
Elizabeth A. Brehm, NY Bar No. 4660353
200 Park Avenue
17th Floor
New York, New York 10166
Tel: (212) 532-1091
aaron@sirillp.com
ebrehm@sirillp.com

Counsel for Plaintiff

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MARCIA BERMAN
Assistant Director, Federal Programs Branch

/s/ Jody D. Lowenstein
JODY D. LOWENSTEIN
Mont. Bar No. 55816869
Trial Attorney
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20005
Phone: (202) 598-9280
Email: jody.d.lowenstein@usdoj.gov

Counsel for Defendants

CERTIFICATE OF SERVICE

On November 4, 2022, I electronically submitted the foregoing document with the Clerk of Court for the U.S. District Court, Western District of Texas, using the Court's electronic case filing system. I hereby certify that I have served all parties electronically or by another manner authorized by Federal Rule of Civil Procedure 5(b)(2).

/s/ Annalise Beube
Annalise Beube
Law Clerk
Siri & Glimstad LLP