UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

FREEDOM COALITION OF DOCTORS FOR CHOICE, Plaintiff, v. CENTERS FOR DISEASE CONTROL AND PREVENTION, Defendant.	Civil Action No. _____

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

Plaintiff, as for its Complaint regarding a Freedom of Information Act request against the above-captioned Defendant, alleges as follows:

INTRODUCTION

1. Between December 2020 and February 2021, the Food and Drug Administration ("**FDA**") issued Emergency Use Authorizations for three COVID-19 vaccines,[1] one of which subsequently received FDA approval in August 2021 and another on January 31, 2022.[2] While FDA approved these vaccines, the Centers for Disease Control and Prevention ("**CDC**"), an agency within the Department of Health and Human Services ("**HHS**"), is charged with monitoring the safety of all vaccines, including COVID-19 vaccines.

[1] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19; https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid; https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[2] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine; https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine.

2. The federal government has mandated that millions of Americans receive these products. HHS has also given pharmaceutical companies complete immunity for injuries caused by these products. Mandating that millions of Americans inject a product for which they cannot hold the manufacturer liable if the product injures them demands complete **transparency**, especially when it comes to releasing the data underlying the product's safety. FOIA exists precisely so that the American people can obtain transparency and, in this case, obtain the core data which supports CDC's claims regarding the safety of these products and its claimed intensive safety monitoring.

3. In that regard, CDC claims that the current "COVID-19 vaccines are being administered under the **most intensive vaccine safety monitoring effort in U.S. history[.]**"[3] FDA and CDC have explained that their prior primary existing vaccine safety monitoring program was incapable of determining causation and was otherwise unreliable to assess the safety of COVID-19 vaccines. As a result, they deployed a new safety monitoring system for the COVID-19 vaccines: **v-safe**.

4. V-safe is an online software program, accessible through the use of a smart phone, that allows vaccine recipients to "tell CDC about any side effects after getting the COVID-19 vaccine."[4] The purpose of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[5]

5. CDC has explained that the data submitted to v-safe is "collected, managed, and

[3] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[5] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

housed on a secure server by Oracle,"[6] a private computer technology company, which CDC explains has access to "aggregate deidentified data for reporting."[7]

6. The v-safe program collected a limited amount of safety information from its approximately 10 million users using check-the-box options. However, the program also provided a free text field (up to 250 characters) for users to provide additional safety information. The CDC has disclosed that that it received 6.8 million free text entries from v-safe users.

7. These free text entries provide the most critical and informative dataset available for assessing the safety and efficacy of the existing COVID-19 vaccines because they were collected from a known universe of users directly reporting their symptoms and reactions. Thus rates at which an adverse event is reported can be calculated and relied upon. Unlike other safety data the government has relied upon, v-safe data is not filtered through the companies selling the vaccines which removes conflicts of interest that could potentially influence the data. The release of this data to the public, and especially the medical and scientific community, is therefore a matter of urgency.

8. Plaintiff Freedom Coalition of Doctors for Choice ("**Plaintiff**") is a nonprofit that exists for the sole purpose of obtaining and disseminating to the public the data from the free-text fields in CDC's v-safe database.[8] This coalition is made up of medical and public health professionals, scientists, and journalists. It takes no position on this data other than that it should be made available to the public and scientific community as soon as possible. All data obtained will be made available on its website, www.drsforchoice.org, upon receipt.

9. Plaintiff requested, pursuant to the Freedom of Information Act (5 U.S.C. § 552, as

[6] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf p. 8.

[7] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf p. 9 (emphasis added).

[8] https://drsforchoice.org/.

amended) ("**FOIA**"), that CDC produce all data obtained from v-safe users from the free text fields within the COVID-19 vaccine v-safe program. Plaintiff also asked for the registrant code associated with each free text field/entry. To provide transparency regarding the government's claim that COVID-19 vaccines are "safe and effective,"[9] the public should have immediate access to this data. Therefore, once CDC produces the data sought in this FOIA request, Plaintiff will make it publicly available.

10. To make public the requested v-safe data as soon as possible, Plaintiff made an expedited request to CDC. Plaintiff's FOIA request was for "**All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry**." CDC issued an acknowledgment letter regarding Plaintiff's expedited request but failed to follow the statutory requirements for processing such a request and denied the FOIA request for expedited processing. Plaintiff brings this action to challenge CDC's denial.

PARTIES

11. Plaintiff is a not-for-profit organization with its headquarters at 600 S Tyler St, Suite 2100 #177, Amarillo, TX 79101. Its three board members are John Thomas, M.D., Camilla Glenn, NP, Richard Bartlett, M.D. Dr. Richard Bartlett is an emergency room physician who practices in Amarillo and Lubbock, Texas. Dr. Bartlett identified and advocated for the use of

[9] *See*, *e.g.*, https://www.fda.gov/media/146269/download (materials for February 26, 2021 meeting of the Vaccines and Related Biological Products Advisory Committee ("VRBPAC") stating "[r]eactogenicity profiles of mRNA vaccines in v-safe monitoring are consistent with what was observed in clinical trials"); https://www.fda.gov/media/150054/download (materials from June 10, 2021 meeting of VRBPAC stating "[i]nitial safety findings from Pfizer-BioNTech COVID-19 vaccination of 12-15-year-olds from v-safe and VAERS surveillance are consistent with results from pre-authorization clinical trials"); https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf (materials from October 21, 2021 meeting of Advisory Committee on Immunization Practices stating "[n]o unexpected patterns of adverse events were identified").

Budesonide in the treatment of COVID-19, which has become a treatment option in hospitals across the country, including the Odessa Medical Center and Odessa Regional Medical Center. The therapeutic effect of Budesonide was confirmed by Oxford University in multiple randomized controlled trials, including the STOIC TRIAL in which Oxford concluded that 90% of COVID hospitalizations could have been prevented with Budesonide respiratory treatment. Camilla Glenn is a Nurse Practitioner and Dr. John Thomas is a general surgeon practicing in Lubbock, Texas. Dr. Thomas is also the founder of Operation H.O.P.E. USA, a non-profit organization that, among other things, provides medical care in areas of the world where there may be scant or no capable medical service.

12. CDC is an agency within the Executive Branch of the United States Government, organized within HHS. CDC is an agency within the meaning of 5 U.S.C.§ 552(f).

JURISDICTION AND VENUE

13. This Court has jurisdiction over this action pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1331. Venue is proper within this District pursuant to 5 U.S.C. § 552(a)(4)(B) and 28 U.S.C. § 1391.

FACTS

A. COVID-19 Vaccines

14. In December 2020, FDA issued emergency use authorizations for the Pfizer-BioNTech[10] and Moderna[11] COVID-19 vaccines. In February 2021, FDA issued an emergency

[10] https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19.

[11] https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid.

use authorization for the Janssen COVID-19 vaccine.[12] There have been subsequent emergency use authorizations issued for these three vaccines for younger age groups, for boosters, and for "mix and match" administration of the three vaccines. In August 2021, FDA licensed the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older.[13]

15. Although all novel COVID-19 vaccines available in the United States were developed at record pace, these products have been mandated for a majority of Americans under the threat of losing their jobs, being separated from the military, being excluded from educational institutions, and from participating in civil society.[14] The federal government has, for example, issued mandates for private employees, public employees, and the military.[15] Some cities and states have gone as far as to require COVID-19 vaccines for entry into restaurants, clubs, gyms, entertainment venues, and indoor events.[16]

16. While mandating this product, the federal government has also given the pharmaceutical companies selling these vaccines, and anyone associated with administering and promoting them, complete legal immunity for any injury caused by these vaccines. 42 U.S.C. § 247d-6d (providing that any "manufacturer" of "any vaccine, used to . . . prevent or mitigate COVID-19" shall be "immune from suit and liability under Federal and State law with respect to

[12] https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine.

[13] https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine.

[14] https://www.whitehouse.gov/covidplan/.

[15] https://www.whitehouse.gov/covidplan/ https://www.federalregister.gov/documents/2021/11/05/2021-23643/covid-19-vaccination-and-testing-emergency-temporary-standard; https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination; https://media.defense.gov/2021/Aug/25/2002838826/-1/-1/0/MEMORANDUM-FOR-MANDATORY-CORONA VIRUS-DISEASE-2019-VACCINATION-OF-DEPARTMENT-OF-DEFENSE-SERVICE-MEMBERS.PDF.

[16] https://sf.gov/information/vaccine-required; https://www1.nyc.gov/site/doh/covid/covid-19-vaccines-keytonyc.page.

all claims . . . resulting from . . . [its] use by an individual"). These pharmaceutical companies are even immune from liability for willful misconduct unless the federal government, which promoted and licensed this product, first brings this claim. *Id*.

B. Vaccine Safety Monitoring

17. Because COVID-19 vaccines are being mandated for millions of Americans, it is essential that our federal health agencies ensure that these products are safe and afford the American people transparency regarding the data supporting that claim.

18. CDC is one of the primary federal agencies responsible for monitoring vaccine safety, including the safety of COVID-19 vaccines. CDC claims that "COVID-19 vaccines are being administered under **the most intensive vaccine safety monitoring effort in U.S. history**[.]"[17]

19. The CDC's premier system for monitoring the safety of COVID-19 vaccines is v-safe, an online program[18] which "uses text messaging and web surveys to give personalized health check-ins after [one] receives a COVID-19 vaccine."[19] The program allows users to "quickly tell CDC if [they] have any side effects after getting a COVID-19 vaccine[,]" which "helps CDC monitor the safety of COVID-19 vaccines in near real time."

20. On November 19, 2020, CDC published a document titled "V-safe active surveillance for COVID-19 vaccine safety" (the "**V-Safe Protocol**").[20] The document explains that "[t]he purpose of v-safe surveillance is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important

[17] https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-10-20-21/05-COVID-Hause-508.pdf.

[18] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html (listing v-safe as one of the ways "CDC expanded and strengthened the country's ability to monitory vaccine safety").

[19] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[20] https://web.archive.org/web/20210102024902/https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

adverse events and safety issues that might impact policy or regulatory decisions."[21]

21. The V-Safe Protocol indicates that "V-safe data will be collected, managed, and housed on a secure server by Oracle."[22] The V-Safe Protocol further provides:

> Oracle staff will not be able to view any individualized survey data (including variables with personally identifiable information [PII]) but, rather, will have access to aggregate deidentified data for reporting. CDC will have "read" access to the individualized survey data, including PII, provided by Oracle. On a continuous basis (either daily or weekly), these survey data will be accessible to CDC through downloads from the secure server.[23]

In addition, V-Safe Protocol states, "No PII [personally identifiable information] will be included in any v-safe analyses, manuscripts, or data sets shared through external data requests."[24]

22. CDC's V-Safe Protocol stresses the importance of this data and that it "is anticipated that v-safe data will be shared with the scientific community and with the public through manuscripts and public reports."[25] Despite these claims, much of the v-safe data is not yet available to the public, especially the primary source documentation of participants' temporal experiences generated from the free text questions and responses within the v-safe program.

23. To ensure that CDC expeditiously acts in furtherance of its commitment to "openness and accountability" regarding the safety of COVID-19 vaccines, and the urgency with which the scientific and medical community need this data, Plaintiff made an expedited FOIA request for the critical primary source documentation of v-safe participants' temporal experiences after taking the novel COVID-19 vaccines.

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[21] *Id*. at 1.

[22] *Id*. at 6.

[23] *Id*. at 6.

[24] *Id*. at 8.

[25] *Id*. at 10.

C. The FOIA Request

24. On January 3, 2023, Plaintiff, through Counsel, submitted the FOIA request to CDC seeking:

> **All data obtained from v-safe users/registrants from the free text fields within the v-safe program for COVID-19 vaccines and the registrant code associated with each free text field/entry. (Note that all records from pre-populated fields, other than registrant code, can be excluded).**

(Exhibit 1 at 3.**)**

25. Pursuant to 5 U.S.C. § 552(a)(6)(E)(i)(I), the FOIA request also sought expedited processing based on a demonstrated "compelling need." (*See* **Exhibit 1** at 3-5.)

26. On January 4, 2023, CDC acknowledged the request, assigned it request number 23-00462-FOIA, and denied Plaintiff's request for expedited processing stating in relevant part:

> **You requested that we expedite processing your request. Your request is denied because:**
>
> **☐ You have failed to show that there is an imminent threat to the life or physical safety of an individual.**
>
> **☐ You have not demonstrated that you are a person primarily engaged in disseminating information.**

(**Exhibit 2**.)

ARGUMENT

27. When an agency denies a request for expedited processing, the decision is subject to immediate judicial review. 5 U.S.C. § 522(a)(6)(E)(iii). A FOIA requester is not required to pursue an administrative appeal before seeking judicial review of its request for expedited processing is denied. *Elec. Privacy Info. Ctr. v. Dep't of Defense*, 355 F. Supp. 2d 98, 100 (D.D.C. 2004).

28. Therefore, as demonstrated above, Plaintiff is authorized to bring this action

because its request for expedited processing was denied by CDC.

29. Furthermore, as explained below – as well as in its FOIA request – Plaintiff can demonstrate a "compelling need" for the expedited processing of its FOIA request. 5 U.S.C. § 552(a)(6)(E)(i)(I); 5 U.S.C. § 552(a)(6)(E)(v)(II).

30. A requestor shows a "compelling need" when it is (1) "primarily engaged in disseminating information," and (2) there is an "urgency to inform the public concerning actual or alleged Federal Government activity." 5 U.S.C. § 552(a)(6)(E)(v)(II). Plaintiff demonstrates its FOIA request satisfies both requirements below:

(1) The requester is primarily engaged in disseminating information.

31. The Freedom Coalition of Doctors for Choice is a not-for-profit organization that exists for the sole purpose of obtaining and disseminating to the public the free text fields in CDC's v-safe database. It is made up of medical and public health professionals, scientists, and journalists. Many of these individuals individually share with the public their findings, research, and professional opinions about COVID-19 and related issues. The coalition itself takes no position on this data other than that it should be made available to the public and the scientific community as soon as possible. It pledges that all data obtained from this request will be made available on its website – drsforchoice.org – upon receipt. Indeed, the *only* purpose of the Coalition is the dissemination of information.

(2) There is an urgency to inform the public concerning actual or alleged Federal Government activity.

32. In determining whether there is an "urgency to inform," and hence a "compelling need," courts must consider at least three factors: (1) whether the request concerns a matter of current exigency to the American public; (2) whether the consequences of delaying a response

would compromise a significant recognized interest; and (3) whether the request concerns federal government activity. *Al-Fayed v. CIA*, 254 F.3d 300, 310 (D.C. Cir. 2001).

33. All three factors are present here and weigh in favor of granting expedited processing of the Plaintiff's FOIA request.

34. CDC is the federal agency responsible for administering and monitoring the v-safe program. CDC's website describes v-safe as an internet-based program that allows participants to "tell CDC how you, or your dependent, feel after getting any dose of COVID-19 vaccine."[26] One of the purposes of the program "is to rapidly characterize the safety profile of COVID-19 vaccines when given outside a clinical trial setting and to detect and evaluate clinically important adverse events and safety issues that might impact policy or regulatory decisions."[27] A major source of information CDC could use to detect and evaluate clinically important adverse events and safety issues was the data obtained from v-safe users generated from the free text questions and responses within the v-safe program – the same information the Plaintiff seeks in this request.

35. The contents of the information sought by this request could be analyzed and synthesized in meaningful ways to enable the public to better understand the potential benefits and risks involved in taking COVID-19 vaccines or – as CDC currently recommends to all people ages 5 years and older – the COVID-19 vaccine booster.[28] Without this information, which CDC currently possesses but has not disclosed, the public is missing critical primary source information regarding v-safe participants' experiences taking the COVID-19 vaccines and the recommended boosters.

[26] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html.

[27] https://www.cdc.gov/vaccinesafety/pdf/V-safe-Protocol-508.pdf.

[28] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html.

36. Delays in disclosing this information prevents the public and the scientific community from immediately accessing, analyzing, and synthesizing critical safety information. These delays compromise the public's significant recognized interest of informed consent, their ability to assess potential harms, develop strategies to prevent such harms, and treating those who have already been harmed.[29] That is, for example, the core mission of numerous medical groups and organizations that have formed to treat individuals injured by COVID-19 vaccines.

37. For example, React19 is a group of over 20,000 individuals, including hundreds of medical professionals, that have all been injured by COVID-19 vaccines. The members of React-19 are desperately seeking reliable data that can help explain the harms they are seeing among their members, currently only being observed in a non-systematic fashion. Consequently, until these harms can be scientifically established through systematic datasets, the medical health establishment (including NIH, universities, etc.) will not fund research to address these harms and insurance companies will not pay for potential treatments. Moreover, irrespective of how many people complain of the harm – even if there are tens of thousands – without systematic datasets, influential segments of the medical health establishment consider these complaints as merely anecdotal. Therefore, these harms are allowed to continue dangerously unabated and that will not change until the public, including groups like React-19, can get the data needed to systematically show what harms are caused by the COVID-19 vaccines. In sum, they desperately need the free-text field data from v-safe to have a dataset that will scientifically validate the harms they are

[29] Notions of informed consent have been codified in jurisdictions across the United States. For example, in Texas, a "recovery may be obtained [when there is] negligence in failing to disclose the risks or hazards that could have influenced a reasonable person in making a decision to give or withhold consent." Tex. Civ. Prac. & Rem. Code § 74.101. Similarly, in New York, "informed consent shall include as a minimum, the specific procedure or treatment or both, their reasons for it, the reasonably foreseeable risks and benefits involved, and the alternatives for care or treatments, if any . . ." 10NYCRR § 405.7 (b)(9).

experiencing so that the medical community will acknowledge them and then provide medical care to them.

38. The information sought is indeed more urgent than ever because the federal government has recently implemented policies and a multi-billion-dollar messaging campaign designed to promote the public's uptake of the COVID-19 vaccines and boosters. However, as it promotes these products to obtain the public's consent to receive them, the federal government has an obligation to at least be transparent with the information it possesses regarding the possible risks and harms from receiving these medical products. This is made even more acute by the fact that the federal government has given nearly everyone immunity from liability for injuries caused by these products. Those who are injured by these products are left with virtually no recourse to obtain compensation. Therefore, the very least the government can do for consumers is to be transparent about the safety data. This transparency will allow consumers to make the most informed decision as possible, and will enable the medical and scientific community to assess ways to avoid and treat some of the harms currently being observed.

39. Transparency is even more critical now that the Advisory Committee on Immunization Practices (ACIP) has voted to add the COVID-19 vaccines to the routine childhood immunization schedule.[30] This new policy may very likely cause states to create policies that grant or restrict certain privileges, such as attending school based upon a child's COVID-19 vaccination status. Without disclosure, parents who are confronted with COVID-19 vaccine mandates are forced to choose between allowing their children to receive a vaccine without all the information available to make an informed decision, or their child being prevented from receiving an education

[30] https://www.aha.org/news/headline/2022-10-21-acip-recommends-adding-covid-19-vaccine-information-immunization-schedules.

based upon their vaccination status. Therefore, no matter a parent's choice when confronted with a COVID-19 vaccine mandate, a delay in the disclosure of the information sought in this request would compromise the public's significant recognized interest of informed consent.

40. Furthermore, the Biden administration has recently launched a major messaging campaign to increase the public's interest in receiving COVID-19 boosters.[31] With the Biden administration's "new push to encourage families to get the updated COVID-19 vaccine" which includes "vaccination events" at "Head Start provider locations" under HHS's "#VaxUpAmerica Family Vaccine Tour," it is critical that the public has the latest information regarding possible signals of adverse reactions from these vaccines.[32] Any delay in the processing of the request would deny families the information they need to provide their informed consent to the external pressures and messaging resulting from the current administration's actions.

41. Therefore, as demonstrated above, Plaintiff has shown (1) it is primarily engaged in disseminating information, and (2) there is an urgency to inform the public concerning actual or alleged federal government activities. Thus, Plaintiff's has a "compelling need" for expedited processing, and its request for the same should have been granted. 5 U.S.C. § 552(a)(6)(E)(i)(I).

CLAIM
FAILURE TO GRANT EXPEDITED PROCESSING

42. Plaintiff repeats and re-alleges all of the foregoing paragraphs as if fully set forth herein.

43. Plaintiff properly asked that CDC expedite the processing of Plaintiff's FOIA request – which seeks agency records within the custody and control of CDC – based on its showing that Plaintiff is clearly a requester primarily engaged in disseminating information and

[31] https://www.whitehouse.gov/briefing-room/statements-releases/2022/10/25/fact-sheet-president-biden-to-announce-additional-efforts-to-help-americans-get-their-free-updated-covid-19-vaccine-this-fall/.

[32] *Id*.

the urgency to inform the public concerning actual or alleged government activity related to the records sought.

44. Defendant denied Plaintiff's request for expedited processing.

45. Plaintiff therefore is entitled to injunctive and declaratory relief with respect to the immediate and expedited processing and disclosure of the requested records.

REQUESTED RELIEF

WHEREFORE, Plaintiff prays that this Court:

a. Order defendant CDC to immediately and fully process Plaintiff's FOIA request and disclose all non-exempt documents immediately to Plaintiff;

b. Issue a declaration that Plaintiff is entitled to immediate processing and disclosure of the requested records;

c. Provide for expeditious proceedings in this action;

d. Retain jurisdiction of this action to ensure no agency records are wrongfully withheld;

e. Award Plaintiff its costs and reasonable attorneys' fees incurred in this action as provided by 5 U.S.C. § 552(a)(4)(E); and

f. Grant such other and further relief as the Court may deem just and proper.

Dated: January 13, 2023

/s/ John C. Sullivan

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