Nos. 21-7000, 21-4108

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

In re: MCP No 165; OSHA Rule on COVID-19 Vaccination and Testing, 86 Fed. Reg. 61, 402

On Petition for Review of Agency Order

NATURAL PRODUCT ASSOCIATION'S OPPOSITION TO RESPONDENTS' EMERGENCY MOTION TO DISSOLVE STAY

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and Sixth Circuit Rule 26.1, Petitioner Natural Products Association states that it does not have a parent corporation and no publicly held corporation owns 10 percent or more of its stock.

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INTRODUCTION

Respondents have moved this Court to dissolve the well-reasoned stay of the enforcement of OSHA's COVID-19 Vaccine and Testing Emergency Temporary Standard (the "ETS") entered by the United States Court of Appeals for the Fifth Circuit. *See* Motion to Dissolve, Doc. 69. Petitioner Natural Products Association ("NPA") respectfully requests that this Court deny Respondents' Motion and keep the stay in full effect until the merits of the myriad challenges to the validity of the ETS have been decided. NPA, along with the other Petitioners before this Court and the general public at large, including many small employers and their unvaccinated and vaccinated workers, will be irreparably harmed should the stay of the ETS be dissolved because of the grave economic harms that the ETS will impose on small employers.

Founded in 1936, the NPA is the nation's largest and oldest nonprofit organization dedicated to the natural products industry. (Natural Products Association, *About Natural Products Association*, *available at* https://www.npanational.org/about/ [hereinafter "About NPA"].) "Natural products" include a wide variety of increasingly popular consumer goods, such as natural and organic foods, dietary supplements, pet foods, health and beauty products, and "green" cleaning supplies. (*Id.*) The hallmark of these goods is that

they are formulated without artificial ingredients and are minimally processed. (*Id.*)

NPA regularly advocates for the rights of its members to continue manufacturing and distributing natural products, and for their consumers to continue to have access to these products. (Declaration of Daniel Fabricant ("Fabricant Decl."), attached hereto as Ex. A, at ¶¶ 3-4.) NPA has over 1,000 members, accounting for more than 10,000 retail, manufacturing, wholesale, and distribution locations of natural products, including foods, dietary supplements, and health/beauty aids. (About NPA.) NPA unites a diverse membership, from the smallest health food store to the largest dietary supplement manufacturer, with approximately seventy percent (70%) of NPA's members considered small businesses with fewer than 500 employees. (Fabricant Decl. at ¶ 5.) All but the smallest of these members, however, would be covered by the ETS should it take effect.

Due to the nature of NPA's industry (*i.e.*, food and cleaning products, dietary supplements), many of its members and their employees are heavily regulated by government agencies and regulations, including the Food and Drug Administration's ("FDA") Current Good Manufacturing Practices for Dietary Supplements. 21 C.F.R. § 111.1 *et seq.* ("cGMP"). These regulations include

stringent requirements on the hiring and training of new employees. *See, e.g.*, 21 C.F.R. §111.12 ("Each person engaged in manufacturing, packaging, labeling, or holding, or in performing any quality control operations, must have the education, training, or experience to perform the person's assigned functions."). In fact, in order to train a new employee once a qualified candidate is found, NPA members subject to these regulations may need, on average, three to six months. (Fabricant Decl. at ¶ 9; *see also* Declaration of Mark LeDoux ("LeDoux Decl."), attached hereto as Ex. B, at ¶ 4.) This, coupled with the current labor shortage, spells disaster for many of NPA's members should the ETS take effect and result in the mass exodus of unvaccinated employees, who are already qualified and trained. (Fabricant Decl. at ¶¶ 7-9; LeDoux Decl. at ¶¶ 5-7.)

The NPA's concerns are not isolated, as other Petitioners have raised similar concerns about the effect of the ETS on their members' workforces. *See, e.g.*, Job Creators Network Opposition, Doc. 98-1 at 4-7. The labor shortages created by the ETS along with the compliance costs cited by OSHA itself (almost $3 billion) are just the tip of the iceberg of the irreparable harm that will befall the NPA's members, the other Petitioners, and the general public at large should the stay be dissolved by this Court. The clear irreparable harm, along with the clear legal defects with the ETS identified by the Fifth Circuit and the complete lack of harm

to OSHA if the stay is continued, lead to only one logical conclusion: the enforcement of the ETS must be stayed unless and until this Court determines that the ETS is legally valid.

ARGUMENT

A stay pending this Court's review is appropriate if the balance of the traditional stay factors weighs in favor of Petitioners. *See SawariMedia, LLC v. Winter*, 963 F.3d 595, 596 (6th Cir. 2020) ("These factors are not prerequisites that must be met, but are interrelated considerations that must be balanced together."). The four factors, as applied to this case, are: (1) Petitioners' likelihood of success on the merits; (2) whether Petitioners will be irreparably harmed without the stay; (3) the potential harm to Respondents if the stay is continued; and (4) whether the stay serves the public interest. *See Hilton v. Braunskill*, 481 U.S. 770, 776 (1981). As the Fifth Circuit already correctly concluded, "[e]ach of these factors favors a stay here." *B.T.S. Holdings, LLC v. Occupational Health and Safety Administration et al*, 17 F.4th 604, 610 (5th Cir. 2021).

I. Petitioners are Likely to Succeed on the Merits as the ETS Suffers from Numerous Legal Defects.

Petitioners, including NPA, have a strong likelihood of success on the merits because the ETS suffers many legal defects, including constitutional and statutory

flaws, understanding that only one of these flaws is sufficient for the Court to strike down the ETS. The legal arguments attacking the validity of the ETS have and will continue to be briefed thoroughly by the other Petitioners in this case, and NPA joins in support of those arguments already made in the Fifth Circuit, by Petitioner Job Creators Network, and by the various amici filing briefs in support of the stay. For the sake of completeness of NPA's position, however, it identifies the following four primary legal defects of the ETS as support for the strong likelihood of Petitioners' success on the merits: (1) the ETS exceeds OSHA's statutory authority; (2) the ETS violates the Commerce Clause; (3) the ETS violates the non-delegation doctrine; and (4) the ETS violates the major questions doctrine.

As an initial matter, the ETS exceeds OSHA's statutory authority to issue emergency temporary standards because it does not meet the requirements for an emergency temporary standard. While OSHA has the authority to issue emergency standards in "exceptional circumstances," this power "'is an extraordinary power that is to be 'delicately exercised' in only certain limited situations.'" *In re Int'l Chem. Workers Union*, 830 F.2d 369, 370 (D.C. Cir. 1987). As evidence of the rarity of valid emergency temporary standards, OSHA has only issued ten such standards over the past fifty years, and out of six court challenges to those

standards, only one emergency temporary standard survived. *B.T.S. Holdings*, 17 F.4th at 609.

Because emergency standards are not subject to the same rulemaking procedures as permanent standards, they are subject to stricter review by the courts. *Asbestos Info Ass'n of N. Am. v. Occupational Health and Safety Administration*, 727 F.2d 415, 421 (5th Cir. 1984); *see also Florida Peach Growers Ass'n, Inc. v. U.S. Dept. of Labor*, 489 F.2d 120, 130 n. 16 (5th Cir. 1974) ("Congress intended a carefully restricted use of the emergency temporary standard."). Indeed, in order to be valid under 29 U.S.C. § 655, the ETS must

> (1) address "substances or agents determined to be toxic or physically harmful"—or "new hazards"—in the workplace; (2) show that workers are exposed to such "substances," "agents," or "new hazards" in the workplace; (3) show that said exposure places workers in "grave danger"; and (4) be "necessary" to alleviate employees' exposure to gravely dangerous hazards in the workplace

B.T.S. Holdings, 17 F.4th at 612. The Fifth Circuit analyzed these factors in detail and determined that the ETS fails for a variety of reasons. *Id.* at 612-16. For example, it held that while the effects of COVID-19 have been dire, a worldwide pandemic is not the type of "grave danger" contemplated by the Occupational Health and Safety Act. *Id.* As Job Creators Network stated in its opposition, "[t]he question is not whether COVID generally presents a grave danger, but whether the lack of a vaccine mandate and weekly testing for the next few months presents" a

sufficient grave danger to allow OSHA to issue the ETS. *See* Job Creators Opposition, No. 21-700, Doc. 98-1 at 15.

The Fifth Circuit also questioned whether the current pandemic situation is an "emergency" that necessitated the issue of the ETS given OSHA's lack of action, including any attempted mandate, over the past twenty-plus months of the pandemic, even during the worst periods of the pandemic. *See id; see also B.T.S. Holdings*, 17 F.4th at 614-15. COVID vaccines have been around for over a year and are now readily available for all but the youngest people in the population, and the pandemic has been threatening lives for almost two years, yet OSHA is just now taking action…after it previously, specifically declined to do so. *See id.*

Additionally, the Fifth Circuit determined that the ETS was both over- and under-broad. *Id.* at 615-16. It is under-broad because it makes an arbitrary distinction between the risk to employees with 100 or more employees and those with 99 or fewer employees, and it is overbroad in that it applies to virtually every industry and two-thirds of all employees in the United States without any regard for specific risk. *Id.* This "one size fits all" approach is not only overly broad, but also directly contradicts OSHA's previous statements on COVID-19 protective measures that "[a]dequate safeguards for workers could differ substantially based on geographic location, as the pandemic has had dramatically different impacts on

different parts of the country" and that "OSHA's time and resources [would be] better spent issuing industry-specific guidance." *Id.* at 615 (*quoting* OSHA's D.C. Circuit Briefing).

OSHA's prior conclusion regarding how COVID-19 should be approached through industry-tailored guidance is the correct approach here. Some industries (and individuals) undoubtedly are at a much higher risk of not only contracting COVID-19, but also of encountering a "grave danger" should they contract the illness. *See id.* The differences between NPA's members and other kinds of employers illustrate this point. Specifically, NPA members who engage in the manufacture of dietary supplements, for example, are already subject to the cGMP, which require the screening of employees for certain illnesses to prevent microbial contamination. *See* 21 C.F.R. § 111.10. This generally entails screening employees for certain symptoms, such as fevers, that could also be indicative of COVID-19 infection, and ensuring that any ill employee is not allowed to remain at work. *See* 21 C.F.R. § 111.10(a). Therefore, in highly-regulated industries, like natural products, the risk of COVID-19 outbreaks is greatly reduced because of the significant measures already in place to keep employees from coming in sick, which makes drastic emergency measures from OSHA unnecessary. *Id.*

In addition to its statutory defects, the ETS runs afoul of the United States Constitution for multiple reasons. First, it violates the Commerce Clause, which gives Congress the power "[t]o regulate commerce…among the several states." U.S. Const. Art. I, § 8, cl. 3. While this power is broad, it has two important limitations that require the ETS to be held invalid. *See B.T.S. Holdings*, 17 F.4th at 617-18. First, the Commerce Clause does not allow Congress (or those agencies to which it delegates power) to regulate an individual's "noneconomic inactivity." *See generally NFIB v. Sebelius*, 567 U.S. 519 (2012). As the Fifth Circuit pointed out, an individual's choice to remain unvaccinated and/or forgo weekly COVID-19 testing – to do nothing – is "noneconomic inactivity" that cannot be regulated by the Commerce Clause. *B.T.S. Holdings*, 17 F.4th at 617. Second, the decision to mandate vaccination is traditionally part of the *States'* reserved police power, not the federal government's power. *See Zucht v. King,* 260 U.S. 174, 176 (1922) (noting that precedent has long "settled that it is within the police power of a state to provide for compulsory vaccination"). "The Commerce Clause power may be expansive, but it does not grant Congress the power to regulate noneconomic inactivity traditionally within the States' police power." *B.T.S. Holdings*, 17 F.4th at 617.

In addition to violating the Commerce Clause, the ETS also violates the major questions and nondelegation doctrines. According to the major questions doctrine, "Congress must 'speak clearly if it wishes to assign to an agency decisions of vast economic and political significance.'" *Id.* (*quoting Util. Air Regul. Grp. v. EPA,* 573 U.S. 302, 324 (2012)). Here, Congress has not spoken clearly to give OSHA the kind of authority it seeks to exert via the ETS. As the Fifth Circuit stated, "[t]he Mandate derives its authority from an old statute employed in a novel manner, imposes nearly $3 billion in compliance costs, involves broad medical considerations that lie outside of OSHA's core competencies, and purports to definitively resolve one of today's most hotly debated political issues." *Id.* If Congress intends to delegate such broad powers to OSHA, then it must do so clearly and unequivocally, and it has not in this case. *Id.*

The ETS also violates the nondelegation doctrine, which provides that "the integrity and maintenance of the system of government ordered by the Constitution mandate[s] that Congress generally cannot delegate its legislative power to another Branch." *Mistretta v. United States*, 488 U.S. 361, 371-72 (1989). By giving OSHA power broad enough to enact the ETS—a mandate that affects society and the economy as a whole in profound ways—Congress would be impermissibly delegating its legislative authority to the executive branch. *B.T.S. Holdings*, 17

F.4th at 617-18. Congress clearly did not do so, given the fundamental questions regarding whether OSHA even has authority over the kind of general health hazard posed by COVID, as opposed to risks specific to the workplace.

Therefore, because the ETS both exceeds OSHA's statutory authority and runs afoul of the United States Constitution, Petitioners, including the NPA, have a high likelihood of success on the merits, and this factor weighs heavily in favor of keeping the Fifth Circuit's stay in effect. *See Nken v. Holder*, 556 U.S. 418, 434 (2009) (stating that the first two factors of the stay test—likelihood of success and irreparable harm—are the most important).

II. Petitioners, Including NPA and Its Members, will be Irreparably Harmed Should the Stay be Dissolved.

As the Fifth Circuit correctly stated, "[i]t is clear that a denial of the petitioners' proposed stay would do them irreparable harm." *B.T.S. Holdings*, 17 F.4th at 618. Contrary to Respondents' assertion that Petitioners "face little prospect of harm [if the stay is lifted] before the [ETS] takes full effect in January 2022" (Motion to Dissolve at 42-43), NPA's members face immediate irreparable harm in the form of exacerbated labor shortages and significant compliance costs immediately upon any lifting of the stay regardless of when the ETS may then go into full effect.

The natural products industry, like many others (*see, e.g.*, Job Creators Network, Exs. A-F), is facing a dire labor shortage (Fabricant Decl. at ¶¶ 6-7; LeDoux Decl. at ¶ 4.). In fact, NPA members have indicated that, on average, they are already dealing with workforces that are reduced by almost one-third. (Fabricant Decl. at ¶ 7.) For NPA members who manufacture natural products in the United States (as opposed to elsewhere), labor shortages are particularly acute because of the regulatory burdens already placed on them (as described below). (*Id*. at ¶¶ 7, 9.) If the ETS is restored, many unvaccinated workers will choose to seek employment with uncovered businesses instead of getting vaccinated or submitting to costly and invasive weekly testing. The mere specter of the ETS, in fact, has already caused unvaccinated workers to consider finding comparable employment with companies not covered by the ETS. (*Id.* at ¶ 9; LeDoux Decl. at ¶ 5.) If the stay is lifted and NPA's members are forced to start complying with the ETS now, there is a high likelihood that workers will begin leaving in droves, worried that the ETS may ultimately be deemed valid. (*See id.*) Should the ETS ultimately be found legally invalid, these employees will already be lost to other businesses, and NPA's members, including those manufacturers that deliver natural products that improve the health of the public at large, will still be faced

with incurring the costs and delays of replacing them. These harms cannot be undone should this Court ultimately rule in Petitioners' favor on the merits.

While labor shortages are detrimental to all businesses, they are especially damaging to NPA's highly regulated members due to the time needed to hire and train replacement employees. Many of NPA's members are subject to regulation by the FDA and its cGMPs. (*Id.* at ¶¶ 7, 9.) As an initial matter, these regulations require that some workers have specific training, and in some instances licensure or certification. *See, e.g.*, 21 C.F.R. §111.12. This, coupled with the fact that unvaccinated individuals would likely not even apply for these positions, greatly shrinks the pool of available and potentially qualified applicants to fill vacated positions. (Fabricant Decl. at ¶ 7.) If these member companies can find a sufficient number of qualified replacement employees (no small feat), it will take even more time and resources in order to properly train and on-board these individuals in compliance with the applicable regulations. (*Id.* at ¶¶ 7, 9; LeDoux Decl. at ¶ 4.) As an example only, those in the dietary supplements industry must be properly trained on extensive hygiene practices to prevent any microbial contamination and on quality control procedures necessary to ensure that products are labeled and packaged correctly. *See* 21 C.F.R. § 111.1 *et seq.* This includes not only

complicated sampling procedures, but also extensive record-keeping requirements. *Id.*

In many instances, it can take up to three to six months to get a replacement employee fully up to speed. (Fabricant Decl. at ¶ 9; LeDoux Decl. at ¶ 4.) Therefore, for every highly-trained, technical employee that leaves, it will take months to replace their lost productivity while the employer trains new individuals, assuming qualified replacements can be found almost immediately. If it takes months to find a replacement and months more to complete required training, the strain on production could last for six months or more. In addition to the lost productivity, which is harmful to members' revenue, they will also lose work, face potential damage to their reputations, and face the distinct possibility of plant shut downs and/or reductions in their vaccinated and unvaccinated workforces because of the negative effects of reduced production. If NPA members cannot operate at full capacity, they will not be able to meet customer needs and could further impact supply chain problems if they, in turn, supply products or materials to other companies. (Fabricant Decl. at ¶ 8; LeDoux Decl. at ¶ 6-7.)

NPA members will also incur significant costs to comply with the provisions of the ETS, unnecessarily if the ETS is ultimately determined to be invalid. The ETS is not a simple regulation, and if NPA members have to prepare to comply

with it, regardless of its ultimate validity, they will incur significant expense. These costs are not speculative, as Respondents disingenuously argue. Instead, businesses, some of whom are already struggling due to the economic effects of the pandemic, will have to spend scarce time and resources determining how to implement the ETS. In fact, OSHA itself has estimated that compliance will cost approximately $3 billion dollars. *See COVID-19 Vaccination and Testing Emergency Temporary Standard*, 86 Fed. Reg. 61402, 61493 (Nov. 5, 2021).

For example, NPA members will have to spend time determining and tracking the ongoing vaccination status of their employees and putting compliant policies in place, which likely will include legal costs. Members who choose the testing option will also have to set up a weekly testing program and, to retain employees and/or comply with applicable state and local laws, may have to shoulder the costs of the weekly testing even though the ETS does not require that they do so. (*See* Fabricant Decl. at ¶ 10.) Depending on their existing infrastructure, NPA members, particularly those smaller businesses, may have to hire additional personnel in order to effectively administer a testing policy and ensure that all necessary records are maintained. (*Id.*)

Moreover, all of these ETS compliance costs are in addition to the costs many NPA members already incur to comply with cGMPs, which already require

that covered manufacturers screen employees for certain types of illnesses and keep records of any related incidents. (*See id.*) And, all of these compliance costs do not even include the potentially exorbitant fines to which NPA members may be subjected if they do not meet all of the highly technical and repetitive requirements of the ETS. Indeed, employers who do not follow rules set out by OSHA can be subject to fines of up to $70,000 per violation, 29 U.S.C. § 666, understanding that OSHA has announced an intent to fine employers up to $14,000.00 per ETS violation.

If the stay is dissolved, all of these costs must be incurred by NPA members *before* this Court rules on the validity of the ETS. If this Court ultimately holds that the ETS is invalid, all of these costs, and the cascading impact of those additional costs on other business decisions, will have been for naught. As the Fifth Circuit stated, "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *B.T.S. Holdings*, 17 F.4th at 618. All of this irreparable harm to NPA, its members, and many other businesses and individuals easily can be avoided, however, if the ETS is stayed until a determination on the merits can be made.[1]

[1] The third factor of the traditional stay elements is the harm that will befall Respondents should the stay be maintained. As the Fifth Circuit stated, OSHA itself will suffer from no harm should the stay be put into effect. *BTS Holdings*, 17 F.4th at 618. Further, Respondents did not outline any harm that they would suffer from the stay in their Motion to Dissolve. Instead, they focused

III. Public Interest Favors Keeping the Stay in Effect until Validity of the ETS is Determined on the Merits

The fourth and final factor that must be considered by this Court – whether the stay is in the public interest – also weighs in favor of keeping the stay in place until a merits determination has been made. Allowing enforcement of the ETS before its validity has been confirmed will cause significant harm not only to Petitioners in this case, but also to many businesses, the economy, and the general public. As the Fifth Circuit stated, "the mere specter of the [ETS] has contributed to untold economic upheaval in recent months." *B.T.S. Holdings*, 17 F.4th at 618. The labor shortages and resulting supply chain problems that will result from the mass exodus of unvaccinated workers will affect not only Petitioners and other businesses, but will also be detrimental to the economy as a whole because it will affect the general public's ability to acquire necessary goods and services. (*See* Fabricant Decl. at ¶¶ 5, 8, & 11; LeDoux Decl. at ¶ 7.) As Job Creators Network stated in its opposition, "[f]ood will not be produced or transported to grocery stores, schools, and nursing homes; household products [including those manufactured by NPA members] will not be manufactured; damaged roofs and sinkholes will not be repaired; snow will not get removed and buildings with

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only on the alleged harm to the general public and unvaccinated employees. *See generally* Respondents' Motion to Dissolve, Doc. 69. Therefore, while this factor weighs in favor of the stay, NPA will not address it in detail in this brief.

broken HVAC systems will turn into freezing meat lockers." Job Creators Network Opposition Brief, Doc. 98-1 at 18. This is just a small sample of the products and services that the general public may have trouble accessing should the supply chain issues in the United States worsen. Further, and more particularly to NPA members, some natural products manufacturers may not be able to maintain the supply of products specifically designed to keep the public healthy, including products that ameliorate the impact of COVID. (See Fabricant Decl. at ¶ 8, 11.) NPA's manufacturing members may also be forced to at least consider moving their production facilities outside of the United States to countries that either do not have or have less stringent COVID-19 protocols. (*Id.* at ¶ 11.) As a general matter, it is not good for the economy and therefore, the general public, for skilled, technical jobs to be threatened via reductions and possible relocations outside of the United States.

In addition to these potentially dire economic consequences, the personal liberty of many individuals is at stake, as many workers around the country will be faced with the choice to take a vaccine, submit to invasive weekly COVID-19 testing, or forfeit their jobs. While economic implications are certainly important, "[t]he public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals to make intensely personal decisions

according to their own convictions—even, or perhaps particularly, when those decisions frustrate government officials." *B.T.S. Holdings*, 17 F.4th at 618-19. Therefore, it is in the best interest of the public for the Fifth Circuit's stay to remain in place.

CONCLUSION

For the reasons set forth above, NPA respectfully requests that this Court deny Respondents' motion to dissolve the Fifth Circuit's stay of the ETS.

Respectfully submitted this 7th day of December, 2021.

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CERTIFICATE OF COMPLIANCE

This document complies with the word limit of Fed. R. App. P. 27(d)(2)(A)because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 4,342 words.

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/s/ Henry M. Perlowski
Henry M. Perlowski

CERTIFICATE OF SERVICE

I certify that on December 7, 2021, a copy of the foregoing was served by the Court's ECF system on counsel of record.

/s/ Henry M. Perlowksi
Henry M. Perlowski

EXHIBIT A

DECLARATION OF DANIEL FABRICANT, Ph.D.

1. My name is Daniel Fabricant, Ph.D. I am over the age of 18 and am competent to make this declaration. The facts set forth in this declaration are based on my personal knowledge.

2. I am the President and Chief Executive Officer of the Natural Products Association ("NPA"), a not-for-profit trade association registered under section 501(c)(6) of the Internal Revenue Code.

3. As the leading voice of the natural products industry, NPA's mission is to advocate for the rights of consumers to have access to products that will maintain and improve their health, and for the rights of retailers and suppliers to sell these products. Members join NPA and receive a weekly newsletter, policy updates, and educational materials, and have the opportunity to participate in networking events, committee meetings and media opportunities, all to advance their interests with the legislative, judicial and executive branches of government and the broader public at large.

4. NPA provides its members with the tools to become the voice of the natural products industry before the media, Congress and state legislatures, and in their communities and workplaces – allowing them to hold policymakers and politicians accountable to job creators and their employees. When NPA members are harmed or face potential harm as a result of public policy that is contrary to their

interests and the interests of the natural products industry as a whole, NPA amplifies their stories in the media to educate policymakers and the public about the significant adverse consequences of such public policy.

5. NPA supports the natural products industry, which is valued at over $50 billion dollars domestically, and is comprised of approximately 70% small businesses nationwide per the Small Business Administration. These members include manufacturers and distributors that provide such important public benefits that they were deemed "essential" during the COVID-19 lockdowns per Department of Homeland Security guidelines. After surviving the lockdowns, the height of the pandemic, and now labor shortages and supply chain uncertainties, these businesses also now face substantial, imminent, and irreparable loss because of the recent OSHA ETS vaccine mandate.

6. To be clear, NPA is not anti-vaccine. In fact, many of its members encourage their employees to get COVID vaccines, and have been implementing other measures consistent with current Good Manufacturing Practices ("cGMP") required by the Food and Drug Administration, all to promote a healthy workforce. With that said, the government-imposed mandate reflected in the OSHA ETS will cause incredible injury to businesses, citizens, and the national economy.

7. The country, and smaller businesses in particular, are facing a severe labor shortage, with companies struggling to hire enough workers to keep up with

demand. NPA board members have indicated that they are already experiencing labor shortages of up to one-third (33%) of the workforces, with my understanding that this prevents some members from running their full complement of production shifts. This labor strain is even more acute for companies within our highly-regulated industry, as cGMPs mandate that workers have specific training, and in some instances, licensure or certification, which makes the pool of available applicants even smaller for our members.

8. Accordingly, if any sizable number of unvaccinated employees are placed on leave and/or resign rather than subject themselves to involuntary vaccination and/or weekly testing, those companies necessarily will not be able to maintain their already challenged levels of production and distribution. Our members simply cannot replace employees immediately and plug a new hire into a hole left by a person who refuses to or cannot comply with the mandates imposed by the OSHA ETS. This negative impact on production and distribution, in turn, will damage the reputations of our members, and increase the distinct possibility of the further loss of shifts, shut downs, and/or headcount reductions, including, of vaccinated workers.

9. It is not mere conjecture that workers will leave companies rather than comply with the OSHA ETS. Given the labor shortage, it is easy for those employees to leave a company with 100 or more employees (covered by the mandate) and go

to work for a smaller company (not covered by the mandate). In fact, even before any deadlines may take legal effect, workers will leave for new jobs in order to maximize their future employment opportunities. This problem is more acute for NPA members and other FDA-regulated businesses because of their highly technical and already highly-regulated workforce. Our industry and our members practically need more time to recruit qualified candidates and then train those newly-hired employees for them to be able to contribute to production. To comply with cGMPs, this training can take from three (3) months to up to six (6) months depending on the specific company and position involved. Recognizing this fact, our small businesses (those with fewer than 500 employees) routinely are given significantly more time for compliance with new rules. For example, for compliance with the highly technical dietary supplement cGMP rule, companies were given two (2) years to comply and the opportunity to shape the rule through notice and comment rulemaking.

10. On top of the labor issues caused by the OSHA ETS mandate, there will be dramatic and possibly redundant compliance costs. In this regard, NPA members will have to stand up systems to track their vaccinated employees and weekly testing of unvaccinated employees. Any oversight or mistake during this process could lead to fines of nearly $14,000.00 per violation. Furthermore, members will have to invest in tracking systems and very likely will bear the costs of testing, either because of

potentially applicable law and/or market conditions. Members also face the prospect of disputes if, for example, an employee suffers an adverse effect from the vaccine, let alone the negative impact on morale, including between vaccinated and unvaccinated workers. The dietary supplement cGMPs and food cGMPs already provide for the control of viruses and colds in the workplace. Industry best practices, which have been required by law since 2008 and have given the United States the safest food and dietary supplement supply in the world, are most frequently based on monitoring symptoms of employees. These systems have over a decade of data to show efficacy of keeping the workplace, employees and products safe from outbreaks of disease. NPA members accordingly are going to have to disrupt these effective systems to determine how to integrate and fully factor the unproven requirements being imposed by the OSHA ETS mandate, all without the opportunity for notice and comment.

11. NPA's members have repeatedly reported the incredible damage that the OSHA ETS mandate will inflict their businesses, which are keeping the country healthy by producing, *e.g.*, products like vitamin D (with low vitamin D status being a major cohort for morbidity and illness from COVID-19). The pressures described on these businesses also inevitably will cause them to, at least, explore the possibility of moving production overseas, particularly in jurisdictions were mandates are not in place.

12. Without any notice and comment for a proposed ETS or a final ETS, our industry has not had the opportunity to have its voice heard. The lack of transparency and public involvement and scrutiny in formulating the OSHA ETS mandate has resulted in harm because NPA members have had no idea what would be included in the mandate, what exceptions might apply, or even whether they will actually be covered by the mandate. That, in turn, has already resulted in disruptions and additional costs to members, which, at least, have now been tempered because of the stay of the OSHA ETS.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 6th day of December, 2021.

Daniel Fabricant, Ph.D.

EXHIBIT B

DECLARATION OF MARK LEDOUX

1. My name is Mark LeDoux. I am over the age of 18 and am competent to make this declaration. The facts set forth in this declaration are based on my personal knowledge.

2. I am the CEO and founder of Natural Alternatives International (NAI), a leading manufacturer of dietary supplements that forms an important part of our country's health and wellness. Our principal place of business is Carlsbad, California. We have repeatedly encouraged our employees to get vaccinated, but we have declined to impose a mandate.

3. NAI is publicly traded with over 200 employees. It is therefore subject to the new OSHA emergency vaccine mandate, which requires the Company's staff to receive a coronavirus vaccine or get tested frequently, with noncompliance resulting in major fines.

4. I believe the new OSHA vaccine mandate will cause irreparable and imminent harm to NAI. The Company is already facing severe labor shortages-which has been national news—and is struggling to hire skilled labor to keep up with production demands. Many of these employees must have specialized training and certifications to work in production and/or our laboratories under US Food and Drug Administration (FDA) current Good Manufacturing Practice (cGMP) requirements. Meaning the company faces a limited pool of potential hires to fill any vacancies.

We also have an intensive on-boarding process, required by the FDA and other regulatory requirements that lasts three to six (3-6) months. We cannot simply hire more employees and have them start quickly.

5. I would estimate that 25% or more of NAI employees would rather walk off the job than be forced to get a vaccine or undergo weekly testing. And to maximize the odds they quickly find new jobs at companies not subject to the OSHA mandate, these workers have an incentive to leave NAI soon after the OSHA mandate's issuance date, regardless of when the mandate formally requires vaccines or testing to begin.

6. Because of the difficulty in finding qualified workers to fill vacancies, NAI will likely lose a substantial number of key workers who simply cannot be readily replaced at any point in the near future. The absence of key employees would be devastating. Our employees are how we make money. A lack of sufficient workforce in production would directly hurt our business, its positive, hard-working culture, its reputation, and its bottom line. Deliveries will be delayed or canceled, resulting in severe financial and reputational damages for the Company, as well as a likely ripple effect of losing business to smaller companies that do not have to comply with the OSHA mandate. If enough workers leave, we would have to consider taking cost reduction measures affecting operations. As an interim measure

to keep the company's finances consistent, we may have to save costs by further reducing our workforce.

7. Delayed or canceled shipments could also have severe negative consequences for the public at large, who depend on companies like NAI to produce dietary supplements and other health and wellness products. The Company's customers include retail and internet distributors, whose products are in great demand due to the pandemic. Put simply, without production, those products like Vitamin D, (a deficiency of which is a major cohort for illness and morbidity due to COVID-19) may not be available to the American public which is doing all it can to stay healthy right now. It is primarily for this reason, NAI was deemed "an essential business" during the COVID lockdowns.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 7th day of December, 2021.

Mark LeDoux