

No. 21-4031

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IN THE UNITED STATES COURT OF APPEALS  
FOR THE SIXTH CIRCUIT

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COMMONWEALTH OF KENTUCKY; *et al.*,

,

*Petitioners,*

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, *et al.*,

*Respondents.*

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On Petition for Review of an Emergency Temporary Standard from the  
Occupational Safety and Health Administration.

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**MOTION FOR LEAVE TO FILE BRIEF OF THE AMERICAN  
MEDICAL ASSOCIATION AS *AMICUS CURIAE* IN OPPOSITION  
TO PETITIONERS' EMERGENCY MOTION FOR STAY PENDING  
FINAL JUDGMENT**

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## **MOTION FOR LEAVE TO FILE BRIEF AS *AMICUS CURIAE***

Pursuant to Federal Rule of Appellate Procedure 29, Proposed *Amicus* moves for leave to file the attached brief in opposition to Petitioners' emergency motion to stay pending final judgment.

Proposed *Amicus* is the American Medical Association ("AMA"). The AMA is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state.

As the leading membership organization of physicians nationally, the AMA has a strong interest in promoting public health and reducing the spread of COVID-19. The attached brief reflects the AMA's extensive review of medical literature supporting the efficacy and safety of the COVID-19 vaccines authorized or approved by the Food and Drug Administration. Accordingly, the proposed brief will assist the Court because it sets forth medical and scientific information demonstrating that the emergency

temporary standard is supported by substantial evidence, that the emergency temporary standard was issued to curtail an occupational health emergency, and that a stay of that standard would cause grave, severe, and irreparable harm to the public interest. *See United States v. State of Mich.*, 940 F.2d 143, 165 (6th Cir. 1991) (recognizing participation of *amicus curiae* upon a “finding that the proffered information of amicus is timely, useful, or otherwise necessary to the administration of justice.”); *Neonatology Assoc., P.A. v. Comm’r of Internal Revenue*, 293 F.3d 128, 129 (3d Cir. 2002) (Alito, J.) (granting leave to file *amicus* brief where “amici have a sufficient ‘interest’ in the case and . . . their brief is ‘desirable’ and discusses matters that are ‘relevant to the disposition of the case’ (quoting Fed. R. App. P. 29(b));

Counsel for the AMA has consulted with the parties’ counsel. Respondents have consented to this motion and to the filing of the attached *amicus curiae* brief. Counsel for Petitioners indicated that they have no objection to this motion.

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), Proposed *Amicus* states that no counsel for any party authored the proposed brief inwhole or in part, and no person or entity, other than *amicus* and its counsel, made a monetary contribution intended to fund the preparation or

submission of this brief.

Dated: November 15, 2021

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limit of Fed. R. App. P. 27(d)(2)(A) and 6th Cir. R. 27 because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 432 words according to the word count function of Microsoft Word 365.

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*/s/ Rachel L. Fried*

Date: November 15, 2021

**CERTIFICATE OF SERVICE**

I hereby certify that on November 15, 2021, a true and accurate copy of the foregoing motion was electronically filed with the Court using the CM/ECF system. Service on counsel for all parties will be accomplished through the Court's electronic filing system.

/s/ Rachel L. Fried

Date: November 15, 2021

No. 21-4031

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## **CORPORATE DISCLOSURE STATEMENT**

The American Medical Association (“AMA”) is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of the AMA.

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## **INTEREST OF *AMICUS CURIAE***

The American Medical Association (“AMA”) is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA’s policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state. The AMA has an interest in providing evidence-based guidance on public health issues and working to reduce the spread of contagious illnesses.<sup>1</sup>

## **INTRODUCTION**

The United States is in an unprecedented and ongoing public health crisis. SARS-CoV-2, the causative agent of COVID-19, has wreaked havoc in communities across the country, taxed hospitals to the point of rationing care, upended the lives of countless families, and killed over

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<sup>1</sup> *Amicus* certifies that no party’s counsel authored this brief in whole or in part, no party or party’s counsel contributed money intended to fund this brief, and no person other than *amicus*, its members, and their counsel contributed money intended to fund this brief.



755,000 Americans. Widespread vaccination is essential to ending the COVID-19 pandemic and preventing thousands more needless deaths.

For nearly two years, the AMA has monitored the COVID-19 pandemic and advocated for evidence-based public health measures to end it. Many COVID-19 outbreaks have occurred in workplaces. The AMA's extensive review of the medical literature demonstrates that COVID-19 vaccines authorized or approved by FDA are safe and effective, and the widespread use of those vaccines is the best way to keep COVID-19 from spreading within workplaces. A stay of OSHA's Emergency Temporary Standard would therefore severely and irreparably harm the public interest.

## **ARGUMENT**

### **I. COVID-19 poses a grave danger to public health.**

COVID-19 presents a severe risk to public health in this Circuit and throughout the nation. Although most people infected with the virus will experience mild to moderate symptoms, individuals with COVID-19 can become seriously ill or die at any age. As of November 5, 2021, there have

been over forty-six million confirmed cases of COVID-19 in the United States, leading to more than 3,250,000 hospitalizations.<sup>2</sup>

Even those who recover from COVID-19 may experience post-COVID conditions with debilitating symptoms lasting for several months after the acute phase of infection. A systematic review of forty-five studies including 9,751 participants found that 73% of infected individuals experienced at least one long-term symptom.<sup>3</sup> Over half of previously hospitalized patients continue to experience cardiopulmonary symptoms and abnormalities six months later.<sup>4</sup> And over 755,000 people in the United States have died from COVID-19—more than twenty-one times the number of people in the United States who die from influenza in the average year.<sup>5</sup> As of November 12, 2021, over 76,000 people have died from COVID-19 in the four states in this Circuit alone.<sup>6</sup>

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<sup>2</sup> *COVID Data Tracker Weekly Review: This is Their Shot*, Centers for Disease Control and Prevention (“CDC”) (Nov. 5, 2021), <https://bit.ly/3EYAdAb>.

<sup>3</sup> Tahmina Nasserie et al., *Assessment of the Frequency and Variety of Persistent Symptoms: A Systematic Review*, JAMA Netw. Open (2021), <https://bit.ly/3qocFkk>.

<sup>4</sup> M.P. Cassar et al., *Symptom Persistence Despite Improvement in Cardiopulmonary Health – Insights from longitudinal CMR, CPET and lung function testing post-COVID-19*, EClinicalMedicine (2021), <https://bit.ly/3H7AeDB>.

<sup>5</sup> *Disease Burden of Flu*, CDC (Oct. 4, 2021), <https://bit.ly/3ocAuZA>.

<sup>6</sup> *United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction*, CDC (Nov. 12, 2021), <https://bit.ly/3kui8SL>.

SARS-CoV-2 is highly transmissible. The original strain was more contagious than the flu, and the Delta variant of SARS-CoV-2, now the leading strain, is more than twice as contagious as the original.<sup>7</sup> Crucially, over 50% of the spread of the virus may be from individuals who have no symptoms at the time of transmission.<sup>8</sup>

Workplace transmission has been a major factor in the spread of COVID-19. COVID-19 outbreaks have occurred among workers in numerous industries, including service and sales, education, hospitality, construction, domestic work, meat-processing, transportation, prison, and of course healthcare industries.<sup>9</sup> Studies found widespread COVID-19 outbreaks in meat- and poultry-processing facilities and “identified high proportions of asymptomatic or presymptomatic infections.”<sup>10</sup>

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<sup>7</sup> *Delta Variant: What We Know About the Science*, CDC (Aug. 26, 2021), <https://bit.ly/3plAmcy>; Apoorva Mandavilli, *C.D.C. Internal Report Calls Delta Variant as Contagious as Chickenpox*, N.Y. Times (Jul. 30, 2021), <https://nyti.ms/3wxXaHB>.

<sup>8</sup> *Use of Cloth Masks to Control the Spread of SARS-CoV-2*, CDC (May 7, 2021), <https://bit.ly/30inWYx>.

<sup>9</sup> *Update 64—COVID-19 Prevention at the Workplace*, World Health Organization (Jul. 28, 2021), <https://bit.ly/307J1V6>; *Investigating and Responding to COVID-19 Cases in Non-Healthcare Work Settings*, CDC (Oct. 25, 2021), <https://bit.ly/3qC74XN>.

<sup>10</sup> Michelle A. Waltenburg et al., *Coronavirus Disease among Workers in Food Processing, Food Manufacturing, and Agriculture Workplaces*, 27 *Emerging Infectious Diseases* 243 (2021), <https://bit.ly/3kp3Lip>.

Forty-five percent more people reported missing work for medical reasons during 2020 than the previous twenty-year average.<sup>11</sup> Another study found that adults who tested positive for SARS-CoV-2 were significantly more likely to report going to an office or school setting than adults who tested negative.<sup>12</sup> Protecting workers from COVID-19 is especially important given that “a large proportion of the United States workforce, across a variety of occupational sectors, are exposed to disease or infection at work more than once a month.”<sup>13</sup>

## **II. Vaccines provide a safe and effective way to help reduce transmission of COVID-19 in the workplace.**

COVID-19 vaccines are safe. Before FDA authorized/approved and CDC recommended use of the COVID-19 vaccines in the population, scientists conducted clinical trials. FDA, CDC, and their advisory committees conducted rigorous reviews of the data.<sup>14</sup> CDC and FDA

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<sup>11</sup> Charisse Jones & Matt Wynn, *Coronavirus and the Workplace: The Virus Causes Record Numbers of Job Absences in 2020*, USA Today (Jan. 21, 2021), <https://bit.ly/3C39lgx>.

<sup>12</sup> Kiva A. Fisher et al., *Telework Before Illness Onset Among Symptomatic Adults Aged ≥18 Years With and Without COVID-19 in 11 Outpatient Health Care Facilities — United States, July 2020*, 69 Morbidity & Mortality Weekly Rpt. 1648 (Apr. 28, 2020), <https://bit.ly/3F5Ybt8>.

<sup>13</sup> Marissa G. Baker et al., *Estimating the burden of United States workers exposed to infection or disease: A key factor in containing risk of COVID-19 infection*, PLoS ONE (2020), <https://bit.ly/3BWD0q8>.

<sup>14</sup> *Benefits of Getting a COVID-19 Vaccine*, CDC (Nov. 5, 2021), <https://bit.ly/3H6BsiF>.

continue to monitor the safety of COVID-19 vaccines through both passive and active safety surveillance systems.<sup>15</sup> A study of over six million people who received the Pfizer or Moderna vaccines found that serious side effects are very rare.<sup>16</sup> Another study concluded that there is no increased risk for mortality among recipients of any of the COVID-19 vaccines, and that vaccine recipients in fact had lower non-COVID-19 mortality risks than did unvaccinated people.<sup>17</sup>

COVID-19 vaccines are also effective. First, each of the three vaccines greatly reduces the likelihood of contracting infection. The Pfizer, Moderna, and J&J/Janssen vaccines are 91.3%, 90%, and 72% effective against infection, respectively.<sup>18</sup> Although the vaccines' efficacy wanes over time, initial data on Pfizer booster shots show that they may

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<sup>15</sup> Nicola P. Klein et al., *Surveillance for Adverse Events After COVID-19 mRNA Vaccination*, 326 J. Am. Med. Ass'n 1390, (Sep. 3, 2021), <https://bit.ly/3F1XQYM>; *COVID-19 vaccine safety surveillance*, FDA (Jul. 12, 2021), <https://bit.ly/3wxPIB>.

<sup>16</sup> Klein et al., *supra* n. 15.

<sup>17</sup> Stanley Xu et al., *COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021*, 70 Morbidity & Mortality Weekly Rpt. 1520 (Oct. 29, 2021), <https://bit.ly/3D1ZRn4>.

<sup>18</sup> Kathy Katella, *Comparing the COVID-19 Vaccines: How Are They Different?*, Yale Med. (Nov. 3, 2021), <https://bit.ly/307jEU5>.

boost the vaccine efficacy to over 95%.<sup>19</sup> For comparison, the flu vaccination reduces the risk of flu illness by between forty and sixty percent.<sup>20</sup>

Second, each of the three vaccines is even more effective against serious illness and death. Studies have estimated the Pfizer, Moderna, and J&J/Janssen vaccines as 95.3–97%, 95%, and 86% effective against severe disease, respectively.<sup>21</sup> The vaccines are likewise highly effective against hospital admissions, “even in the face of widespread circulation of the delta variant.”<sup>22</sup> According to one analysis, between March 11 and August 15, 2021, unvaccinated people accounted for 84.2% of patients hospitalized for COVID-19, including those infected with the Delta variant.<sup>23</sup>

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<sup>19</sup> *Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine*, Pfizer (Oct. 21, 2021), <https://bit.ly/3EXQa9K>.

<sup>20</sup> *How Well Flu Vaccines Work: Questions & Answers*, CDC (last visited Nov. 9, 2021), <https://bit.ly/3HifLMP>.

<sup>21</sup> Katella, *supra* n. 18.

<sup>22</sup> Sara Y Tartof et al., *Effectiveness of mRNA BNT162b2 COVID-19 Vaccine Up to 6 Months*, 398 *Lancet* 1407, 1407 (Oct. 16, 2021).

<sup>23</sup> Mark W. Tenforde, *Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity*, *J. Am. Med. Ass’n* (Nov. 4, 2021), <https://bit.ly/3bZBHhb>.

The initial rollout of COVID-19 vaccines in the United States “was associated with reductions in COVID-19 cases, emergency department visits, and hospital admissions among older adults.”<sup>24</sup> In August 2021, unvaccinated people had a 6.1 times greater risk of testing positive for COVID-19, and an 11.3 times greater risk of dying from COVID-19, than fully vaccinated people.<sup>25</sup>

Third, as OSHA acknowledged, evidence suggests that those who are fully vaccinated are contagious for shorter periods than unvaccinated people.<sup>26</sup> Most importantly, “[r]egardless of viral loads in vaccinated and unvaccinated individuals, the fact remains clear that unvaccinated people pose a higher risk of transmission to others than vaccinated people, simply because they are much more likely to get COVID-19 in the first place.”<sup>27</sup>

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<sup>24</sup> Lucy A. McNamara et al., *Estimating the Early Impact of the US COVID-19 Vaccination Programme on COVID-19 Cases, Emergency Department Visits, Hospital Admissions, and Deaths Among Adults Aged 65 Years and Older: An Ecological Analysis of National Surveillance Data*, *Lancet* (Nov. 3, 2021), <https://bit.ly/31NqTRq>.

<sup>25</sup> *Rates of COVID-19 Cases and Deaths by Vaccination Status*, CDC (last visited Nov. 9, 2021), <https://bit.ly/3F3YMLV>.

<sup>26</sup> See COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402, 61,419 (Nov. 5, 2021).

<sup>27</sup> *Id.*

### III. The more workers who get vaccinated, the safer the workplace becomes.

The more workers who get vaccinated, the closer we are to slowing the spread of the virus and creating a safer environment. As the AMA has explained, “[t]he only way to truly end this pandemic is to ensure *widespread* vaccination.”<sup>28</sup> Infectious diseases such as COVID-19 continue to circulate as long as the average infected individual is able to transmit the disease to one or more uninfected individuals within the community.<sup>29</sup> Widespread vaccination is the only practical way to push the effective reproduction rate of the SARS-CoV-2 virus below one, the rate at which endemic transmission begins to die out.

Widespread vaccination reduces the likelihood of infections among both vaccinated and unvaccinated people. “[S]tates with high vaccination rates (>70% of the population) are reporting lower numbers of vaccine breakthrough cases as well as hospitalizations and deaths from COVID-19.”<sup>30</sup> This is particularly important for people who cannot get vaccinated

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<sup>28</sup> Press Release, Am. Med. Ass’n, *AMA, AHA, ANA urge vaccinations as U.S. reaches 750,000 COVID-19 deaths* (Nov. 4, 2021) (emphasis added), <https://bit.ly/3C07CIS>.

<sup>29</sup> See generally Paul Fine et al., *“Herd Immunity”: A Rough Guide*, 52 *Clinical Infectious Diseases* 911 (2011).

<sup>30</sup> Carlos del Rio et al., *Confronting the Delta Variant of SARS-CoV-2, Summer 2021*, 326 *J. Am. Med. Ass’n* 1001, 1002 (2021), <https://bit.ly/3bVL5Cj>.



due to age or medical condition, as well as immunocompromised people, who remain particularly susceptible to infection even after vaccination.<sup>31</sup>

History has shown that vaccine requirements are critical to achieving the degree of vaccination necessary to curb or eradicate infectious disease. Countries or states that mandated smallpox vaccination saw 10 to 30 times fewer smallpox cases than those that declined to do so.<sup>32</sup> Before compulsory school vaccination laws were in place throughout the United States, states with strict vaccination requirements had incidence rates of measles less than half those of states that did not.<sup>33</sup> More recently, in 2014, two Ohioans were exposed abroad, which resulted in “the largest [measles] outbreak documented in the United States in more than two decades,” with 383 confirmed cases.<sup>34</sup> Approximately 89% of the individuals who contracted measles were unvaccinated before the outbreak, but “high baseline vaccination

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<sup>31</sup> *How Effective Are COVID-19 Vaccines in Immunocompromised People?*, Am. Soc’y for Microbiology (Aug. 12, 2021), <https://bit.ly/3F24HBh>.

<sup>32</sup> Rajaie Batniji, *Historical Evidence to Inform COVID-19 Vaccine Mandates*, 397 *Lancet* 791 (2021) (citing Frank Fenner, et al., World Health Org., *Smallpox and Its Eradication* (1988)).

<sup>33</sup> Kevin M. Malone & Alan R. Hinman, *Vaccination Mandates: The Public Health Imperative and Individual Rights*, in *Law in Public Health Practice* 262 (1st ed., 2003), <https://bit.ly/3BUviyg>.

<sup>34</sup> Paul A. Gastañaduy et al., *A Measles Outbreak in an Underimmunized Amish Community in Ohio*, in *New Eng. J. Med.* 1343, 1349 (2016), <https://bit.ly/3Cm0RkY>.

coverage in the general community was probably effective against further spread of measles.”<sup>35</sup>

COVID-19 spreads in communities with fewer vaccinated individuals, even if they are within or adjacent to communities with a higher proportion of vaccinated individuals. The more people who share a workspace who are vaccinated, the better protected all workers—vaccinated and unvaccinated alike—will be.

#### **IV. Widespread vaccination is the most effective way to protect workers from COVID-19.**

The statistics on COVID-19 vaccine efficacy speak for themselves. No other measure has been shown to reduce the risk of infection, hospitalization, and death to the degree that vaccination does. Although misinformation about the efficacy of vaccines abounds, the science is clear: no arguments against the need for vaccination are medically valid, other than instances where an individual has a medical contraindication.

Natural immunity—the immunity against SARS-CoV-2 that develops following recovery from infection—is not an adequate substitute

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<sup>35</sup> *Id.* at 1350.

for vaccination.<sup>36</sup> Infection carries a significant risk of death or serious illness; vaccination does not. Moreover, vaccination better protects previously infected people against reinfection. Studies have shown that unvaccinated people are at least twice as likely to become reinfected as are vaccinated people.<sup>37</sup> There is no evidence that vaccination is harmful to people who were previously infected.

Other mitigation measures, such as mask wearing and social distancing, remain important. They do not, however, provide the same level of protection against COVID-19 as does vaccination. Although wearing a face mask can be highly effective at limiting the transmission of SARS-CoV-2, many people choose not to wear face masks, even when encouraged or legally required to do so. Noncontinuous face mask

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<sup>36</sup> See Catherine H. Bozio et al., *Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity – Nine States, January–September 2021*, 70 *Morbidity & Mortality Weekly Rpt.* 1539 (Nov. 5, 2021), <https://bit.ly/3kvoBwR> (finding 5.5 times higher odds of laboratory-confirmed COVID-19 among previously infected patients than among fully vaccinated patients).

<sup>37</sup> Alyson M. Cavanaugh et al., *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination – Kentucky, May–June 2021*, 70 *Morbidity & Mortality Weekly Rpt.* 1081 (2021); Meredith Wadman, *Having SARS-CoV-2 Once Confers Much Greater Immunity Than a Vaccine – but Vaccination Remains Vital*, 373 *Science* 1067 (Aug. 26, 2021), <https://bit.ly/2YB8I08>.

wearing has been shown to result in the spread of COVID-19 in the workplace.<sup>38</sup>

The ETS's alternative to vaccination—testing at regular intervals—protects workers better than no requirement at all. It does not, however, rise to the level of protection that widespread uptake of vaccinations would provide. The ETS is appropriately structured to “strongly encourag[e] vaccination.”<sup>39</sup> Immediate, widespread vaccination against COVID-19 is the surest way to protect the U.S. workforce and the public and to end this costly pandemic.

### CONCLUSION

For the reasons stated above and in Respondents' filings, the American Medical Association urges this Court to deny Petitioners' motion to stay enforcement of the ETS.

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<sup>38</sup> Donatella Sarti et al., *COVID-19 in Workplaces: Secondary Transmission*, 65 *Annals of Work Exposures & Health* 1145 (2021), <https://bit.ly/3Cj6oJ3>.

<sup>39</sup> 86 Fed. Reg. at 61,402.

Respectfully submitted,

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## CERTIFICATE OF COMPLIANCE

This document complies with the type-volume limit of Fed. R. App. P. 29(a)(5) because, excluding the parts of the document exempted by Fed. R. App. P. 32(f) and 6th Cir. R. 32(b), this document contains 2,597 words according to the word count function of Microsoft Word 365.

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/s/ Rachel L. Fried

Date: November 15, 2021

**CERTIFICATE OF SERVICE**

I hereby certify that on November 15, 2021, a true and accurate copy of the foregoing motion was electronically filed with the Court using the CM/ECF system. Service on counsel for all parties will be accomplished through the Court's electronic filing system.

/s/ Rachel L. Fried

Date: November 15, 2021