No. 24-173

In the Supreme Court of the United States

MALCOLM JOHNSON, *et al.*,
Petitioners,

v.

TINA KOTEK, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

BRIEF OF MEGAN REGAL, ERNEST RAMIREZ, SR., KEITH WILKINS, III, AND ALBERT BENAVIDES AS *AMICI CURIAE* SUPPORTING PETITIONERS

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INTEREST OF *AMICI CURIAE*[1]

Three of the *amici curiae* are individuals who have suffered loss of their right to refuse medical treatment based on informed consent, a constitutionally protected liberty interest guaranteed by the due process clause of the Fourteenth Amendment. These individuals suffered concrete injury and personal loss from government misinformation or mandates concerning unlicensed, unsafe, and ineffective COVID-19 "investigational vaccines."

Megan Regal, a nurse practitioner and sole breadwinner for a family of six, was required by her employer to be injected with a Covid drug authorized by FDA for emergency use ("EUA"), and suffered such disability that she can no longer hold a job and is unable to care for herself. Ernest Ramirez, Sr. trusted government misinformation that COVID-19 shots were "safe for teenagers." His 16-year-old son died just five days after receiving the Pfizer injection. Keith Wilkins, III was an 20-year educator in Oregon when Governor Kate Brown declared all teachers submit to COVID-19 investigational injections or lose their jobs. When he resisted this unconstitutional condition and exercised his right to refuse, he lost his property interest in his teaching license, as well as his home, truck, and life savings.

One *amicus*, Albert Benavides, experienced in medical billing and auditing claims, conducted extensive research regarding adverse events reported

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[1] It is hereby certified that counsel of record for all parties received notice of the intention to file this brief at least 10 days prior to the filing of it, pursuant to Supreme Court Rule 37.2. Further, no person or entity other than the named *amici* or counsel has authored or prepared this brief in whole or in part. The cost of printing has been paid by the Energetic Health Institute.

to the VAERS system from the onset of the COVID-19 EUA vaccines, and discovered what appears to be deliberately delayed and hidden data, which suppressed the mechanism Congress designed to inform the government, pharmaceutical industry, and individuals of the risks of drugs approved or authorized by the FDA.

Amici curiae are individuals who serve as examples of what happens when the doctrine of legally effective informed consent and the rights conferred in the EUA statute and PREP Act are obliterated in the name of combating a "global pandemic" with a 99.95 percent survival rate. They are concerned that the doctrine of informed consent is nullified whenever state executives, federally funded employers, or legislators "mandate" the use of investigational drugs in violation of federal law and the Constitution.

This *amicus* brief is submitted in support of the Petitioners Malcom Johnson, *et al.*

SUMMARY OF ARGUMENT

Congress created the right to refuse emergency use treatments and established the doctrine of legally effective informed consent to avoid the very results that have occurred to millions of Americans, including *Amici* Regal and Ramirez — devastating personal injuries and death after being injected with EUA/PREP Act investigational drugs. The essence of legally effective informed consent is that it is given freely, without pressure or penalty, and with all necessary information to inform the potential recipient of the drug's safety and efficacy or lack thereof. So, when the government retaliates against a teacher, like *Amicus* Wilkins, simply because he exercised his right to refuse, 42 U.S.C. §1983 affords

a federal cause of action to seek redress for deprivation of Constitutional and federal statutory rights conferred upon him under the EUA statute (right to refuse) and the PREP Act (voluntary nature of the program).

In the course of the Covid event, from 2020 onwards, at every possible turn, the federal government withheld the pertinent information necessary to achieve legally effective informed consent. From failing to provide the ingredients of the EUA injections, to using PCR tests with high rates of false positives, from incentivizing the entry of false data on hospital and death records, to delaying and even deleting publication of adverse side effects from the EUA injections, the government failed to provide any basis for informed consent. Thus, Governor Brown, already lacking authority to order Oregonians to submit to EUA/PREP Act injections in violation of federal law, also lacked any reliable data upon which to base her illegal executive order.

ARGUMENT

Amici recognize that one of the most powerful arguments for the right of informed consent consists of real-life injuries suffered by real people who have been denied their right to informed consent before being coerced or persuaded to be injected with "investigational vaccines." Whether through misinformation or suppressed information, or state executive orders that fail to provide informed consent for these drugs, the concrete injuries suffered by the people evinces their need for redress, guaranteed by the Supreme Law, especially where Congress has set forth the right to informed consent, and prescribed a remedy in 42 U.S.C. §1983.

I. Healthy nurse practitioner and mother of four teenagers is now an invalid.

In her 29th year of caring for patients as a full-time nurse practitioner, Megan Regal, a mother of four teenagers, who was the sole provider of income and health insurance for her family, was required by her employer to be injected with what the FDA described in a December 11, 2020 EUA letter to Pfizer as an "investigational vaccine not licensed for any indication."[2] After being injected, Ms. Regal was plunged into four months of being unable to remain conscious in an upright position followed by three years and counting of severe, unrelenting, ongoing suffering, including postural orthostatic tachycardia syndrome/dysautonomia (inability to be upright without racing heart rate, fainting, lack of drive to breathe, brain fog, debilitating fatigue), encephalitis (high pressure in the brain), compression of cranial nerves with blurred vision, head, jaw and neck pain, agitation, aphasia (difficulty speaking), stuttering and jerky gait, small fiber neuropathy (severe nerve pain all over, tingling down arms into hands, loss of temperature sensation from the shins down, severe overwhelming hot flashes, and severe intermittent random stabbing pain all over), interstitial cystitis (severely painful bladder spams and incontinence), amenorrhea, transverse myelitis (temporary paralysis from the waist down), eosinophilic esophagitis (choking and swallowing issues), and gastroparesis, among others.

For individuals like Ms. Regal, who wanted to first evaluate the likelihood of success versus the potential dangers of these drugs, legally effective informed consent was impossible because pharma-

[2] 86 Fed. Reg. 5202.

ceutical companies have not been required to disclose the contents of the investigational vials even to this day. While traditional medical standards demand doctors inquire about drug interactions, these drugs were marketed *without listing* any ingredients; the package inserts were completely blank. How can a government or employer, especially a hospital, deprive an individual of her right to informed consent and require that she be injected with an unknown substance that is neither safe (causing historic numbers of reported adverse events) nor effective (admittedly failing to prevent transmission of infection), without being held responsible?

II. Father loses healthy, active 16-year-old son after Pfizer shot.

On April 24, 2021, five days after dutifully following the recommendations of the CDC and receiving a Pfizer COVID-19 shot, 16-year-old Ernest Ramirez, Jr. collapsed while running in a park and, despite attempts by a police officer to perform CPR, died in an ambulance on the way to the hospital. According to the autopsy report, Ernest, Jr. died of an enlarged heart and cardiac arrhythmia, with acute inflammatory cells in his heart and liver.

After losing his son, Ernest Ramirez, Sr. reached the darkest point of his life and no longer wanted to go on living. Mr. Ramirez could not understand how his son had paid the ultimate price for taking a pharmaceutical product that government officials told him was "safe for teenagers" and would "help protect others" when the drugs were demonstrably not safe nor effective at preventing transmission or infection.

Moreover, by the time Ernest, Jr. received his Pfizer shot, cases of myocarditis, particularly among

young male recipients, were reported to the Vaccine Adverse Event Reporting System ("VAERS"), including sudden cardiac death.[3] To add insult to injury, after making a FEMA claim for COVID-19 funeral expenses, FEMA called Mr. Ramirez asking him to change his son's death certificate to say Ernest, Jr. died from Covid, rather than from a COVID-19 "vaccine." Mr. Ramirez declined to make such a false statement to the federal government, and so was denied FEMA funeral benefits.

Mr. Ramirez trusted his government when it reassured him that the COVID-19 shots were safe for his son. Not only did the government fail to share the risks, but it refused to investigate his son's death, despite being tasked with investigating every death from these investigational drugs. Because Mr. Ramirez had not been given the truth about the risks associated with these investigational drugs, the "consent" he gave for his son to be injected failed to qualify as the required legally effective informed consent.

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III. Teacher reduced to living in his van for 14 months after refusing to be injected with investigational drugs.

Keith M. Wilkins, III, worked as an educator in Bend LaPine School District in Oregon for 20 years when, in early 2020, he refused to comply with the unconstitutional edict issued by then-Governor Kate Brown that all holders of state-issued teaching licenses (a property interest) must relinquish those licenses, with no due process, if they refuse to be injected with EUA/PREP Act investigational drugs

[3] *See, e.g.,* https://www.cdc.gov/mmwr/volumes/73/wr/mm7314a5.htm, last visited September 14, 2024.

known as COVID-19 "vaccines." Mr. Wilkins studied the issue and determined that Gov. Brown's Executive Order was arbitrary and capricious because it did not align with previously and universally accepted medicine and science. Mr. Wilkins' reward for independent thinking and research and for asserting his fundamental rights of bodily autonomy and refusing unwanted medical treatment was to be placed on unpaid leave and denied unemployment benefits. After losing his home, truck, salary, benefits, and the life savings he accumulated teaching Oregon's children, Mr. Wilkins was relegated to homelessness, living in a van for 14 months. Not satisfied that Mr. Wilkins had suffered enough, the State of Oregon subjected him to disciplinary proceedings in an attempt to revoke his teaching license, and then formally terminated him.

IV. Auditor finds major, significant problems with VAERS.

Albert Benavides has over 25 years of experience in medical and revenue cycle billing and management, both as an HMO claims auditor evaluating medical bills submitted to health insurance companies by hospitals and other medical providers, and working on the opposite side of the process by owning and managing a medical billing company submitting medical bills to insurance companies on behalf of health care providers. Since the COVID-19 pandemic began, and continuing for the last four years, Mr. Benavides applied his auditing experience and knowledge of the medical billing and reporting industry to evaluate and investigate the data reported by VAERS.

VAERS is a national safety surveillance program co-monitored by the FDA and the CDC. It is intended

to detect signals of adverse side effects that occur when U.S.-licensed or authorized vaccines are administered. Mr. Benavides' analysis revealed that the CDC, FDA, and managers of VAERS have hidden data that would have harmed the reputation of the COVID-19 drugs. In June 2021, Mr. Benavides became aware that over 150,000 Covid "vaccine" adverse event reports disappeared from the VAERS evaluators' queues, without explanation. By evaluating the response to a FOIA request made to General Dynamics, a federal contractor that hired over 200 people to process VAERS reports pursuant to a CDC contract, Mr. Benavides discovered that by the end of 2021, the number of Covid "vaccine" adverse event reports *deleted* from the VAERS system rose to over 200,000, without explanation.

Over 2.6 million adverse event reports have been submitted from *all* vaccines to VAERS since its inception in 1990. Of those, 994,428 are for all FDA-licensed non-Covid vaccines (*i.e.,* traditional vaccines) since 1990 ***combined***, whereas there are 1,644,249 adverse event reports just for the non-FDA-licensed COVID-19 "vaccines," with the earliest reported on December 18, 2020. Thus, in only four years, nearly twice as many adverse events were reported for the Covid shots than for *all other vaccines over 30 years*. This discrepancy speaks to what happens when the government and pharmaceutical industry abandon the amount of time necessary to conduct studies into the true safety and efficacy of drugs designed for the human body.

If that statistic is not shocking enough, from a historical standpoint, VAERS only receives about one percent of all adverse events experienced by vaccine recipients, as estimated by the Harvard Pilgrim Health Care study entitled, "Electronic Support for Public Health-Vaccine Adverse Event Reporting

System" submitted to the Department of HHS after studying VAERS data from December 2007 through September 2010, well before the politically charged Covid era.[4]

A particularly egregious example of under-reporting due to deletion is the death of a Pfizer vaccine trial patient from Florida who received the shot in October 2020, before the official availability to the public in December 2020. She died in April 2021, and her report was published in May 2021, where it remained in the public domain for three weeks but was then deleted. Giving the benefit of the doubt to the system, Mr. Benavides searched for a live duplicate of the report in VAERS, which would justify the deletion of the initial report. No duplicate report exists for a 51-year-old female from Florida with a vaccine date in October 2020.

Other examples of deliberate underreporting exist, like the "bundling" of multiple death reports into one report, thereby reducing the readily identifiable deaths in the data totals. If all deaths were reported individually, as required, Mr. Benavides estimates that there would be more than 2,000 additional reported deaths attributable to these drugs.

A final example of underreporting involves the CDC's delay in publishing adverse event reports submitted to VAERS. VAERS guidelines allow the CDC four to six weeks to "vigorously authenticate" a report before publishing it. Instead of consistently meeting this deadline, the CDC appears to purposefully delay reporting adverse events by weeks, months, and even years. Mr. Benavides' investigation and analysis show that thousands of

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[4] https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

death reports were not published in VAERS for over 300 days, with the most delayed report published over 1200 days after submission. This omission of reliable real-time data made these investigational drugs appear to be less dangerous than they are, thereby adversely affecting legally effective informed consent.

The underreporting of adverse events results in potential recipients having inaccurate and unreliable data regarding the dangers associated with these unlicensed, investigational EUA drugs built on the novel mRNA technology. Combine that lack of knowledge with the fact that these drugs are shielded from liability by the PREP Act, and this Court can easily see how Petitioners, *amici*, and the majority of the American public were denied legally effective informed consent before injection of these drugs. Objectively, the overreaching executive order of Gov. Brown denied Petitioners and other Oregon citizens the right to informed consent and the related right to refuse investigational EUA drugs without penalty or pressure.

V. Investigational drugs labeled for interstate commerce cannot be "mandated" under federal law.

There can be no reasonable debate over the status of the Covid drugs *available* under every 2021 "mandate" — they were "investigational vaccine[s] with no license for any indication." *See, e.g.,* FDA EUA letter to Pfizer, *supra*, p. 1.

Congress places strict requirements upon persons relating to investigational drugs under 21 U.S.C. §§321, 331, 351, 352, 355, 360bbb, and 371; 42 U.S.C. §262; 10 U.S.C. §1107; 45 C.F.R. Part 46; 21

C.F.R. Parts 50, 56; 10 U.S.C. §980; 21 C.F.R. Part 312; and the *Belmont Report*.[5] The primary requirement of these statutes and regulations is that a person offering a federally funded investigational drug must ensure that the potential recipient is never under outside pressure to receive investigational drugs or medical treatments, such outside pressures being "sanctions," "coercion," "undue influence," and "unjustifiable pressures."

The right to refuse investigational medical treatments is a fundamental right that is pervasive, historical, and deeply rooted in the $600 billion pharmaceutical industry and this nation. No constitution, statute, regulation, or treaty provides any person any authority to require another person to be injected with an investigational drug under threat of penalty. This right to refuse investigational drugs is well understood by the governments of all states, territories, counties, and every major pharmaceutical company, hospital, and university.

Upholding executive order mandates under the color of state law effectively allows forced injection of EUA/PREP Act investigational drugs into workers, with no one to recover from in the case of injury. This Court has long held that "forced medication [i]s a

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[5] *The Belmont Report* was published in the Federal Register on April 18, 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. This commission was established by the 1974 National Research Act to, *inter alia*, consider "the nature and definition of informed consent in various research settings." The Commission found that "informed consent requires conditions free of coercion and undue influence," and that "[c]oercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance." Further, "[u]njustifiable pressure usually occurs when persons in positions of authority or commanding influence — especially where possible sanctions are involved — urge a course of action for a subject."

battery, and the long legal tradition protecting the decision to refuse unwanted medical treatment" is well settled. *Washington v. Glucksberg*, 521 U.S. 702, 725 (1997). "[T]he common-law doctrine of informed consent is viewed as generally encompassing the right of a competent individual to refuse medical treatment." *Id*, at 724, quoting *Cruzan* v. *Director, Mo. Dept. of Health,* 497 U. S. 261, 277 (1990).

Again, investigational drugs, including the ones at issue, are not licensed by the FDA with a legal indication to achieve any result and therefore are legally considered investigational medical treatments according to their labeling. Congress has only allowed investigational medical products to be introduced into commerce under strict voluntary conditions, in which public or private entities are preempted from interfering under the Supremacy Clause and the express preemption language of the PREP Act. No one can constitutionally mandate using investigational drugs or receiving unwanted medical treatments as a condition of anything, including the enjoyment of a public benefit like a state-issued medical license, teaching license, or a public high school education (all of which are property interests), nor can anyone use the EUA statute as a "procedural device" to "produce a result which…could not [be] command[ed] directly." *Perry v. Sindermann*, 408 U.S. 593, 597 (1972), *quoting Speiser v. Randall*, 357 U.S. 513 (1958).

VI. Conferred rights are violated without legally effective informed consent.

This Court recently held in *Health and Hospital Corporation of Marion County v. Talevski*, 599 U.S. 166, 183–184 (2023) — a case district courts appear loathe to address in Covid mandate cases — that a

federal statute having rights-creating language for an individual is presumed enforceable under 42 U.S.C. §1983 when the statute does not contain a specific civil right of action:

> *Gonzaga* [*Univ. v. Doe*, 536 U.S. 273 (2002)] sets forth our established method for ascertaining unambiguous conferral [of individual rights]. Courts must employ traditional tools of statutory construction to assess whether Congress has "unambiguously conferred" "individual rights upon a class of beneficiaries" to which the plaintiff belongs. [citations omitted] Notably, it must be determined that "Congress intended to create a federal right" *for* the identified class, not merely that the plaintiffs fall "within the general zone of interest that the statute is intended to protect." *Gonzaga,* 536 U.S., at 283. ... This paradigm respects Congress's primacy in this arena and thus vindicates the separation of powers. *Id*., at 286.
>
> We have held that the *Gonzaga* test is satisfied where the provision in question is "phrased in terms of the persons benefited" and contains "rights-creating," individual-centric language with an "'unmistakable focus on the benefited class.'" *Id*., at 284, 287. ... Conversely, we have rejected §1983 enforceability where the statutory provision "contain[ed] no rights-creating language"; had "an aggregate, not individual, focus"; and "serve[d] primarily to direct the [Federal Government's] distribution of public funds." *Id*., at 290.

This Court held that the "right to be free from ...

any physical or chemical restraints" and the right to advanced notice of discharge provisions of the FNHRA statute "meet[s] this test," stating that "[t]his framing is indicative of an individual "rights-creating" focus. *Talevski*, *citing Gonzaga*, 536 U. S., at 284.

Amici assert that Congress created a right for any potential recipient of EUA drugs under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). In pertinent part:

> The Secretary ... shall establish ... conditions ... to ensure that individuals to whom the product is administered are informed ... of the option to accept or refuse administration of the product ...

This language "unambiguously confers" the right to be informed of the option to accept or refuse administration of investigational drugs. It also speaks in terms of "individual rights upon a class of beneficiaries" to which all potential recipients belong. The provision actually uses the word "individuals" when describing to whom the right is conferred. The class of beneficiaries are those contemplating the "administration of the product." By describing the right the way it did, Congress intended to create a federal right for potential recipients.

Moreover, the PREP Act expressly preempts any person from interfering in any requirement applicable to a countermeasure under the EUA statute. Thus, Congress incorporated any requirement under FDCA[6] into the PREP Act, which includes the rights-creating language under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III), and such language supports a §1983 cause of action.

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[6] 21 U.S.C. §301 *et seq.*

Talevski specifically extended §1983 to federal contracts involving an individual's statutory entitlement, and thus the CDC COVID-19 Vaccination Program Provider Agreement (CDC Program) requires state and local governments to comply with the FDCA, any EUA, and all applicable state vaccination laws, which incorporate the rights-creating language under 21 U.S.C. §360bbb-3(e)(1)(A)(ii)(III). The CDC Program was designed to administer federal investigational drugs to individuals but under the explicit condition that all persons had the explicit right to accept or refuse without consequence or being placed under "sanctions," "coercion," "undue influence," or "unjustifiable pressures."

Acting under the color of state law, state and local governments — including the Governor of Oregon and the hospitals who signed the CDC COVID-19 Vaccination Program Provider Agreement — violated potential recipients' right to refuse. Moreover, because 10 U.S.C. §980 places a duty upon any person offering another person DoD-funded investigational drugs (which the COVID-19 vaccines are), to obtain their informed consent prospectively, the duty creates a right of the potential recipient to give informed consent, which must be "legally effective." *See* 45 C.F.R. Part 46. Therefore, state and local governments subjected potential recipients to DoD-funded drugs and did not obtain legally effective informed consent in violation of 10 U.S.C. §980 and 45 C.F.R. Part 46. This violation of federal law is enforceable pursuant to 42 U.S.C. §1983.

VII. State officials may not impose unconstitutional conditions on licenses.

Requiring individuals to be injected with federally funded COVID-19 EUA/PREP Act investigational drugs as a condition of using their state-issued healthcare license, or their state-issued teaching license, or attending public high school, violates the Unconstitutional Condition Doctrine, as set forth by this Court in *Frost & Frost Trucking Co. v. Railroad Comm'n*, 271 U.S. 583, 593–94 (1926):

> [T]he state, having power to deny a privilege altogether, may grant it upon such conditions as it sees fit to impose. But the power of the state in that respect is not unlimited; and one of the limitations is that it may not impose conditions which require the relinquishment of constitutional rights. If the state may compel the surrender of one constitutional right as a condition of its favor, it may, in like manner, compel a surrender of all. It is inconceivable that guaranties embedded in the Constitution of the United States may thus be manipulated out of existence.

VIII. Unreliable data vitiates legally effective informed consent.

One reason for the right to refuse EUA drugs without penalty or pressure is that the drugs are unlicensed for that use and therefore, have not been tested and evaluated for safety and efficacy as they would have been if they had obtained approval in the usual Biologics License Application process. Another

reason is that the data upon which potential recipients make their decisions is unreliable. The data given to the public is dependent upon data protocols, including the creation of new ICD-10 codes and ICD-10 code protocols[7] that were formulated on a shortened time frame due to the pandemic and that resulted in unreliable data about "new cases," deaths ("with Covid" versus "from Covid"), and adverse events (estimated at 1 percent of actual adverse events, *supra*). This data was made even more unreliable by CDC delays in reporting VAERS data, or outright deletion of that data.

A major factor in the unreliability of the data is the federal agencies' use of financial incentives for hospitals and doctors who treated COVID-19 patients. Hospitals were financially incentivized to report that a patient died "from Covid" because the hospital was paid an additional percentage of the hospital bill. Similar incentives were given for treating non-terminal Covid cases. Unfortunately, financial incentives have resulted in overreporting of Covid cases and deaths.

Thus, the mandates relied upon false or inaccurate infection and mortality data that were fraudulently constructed, applied, and propagated, which vitiates all executive orders relying upon that data.

The gold standard for measuring a pandemic is to monitor deaths ("mortality data"). In mid-April 2020 when deaths caused by Covid were on the decline, the federal "health" apparatus (HHS/ CDC/NIH/NIAID) made an arbitrary and capricious decision to move away from "mortality data" as the gold standard and move to using "new cases," no matter the severity, as the measuring stick for

[7] International Classification of Diseases, Tenth Revision.

"grading" the pandemic.

To make matters worse, to determine whether someone counted as a "new case," the federal agencies relied upon PCR tests calibrated to a cycle rate that greatly exceeded conventional levels. Each additional cycle makes it more and more likely to "find" coronavirus in whatever substance one tests, leading to exceedingly large numbers of false positives.

An indicator that the PCR tests were set to be too sensitive is that in mid-2020, for the first time, there were no, or almost no, cases of seasonal influenza because all (or almost all) patients with the flu were being diagnosed with Covid, likely due to the inaccurate PCR tests.

In evaluating the allegations made by the State of Oregon, *amici curiae* encourage this Court to be mindful of the inaccurate nature of the data upon which Oregon's mandates were based.

CONCLUSION

For the foregoing reasons, *amici* respectfully request the Court grant a writ of certiorari and affirm Petitioners' right of redress under 42 U.S.C. §1983.

Respectfully submitted,

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