No. 22-339

IN THE
Supreme Court of the United States

PFIZER INC.,
*Petitioner,*
v.
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, *et al.*,
*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

# BRIEF OF *AMICI CURIAE* JOHNSON & JOHNSON PATIENT ASSISTANCE FOUNDATION, INC. AND JANSSEN PHARMACEUTICALS, INC. IN SUPPORT OF PETITIONER

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## INTEREST OF *AMICI CURIAE*[1]

*Amici curiae* Johnson & Johnson Patient Assistance Foundation, Inc. ("JJPAF") and Janssen Pharmaceuticals ("Janssen"), are both committed in their separate work to find ways to ensure that financially needy patients have access to the medications that their medical providers have determined they need. JJPAF is a not-for-profit, private charitable foundation. JJPAF makes medicines donated from Janssen available to financially needy patients, including patients who have prescription drug coverage under the Medicare Part D program. Many Medicare and other patients cannot afford the cost-sharing amounts imposed by their insurance programs.

Janssen is a Johnson & Johnson family company and pharmaceutical manufacturer that supports JJPAF with free product and financial donations to operate the program. In addition to the donations it makes to JJPAF, Janssen also provides monetary contributions to independent charities, not affiliated with JJPAF, called cost-sharing charities. These charities provide funding to patients who meet specified financial eligibility standards. Patients use that funding to pay the deductibles, co-payments, and co-insurance required under their insurance coverage.[2]

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[1] Counsel of record for all parties received timely notice of *amici*'s intent to file this brief and have consented to its filing. No counsel for any party authored this brief in whole or in part, and no person or entity aside from *amici* and their counsel funded its preparation or submission. Counsel for *amici*'s law firm is filing a brief on behalf of a separate *amicus* that has a different perspective on the issue presented by the petition.

[2] Collectively, these significant financial barriers to access are referred to as patient cost-sharing.

JJPAF and Janssen have a substantial interest in this case. The Second Circuit's erroneous interpretation of the Federal Anti-Kickback Statute ("AKS") already has been applied by Respondents in refusing to permit a charity to provide assistance to financially needy patients.[3] More broadly, given the very limited patient assistance pathways Respondents have permitted, the sweeping holding in the decision below leaves Janssen, JJPAF, and other charities without any practical way to address the growing and urgent patient need for access to life-sustaining medications.

## SUMMARY OF ARGUMENT

JJPAF and Janssen submit this brief because they have a unique perspective on the consequences of the Second Circuit's erroneous interpretation of the AKS. Over the last two decades, JJPAF and Janssen have tried, within the extremely restricted limits that Respondent Office of the Inspector General for the Department of Health and Human Services ("OIG") has permitted, to provide patient assistance to meet patients' needs. But efforts to improve access through patient assistance are now hopelessly disrupted as a result of the broad reading of the AKS advanced by OIG and affirmed by the Second Circuit below. Cost-sharing charities and their donors labor under restrictions and enforcement risks that have resulted in the vast majority of charitable funds being forced to close. Free drug programs like JJPAF's are overwhelmed in the face of the collapse of the independent charity disease funds that have historically helped patients pay their cost-sharing. In light of the Second Circuit's decision, none of the limited, existing pathways that

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[3] *See* U.S. Dep't of Health & Hum. Servs., *OIG Advisory Opinion No. 22-19* (Sept. 30, 2022), https://oig.hhs.gov/documents/advisory-opinions/1056/AO-22-19.pdf ("PCPA Advisory Opinion").

Respondents permit leads to a place where financially needy patients have an adequate means to secure access to medications which, in many cases, can be the difference between life or death.

Under the Second Circuit's broad reading of the AKS, any attempt by a charity, like JJPAF, to assist patients constitutes "remuneration" under the AKS and raises the risk of criminal prosecution. Petitioner has explained that the language, structure, and history of the AKS show that Congress did not intend to adopt such a limitless interpretation of the scope of the AKS. Given the grave public health issues at stake, the Court should grant Pfizer's petition.

Indeed, review should be granted because the Second Circuit's decision effectively criminalizes efforts by charities, protected under the First Amendment, to address the barriers faced by low-income and disadvantaged patients to critically important, prescribed medications. If left uncorrected, the Second Circuit's decision effectively cuts off any hope of meeting the urgent needs of many needy patients to obtain access to critically important medications. The Petition should be granted in light of the public health consequences that flow directly from the Second Circuit's decision and its impermissibly broad interpretation of the AKS.

## ARGUMENT

### I. THE NEED FOR PATIENT ASSISTANCE IS IMMENSE, AND THE IMPACT ON PUBLIC HEALTH IS ENORMOUS.

Patient access to medical treatment remains a critical challenge given the inability of patients with lower incomes to meet the out-of-pocket costs imposed by the Medicare program.

A series of recent studies has confirmed that out-of-pocket costs under Medicare Part D, which supplies outpatient drug coverage to the aged and disabled, are associated with significantly higher rates of abandonment, reductions or delays in medication therapy, or even failure to initiate medical treatment.[4] For example, studies show materially adverse outcomes resulting from non-adherence in cancer medication, including adverse patient outcomes, increased hospitalizations and an overall increase in healthcare system expenditures.[5]

The American Cancer Society has underscored the nature of the problem.[6] In a survey of 1,248 patients with cancer and survivors conducted in late 2021, sixty-one percent of respondents reported that it was either very or somewhat difficult for them to afford

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[4] *See* J.A. Doshi, *Addressing Out-Of-Pocket Specialty Drug Costs In Medicare Part D: The Good, The Bad, The Ugly, And The Ignored*, Health Affairs (July 25, 2018); *see* S.B. Dusetzina et al., *Cost Sharing and Adherence to Tyrosine Kinase Inhibitors for Patients With Chronic Myeloid Leukemia*, 32 J. Clinical Oncology 306 (Feb. 1, 2014); A.I. Neugut et al., *Association Between Prescription Co-Payment Amount And Compliance With Adjuvant Hormonal Therapy In Women With Early-Stage Breast Cancer*, 29 J. Clinical Oncology 2534 (June 20, 2011).

[5] *See* R.L. Cutler et al., *Economic Impact Of Medication Non-Adherence By Disease Groups: A Systematic Review*, BMJ Open (Jan. 21, 2018); *see also* D.L. Hershman et al., *Early Discontinuation And Non-Adherence To Adjuvant Hormonal Therapy Are Associated With Increased Mortality In Women With Breast Cancer*, Breast Cancer Res. Treatment (Apr. 2011); L. Noens et al., *Prevalence, Determinants, And Outcomes Of Nonadherence To Imatinib Therapy In Patients With Chronic Myeloid Leukemia: The ADAGIO study*, 113 Blood 5401 (May 28, 2009).

[6] *See* Am. Cancer Soc'y, *Survivor Views: Affordability, Prescription Drugs, & Pain, American Cancer Society Cancer Action Network* (Dec. 15, 2021).

their oncology care. Needy patients confronted with cost-sharing obligations often never begin life-sustaining therapy – or, if they do, abandon it early. In turn, patient mortality and morbidity needlessly increase because patients cannot pay required cost-sharing amounts.

Patients with cancer are just one example of the patients who are negatively affected by out-of-pocket costs that interfere with their care and adversely affect their health. Studies have repeatedly shown the deeply concerning connection between medication non-adherence, cost-sharing obligations, and increased mortality and morbidity in numerous patient groups.[7] A study of the Medicare Part D program, for example, showed that increases in out-of-pocket costs cause "a 32.7% increase in monthly mortality."[8]

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[7] *See, e.g.,* J. De Avilla et al., *Prevalence and Persistence of Cost-related Medication Nonadherence Among Medicine Beneficiaries at High Risk of Hospitalization*, JAMA Network Open (Mar. 3, 2021) (cost-related non-adherence had adjusted prevalence of 53.6%); R. Khera et al., *Cost-Related Medication Non-Adherence in Adults With Atherosclerotic Cardiovascular Disease in the United States, 2013 to 2017*, Am. Heart Ass'n (Dec. 17, 2019); M. Fischer et al., *Primary Medication Non-Adherence: Analysis of 195,930 Electronic Prescriptions*, J. Gen. Internal Med. (Feb. 4, 2010) ("Underuse of prescription medicines constitutes a large problem" and "[m]edication nonadherence is related to greater morbidity and mortality in chronic disease"); M. Nili et al., *Asthma-Chronic Obstructive Pulmonary Disease Overlap And Cost-Related Medication Non-Adherence Among Older Adults In The United States*, J. Asthma (Jan. 19, 2021) .

[8] A. Chandra et al., *The Health Costs of Cost Sharing*, Nat'l Bureau of Econ. Rsch. (Feb. 2021). Indeed, a substantial number of patients react to co-payments by not filling *any* drug prescription "regardless of how many drugs they had been on previously, or their health risks." *Id.*

Cost-sharing burdens imposed by Medicare and other insurance programs also contribute significantly to health disparities. Members of both "Black and Hispanic households," for example, are disproportionality "likely . . . to restrict the use of essential prescription medications due to cost."[9] Indeed, "the totality of published evidence strongly supports the notion that increases in consumer cost-sharing negatively affects vulnerable populations." *Id*. "[C]ost-related non-adherence" to medication therapy is "well-documented" and has a "negative clinical impact on vulnerable populations." *Id*. African-Americans report higher "cost-related barriers to [medication] adherence."[10] "Cost-related non-adherence is a growing problem" and has resulted in a "significant decline in self-reported health among vulnerable populations." *Id*.

An example of a racial disparity with clear medication access implications is that "African American women have double the incidence rate of triple negative breast cancer," which is one of the fastest growing cancer types.[11] More broadly, "5-year cancer survival rates are lower for blacks than white, non-Latinos."[12]

Notwithstanding these critical problems, the Court below embraced an interpretation of the AKS

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[9] Univ. of Mich. Ctr. for Value-Based Design, *V-BID in Action: The Role of Cost-Sharing in Health Disparities* (Aug. 26, 2016).

[10] J. Lewey et al., *Medication Adherence and Healthcare Disparities: Impact of Statin Co-Payment Reduction*, 21 Am. J. Managed Care 696, 696–701 (Oct. 2015).

[11] *See* Am. Ass'n for Cancer Rsch., *Cancer Health Disparities*, https://www.aacr.org/patients-caregivers/about-cancer/cancer-health-disparities/ (last visited Nov. 14, 2022).

[12] E. Goss et al., *American Society of Clinical Oncology Policy Statement: Disparities in Cancer Care*, 27 J. Clinical Oncology 2881, 2882 (June 10, 2009).

advocated by Respondents that exacerbates this public health threat by effectively preventing efforts to assist patients to obtain access to the medications they desperately need. Under the Second Circuit's ruling, any payment that has the capacity to influence or persuade a patient to proceed with a course of action, see Pet. App. 11a – here, a payment making it possible for a patient to obtain medical treatment – would qualify as "remuneration . . . to induce" a course of action under the AKS. *Id.* at 15a. In a telling indication of the breadth of its holding, the court below acknowledged that "one can persuade another to take an action with good or bad motives." *Id.* That necessarily means that, under the Second Circuit's erroneous reading of the statute, what patient assistance programs are designed to do is "illegal remuneration" under the AKS.

## II. JJPAF'S AND JANSSEN'S EXPERIENCE DEMONSTRATES THAT AN OVERBROAD INTERPRETATION OF THE AKS HAS UNDERMINED PATIENT ASSISTANCE PROGRAMS.

In reliance upon the same broad definition of "remuneration" affirmed by the Second Circuit, Respondents have effectively thwarted every effort by *amici* to provide necessary assistance to needy patients, leaving the entire system by which charities attempt to meet patient need at the point of collapse.

Consistent with its broad interpretation of the AKS, Respondents only have permitted strictly limited mechanisms for federal health care program patients to receive patient assistance with their medications.[13] Specifically, as relevant here, agency guidance issued

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[13] OIG, Publication of OIG Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005).

by Respondent OIG in 2005 offered manufacturers and charities funded by manufacturers effectively three highly-restrictive pathways to provide patients assistance:

(1) **Independent Charity Pathway**. Independent charities that receive funding from manufacturers, subject to numerous restrictions, may provide cost-sharing assistance to needy patients as part of disease-specific funds, *id.* at 70626,

(2) **Free Drug Pathway**. Manufacturers may provide, subject to significant restrictions, free drugs to patients; *id.* at 70627, and

(3) **Coalition Pathway**. A coalition of manufacturers may fund cost-sharing assistance for needy patients, if, among other requirements, a broad array of medications is included in the coalition, *id*.

As JJPAF's and Janssen's experience illustrates, each of these pathways, however, has proven wholly inadequate to deliver necessary assistance to patients with the greatest unmet needs.

### A. The Collapse of the Independent Charity Disease Fund Pathway and Its Impact on the Free Drug Pathway.

As discussed below, the Independent Charity Pathway has been crippled by Respondent's expansive view of the AKS statute such that the charities operating under Respondents' restrictions are now unable to address the needs of most Medicare and other federal program patients. Its collapse, in turn, has placed so much pressure on free drug programs that they, too, are now overwhelmed by the demand for assistance from needy patients. As a consequence, Respondents'

overbroad interpretation of the AKS has created a crisis in access to medical care.

The Independent Charity Pathway is now at the point of collapse. Alarmed by a dramatic fall-off in the co-payment assistance available to patients from independent charities, JJPAF performed a review this year of independent charity disease funds designed to provide patient assistance. Specifically, JJPAF examined 14 different disease funds for such important conditions as prostate cancer, Crohn's Disease, and chronic lymphocytic leukemia. Over a nineteen week period, only 15.7% of these funds were open and available to provide assistance. The results of JJPAF's research confirmed that the system, operating under conditions imposed based on Respondent's overbroad interpretation of the AKS, is at a breaking point.

The collapse of the Independent Charity Pathway has, in turn, placed an unsustainable burden on free drug programs, like JJPAF's. For example, the demand for free drug assistance has doubled each year over the last three years, involving billions in free drug assistance. Medicare patients are the prime driver of these unsustainable increases, with their need far outstripping the percentage of Medicare patients in the U.S. population as a whole.[14]

### B. Respondents' Refusal to Provide JJPAF and Janssen with Reasonable Assurances that They Can Avoid Criminal Exposure Under the AKS.

The decline in independent charity fund assistance has been driven primarily by concern that Respondents' overly-broad interpretation of the AKS will

[14] Although Medicare patients make up only 28% of the U.S. population, Medicare patients account for about 44% of JJPAF's patient population.

subject both charities and their donors to criminal prosecution. Hoping to prevent a further deterioration in the situation, and to protect itself against the risk of overcriminalization, JJPAF sought a safe harbor and then an advisory opinion from Respondents that would provide a reasonable measure of protection to charities, like JJPAF, and donors, like Janssen. Respondents have rejected or ignored those efforts.

JJPAF first attempted to secure a safe harbor. Writing to OIG in 2016, JJPAF noted the substantially "increased need for PAP assistance" created by "the legal risks . . . associated with assisting patients." Seeking to find a solution that would provide reasonable assurances to the government, JJPAF offered a safe harbor design that included robust safeguards and effectively combined many of the requirements under the free drug and the independent charity pathways. Despite Congress' direction to OIG to create safe harbors for "beneficial arrangements," OIG never responded to the safe harbor request.

Determined to find some mechanism to provide patient assistance without exposing themselves to enforcement risk, JJPAF followed its unsuccessful effort to secure a safe harbor with a more narrow request for an advisory opinion. The advisory opinion request focused on JJPAF's on-going efforts to provide free drug products to patients. These patients include patients with no insurance at all or patients who are covered by insurance, but the payor provides no meaningful access to the drug therapy through coverage restrictions or overly burdensome requirements. These patients include some Medicare patients.

The advisory opinion request was limited to providing entirely free-of-cost medications. That is, under the proposal, there would be no cost incurred by the patient or its insurance company, including a federal

program. The advisory opinion proposal committed JJPAF to operate only under a series of restrictions.[15] The proposal likewise tracked the pathway set forth in Respondent OIG's 2005 Guidance. But, after reviewing the advisory opinion request, OIG informed JJPAF that it would not issue a favorable advisory opinion.

With the need for JJPAF's free drug assistance rising at an unsustainable pace, JJPAF made another attempt to engage with Respondents earlier this year. Shortly before meeting again with OIG, JJPAF had been forced to make the difficult decision that it could not continue, as it had for 25 years, to provide free medication to eligible patients without requiring them to exhaust other alternatives for support first. As difficult as this decision was, the unsustainable increase in patient assistance requests required JJPAF to take this step to ensure the available assistance goes to the patients most in need.

JJPAF explained the enormous increase in requests for assistance that it was receiving and that those increases were "[p]redominantly" driven by Medicare patients "unable to secure third party copay support." As JJPAF stressed, the "limited disease state funding" available was "adversely impact[ing] . . . access" to necessary medications. OIG acknowledged receipt of the information from JJPAF, but has taken no steps to review its positions in light of these disturbing developments.

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[15] The proposed restrictions included, among others, requirements for (1) a charitable structure, (2) independent governance and operations, and (3) independently established patient eligibility standards. It also included all of the protections incorporated under a 2007 Advisory Opinion granted by OIG to JJPAF which permitted it to provide free product to some, but not all, Medicare patients.

### C. Janssen's Effort to Find a Solution Under the Coalition Pathway Is Thwarted.

Given the threats to viability of the Independent Charity and Free Drug Pathways, Janssen, in conjunction with other manufacturers, initiated an effort in 2019 to seek a separate advisory opinion under the Coalition Pathway. Unfortunately, this effort ultimately resulted in the negative advisory opinion that Pfizer cites in its petition. See Pet. 32 (citing PCPA Advisory Opinion). In that unfavorable Advisory Opinion, Respondent OIG expressly relied upon the Second Circuit's ruling in this case to conclude that efforts by a charity that OIG admitted would be "agnostic" as to which drug a patient ultimately would purchase, nevertheless would involve prohibited remuneration under the AKS because the payment would "persuad[e] another person to take a course of action.'" PCPA Advisory Opinion, at 13 n.31, 15. The Second Circuit's broad reading of the AKS has already negatively affected efforts to provide patient assistance to needy patients.

The coalition that Janssen and other manufacturers initially created was called the Pharmaceutical Coalition for Patient Access ("PCPA"). Based upon the Coalition Model from OIG's 2005 Guidance, in an advisory opinion request to OIG, PCPA stressed the increasing threat to patients with cancer created by the dramatic increase in independent charity disease fund closures. The advisory opinion request presented research discussing the growing financial need of patients and the impact on mortality and morbidity. Under the proposal, as required by OIG's 2005 Guidance, a large number of Part D manufacturers would participate, giving patients with cancer a broad range of treatment options. Treatments would only be selected by the patients' independent medical providers. The advisory

opinion request included multiple safeguards over and above the requirements in OIG's 2005 Guidance.[16]

Janssen and the other manufacturers specifically addressed the factors that OIG discussed in the 2005 Guidance. The proposal focused on an area of widely recognized need—oncology care—where products are highly unlikely to be overutilized. OIG agreed that manufacturers constituting 90% or more of the Medicare Part D market would likely participate. With such a broad level of participation, the proposal was a compelling example of how, if a "wide range" of medication options were included in a coalition, the effect was, as OIG described in the 2005 Guidance, to "sever any nexus" between the assistance offered and the patient's choice of drug. See OIG 2005 Guidance, 70 Fed. Reg. at 70,627.[17]

Shortly after the initial advisory opinion request was submitted in September 2019, the COVID public health emergency was declared, and the case for the proposal became even more compelling. The pandemic led to a crisis in oncology care, as patients were not able to gain access to health care facilities and cancer care and cancer screenings plummeted.[18] PCPA

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[16] For example, although not required by the Coalition Guidance, the PCPA proposal included the use of an independent administrator to administer all facets of the program.

[17] Such a coalition has operated in the past and had been praised by the Centers for Medicare and Medicaid Services, the agency that administers the Medicare program. *See* CMS, Medicare Program; Medicare-Endorsed Prescription Drug Card Assistance Initiative; Final Rule, 67 Fed. Reg. 56618, 56657 (Sept. 4, 2002). Specifically, TogetherRx was a coalition that operated in the period between when the Medicare Part D program was enacted and implemented.

[18] Preventive cancer screenings dropped between 86% to 94% during the early months of the pandemic, and the National

emphasized to OIG that it could quickly implement its program and significantly address this crisis.

But, after the advisory opinion request languished for more than a year, OIG stated that it would not issue a favorable opinion. Again asserting its overly broad interpretation of the AKS, OIG's response cast doubt on the ability of the public to rely even on the limited pathways set out in its 2005 Guidance. All of the reasons that OIG listed for its decision to not issue a favorable opinion were either not a part of that guidance or directly contrary to it.[19]

In an effort to address OIG's stated reasons for refusing to issue a favorable opinion, Janssen and the other manufacturers encouraged PCPA to reestablish itself as an independent charity, with an entirely independent board. Janssen and others provided funding to the new PCPA entity to revisit, redesign, and alter the proposed program as it saw fit in light of OIG's list of issues and the independent board's own views. The manufacturers were not a part of the board's work. But that effort, which took more than an additional year, produced the same disappointing result.

On September 30, 2022, OIG rejected a significantly revised PCPA coalition proposal that addressed, based on the description of it in the Advisory Opinion, each of the issues that OIG had previously raised. See

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Cancer Institute has predicated nearly 10,000 excess deaths from breast and colorectal cancer in the next decade alone as a result of the pandemic. *See*, *e.g.*, Epic Health Rsch. Network, *Delayed Cancer Screenings* (May 4, 2020); N. Sharpless, *COVID-19 And Cancer*, 368 Science 1290 (June 19, 2020), https://science.sciencemag.org/content/368/6497/1290. *See also* R.L. Cutler, *supra* n.5.

[19] For instance, OIG stated that PCPA was not, at that time, independent enough from the supporting manufacturers. But, "independence" is an element of the independent charity disease fund pathway—not the coalition pathway.

PCPA Advisory Opinion. OIG's legal analysis of the proposed program was limited to approximately 2 pages, and relied heavily on the Second Circuit's opinion in *Pfizer* and the opinion of the district court affirmed by the Second Circuit. *Id.* at 14 & n.31, 15 & n.36. OIG adopted the same definition of "induce" as that affirmed by the Second Circuit, that is, induce means nothing more than having a capacity to "persuade" or to "influence a decision about medical care." *Id.* at 15 n.36. Citing the district court opinion affirmed by the Second Circuit in *Pfizer*, OIG rejected any requirement under the AKS that prohibited remuneration must involve some element of corruption. *Id.* (rejecting position that "induce" premises liability "on a corrupt" transaction).[20]

JJPAF and Janssen have tried to address the needs of patients under the restrictive pathways OIG permitted in its 2005 Guidance. Unfortunately, their experience demonstrates that these limited pathways, which were never adequate, have collapsed, are straining under an unsustainable burden, or are foreclosed by the Second Circuit's and Respondent's overbroad interpretation of the AKS. When new solutions are necessary to meet the urgent needs of patients, the Second Circuit's decision presents an insurmountable barrier to such efforts.

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[20] Notwithstanding that PCPA highlighted that denial of its advisory opinion request implicated important First Amendment considerations, OIG's negative opinion did not consider PCPA's or its donors' First Amendment rights. *See*, *e.g.*, *Riley* v. *Nat'l Fed'n of the Blind*, 487 U.S. 781, 788 (1988); *Vill. of Schaumburg* v. *Citizens for a Better Env't*, 444 U.S. 620, 632 (1980).

## CONCLUSION

For these reasons, and those set forth in the Petition, the Petition for Certiorari should be granted.

Respectfully submitted,

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