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 Writ of Certiorari to the United States Court of Appeals for the Second Circuit

BRIEF FOR *AMICUS CURIAE* PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA IN SUPPORT OF PETITIONER

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INTEREST OF AMICUS CURIAE[1]

The Pharmaceutical Research and Manufacturers of America (PhRMA) is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. PhRMA's member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures—more R&D investment than any other industry in America.

PhRMA's mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA thus frequently participates as amicus curiae in cases, like this one, that affect its members. Like Pfizer, many pharmaceutical companies are pursuing new programs to ensure patient access to life-saving treatments. The Second Circuit's overbroad interpretation of the Anti-Kickback Statute threatens many beneficial and innovative programs of PhRMA's members. This Court should grant certiorari and reverse to clarify that the AKS criminalizes only alleged "inducements" made with corrupt intent.

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[1] The parties received timely notice of this brief under Rule 37.2(a). Petitioners and respondents have consented to the filing of this brief. Pursuant to Rule 37.6, amici curiae state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from amici curiae, their members, or their counsel, made any monetary contribution intended to fund the preparation or submission of this brief.

INTRODUCTION AND SUMMARY OF THE ARGUMENT

This case presents critical questions about the scope and meaning of the Anti-Kickback Statute (AKS). Correctly construed, that statute protects federal healthcare programs and their beneficiaries by prohibiting corrupt inducements. But as interpreted by the Second Circuit, the AKS is an object lesson in overcriminalization that threatens beneficial programs designed to improve patient access to needed treatments.

The Second Circuit held that the AKS does not require a corrupt intent, expanding the statute's scope beyond what its text, structure, and history allow. Without a requirement of corrupt intent—intent to induce a transaction that otherwise would not and should not happen, and to cause it to happen for a bad reason—the AKS is limitless. Every company, after all, can be said in a loose sense to intend everything it does to increase its sales directly or indirectly. If such a generalized intent to increase utilization of a company's products suffices, even under circumstances when the products *should be* used and without any corruption of anyone's medical judgment, then companies may be unable to increase patient access to needed (and prescribed) medicines by helping pay for them.

That result may save the government money. But the AKS is not supposed to be a care-rationing statute. Sparing the government from having to pay its lawful share of the cost of a treatment that a patient needs—by depriving the patient of the ability to access the treatment—has nothing to do with protecting

physicians' medical judgment from improper influence. Beyond its chilling effect on beneficial pharmaceutical company programs like Pfizer's, the Second Circuit's interpretation makes criminals of charities, generous family members, and even patients themselves, for nothing more than increasing access to needed treatments.

The Due Process Clause forbids such "standardless" criminal statutes. *McDonnell v. United States*, 579 U.S. 550, 576 (2016) (quoting *Kolender v. Lawson*, 461 U.S. 352, 358 (1983)). When a statute criminalizes a broad swath of "commonplace" innocent conduct—chilling normal, everyday activities—it violates due process. *Id.* at 575. The government's usual refrain when confronted with such a broad statute is "trust us." But this Court has repeatedly admonished that the government's prosecutorial discretion is not a sufficient check on an all-encompassing criminal statute. *E.g.*, *United States v. Stevens*, 559 U.S. 460, 480 (2010). Instead, a criminal statute must have "explicit standards" to prevent arbitrary enforcement. *Grayned v. City of Rockford*, 408 U.S. 104, 108 (1972). This due process safeguard is fundamental to preserving the rule of law—the antithesis of a regime where everyone is guilty and the government can simply choose whom to prosecute.

If the AKS truly compelled the Second Circuit's interpretation, this Court would have to confront the question whether such a limitless statute, making felons out of so many for such innocent conduct, satisfies the Due Process Clause. But the AKS does not compel the Second Circuit's interpretation. Far from it: for the reasons set forth in Pfizer's petition,

the best reading of the AKS's text, structure, and context is that it requires corrupt intent. The statutory interpretation arguments set forth in the petition should resolve this case without the need to invoke the canon of constitutional avoidance. If any doubt remained, however, that canon would dispel it, as the Second Circuit's interpretation presents significant due process problems.

The stakes are high, and the time for this Court's review is now. The Second Circuit's holding gives the government limitless discretion to prosecute healthcare providers and pharmaceutical companies for beneficial practices. Unless the Court grants review here, those victims of government overreach may never get the opportunity to challenge the government's actions in court. The draconian nature of the AKS discourages litigation: even apart from the prospect of massive fines (and, for individuals, prison time), an AKS conviction triggers mandatory exclusion from federal healthcare programs—a death sentence for practically any company in the pharmaceutical or healthcare industry. 42 U.S.C. § 1320a-7b(b)(4); 2 C.F.R. §§ 180.800, 376.10.

This case thus presents what may be the Court's only chance to answer a critically important question of federal law and to rectify the Second Circuit's overreading of the AKS.

ARGUMENT

I. The decision below encourages arbitrary enforcement and raises serious due process concerns.

A. The Second Circuit's reading of the AKS makes commonplace conduct criminal.

"[E]xpansive interpretation[s]" of criminal statutes that sweep up "commonplace" conduct "raise significant constitutional concerns." *McDonnell*, 579 U.S. at 574–75. This principle—"related" to the prohibition of vague criminal statutes—sounds in fair notice and citizens' right to be protected from arbitrary government conduct. *Id.* at 574–76; *see United States v. Kozminski*, 487 U.S. 931, 949–50 (1988); *Wooden v. United States*, 142 S. Ct. 1063, 1082 (2022) (Gorsuch, J., concurring) ("'[P]enal laws are to be construed strictly' because of 'the tenderness of the law for the rights of individuals'—and, more specifically, the right of every person to suffer only those punishments dictated by 'the plain meaning of words.'" (quoting *United States v. Wiltberger*, 18 U.S. (5 Wheat.) 76, 95–96 (1820))). When a court interprets a criminal statute to have a "standardless sweep," then ordinary citizens "could be subject to prosecution, without fair notice, for the most prosaic interactions." *McDonnell*, 579 U.S. at 576 (cleaned up).

This "inject[s] arbitrariness into the assessment of criminal liability." *Van Buren v. United States*, 141 S. Ct. 1648, 1662 (2021); *accord McDonnell*, 579 U.S. at 574–576; *Grayned*, 408 U.S. at 108–09. A statute that expansively criminalizes common conduct empowers the government to pick and choose whom to prosecute,

leaving the public "at the mercy of *noblesse oblige*." *FCC v. Fox Television Stations, Inc.*, 567 U.S. 239, 255 (2012) (quoting *Stevens*, 559 U.S. at 480). For exactly that reason, this Court has refused to accept broad and problematic constructions of "criminal statute[s] on the assumption that the Government will 'use [the statute] responsibly.'" *McDonnell*, 579 U.S. at 576 (quoting *Stevens*, 559 U.S. at 480).

As Pfizer's petition explains, the Court in recent decades has taught over and over again that courts cannot "rely on 'the Government's discretion' to protect against overzealous prosecutions"; they should instead interpret criminal statutes to avoid that risk in the first place. *Id.* (quoting *United States v. Sun-Diamond Growers*, 526 U.S. 398, 408 (1999)). For starters, as here, the fact that a statutory interpretation would "attach criminal penalties to a breathtaking amount of commonplace … activity" often "underscore[s] the implausibility of the … interpretation." *Van Buren*, 141 S. Ct. at 1661. But even when a statute's text could plausibly be read so broadly, constitutional concerns demand a narrower reading. *McDonnell*, 579 U.S. at 574–76. That is why this Court has often rejected the government's expansive interpretations of criminal statutes. *E.g.*, *id.* (narrowly interpreting federal bribery statute to avoid a "standardless sweep" (quoting *Kolender*, 461 U.S. at 358)); *Kozminski*, 487 U.S. at 949–50 (rejecting interpretation that "would appear to criminalize a broad range of day-to-day activity"); *see also* Pet. 18.

Due process informs this Court's narrowing constructions of criminal statutes. For example, in *Skilling v. United States*, 561 U.S. 358 (2010), this

Court rejected a broad interpretation of the honest-services fraud statute because "[r]eading the statute to proscribe a wider range of offensive conduct … would raise the due process concerns underlying the vagueness doctrine." *Id.* at 408. "To satisfy due process, a penal statute must define the criminal offense … in a manner that does not encourage arbitrary and discriminatory enforcement." *Id.* at 402–03 (cleaned up).

If the Second Circuit's interpretation of the AKS were correct, then the AKS would present the serious due process problems created by overbroad criminal statutes. The court below held that the AKS does not require corrupt intent, but instead prohibits literally any payment or compensation made with even a partial intent to "entic[e] or persuad[e]" another person to make a certain decision about medical care or purchases. App. 14a (citation omitted). That interpretation would criminalize "the most prosaic interactions," *McDonnell*, 579 U.S. at 576, between pharmaceutical companies, patients, and healthcare providers.

For-profit companies exist to sell their products or services. *Cf. United States v. Pfizer, Inc.*, 188 F. Supp. 3d 122, 134 (D. Mass. 2016) (rejecting AKS claim and noting that it was "unremarkable that Pfizer tracked its return on investment" from a speaker series, because "as a for-profit company, this is to be expected"). Every decision a for-profit healthcare company makes, therefore, could be characterized as partially motivated at some level by a desire "to influence a decision about medical care or purchases." App. 57a. By treating any remuneration, in any

amount, in any form, made with even this generalized "intent" as a violation of the AKS, the Second Circuit's decision suggests that all healthcare companies are criminals.

That endangers countless innocent and beneficial practices. For example, hospitals may subsidize continuing medical education classes for doctors and may harbor the hope that doing so will foster goodwill with the doctors and that some doctors may be more likely to refer patients to the hospital. Helping doctors access such classes is good for the doctors and their patients, and where there is nothing corrupt about the arrangement, it should not be inhibited. But under the decision below, if doctors who attended those classes later refer patients to the hospital, it would be easy for the government to allege that the hospital had "induced" the referrals.

The Second Circuit's interpretation could even sweep in innocuous conduct by the general public. For example, a mother would violate the AKS by giving her adult child money to pay for a prescribed medical treatment that she wanted the child to obtain but that the child might otherwise have been unable to access. The Second Circuit's interpretation would ask only whether part of her intent was to encourage the child to pursue the treatment—to "persuad[e]" the child to obtain the treatment rather than be forced to forgo it for lack of money—and of course the answer is yes. To add insult to injury, the Second Circuit's interpretation also makes criminals out of *patients* who accept assistance so they can access needed medication. Pet. 31; *see* 42 U.S.C. § 1320a-7b(b)(1) (AKS applies to "[w]hoever knowingly and willfully

solicits *or receives* any remuneration" (emphasis added)). It is implausible in the extreme that Congress intended to criminalize such conduct, and there is something plainly wrong with an interpretation of the AKS that does so.

These concerns are not hypothetical. Just two months ago, OIG issued an advisory opinion finding that, "if the requisite intent to induce or reward referrals of Federal health care program business were present," a charitable organization funded by a coalition of manufacturers would violate the AKS by covering 90% of the cost of oncology medications. Advisory Op. No. 22-19, at 9 (HHS OIG Sept. 30, 2022). In 2020, OIG found that a program providing housing for families living far from treatment centers could violate the AKS—again, "if the requisite intent … were present"—though OIG indicated that it would not pursue sanctions. Advisory Op. No. 20-02, at 2 (HHS OIG Jan. 15, 2020), *modified by* Notice of Modification of OIG Advisory Op. 20-02 (HHS OIG June 1, 2022). Given the Second Circuit's holding that the mere hope of influencing a purchasing decision violates the AKS, "the requisite intent" will always be present, so OIG's seeming caveat regarding intent is no caveat at all and does nothing to confine the statute to reasonable bounds. *Cf. Kozminski*, 487 U.S. at 950 (holding that intent requirement did not "eliminate[]" due process concerns with overbroad interpretation of statute); *United States v. Valle*, 807 F.3d 508, 525, 528 (2d Cir. 2015) (invoking rule of lenity to narrow criminal statute's application despite heightened mens rea requirement).

OIG, in its discretion, sometimes informs a requestor that it does not intend to pursue enforcement action against a practice that OIG believes could run afoul of the AKS. Like OIG's caveat regarding "the requisite intent," that practice does not mitigate the problems with the Second Circuit's interpretation. First, as discussed above, prosecutorial discretion is no answer to an overbroad interpretation of a criminal statute. Second, OIG's occasional blessing to engage in conduct it believes may violate the AKS underscores the implausibility of the Second Circuit's interpretation: if the conduct is so innocent and unproblematic that OIG is comfortable with it occurring, it would be highly anomalous for that conduct to nonetheless be a federal felony.

The draconian nature of the AKS's penalties exacerbates the problems with the government's and the Second Circuit's overbroad interpretation. Even if some beneficial conduct might eventually be found lawful in a contested court action under the Second Circuit's interpretation, who is going to be willing to take that risk? Individuals convicted of an AKS violation face ten years in prison. 42 U.S.C. § 1320a-7b(b). And entities can be excluded from participating in government healthcare programs and barred from contracting with the government, 2 C.F.R. §§ 180.800, 376.10—a death sentence for most companies in the modern healthcare industry. *United States v. Facteau*, No. 15-CR-10076-ADB, 2020 WL 5517573, at *1 (D. Mass. Sept. 14, 2020) ("exclusion from healthcare programs" is "likely a death knell for any company"). The risk of these outcomes under the decision below will chill beneficial healthcare practices and prevent patients from getting treatments they need.

The facts of this case betray the government's true purpose in pressing such a broad interpretation of the AKS. It is not to protect patients from having their doctors' decisionmaking skewed by corrupt influence, since the government has never suggested that Pfizer's program would do so—or explained *how* it could do so given that the program applies only where the patient's doctor has already prescribed the drug (and involves a drug that is the sole FDA-approved therapy for a fatal disease). Instead, the government is simply trying to save money. Below, a group of insurance companies gave away the game, arguing as amici in support of the government that the purpose of the AKS was to "contain costs." America's Health Ins. Plans Amicus Br. at 15 (CA2 ECF No. 148).

But the AKS was never intended to "contain costs" by denying patients treatment they need, prescribed by doctors whose decisionmaking was not corruptly influenced. Under the Second Circuit's decision, the AKS is transformed from an anti-corruption law into a healthcare-rationing law. The patients at issue in this case really need Pfizer's drug. They have a rare and fatal disease, the drug is on-label for it, their treating physician prescribed it, there is no other approved treatment, and they want to take the drug but for their inability to afford it. The government offers no other form of relief for these patients, so Pfizer's program is the last resort. Many of these patients will be unable to access the drug if the Second Circuit's decision stands and Pfizer is forbidden from providing assistance. That troubling result powerfully confirms that the AKS has come loose from its moorings and that this Court's review is needed.

B. The Second Circuit did not meaningfully engage with these due process concerns.

The Second Circuit dismissed the far-reaching implications of its interpretation, speculating that "[i]t seems very unlikely to us that a charitable or concerned family member who is merely trying to help a loved one would meet [the knowingly and willfully] mens rea element." App. 23a–24a. Further, it stated "to violate the AKS, one must intend to induce the purchase of a *federally reimbursable* healthcare product," noting that a "concerned family member … just wants to ensure her relative receives medical treatment." *Id.* (emphasis in original).

But this is no answer to the due process concerns here. There is no limiting principle in the Second Circuit's reading. Rather, the court just assumes that a family member paying for a relative's treatment would be unaware of the law and the fact that her loved one's treatment is federally reimbursable. That assumption is, at best, questionable. Many people are involved, or have family or friends involved, in the healthcare or pharmaceutical industries and are at least generally aware that the law prohibits certain payments. *See* Pet. 32. And the AKS's mens rea element does not require a person to know that the AKS exists or that her conduct violates the AKS. Pet. 29–30 (noting that "Congress amended the AKS in 2010 to clarify that 'a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of this section' to be held criminally liable" (quoting Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 759 (2010)). Instead, it requires only that a defendant know her

conduct is prohibited in a more generalized sense. And most people know that drugs for older and disabled Americans are often covered by Medicare. So even if the Second Circuit is right that the AKS's mens rea element requires knowledge that the healthcare item at issue is "*federally reimbursable*," this would not meaningfully limit the expansive scope of the statute.

When a criminal statute falls short of due process requirements, this Court will not uphold it "merely because the Government promise[s] to use it responsibly." *Stevens*, 559 U.S. at 480. The Second Circuit should not have invoked the prospect of responsible prosecutorial discretion to minimize the concerns raised by its broad interpretation. This "fallout underscores the implausibility" of the Second Circuit's interpretation of the AKS. *Van Buren*, 141 S. Ct. at 1661. And it triggers the "cardinal principle," *Ashwander v. Tenn. Valley Auth.*, 297 U.S. 288, 348 (1936), that courts should "avoid constitutional difficulties" with a statute "by [adopting a limiting interpretation] if such a construction is fairly possible," *Boos v. Barry*, 485 U.S. 312, 331 (1988); *see also United States v. Caronia*, 703 F.3d 149, 162 (2d Cir. 2012) (narrowing Food, Drug & Cosmetic Act to avoid criminalizing truthful, non-misleading "promotion of a drug's off-label use").

Here, an interpretation of the AKS that would avoid due process concerns is not just "fairly possible," *Boos*, 485 U.S. at 331—for the reasons set forth in Pfizer's petition, it is the only interpretation consistent with the statute's text, structure, and history. Pet. 20–30. But even if the AKS could bear the Second Circuit's broader reading, constitutional

avoidance would still require this Court to reject it. As explained above, the Second Circuit's interpretation criminalizes a breathtaking range of beneficial and common conduct in the healthcare industry. Pfizer's interpretation—requiring a corrupt quid pro quo—would solve that problem while maintaining the AKS's important role in protecting patients from doctors whose decisionmaking has been corrupted. *See* Pet. 5 (citing Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972); Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179–83 (1977)).

The choice should be easy: a criminal statute "that can linguistically be interpreted to be either a meat axe or a scalpel should reasonably be taken to be the latter." *McDonnell*, 579 U.S. at 576 (cleaned up). The rule of lenity likewise requires that any ambiguity be resolved in favor of the narrower construction of the AKS. *See, e.g.*, *United States v. Granderson*, 511 U.S. 39, 54 (1994); *United States v. Thompson/Ctr. Arms Co.*, 504 U.S. 505, 517–18 (1992). "[W]here uncertainty exists, the law gives way to liberty." *Wooden*, 142 S. Ct. at 1082 (Gorsuch, J., concurring). The Due Process Clause's protection of citizens from the risk of arbitrary enforcement of sweeping criminal statutes and the rule of lenity require the same result here: this Court should reject the Second Circuit's interpretation of the AKS.

C. The Second Circuit's interpretation will lead to a flood of False Claims Act lawsuits against healthcare companies.

An increase in criminal prosecutions is not the only risk created by the Second Circuit's decision. Its broad interpretation of the AKS also opens the

floodgates to yet more *qui tam* actions under the False Claims Act (FCA) based on allegations of AKS violations. This makes the Court's review all the more urgent.

As a matter of law, "a claim that includes services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of the FCA." *Dhaliwal v. Salix Pharms., Ltd.*, 752 F. App'x 99, 100 (2d Cir. 2019) (mem.) (cleaned up). And anyone can file a *qui tam* action. 31 U.S.C. § 3730(b). So the decision below will expose healthcare companies to an increased number of FCA lawsuits alleging AKS violations, even if the government would not take action against the challenged conduct. And because the government must investigate *qui tam* allegations, 31 U.S.C. § 3730(a), companies incur substantial costs even in *qui tam* matters in which the government does not intervene, even apart from the relator's right to proceed with the action despite the government's declination.

The Second Circuit's interpretation of the AKS will therefore impose a significant economic burden. Every year, FCA claims cost healthcare companies "billions." John T. Bentivoglio et al., *False Claims Act Investigations: Time for a New Approach?*, 3 Fin. Fraud L. Rep. 801, 801 (2011). Since 2010, relators have filed almost 600 (and sometimes more) *qui tam* actions each year. *See* U.S. Dep't of Justice, Fraud Statistics – Overview: Oct. 1, 1986 – Sept. 30, 2021, https://bit.ly/34vxS2K. In 2020 alone, relators filed an average of almost thirteen new cases a week, 68% of which were related to healthcare—more than one

every day.[2] These cases can drag on for many years, requiring defendants to incur significant defense costs and attorney's fees even when they ultimately prevail.

And the FCA's harsh remedies—treble damages, plus per-claim penalties, plus attorney's fees and expenses—make FCA actions particularly problematic. 31 U.S.C. §§ 3729(a), 3730(d)(1)–(2). Every innocent practice prohibited by the Second Circuit's overbroad interpretation of the AKS could also support a catastrophic FCA verdict. "Faced with even a small chance of a devastating loss, defendants will be pressured into settling questionable claims." *AT&T Mobility LLC v. Concepcion*, 563 U.S. 333, 350 (2011). And since neither OIG's advisory opinions nor prosecutors' enforcement decisions can bind private *qui tam* plaintiffs, the only cure is for this Court to reject the Second Circuit's interpretation.

II. This case is an ideal vehicle for this Court to decide the scope of the AKS.

For the reasons given above and in Pfizer's petition, the question presented in this case is more than important enough to justify this Court's review. And while this Court sometimes allows even important issues to percolate until a circuit split emerges, it should not do so here.

That is because it is highly unlikely that other federal appellate courts will address the question

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[2] *See* U.S. Dep't of Justice, Fraud Statistics – Overview: Oct. 1, 1986 – Sept. 30, 2020, https://bit.ly/3egHss4; George B. Breen et al., *DOJ False Claims Act Statistics 2020: Over 80% of all Recoveries Came from the Health Care Industry*, Nat'l L. Rev. (Jan. 21, 2021), https://bit.ly/327ig4G.

presented. The AKS's harsh penalties discourage companies from litigating AKS claims at all, let alone all the way to this Court. The risks are too high, all but guaranteeing that AKS defendants will settle the government's claims or accede to OIG's advisory opinions. The same is true of FCA defendants, who almost inevitably settle *qui tam* actions that are not dismissed at the pleading stage. This dynamic will insulate the Second Circuit's erroneous interpretation of the AKS from review in other courts of appeals.

This Court thus may not have another opportunity to decide this issue. Moreover, even if the issue does arise in a future case that makes its way to this Court, it is unlikely to be presented as cleanly as in this case. Here, there is an extensive administrative record establishing that Pfizer does not intend to use its patient assistance program to corruptly induce improper prescribing, and the case was decided on the pure issue of law reflected in the question presented, uncomplicated by factual questions about intent. Pet. 34–35. Vehicles do not come any cleaner.

The industry would face serious challenges if this Court were to deny review. PhRMA members risk criminal sanctions under the AKS and exclusion from federal healthcare programs if they proceed with patient assistance programs like Pfizer's. And patients would suffer too. If the Second Circuit's ruling stands, then the patients Pfizer seeks to help—the middle-income Medicare beneficiaries who need its medications to treat a rare and debilitating disease—would be deprived of a lawful means to access life-saving treatments that they otherwise cannot afford. But the decision below does not just deprive patients

who need Pfizer's drug of the ability to access it. The Second Circuit's decision will cause much broader harm, because many other pharmaceutical manufacturers may never develop or implement other beneficial programs if the decision below stands, leaving untold numbers of patients who need other life-sustaining drugs without access to them. Because those programs will never see the light of day, they will not lead to cases giving this Court opportunities to decide the question presented in the future. This Court's review is needed and is needed now.

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

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