

**United States Court of Appeals
for the Federal Circuit**

VANDA PHARMACEUTICALS INC.,

Plaintiff-Appellant,

– v. –

UNITED STATES,

Defendant-Appellee.

*On Appeal from the United States Court of Federal Claims
in No. 1:23-cv-00629-AOB*

**AMICI CURIAE BRIEF OF PROFESSORS OF LAW,
MEDICINE, AND PUBLIC HEALTH IN SUPPORT OF
APPELLEE AND AFFIRMANCE**

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STATEMENT OF PARTY INTEREST & FINANCIAL CONTRIBUTIONS

1. Amici are the sole authors of this brief. No party or party's counsel authored this brief, in whole or in part.
2. No party or party's counsel contributed money that was intended to fund preparing or submitting the brief.
3. No person contributed money that was intended to fund preparing this brief.

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IDENTITY AND INTERESTS OF THE *AMICI CURIAE*¹

Amici curiae are professors of law, medicine, and public health. They are, variously, experts in trade secrecy law, administrative law, Food and Drug Administration (FDA) law and policy, patient care, and related subjects. *Amici* have no personal interest in the outcome of this litigation but share a professional interest in seeing that trade secrecy and takings laws are applied in a manner that is doctrinally consistent, properly promote innovation and competition, align with federal regulatory authority, and protect patients and public health. *Amici* believe that appellant Vanda has fundamentally misinterpreted the Supreme Court's and this Court's precedents on the intersection of trade secrecy and takings law. Endorsement of Vanda's view of the law would not only flout precedent; it would also imperil public health and federal regulatory authority. *Amici* present this brief to aid the Court's understanding of trade secrecy doctrine and FDA's crucial role in protecting public health. A list of *amici* is provided in Appendix A.

¹ *Amici* submit this brief pursuant to Federal Rule of Appellate Procedure 29(a)(2) and state that all parties have consented to its timely filing. *Amici* further state that no counsel for any party authored this brief in whole or in part, and no entity or person, aside from the *amici curiae* and their counsel, made any monetary contribution intended to fund the preparation or submission of this brief. *Amici* file this brief in their individual capacities as scholars; they provide institutional affiliations solely for the purpose of identification.

I. INTRODUCTION

As the Court of Federal Claims (CFC) correctly discerned, Vanda impermissibly attempts to claim proprietary interests in information that it did not generate or keep secret, which are *not* its trade secrets. On this basis alone, the CFC's decision should be affirmed.

Our brief provides an additional basis to affirm. Even if Vanda's alleged categories of information were valid trade secrets—and they are not—and even if FDA disclosed the information outright to Vanda's competitors—and it did not—this Court should still affirm the CFC's dismissal of the case. This is because Vanda was never given a promise of secrecy by the government that would give rise to a viable takings claim. Vanda's brief characterizes *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986 (1984) as providing that the disclosure of trade secrets by the government constitutes a *per se* taking. This interpretation of *Monsanto* is misguided. In fact, *Monsanto* held that no alleged taking of a trade secret can succeed without a government promise of secrecy. If Vanda's arguments were made law, harmful precedent could be created that would diverge from the Supreme Court's carefully crafted interplay of trade secrecy and federal takings law.

As this brief will show, adopting Vanda's arguments would have consequences far beyond FDA's approval of generic drugs. FDA would be broadly

censored from communicating essential public health information. Other federal agencies would end up withholding information critical to public safety out of fear of litigation. Vanda offers a dangerous mischaracterization of *Monsanto* that, if adopted, would substantially weaken federal regulatory authority and harm the public.

II. ARGUMENT

A. *Monsanto* confirms that FDA worked no taking by using the information at issue as it did.

Vanda's opening brief frequently cites the Supreme Court's landmark 1984 decision on the interplay of state trade secrecy and federal takings law, *Ruckelshaus v. Monsanto*, 467 U.S. 986 (1984). See Vanda Opening Br. at 27, 29, 32–34, 60–61. And Vanda's brief suggests, at points, that *Monsanto* or other binding precedents hold that FDA or another administrative agency's disclosure of a trade secret is a per se taking. See, e.g., Vanda Opening Br. at 1 (“The Supreme Court and this Court have long recognized that the disclosure by an agency of such confidential, trade-secret information gives rise to a compensable taking of private property under the Fifth Amendment.”).

Yet Vanda's brief omits key passages of *Monsanto* that foreclose the company's takings claims. In *Monsanto*, Monsanto's core takings claims were soundly rejected by the Supreme Court, and the Court articulated legal rules that generally protect federal agencies' power to gather, use, and disseminate

information, even when that information qualifies as a trade secret. As Professor Pamela Samuelson has written, “[t]he strong property right theory that Monsanto propounded was soundly trounced in *Ruckelshaus [v. Monsanto]*.” Pamela Samuelson, *Principles for Resolving Conflicts Between Trade Secrets and the First Amendment*, 58 Hastings L.J. 777, 809 (2007).

In this section of our Argument, we provide the Court with key facts and holdings of *Monsanto* that Vanda ignores. We agree that *Monsanto* controls Vanda’s takings claims but disagree that it supports Vanda’s cause. Properly applied to the facts in the record, *Monsanto* precludes Vanda’s takings claims. *Monsanto* thus offers the Court an independent basis on which the Court must reject appellant’s meritless takings claims.

1. Under *Monsanto*, no takings claim alleging interference with trade secrets can succeed without a promise of secrecy.

Monsanto held that, in the absence of a statutory “guarantee of confidentiality to submitters of data,” parties submitting trade secrets to federal agencies have “no reasonable, investment-backed expectation that [their] information would remain inviolate in the hands of” the agencies. *Monsanto*, 467 U.S. at 1008. “In *Ruckelshaus [v. Monsanto]* . . . the Supreme Court concluded that plaintiffs only had a reasonable expectation in the confidentiality of trade secrets disclosed to the [Environmental Protection Agency (EPA)] in pesticide registration applications *to the extent that the relevant statute explicitly guaranteed*

confidentiality at the time of submission.” *Love Terminal Partners, L.P. v. United States*, 889 F.3d 1331, 1345 (Fed. Cir. 2018) (emphasis added); *see also Pharm. Rsch. & Manufacturers of Am. v. Stolfi*, No. 24-1570, 2025 WL 2448851, at *25 (9th Cir. Aug. 26, 2025) (*Monsanto* permitted disclosure “when the statutory scheme was silent as to the disclosure of trade secret information”). In other words, federal agencies’ disclosures of trade secrets *may*, but *do not necessarily*, amount to compensable takings under the Fifth Amendment. *Monsanto*, 467 U.S. at 1004–06. Even when a plaintiff demonstrates that a regulator disclosed a trade secret, Takings Clause liability cannot attach unless the plaintiff also demonstrates that it had a “reasonable, investment-backed expectation” of nondisclosure—and no such expectation can exist without a promise of secrecy. *Id.* at 1008. In short, without a guarantee of confidentiality, no taking of trade secrets by regulators can occur.

In *Monsanto*, the Court considered a fact pattern similar to, and if anything, less favorable for the agency than the present case. EPA had shared with some of Monsanto’s competitors, without Monsanto’s permission, certain information pertaining to the composition and properties of Monsanto’s pesticides to help those competitors get their own follow-on products through development and regulatory approval. *Id.* at 992, 998–99, 1023. The Court held that much of this sharing did not work a taking. *Id.* at 1020. The Court carefully parsed three distinct statutory periods governing EPA, and the dispositive fact in its analysis was whether

Congress had affirmatively promised secrecy in the legislation that governed during the period in which Monsanto submitted the information at issue. If Congress had promised secrecy, information submitted to regulators could not be disclosed without disrupting those submitters' investment-backed expectations. *Id.* at 1008, 1011. If Congress did *not* promise Monsanto secrecy, however, there was no taking. *Id.* at 1009–14. Even after accepting that the information at issue was a trade secret, the Court rejected Monsanto's claim that EPA had worked a taking by sharing Monsanto's commercial information with the company's competitors during a period in which the relevant statute had *not* promised secrecy. *Id.* at 1004–08. Thus, if any of Vanda's information relating to dissolution specifications, impurities control, and micronization did in fact qualify as a trade secret, the facts of *Monsanto* are squarely instructive.

Notably, *Monsanto* considered two distinct statutory regimes that made no promise of secrecy—one that expressly authorized disclosure of trade secrets and another that was silent on the possibility of disclosure—and held that neither created a viable takings claim. *Id.* at 1005–10.

Particularly relevant to the case at hand is *Monsanto*'s latter holding: A statute that is silent on the possibility of disclosure of trade secrets does not give rise to a viable takings claim. The Supreme Court observed that “[p]rior to the 1972 amendments, [the relevant statute, the Federal Insecticide, Fungicide, and

Rodenticide Act (FIFRA)] was silent with respect to EPA’s authorized use and disclosure of data submitted to it in connection with an application for registration.” *Id.* at 1008. Monsanto argued that this statutory silence, in conjunction with the Trade Secrets Act, 18 U.S.C. § 1905, created some expectation of confidentiality on EPA’s part and consequent investment-backed expectations, which supported a viable takings claim.² *Id.* The Supreme Court rejected this argument, holding that statutory silence, even considered in conjunction with the Trade Secrets Act, does not create the promise of secrecy that a viable takings claim requires:

[T]he Trade Secrets Act is not a guarantee of confidentiality to submitters of data, and, absent an express promise, Monsanto had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA. In an industry that long has been the focus of great public concern and significant government regulation, the possibility was substantial that the Federal Government, which had thus far taken no position on disclosure of health, safety, and environmental data concerning pesticides, upon focusing on the issue, would find disclosure to be in the public interest.

Id. at 1008–09. Observing that, “[a] *fortiori*, the Trade Secrets Act cannot be construed as any sort of assurance against internal agency use of submitted data

² Vanda’s brief likewise gestures at the Trade Secrets Act, suggesting in passing that the provision should be construed as “generally prohibiting agencies from disclosing confidential information submitted to them in the course of their work.” Vanda Opening Br. at 4.

during consideration of the application of a subsequent applicant for registration,” the Court dismissed Monsanto’s pre-1972 takings claim. *Id.* at 1009–10.

Drawing nearer to the facts here, the Supreme Court in *Monsanto* even examined and sanctioned the practice of a regulator referring to and using data submitted by a first-mover manufacturer in deciding whether to approve products made by follow-on manufacturers. Finding that “there is some evidence that [EPA’s] practice of using data submitted by one company during consideration of the application of a subsequent applicant was widespread and well known,” the Court reasoned that Monsanto could not have expected that “EPA would maintain those data in strictest confidence.” *Id.* at 1009–10. *Monsanto* further held that “[i]n considering the data of one applicant in connection with the application of another, EPA does not violate any of [the prohibitions of the Trade Secrets Act].” *Id.* at 1009 n.13.

2. Under *Monsanto*, Vanda’s takings claims fail because neither Congress in the FDCA nor FDA promised secrecy.

a. Vanda’s takings claim fail because it has pled no statutory promise of secrecy.

Like the statute at issue in *Monsanto*, the Food, Drug, and Cosmetic Act (FDCA) does not “guarantee . . . confidentiality to submitters of data.” *Id.* at 1008. Vanda’s opening brief lacks any citation to a statutory guarantee of secrecy—presumably because no such guarantee exists. *See Vanda Opening Br.* at 3, 5, 25,

42, 66–67 (citing various provisions of the FDCA that do not promise confidentiality for data submitted to FDA). As far as we can tell, Vanda has never made any concrete claim that the FDCA or another relevant federal statute promised secrecy of the specific information at issue in this appeal.³

On this basis alone, *Monsanto* forecloses Vanda’s takings claims.

Not only does the FDCA not expressly promise secrecy as to the sorts of information at issue here, but when Vanda submitted the New Drug Applications at issue, it was “publicly known . . . that there was [no] explicit guarantee of exclusive use” of the dissolution specifications—just as was true of EPA and the pesticide data it managed. *Monsanto*, 467 U.S. at 1009 n.14.

Indeed, as both Association for Accessible Medicines (AAM) and the government explained in their CFC briefing, Congress’s command to FDA to administer the Hatch-Waxman Act and shepherd generic drugs onto the U.S. market requires *some* information sharing with generic applicants:

[T]he entire premise of the Hatch-Waxman regime is that FDA can and should build on its previous approval decisions: FDA’s previous

³ Vanda’s complaint does make a token argument that the federal Trade Secrets Act promises secrecy. Compl. ¶¶ 40, 41. But as noted above, *Monsanto* held that the Trade Secrets Act alone, absent some other statutory guarantee of secrecy, cannot give rise to a cognizable takings claim. Vanda’s complaint makes passing reference to 21 U.S.C. § 331(j), a provision of the FDCA that prohibits disclosure of “any method or process which as a trade secret is entitled to protection,” but this section expressly protects only information on methods and processes, not information on the products of those processes, as is at issue here. See *Anderson v. Dep’t of Health & Hum. Servs.*, 907 F.2d 936, 951 (10th Cir. 1990).

finding that a brand drug is safe and effective for its intended use is treated as determinative that a generic version of the drug is safe and effective too, provided the agency finds the products are the ‘same’ in all relevant respects.

Br. for AAM as Amicus Curiae at 10, *Vanda Pharms. Inc. v. United States*, No.

1:23-cv-629 (Fed. Cl.), Dkt. No. 45-1. *See also* Def.’s Mot. J. Plgs. at 39, *Vanda*

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(“Guaranteeing the findings of ‘same[ness]’ required by the Hatch-Waxman

Amendments necessarily requires the imposition of regulatory requirements on

marketed drug products.”) (citation omitted); *id.* at 39 n.13 (“To the extent that

Congress wants to strike a different balance between brand name and generic drugs

and FDA’s communications with generic applicants during the drug approval

process, it is free to do so.”). As a result, Vanda cannot claim the FDCA has

promised secrecy, nor can Vanda show that it had a reasonable, investment-backed

expectation in nondisclosure of its alleged trade secrets. *Monsanto*, 467 U.S. at

1009 n.14 (declining to find takings liability flowing from federal regulators’ use

of protected trade secret information to “evaluat[e] the application of another”

firm). By entering an industry subject to “strict regulation,” Vanda “should have

‘reasonably anticipated’ that [FDA] might” disclose information submitted in its

NDAs to generic competitors. *See Taylor v. United States*, 959 F.3d 1081, 1088–89

(Fed. Cir. 2020). As this Court has recognized, “the complete absence of

reasonable distinct investment-backed expectations can weigh sufficiently heavily

to be dispositive of a takings claim.” *Anaheim Gardens, L.P. v. United States*, 953 F.3d 1344, 1351 (Fed. Cir. 2020); *see Monsanto*, 467 U.S. at 1005 (finding that Monsanto’s lack of reasonable, investment-backed expectations “disposes of the taking question” when the statute did not promise secrecy).

Even if FDA’s use of brand company data to inform its evaluation of generic firms’ submissions were not publicly known, the pharmaceutical industry “long has been the focus of great public concern and significant government regulation,” so “the possibility was substantial that the Federal Government . . . would find disclosure to be in the public interest.” *Monsanto*, 467 U.S. at 1008–09. *See also Stolfi*, 2025 WL 2448851, at *26 (“If manufacturers choose to run the risk of public disclosure of their trade secrets to do business in the highly regulated pharmaceutical industry, they ‘can hardly argue that [their] reasonable investment-backed expectations are disturbed when [the State] acts to . . . disclose the data in a manner that was authorized by law at the time of the submission.’”) (citing *Monsanto*, 467 U.S. at 1006–07).

Under *Monsanto*, the absence of any Congressionally-backed promise of secrecy dooms Vanda’s takings claims and offers a basis for affirmance.

b. Vanda’s proffered evidence does not establish that FDA promised secrecy, either.

Instead of showing any statutory guarantee of secrecy, Vanda purports to locate assurances of secrecy in a smattering of agency regulations. Vanda Opening

Br. at 4; Vanda’s Compl. ¶ 38. The regulations Vanda cites, however, do not prohibit FDA from using the information to support and streamline the agency’s work of reviewing generic drug applications. *See* 21 C.F.R. §§ 20.61(c)–(d); 314.430(g)(1).

Notably, *Monsanto* did not make clear whether agencies’ nonstatutory promises of secrecy—made in notice-and-comment regulations or otherwise—may give rise to cognizable takings claims when the relevant statute does not guarantee secrecy. But *Monsanto* suggests only statutes control. *See, e.g., Monsanto*, 467 U.S. at 1008 (“It is true that, prior to the 1972 amendments, neither FIFRA nor any other provision of law gave EPA authority to disclose data obtained from Monsanto. But the Trade Secrets Act is not a guarantee of confidentiality to submitters of data, and, absent an express promise, Monsanto had no reasonable, investment-backed expectation that its information would remain inviolate in the hands of EPA.”). This Court has reasonably interpreted *Monsanto* to hold that only a statutory promise of secrecy can create a viable takings claim arising from alleged agency interference with trade secrets. *Love Terminal Partners*, 889 F.3d at 1345 (“In *Ruckelshaus [v. Monsanto]* . . . the Supreme Court concluded that plaintiffs only had a reasonable expectation in the confidentiality of trade secrets disclosed to EPA in pesticide registration applications to the extent that the relevant statute explicitly guaranteed confidentiality at the time of submission.”).

As such, the question of whether FDA promised Vanda secrecy is irrelevant. The Court could dismiss Vanda's takings claims on the basis that no federal statute promises secrecy.

To the extent that the Court reads *Monsanto* to permit a viable takings claim on the basis of some nonstatutory guarantee of secrecy, the burden is on Vanda to plead that FDA made such a promise. Vanda has not done so in the record below.

Under the statutory plan of the FDCA, FDA's regulatory mission depends on its ability to learn from and synthesize information from prior applications. *See, e.g., Braeburn Inc. v. Food & Drug Admin.*, 389 F. Supp. 3d 1, 6 (D.D.C. 2019) (the FDCA allows follow-on manufacturers "to rely on investigations that were 'not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted'" (quoting 21 U.S.C. § 355(b)(2))). This sort of intra-agency information-sharing has been FDA's standard practice for decades. It is thus unsurprising that Vanda cannot point to an FDA regulation barring the practice. In fact, Vanda itself has argued elsewhere that FDA's congressionally-mandated regulation of pharmaceuticals necessarily involves evaluating follow-on applicants' submissions using "dissolution and pharmacokinetic testing results obtained independently by both [initial product sponsors and follow-on manufacturers] *for the reference listed drug.*" Memorandum in Support of

Plaintiff’s Motion for Summary Judgment at 20, *Vanda Pharms. Inc. v. Food & Drug Admin.*, No. 23-CV-2812 (CRC), 2024 WL 4133623 (D.D.C. Sept. 10, 2024), Dkt. No. 24-1 (emphasis in original). As then-Judge Ketanji Brown Jackson once explained, any assertion that the “FDA cannot consult or rely upon third-party data in the absence of a right of reference, or conversely, that it must secure such right if it desires to access third-party data, has practical implications that render the assertion manifestly inconsistent with the Hatch-Waxman scheme, which is perhaps why no such limitation on FDA authority is articulated anywhere in the FDCA or the agency’s regulations.” *Takeda Pharms., U.S.A., Inc. v. Burwell*, 78 F. Supp. 3d 65, 88 (D.D.C. 2015), *aff’d in part, vacated in part*, 691 F. App’x 634 (D.C. Cir. 2016).⁴

- B. Vanda’s interpretation of the law would obstruct generic competition, FDA’s ability to communicate important health and safety information to the American public, and federal regulation writ large.**
- 1. Vanda’s interpretation of the law would thwart generic competition, harm patients, and burden FDA.**

⁴ Vanda’s token arguments that FDA’s actions work a per se taking are meritless. As the Ninth Circuit recently observed, per se takings claims likely only apply to tangible property, not to intangible property like trade secrets. *Stolfi*, 2025 WL 2448851, at *23. In any event, Vanda has not alleged that FDA’s actions completely eliminated the value of the company’s information, thus foreclosing any conceivable per se takings claim. *Id.*; Vanda Compl. at 42, Dkt. No. 1 (FDA’s disclosures “*substantially* diminished the value” of the information at issue) (emphasis added); see *Lucas v. S.C. Coastal Council*, 505 U.S. 1003, 1019 (1992).

A ruling that FDA’s use of Vanda’s alleged trade secrets constitutes a taking would obstruct generic competition and some of the agency’s core regulatory work. Vanda’s incorrect interpretation of *Monsanto* could improperly constrain FDA’s internal sharing and use of basic quality-control parameters about the drug at issue—on dissolution specifications, impurities, micronization, and potentially more. Vanda’s incorrect interpretation would also hamper FDA’s communication of its own analysis of this information to generic companies. Such information sharing is essential for generics to demonstrate bioequivalence, a requirement for FDA approval. As a result, generic companies would face increased costs and delays in product approval, leading to higher expenses for patients and payers, reduced drug choice, and increased risk of medication shortages. This outcome directly contradicts Congress’s statutory plan for the Hatch-Waxman Act: to create an expedited pathway for generic drug approvals. *Caraco Pharm. Lab’ys, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399, 405 (2012) (“[T]his process is designed to speed the introduction of low-cost generic drugs to market.”). As this Court has recognized, a central purpose of the Hatch-Waxman Act and the subsequent ANDA declaratory judgment amendment to that Act is “to enable competitors to bring cheaper, generic . . . drugs to market as quickly as possible.” *Teva Pharms. USA, Inc. v. Novartis Pharms. Corp.*, 482 F.3d 1330, 1344 (Fed. Cir. 2007) (citing remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health,

Education, Labor, & Pensions, 149 Cong. Rec. S15885 (2003)). Extreme caution must be exercised before adopting Vanda’s incorrect reading of *Monsanto* and undermining Congress’s plan for the Hatch-Waxman Act.

2. FDA would be censored from communicating essential public health information to regulated companies and the broader public.

The consequences of adopting Vanda’s arguments extend beyond obstruction of generic competition. Vanda’s excessively broad definition of a “trade secret,” coupled with its cramped understanding of federal regulatory authority under *Monsanto*, would lower the bar for a takings claim, allowing drug manufacturers and other regulated entities to challenge and censor much of FDA’s communications with the companies it regulates and the public. This directly conflicts with FDA’s mission of “advancing the public health . . . by helping the public get the accurate, science-based information they need to use medical products and foods to maintain and improve their health.” *What We Do*, U.S. Food & Drug Admin. (last updated Nov. 21, 2023).⁵

Pursuant to that mission, FDA currently uses broad discretion delegated by Congress to collect, regulate, or communicate key information to the public, including drug toxicity data and manufacturing inspection reports. Vanda’s

⁵ <https://www.fda.gov/about-fda/what-we-do>.

arguments, if made law, could chill these communications—putting Americans’ health at risk.

a. FDA could be censored from communicating drug safety data.

One key category of public communication at risk is FDA’s communication of drug safety data. To support post-marketing safety surveillance of approved drugs and therapeutic biologic products, FDA currently publishes adverse event reports, medication error reports, and product quality complaints resulting in adverse events in its public “FDA’s Adverse Event Reporting System” (FAERS) database. *FDA’s Adverse Event Reporting System (FAERS)*, U.S. Food & Drug Admin. (last updated Nov. 8, 2024).⁶ The database is not limited to voluntarily reported safety information. Instead, agency regulations require industry members to report certain adverse events to FDA. For example, sponsors of investigational new drug applications are required to report all potentially serious risks of the drug to the agency. *IND Application Reporting: Safety Reports*, U.S. Food & Drug

⁶ <https://www.fda.gov/drugs/surveillance/fdas-adverse-event-reporting-system-faers>. An “adverse event” is “any undesirable experience associated with the use of a medical product in a patient.” *What is a Serious Adverse Event?*, U.S. Food & Drug Admin. (May 18, 2023), <https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event>.

Admin. (last updated Oct. 19, 2021).⁷ Information from these reports are then keyed into the FAERS database.

The database is a valuable source of raw data that allows both FDA and independent researchers to conduct individual drug safety investigations. See Valentina Giunchi et al., *Challenges and Opportunities in Accessing and Analysing FAERS Data: A Call Towards a Collaborative Approach*, 46 Drug Safety 921, 921 (2023). FDA publicly posts potential signals of serious risks and new safety information identified using the FAERS database during the indicated quarter. *Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)*, U.S. Food & Drug Admin. (last updated Sept. 2, 2025).⁸ Independent researchers also conduct safety evaluations based on the FAERS database. Exemplary studies have been published for flumazenil, a drug used prominently in emergency care and anesthetic recovery; niraparib, a cancer therapeutic; midazolam, a potent sedative; and sulfasalazine, an anti-inflammatory agent. Manli An & Jingjing Jiang, *Comprehensive Evaluation of Flumazenil Adverse Reactions: Insights from FAERS Data and Signal Detection*

⁷ <https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-application-reporting-safety-reports>.

⁸ <https://www.fda.gov/drugs/fdas-adverse-event-reporting-system-faers/potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event-reporting-system>.

Algorithms, *Medicine* (Mar. 7, 2025) (flumazenil);⁹ Menglin Guo et al., *A Real-world Pharmacovigilance Study of FDA Adverse Event Reporting System (FAERS) Events for Niraparib*, *Sci. Reps.* (Nov. 29, 2022) (niraparib);¹⁰ Jieyuan Chen et al., *Assessing the Safety of Midazolam: A Comprehensive Analysis of Adverse Events from FAERS*, *Toxicol. In Vitro* (Feb. 11, 2025) (midazolam);¹¹ Dandan Guo et al., *A Real-world Pharmacovigilance Study and Pharmacological Analysis of Sulfasalazine Based on the FDA Adverse Event Reporting System (FAERS) Database*, *Expert Op. on Drug Safety* (May 5, 2025) (sulfasalazine).¹² Safety signals identified from FAERS, like the ones mentioned above, play a role in FDA's ultimate decisions to issue safety communications and boxed warnings, which in turn affect prescribing practices, patients' choice of drug, and even insurance coverage. Meera Dhodapkar et al., *Characterization and Corroboration of Safety Signals Identified from the US Food and Drug Administration Adverse Event Reporting System, 2008-19: Cross Sectional Study*, *BMJ* (Oct. 5, 2022).¹³

Public health organizations also use FAERS data. For example, a 2009 citizen petition by Public Citizen raised concerns about the diet drug sibutramine,

⁹ <https://pmc.ncbi.nlm.nih.gov/articles/PMC11902964/>.

¹⁰ <https://pmc.ncbi.nlm.nih.gov/articles/PMC9709073/>.

¹¹

<https://www.sciencedirect.com/science/article/pii/S0887233325000177?via%3Dihub>.

¹² <https://www.tandfonline.com/doi/full/10.1080/14740338.2025.2488241?src=>.

¹³ <https://www.bmj.com/content/379/bmj-2022-071752>.

based on FAERS and other data. This petition, among other supporting evidence, helped convince FDA to urge the manufacturer to withdraw the drug from the market. Sidney Wolfe, *Petition to Ban Sibutramine (Meridia)*, Pub. Citizen (Dec. 3, 2009);¹⁴ Sidney Wolfe, *FDA's Decision to Pull Diet Pill Meridia Commendable, But Took Too Long for Drug's Victims*, Pub. Citizen (Oct. 8, 2010).¹⁵

Recognizing the importance of these data for public health and safety, FDA announced in August 2025 that it had begun real-time, daily publication of FAERS adverse event data. *FDA Begins Real-Time Reporting of Adverse Event Data*, U.S. Food & Drug Admin. (Aug. 22, 2025).¹⁶

Under Vanda's excessively broad definition of a "trade secret" and erroneous understanding of the necessary elements of a takings claim, drug manufacturers could conceivably allege that adverse event data are trade secrets to bring takings claims against FDA for collection and disclosure of the data in the FAERS database. Although 21 U.S.C. § 355(k) gives FDA discretion to collect data on adverse events where necessary to take appropriate action to ensure protection of public health, the risk of litigation could strong-arm FDA into

¹⁴ <https://www.citizen.org/article/petition-to-ban-sibutramine-meridia/>.

¹⁵ <https://www.citizen.org/news/fdas-decision-to-pull-diet-pill-meridia-commendable-but-took-too-long-for-drugs-victims/>.

¹⁶ <https://www.fda.gov/news-events/press-announcements/fda-begins-real-time-reporting-adverse-event-data>.

shrinking or taking down the database—with patients, prescribers, and the American public suffering the consequences.

b. FDA could be censored from communicating manufacturing inspection reports.

Another key category of information imperiled by Vanda’s arguments is FDA’s reporting of inspections in accordance with good manufacturing practices (GMPs). As part of FDA’s regulatory mission to promote GMPs and under 21 U.S.C. § 374, FDA has authority to inspect facilities. Consistent with this authority, FDA also has discretion to publicize Form 483 reports that disclose the results of inspections that may reveal violations of the FDCA or FDA regulations. *Inspection Observations*, U.S. Food & Drug Admin. (last updated Jan. 13, 2025).¹⁷

FDA publication of Form 483 reports informs the public of potential GMP violations. Importantly, Form 483 reports reveal potential contamination of drugs and violations of food safety procedures. *See* U.S. Food & Drug Admin., FDA Inspection Report for Taylor Farms Colorado, Inc. (2024) (hereinafter “2024 Inspection”);¹⁸ U.S. Food & Drug Admin., FDA Inspection Report for Catalent Indiana, LLC (2023) (hereinafter “2023 Inspection”).¹⁹ This transparency mechanism helps ensure compliance with the FDCA and FDA’s regulations; it

¹⁷ <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/inspection-observations>.

¹⁸ <https://www.fda.gov/media/185084/download>.

¹⁹ <https://www.fda.gov/media/177229/download>.

warns regulated companies of the laws and regulations that promote safe and sanitary manufacturing practices. It also helps keep unsafe products away from consumers. For example, FDA's publication of a Form 483 report of violations of food safety and sanitary procedures at Taylor Farms, a McDonald's supplier linked to an *E. coli* outbreak, led to McDonald's switching suppliers and Taylor Farms issuing recalls of potentially contaminated food. 2024 Inspection, *supra*; Alexander Tin, *FDA finds little handwashing, dirty equipment at McDonald's supplier linked to E. coli outbreak*, CBS News, Jan. 10, 2025.²⁰ Repeated FDA Form 483 reports also led to scrutiny of an Indiana drug manufacturing facility where contamination and equipment failures in violation of GMPs contributed to delays in cancer medication approval and COVID-19 vaccine distribution; the affected companies have since vowed to improve the facility. Frasier Kansteiner, *Novo Plant Acquired by Catalent Buyout Faces Renewed FDA Scrutiny with Form 483*, Fierce Pharma, Aug. 22, 2025;²¹ Kevin Dunleavy, *Moderna's New Booster Launch Tripped up by Production Issues at Catalent Plant*, Fierce Pharma, Sep. 21, 2022;²² 2023

²⁰ <https://www.cbsnews.com/news/fda-report-e-coli-outbreak-onions-taylor-farms/>.

²¹ <https://www.fiercepharma.com/manufacturing/novo-plant-acquired-catalent-buyout-faces-renewed-fda-scrutiny-form-483-sta>.

²² <https://www.fiercepharma.com/manufacturing/fda-cites-catalent-issues-indiana-plant-which-caused-delay-moderna-booster>.

Inspection, *supra*; U.S. Food & Drug Admin., FDA Inspection Report for Catalent Indiana, LLC (2025).²³

FDA regulations and inspection manuals already mandate redaction of trade secret information and other confidential information from disclosure in Form 483 reports, pursuant to the agency’s narrow definitions of a “trade secret” and “commercial or financial information which is privileged or confidential.” 21 C.F.R. § 20.61; *Investigations Operations Manual 2025*, U.S. Food & Drug Admin., § 2.3 (last updated May 6, 2025).²⁴ However, Vanda’s excessively broad definition of a “trade secret,” if applied to FDA in the manner that Vanda seeks, may censor the agency from disseminating *any* information about manufacturing and research processes, including unsanitary conditions.

This censorship could have harmful consequences. Health professionals and health systems rely on drug contamination information contained in Form 483 reports to make drug prescribing and procurement decisions. Without this information, health professionals may be more likely to unknowingly provide patients with improperly manufactured, unsafe products, and less able to identify alternative suppliers in time to avoid rationing and shortages. Broadening the definition of a “trade secret” would also hamper FDA’s ability to communicate

²³ <https://www.statnews.com/wp-content/uploads/2025/08/catalent-form-483-jul-2025.pdf>.

²⁴ <https://www.fda.gov/media/166529/download?attachment>.

non-trade secret confidential information with state and local governments on public health issues, which is an important current practice of the Agency.

Information Sharing, U.S. Food & Drug Admin. (last updated Jul. 10, 2018).²⁵

Censoring FDA in this way would undermine FDA's mission to promote GMPs in facilities around the world, endangering public health and placing more unsafe products in patients' hands.

3. Vanda's interpretation would exacerbate FDA's existing practice of overprotecting certain public health information.

Vanda's misguided interpretation of the law would not only threaten what FDA already does well but also exacerbate FDA's existing harmful practice of overprotecting certain public information. FDA's tendency toward undercommunication appears to stem from concerns that submitted information could be trade secrets and thus create takings or other liability if disclosed. *See, e.g.,* C. Joseph Ross Daval et al., *The Origins of "Confidential Commercial Information" at the FDA*, 332 JAMA 533, 533 (2024); Christopher J. Morten & Amy Kapczynski, *The Big Data Regulator, Rebooted: Why and How the FDA Can and Should Disclose Confidential Data on Prescription Drugs and Vaccines*, 109 Calif. L. Rev. 493, 549 (2021).

²⁵ <https://www.fda.gov/federal-state-local-tribal-and-territorial-officials/communications-outreach/information-sharing>.

FDA's recent policy shift on public disclosure of complete response letters (CRLs) is an example of FDA's tendency to err on the side of secrecy—and the agency's potential for change. CRLs are detailed letters written by FDA, documenting the reasons for the agency's decision declining to approve a given drug application. *FDA Embraces Radical Transparency by Publishing Complete Response Letters*, U.S. Food & Drug Admin. (Jul. 10, 2025).²⁶ CRLs identify deficiencies in drug product applications, making them highly useful to researchers, patients, and clinicians. Peter Lurie et al., *Comparison of Content of FDA Letters Not Approving Applications for New Drugs and Associated Public Announcements from Sponsors: Cross Sectional Study*, *BMJ* (Apr. 2015).²⁷ FDA had for years refused to make CRLs public prior to a drug's approval out of concern that such letters contain confidential information. *Id.* However, the agency recently reversed course. Moving forward, FDA will be releasing CRLs in real time, regardless of a drug application's approval status. *FDA Announces Real-Time Release of Complete Response Letters, Posts Previously Unpublished Batch of 89*, U.S. Food & Drug Admin. (Sept. 4, 2025).²⁸ This move shows that FDA is often reluctant to exercise its full authority to disclose information.

²⁶ <https://www.fda.gov/news-events/press-announcements/fda-embraces-radical-transparency-publishing-complete-response-letters>.

²⁷ <https://www.bmj.com/content/350/bmj.h2758>.

²⁸ <https://www.fda.gov/news-events/press-announcements/fda-announces-real-time-release-complete-response-letters-posts-previously-unpublished-batch-89>.

This Court should reaffirm FDA’s longstanding authority to close informational gaps and protect the American public by reaffirming that Vanda’s reading of *Monsanto* is incorrect.

a. Vanda’s arguments could exacerbate FDA’s reluctance to publicly communicate clinical trial study protocols.

One key category of information that FDA holds but does not currently publicly disclose is clinical trial study protocols, which explain why the trial is being conducted, how it will be conducted, and what the trial is measuring. Pursuant to 21 U.S.C. § 355(i), drug sponsors conducting clinical trials must first obtain FDA authorization of the drug as an Investigational New Drug (IND). *Investigational New Drug (IND) Application*, U.S. Food & Drug Admin. (Sept. 16, 2025).²⁹ FDA requires detailed study protocols to be submitted as part of IND applications. *Id.* However, FDA currently does *not* publicly disclose the study protocols it receives as part of IND applications.

Some may argue that FDA’s overprotection of study protocols is not harmful, given that NIH requires the public disclosure of similar information on ClinicalTrials.gov. However, the public’s access to study protocols on ClinicalTrials.gov is delayed and incomplete. NIH only requires protocols for most device, vaccine, and drug trials conducted in the United States to be uploaded to

²⁹ <https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application>.

ClinicalTrials.gov by *one year after* the primary completion date of the study. See 42 C.F.R. § 11.48(a)(5); *Results Data Element Definitions for Interventional and Observational Studies*, ClinicalTrials.gov (Dec. 31, 2024).³⁰ Additionally, NIH only mandates the submission of full study protocols and statistical analysis plans for studies with a primary completion date on or after January 18, 2017—meaning study protocols are still lacking for many older drugs. *Id.* Study protocols on ClinicalTrials.gov have also been critiqued as containing incomplete eligibility criteria, which hinders researchers’ identification of the relevant study population. Laura Miron et al., *Obstacles to the Reuse of Study Metadata in ClinicalTrials.gov*, *Sci. Data* (Dec. 18, 2020).³¹

The public would benefit from earlier and more complete access to study protocols. Study protocols contain invaluable information on how clinical investigators plan to proceed with the study, the statistical analysis plan, and the prespecified endpoints the study will evaluate. Early access to study protocols deters poor study design, inappropriate changes to selected statistical methods and outcomes, and selective reporting of results. David Campbell et al., *Access to Unpublished Protocols and Statistical Analysis Plans of Randomised Trials*, *Trials* (Aug.17, 2022).³² Even after study results are published, access to complete study

³⁰ <https://clinicaltrials.gov/policy/results-definitions#documentUploadInformation>.

³¹ <https://www.nature.com/articles/s41597-020-00780-z>.

³² <https://pmc.ncbi.nlm.nih.gov/articles/PMC9387046/>.

protocols allows fellow researchers to assess the study population, evaluate a study's design for bias, and identify whether prespecified endpoints differ from the final endpoints described in the study publication, to weigh the reliability and generalizability of the results.

An example of early disclosure of study protocols resulting in meaningful public health benefits occurred during the COVID-19 pandemic, when companies testing COVID-19 vaccines, faced with public pressure, voluntarily agreed to release the protocols for their studies. Allison Durkin et al., *Addressing the Risks That Trade Secret Protections Pose for Health and Rights*, 23 Health & Hum. Rts. 129, 133 (2021). The disclosure of study protocols allowed researchers to evaluate the endpoints used in the various studies for the different vaccines, and thus facilitated discussions of vaccines' effectiveness. *Id.* On the flip side, lack of timely access to protocols contributed to confusion around *which* patients with COVID-19 benefit from the antiviral pill nirmatrelvir/ritonavir (Paxlovid), rendering doctors unsure whether their patients would benefit from treatment. *See* Rachel Gutman-Wei, *Of Course Biden Has Rebound COVID*, The Atlantic (July

2022);³³ Jessica McDonald, *Q&A On Paxlovid, Pfizer's COVID-19 Oral Antiviral*, FactCheck.org (May 2022).³⁴

Delay in public access to clinical protocols could be reduced if FDA started to publicly share study protocols upon obtaining them as part of IND applications. FDA's choice to keep clinical trial study protocols seems to stem from the potential for such information to be claimed as trade secrets. Morten & Kapczynski, *supra*, at 549. By reaffirming the limits of trade secret protection and the correct reading of *Monsanto*, the court could help alleviate these concerns and encourage FDA to exercise its authority to disclose protocols, leading to earlier and fuller discussions of the efficacy and safety of drugs.

b. Vanda's arguments could exacerbate FDA's reluctance to publicly communicate drug shortages.

Another existing gap is FDA's effective communication of drug shortages to providers and patient organizations.

By statute, FDA is currently mandated to distribute "to the maximum extent practicable" information on discontinuation or interruption of drugs' availability. 21 U.S.C. §§ 356c & 356d. However, the statute does not mandate or expressly authorize disclosure of information that meets the definitions of trade secret and

³³ <https://www.theatlantic.com/health/archive/2022/07/biden-paxlovid-covid-drug-rebound-infections/671009/>.

³⁴ <https://www.factcheck.org/2022/05/scicheck-qa-on-paxlovid-pfizers-covid-19-oral-antiviral/>.

confidential commercial information under the Freedom of Information and Trade Secrets Acts. 21 U.S.C. § 356c(d). FDA currently publicizes a list of current and resolved drug shortages, along with discontinuations of certain drug products. *See FDA Drug Shortages*, U.S. Food & Drug Admin.³⁵

Yet patients and clinicians have reported that the current system does not effectively communicate which drugs are at risk of shortage, when shortages are predicted to end, and how patients can access necessary drugs during a shortage. *See* Yuki Noguchi, *The hospital ran out of her child's cancer drug. Now she's fighting to end shortages*, NPR (Oct. 23, 2023);³⁶ Josh Serchen et. al, *Bolstering the Medication Supply Chain and Ameliorating Medication Shortages: A Position Paper From the American College of Physicians*, *Annals of Internal Med.* (Aug. 12, 2025).³⁷ This gap in regulatory communication is partially due to broad trade secret assertions by drug manufacturers that discourage FDA from disclosing information that might possibly be the subject of a trade secrecy claim—and, in turn, obfuscate the causes and risks of shortages. *Id.*

Vanda's excessively broad definition of trade secrets and incorrect interpretation of *Monsanto* would exacerbate this problem, preventing FDA from addressing gaps in reporting and effectively communicating drug shortages. Under

³⁵ <https://www.accessdata.fda.gov/scripts/drugshortages/#tab2>.

³⁶ <https://www.npr.org/sections/health-shots/2023/10/23/1204856094/hospital-ran-out-child-cancer-drug-shortage>.

³⁷ <https://www.acpjournals.org/doi/10.7326/ANNALS-25-00607>.

Vanda’s view of the law, manufacturers may assert trade secret protection to prevent disclosure of essentially *any* information tangentially related to manufacturing processes and raw materials. The FDA might come to withhold not only information covered by federal definitions of a trade secret but the very broadest state law definitions as well. The result would be more secrecy and worsening gaps in communication of drug shortages, ultimately leaving patients with even less information about the medications they rely on. However, a clear ruling by the Court on the limits of trade secret protection and takings law under *Monsanto* could embolden FDA to better communicate drug shortage information to patients who rely on those medications.

4. Other federal regulators would also be censored from communicating essential information to the American public.

Finally, the risks of Vanda’s erroneous legal arguments extend beyond FDA’s regulatory authority. They risk undermining broader federal regulatory authority to disclose data that impact public safety.

For example, consider the work of the National Highway Transportation Safety Administration (NHTSA). Since 2021, NHTSA has released reports on crashes and incidents of “self-driving cars” (cars equipped with advanced driver assistance or fully automated driving systems), following its General Order requiring manufacturers to report such incident information. *Standing General Order on Crash Reporting*, Nat’l Highway Traffic Safety Admin. (last visited Sept.

21, 2025).³⁸ NHTSA’s 2021 General Order explicitly informed manufacturers that incident information – with limited exceptions—is not considered by the agency to be confidential business information and thus will be made publicly available. Nat’l Highway Traffic Safety Admin., Third Amended Standing General Order 2021-01 (amended 2025), at 10.³⁹ This disclosure helps inform would-be buyers, investors, and the broader public about the risks of new self-driving car technology. It also helps shape municipal and state regulation of these cars. Mark MacCarthy, *The evolving safety and policy challenges of self-driving cars*, Brookings (July 31, 2024).⁴⁰

If the Court embraces Vanda’s view of the law, NHTSA may be prevented from disclosing crash data. Tesla and other carmakers have criticized NHTSA’s disclosure program—but stopped short of filing claims alleging a taking of trade secrets. Jarrett Renshaw et al., *Exclusive: Trump team wants to scrap car-crash reporting rule that Tesla opposes*, Reuters (Dec. 17, 2024).⁴¹ If NHTSA comes to fear that its disclosure of crash information is subject to a viable takings claim, it may cease disclosure. This could jeopardize public knowledge of the risks

³⁸ <https://www.nhtsa.gov/laws-regulations/standing-general-order-crash-reporting>.

³⁹ https://www.nhtsa.gov/sites/nhtsa.gov/files/2025-04/third-amended-SGO-2021-01_2025.pdf.

⁴⁰ <https://www.brookings.edu/articles/the-evolving-safety-and-policy-challenges-of-self-driving-cars/>.

⁴¹ <https://www.reuters.com/business/autos-transportation/trump-transition-recommends-scraping-car-crash-reporting-requirement-opposed-by-2024-12-13/>.

involved with this new technology and make local regulation more difficult, harming passenger and pedestrian safety.

III. CONCLUSION

For the foregoing reasons, the Court should affirm the decision of the Court of Federal Claims.

Date: October 6, 2025

Respectfully submitted,⁴²

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APPENDIX A

List of Signatories (Amici Curiae Professors of Law, Medicine, and Public Health)

(Amici sign on their own behalf. Institutions are listed for identification only. Views expressed in this brief do not necessarily reflect the views, if any, of listed institutions.)

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