No. 102490-8
Court of Appeals No. 84140-8-I

SUPREME COURT OF THE STATE OF WASHINGTON

STATE OF WASHINGTON,

Respondent,

v.

JOHNSON & JOHNSON, et al.,

Petitioners.

STATE OF WASHINGTON'S ANSWER TO PETITION FOR REVIEW

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

I. INTRODUCTION

Every day that passes, 136 more Americans die from opioid overdoses.[1] Washington's overdose deaths are the fastest rising in the nation—while the United States as a whole had a 0.6 percent decrease in reported drug overdose deaths from June 2022 to June 2023, Washington's overdose deaths increased by 36.84 percent during the same period, and this may be an underestimate.[2]

The State's lawsuit against Johnson & Johnson (J&J), the longtime top manufacturer of the active opioid ingredient in all pharmaceutical opioids, should have gone to trial in September 2022. Instead, J&J demanded the private health data

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[1] *Drug Overdose Death Rates*, National Center for Drug Abuse Statistics, https://drugabusestatistics.org/drug-overdose-deaths/#:~:text=Opioids%20kill%20more%20than%20136,increase%2C%20from%202015%20to%202016 (last accessed Nov. 27, 2023).

[2] *Provisional Drug Overdose Death Counts*, National Vital Statistics System, Centers for Disease Control and Prevention, https://www.cdc.gov/nchs/nvss/vsrr/drug-overdose-data.htm (last accessed Nov. 27, 2023).

of millions of Washingtonians to explore a defense irrelevant to the State's claims, grinding the case to a halt and forcing the State to seek discretionary review by the Court of Appeals in order to properly preserve healthcare and substance use disorder (SUD) treatment records in accordance with federal law.

The Court of Appeals' unanimous decision confirms that SUD patient information must be de-identified in accordance with the Health Insurance Portability and Accountability Act (HIPAA) before release, thereby ensuring that patient privacy in Washington will be maintained going forward. Nonetheless, J&J now seeks discretionary review, arguing that the public's interest lies not with protecting the privacy rights of nonparties, but with J&J's right to obtain the sensitive health information of 4.5 million Medicaid patients. There is no such public interest. Nor does J&J's assertion that it cannot understand decades-old HIPAA requirements, or its arguments that its expert performed an analysis found nowhere in the record, warrant Supreme Court review.

This Court should deny J&J's petition for pretrial review. While the possibility of the unlawful release of patient identifying data is an issue of substantial public interest, the failure of J&J's expert to satisfy basic HIPAA requirements is not. It is time to proceed to trial.

II. STATEMENT OF THE ISSUE

Does J&J's discovery dispute—over an analysis it has not even established is relevant to its defense—present an issue of substantial public interest that should be resolved by the Supreme Court prior to the normal trial and appellate process?

III. STATEMENT OF THE CASE

A. Federal Law Prohibits the Disclosure of Treatment Records for Patients with Substance Use Disorders Without Their Knowledge or Consent

Congress enacted 42 U.S.C. § 290dd-2 to protect the confidentiality that "is absolutely essential to the success of all drug abuse prevention programs," and to encourage patients with SUD to seek treatment without the "fear of public disclosure of drug abuse or of records that will attach for life," which "will

discourage thousands from seeking the treatment they must have." H.R. Rep. No. 92-775, at 33 (1972). The statute and its implementing regulations, 42 C.F.R. §§ 2.1–2.67 (Part 2), dictate "[u]nconditional compliance," forbidding the disclosure of "information by which the identity of a patient . . . can be determined . . . either directly or by reference to other information," unless the patient is provided notice and an opportunity to be heard. 42 C.F.R. §§ 2.11, 2.13(a)–(b), 2.64.

Through the HIPAA Privacy Rule, incorporated by Part 2, information in patient files is deemed individually identifiable unless it is de-identified through one of two methods: (1) the Safe Harbor Method or (2) the Expert Determination Method.

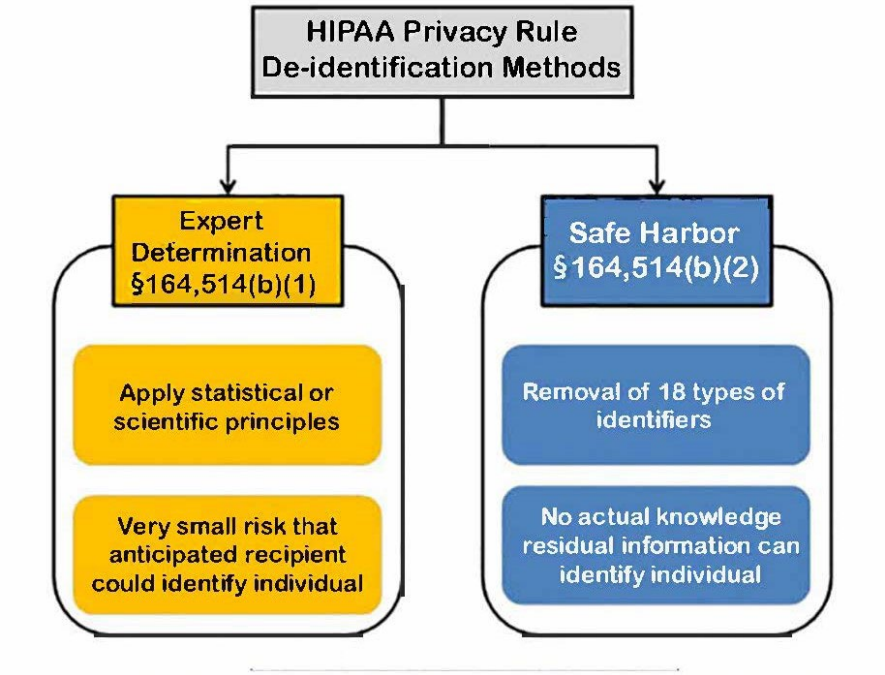


Figure 1. Methods to achieve de-identification in accordance with the HIPAA Privacy Rule.

CP 138 (*Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the [HIPAA] Privacy Rule*, provided by the U.S. Department of Health & Human Services) (HHS Guidelines).[3]

The Safe Harbor Method requires the removal of eighteen demographic identifiers—including the day and month (but not year) of a patient's treatment or prescriptions. Privacy Rule

[3] This guide sets forth the principles used by experts in determining the anonymity of health information. *See generally* CP 134–68.

Preamble, Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462, 82,543 (Dec. 28, 2000); CP 138–39. The Expert Determination Method, by contrast, allows the release of Safe Harbor-protected medical information, but *only* if an expert sufficiently qualified in de-identification methodologies can document and prove through "generally accepted methods" that "the risk is very small that the information could be used, either by itself or in combination with other available information, by anticipated recipients to identify a subject of the information." CP 138. Where patient data is not de-identified through either of these two methods, Part 2 forbids disclosure, even "in any civil, criminal . . . or legislative proceedings," without patient notice and opportunity to respond. 42 C.F.R. §§ 2.13(a), 2.64(b).

B. The State Sued J&J for Its Role in Creating the State's Opioid Crisis

The State sued J&J in January 2020, alleging that J&J's deceptive marketing campaign violated Washington's Consumer Protection Act, RCW 19.86, and contributed to the public

nuisance of Washington's opioid epidemic. *See* CP 120–25. While J&J claims it sold only "niche prescription opioid medications," Pet. at 2, this dramatically undersells its role in the crisis. J&J developed the mutant Norman poppy that it characterized as a "transformational technology that enabled the growth of oxycodone," and provided the opioid active pharmaceutical ingredient (API) in OxyContin, as well as hydrocodone, morphine, codeine, fentanyl, sufentanil, buprenorphine, hydromorphone, and naloxone. CP 52–53, 81–82. For years, J&J was the number one supplier of API, and it profited richly. CP 85–89.

The State's Complaint alleged that J&J marketed opioids as "a powerful medicine, safe to use as prescribed, and effective to relieve chronic pain," and did so without any supporting evidence. CP 52. Since J&J's marketing campaign included unsubstantiated statements about *all* opioids—as J&J's API supplier business benefitted whether the opioids prescribed were ones it manufactured or not—the State's claims would be the

same whether J&J's own branded opioid medicines had 50 percent of the market share, or 0.05 percent.

C. J&J Requested the Release of HIPAA-Protected Data Fields in the State's Medicaid Claims Data

Ignoring the State's actual claims, J&J has focused on its own branded opioid medications throughout discovery, NUCYNTA® and NUCYNTA® ER (tapentadol immediate release and extended-release tablets), and DURAGESIC® (fentanyl patch). *See, e.g.*, CP 19 (demanding the State "[i]dentify every person who allegedly became addicted to any substance or were otherwise harmed as a result of one of Defendant's Opioid medications"). J&J requested data about patients with opioid use disorder (OUD)[4] from a dozen State databases, including the Medicaid claims database containing private health data for 4.5 million Washingtonians. CP 197–98, 205. Although each database was produced in compliance with applicable privacy laws, the State's databases—

[4] SUD and OUD are used interchangeably throughout this brief.

totaling five terabytes of medical information—contain what the Special Master described as "an extraordinary trove of personal information regarding these patients[.]" CP 278. J&J also subpoenaed health information from private insurers. *See, e.g.*, CP 315–21. And, of course, J&J has access to public records containing demographic information, including death certificates, newspaper articles, residential addresses, licensing information, court records, and birth certificates, all easily accessible on the Internet.

Because information about patients diagnosed with or treated for OUD could not be culled from the Medicaid claims database, the State and its agencies de-identified the Medicaid claims data pursuant to the HIPAA Safe Harbor Method, including the removal of month and day fields. 42 C.F.R. §§ 2.61, 2.64(d)–(e); 45 C.F.R. § 164.514(b)(2); CP 35–38, 197–98.

D. The Special Master Denied J&J's Motion to Compel Month and Day Fields for Failure to Satisfy the Expert Determination Method

J&J was not satisfied with the de-identified Medicaid database, maintaining that it wanted to determine whether patients with OUD took J&J-branded medications before or after their diagnoses. In October 2021, J&J moved to compel the State to produce day and month fields, which provide the dates that millions of patients were prescribed and picked up their opioid prescriptions, received treatment for SUD, and/or overdosed (in addition to irrelevant but incredibly personal information about births, abortions, sexually transmitted infections, other drug addictions, significant illness, hospice care, etc.). CP 823–835. J&J argued this data would "determine the extent to which prescriptions for Janssen[5] opioid medications preceded diagnoses for opioid use disorder." CP 2–5. The State objected,

[5] Janssen Pharmaceuticals, Inc. is a wholly owned subsidiary of J&J, which manufactures, promotes, markets, and distributes opioids throughout the United States. CP 54. Janssen and J&J are referred to interchangeably throughout this brief.

arguing J&J's request sought irrelevant information and would violate Part 2.

While the motion was pending, and in response to J&J's professed need to determine whether its opioid medications were prescribed before or after a patient developed an addiction—the only justification provided in J&J's briefing—the State offered J&J a chronologically sequenced overlay that would not disclose day and month information, but would allow J&J to determine whether a patient was prescribed a J&J-branded opioid after developing an OUD. CP 2, 15–27, 207–208. J&J rejected the State's offer. *See, e.g.*, CP 279.

After briefing and argument, the Special Master agreed with the State that producing day and month information would jeopardize the privacy rights of Medicaid patients, and ordered J&J to satisfy the Expert Determination Method. CP 754–55.

J&J subsequently submitted a five-page double-spaced declaration from statistician Dr. Laurentius Marais that lacked any methodology, calculations, or serious analysis of the risk

associated with the release of the protected data fields. CP 935–41. Dr. Marais inexplicably compared the Medicaid dataset to just two other State datasets—from the Department of Labor and Industries (LNI) and the Public Employees Benefits Board (PEBB)—ambiguously claiming he "reviewed" data fields in just these three datasets and "determined there was nothing he could match that would . . . connect one [of those three] data set[s] to the next." CP 476.

Dr. Marais did not analyze the risk posed by the full set of datasets produced by the State, including the Washington State Department of Health's (DOH) death data compiled from death certificates registered in Washington State, which includes names, date and cause of death. Dr. Marais also failed to even acknowledge the private insurers' information, or publicly available data that has been used by data scientists, journalists, and corporations to re-identify patients based on the date of medical services. CP 938–40; *see, e.g.*, CP 848–52. In fact, Dr. Marais "base[d] []his opinion on the simple fact" that J&J

"does not have access to identified versions of" any "naming data source[s]" that overlaps with the Medicaid data. CP 938. As stated above and noted by the Court of Appeals, J&J's possession of the DOH death dataset—a "naming data source"—among other publicly available naming datasets that can be linked to specific date information shows Dr. Marais' glaring error. *State v. Johnson & Johnson*, 536 P.3d 204, 212 (Wash. Ct. App. 2023) ("It is undisputed that the Death Dataset included identifiable information, including names."); *see also* CP 820, 919 (finding the names of 18 out of 20 cancer patients when provided with only the type of cancer, zip code, and date of diagnosis); CP 846 (identifying patient medical histories, including drug and alcohol abuse and sexually transmitted infections by linking unrelated news articles to the month patients were hospitalized).

Moreover, Dr. Marais did not document, let alone detail, any methodology or provide anything close to a fulsome analysis supporting his conclusion. During argument, in fact, J&J acknowledged that Dr. Marais did not do any calculations, let

alone perform a generally accepted analysis of the risks of re-identification. CP 476.

As the Court of Appeals Commissioner explained when granting the State's Motion for Discretionary Review, "contrary to the characterization by Dr. Marais and the superior court," the Expert Determination Method is not "satisfied by a mathematician's bare assurance that the State's 'level of concern' as to the risk of re-identification is unwarranted. Instead, it appears that the federal regulations require that an expert actually analyze, demonstrate, and explain the risk of re-identification[.]" Comm'r's Ruling Granting Discretionary Rev. at 5.

To illuminate the fundamental flaws in Dr. Marais' short submission, the State submitted a declaration from Dr. Latanya Sweeney, whose groundbreaking work at MIT pioneered the data privacy field (and who is cited in the HIPAA Privacy Rule Preamble, *see* Standards for Privacy of Individually Identifiable Health Information, 65 Fed. Reg. 82,462 at 82,710

n.17 (Dec. 28, 2000)). Dr. Sweeney performed multiple detailed experiments and described her methodology to demonstrate that *90 percent* of the individuals in the State's Medicaid database would be identifiable if the day and month fields were produced. CP 871–76.

After reviewing both declarations, the Special Master found Dr. Marais' conclusion of a "de minimis" risk of re-identification to be unsupported "*ipse dixit*." CP 524. Further, the Special Master concluded that the sequenced database would adequately permit "Dr. Marais to opine on the number of OUD diagnoses preceded by a defendant's prescription, or drug, [within] two calendar years from that diagnosis." CP 525. The State produced the sequenced database to J&J.

E. The Superior Court Reversed the Special Master's Order, Substituting Its Own Conclusions for the Required Expert Analysis

J&J appealed the Special Master's ruling to the superior court. The superior court reversed and ordered the State to produce the day and month fields. The superior court did not

address the Special Master's finding that the State's date-sequenced Medicaid dataset fulfilled J&J's stated need. CP 942–46.

Instead, the superior court faulted the State and the Special Master for adopting an "unforgiving standard" by "suggest[ing] that any risk of re-identification is unacceptable." CP 943–44 (emphasis in original). But the superior court ignored Dr. Sweeney's findings that risk of re-identification—*up to 90 percent of the 4.5 million patients in the dataset*—is an astronomical risk that would be unacceptable under even the most lenient federal privacy standards. CP 873–74.

Ultimately, the superior court disregarded the Safe Harbor *and* Expert Determination methods to state that any risk was excusable because J&J promised to "make no effort" to re-identify patients, and to limit distribution to J&J's attorneys and experts. CP 944. This ruling is directly contrary to the Part 2 requirements of "[u]nconditional compliance," "whether or not"

the person seeking the information "asserts any other justification for a disclosure or use." 42 C.F.R. § 2.13(b).

The superior court *sua sponte* ordered the State to produce the Medicaid claims data with full dates "but without birth year, gender, marital status, and race/ethnicity variables." CP 945–46. No expert calculated the impact of these conditions. *See generally* CP 45–47, 445–47, 815–77, 935–41 (expert reports).

Finally, the superior court found that Dr. Marais had conducted a risk assessment analysis by pointing to a calculation purporting to show a "risk of re-identification [of] 0.004%," which the court found "is acceptably a 'very small' risk of identification pursuant to 45 C.F.R. § 164.514[.]" CP 945. Yet, as the Court of Appeals subsequently noted, Dr. Marais never performed this calculation. *Johnson & Johnson*, 536 P.3d at 214; *see* CP 45–47, 445–47, 935–41. Rather, J&J's attorneys proposed the calculation, using numbers picked at random from separate experiments with different variables and populations.

CP 455. The calculation was also contradicted by both expert reports. CP 46, 863–68; *see also* CP 938.

F. The Court of Appeals Unanimously Reversed, Agreeing with the Special Master that J&J Failed to Satisfy the Expert Determination Method

The State petitioned for discretionary review by the Court of Appeals prior to release of the protected identifiers. On review, the Court of Appeals concluded that the superior court had "misread the record" in concluding Dr. Marais satisfied the Expert Determination Method, and in relying on a calculation invented by J&J's lawyers. *Johnson & Johnson*, 536 P.3d at 213.

Among other problems with the superior court's decision, the Court of Appeals noted that while "Janssen argues that 'Dr. Marais considered all of the "data sets produced in this proceeding" and publicly available dataset[s]' . . . Dr. Marais made no such claim." *Id.* Instead, "[h]e based his opinion on the 'simple fact' that Janssen does not have 'another, complementary data source that could reveal the identities of individual

patients' . . . [when] [i]t is undisputed that the Death Dataset included identifiable information, including names." *Id.*

The Court of Appeals confirmed that Dr. Marais did not satisfy the Expert Determination Method, and held that the superior court had abused its discretion by ordering the production of the additional Medicaid claims data fields. *Id.*

IV. ARGUMENT

J&J brings its Petition solely under RAP 13.4(b)(4), arguing that that there is a question of substantial public interest that this Court should resolve. Pet. at 2. J&J is wrong.

A. J&J's Petition Does Not Raise an Issue of Substantial Public Interest Requiring Interim Review

The State agrees that patient privacy is an issue of substantial public importance—that is why it has resisted J&J's efforts to obtain private medical data in violation of the requirements of HIPAA and Part 2. But the Court of Appeals' published opinion confirming that Part 2-protected patient information must be de-identified before release ensures that patient privacy in Washington will be maintained. Thus, there is

no need for this Court to weigh in, particularly while this case is in an interlocutory posture. Moreover, J&J's arguments here are tethered to the fact-specific nature of its expert's declaration and qualifications, which this Court need not review.

B. The Court of Appeals Properly Concluded That J&J Did Not Satisfy the Expert Determination Method

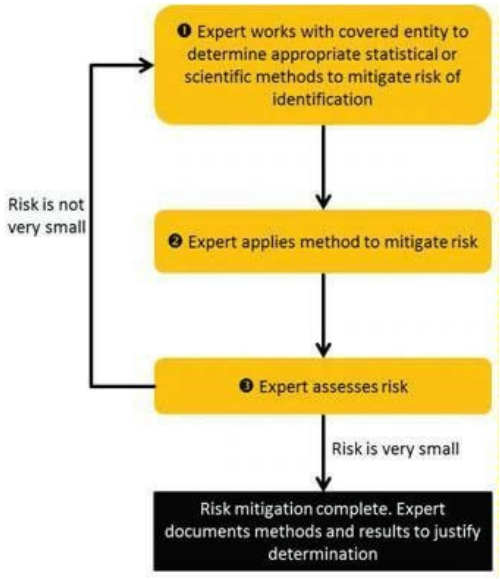
1. The Court of Appeals correctly applied HIPAA's clear requirements for the Expert Determination Method

A core premise of J&J's Petition is its professed confusion as to what the Court of Appeals opinion and the Expert Determination Method actually require. Pet. at 18. But this argument only highlights J&J's failure to retain an expert who is conversant in HIPAA de-identification and data privacy. The decision of the Court of Appeals is not unclear. Nor, for that matter, are the HIPAA de-identification requirements. Indeed, J&J never sought clarity on the requirements from the Court of Appeals. *See generally* Resp. Br. Rather, J&J asked the Court to find that Dr. Marais has experience with HIPAA de-identification, documented a generally accepted analytical

method for de-identifying data, and considered all datasets available to J&J, when, as the Court of Appeals noted, these arguments lack any support in the record. *Compare* Resp. Br. at 39–47 *with* CP 936–40; *Johnson & Johnson*, 536 P.3d at 214.

J&J itself recognizes that the U.S. Department of Health and Human Services outlines suggested methods for using the Expert Determination Method, and it does so in both descriptive and visual detail.[6] Pet. at 20; CP 134–68. This guidance is readily available on the HHS website, including to those who simply Google "Expert Determination Method."

[6] The HHS Guidelines are "meant to provide covered entities with a general understanding of the de-identification process applied by an expert. [They do] not provide sufficient detail in statistical or scientific methods to serve as a substitute for working with an expert in de-identification." CP 138, 143.



CP 138, 143.

The HHS Guidelines provide detailed answers, with example scenarios, to questions such as "What are the approaches by which an expert assesses the risk that health information can be identified?" CP 138, 147–48. The Guidelines also outline methodological principles, cite to literature containing generally accepted methods (including those invented by Dr. Sweeney, the State's expert), and provide examples relating to "Replicability," "Data [S]ource Availability," and "Distinguishability," none of which Dr. Marais discussed. *Compare* CP 144–47 *with* CP 936–40. The Guidelines advise

experts "to consider how data sources that are available to a recipient of health information (e.g., computer systems that contain information about patients) could be utilized for identification of an individual," including to "separate the 'features,' or types of data, into classes of relatively 'high' and 'low' risks." CP 144–45. Dr. Marais made no attempt to discuss data features or types, or parse out data into relatively high or low risks. CP 936–40.

Consistent with these clear requirements, the Court of Appeals affirmed that an expert must document generally accepted principles and methods, and that the superior court did not have discretion to circumvent the Expert Determination Method. *Johnson & Johnson*, 536 P.3d at 207, 213–14. As J&J acknowledges, the Expert Determination Method explicitly requires that an expert with experience with generally accepted scientific or statistical de-identification techniques apply this experience to determine that the re-identification risk is very small, and document the methods and results of this analysis.

45 C.F.R. § 164.514(b)(1). The Supreme Court does not need to clarify these straightforward requirements, especially by further delaying a trial that should have started over 14 months ago. J&J's attempt to manufacture uncertainty where none exists must fail.

2. The Court of Appeals properly ruled that J&J's expert did not perform or document the required analysis

J&J did not retain a qualified expert and the expert it did retain did not meet the requirements of 45 C.F.R. § 164.514(b)(1), even with the benefit of the HHS Guidelines. Dr. Marais did not properly consider available sources of data, perform a generally accepted analysis, or document his methods. He did not fulfil the Expert Determination Method and therefore J&J cannot justify de-identifying the protected health information of millions of patients. This Court's review of a decision properly so holding is unnecessary.

C. The Court of Appeals Correctly Held the Superior Court Abused Its Discretion

The Court of Appeals correctly held that the superior court abused its discretion by making clearly erroneous findings of fact to conclude that Dr. Marais satisfied the Expert Determination Method. First, the superior court misread the record by incorrectly finding that the State and Special Master relied on a standard that did not permit "any risk" of re-identification, instead of the "very small" risk contemplated by HIPAA. *Johnson & Johnson*, 536 P.3d at 213. As the Court of Appeals noted, Dr. Sweeney "acknowledged that HIPAA does not require the risk to be zero before health data may be shared," but her analysis demonstrated a risk to *90 percent of the patients in the database*. *Id.*; CP 858–59. While J&J asserts that "Dr. Marais's analysis passes muster regardless of whether the Expert Determination Method imposes a 'no risk' or 'very small risk' standard," Pet. at 30, Dr. Marais announced the risk to patients is "nil" without "having applied principles and methods for rendering information not individually identifiable" or

"review[ing] or consider[ing] the consequences of the Death Dataset." *Johnson & Johnson*, 536 P.3d at 213; CP 938. There is no dispute that the Expert Determination Method requires more, and an expert opinion meant to keep millions of patients safe should not rest upon basic factual errors.

Second, the superior court "incorrectly attributed to Dr. Marais an analysis and formula that he did not make or suggest." *Johnson & Johnson*, 536 P.3d at 213. While J&J now argues this calculation is "irrelevant," Pet. at 27–28, the superior court cited the calculation as the "most probative portion of [Dr. Marais'] analysis" and it was the basis for the superior court's conclusion that releasing the day and month fields poses an "acceptably [] 'very small' risk of identification." CP 945. Yet J&J's attorneys invented the calculation and proposed it in their brief. *See* CP 455. J&J does not say otherwise in its Petition—instead, it continues to argue that Dr. Sweeney's detailed calculations and conclusions are somehow incorrect. Pet. at 27–28. At the risk of stating the obvious, there is no

evidence within the record that J&J's attorneys are qualified experts under the Expert Determination Method—let alone more qualified than the country's leading HIPAA privacy expert. *See Johnson & Johnson*, 536 P.3d at 214 ("[T]he trial court could not substitute its opinion or the opinion of the Janssen attorneys for that of a qualified expert under 45 C.F.R. § 165.514(b)(1)(i) and (ii).").

D. There Is No Need for Further Review Before Trial

1. The protected data fields are neither relevant nor necessary for trial

J&J's Petition asserts that the superior court and Special Master found the protected data fields relevant to this case. Pet. at 15. In actuality, the superior court ordered the State to produce these records with only a single reference to their purported relevance: a citation to the Special Master's finding during the first hearing on J&J's motion to compel. CP 999 (citing CP 753). But following that first hearing, the Special Master actually found that the sequenced dataset the State produced fulfills J&J's purported need "to determine the extent

to which prescriptions for Janssen opioid medications preceded diagnoses for OUD." CP 2, 525 ("Although imperfect, the sequencing data should permit Dr. Marais to opine on the number of OUD diagnoses preceded by a defendant's prescription, or drug, not more than two calendar years from that diagnosis.").

Indeed, other than Dr. Marais' brief reference to an undescribed "sensitivity analysis" in a supplemental declaration, CP 445–46, the record lacks a complete explanation as to why J&J needs identifiable patient information for any claim or defense beyond what it already has in the sequenced dataset. *See* CP 1–1026. Whether the Medicaid data could show that some patients received J&J-branded opioids only after they developed an addiction makes no difference where the State's claims do not require it to prove causation or hinge upon patient use of J&J's branded opioids or upon J&J's market share. *See State v. Mandatory Poster Agency, Inc.*, 199 Wn. App. 506, 518, 398 P.3d 1271 (2017) ("[U]nder the CPA, the State is not

required to prove causation or injury" to any particular individual, or collectively); *see also Mavroudis v. Pittsburgh-Corning Corp.*, 86 Wn. App. 22, 32, 935 P.2d 684 (1997) (noting a plaintiff must demonstrate the defendant "played a role in causing" a nuisance, not demonstrate causation in fact).

In reviewing J&J's demand for similar claims data in its California opioid litigation, the California Court of Appeals held J&J's argument "that such data is necessary to determine any 'causal chain' (or lack thereof) between Defendants' conduct and any alleged 'adverse consequences' as alleged by the People" was "not sufficient to justify disclosure in light of the serious potential invasion of privacy rights that exists in this case." *County of Los Angeles v. Superior Ct.*, 65 Cal. App. 5th 621, 654, 280 Cal. Rptr. 3d 85, 113 (Cal. Ct. App. 2021) (cleaned up). J&J provides even less support here, where it already has the chronologically sequenced claims dataset.

While Part 2 prohibits disclosure of SUD patient information regardless of the purported relevance, the disclosure of any sensitive patient information should require more than vague references to relevance. 42 C.F.R. § 2.13(b) ("[u]nconditional compliance required" regardless of any "justification for a disclosure or use which is not permitted by the regulations"); *see also Bd. of Registered Nursing v. Superior Ct. of Orange Cnty.*, 59 Cal. App. 5th 1011, 1041, 1046, 273 Cal. Rptr. 3d 889 (Cal. Ct. App. 2021), *review denied* (Apr. 21, 2021) ("[G]eneralities like the need to 'measure trends and test causal relationships' . . . are insufficient to justify such a vast production of medical information from the nonparties here."). J&J's flimsy relevance claims do not merit discretionary review under RAP 13.4.

2. Even if the Court of Appeals was wrong, any error could be cured through the normal appellate process after trial

While the State sought interim review of a decision that risked the privacy rights of millions of Washingtonians, J&J has

asserted no comparable need for review here. Courts across the country have held that disclosure of protected health information could cause "irreparable injury" because "subsequent appellate vindication does not . . . totally repair[] the error." *See Maness v. Meyers*, 419 U.S. 449, 460, 95 S. Ct. 584, 42 L. Ed. 2d 574 (1975); *see also County of Los Angeles*, 65 Cal. App. 5th at 636 (granting interlocutory review of an order requiring production of claims data in J&J's California opioid litigation, "because petitioners lack an 'adequate remedy at law' to vindicate the third-party privacy rights at stake in their petitions and those third parties 'will suffer an irreparable injury' if a writ is not granted"). Here, by contrast, "subsequent appellate vindication" could "totally repair[] the [alleged] error" if J&J is correct (despite the record demonstrating it is not).

This case should finally move to trial without further interim appellate review.

V. CONCLUSION

For the above reasons, this case presents no issue of substantial public interest that warrants review by the Supreme Court prior to trial under RAP 13.4(b). The State therefore asks that the Court deny the petition for review.

This document contains 4,808 words, excluding the parts of the document exempted from the word count by RAP 18.17.

RESPECTFULLY SUBMITTED this 29th day of November 2023.

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DECLARATION OF SERVICE

I hereby declare that on this day I caused the foregoing document to be electronically filed with the Clerk of the Court using the Court's electronic filing system, which will serve a copy of this document upon all counsel of record.

I declare under penalty of perjury under the laws of the State of Washington that the foregoing is true and correct.

DATED this 29th day of November 2023, at Seattle, Washington.

s/ Lia E. Pernell
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WA AGO

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