NO. 1019947

IN THE SUPREME COURT
OF THE STATE OF WASHINGTON

TANESSA DESRANLEAU, individually and as the Personal Representative of the ESTATE of JAY'BREON DESRANLEAU,

Plaintiff-Respondents,

v.

HYLANDS, INC., STANDARD HOMEPATHIC LABORATORIES, INC., and STANDARD HOMEPATHIC COMPANY, and MICHELLE REID,

Defendants-Petitioner.

RESPONDENTS' OPPOSITION TO PETITION FOR DISCRETIONARY REVIEW

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I. INTRODUCTION

This case was wrongfully dismissed, a second time, premised upon arguments that were embodied in, and rejected by, a prior published opinion from this Court in the same case. *Desranleau v. Hyland's, Inc*., 10 Wash. App. 837, 841-6, 450 P.3d 1203 (2019). Despite a detailed explanation from this Court that this case should proceed to a jury as a battle of the experts, the defense lawyers fooled the trial judge into dismissing this matter on a false premise. Specifically, the defense lawyer lied to the trial judge about the fundamental basis of the plaintiff's expert's testimony. The trial judge bought the misleading arguments hook-line-and-sinker. The Court of Appeals reviewed the file and reversed the trial court based upon basic evidentiary principles: *Desranleau v. Hyland's, Inc*., 527 P.3d 1160 (April 17, 2023). Nothing about this matter warrants further Supreme Court review. *Id*.

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II. STATEMENT OF THE CASE

This case involves the poisoning death of a child named Jay'Breon with tainted pills manufactured by the defendant, Hyland's. *Desranleau v. Hyland's, Inc*., 10 Wash. App. 837, 841-6, 450 P.3d 1203 (2019). In a published opinion, Division 1 already determined that the evidentiary record supports the reasonable inference that Jay'Breon ingested (stratified) Hyland's tablets:

> In 2012, the United States Food and Drug Administration (FDA) informed Hyland's that it was concerned with Hyland's dilution process related to a separate product. The FDA wrote that Hyland's dilution process may lead to batch stratification—where some tablets within a single batch have significantly higher concentrations of an ingredient than others. The FDA recommended a liquid dilution process rather than a dry dilution process. These concerns remained in 2017, when the FDA again informed Hyland's that it was concerned with their manufacturing process. The FDA wrote:
>
> > You manufacture drug products ... from ingredients that pose potentially toxic effects. Specifically, Hyland's Baby Teething Tablets and Hyland's Baby Nighttime Teething Tablets contain belladonna[1] and are

> marketed for vulnerable patient populations, including infants and children. ...
>
> FDA's analysis of samples of your [products] ... found that the alkaloid content far exceeded the claim on your label.... The testing found inconsistency in levels of belladonna, a toxic substance, and reveals that your manufacturing process is poorly controlled and may pose unnecessary risk to infants and children.

Though the FDA's concerns were specifically related to stratification of belladonna in Hyland's teething products, and belladonna is not contained in Hyland's cold medicines, Hyland's admitted that its manufacturing process is substantially similar in all of its products. Therefore, Desranleau alleges that stratification of the alkaloid *Gelsemium sempervirens,* which can be toxic in high doses and is found in Hyland's cold medicines, likely also occurs. The possibility of stratification coupled with the potential for *Gelsemium sempervirens* to be toxic in high doses is what Desranleau alleges caused Jay'Breon's death.

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Even without Reid's statements, it would be reasonable for a jury to infer that Jay'Breon ingested Hyland's cold medicine from the chain of circumstantial evidence. First, Jay'Breon had a cold leading up to his death. Second, an open bottle of Hyland's cold medicine—specifically designed for infants who were experiencing a cold—was recovered from the scene. Third, the police found this medicine in a separate location from the other

> household occupant's medications, indicating that it was not their medication. And fourth, the police recovered this medication as evidence from where Jay'Breon was found. There was enough circumstantial evidence in the record, when viewed in the light most favorable to Desranleau, for a jury to find that Jay'Breon ingested Hyland's cold medicine.

id, at 841-6.

A key ingredient contained within Cold Tablets is a plant, Gelesemium Sempervirens, also an alkaloid.[1] At least as early as May of 2012, the FDA warned Hyland's of the dangers associated with Gelesemium Sempervirens, and that products including this ingredient likely suffered the same production deficiencies as the Teething Tablets.[2] The FDA noted that "*All parts of Gelesemium Sempervirens (Carolina Jessamine) contain the toxic alkaloids gelsemine and gelseminine. Both human and animal poisoning cases, including deaths, have been reported*."[3] A consulting expert with Hyland's noted that infant

[1] CP 1770-2: Declaration of Pietruszka, Pages 2-4
[2] CP 1777-9: Declaration of Pietruszka: Exhibit 1
[3] CP 1778: Declaration of Pietruszka: Exhibit 1

renal development raises serious Gelsemium Sempervirens ingestion concerns.[4]

The CEO of Hyland's, J.P. Borneman, undertook an individual consultation with an authority in the field of homeopathic medicines, Wilfried Stock, PhD.[5] Dr. Stock is the head of the toxicology and safety committee for the organization which is considered the leading authority regarding the production of homeopathic medicines: the Homeopathic Pharmacopeia Convention of the United States (*a.k.a.* HPUS).[6] According to Dr. Stock, products containing Gelesemium Sempervirens should not be given to small children in the absence of physician supervision.[7] In a "*Risk Calculation*" sent directly to CEO Borneman, Dr. Stock referenced other resources indicative that Gelesemium Sempervirens is "**No longer considered safe**" in any quantity, and should not be given to

[4] CP 1770-2: Declaration of Pietruszka: Exhibit 1
[5] *Id*.
[6] CP 755-824: Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 31)
[7] CP 1789: Declaration of Pietruszka: Exhibit 3

anyone, for any reason.[8] Vice President Baier indicated that Hyland's disagrees with Dr. Stock, and does not follow his recommendations, in relation to Gelsemium Sempervirens consumption: "*I'm not exactly sure of the context of that statement, but Hyland's would not agree that Gelsemium is not a typical drug for small children. We're a hundred year old company – plus and we have a lot of experience with infant formulas. And it's been our experience that Gelsemium is not unsafe for small children*."[9]

It is generally accepted in the medical community that Gelsemium ingestion can prove lethal:

CONCLUSION

Gelsemium elegans is highly toxic. Although patients may die within 30 min due to its strong respiratory depressive effect, they can survive with timely respiratory support and enjoy gradual improvement without delayed postanoxic encephalopathy.[10]

This medical conclusion in the attached literature relies upon thirty-seven (37) other medical studies which reached the same

[8] *Id*.
[9] CP 755-824: Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 30)
[10] CP 1789: Declaration of Pietruska: Exhibit 3 pages 48-52

and/or similar conclusions.[11] The supportive studies are not equivocal:

Fitoterapia. 2015 Jan;100:35-43. doi: 10.1016/j.fitote.2014.11.002. Epub 2014 Nov 11.

FULL-TEXT ARTICLE

Gelsemium analgesia and the spinal glycine receptor/allopregnanolone pathway.

Zhang JY[1], Wang YX[2].

Author information

Abstract

Gelsemium, a small genus of flowering plant from the family Loganiaceae, comprises five species including the popular Gelsemium sempervirens Ait. and Gelsemium elegans Benth., which are indigenous to North America and China/East Asia, respectively. Approximately 120 alkaloids have been isolated and identified from Gelsemium, with the predominant indole alkaloids including **gelsemine**, koumine, gelsemicine, gelsenicine, gelsedine, sempervirine, koumidine, koumicine and humantenine. **Gelsemine** is the principal active alkaloid in G. sempervirens Ait., and koumine and **gelsemine** are the most and second-most dominant alkaloids in G. elegans Benth. Gelsemium extract and its active alkaloids serve a variety of biological functions, including neurobiological, immunosuppressive and antitumor effects, and have traditionally been used to treat pain, neuralgia, anxiety, insomnia, asthma, respiratory ailments and cancers. This review focuses on animal-based studies of Gelsemium as a pain treatment and its mechanism of action. In contrast to morphine, when administered intrathecally and systemically, koumine, **gelsemine** and gelsenicine have marked antinociception in inflammatory, neuropathic and bone cancer pains without inducing antinociceptive tolerance. Gelsemium and its active alkaloids may produce antinociception by activating the spinal α3 glycine/allopregnanolone pathway. The results of this review support the clinical use of Gelsemium and suggest that its active alkaloids may be developed to treat intractable and other types of pain, preferably after chemical modification. However, Gelsemium is a known toxic plant, and its **toxicity** limits its appropriate dosage and clinical use. To avoid or decrease the side/toxic effects of Gelsemium, an individual monomer of highly potent alkaloids must be selected, or alkaloids that exhibit greater α3 glycine receptor selectivity may be discovered or modified.

[12]

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[11] *Id* at 5

[12] CP 1349-90: Reply on Reconsideration

Confirmation of Gelsemium Poisoning by Targeted Analysis of Toxic Gelsemium Alkaloids in Urine

Chi-Kong Lai* and **Yan-Wo Chan**
Department of Pathology, Princess Margaret Hospital, Hong Kong, China

Abstract

The gelsemium plants are highly poisonous but toxicological evaluation of suspected poisoning cases has been hampered by the chemical complexity of the gelsemium toxins involved. A novel liquid chromatography–tandem mass spectrometry protocol was optimized for the collective detection of gelsemine and related alkaloids from *Gelsemium elegans*. The screening protocol was applied to the clinical investigation of unexplained intoxications following the ingestion of seemingly nontoxic herbs. In three clusters of toxicological emergencies ranging from severe dizziness to respiratory failure, *Gelsemium elegans* mistaken for various look-alike therapeutic herbs was suspected to be the hidden cause of poisoning. Nine cases of gelsemium poisonings were thus ascertained by the diagnostic urine alkaloid profiles. Gelsemine was sustained as the main urinary marker of *Gelsemium* exposure.

in committing suicide and homicide (5,6). In a
gelsemium plant grows as a twining vine, and it ma
with other edible plants, leading to inadvertent co
Typical symptoms of intoxication include rapid-
ness, nausea, vomiting, blurred vision, limb paralys
difficulty, coma, and convulsion. In severe pois
threatening respiratory depression would lead t
The alkaloids from *G. elegans* have also been stu
sively; the chemical diversity of the main gelsemi
is illustrated in Figure 1. The most abundant
koumine (LD_{50} ~ 100 mg/kg mice i.p.), which s
toxicity comparable to gelsemine. However, the la
alkaloid gelsenicine (humantenmine) proved to th
(LD_{50} ~ 0.2 mg/kg mice i.p.) (7,8). Indeed, the fa
gelsenicine by respiratory inhibition in experimer
(9) is analogous to that of gelsemicine (3), althou
mechanism of their action appears controversial (13

There is consensus within the medical community as to this medical fact: ingesting Gelsemium can prove lethal.[14]

In this most recent study from 2017, a patient had a near death experience after ingesting Gelsemium: "*She continued to be hospitalized at her local medical center for 11 days but failed to identify the cause of the coma*."[15] The study did not observe any specific quantification of Gelsemium:

[13] *Id.*
[14] *Id.*
[15] *Id.*

History was taken in detail several times; finally, her husband recalled that there was a bottle of broth of herbs at her bedside table. The herbs looked like *G. elegans*. Samples of interest taken in the scene were then analyzed and toxic *Gelsemium* alkaloids were detected by the China National Analytical Center of the Chinese Academy of Sciences. Therefore, diagnosis of *G. elegans* poisoning was established.

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Because the patient had already ingested the Gelsemium, it was not possible to measure the quantity:

The diagnostic process for *G. elegans* intoxication may be time consuming and could likely involve forensic investigation (10). *Gelsemium* alkaloids can be detected in the urine, suggesting that urinary gelsemine is a practical marker of *Gelsemium* exposure in human subjects (36). Because of the relatively short half-life of *Gelsemium* alkaloids (37), urine specimens need to be collected in a timely manner. 17

Even in the absence of any confirmatory testing, the study was peer reviewed by assorted medical professionals (including a professor from the Yale Medical School), and given upon the circumstantial evidence, the medical professionals concluded that the patient had been poisoned by Gelsemium.[18]

[16] *Id.*
[17] *Id.*
[18] *Id.*

The trial court agreed that the circumstantial evidence supports the inference that Jay'Breon ingested gelesemium: "My analysis is that there certainly evidence in the record from which an inference could be drawn that gelesemium is present."[19] The plaintiff's causation expert, Dr. Pietruska, opined that Jay'Breon died as a result of Gelsemium ingestion.[20] The quantity of Gelsemium cannot be measured simply because the pills at issue were already consumed and ingested.[21] The medical literature confirms that it is possible to diagnose Gelsemium poisoning (1) based upon the circumstantial evidence and (2) in the absence of laboratory testing.[22] That same literature made it clear that the "*diagnostic process for G. elegans intoxication may be time consuming and could likely involve forensic investigation*."[23]

In reliance upon the previously inconclusive autopsy conducted by Dr. Harruff and coupled with the additional

[19] Verbatim Report of Proceedings, Page 43
[20] CP 882-3: Declaration of Pietruska dated December 22, 2020
[21] *Id*.
[22] CP 1786-87: Declaration of Pietruska: Exhibit 3
[23] *Id* at 4

information about the lethality of Gelsemium, Dr. Pietruska utilized standard forensic methodology:

> A The other opinions, there are no -- there are no inherent medical conditions that would have caused this child to die suddenly. This case was described as sudden unexplained infant death with a concern about the cause. I have to look up the actual terminology,
>
> Page 14
>
> the way they wrote it. But I believe that we do have some information here that will explain that.
>
> What else do we have?
>
> The -- I performed an extensive differential diagnosis of cause of death in this case. I have reviewed the autopsy. I did not find any aspects of the autopsy to identify any medical condition that could have caused this baby's death.
>
> I believe that the biochemical nature of Gelsemium in the setting in which it has been dispensed can readily explain how and why this baby died when he died.

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[24] CP 1812-4: Declaration of Vollans: Exhibit 6 – Deposition of Pietruska, Pages 13-14

A Typical toxicologic analysis deals with a dose-response relationship. And I would agree in the general sense that a dose-response relationship is necessary for a toxic effect.

However, more recently, with a greater understanding of the effects of nanoparticles on the human body and the use of nanoparticles in various treatments, it becomes clear that homoeopathy, the concept of homeopathy and the mechanism by which homeopathy works, deals essentially with the ability of nanoparticles, very small particles of, in this case, a toxic substance to enter into the system and to affect an adverse occurrence on cell structures -- on cell structures.

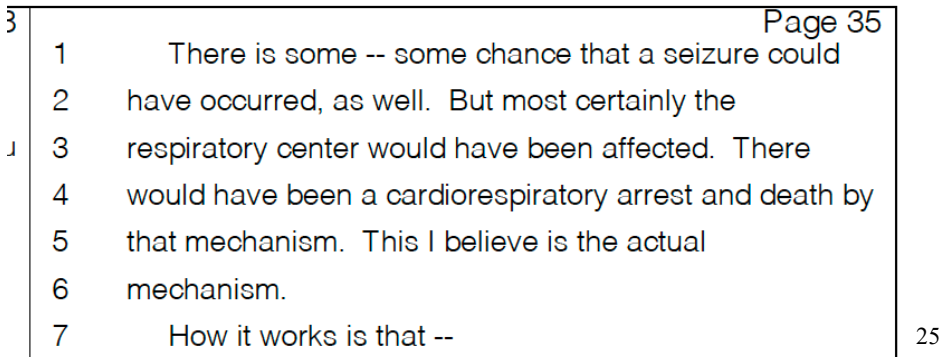
So in this case what my understanding is -- if I want to get to the real basic what happened, is you have -- an infant is administered at least eight tablets a day of Gelsemium, Gelsemium contained within tablets. The exact concentration of that Gelsemium is not known. There is some concern about the manufacturing process. We don't know if the chemicals

in those tablets are evenly distributed through all the tablets or whether some have higher concentration than others.

Nevertheless, even small concentrations of Gelsemium are described in the literature as potentially toxic.

And what has happened is, over the period of three days there's been a repeated administration of a drug that affects the central nervous system. In an infant, administration of Gelsemium, which contains alkaloids that are essentially of the strychnine family, causes paralysis and has a toxic effect on the -- of the nerves at the base of the brain. It affects -- it gets absorbed through the soft palate. It can affect essentially from the neck up of the baby.

This baby did not have the ability to just swallow it. It stayed in the mouth and would have been dissolved in the mouth and would have essentially penetrated the soft palate and entered into the base of the brain, where the medulla and the cranial nerves would be located. Over a period of time, days, the child would then be exposed to increasing amounts of the neurotoxin Gelsemium, which would ultimately cause a respiratory paralysis, respiratory center paralysis, and secondarily a cardiac arrhythmia and death.



Page 35

There is some -- some chance that a seizure could have occurred, as well. But most certainly the respiratory center would have been affected. There would have been a cardiorespiratory arrest and death by that mechanism. This I believe is the actual mechanism.

How it works is that --

The King County Medical Examiner's specific anatomical findings during the autopsy are supportive of Dr. Pietruska's conclusions.[26] In the published opinion in this case, the Court of Appeals noted:

> The medical examiner ruled out numerous causes of death including asphyxiation, hyperthermia, and other natural causes of death other than sudden infant death syndrome. But the medical examiner did not have the benefit of the information about Hyland's cold medicine available to him when he conducted his investigation; Dr. Pietruska did. As this is a review of a summary judgment order, where we view all of the evidence and reasonable inferences from the record in the light most favorable to Desranleau, we cannot conclude, as a matter of law, that Dr. Pietruska's expert opinions should be disregarded.

Desranleau. 10 Wash App. at 847.

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[25] *Id*
[26] *Id*

The trial court dismissed the case based upon a false representations on the part of the same defense lawyer.[27] As Dr. Pietruska explained on reconsideration:

> 3. Second, it is *not* my opinion that a nanoparticle of Gelesemium Sempervirens caused Jay'Breon's death. That is a false representation by the defense. By contrast, it *is* my opinion that as little as a nanoparticle "could" cause death. Here, Jay'Breon ingested multiple Hyland's Cold Tablets over a period of several days. Because the pills every few hours over a period of days were consumed by Jay'Breon, it is not possible to measure the quantity ingested. However, given that there was a stratification problem during the production process, it is reasonable to assume that Jay'Breon ingested stratified pills. Regardless, the lethal effect of Gelesemium Sempervirens is cumulative with the more pills consumed over time. My opinion is that Jay'Breon, more likely than not, ingested a sufficient quantity of Gelesemium Sempervirens to cause his death. The specific amount of Gelesemium Sempervirens cannot be quantified and doesn't need to be for my forensic analysis. Moreover, the quantity of Gelesemium Sempervirens that would prove harmful varies between individuals and circumstances. [28]

Specifically, defense counsel's false representations related to (1) Dr. Pietruska's well established methodology, (2) the quantification of lethality of Gelesemium, and (3) the relevancy of the phraseology "nanoparticles" in relation to this case. The trial court's ruling was brazenly inconsistent with (1) the facts of the case, (2) the actual opinions of Dr. Pietruska, and (3) the

[27] Verbatim Report of Proceedings, Page 43
[28] CP 882-3: Declaration of Pietruska

Supreme Court's controlling precedent and should therefore be reversed. Therefore, Division 1 reversed again. *Desranleau v. Hyland's, Inc*., 527 P.3d 1160 (April 17, 2023).

III. ARGUMENT

Division 1's ruling was simple and determined that the trial court misapplied the *Frye* standard and also ER 702. *Id*. The underlying ruling did not create any new law. *Id*. The ruling was fact specific to the contours of this case. *Id*. The underlying opinion was a product of a careful analysis of the evidentiary record. *Id*. On appeal, Hyland's lawyers were unable to fool Division 1's court clerks into affirming their ongoing false representations and meritless arguments. *Id*. The underlying ruling simply followed existing Supreme Court precedent won by the undersigned counsel. *Anderson v. Akzo Nobel Coatings, Inc.,* 172 Wash.2d 593, 610, 260 P.3d 857 (2011).

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IV. CONCLUSION

This matter does not meet any standard that would justify further review by the Supreme Court.

DATED this 30th day of June, 2023.

CONNELLY LAW OFFICES, PLLC

By Lincoln C. Beauregard
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DECLARATION OF SERVICE

I hereby declare that on the 30th day of June, 2023, I caused to be electronically filed the foregoing documents with the Clerk of the Court using the CM/ECF system which also will send notification of such filing to the following parties.

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DATED this 30th day of June, 2023.

Marla Folsom

_____

Marla Folsom
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VICKIE SHIRER

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