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### NO. 78343-2-I

# COURT OF APPEALS, DIVISION I OF THE STATE OF WASHINGTON

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

Appellants,

v.

### HYLAND'S, INC., STANARD HOMEPATHIC LABORATORIES, INC., and STANDARD HOMEPATHIC COMPANY, and MICHELLE REID,

Respondents.

### RESPONSE TO PETITION FOR DISCRETIONARY REVIEW

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### I. INTRODUCTION

Appellant/plaintiff Tanessa Desranleau submits this memorandum in opposition to Hyland's petition for discretionary review. Nothing about Hyland's arguments or this case justify granting review under RAP 13.4. This is a straightforward case wherein Hyland's was caught by the FDA selling tainted baby medicines. In this case, discovery revealed that the manufacturing processes that were faulty in the originally recalled medicine that killed babies extended to other product lines including the medicine ingested by the deceased child in this case. By way of expert testimony, Ms. Desrenleau will prove at trial that when a dead baby with a cold is found next to an open bottle of basically poison pills, it is reasonable for a jury to infer that the poison pills killed the baby. The Court of Appeals agreed.

#### **II. STATEMENT OF FACTS**

On January 18, 2014, Jay'Breon was found dead in his crib.<sup>1</sup> At the time, Jay'Breon was under the care of his birth father, Jimi Williams, and his girlfriend, co-defendant Michelle Reid.<sup>2</sup> The police investigation revealed that Jay'Breon had been administered successive doses of Hyland's Tiny Cold Tablets immediately prior to his death.<sup>3</sup> The

<sup>&</sup>lt;sup>1</sup> CP 334-61: (Hyland's MSJ, Page 4 Lines 1-2)

 $<sup>^{2}</sup>$  Id.

<sup>&</sup>lt;sup>3</sup> CP 334-61: (Hyland's MSJ Page 3 Lines 18-20; Declaration Umberger: Exhibit 3 (Hyland's 000026))

investigation file reveals that Jay'Breon was also administered other over the counter medications such as Tylenol and Vick's vapor rub.<sup>4</sup> Ms. Reid admitted to the investigating officers the amount and quantity of tablets that were given to Jay'Breon.<sup>5</sup> There is no dispute but that Jay'Breon ingested Hyland's Tiny Cold Tablets.<sup>6</sup> Hyland's admitted that the Cold Tablets were collected at the crime scene.<sup>7</sup>

During the proceedings below, Hyland's submitted the Federal Way Police Department report containing multiple declarations of investigating officers.<sup>8</sup> One of the officers, R. Franco, swore under oath that co-defendant Michelle Reid informed Officer Franco of the assorted medicines that Ms. Reid administered to Jay'Breon, and Officer Franco then collected the evidence:

\* \* \*

Michelle was sitting outside on the curb in the parking as I spoke with her. Michelle appeared distraught and visibly upset. Michelle said Jaybreon had been sick the past 2 days with a chest congestion. Michelle said that she had given him 2 tablets of infant cold medicine, prior to him Infant Tylenol (medications were recovered from Michelle and booked in to evidence) at 0600 hrs. Michelle said she left the room with Jaybreon sleeping on his back.

<sup>&</sup>lt;sup>4</sup> Id.

<sup>&</sup>lt;sup>5</sup> CP 1378-79: (Declaration of Detective Adrienne); CP 362-504: (Declaration of Umberger: Exhibit 3, Hyland's 000026 (Sworn Federal Way Investigation Report).) <sup>6</sup> *Id*.

 $<sup>^{7}</sup>$  Id.

<sup>&</sup>lt;sup>8</sup> CP 224-333: (Declaration of Umberger, Exhibit 3: Docket No. 55C)

I CERTIFY UNDER PENALTY OF PERJURY UNDER THE LAWS OF THE STATE OF WASHINGTON THAT ALL STATEMENTS MADE HEREIN ARE TRUE AND ACCURATE AND THAT I AM ENTERING MY AUTHORIZED USER ID AND PASSWORD TO AUTHENTICATE IT (RCW 9A.72.085).

Electronically Signed: Yes	Signature: R. Franco #188
Federal Way/King/Washington	Date:01/19/14
	9

Subsequently, the evidence that was collected by Officer Franco was conveyed to counsel for Hyland's as certified by Rodney Umberger:

11. On October 18, 2017, my office received from Federal Way Police Detectives a sealed evidence can containing the Hyland's Tiny Cold Tablets that were collected as evidence by the Federal Way Police Department during their investigation of Jay'Breon's death. The Hyland's Tiny Cold Tablets that my office received from the Federal Way Police Department remain in the sealed evidence container.

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The Federal Way Police Department's conveyance of the residual tablets to Ms. Umberger proves that the medicines were those collected by Officer Franco in response to Ms. Reid indications about administering the product.<sup>11</sup> During this litigation, Hyland's argued that the residual pills were representative of the quantities of the product that Jay'Breon ingested.<sup>12</sup> Based upon this evidence, including (1) Ms. Reid's admissions to Officer Franco coupled with (2) the actual evidence/medicine collected

<sup>&</sup>lt;sup>9</sup> Id.

 $<sup>^{10}</sup>$  CP 362-504 (Declaration of Umberger dated January 24, 2018, Paragraph 11: Docket No. 85)

<sup>&</sup>lt;sup>11</sup> Id.

<sup>&</sup>lt;sup>12</sup> CP 224-333: (Docket Nos. 55B-60)

at the scene, and also (3) Hyland's possession of the residual packaging that was obtained from the Federal Way Police Department, in accord with CR 56, there is ample evidence upon which to infer that Jay'Breon ingested a portion of the pills collected at the evidence scene.

In relation to Hyland's products, the company develops and produces homeopathic "medicines" that are marketed all throughout the world.<sup>13</sup> All of the relevant manufacturing, regulating, testing, and monitoring of the products occurs in California.<sup>14</sup> Hyland's markets other products that have been recalled from store shelves, most notably Hyland's Teething Tablets.<sup>15</sup> The Teething Tablets have been associated with multiple deaths of small children. Hyland's maintains that the Teething Tablets could not possibly have been the cause of the deaths, but removed them from store shelves regardless.<sup>16</sup> Other products, such as the Cold Tablets at issue, remain on sale for the general public in multiple countries throughout the world.<sup>17</sup>

For several years, Hyland's has been monitored and admonished by the Food and Drug Administration (FDA) for failing to adhere to safe

<sup>&</sup>lt;sup>13</sup> CP 362-504: (Declaration of Umberger: Exhibit 1, Hyland's 000071-75)

 $<sup>^{14}</sup>$  *Id*.

<sup>&</sup>lt;sup>15</sup> Id. <sup>16</sup> Id.

 $<sup>^{17}</sup>$  Id.

ш.

production practices.<sup>18</sup> Documents revealed during discovery confirm that at least as early as May 14, 2012, Hyland's was on notice that the production processes were resulting in the sale of toxic homeopathic products to the public for the administration upon infant populations.<sup>19</sup> Specifically, the FDA admonished Hyland's in relation to the Teething Tablets noting that dangerous levels of alkaloids ("belladonna" in the Teething Tablets) survived the production process at unsafe "concentration levels."<sup>20</sup> The FDA warned Hyland's CEO, J.P. Borneman, directly.<sup>21</sup> Subsequent inspections proved that the problems were systemic and branched out between the entire Hyland's product line.<sup>22</sup> The FDA continued to notify CEO Borneman of the same un-remediated violations of product safety and labeling standards as recently as September 1, 2017.<sup>23</sup>

At least as early as May of 2012, the FDA put Hyland's CEO, Borneman, on notice that the deficiencies associated with the Teething Tablets was not limited to only that specific product line: "you have not provided evidence that you have extended your corrective actions to other products intended for use in in infants and children that are derived from

<sup>&</sup>lt;sup>18</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046-48)

<sup>&</sup>lt;sup>19</sup> *Id*.  $^{20}$  *Id*.

 $<sup>^{21}</sup>$  *Id*.

<sup>&</sup>lt;sup>22</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000071-75)  $^{23}$  *Id*.

potentially toxic compounds..."24 The FDA further noted that the production processes in place do "not appear to evaluate the potential impact of the blend particle size and the distribution on the overall product potency."<sup>25</sup> "DPA's work identified different concentrations of alkaloid on different particle sizes of lactose and there is a potential for stratification to occur in a bland over extended hold times."<sup>26</sup> "Therefore, our concerns remains that your manufacturing process does not have adequate controls."27

A key ingredient contained within Cold Tablets is a plant, Gelsemium Sempervirens, also an alkaloid.<sup>28</sup> At least as early as May of 2012, the FDA warned Hyland's of the dangers associated with Gelsemium Sempervirens, and that products including this ingredient likely suffered the same production deficiencies as the Teething Tablets.<sup>29</sup> The FDA noted that "All parts of Gelsemium Sempervirens (Carolina Jessamine) contain the toxic alkaloids gelsemine and gelseminine. Both human and animal poisoning cases, including deaths, have been reported."<sup>30</sup> Many other commonly available resources confirm the toxic dangers associated with

<sup>&</sup>lt;sup>24</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046-48)

<sup>&</sup>lt;sup>25</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046) <sup>26</sup> Id.

<sup>&</sup>lt;sup>27</sup> Id.

<sup>&</sup>lt;sup>28</sup> CP 681-708: (Declaration of Pietruszka, Pages 2-4)

<sup>&</sup>lt;sup>29</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046-48)

<sup>&</sup>lt;sup>30</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000047)

Gelsemium Sempervirens.<sup>31</sup> A consulting expert with Hyland's noted that infant renal development raises serious Gelsemium Sempervirens ingestion concerns.<sup>32</sup>

Hyland's relies upon a process of heavy ingredient dilution in order to ensure the purported safety of the assorted products.<sup>33</sup> When diluted correctly, the dilution process results in miniscule amounts of the "active ingredients" (such as alkaloids) so as to prove relatively pointless and ineffective.<sup>34</sup> Hyland's production process has proven faulty, as noted by the FDA.<sup>35</sup> Specifically, the dilution process has not always been effective resulting in "stratification" of the alkaloids – meaning dangerously high and inconsistent quantities as between product tablets.<sup>36</sup> The FDA, and prior occurrences, focused upon the inconsistent levels of alkaloids appearing with the Teething Tablets.<sup>37</sup> The discovery process has revealed (in the form of a binding CR 30(b)(6) deposition of Hyland's Vice President of Quality Control Eric Baier) that the product process of the Teething Tablets versus the Cold Tablets differs in only one way, the Cold Tablets are not as heavily diluted:

<sup>&</sup>lt;sup>31</sup> CP 362-504: (Declaration of Umberger: Exhibit 1)

<sup>&</sup>lt;sup>32</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1)

<sup>&</sup>lt;sup>33</sup> CP 677-680: (Declaration of Baier)

<sup>&</sup>lt;sup>34</sup> *Id*.

<sup>&</sup>lt;sup>35</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046-48)

<sup>&</sup>lt;sup>36</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046-48)

<sup>&</sup>lt;sup>37</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000046-48)

Q. Okay. So the – you've identified differences in the degrees of dilution in relation to the Teething Tablets as compared to the Cold Tablets; is that fair?

A. Yes.

- Q. Any other differences?
- A. In the manufacture? No.<sup>38</sup>

Further discovery revealed that as of an FDA inspection that occurred in the fall of 2016, Hyland's failed to implement appropriate corrective measures.<sup>39</sup> The FDA noted that, "Because your methods, facilities, or controls for manufacturing, processing, packing, or holding do not conform to CGMP, your drug products are adulterated within the meaning of section 501(a)(2)(B) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), 21 U.S.C. 351(a)(2)(B)."<sup>40</sup> The FDA "collected and analyzed samples of some of your drug products…and…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 risks to infants and children. These test results demonstrate that your

<sup>&</sup>lt;sup>38</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 80-81))

<sup>&</sup>lt;sup>39</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000071-75)

<sup>&</sup>lt;sup>40</sup> Id.

*manufacturing process validation was inadequate to ensure that your drugs are uniform character and quality.*<sup>"41</sup> The FDA documented Hyland's admission that the same manufacturing process extends across product lines.<sup>42</sup> The FDA also noted that failure to conduct mandatory annual product safety reviews.<sup>43</sup> And the FDA also noted many federal statutory misbranding violations.<sup>44</sup>

Prior to filing this lawsuit, Ms. Desranleau retained an expert witness, Marvin Pietruszka, M.D., to review the potential causes of Jay'Breon's death.<sup>45</sup> Dr. Pietruszka reviewed the available information and concluded, in the fall of 2016, that the ingestion of Hyland's Cold Tablets was the likely cause of Jay'Breon's death.<sup>46</sup> Prior to Dr. Pietruszka's confirmation, Ms. Desranleau was not aware, and had no way of suspecting, that the Cold Tablets were the issue.<sup>47</sup> On January 3, 2017, Ms. Desranleau promptly filed this lawsuit, and included a claim for punitive damages.<sup>48</sup> Ms. Desranleau bases these allegations upon the entirety of the evidence including Hyland's ongoing faulty manufacturing processes as have been

<sup>&</sup>lt;sup>41</sup> *Id*.

<sup>&</sup>lt;sup>42</sup> Id.

<sup>&</sup>lt;sup>43</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000073)

<sup>&</sup>lt;sup>44</sup> Id.

<sup>&</sup>lt;sup>45</sup> CP 362-504: (Declaration of Umberger: Exhibit 9)

<sup>&</sup>lt;sup>46</sup> CP 681-708: (Declaration of Pietruszka, *Generally*)

<sup>&</sup>lt;sup>47</sup> CP 812: (Declaration of Desranleau)

<sup>&</sup>lt;sup>48</sup> CP 362-504: (Declaration of Umberger: Exhibit 1)

ongoing for many years, including at least as late as 2016.<sup>49</sup> The FDA informed Hyland's of the serious safety deficiencies – selling variable levels of known lethal toxins to infants under the guise of safe medicine – at least as early as 2012.<sup>50</sup> The manufacturing problem was never fixed.<sup>51</sup>

The discovery process has revealed further alarming information about Hyland's Cold Tiny Cold Tablets.<sup>52</sup> The CEO of Hyland's, J.P. Borneman, undertook an individual consultation with an authority in the field of homeopathic medicines, Wilfried Stock, PhD.<sup>53</sup> 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).<sup>54</sup> According to Dr. Stock, products containing Gelsemium Sempervirens should not be given to small children in the absence of physician supervision.<sup>55</sup> In a "*Risk Calculation*" sent directly to CEO Borneman, Dr. Stock referenced other resources indicative that Gelsemium Sempervirens is "**No longer considered safe**" in any quantity, and should

<sup>&</sup>lt;sup>49</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 1, Hyland's 000071-75)

<sup>&</sup>lt;sup>50</sup> Id. <sup>51</sup> Id.

<sup>&</sup>lt;sup>52</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 3; Declaration of Beauregard); CP 722-811: (Exhibit 2 (Deposition of Baier, Page 30))

<sup>&</sup>lt;sup>53</sup> Id.

<sup>&</sup>lt;sup>54</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 31))

<sup>&</sup>lt;sup>55</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 3)

not be given to anyone, for any reason.<sup>56</sup> 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."<sup>57</sup>* 

In this case, on the topic of risks, Ms. Desranleau's expert on causation, Dr. Pietruszka, agrees with Dr. Stock's Risk Calculation, and that there is no safe ingestible quantity of Gelsemium Sempervirens.<sup>58</sup> Vice President Baier is generally aware that there are studies indicating that Gelsemium Sempervirens is a potentially lethal toxin: "*I know that there's been studies on Gelsemium to – that have, again, identified the alkaloid gelesemine which has the potential to be toxic if consumed in sufficient amounts.*"<sup>59</sup> Vice President Baier does not know, and could not identify, in what quantity Gelsemium becomes lethal to an infant.<sup>60</sup> There is no known

<sup>&</sup>lt;sup>56</sup> CP 681-708: (Declaration of Pietruszka: Exhibit 3)

 <sup>&</sup>lt;sup>57</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 30))
 <sup>58</sup> Id.

<sup>&</sup>lt;sup>59</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 19-20))

<sup>&</sup>lt;sup>60</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 8))

safe quantity of Gelsemimum for infants.<sup>61</sup> Hyland's does provide a warning on the Cold Tablet packaging that for usage upon children under 6-months, the parent should consult a physician.<sup>62</sup> Vice President Baier does not know why Hyland's adheres to a 6-month threshold, and he is personally unaware of any data to support this assertion.<sup>63</sup> Vice President Baier Baier doesn't even know why, after the dilution process, the tablets are manufactured to a weight of 64.8 milligrams.<sup>64</sup>

Dr. Pietruszka relied upon the same scientific methodology as did the Medical Examiner, Richard Harruff, M.D.<sup>65</sup> However, Dr. Pietruszka additionally relied upon the newly discovered information about the faulty Hyland's production process, as well as Dr. Stock's observations.<sup>66</sup> Dr. Pietruszka observes that any post-mortem toxicology testing would likely prove unreliable.<sup>67</sup> Moreover, testing the residual tablets that Jay'Breon did not ingest would be similarly lacking in probative value given the likelihood of product stratification as between tablets.<sup>68</sup> Any such testing can prove confirmatory, because alkaloids should never occur in high concentrations

<sup>&</sup>lt;sup>61</sup> *Id.*; CP 681-708: (Declaration of Pietruszka: Exhibit 3)

<sup>&</sup>lt;sup>62</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 41))

<sup>&</sup>lt;sup>63</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 41-42))

<sup>&</sup>lt;sup>64</sup> CP 722-811 (Declaration of Beauregard: Exhibit 2 (Deposition of Baier, Page 69))

<sup>&</sup>lt;sup>65</sup> CP 681-708: (Declaration of Pietruszka, Paragraph 8)

<sup>&</sup>lt;sup>66</sup> CP 681-708: (Declaration of Pietruszka, *Generally*)

<sup>&</sup>lt;sup>67</sup> CP 681-708: (Declaration of Pietruszka, Paragraph 11)

<sup>&</sup>lt;sup>68</sup> Id.

within the human body, and not exculpatory, for the reasons already noted.<sup>69</sup> For those reasons, Dr. Pietruszka is able to confirm his conclusions in the absence of any product and/or toxicology testing.<sup>70</sup>

Hyland's has sold Cold Tablets for decades.<sup>71</sup> When deposed, Hyland's own quality control officer, Vice President Baier, indicated that no product testing and/or safety verification (other than the guidelines provided by the HPUS) even existed.<sup>72</sup> "*It's – homeopathic drugs typically do not go through these processes and that's industry standard*."<sup>73</sup> Vice President Bair, does not know why certain ingredient levels are maintained: "Again, the particular remedies and their choices and potencies were not made. But it is my responsibility to ensure that those potencies are at a – an appropriate level. It's my responsibility that they're checked against the Homeopathic Pharmacopoeia, and it's my responsibility to also ensure that we factor in additional safety factors that are company policy."<sup>74</sup> CEO Borneman's father "Jack" (a co-owner of the Hyland's company), has sat on the HPUS Board of Directors for decades.<sup>75</sup> Vice President Baier

<sup>&</sup>lt;sup>69</sup> Id.

<sup>&</sup>lt;sup>70</sup> Id.

 <sup>&</sup>lt;sup>71</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 30))
 <sup>72</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 10-12))

 <sup>&</sup>lt;sup>73</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 35))
 <sup>74</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 13-14))

<sup>&</sup>lt;sup>75</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Page 9-11))

admitted that, if not properly diluted enough, Gelsemium Sempervirens is considered "*a prescription drug*."<sup>76</sup>

As a matter of practice, Hyland's sells the products to the consuming product and then relies upon the absence of Serious Adverse Events as authority that the products are not doing any harm.<sup>77</sup> Vice President Baier explained that Hyland's has a "*1-800…phone number*" on the package and that, presumably, injured consumers, law enforcement officers, and/or "*medical professionals*" would know that the product caused injuries and call back and give a report.<sup>78</sup> Hyland's considers the absence of reported adverse events as evidence that the Cold Tablets are safe.<sup>79</sup> Hyland's asserted as much in the underlying motion for summary judgment and submitting the table of adverse events as supportive of an alleged "0.0000081" rate of negative occurrences.<sup>80</sup> Notably, other adverse events from 2012 indicate that children were experiencing "*convulsions*" and "*hallucinations*" after consuming Hyland's Cold Tablets.<sup>81</sup> Between April

 <sup>&</sup>lt;sup>76</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Page 71))
 <sup>77</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 31-34)); CP 362-504: (Declaration of Umberger: Exhibit 10)

<sup>&</sup>lt;sup>78</sup> CP 722-811: (Declaration of Beauregard: Exhibit 2 (Deposition of Eric Baier, Pages 13-14))

<sup>&</sup>lt;sup>79</sup> *Id*.

<sup>&</sup>lt;sup>80</sup> CP 334-361: (Hyland's MSJ, Page 24 Lines 21—25 to Page 25 Lines 1-2); CP 362-501: (Declaration of Umberger: Exhibit 10)

<sup>&</sup>lt;sup>81</sup> CP 362-501: (Declaration of Umberger: Exhibit 10)

2016 to April 2017 alone, Hyland's received 35 complaints related to the Cold Tablets.<sup>82</sup>

Dr. Pietruszka opined that this method of product safety verification is unreliable, and even unethical.<sup>83</sup> A commonly conducted autopsy would not take the possibility of alkaloid poisoning into consideration and toxicology screening would not prove probative.<sup>84</sup> Hyland's is basically utilizing the consuming public as lab rats.<sup>85</sup> According to Dr. Pietruszka, the general public would have no way of knowing and/or suspecting that the Hyland's products were the cause of any adverse events, or deaths: "*the general Cold Tablet consuming public, law enforcement, and other coroners, would not necessarily even know to evaluate an adverse event as attributable to alkaloid related poisoning.*"<sup>86</sup> Many other children could have died from ingesting alkaloid tainted Cold Tablets, and nobody would ever have known and/or even checked.<sup>87</sup>

### III. ARGUMENT RE: MARVIN PIETRUSZKA, M.D.'s EXPERT TESTIMONY

There is nothing unique about the Court of Appeal's ruling in relation to the admissibility of Dr. Pietruszka's testimony. *Desranleau v.* 

 <sup>&</sup>lt;sup>82</sup> CP 722-811: (Declaration of Beauregard: Exhibit 1 (Hyland's Redacted Documents))
 <sup>83</sup> CP 681-708: (Declaration of Pietruszka, Paragraphs 10-13)

 $<sup>^{80}</sup>$  CP 681-708: (Declaration of Pietruszka, Paragraphs 10-13)  $^{84}$  Id.

<sup>&</sup>lt;sup>64</sup> *Id*. <sup>85</sup> *Id*.

 $<sup>^{86}</sup>$  Id.

 $<sup>^{87}</sup>$  Id.

Hyland's, Inc., 450 P.3d 1203 (2019). In that regard, the Court of Appeals

explained:

Desranleau also offered Dr. Pietruszka's expert opinion to establish that Hyland's products contained potentially lethal doses of alkaloids and therefore were likely the cause of Jay'Breon's death. Hyland's argues on appeal that we should disregard Dr. Pietruszka's opinion and that because Dr. Pietruszka's opinion should be excluded, Desranleau cannot establish legal causation.

¶25 But Hyland's bases its argument on fact based questions such as whether Dr. Pietruszka relied on improper information in reaching his conclusion, and whether he adhered to the proper scientific method. This indicates that material questions of fact remain as to whether Dr. Pietruszka's opinions properly conclude that Hyland's products caused Jay'Breon's death.

\*1209 ¶26 Further, Hyland's asks this court to rule on the credibility of Dr. Pietruszka. The trial court did not rule on the admissibility of Dr. Pietruszka's opinions. See <u>Volk v.</u> <u>DeMeerleer, 187 Wash.2d 241, 277, 386 P.3d 254</u> (2016) ("[a]dmission [of an expert witness] is proper provided the expert is qualified and his or her testimony is helpful [to the trier of fact.]").

¶27 The medical examiner ruled out numerous causes of death including <u>asphyxiation</u>, <u>hyperthermia</u>, 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. Pietruszka 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. Pietruszka's expert opinions should be disregarded.

¶28 "Proximate cause is ordinarily a question for the jury." Fabrique, 144 Wash. App. at 683, 183 P.3d 1118. Since here

"the facts are []disputed and the inferences therefrom are [not] plain and incapable of reasonable doubt or difference of opinion,"<sup>6</sup> we reverse. Desranleau rebutted Hyland's motion for summary judgment with sufficient evidence to reach the trier of fact on the questions of whether Jay'Breon consumed Hyland's cold medicine before his death and whether that medicine was the cause of his death.

*Id* at 1208. Again, in the petition for Supreme Court review, Hyland's offers nothing other than "fact based questions" on appeal. *Id*. Hyland's strains all credibility by even arguing that this portion of the Court of Appeals ruling is on conflict with other precedent. *Id*.

### IV. ARGUMENT RE: EVIDENCE OF INGESTION

Hyland's counsel has a history of offering any form of assertions, no matter how untrue or unsupported by the record on this file. In this instance, Hyland's boldly claims that the Court of Appeals ruled that Ms. Reid's statements within the police investigatory reports were not hearsay, whereas, the published ruling concluded the direct opposite:

The trial court determined that Reid's statements to the police officers were inadmissible hearsay. Hearsay is "a statement, other than one made by the declarant while testifying at the trial or hearing, offered in evidence to prove the truth of the matter asserted." ER 801. Hearsay is inadmissible unless covered by a recognized exception. ER 802. Since Desranleau was attempting to rely on Reid's statements for the truth of the matter asserted—that Reid administered Jay'Breon Hyland's cold medicine—Reid's statements were hearsay. See State v. Hines, 87 Wash. App. 98, 941 P.2d 9 (1997) (holding that the admission of a police officer's investigation report was error because it was hearsay not covered by an applicable exception).

Desranleau argues that Reid's statements are not hearsay because they are admissions by a party-opponent. ER 801(d)(2) provides that a statement is not hearsay if it is "offered against a party and is (i) the party's own statements ... or (ii) a statement of which the party has manifested an adoption or belief in its truth." Desranleau contends that because Reid is a codefendant ER 801(d)(2) applies to her statements.

¶18 But Desranleau ignores that even though Reid is a codefendant in this suit, under ER 801(d)(2), Reid's statements could only be used against her; they could not be used against Hylands. See ER 801(d)(2) (a statement is not hearsay if "offered against a party and is ... the <u>party's own</u> statements.") (Emphasis added). See <u>also Feldmiller v. Olson</u>, 75 Wash.2d 322, 324, 450 P.2d 816 (1969) ("statements made by Mr. Olson may or may not be admissions on his part against him. They are admissible as evidence only against him (Olson) and they would not be evidence against the other defendant Leonard.") (alteration in original). Therefore, Reid's statements are not admissible against Hyland's under ER 801(d)(2).

Id at 1207. By contrast, the Court of Appeals reversed the trial court on

the basis that finding a dead child with a cold next to a bottle of open cold

medicine creates a "reasonable inference" that the dead child ingested the

medicine:

It was undisputed that Jay'Breon had a cold for the few days prior to his death. Hyland's admits as such in its briefing to this court, and the medical examiner's report described Jay'Breon's lungs at the time of his death as congested.

¶22 There was also evidence that the police recovered Hyland's infant cold medicine from the scene: Officer Rego reported that he recovered cold medications from the scene and booked them into evidence, and the police report contains an evidence description of cold medications with the brands "Tylenol & Hyla." This evidence

was retained by the police and later transferred to Hyland's counsel.<sup>5</sup> Further, Officer Mickelsen reported that while photographing the kitchen and dining room, he located numerous medications on the counter that were prescribed to the other residents of the house.

¶23 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 1208. There is nothing novel about this ruling and it does not justify granting discretionary review.

### V. CONCLUSION

The Court of Appeals did not err and nothing about this case or the underlying rulings justify review under RAP 13.4. Hyland's wants to engage in a battle of the experts on paper before this Court whereas a jury must decide this case. For these reasons, discretionary review should not be granted. DATED this 27<sup>th</sup> day of November, 2019.

Respectfully submitted

# Líncoln Beauregard

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### COURT OF APPEALS, DIVISION I STATE OF WASHINGTON

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

No. 78343-2-I

### CERTIFICATE OF SERVICE

Appellants,

v.

HYLAND'S, INC., STANARD HOMEPATHIC LABORATORIES, INC., and STANDARD HOMEPATHIC COMPANY, and MICHELLE REID,

Respondent.

The undersigned certifies under penalty of perjury under the laws of the state of

Washington, that she is now, and at all times materials hereto, a citizen of the United States,

a resident of the state of Washington, over the age of 18 years, not a party to, nor interested

in the above entitled action, and competent to be a witness herein.

I caused to be served this date the following:

• Response to Petition for Discretionary Review

in the manner indicated to the parties listed below:

Rodney Umberger Ryan Vollans Williams Kastner |601 Union Street, Suite 4100

Seattle, WA 98101-2380 Attorney for Defendant (Hyland's Inc.)

DATED this 27<sup>th</sup> day of November, 2019.

# Víckie Shírer

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# VICKIE SHIRER

# November 27, 2019 - 1:22 PM

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### **Comments:**

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