PLAINTIFF'S MOTION FOR PARTIAL

SUMMARY JUDGMENT - 1

LAW FIRM

1325 4th Avenue, Ste 1730

Seattle, WA 98101 Phone: (206) 487-7371

- 1. Plaintiff's Motion for Partial Summary Judgment Re: Misbranded Drugs;
- 2. Declaration of Evelyn Cadman Re: Misbranding, Drugs, and New Drugs, with Exhibits;
- 3. Declaration of Stuart M. Rosenblum, MD, PhD Re: Drugs, New Drugs, and Labels;
- 4. Declaration of Stuart M. Rosenblum, MD, PhD Re: Medical Causation;
- 5. Declaration of Michael Cowgill In Support of Motion;
- 6. Defendant Society Botanicals, LLC's Response to Plaintiff's Partial Motion for Summary Judgment, Re: Misbranding;
- 7. Declaration of Stephen G. Leatham, In Support of Society's Response, RE; Misbranding;
- 8. Plaintiff's Reply In Support of Summary Judgment, Misbranding;
- 9. Declaration of Stuart M. Rosenblum, MD, PhD, Re: Leatham Opinion;

The Court has considered all pleadings referenced and heard the arguments of counsel, and being otherwise fully advised, the Court makes the following findings and conclusions:

- Plaintiff's motion does not seek a ruling regarding whether Kratom Divine fell
 under the Pre-Market NDI requirements, as the Court previously ruled that this
 issue involved a difference of opinion by the experts and would be for the finder
 of fact to determine;
- 2. Plaintiff's motion does not seek a ruling regarding proximate cause, as the Court previously ruled that this issue was for the finder of fact to determine;
- The Court makes no ruling as to whether the Society Botanicals product was a
 defective product or was unmerchantable, as those issues are for the finder of fact

to determine.

- 4. There is no question of fact that Society presented marketing materials through its website promoting the use of Kratom to address a variety of medical or psychological maladies;
- 5. On the facts presented, it is a material fact for the trier of fact to determine if Kratom, as marketed by Society, is a drug or a supplement or something else;
- 6. There is no question of fact that Society's labeling (i.e., warnings and instructions) on the Kratom Divine product was deficient as it relates to the decedent, Patrick Coyne; and
- 7. The Court's January 20, 2023 ruling on this motion is attached hereto and incorporated herein.
- 8. The Court has not ver decided the Consumer Protection Act issue in the motion

whether it was an unfair and/or deceptive act for Society to provide warnings or

instructions beyond those on the Kratom Divine labeling, [

It is now, therefore:

ORDERED, Adjudged and Decreed that Plaintiff's Motion for Partial Summary Judgment is GRANTED as to the following issues:

- 1. **Inadequate Warnings and Instructions.** Society Botanicals was negligent as that term is used in RCW 7.72.030(1) and RCW 7.72.040(1), because adequate warnings or instructions were not provided with the Kratom Divine product.
- 2. **Unfair and Deceptive Act.** The court denies Plaintiff's motion as to the issue of an unfair and deceptive act based on a finding of genuine dispute as to whether it was

[PROPOSED] ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT - 3 MAGLIO CHRISTOPHER & TOALE LAW FIRM

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1	unfair or deceptive not to provide warnings or instructions beyond those on the labels.
2	Again, this Order granting partial summary judgment does not address the other elements or
3	issues in this case, including causation and damages.
4	DONE IN OPEN COURT this 2nd day of February, 2023.
5	
6	/s/ Hon Gary Bashor
7	HON. GARY BASHOR SUPERIOR COURT JUDGE
8	Conformed during zoom hearing by Talis Abolins, 2/2/23
9	Presented this 2 nd day of February, 2023.
10	ATTORNEYS FOR PLAINTIFFS
11	
12	Curis Showing
13	Talis M. Abolins WSBA No. 21222 Michael Cowgill WSBA No. 55303
14	MAGLIO CHRISTOPHER & TOALE, PA
15	1325 4 th Avenue, Suite 1730 Seattle, WA 98101
	Phone: (206) 487-7371
16	Fax: (206) 260-1309
17	Email: tabolins@mctlaw.com Email: mcowgill@mctlaw.com
18	
	Approved as to form, notice of presentation waived:
19	ATTORNEYS FOR DEFENDANTS
20	11 1
21	Curis Showing for:
22	Stephen G. Leatham HEURLIN, POTTER, JAHN, LEATHAM,
23	HOLTMANN & STOKER, P.S. Attorneys for Society Botanicals LLC and the Rooks
24	sgl@hpl-law.com
25	

[PROPOSED] ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT - 4

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1325 4th Avenue, Ste 1730 Seattle, WA 98101 Phone: (206) 487-7371

1	
2	
3	
4	Ronald Webster, WSBA No. 36097
5	LAW OFFICES OF KATHERYN REYNOLDS MORTON
6	Attorneys for Defendants JSC USA, LLC Ronald.Webster@LibertyMutual.com
7	
8	
9	Natasha Cobb, WSBA No. 55164 KANG LAW GROUP
10	David Aman, OR Bar No. 962106
11	AMAN LAW, LLC Attorneys for Defendants Chol Pak and Blue Tree Candy, LLC
12	natasha@kanglaw.net david@amanlawpdx.com
13	
14	
15	Kevin Clonts, WSBA No. 45900
16	RIZZO MATTINGLY BOSWORTH Attorneys for Defendants GAIA Ethnobatanical, LLC
17	kclonts@rizzopc.com
18	
19	Hilary A. Boyd, WSBA No. 38821 DAVIS ROTHWELL EARLE & XOCHIHUA, P.C.
20	Attorneys for Defendants Young's J.K., Inc. hboyd@davisrothwell.com
21	asaak@davisrothwell.com
22	
23	
24	
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[PROPOSED] ORDER GRANTING PLAINTIFF'S MOTION FOR PARTIAL SUMMARY JUDGMENT - 5

MAGLIO CHRISTOPHER & TOALE LAW FIRM 1325 4th Avenue, Ste 1730

Seattle, WA 98101 Phone: (206) 487-7371

SUPERIOR COURT OF WASHINGTON FOR COWLITZ COUNTY

SYBIL COYNE, et al,

Plaintiffs,

No. 20-2-00874-08

And

WENDIANNE ROOK, et al,

Defendants.

ORDER ON SUMMARY
JUDGEMENT – MISBRANDED
DRUGS

This matter having come on before the undersigned Judge of the above Court November 10, 2022 upon Plaintiff Coyne's Motion for Summary Judgment.

The Court has reviewed various documents filed regarding this motion noted below, as well as the arguments of counsel. The Court has also reviewed cited cases and statutes in order to assess Plaintiff's motion. Specifically, the Court has reviewed:

- 1. Plaintiff Coyne's MSJ and supporting declarations,
- 2. Defendant Society's Response and attachments,
- 3. Plaintiff Coyne's Reply filings.

ORDER ON SUMMARY JUDGEMENT MISBRANDED DRUG Page 1 of 6

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Discussion

Plaintiffs motion for summary judgement Re: Misbranded Drugs seeks a ruling on 4 discrete points as it relates to the claims against defendant Society for violation of certain regulatory and industry standards by its selling of Kratom.

Plaintiff seeks findings by the Court that Defendant's activities are by law:

- 1. Negligent violation of standards of care without justification.
- 2. Sale of a defective product without adequate warnings.
- 3. Sale of an unmerchantable product not fit for its intended purpose.
- 4. An unfair and deceptive act under the CPA.

It is of note, Kratom is legal to sell under Federal Law, and appears to be legal to sell in both Washington and Oregon. There have been no actions brought to the Court's attention as to actions against any of the defendants, either in Washington or Oregon by those states' respective state attorney's offices. The issue before the Court in this motion is whether Defendant Society's method of marketing substantiates any of the 4 findings above.

Portions of Plaintiffs motion do appear to have been previously addressed by this Court's earlier ruling on Plaintiff's March 3, 2022, summary judgement motion related to the FDA characterization of the sales of Kratom. There are subtle differences, however Plaintiff had requested the Court make very similar findings as requested in the instant motion, utilizing at least some of the same declarations here as there.

The Court previously found there was a difference of opinion by the experts as to whether this product fell under the Pre-Market NDI requirements, and further denied Plaintiff's request to find the sale of Kratom was negligence per se under either the Products Liability Act or the Consumer Protection Act.

The Court has further previously found the cause of death was a material fact in dispute based on the various expert opinions¹. The order denying summary judgement agreed to by the parties and entered by the Court did not include significant findings, other than the Court denied Plaintiff's motion.

Plaintiff further argues she is not seeking the Court to rule regarding proximate cause², which the Court has previously determined the cause of death was a material fact in dispute³. This motion appears to be simply one of trying to establish negligence, without any attachment of proximate cause.

The Court reviewed defendant's internet marketing materials provided by Plaintiff, as well as deposition testimony by Wendy Rook and others. Society seems to be similarly similar to the factual patterns espoused in the various "warning letters" and "debarment notices" included with Plaintiff's Motion. Warning letters appear to be an informal and advisory agency action as opposed to a final agency action⁵.

It seems beyond question that Society presented marketing materials through its website promoting the use of Kratom to address a variety of medical or psychological maladies. There is no evidence those claims were made on the packaging or the retail displays. There is also no evidence that the deceased ever visited Society's website, viewed Defendant W. Rook's e-book, or in any other way received communication from Society as to the purported benefits of Kratom. The only evidence before the Court is the decedent learned of the substance from a co-

¹ It should be noted that prior orders prepared by counsel did not fully set forth the Courts findings regarding proximate cause, and various other findings. The Court denied Plaintiff's motion outright..

² Plaintiff's reply, page 2, number 1.

It should be noted that prior orders prepared by counsel did not fully set forth the Courts findings regarding proximate cause, and various other findings.
 Debarment appears from 21 U.S.C. § 335a to be related to activities somewhat different than present in

the instant case, i.e. Importing or interfering with new drug applications.

⁵ FDA Regulatory Procedures Manual, chapter 4, June 2022, revision 11, page 4.

worker. The marketing efforts of Society seem disconnected to the decedent's actual use of or his decision to use Kratom.

Defendant Wendy Rook takes the position in her deposition Society's Kratom products are not drugs, nor are they supplements. They are specifically marketed as "not for human consumption." It seems to be self-evident that a product that is advertised to address a physical or emotional ailment is most likely a drug or a supplement. To promote the health benefits of a substance that can only have any effect if ingested in some manner as "not for human consumption" makes no logical sense. It is unclear in the motion whether the "not for human consumption" claim was being made at the time of the decedent's use or was ever relayed to him in any format.

There are notable differences between the packaging provided under the Cowgill declaration exhibits C and D. Exhibit D contains a new disclaimer that "This Product has not been evaluated by the FDA and is not intended to treat, prevent, cure or diagnose any illness." That package also directs a purchaser to consult with a doctor for other drug interactions. This would indicate Society, at the time it changed labeling, was considering its Kratom products a supplement as opposed to a drug, at least by the time that packaging came into use⁶. The one package found with the deceased did not contain the disclaimer, though no claims are made anywhere on the package as to benefits of the product. All references are to the Society website.

The undisputed facts before the Court on this motion is that Society marketed Kratom and espoused certain health benefits from its use only via their website. The labels on at least some of the product in Patrick Coyne's possession contained no references to the supplement disclaimer. Wendy Rook's e-book delineates several use cases, instructions for how to prepare and ingest the

⁶ The only information before the Court is the label change was made prior to Mr. Coyne's death. The language used is mandated language for supplements. 21 USC 1(B) section 101.93

product. Chapter 5 of the book clearly states Kratom is illegal in several states but defends Kratom as a product in a fight with "big pharma". Chapter 6 seems to make claims not backed up by any research or even anecdotal findings. The claims <u>may</u> be factual, but there is no factual basis cited for the statements the court can find in the materials, and taken as a whole, the statements tend to minimize the potential dangers of Kratom. Furthermore, Society is marketing a product that certainly appears to be ingested and no compliant labeling is included.

Plaintiff states she is not seeking to have a ruling regarding proximate cause⁷, as the Court has previously ruled it was a material fact for the finder of fact to determine.

In the instant motion, Plaintiff asks for a finding of negligence per se based on the theory of violation of "standards", sale of a defective product, and sale of an unmerchantable product.⁸ Before making such findings, the finder of fact needs to determine whether Kratom as marketed is a drug, supplement, or something else. That seems to be a material question of fact. On the facts presented it is a material fact for the trier of fact to determine if Kratom, <u>as marketed by Society</u> is a <u>drug</u> or a <u>supplement</u>. This is a material fact which is not clear, and the Court cannot make that determination on the evidence presented.

For the Court to find negligence the undisputed facts need to establish Society failed to exercise the standard of care that a reasonably prudent person would have exercised in a similar situation⁹. The Court finds the labeling under any determination of the finder of fact was deficient as it relates to the decedent. As such, Society is negligent as to the labeling of its products.

It is up to a finder of fact to determine whether this finding substantiates the other theories under which plaintiff requests relief. This is not a specific finding or

⁷ Plaintiff's reply, page 2, number 1.

⁸ Plaintiff's motion caption references misbranded drugs, not the requested relief.

⁹ Black's Law Dictionary, 9th Edition, page 1133,

standards of care without justification. It is not a finding the product is defective.

The evidence presented the court by the parties does not support a finding Kratom is unmerchantable, nor is it a determination of proximate cause. These are all proper determinations for the finder of fact.

There is no evidence before the Court that the deceased ever viewed any of Society's marketing materials outside of the individual packaging. The Court's finding on this motion Society's marketing its products without proper labeling was negligent does not dictate a finding of proximate cause for Plaintiff's claimed injuries, nor is it a finding that Kratom is a "defective product". One does not follow the other.

To the extent the Court has found negligence, not necessarily under the specific theories itemized above, the Court will grant a limited order of Summary Judgment.

The proposed orders provided by counsel do not include appropriate findings, and do not adequately espouse the Court's decision. The parties should prepare an order, which either incorporates the findings in this order, or which incorporates this decision by reference for the Court to sign.

Dated this 20 day of January, 2023.

Judge Gary Bashor