



**TOOMEY
V.
ALAMEDA**

**2023-2024
MOCK TRIAL**



**INDIANA BAR
FOUNDATION**

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Indiana Bar Foundation

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Civility

Rule 1.3 from the Indiana High School Mock Trial Rules of Competition

The Indiana Rules of Professional Conduct, which are adopted by the Indiana Supreme Court, govern the conduct of all Indiana attorneys. The Preamble to the Rules reads, in part:

- A lawyer, as a member of the legal profession, is a representative of clients, an officer of the legal system and a public citizen having special responsibility for the quality of justice. Whether or not engaging in the practice of law, lawyers should conduct themselves honorably.
- A lawyer should use the law's procedures only for legitimate purposes and not to harass or intimidate others. A lawyer should demonstrate respect for the legal system and for those who serve it, including judges, other lawyers and public officials.
- In addition, a lawyer should further the public's understanding of and confidence in the rule of law and the justice system because legal institutions in a constitutional democracy depend on popular participation and support to maintain their authority.

Specific provisions of the Indiana Rules of Professional Conduct require an attorney to: avoid offensive tactics and treat all persons involved in the legal process with courtesy and consideration [Rule 1.3]; not use means that have no substantial purpose other than to embarrass, delay, or burden a third person [Rule 4.4(a)]; and avoid conduct involving dishonesty, fraud, deceit, or misrepresentation or conduct that is prejudicial to the administration of justice [Rule 8.4(c) and (d)].

All participants in the Indiana Mock Trial Program should strive to follow these principles of civility while representing the interests of their clients and can expect the scoring jurists to be favorably impressed as a result. The failure to maintain civility should be expected to have a negative impact on the scoring jurists.

It will usually be more effective for a witness to respond courteously to the attorneys' questions, not to interrupt the attorney, and to wait while an attorney interposes an objection to the question just put to the witness. It is never a good idea, no matter how disorderly the character being portrayed, for a witness to show disrespect to the court.

As for the attorneys, not only is civility expected, it can be surprisingly effective. Being civil does not mean being a push-over. Stridency often distracts from the inherent forcefulness of the argument being made. Cross-examination does not have to be badgering to be thorough and effective to the point where the witness's testimony is completely discredited; indeed, a badgering tone may only engender sympathy for the witness.

It is expected that students, advisors, coaches, administrators, and parents will, at all times, inside and outside the courtroom, online and in real life, model civil behavior towards and respect for the court, the Indiana Bar Foundation volunteers, and members and supporters of other teams.

Blake Toomey v. Alameda

CASE BACKGROUND:

Note: The case background is for informational purposes only. It is of no legal significance and is used for convenience only. It is not admissible for impeachment or any other purpose.

Is it over the counter or just over the top? Blake Toomey immigrated to the United States in 1946, following their spouse home post-WWII. Having lived through the London Blitz, Blake has proven to be made of sterner stuff, and has made the most out of their 97 years of age.

During their long life, Blake has gotten to enjoy their passion for food. Though this passion has come at the cost of heartburn. When they saw an advertisement for a new medicine that would seemingly eliminate this issue. They were incredibly relieved to find that Bikwell, a medication made by Alameda, brought relief.

Blake began to take Bikwell frequently thereafter, using it to be able to continue eating the best, or in some cases the worst, food they could find.

While watching some of their favorite TV programs, Blake noticed that their legs were more energetic than usual. This restlessness turned out to be restless leg syndrome, which Blake is alleging was caused by their use of Bikwell.

Alameda takes their reputation and care of their consumers very seriously and are denying the linkage of Bikwell to restless leg syndrome. They have sent Jadon Wong to represent their company in this case.

On top of this is a family drama, two of Blake's family, Angel Jones and Kendall Ramirez, are witnesses in this case. While Angel is choosing to support their parent in this case, Kendall is skeptical of the validity of the claims.

STIPULATIONS:

1. This case is a work of fiction. Any references to dates, people, items, etc. is purely for the purpose of creating the mock trial case. No student should conduct outside research to determine if any date, person, item, etc. is actual or matches any date, person, item in real life.
2. This case takes place in a world where COVID-19 did not and does not exist. Any dates occurring where the COVID-19 pandemic has taken place should not reference or worry about COVID-19 restrictions.
3. All exhibits included in the case materials are authentic and accurate. No objections to the authenticity of exhibits will be honored.
4. All witness statements are written statements of fact voluntarily made by the affiant under an oath or affirmation which is administered by a person who is authorized to do so, under penalty of perjury. Each statement must be taken as true, accurate, and authentic by the witness.
5. All characters who are eligible to be called as witnesses at the trial are to be written in this case as gender neutral. The occurrence of gender specific pronouns referring to one of the witnesses is accidental and should be treated as gender neutral.

Witnesses:

The following witnesses are available to be called by the parties. Prosecution witnesses may not testify or be called on behalf of the defendant. Defense witnesses may not testify or be called on behalf of the prosecution. Each side must call all three of their witnesses.

For Blake Toomey (Plaintiff):

- Blake Toomey (Plaintiff)
- Angel Jones¹ (Child of Plaintiff)
- Dr. Logan Earnhardt (PharmFresh CEO)

For Alameda (Defense):

- Kendall Ramirez (Child of Plaintiff)
- Jadon Wong (Alameda Representative)
- Dr. Aaron/Erin Parker (Sleep Medicine Physician)

Exhibits

Teams in competition may use the following exhibits.

1. Curriculum Vitae for Dr. Logan Earnhardt
2. Curriculum Vitae for Dr. Aaron/Erin Parker
3. Box for Bikwell front and back.
4. Screenshot taken from Bikwell commercial.

¹ Changed via Q&A 1

STATE OF INDIANA) IN THE TIPPECANOE SUPERIOR COURT
) CIVIL DIVISION
COUNTY OF TIPPECANOE) CAUSE NUMBER:

BLAKE TOOMEY,)
)
Plaintiff,)
)
vs.)
)
ALAMEDA LLC,)
)
)
Defendant.)

COMPLAINT

Plaintiff, Blake Toomey (hereinafter “Toomey”), for the Complaint for damages against Defendant Alameda LLC (hereinafter “Alameda”) states as follows:

INTRODUCTION

1. The Plaintiff seeks money damages against Defendant for violation of rights as guaranteed under the United States Constitution, Indiana State Constitution, Indiana common law, and/or state or federal statutes.

JURISDICTION, VENUE, AND APPLICABLE LAW

2. Jurisdiction and venue in this Court are proper because a substantial portion of the events or omissions giving rise to this Complaint occurred in Tippecanoe County, Indiana.
3. The Indiana Products Liability Act (IPLA), included within Indiana Code Section 34-20-1-1, applies to all cases brought by a user or consumer against a manufacturer or seller for physical harm caused by a product regardless of the legal theory upon which the action is brought. See *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.2d 953, 956 (Ind. 2018).

4. Under the IPLA, a product can be defective if it is defectively designed, if it has a manufacturing flaw, or if it lacks adequate warnings or instructions. *Brewer v. PACCAR, Inc.*, 124 N.E.2d 616, 621 (Ind. 2019).
5. A product is not defective if an injury occurs due to handling, preparation for use, or consumption that is not reasonably expectable. Ind. Code Section 34-20-4-3.

PARTIES

6. Toomey resides in Tippecanoe County, Indiana.
7. Alameda LLC is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Alameda developed and manufactures the drug Bikwell in its manufacturing facility in Indianapolis.

FACTUAL BACKGROUND

8. Toomey immigrated to the United States in 1946, following their spouse home after World War II.
9. Having lived in London during ominous times and through the London Blitz, Blake has proven to be made of sterner stuff, and has made the most out of their nine decades on this planet.
10. During their long life, Blake has gotten to enjoy her passion of food.
11. The enjoyment of food has come at a cost through bouts with heartburn.
12. Toomey saw an advertisement on television by Alameda for the miracle drug Bikwell that would seemingly eliminate the bouts with heartburn.
13. They were incredibly relieved to find that Bikwell, made by Alameda, brought the relief for heartburn they were looking for.
14. Toomey went to their regular physician and discussed their heartburn issue and the possibility of taking Bikwell.
15. Toomey discussed Bikwell with their physician and the medicine was given with the physician's recommendation.
16. In such an advanced age, Toomey went home and studied the bottle and the insert provided on the box that outlined the side effects of the drug.
17. Toomey began to take Bikwell thereafter, using it to be able to continue eating the best, or in some cases the worst, food they could find.
18. Nearly immediately after taking the drug, Toomey was watching some of their favorite TV and noticed that their legs were more restless than usual.
19. Toomey returned to the physician and was diagnosed with restless leg syndrome.

COUNT I: Negligence

20. Plaintiff incorporates by reference all allegations of the foregoing paragraphs as though set forth herein.
21. Alameda owed Toomey a duty. Specifically, Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of their drug Bikwell, which Alameda introduced into the stream of commerce, including a duty that consumers would not suffer from unreasonable, dangerous, or untoward adverse side effects.

22. Alameda breached that duty by allowing their conduct or inaction to fall below the standard of care that they owed to Toomey.
23. Alameda failed to include a precaution against the consumer acquiring restless leg syndrome.
24. Alameda failed to disclose to the medical community the risk of acquiring restless leg syndrome if consumed.
25. Alameda's breach of that duty proximately caused compensable injury to Toomey.

COUNT II: Failure to Warn

Plaintiff incorporates by reference all allegations of the foregoing paragraphs as though set forth herein.

26. Plaintiff is the class of persons that the Defendant should reasonably foresee as being subject to the harm caused by defectively designed medicine so far as Plaintiff was the type of person for whom the medicine was intended to be used.
27. Defendant was engaged in the business of selling the products, manufactured, and supplied medication and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceed the benefits associated with the design and/or formulation of the product.
28. Alameda as a drug manufacturer failed to provide an adequate warning of the possible side effects.
29. The inadequate warning was a direct cause of Toomey's injuries.

REQUESTED RELIEF

30. Plaintiff respectfully requests:
 - a. Damages including compensatory damages;
 - b. Pre- and post-judgment interest on all amounts that are recovered;
 - c. All appropriate injunctive relief;
 - d. The costs and attorneys' fees incurred in the prosecution of this action; and
 - e. All just and proper relief.

DEMAND FOR A JURY TRIAL

31. Plaintiff demands a jury trial pursuant to the Seventh Amendment of the United States and Article 1, Section 20 of the Indiana Constitution for all claims.

Respectfully Submitted,

Counsel for Blake Toomey
230 East Ohio Street, Suite 600
Indianapolis, Indiana 46204

STATE OF INDIANA) IN THE TIPPECANOE SUPERIOR COURT
) CIVIL DIVISION
COUNTY OF TIPPECANOE) CAUSE NUMBER:

)
BLAKE TOOMEY,)
)
Plaintiff,)
)
vs.)
)
)
ALAMEDA LLC,)
)
)
Defendant.)

ANSWER TO COMPLAINT

Plaintiff, Blake Toomey (hereinafter “Toomey”), for the Complaint for damages against Defendant Alameda LLC (hereinafter “Alameda”) states as follows:

INTRODUCTION

1. The Plaintiff seeks money damages against Defendant for violation of rights as guaranteed under the United States Constitution, Indiana State Constitution, Indiana common law, and/or state or federal statutes.
 - a. Defendant denies that Plaintiff is entitled to any relief whatsoever.

JURISDICTION, VENUE, AND APPLICABLE LAW

2. Jurisdiction and venue in this Court are proper because a substantial portion of the events or omissions giving rise to this Complaint occurred in Tippecanoe County, Indiana.
 - a. Admitted.
3. The Indiana Products Liability Act (IPLA), included within Indiana Code Section 34-20-1-1, applies to all cases brought by a user or consumer against a manufacturer or seller for physical harm caused by a product regardless of the legal theory upon which the action is

brought. See *Campbell Hausfeld/Scott Fetzer Co. v. Johnson*, 109 N.E.2d 953, 956 (Ind. 2018).

- a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
4. Under the IPLA, a product can be defective if it is defectively designed, if it has a manufacturing flaw, or if it lacks adequate warnings or instructions. *Brewer v. PACCAR, Inc.*, 124 N.E.2d 616, 621 (Ind. 2019).
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
5. A product is not defective if an injury occurs due to handling, preparation for use, or consumption that is not reasonably expectable. Ind. Code Section 34-20-4-3.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

PARTIES

6. Toomey resides in Tippecanoe County, Indiana.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
7. Alameda LLC is an Indiana limited liability company with its principal place of business in Indianapolis, Indiana. Alameda developed and manufactures the drug Bikwell in its manufacturing facility in Indianapolis.
 - a. Admitted.

FACTUAL BACKGROUND

8. Toomey immigrated to the United States in 1946, following their spouse home after World War II.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
9. Having lived in London during ominous times and through the London Blitz, Blake has proven to be made of sterner stuff, and has made the most out of their nine decades on this planet.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
10. During their long life, Blake has gotten to enjoy her passion of food.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
11. The enjoyment of food has come at a cost through bouts with heartburn.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
12. Toomey saw an advertisement on television by Alameda for the miracle drug Bikwell on that would seemingly eliminate the bouts with heartburn.
 - a. Denied in part and admitted in part. Defendant admits that it advertises Bikwell on television. As to the remainder facts, Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

13. They were incredibly relieved to find that Bikwell, made by Alameda, brought the relief for heartburn they were looking for.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
14. Toomey went to their regular physician and discussed their heartburn issue and the possibility of taking Bikwell.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
15. Toomey discussed Bikwell with their physician and the medicine was the physician's recommendation.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
16. In such an advanced age, Toomey went home and studied the bottle and the insert provided on the box that outlined the side effects of the drug.
 - a. Denied in part and admitted in part. Defendant admits that Bikwell complies with federal and state law by including warnings and inserts that outlines the potential dangers and side effects of the drug. As to the remainder facts, Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
17. Toomey began to take Bikwell thereafter, using it to be able to continue eating the best, or in some cases the worst, food they could find.
 - a. Denied in part and admitted in part. Denied. Defendant admits that it advertises Bikwell on television. As to the remainder facts, Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
18. Nearly immediately after taking the drug, Toomey was watching some of their favorite TV and noticed that their legs were more restless than usual.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
19. Toomey returned to the physician and was diagnosed with restless leg syndrome.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

COUNT I: Negligence

20. Plaintiff incorporates by reference all allegations of the foregoing paragraphs as though set forth herein.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
21. Alameda owed Toomey a duty. Specifically, Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion, and sale of their drug Bikwell, which Alameda introduced into the stream of commerce, including a duty that consumers would not suffer from unreasonable, dangerous, or untoward adverse side effects.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

22. Alameda breached that duty by allowing their conduct or inaction to fall below the standard of care that they owed to Toomey.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
23. Alameda failed to include a precaution against the consumer acquiring restless leg syndrome.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
24. Alameda failed to disclose to the medical community the risk of acquiring restless leg syndrome if consumed.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
25. Alameda's breach of that duty proximately caused compensable injury to Toomey.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

COUNT II: Failure to Warn

Plaintiff incorporates by reference all allegations of the foregoing paragraphs as though set forth herein.

26. Plaintiff is the class of persons that the Defendant should reasonably foresee as being subject to the harm caused by defectively designed medicine so far as Plaintiff was the type of person for whom the medicine was intended to be used.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.²
27. Defendant was engaged in the business of selling the products, manufactured, and supplied medication and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceed the benefits associated with the design and/or formulation of the product.
 - a. Defendant admits to being engaged in the business of selling products. Defendant denies remaining allegations in this paragraph.
28. Alameda as a drug manufacturer failed to provide an adequate warning of the possible side effects.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.
29. The inadequate warning was a direct cause of Toomey's injuries.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

REQUESTED RELIEF

30. Plaintiff respectfully requests:
 - a. Damages including compensatory damages;
 - b. Pre- and post-judgment interest on all amounts that are recovered;
 - c. All appropriate injunctive relief;
 - d. The costs and attorneys' fees incurred in the prosecution of this action; and
 - e. All just and proper relief.

² Changed per Q&A 2 #23

Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

DEMAND FOR A JURY TRIAL

31. Plaintiff demands a jury trial pursuant to the Seventh Amendment of the United States and Article 1, Section 20 of the Indiana Constitution for all claims.
 - a. Denied. Defendant is without sufficient knowledge to form a belief as to the allegations contained in this paragraph, and therefore they are denied.

AFFIRMATIVE AND OTHER DEFENSES

1. The complaint fails to state any claim upon which relief may be granted.
2. Upon information and belief, Plaintiff's claim are barred in part or in whole by the doctrines of waiver or estoppel.
3. Upon information and belief, Plaintiff's claims are barred by the Plaintiff's failure to take reasonable steps to mitigate their claims of damages to the extent that any exist.
4. Plaintiff is not entitled to damages because Defendant made good faith efforts to comply with all applicable laws. See I.C. 34-20-5-1.
5. Defendant is entitled to relief because Plaintiff altered, modified, or misused the product in a manner that was not reasonably expected. I.C. 34-20-6-4 and/or I.C. 34-20-6-5.
6. Defendant's product was in conformity with generally recognized state of art regarding safety of the product and it complied with all applicable codes, standards, regulations or specifications set forth by the United States or Indiana. See I.C. 34-20-5-1.
7. Defendant properly packaged and labeled Bikwell and gave reasonably complete instructions on its proper use and appropriate warnings. See I.C. 34-20-4-2.
8. Defendant asserts that any alleged damage was the fault of the Plaintiff or the fault of others other than the Defendant who caused or contributed to cause the harm. See I.C. 34-51-2-7, I.C.

Respectfully Submitted,

/s/ Counsel

Counsel for Alameda LLC

111 Monument Circle

Indianapolis, Indiana 46204

Indiana Code:

Note: Indiana Code is provided to assist teams in devising their legal strategies. The parties must accurately prepare its case to meet the legal requirements of the claims raised by a preponderance of the evidence.

Indiana code is the law as written by the legislature. For the purposes of Indiana Mock Trial, the trier of fact is a jury.

Indiana code is not an exhibit.

IC 34-20-2-1 Grounds for action

Sec. 1. Except as provided in section 3 of this chapter, a person who sells, leases, or otherwise puts into the stream of commerce any product in a defective condition unreasonably dangerous to any user or consumer or to the user's or consumer's property is subject to liability for physical harm caused by that product to the user or consumer or to the user's or consumer's property if:

- (1) that user or consumer is in the class of persons that the seller should reasonably foresee as being subject to the harm caused by the defective condition;
- (2) the seller is engaged in the business of selling the product; and
- (3) the product is expected to and does reach the user or consumer without substantial alteration in the condition in which the product is sold by the person sought to be held liable under this article.

IC 34-20-4-1 Products considered defective

Sec. 1. A product is in a defective condition under this article if, at the time it is conveyed by the seller to another party, it is in a condition:

- (1) not contemplated by reasonable persons among those considered expected users or consumers of the product; and
- (2) that will be unreasonably dangerous to the expected user or consumer when used in reasonably expectable ways of handling or consumption.

IC 34-20-4-2 Failure to provide adequate warnings or instructions

Sec. 2. A product is defective under this article if the seller fails to:

- (1) properly package or label the product to give reasonable warnings of danger about the product; or
- (2) give reasonably complete instructions on proper use of the product; when the seller, by exercising reasonable diligence, could have made such warnings or instructions available to the user or consumer.

IC 34-20-5-1 Rebuttable presumption

Sec. 1. In a product liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product:

- (1) was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled; or

(2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

IC 34-20-6-4 Misuse of product

Sec. 4. It is a defense to an action under this article that a cause of the physical harm is a misuse of the product by the claimant or any other person not reasonably expected by the seller at the time the seller sold or otherwise conveyed the product to another party.

IC 34-20-6-5 Modification or alteration of product

Sec. 5. It is a defense to an action under this article that a cause of the physical harm is a modification or alteration of the product made by any person after the product's delivery to the initial user or consumer if the modification or alteration is the proximate cause of physical harm where the modification or alteration is not reasonably expectable to the seller.

IC 34-51-2-7 Jury Instructions; single party defendant

Sec. 7. (a) This section applies to an action based on fault that is:

- (1) brought against one (1) defendant or two (2) or more defendants who may be treated as a single party; and
- (2) tried to a jury.

(b) The court, unless all the parties agree otherwise, shall instruct the jury to determine its verdict in the following manner:

(1) The jury shall determine the percentage of fault of the claimant, of the defendant, and of any person who is a nonparty. The jury may not be informed of any immunity defense that is available to a nonparty. In assessing percentage of fault, the jury shall consider the fault of all persons who caused or contributed to cause the alleged injury, death, or damage to property, tangible or intangible, regardless of whether the person was or could have been named as a party. The percentage of fault of parties to the action may total less than one hundred percent (100%) if the jury finds that fault contributing to cause the claimant's loss has also come from a nonparty or nonparties.

(2) If the percentage of fault of the claimant is greater than fifty percent (50%) of the total fault involved in the incident which caused the claimant's death, injury, or property damage, the jury shall return a verdict for the defendant and no further deliberation of the jury is required.

(3) If the percentage of fault of the claimant is not greater than fifty percent (50%) of the total fault, the jury then shall determine the total amount of damages the claimant would be entitled to recover if contributory fault were disregarded.

1 **STATEMENT OF BLAKE TOOMEY**

2 My name is Blake Toomey. I live at 1786 Bleecker Street, Birdseye, Indiana – in the
3 same house that my spouse and I purchased back in 1946, when I was twenty years old. The two
4 of us could afford the whole thing on the GI Bill back then, believe it or not. The house was
5 small at first and, after the first two kids arrived, we felt a bit trapped. We almost moved uptown.
6 But I convinced my spouse Mel to add on a few more rooms and to finish the basement. We
7 raised four kids in that house: Angel, Kendall, Paul, and Terry. And then they went on to have
8 eight grandkids. If you can't tell, our holiday gatherings are packed. Maybe to protest this
9 biological anomaly, Mel and I decided in our sixties to become foster parents to some at-risk
10 teens. That was challenging, but one of the best things I've ever done. My home has been loud
11 and full every Christmas.

12 In case you didn't want to do the arithmetic, I'll do it for you: I'm 97. Mel passed away
13 16 years ago, at the age of 81. The two of us were members of what some (including myself) call
14 "The Greatest Generation." I actually grew up in London. I remember having to go down into the
15 tube to take shelter when the bombs went off in the Blitz. I never did see one of those "Keep
16 Calm and Carry On" posters that the British government commissioned, but that poster captures
17 how we all felt back then. I actually think that poster reflects one of the biggest societal changes
18 I've noticed in my 97 years on this earth. Back then, the Germans literally dropped bombs on top
19 of us, and what was our response? We heard the sirens, we went down into the tube, we waited
20 as the bombs fell, and then we came back up. We didn't cry about it, but we dealt with it and
21 rallied as a country. I guess by today's standards, the psychotherapists would say we suppressed
22 our trauma. But I think today we've all overcorrected: kids nowadays can't get so much as a
23 splinter without posting about it on TikChat or Tokgram or whatever the kids are on, using the

24 pain as a conduit for attention. And the neighborhood kids keep running across my lawn!
25 Seriously, I wish they would get off my lawn!

26 Mel was doing a tour overseas and that's how we met. I was a British citizen living in
27 London at the time. I first saw Mel at The Bell pub near the Petticoat Lane Market. I don't
28 believe in love at first sight, and rest assured, it took Mel multiple trips back to the pub to woo
29 me – basically every time they had off from the base, Mel would come searching for me. I
30 eventually fell for Mel's quick wit. Mel wrote me plenty of letters over the years. All those
31 letters lie in a little basket to the right of our bed now, where I can pull them out and read them
32 before falling asleep each night. We had a great life together. I miss Mel dearly. The two of us
33 will reunite soon, I expect.

34 Let's turn to a happier topic: food. For all my life, I've loved to eat and have enjoyed
35 foods from across the world. There's no way around it. Food is just a part of what gives life joy.
36 Especially after Mel passed, I used it as a way to remember them. I can go to any of our old
37 mainstays - Archie Moore's on Willow Street, Nica's on Orange Street, or Mo's on Boo Lane -
38 and order the meals we'd always enjoyed together. But when it comes to food, it's my
39 fascination.

40 My food consumption hasn't been without its issues, though. As far back as I can
41 remember – maybe as early as my 30s – I have had heartburn and indigestion. I suffered through
42 it most of my life (the food was worth it). But then I saw an advertisement for Bikwell in March
43 2019. I still remember the commercial: a happy man was at a baseball game, wearing a baseball
44 hat and one of those silly foam fingers. He smiles as he enjoys a hot dog and a beer and some
45 peanuts and then – WHAM! – his smile turns into a grimace as he grabs his stomach. “Don't
46 worry” says his friend sitting next to him, “Try this – my doctor just recommended it to me! It's

47 called Bikwell.” The man takes a little circular white pill from his friend and swallows it. Almost
48 instantly, he smiles again, as if he just swallowed an ice cube to squelch his stomach’s fire. “Ask
49 your doctor about Bikwell” the ad ends.

50 Well, I did exactly that. I asked Dr. Jackson (my Primary Care Physician) as soon as I
51 could get in their clinic. She said it was new, but worth a shot. This wasn’t the first medication I
52 brought up to her. I don’t recall her ever saying no to writing a prescription for a drug that I
53 indicated would be helpful to me. She offered to give me some at that moment as she had some
54 samples that were given to her by a sales rep, but I turned it down. I had heard Bikwell was
55 available over the counter. I won’t bore you with the details, but it’s almost always cheaper to
56 purchase drugs over the counter, under my health plan. Anytime thereafter, though, whenever I
57 would go see Dr. Jackson for a check-up, I’d let her (or the nurse) know that I was taking
58 Bikwell. They’d ask me what medications I was on, and I’d rattle off the list. I would let them
59 know I was consistently taking Bikwell though. You reach my age, and it takes a while to get
60 through the list. If Bikwell’s not in my medical record, I assure you that it is due to an error on
61 Dr. Jackson’s part, not mine!

62 Before I started taking the drug, I read the box and the insert that outlined the side effects
63 and the warnings. I read the label and the insert all the way through. I don’t recall any warnings
64 about restless leg syndrome. However, I do recall reading something about potential muscle
65 spasms. The warnings also indicated that if you were an advanced age, you should seek a
66 physician’s opinion before taking. The warnings also included plenty of other legal mumbo
67 jumbo, but I can’t remember it all.

68 Between March 2019 and the Bikwell market withdrawal, I’d say I took a pill of Bikwell
69 once a day on average (sometimes twice a day or more, if I ate something spicy, like Italian

70 meatballs). I bought it at the local pharmacy where one of my foster kids, Beau, works as a
71 cashier. Beau would check me out most of the time. I'd buy a Snickers on the way out, along
72 with a few scratch-offs. I love a good scratcher! Beau would often comment on the candy and
73 the medicine "Mom/Dad, you wouldn't need to take this stuff if you would just lay off the candy
74 a little. I love you, but think about your health!" I bought about one 40-count box of Bikwell pills
75 once a month. Beau can verify this! I was such a fool to throw away all of my empty Bikwell
76 bottles before I realized that those bottles would be important for a lawsuit.

77 I kept my Bikwell in two different places. First, I kept it in the cabinet by the stove in the
78 kitchen. That place is poorly ventilated, and it gets hot in there when someone is cooking. The
79 pills wouldn't disintegrate or anything or get so soft that they'd lose their form. But it definitely
80 was hot in there. And then the second place I kept the Bikwell was in my car glove box. That
81 way, if I was out to eat and had a heartburn attack, I was good to go. Every once in a while, I'd
82 wrap a Bikwell or two in some tinfoil and put them in my pocket (that way I wouldn't have to
83 carry a whole bottle around with me). But between the kitchen and the car, that'd be about 95%
84 of it, I think. It's just sickening to hear that I would have been better off keeping the pills in a
85 cool, dry place. If only the drug manufacturer (Alameda) had told me that!

86 Around a year ago, I was watching Matlock reruns on TV, laying on my couch, when I
87 experienced something I had never experienced before. My legs just felt antsy: I don't know how
88 else to put it. It felt like there was energy in them, but I couldn't get it out. Like an overcharged
89 battery. I stood up and shook my legs – one at a time – but that didn't seem to help. I paid it no
90 mind at the time (I am old - lots of things happen when you get old). But then it came back the
91 next day, when I was watching M*A*S*H, and the day after, when I was watching Trebek (RIP)
92 on Jeopardy. It seems like whenever I sit down or lay down to watch TV now, I get this

93 sensation in my legs. It makes it really hard to enjoy all the shows and television that I once
94 loved. I got into Doctor Jackson's the next day and was officially diagnosed with restless leg
95 syndrome.³ I know some people think that restless leg syndrome is made-up, or psychosomatic.
96 Trust me, I have plenty of illnesses in my old age: diabetes, high blood pressure, obesity, and
97 high cholesterol. Why would I feel the need to make this one up? It's awful.

98 I've heard Alameda is going to try to make it out that my smoking caused all this. But I
99 only ever smoked around five cigarettes a week, give or take a few, from the War to about ten
100 years ago. Again, if my medical record says otherwise, that's an error on Dr. Jackson's part, not
101 mine. I heard from a nurse that sometimes they just "copy/paste" the past medical history from
102 one appointment's notes to the next appointment's notes. So, all it would take is one error in the
103 medical record – one nurse mishearing a thing – to be copy/pasted forever.

104 One day I was watching Golden Girls, trying not to let the restless leg syndrome bother
105 me, and I saw an advertisement from a plaintiff's law firm. It told me that Bikwell had been
106 recalled from the market, that it had been linked to restless leg syndrome, and that I should call a
107 hotline to have my case represented. After Mel's passing, I wasn't eager to get involved in a
108 lawsuit, but, with Angel's encouragement, I ultimately decided to file. I'm 97 and I hope to hit
109 100, but, after that, I don't think I'll live much longer. And that's okay, I've lived a great life
110 and I am ready to go anytime. It would be nice to leave some money for my family – as well as
111 my foster kids, like Beau. And even now, it feels like my legs are going to short circuit. I wish
112 Alameda had warned me – if I'd known, I would have never taken Bikwell. This never happened
113 before I took that pill.

³ Changed via Q&A 1 #15

1 **STATEMENT OF ANGEL JONES**

2 My name is Angel Jones, and I am the child of Blake Toomey. I went to Indiana
3 University for a couple of years but never graduated. I was always more focused on working
4 than going to class and couldn't keep up with my studies. I never missed a good party though
5 and could tell you where and when the good ones were! I eventually found a great job at Kroger
6 and worked my way up from cashier all the way to my current position of being a store manager.
7 My parent, Blake Toomey was always very supportive of me, and I helped them out any time
8 they ever needed.

9 About 10 years ago, I was having a rough time financially and ended up moving back in
10 with my parent. It was supposed to be temporary, but I've been there ever since. We actually got
11 along really well and it's a good living arrangement most of the time. Now it is just Blake and
12 me. I help them as they're getting older, and the rent is super cheap! I'm able to spend more time
13 with Blake in the evenings and weekends and also keep an eye out since they're no spring
14 chicken at this point. Living with a parent was a bit of an adjustment at first but we settled in
15 okay. I've got an eye out for some changes that need to be made around the house, and we'll just
16 say my style and vision isn't exactly in line with current decorations.

17 Blake is still pretty spry for being that old, but I do help out a lot around the house. I've
18 noticed more and more that Blake seems to be forgetful and having a few "senior moments." I
19 cook a lot of our meals, and Blake loves to eat! Blake will eat almost anything, even the really
20 spicy food that I love. Do I think the spicy food was giving them indigestion? Maybe, but
21 whatever the cause they complained about it all the time! It was a complaint of theirs even before
22 I moved in too.

23 I think our family believes food is love. It opens new cultures and cuisines. It lets my
24 parents bring their home British culture and food to our American home. It allows us to mentally
25 travel to Japan or Mexico or Italy through food. Have you ever had a really good Pad Thai?
26 Takes me to what (I think) Bangkok would be like! It brings us together around the dinner table,
27 which I think has brought most of our family closer than if we didn't have that dedicated time to
28 be together over meals. I wouldn't say we are gluttonous with our food, but it does play a
29 prominent role in various aspects of our family culture.

30 Blake mentioned taking some pills for indigestion and it seemed to help for a while, but
31 the problem would always come back again sometime later. They had a little cabinet near the
32 stove with all of their meds, but I never looked specifically at what the pills were. I thought it
33 was a weird place to keep pills, but it was easy to get to. Blake told me one time what the pills
34 were and where they got them, but I was so involved in making my World Famous "Angel's
35 Diablo Chili" that I didn't pay much attention. If I don't get my spice measurements exactly right
36 the whole thing would be ruined. That particular recipe includes the famous Carolina Reaper,
37 which you have to be careful with. Can you even imagine, mistaking $\frac{1}{4}$ teaspoon with $\frac{1}{2}$
38 teaspoon because of some inane thing like the name of some pills your parent is rambling on
39 about? I didn't really feel the need to ask more questions after I was done either, since it was
40 honestly so exhausting hearing them complain about my spicy food. I do very clearly remember
41 whenever Blake would make comments about the food being too spicy, they would go and take a
42 pill with a glass of room temperature water. The only thing I ever grabbed out of there was
43 ibuprofen for the headache the complaining would give me.

44 I was more concerned with Blake being a little unhealthy and told them to eat less and
45 exercise more, but I'm not a doctor. I was concerned though since Blake was never a particularly

46 active parent. When we were younger some families would go to Holiday World, or Brown
47 County State Park, or see nature...we'd watch movies or go out to eat.

48 Don't get me wrong, I absolutely love my parent and wouldn't trade them for the world.
49 There are certain things though that we do disagree on. We've had a bunch of arguments over the
50 thermostat. I would come home from work, and it would be at 78 degrees! In the middle of the
51 summer in Indiana! I would always move it down to a much more reasonable 70. I think Blake
52 would turn it back up the second I left for work every day. Blake used to be a smoker, but quit
53 that a little while after I moved in. They must've smoked for about a decade! I'm not sure how
54 many cigarettes a day Blake smoked, but even one was something I wasn't going to put up with,
55 and that was a huge fight believe me.

56 Blake and I got to a point where everything was going well, and pretty routine and boring
57 for several months. Then, one night something strange started happening. I was awake
58 downstairs on my computer late at night doing an inventory report for my job when I heard a
59 creaking upstairs. I went to check on Blake and found them still awake. Blake said that their legs
60 just felt like they had ants in them, and they couldn't get to sleep. I told them to take a Tylenol
61 PM and go back to bed thinking it was just something minor. I finished my inventory report and
62 didn't think much of it. About a week later, Blake told me at dinner that they had trouble sleeping
63 for a couple days because of their legs. I don't know why but I just had this weird feeling about it
64 like something was seriously wrong. Blake said the feeling had gotten worse and it was like they
65 couldn't stop moving no matter what.

66 I told Blake they should get it checked out by a doctor, but I don't know if Blake actually
67 went or not. Blake's always tired now, and it has really affected their mood and attitude. We used
68 to get along very well and now Blake's just really snippy at me all the time. Blake told me that

69 they⁴ have restless leg syndrome and that they can't sleep because of it. I believe them,
70 considering how tired they look all the time every time I see them. Blake just hasn't been their
71 usual self because of Bikwell.

72 After dealing with this problem for so long, one day Blake seemed to have figured it out.
73 Blake told me at dinner that they saw one of those bad lawyer ads, like the ones from "Better
74 Call Saul," and said that they were talking about the drug that Blake had taken for indigestion for
75 all those years. I just laughed, and asked what Blake meant. Apparently, they saw a billboard
76 along the interstate that said something like "Restless Legs? We Won't Rest Until You Win." I
77 thought it was strange, and I had to wrack my brain but eventually remembered when Blake
78 would take a pill when we would eat spicy food. It made me upset at first, because I would hate
79 to think that my cooking made them take something that caused so much harm.

80 I know people might laugh at something like "restless leg syndrome" but it's real, and it
81 wasn't around until Blake started using Bikwell. I've seen how much Blake just isn't themselves
82 anymore because of it. The more I keep thinking about it and learning more, the more I get
83 angry at Alameda. How could they put something like this on the market and have people take
84 this flawed medicine? I'm now watching Blake suffer from lack of sleep, which is causing
85 irritability. It's just heart-wrenching.

⁴ Grammatical error corrected from previous version via Q&A#1

1 **STATEMENT OF DR. LOGAN EARNHARDT**

2 My name is Logan Earnhardt. I received a Doctor of Pharmacy degree from Purdue
3 University in 2012, and I have been working in the pharmaceutical industry ever since. I am
4 board certified by the American Board of Pharmacy. I have obtained specializations in
5 ambulatory pharmacy, nuclear pharmacy, and pharmacotherapy from the Board of Pharmacy
6 Specializations. While at Purdue, I did a year-long externship in Paris at Sanofi, the French drug
7 company. I spent most of my time working in a lab. Specifically, I was studying the interaction
8 between levodopa and dopamine decarboxylase inhibitor as a potential treatment for restless leg
9 syndrome.

10 I got a great early start and began working for the United States Food and Drug
11 Administration as a Consumer Safety Officer. I worked with the FDA for five years before
12 taking some time to focus on myself. My focus at the FDA was on drug safety, drug and device
13 development, regulatory, health outcomes research and health policy.

14 I spent a portion of my career at the FDA focused on labeling. The FDA requires that
15 drug labeling include a summary of essential scientific information needed for the safe and
16 effective use of the drug and includes the prescribing information. Labeling is critically
17 important and the primary tool for communicating drug information to healthcare professionals,
18 patients, and caregivers. Not a lot of people know, but there are different labels for different
19 groups. Prescribing information is labeling for healthcare professionals. Carton and container
20 labeling is primarily for patients. And there are also medication guides, package inserts, and
21 instructions that are also for the patient or caregiver. The FDA has a rigorous process that
22 reviews all prescription medicines and their associated labeling.

23 Labeling is important because prescription drugs go through extensive studies and tests.
24 Those instructions ensure that the drug is taken within the guidelines and parameters of the
25 testing so that the patient is safe. Essentially, if a drug is taken contrary to the instructions, it can
26 be unsafe.

27 A couple years into my time at the FDA, I had a slip up and ended up with a discipline
28 notice for an unintentional data leak. I owned up to the mistake and made the proper changes to
29 continue doing my job to the best of my ability. Even with that small bump in the road, by the
30 time that I left the FDA in 2019, to take time to really find myself, I had made it to a
31 management position.

32 I took some down time to figure out who I am and where I wanted to go next. I was
33 fortunate enough to be cast on the show Survivor. While I was on the island, I did some soul
34 searching and decided that I was frustrated by what I had seen in the pharmaceutical industry, I
35 wanted to follow my passion, and take a more holistic approach to Western medicine. I co-
36 founded a company called PharmFresh. The goal was to provide a fresh, innovative approach to
37 pharmacy oversight. I love owning a company. It gives me more time to pursue my hobbies, like
38 heliskiing, free climbing, and deep-sea diving.

39 PharmFresh provides regulatory program development and operational management for
40 drugs and devices. As its name would imply, PharmFresh is using fresh and novel techniques to
41 test pharmaceuticals that are already on the market. At PharmFresh, we take a holistic approach
42 to the study of medicine, but we don't ignore traditional science. We help develop safety and
43 efficacy programs in support of drug approval and post marketing surveillance. I like to think
44 we're "disruptors," but in a good way. The big guys don't always like a scrappy little company
45 pointing out a possible safety issue, but if we don't, who will? Here's what the FDA won't tell

46 you: when a drug gets approved, even with stringent testing, there's always going to be some
47 percentage of users who experience side-effects. We think that number should be zero! I have
48 provided expert testimony in seventeen product liability⁵ cases in the past ten years, providing
49 testimony on behalf of people who have been impacted by drugs that made them sick. Over the
50 course of this litigation, I have an hourly rate of \$800 per hour and have been paid \$25,000 USD
51 and an additional sum in bitcoin for consulting, my deposition testimony, and my testimony here
52 today.

53 One of the drugs that PharmFresh has studied is Bikwell, which people used to treat
54 indigestion. I have studied the drug extensively. Bikwell contains a particularly advanced
55 chemical compound and active ingredient, aluminum hydroxide magnesium hydroxide
56 ("AHMH") that could cause Willis-Ekbom disease, which is commonly known as restless leg
57 syndrome. Willis-Ekbom disease, as its nickname would suggest, is characterized by an
58 uncontrollable need to move one's legs. The condition causes great discomfort to those it affects.
59 It can disrupt sleep and interfere with a person's daily life activities. Though Willis-Ekbom
60 disease can appear at any age, it tends to worsen as a person gets older.

61 The three main factors in people with restless leg syndrome are 1) malfunctioning
62 dopamine-receptors, 2) poor iron metabolism, and 3) chronic/long-term inflammation. The
63 second and third factors are particularly susceptible to outside influence factors like diet,
64 supplements, and exercise.

65 In the case of Bikwell, the patient should not take iron supplements. Doing so would
66 dramatically impact the effectiveness of the drug and could cause serious side effects.
67 Any time we are looking at a drug, we take note of the label. The Bikwell label states as follows:

⁵ Grammatical error corrected from previous version via Q&A#1

68 Main ingredients: AHMH, sucrose, starch, Hydropropyl oxide, cellulose.

69 Warnings included:

- 70 • This medication may cause dizziness.
- 71 • Drug may impair ability to operate a vehicle, vessel or machine. Use with care.
- 72 • May cause dry cough. If cough persists, contact your physician.
- 73 • Do not use if allergic.
- 74 • Keep out of reach of children.
- 75 • If indigestion persists, contact your physician.
- 76 • Stop use and ask your doctor if (1) the condition worsens (2) symptoms last more than 48
- 77 hours, clear up and return or (3) an allergic reaction occurs.
- 78 • Take with water and food.
- 79 • This drug was not tested on lab animals.
- 80 • In some cases, misuse of Bikwell has been known to cause serious side effects, including
- 81 death, use only as directed.
- 82 • May cause muscle spasms.

83

84 The label lists the purpose of the drug as “treatment for mild to moderate indigestion.” For
85 adults and children ages thirteen years of age or older, the recommended dose of Bikwell is two
86 tablets every four to six hours until symptoms subside. A person should not take more than eight
87 tablets in a twenty-four hour period.

88 The warnings are also included at the end of a Bikwell commercial which shows a large,
89 purple caricature of a stomach called “Grumble Gut” fighting with a large package of Bikwell
90 until the grumbling subsides and the soothing theme music comes on. Screenshots of the
91 commercial are now frequently used in memes.

92 To study Bikwell, we followed two hundred individuals over the course of two years.

93 Patients were individuals ranging in age from twenty-one to seventy-five who regularly suffered
94 indigestion. Patients took the drug exclusively to treat their indigestion, and as part of the study,
95 they agreed to take no other drugs in their treatment. Patients were asked to track when they
96 suffered indigestion and report that they had taken the drug. Every six months, patients would
97 come to one of our state-of-the art testing facilities, where we would conduct a variety of tests.

98 At the conclusion of two years, we determined that patients who reported taking Bikwell more

99 than twelve times each month, showed that their body was not properly processing AHMH out of
100 their system. The lab's study found that the AHMH in Bikwell arose both endogenously (when it
101 metabolized in the human stomach) and exogenously (when Bikwell tablets were exposed to heat
102 and humidity).

103 During the course of the study, patients were asked to fill out a questionnaire about their
104 current medical conditions. We asked about everything from dermatological conditions—like
105 acne and psoriasis—to more serious life-threatening conditions. RLS was a condition listed on
106 the survey. Patients who had taken Bikwell more than twelve times per month experienced an
107 increased incidence of RLS.

108 Our lab is full-service, so in addition to conducting patient studies, we also test the drug
109 itself for unforeseen side effects, which includes seeing how certain conditions may impact it.
110 Our lives don't exist in a vacuum, when you're deep sea diving or heliskiing, you need to know
111 that your medications can hold up in the elements just like they would in a medicine cabinet. So,
112 we expose drugs to the harshest of the conditions and test—at our state-of-the-art facilities—to
113 determine if the drug is impacted by adverse conditions. I can't explain our process because it is
114 so new that it is still pending patent, but I can say this—if space travel is ever going to really take
115 off, we're going to need a whole new approach to medicine. When Bikwell was exposed to
116 temperatures above eighty five degrees or in areas where the humidity levels are over 70% for
117 more than five hours, the lab found increased levels of AHMH in Bikwell.

118 In my opinion, based on my education, expertise, and experience in the field, Blake
119 Toomey's repeated consumption of Bikwell is the cause of her RLS.

1 **STATEMENT OF KENDALL RAMIREZ**

2 My name is Kendall Ramierz, I'm a child of Blake Toomey. I don't know why Blake has
3 involved me in this mess. But Blake has really thrown me in it. I love Blake, but they can be high
4 maintenance and dramatic, especially when it comes to worrying about money and Blake's
5 image within the family.

6 Well, the attorneys who filed this lawsuit and the attorneys for Alameda all had me in for
7 a deposition and somehow based on what I said I've been subpoenaed as a witness for Alameda.
8 This is nonsense. I don't want to be here, but a friend of mine is a lawyer for the school district
9 where I work, and she said I have to show up and cooperate since I received a subpoena.

10 This all started during a family reunion, of all things. My sibling Paul and his wife Kelsi
11 announced to everyone that they had sold their cat food brand Stealth Felidae to Purina PetCare
12 for \$20 million. That news really depressed Blake. It's bizarre. No one in the family is poor.
13 Everybody has everything they've ever needed and more. But not being able to leave kids and
14 grandkids with a huge wad of money has put Blake in a bad place.

15 A couple weeks after the reunion I'm at Blake's house for our weekly Golden Girls
16 Marathon and Sunday brunch and one of those attorney advertisement commercials comes on
17 talking about this drug Bikwell and Restless Leg Syndrome. You know the type of commercials
18 that say, "If you've ever been at Camp Lejeune; If you've ever used Roundup." All the sudden
19 Blake says, "that's my ticket, that's the inheritance, right there." Blake starts asking me if I
20 remember their indigestion issues and picking up medications for them. I tell them we're all fine
21 financially and to pass the pancakes.

22 Out of the blue in January, I got a call from Blake's lawyer's office about a case
23 concerning the drug Bikwell. Blake hadn't mentioned anything about a lawsuit or claim. I told

24 Blake I wasn't going to get involved with any lawyers or big pharmaceutical companies, no way.
25 Blake cried so I agreed to answer some questions.

26 I do remember at least one time picking up a box of Bikwell for Blake. I remember
27 having to go to three different pharmacies to try and find it! I had to go to one of those
28 independent pharmacies to find it. It wasn't at any of the chains. Even though Blake is way past
29 the age where most people are still active, Blake still drives and manages their own life just like
30 Warren Buffett or Charlie Munger. By life I mean taking medications, paying bills, walking their
31 dog, driving... all of it. It was rare that I was asked or needed to do any of those daily life kind of
32 things for Blake. But Blake had tripped over their massive stack of Soap Opera Digest, and
33 twisted their ankle so they couldn't drive for a few days. Anyways, I looked Bikwell up on
34 Google to see if I could find something that would treat the same symptoms, but I couldn't. I did
35 see an article about Bikwell and something called AHMH on Google, but I didn't read the
36 article. While looking at the pharmacy, I went and asked if there was anything else they could
37 take, they just said Bikwell will work. I don't know what that means. If Blake was trying it for
38 the first time or if it was a regular thing, Blake's medications⁶ are their business. Anytime I've
39 tried to help by getting one of those pill daily organizers I was told to "mind my own business,"
40 because I was not a licensed medical provider.

41 Blake takes a number of medications and I worry about Blake keeping them straight.
42 That's what I mean by high maintenance. One minute we're fine, the next minute I've
43 overstepped my bounds. Blake will complain about not being able to keep up on the yard or
44 housework, but if I offer to help or hire someone, it's "mind your own business." A few years
45 ago, after my divorce, I suggested that Blake move into my house. It's a one story with plenty of

⁶ Grammatical error corrected from previous version via Q&A#1

46 room. But Blake wouldn't have it, as they felt comfortable living with Angel. I wanted to look
47 after Blake, but they won't let me. Actually, I'm better off without Blake in my house, Blake
48 never has the thermostat below 80 degrees. Their house is like living in a tropical jungle. Blake
49 says that according to the internet it's likely they are always cold because of their thyroid.

50 Blake has had indigestion issues for years. I remember even when I was a kid seeing
51 them taking lots of Tums. There was a time when their stomach problems seemed to improve
52 when I was in high school, but that was the only time I can think of. It might have been when
53 they had taken a break from smoking, after reading an article about it. But they did start up
54 again, despite my protesting. Although, it's funny, Blake's spouse, Mel, used to tease them and
55 say Blake never really smoked, that Blake just lit a cigarette and posed with it like it was a cool
56 thing to do. But, I think it was real smoking because Blake used to cough a lot when Blake was
57 smoking

58 The restless leg syndrome thing. The first time I ever heard Blake mention it was during
59 that commercial during Sunday brunch that day. I've seen Blake take naps and sleep over the
60 years and only one time did I notice any leg movement. It was years ago when we shared a room
61 at my aunt's lake house. I was in one bed in the room and Blake was in the other bed in the
62 room. In the middle of the night, I hear this rustling and hear Blake screaming. I'm scared. Blake
63 woke up crying. When I asked what was wrong, Blake told me that everything was fine and to go
64 back to sleep. The next morning Blake didn't want to talk about why they woke up crying. I
65 asked my aunt about it, and she told me this horrific story of what happened when Blake was 10
66 years old. Blake and a friend were tent camping in the backyard. Suddenly the neighbor's shed
67 caught on fire. The fire spread to the yard and caught the tent on fire. Blake grabbed the friend
68 and ran out of the tent. The entire backyard was on fire. Blake ran past the flames to the

69 backdoor of the house. Blake pounded on the door and screamed to get help. The family legend
70 is that Blake and her friend hosed down the entire backyard and the back of the house. Blake's
71 parents were inside the house and didn't hear a thing until the fire squad came with blaring
72 horns. According to my grandma, over the years Blake sometimes had nightmares about the
73 incident and ran in their sleep. What an awful thing for a 10-year-old to experience.

74 As far as anyone else in the family with restless leg syndrome. My Aunt Edna, Blake's
75 sister, sometimes had this uncontrollable kicking motion with her right leg. I never knew what it
76 was, but Aunt Edna would laugh and say it was because she was part bunny rabbit and ready to
77 hop.

78 That's all I know, except Blake is really mad at me for being of "no help in securing an
79 inheritance." But, I'm not going to say I know things that I don't know or say anything that I
80 can't verify. It's Blake's fault I'm a witness for the defense. Blake should have listened when I
81 said I didn't want to be involved.

1 **STATEMENT OF JADON WONG**

2 My name is Jadon Wong and I am currently one of several Vice Presidents of Marketing
3 for Alameda. I am a graduate of Butler University. I started my college career thinking I would
4 major in biology and I did well in those courses, but I discovered that my real passion was in
5 more direct interaction with people. So, after my freshman year, I decided to switch to a
6 marketing major at Butler’s Lacy School of Business. One of the classes I took was on business
7 ethics, it really made an impression on me. I strongly feel that, as a businessperson, I have a duty
8 to act ethically and honestly at all times. When I graduated and started looking at potential
9 positions, it was important to me to find a company that shared my belief that business can be
10 both ethical and profitable. I found the perfect fit with Alameda. It is my personal belief that I
11 use my gifts to do something good in the world to help people and this company allows me to do
12 that.

13 My training at Alameda was more than I could have hoped for. In addition to the standard
14 orientation, there was a great deal of substantive education about the various drugs that Alameda
15 was developing and marketing. And, before sending me out to actually market drugs, I had a
16 great opportunity to spend 3 months in the development department. That experience gave me
17 real insight into how drugs are developed. What I learned is that patience, perseverance, and
18 attention to detail are key in the drug industry. There are a lot of great ideas for drugs and there
19 are always several drugs “in the pipeline” of development, but not all drugs make it through
20 trials and approvals by the Food and Drug Administration. It is a surprisingly complex process of
21 developing a drug based on a theory of potential benefits, running all types of tests on that drug,
22 refining it, eventually testing the drugs on human volunteers, and then working through an
23 exhaustive process of approvals by the Food and Drug Administration. I was surprised to learn

24 that the average development process for drugs, from early testing to approval and distribution to
25 the public,⁷ can be as long as ten years. That is a big investment by a drug company and, of
26 course, not all drugs make it. Those that do essentially pay for those that do not. So, it is
27 important to have some real successes to continue to be a profitable company.

28 After my time in development, I was in the marketing area for five years before I made
29 my way into a supervisory role (which I held for a couple of years) and then to my current
30 position as one of several Vice Presidents of Marketing. My quick rise in the company is a
31 reflection of the success I had in marketing. My role as Vice President of Marketing still includes
32 marketing drugs but I am also responsible for supervising a team of salespeople and I am
33 involved in the administration of the company. I sit in on the Board of Director Meetings at
34 which I have access to the inner workings of Alameda. I receive reports on how we are doing
35 financially but, more importantly, I have a role in helping to develop marketing strategy. Even
36 the best drugs cannot help people if the doctors do not know about them. It is all about
37 marketing!

38 One of the lessons I took from learning the development procedures for drugs is that
39 when you are successful you need to make sure to communicate that success. Bikwell is, or at
40 least was, one of Alameda's success stories. Sure, Bikwell could help the bottom line and
41 potentially bring in big profits for the company, but profits were never my or the company's
42 primary motivation. Our moto is "do the right thing success will take care of itself."

43 You see, there are a couple of theories on how to be a successful businessperson and how
44 to run a successful company. One theory suggests you look to the profit as the goal and you do
45 what you need to do to achieve profit. The other suggests that you focus on your stakeholders,

⁷ Grammatical error corrected from previous version via Q&A#1

46 your customers, your employees, your suppliers, and create a positive working environment for
47 them. Rather than fixating on goal of making a profit, you instead focus on your stakeholders and
48 the profit will take care of itself. Alameda shared my view that if you focus on doing the
49 right thing and not be blinded by the drive for profit, then your actions will be both ethical and
50 economically successful.

51 Consistent with the training I received from Alameda, when I approached doctors to
52 market Bikwell, I provided them with the best information that was available to me. That
53 included marketing brochures created by the company that described the benefits of Bikwell and
54 that contained testimonials of patients who had great results from using the drug. And I have to
55 say, there were a lot of success stories.

56 The brochures, at times, also included testimonials from not-for-profit groups that had
57 conducted independent research and that had reached positive conclusions about the
58 effectiveness of Bikwell. In my experience with Alameda, having independent research that
59 supports the value of the drugs we are marketing is invaluable. Don't just take our word for it,
60 our facts are supported by independent sources! And, really, it is a win-win situation for those
61 research companies. Alameda provides donations to help fund the research and the positive
62 reports created by the companies help Alameda fund more independent research. In addition to
63 that, and importantly, our drugs are scrutinized and approved by the federal government.

64 Alameda has clearly been good at predicting the success of drugs like Bikwell because I
65 have never seen an independent research report that was not positive about the impact of
66 Bikwell. I never saw an independent research report that reported any significant side effects of
67 Bikwell. I certainly never saw an independent research report that identified restless leg
68 syndrome as a potential side effect of Bikwell. Of course, in the end it is the patients who,

69 ultimately, benefit because we are able to get the word out to doctors and educate doctors on
70 what is available, like Bikwell. That allows the doctors to help their patients.

71 I understand, and I make sure those salespeople I supervise understand, that we are not
72 doctors. A medical degree is a hard-earned honor. Doctors are busy taking care of patients and
73 are generally not focused on the development of drugs. In fact, I do not believe that any of the
74 independent research companies that provided reports to us on Bikwell employed any doctors.
75 My role as salesperson, and the role of the salespeople I supervised, was to provide accurate and
76 complete information to the doctors so that the doctors could reach their own opinion on whether
77 Bikwell would be beneficial for their patients. We were providing a valuable service. We all
78 know doctors are busy. I tried to make their job easier by telling them of opportunities for
79 treatments that they otherwise would not have known about. I coached my salespeople to do the
80 same thing.

81 I know from the company financial information I was provided at Board meetings that
82 Bikwell is an important drug for Alameda and that the company⁸ had high expectations that it
83 would be incredibly profitable. I know from my business education that shareholders want a
84 good return on their investment. But I also know that long term benefits can often be more
85 important than short term profits. What I can say is that while my success as a rep was measured
86 by sales, I was able to generate, I never felt any pressure to misrepresent anything about Bikwell.
87 Likewise, I never pressured any of the salespeople that I supervised to make any
88 misrepresentations about Bikwell, we didn't need to. The success of the drug spoke for itself.

89 We have monthly sales meetings at Alameda where a cash prize is given to the
90 salesperson who sold the most Bikwell during the prior month. Myself and the other Vice

⁸ Grammatical error corrected from previous version via Q&A#1

91 Presidents of Marketing try to make the meetings interesting and engaging. In fact, those
92 meetings probably feel more like pep assemblies than formal, stuffy, company meetings. That is
93 by design. You have to get people fired up to be effective in marketing. It is a big deal to win
94 salesperson of the month. Not only is there recognition among your peers and co-workers, but
95 the company gives a decent bonus to each winner. I won it several times when I was a
96 salesperson and I expect that the salespeople I supervise will also show their loyalty to the
97 company by making the effort necessary to win that award.

98 By the end of 2022 sales of Bikwell were up and everyone was happy. Then the bottom
99 fell out. It seemed like all of a sudden several of the salespeople I was supervising were reporting
100 back that some patients using Bikwell were experiencing⁹ something called “restless leg
101 syndrome.” At first the number of reports were not significant enough to pass on to the Board. I
102 wasn’t going to waste the Board’s time on a few isolated incidents. That is especially true
103 because I was not convinced that there was a link between using Bikwell and restless leg
104 syndrome. None of the independent research reports had identified any link.

105 After several months of periodic reports of restless leg syndrome, however, one of the
106 other Vice Presidents of Marketing put the subject on an agenda for a Board Meeting. We take a
107 very proactive approach once we have enough reports to suggest even the possibility of a link
108 between one of our drugs and an unanticipated side effect. We take seriously the health of
109 patients who use our drugs. But we also have to balance the potential negative impact on a few
110 against the significant benefits for the majority of those using Bikwell. That is what it means to
111 be a responsible ethical company.

⁹ Typo corrected from previous version via Q&A#1

112 Ultimately, as a Board, and after a great deal of debate, we made the decision to stop
113 marketing Bikwell. As a Board, we were not convinced that there was any link between Bikwell
114 and restless leg syndrome, but we took the abundance-of-caution approach by stopping our
115 marketing efforts for Bikwell. It was available for distribution for several months after we
116 stopped marketing it because we did not want to leave those getting relief from Bikwell without
117 another way to get relief.

1 **STATEMENT OF DR. AARON/ ERIN PARKER**

2 My name is Dr. Aaron/Erin Parker, and I am a board-certified sleep medicine physician
3 with over 20 years of experience in the diagnosis and treatment of sleep disorders. I am the
4 founder and CEO of the Indianapolis Sleep Center. You may have heard one of our commercials:
5 if you can't sleep, give me a beep. I started by completing my undergraduate degrees in biology
6 and neuroscience from Johns Hopkins University. I then went on to complete my doctorate from
7 Stanford University & a medical degree from Harvard where I focused on sleep medicine and
8 conducted several projects on sleep disorders. I then came back to Indiana, where I was born and
9 raised, and completed both my residency and fellowship at IU Health University Hospital, and
10 focused my specialization in sleep medicine. I have worked with patients with insomnia,
11 parasomnia, sleep apnea, narcolepsy, and other sleep-related movement disorders such as restless
12 leg syndrome, or RLS.

13 I guess one would ask why I would get into something like sleep therapy but this wasn't
14 just a random choice or for just the overall joy of a well-rested night. As with all great
15 physicians, I come with my share of a bit of family history. My first encounter with sleep
16 medicine happened when I was in high school, and my father was diagnosed with insomnia and
17 my mother, restless leg syndrome. I wasn't able to always go to football games or the county fair
18 since my sleep deprived parents were exhausted all the time. People often don't take something
19 like getting enough sleep seriously but when your parents struggle day¹⁰ to day just to be able to
20 live and work normally; it does take a toll. But if there was a silver lining, I became interested in
21 helping people like my parents, and now, here I am providing people and families with the well-
22 rested care and compassion that they need.

¹⁰ Grammatical error corrected from previous version via Q&A#1

23 I was called in on this case to give you my expert opinion on how Bikwell could have
24 possibly caused Blake Toomey's restless leg syndrome. I am paid upwards of 800 dollars an
25 hour for my consulting and statement here today.¹¹ And it couldn't. I was made aware of Bikwell
26 a month after it was released. Why would a sleep expert physician be aware of a drug for
27 indigestion you ask? To put it briefly, because when we sleep, our body also repairs all the
28 regular wear-and-tear it has experienced during the day - this applies to our digestive system as
29 well. During our sleep, our digestive system is busy repairing and rebuilding tissues in our gut,
30 while also growing the good gut bacteria that aid our digestive processes. Lack of sleep also
31 leads to stress which in turn affects the gut. It also works the other way around. Chronic
32 digestive diseases also lead to shorter and poor quality sleep.

33 But back to why we're all here. I never personally recommended Bikwell to my patients
34 but knew of several patients who had other doctors recommended it for indigestion, and they had
35 started taking their first few doses. It seemed to help as far as I could tell. None of my patients
36 had noticed any serious side effects, and it seemed just like the drug had proposed. However,
37 after about a year, I had about half a dozen patients come into my sleep center, who had just
38 started suffering symptoms of RLS. While reviewing the patient's medical history I made sure to
39 get a detailed medical history, including a list of every medication the patient was taking.
40 Despite the RLS, Bikwell was improving my patient's indigestion. After extensive review of
41 each of the patients, we were able to determine other medical explanations for the RLS. Most
42 were able to treat the issues that caused the RLS, and gain better sleep function, and having a
43 better functioning gut helped.

¹¹ Change per Q&A #13

44 As I mentioned before, my specialization also included diagnosing and treating RLS.
45 RLS is both a sleep disorder, because the symptoms are triggered by resting and attempting to
46 sleep, and a movement disorder, because people with RLS are forced to move their legs in order
47 to relieve symptoms. Patients with RLS showed reduced total sleep time, poor sleep efficiency,
48 and increased wakefulness during the sleep period as compared to those with a relatively healthy
49 sleep pattern. A combination of sleep pattern, gut function and RLS led me to become more
50 interested in Bikwell as a possible cure to the side effects of, to put it lightly, bad sleep. I did
51 have a pharma rep from Alameda come to me to see if I would be willing to recommend the drug
52 myself but as I had mentioned before, the priority of my practice was focused on sleep therapy
53 and this drug was not directly related to my patients' overall treatment. But I was curious, so I
54 heard them out. As I had figured, not a lot of patients had reported anything serious, but they did
55 mention a few cases of some of them reporting some minor side effects but again, with the drug
56 being as new as it was, nothing concrete.

57 I was contacted by defense counsel a few months after the drug had been released to
58 provide my expert opinion on a Patient's RLS being possibly caused as a side effect of Bikwell. I
59 jumped at the opportunity as it is in my area of expertise, but also, it would give me a chance to
60 better study how the drug could affect my patient's treatment. I reviewed all pieces of evidence
61 provided through the discovery process, all witness statements, and was given an opportunity to
62 speak with Blake Toomey as a part of my assessment. I used my normal method to address RLS
63 cases: interview, investigate, and intervene, which is now the gold standard method in RLS
64 cases.

65 In my interview with Toomey, I learned a lot of information about them including name,
66 age, medical history, family situation and family medical history, and then we discussed their

67 RLS symptoms. Toomey revealed that they had four children and a large number of grandkids.
68 As an adult they dealt with normal indigestion, which was treated with regular old antacids until
69 they started trying to self-prescribe more intense medicines to help. They had heard from several
70 friends that Bikwell had helped with indigestion, and they decided to try it out. Toomey was not
71 able to give me an exact amount of Bikwell they took on a daily basis, but they did say they
72 normally took between 1 to 4 150mg tablets a day, starting in March of 2019.

73 I then investigated the RLS based on the information I had. I calculated the amount of
74 Bikwell that had possibly been used by the plaintiff to determine whether or not they had taken
75 enough to cause the RLS. I then researched other cases where Bikwell was being taken when
76 RLS occurred to determine the amount of Bikwell used. I then compared the amount of Bikwell
77 that was present in those cases as almost 20 times the amount that Plaintiff would have ingested.

78 My next step would have been to intervene. Intervening is where I inform the patient
79 where the RLS came from and how to treat it. Since this was not one of my patients, I did not
80 make these recommendations to the patient. However, I believe my diagnosis is relevant to this
81 assessment. In the plaintiff's case my expert medical opinion is that the RLS would have been
82 more likely to have been caused by genetic and physical factors and not a side effect from
83 Bikwell.

84 In conclusion, what I learned from this particular case was that there were other factors
85 contributing to Toomey's symptoms apart from the drug. Firstly, Blake was elderly in age
86 meaning they had a higher risk of acquiring RLS with or without a drug. Blake didn't have a
87 serious talk with their provider about taking Bikwell, and taking a drug without medical
88 consultation could have serious consequences. Blake also wasn't in great health, being in the 98

89 percentiles, which indicates poor health,¹² for their age and gender. In addition, Toomey was a
90 smoker for up to 70 years. They would have had to talk to a doctor before taking any sort of
91 medication, especially a newer drug. Based on my analysis, there were other contributing factors
92 apart from the drug that led to Blake's symptoms. Several of my patients have taken Bikwell;
93 none developed serious side effects. It is my expert opinion that the drug itself was not a cause
94 of Toomey's RLS. Instead, it was caused by their unhealthy diet and lifestyle choices.

¹² Changed per Q&A 1 #14

Exhibit 1

Curriculum Vitae
Logan Earnhardt, Phd.
1989 Swift Drive, Lafayette IN 47901
765-466-3902, director@pharmfresh.org

Summary

American Board of Pharmacy certified pharmacist with an extensive background in drug safety, drug and device development, and research. Driven to provide consumers with complete and accurate information about consumer medicines.

Skills

- Board-certified by the American Board of Pharmacy since 2012.
- Obtained specializations in ambulatory pharmacy, nuclear pharmacy, and pharmacotherapy from the Board of Pharmacy Specializations.
- Extensive background in FDA drug labeling.
- Developed safety and advocacy programs in the FDA pharmaceutical field¹³.

Experience

PharmFresh; Lafayette, IN; 2020 – Present

- Co-Founder and Regulatory Program Development Director
- Provided a holistic approach to the study of pharmaceutical oversight
- Developed safety and efficacy programs in support of drug approval and post marketing surveillance.
- Conducted patient studies on adverse drug side effects
- Drug testing for unknown side effects from environmental effects

United States Food and Drug Administration; Silver Spring, Maryland; 2014-2019

- Consumer Safety Officer 2014-2018; Consumer Safety Team Manager 2018-2019
- Researched health outcomes from different medications
- Monitored drug safety in pharmaceutical landscape
- Reviewed labeling process to ensure that medications had appropriate warnings
- Managed team of labeling compliance specialists

Education

- PhD, Pharmacy; Purdue University; Lafayette, Indiana; 2009-2012
- BS, Biochemistry; Valparaiso University; Valparaiso, Indiana; 2005-2009

Certifications

- Board Certification; American Board of Pharmacy

¹³ Added via Q&A#1

Exhibit 2

Curriculum Vitae
Dr. Aaron/Erin Parker
1982 Sleep Circle, Indianapolis IN 46278
317-555-1982, SleepDoc@ISC.com

Summary

Board-certified sleep medicine physician with over 20 years of experience in the diagnosis and treatment of sleep disorders. Proven ability to provide compassionate, patient-centered care in a variety of settings. Strong research and teaching experience.

Skills

- Board-certified in sleep medicine by the American Board of Sleep Medicine (ABSM) since 2003.
- Extensive experience in the diagnosis and treatment of sleep disorders, including insomnia, sleep apnea, narcolepsy, and restless leg syndrome.
- Proficient in the use of sleep studies and other diagnostic tools.
- Excellent communication and interpersonal skills.
- Strong research and teaching experience.

Experience

Indianapolis Sleep Center; Indianapolis, IN; 2003 - Present

- Co-Founder and CEO¹⁴; Sleep Medicine Physician
- Provided comprehensive care to patients with sleep disorders.
- Conducted sleep studies and interpreted results.
- Developed and implemented treatment plans.
- Collaborated with other healthcare professionals to provide the best possible care for patients.
- Conducted extensive research on sleep disorders including
 - Circadian rhythm sleep disorders
 - Parasomnias
 - Insomnia
 - Sleep apnea
 - Narcolepsy; and
 - Sleep-related movement disorders: Restless legs syndrome (RLS), periodic limb movement disorder (PLMD), and REM sleep behavior disorder (RBD).
- Taught more than 200 medical students and residents about sleep medicine.
- Provided expert medical testimony in civil litigation in approximately 50 cases, working with both plaintiff and defense Counsel.

IU Health University Hospital; Indianapolis IN; Sleep Medicine Resident Doctor 1999-2002 / Fellow 2002-2003

- Conduct physical exams and research on patients with sleep disorders.
- Published research papers in peer-reviewed journals.

¹⁴ Typo corrected from previous version via Q&A#1

- Guest lecture at the IU medical school.

Education

- MD, Harvard Medical School; Boston, MA; 1995 - 1999
- PhD, Neuroscience; Stanford University; Stanford, CA 1991 - 1995
- BS, Biology; Johns Hopkins University; Baltimore, Maryland; 1987-1991
- BS Neuroscience; Johns Hopkins University; Baltimore, Maryland; 1987-1991

Awards and Honors

- American Academy of Sleep Medicine (AASM) Sleep Research Award
- American Sleep Disorders Association (ASDA) Young Investigator Award
- Harvard Medical School Dean's Award for Excellence in Teaching

Publications

- Sleep in the 21st Century; the Stanford Medicine; 1992: 29:678-710.
- Sleep Apnea and its Impact on Cognitive Function in Older Adults. Journal of Sleep Medicine. 2008;39:123-130.
- The Prevalence of Sleep Disorders in the United States. Sleep Medicine Yearly. 2010;40:123-130.
- How to Sleep with Restless Leg Syndrome. Sleep Medicine Reviews. 2016;20:123-130.



Bikwell box (front)

<p>Drug Facts</p> <p>Active Ingredient (in each tablet) Purpose AHMH Pepsin Inhibitor</p>	
<p>Uses Temporarily relieves these symptoms caused by indigestion:</p> <ul style="list-style-type: none"> • Heartburn • Indigestion • Nausea • Diarrhea • Stomach Pains 	<p>Keep out of reach of children</p> <p>In the event of an overdose, get medical help or contact a Poison Control Center right away Stop use and ask your doctor if (1) the condition worsens (2) symptoms last more than 48 hour, clear up and return (3) an allergic reaction occurs</p>
<p>Warnings</p> <p>Ask a doctor before use of Bikwell</p> <p><u>Ask a doctor or pharmacist before use if you are on sedatives or tranquilizers</u></p> <p>When using this product</p> <ul style="list-style-type: none"> • This product may cause dizziness • Drug may impair ability to operate a motor vehicle or machinery • Do not use if allergic • May cause dry cough, contact doctor if persistent • If indigestion persists, contact your doctor • May cause muscle spasms 	<p>Directions</p> <ul style="list-style-type: none"> • Take with water and food • For adults and children over the age of 13, the recommended dose is 2 tablets every 4 to 6 hours until symptoms subside • Person should not take more than 8 tablets in a 24hr period <p>Other Information</p> <p>This drug was not tested on animals</p> <p>Inactive Ingredients</p> <p>Sucrose, Starch, Hydropropyl oxide, Cellulose</p>

¹⁵ Typo corrected from previous versions via Q&A#1

Exhibit 4

Screenshot of Bikwell Advertisement

