Exhibit A

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	
LEACHCO, INC.	)	CPSC DOCKET NO. 22-1
Respondent.	)	

COMPLAINT

Nature of the Proceedings

1. This is an administrative enforcement proceeding pursuant to Section 15 of the Consumer Product Safety Act ("CPSA"), as amended, 15 U.S.C. § 2064, for public notification and remedial action to protect the public from the substantial risks of injury presented by various models of infant lounging pillows ("Podsters") which were manufactured and distributed by Leachco, Inc. ("Respondent").

2. This proceeding is governed by the Rules of Practice for Adjudicative Proceedings before the Consumer Product Safety Commission (the "Commission"), 16 C.F.R. Part 1025.

Jurisdiction

3. This proceeding is instituted pursuant to the authority contained in Sections 15(c), (d), and (f) of the CPSA, 15 U.S.C. § 2064(c), (d), and (f).

Parties

4. Complaint Counsel consists of attorneys in the Division of Enforcement and Litigation within the Office of Compliance and Field Operations representing the staff of the

Commission. 16 C.F.R. § 1025.3(d). The Commission is an independent federal regulatory agency established pursuant to Section 4 of the CPSA. 15 U.S.C. § 2053.

5. Respondent is an Oklahoma corporation with its principal place of business located at 130 E. 10th Street, Ada, Oklahoma.

6. Upon information and belief, Respondent is a "manufacturer" and/or "distributor" of a "consumer product" that is "distribute[d] in commerce," as those terms are defined in Sections 3(a)(5), (7), (8), and (11) of the CPSA, 15 U.S.C. § 2052(a)(5), (7), (8), and (11).

The Podsters

7. The Podsters consist of various models of infant lounging pillows that were manufactured and/or distributed in U.S. commerce and offered for sale to consumers for their personal use in or around a permanent or temporary household or residence, school, in recreation, or otherwise.

8. The Podsters are manufactured at Respondent's facilities in Ada, Oklahoma.

9. Upon information and belief, the Podsters include, but are not limited to, the following models: Podster, Podster Plush, Bummzie, and Podster Playtime.

10. Upon information and belief, approximately 180,000 Podsters have been manufactured and distributed in U.S. commerce since 2009. The Podster and Podster Plush models have been sold from 2009 to present; the Bummzie was sold exclusively at Walmart from 2010 to 2018; and the Podster Playtime was sold from 2014 to 2017.

11. Upon information and belief, the retail price for the Podsters ranges from approximately $49 and $89.

12. The Podsters are sold at various retail chains including, but not limited to, Amazon.com, Bed Bath and Beyond, Buy Buy Baby, Kohls, Macy's, Toys R Us/Babies R Us,

and Walmart.

13. The Podster is a product marketed for caregivers to use for infant lounging and to "provide[] a warm and cozy caress for infants." It was designed to permit a caregiver to keep an infant in a safe environment, allowing for hands-free supervision.

14. The Podster is not and has never been advertised by Respondent as a sleep product.

15. The Podster contains warnings that the product should not be used for sleep and that adult supervision is always required.

16. The Podster contains warnings that the product should only be used on the floor, and not in another product, such as a crib, on a bed, table, playpen, counter, or any elevated surface.

17. The Podster contains warnings that infants should not be placed prone or on their side in the product.

18. The Podster contains instructions that it should be used for infants not to exceed 16 pounds, and should not be used if an infant can roll over.

19. The Podster contains warnings and instructions that use of the product in contravention to these warnings could result in serious injury or death.

The Podsters' Defects Create a Suffocation Hazard

20. Despite the warnings and instructions, it is foreseeable that caregivers will use the Podster without supervision. It is also foreseeable that caregivers will use the Podster for infant sleep.

a. The Podsters are marketed for use with infants, and caregivers may trust that the products are safe places to leave infants. Because the Podsters appear simple to use, are likely to be used frequently, and do not appear dangerous, it

is foreseeable that some caregivers may disregard or not fully read the Podsters' warnings.

b. If an infant falls asleep in the Podster, a caregiver may choose not to disturb the infant and may leave the infant asleep in the product.

c. Caregivers facing difficulties in getting their infant to sleep may choose to use the Podster for that purpose if the Podster appears to help with sleep or if the infant appears to be comfortable in the Podster, even if the caregiver is aware of the contrary product warnings.

d. Caregivers with an infant who are traveling or who are dealing with significant financial hardship may be more likely to allow an infant to sleep in the Podster, as they may not have a crib or safe infant sleep product readily available.

e. If an infant falls asleep in the Podster, it is foreseeable that the caregiver may intentionally sleep while the infant is asleep, may accidentally fall asleep while the infant is asleep, may use the time that the infant is asleep to catch up on work or chores, or otherwise may leave the infant unsupervised.

21. Unsupervised infants can roll or move on the Podster into a position where their nose and mouth are obstructed by the Podster.

22. Unsupervised infants can roll or move off the Podster into a position where their nose and mouth are obstructed by another object, such as soft bedding.

23. Despite warnings and instructions, some caregivers may not place infants on their backs in the Podster and may place infants in positions where their nose and mouth may be obstructed by the Podster.

24. The Podster is defective because it can cause airflow obstruction if an unsupervised infant rolls, moves, or is placed in a position where the infant's nose and mouth

are obstructed by the Podster.

25. The Podster is defective because it is constructed of thick, soft padding that has a concave shape which can envelop an infant's face and cause airflow obstruction if an unsupervised infant rolls, moves, or is placed in a position where the infant's nose and mouth are obstructed by the Podster.

26. The Podster is defective because it lacks rigid underlying components, which can impede the ability of an infant to self-rescue in the event that the infant rolls, moves, or is placed in a position where the infant's nose and mouth are obstructed by the Podster.

27. The Podster is defective because it facilitates an infant's movement on the Podster, enhancing the risk that the infant's nose and mouth will be obstructed by the Podster.

28. The Podster is defective because it facilitates an infant's movement off the Podster, enhancing the risk that the infant's nose and mouth will be obstructed by another object in the infant's environment, such as soft bedding.

29. The design of the Podster allows infants to bend their knees and push off the raised edges of the Podster with their feet, allowing an infant to roll or move on or off the Podster.

30. The Podster may allow an infant to roll, even if the infant is not able to roll on a flat surface, such as in a crib or bassinet.

31. The Podster's design also can lead to unsafe bedsharing where the infant sleeps in an adult bed with one or more adult caregivers.

32. The Podster may be attractive to caregivers who wish to bedshare with an infant because it is soft and portable, and caregivers may believe that the product's high sides will act as a sufficient barrier between the adult and the infant to keep the infant secure in the

Podster.

33. Bedsharing with an infant in a Podster can result in an infant moving into a compromised position within the Podster and suffocating, or moving outside the Podster and suffocating on another person or object, such as soft bedding or the adult bed.

34. If an infant rolls, moves, or is placed in a position where the infant's nose and mouth are obstructed by the Podster or another object, such as soft bedding, the infant can suffocate and die in three to 10 minutes.

Fatal Incidents Caused by the Podsters

35. The Podster's defects have led to the deaths of at least two infants.

36. Upon information and belief, on or about December 16, 2015, a 4-month-old infant suffocated after being placed face-up or on their side in the Podster in a crib. The infant was found face-down on the Podster and later died of complications from asphyxia.

37. Upon information and belief, on or about January 27, 2018, a 17-day-old infant suffocated after being placed face up in the Podster on an adult bed between two caregivers. Upon information and belief, the infant had moved off the Podster onto the adult bed after one of the caregivers rolled onto the Podster and infant.

The Substantial Risk of Injury Posed by the Podsters

38. It is foreseeable that caregivers will use the Podster for infant sleep, despite the instructions and warnings. It is also foreseeable that caregivers will use the Podster without supervision.

39. It is foreseeable that some caregivers will not place infants on their backs in the Podster.

40. It is foreseeable that caregivers will place infants in Podsters and use the Podster for bedsharing in an adult bed.

41. If an infant rolls, moves, or is placed in a position where the infant's nose and

mouth are obstructed by the Podster itself or by another object or person with whom the infant is bedsharing, the infant may not be able to self-rescue and can suffocate within minutes.

42. Upon information and belief, at least two infants, members of a vulnerable population, have suffocated and died after being placed in the Podster for unsupervised sleep.

Legal Authority Under the CPSA

43. Under the CPSA, the Commission may order a firm to provide notice to the public and take remedial action if the Commission determines that a product "presents a substantial product hazard." 15 U.S.C. § 2064(c) and (d).

44. Under CPSA Section 15(a)(2), a "substantial product hazard" is "a product defect which (because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise) creates a substantial risk of injury to the public." 15 U.S.C. § 2064(a)(2).

45. A product may contain a design defect even if it is manufactured exactly in accordance with its design and specifications if the design presents a risk of injury to the public. *See* 16 C.F.R. § 1115.4.

46. A defect can also occur in a product's contents, construction, finish, packaging, warnings, or instructions.

47. In assessing whether a product contains a defect, the Commission may consider a consumer's foreseeable use or misuse of the product. *See* 16 C.F.R. § 1115.4.

Count I

The Podsters Are a Substantial Product Hazard Because They Contain Defects That Create a Substantial Risk of Injury to the Public

48. Paragraphs 1 through 47 are hereby realleged and incorporated by reference as if fully set forth herein.

49. The Podsters are consumer products.

50. The Podsters contain defects because it is foreseeable that caregivers will use the product for infant sleep and it is foreseeable that caregivers will leave infants unattended in the product, and:

a. The Podster can cause airflow obstruction leading to suffocation if an infant rolls, moves, or is placed in a position where their nose and mouth are obstructed by the Podster;

b. The design of the Podster prevents infants from self-rescuing once their nose and mouth are obstructed by the Podster;

c. The design of the Podster facilitates infant movement on the Podster, which can result in an infant's nose and mouth becoming obstructed by the Podster;

d. The design of the Podster facilitates movement off the Podster, which can result in an infant's nose and mouth being obstructed by another object in the infant's environment, such as soft bedding; and

e. The design of the Podster may lead to it being used for bedsharing, which can facilitate an infant's rolling off the product onto an adult bed, leading to the infant's nose and mouth being obstructed by another object or an individual sleeping in the bed.

51. These defects separately, and in combination, create a substantial risk of injury to infants because of the pattern of defect, the number of defective products distributed in commerce, the severity of the risk, or otherwise.

52. Therefore, the Podsters present a substantial product hazard within the meaning of Section 15(a)(2) of the CPSA, 15 U.S.C. § 2064(a)(2).

RELIEF SOUGHT

WHEREFORE, in the public interest, Complaint Counsel requests that the Commission:

A. Determine that the Podsters present a "substantial product hazard" within the meaning of Section 15(a)(2) of the CPSA, 15 U.S.C. § 2064(a)(2).

B. Determine that extensive and effective public notification under Section 15(c) of the CPSA, 15 U.S.C. § 2064(c), is required to adequately protect the public from the substantial product hazard presented by the Podsters, and order Respondent under Section 15(c) of the CPSA, 15 U.S.C. § 2064(c), to:

(1) Notify all persons who sell or distribute the Podsters, or to whom such Podsters have been sold or distributed, to immediately cease distribution of the Podsters;

(2) Notify appropriate state and local public health officials;

(3) Give prompt public notice of the defect in the Podsters, including the incidents and injuries associated with the use of the Podsters, including posting clear and conspicuous notice on Respondent's website, and providing notice to any third-party website on which Respondent has a presence, and provide further announcements in languages other than English and on radio, television, and social media;

(4) Mail and email notice to each distributor and retailer, of the Podsters; and

(5) Mail and email notice to every person to whom the Podsters were delivered or sold.

C. Determine that action under Section 15(d) of the CPSA, 15 U.S.C. § 2064(d), is in the public interest and additionally order Respondent to:

(1) Refund the purchase price of the Podster;

(2) Reimburse distributors, retailers, and any other third parties

for expenses in connection with carrying out any Commission Order issued in this matter, as provided by Section 15(e)(2) of the CPSA, 15 U.S.C. § 2064(e)(2);

(3) Submit a plan satisfactory to the Commission, within ten (10) days of service of the Final Order, directing that actions specified in Paragraphs B(1) through (5), above and C(1) through (2) be taken in a timely manner;

(4) Submit monthly reports, to the Commission, documenting the progress of the corrective action program ordered pursuant to this matter;

(5) For a period of five (5) years after issuance of the Final Order in this matter, keep records of its actions taken to comply with Paragraphs B(1) through (5), C(1) through (4), above, and supply these records to the Commission for the purpose of monitoring compliance with the Final Order; and

(6) For a period of five (5) years after issuance of the Final Order in this matter, notify the Commission at least sixty (60) days prior to any change in its business (such as incorporation, dissolution, assignment, sale, or petition for bankruptcy) that results in, or is intended to result in, the emergence of a successor corporation, going out of business, or any other change that might affect compliance obligations under a Final Order issued by the Commission in this matter.

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D. Order that Respondent take other and further actions as the Commission deems necessary to protect the public health and safety and to comply with the CPSA.

ISSUED BY ORDER OF THE COMMISSION:

ALBERTA MILLS Digitally signed by ALBERTA MILLS Date: 2022.02.09 15:32:24 -05'00'

Dated this 9th day of February 2022

ROBERT KAYE Digitally signed by ROBERT KAYE Date: 2022.02.09 16:03:33 -05'00'

By: Robert Kaye
Assistant Executive Director
Office of Compliance and Field Operations
(301) 504-6960

Mary B. Murphy, Director, Division of Enforcement and Litigation
Leah Ippolito, Supervisory Attorney
Brett Ruff, Trial Attorney
Rosalee Thomas, Trial Attorney

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Office of Compliance and Field Operations
U.S. Consumer Product Safety Commission
Bethesda, MD 20814
Tel: (301) 504-7809

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of	)	
LEACHCO, INC.	)	CPSC DOCKET NO. 22-1
Respondent.	)	

LIST AND SUMMARY OF DOCUMENTARY EVIDENCE

Pursuant to 16 C.F.R. § 1025.11(b)(3) of the Commission's Rules of Practice for Adjudicative Proceedings, the following is a list and summary of documentary evidence supporting the charges in this matter. Complaint Counsel reserves the right to offer additional or different evidence during the course of the proceedings, or to withhold evidence on the basis of any applicable legal privileges.

1. Claims, complaints, records, reports, CPSC's In-Depth Investigations, and lawsuits concerning incidents or injuries involving infant lounging pillows manufactured and distributed by Respondent Leachco, Inc. ("Podsters").
2. CPSC Product Safety Assessments.
3. Correspondence between Respondent and CPSC staff related to the Podsters.
4. Documents and information related to the Podsters, including notices issued regarding the Podsters and similar products.

Dated this 9th day of February 2022

Mary B. Murphy

Mary B. Murphy, Director, Division of Enforcement and Litigation
Leah Ippolito, Supervisory Attorney
Brett Ruff, Trial Attorney
Rosalee Thomas, Trial Attorney

Complaint Counsel
Office of Compliance and Field Operations
U.S. Consumer Product Safety Commission
Bethesda, MD 20814
Tel: (301) 504-7809

CERTIFICATE OF SERVICE

I hereby certify that on February 10, 2022, I served the foregoing Complaint and List and Summary of Documentary Evidence upon all parties of record in these proceedings by delivering them in person to the following individual:

James A. Leach

Leachco, Inc.
130 E 10th Street
Ada, OK 74820

Mark Brown
Product Safety Investigator
U.S. Consumer Product Safety Commission

Exhibit B

UNITED STATES OF AMERICA
CONSUMER PRODUCT SAFETY COMMISSION

In the Matter of LEACHCO, INC. Respondent.	CPSC DOCKET NO. 22-1

RESPONDENT LEACHCO INC.'S ANSWER TO COMPLAINT

Pursuant to 16 C.F.R. § 1025.12, Respondent, Leachco, Inc. ("Leachco"), by and through its undersigned counsel, hereby files this Answer and responds to the specific allegations in the numbered paragraphs in the CPSC's Complaint, and states:

When Leachco says that something "speaks for itself," it does not admit that the referenced material exists, is accurate, or is placed in the proper context.

Leachco is not obligated to respond to the headings of the Complaint. The headings are re-produced here for ease of reference. Inclusion of the headings does not constitute an admission of the Complaint's allegations or characterizations. Leachco denies all titles and subheadings in the Complaint.

"Nature of Proceedings"

1. The allegations contained in Paragraph 1 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations contained in Paragraph 1 of the Complaint.

2. This Paragraph states legal conclusions to which no response is required. To the extent a response is required, Leachco states that 16 C.F.R. § 1025 speaks for itself, states that other sources of substantive and procedural law may apply to this proceeding, and otherwise denies the allegations in this Paragraph.

"Jurisdiction"

3. The allegations contained in Paragraph 3 of the Complaint are legal conclusions and a characterization of the complaint to which no response is required. To the extent a response is required, Leachco states that 15 U.S.C. §§ 2064(c) and (d) speak for themselves. Leachco otherwise denies the allegations contained in Paragraph 3 of the Complaint.

"Parties"

4. The allegations contained in Paragraph 4 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco states that 15 U.S.C. § 2053 speaks for itself and otherwise denies the allegations in Paragraph 4 of the Complaint.

5. Leachco admits the allegations contained in Paragraph 5 of the Complaint.

6. The allegations contained in Paragraph 6 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco states that Sections 3(a)(5), (7), (8), and (11) of the CPSA, 15 U.S.C. § 2052(a)(5), (7), (8), and (11) speak for themselves and otherwise denies the allegations in Paragraph 6 of the Complaint.

"The Podsters"

7. Leachco admits that it manufactures and distributes Podsters®, which are infant loungers that were offered for sale to consumers for personal use. Leachco denies all remaining allegations contained in Paragraph 7 of the Complaint not specifically admitted herein.

8. Leachco admits the allegations contained in Paragraph 8 of the Complaint.

9. Leachco admits the allegations contained in Paragraph 9 of the Complaint.

10. Leachco admits the allegations contained in Paragraph 10 of the Complaint. Leachco admits the allegations contained in Paragraph 11 of the Complaint.

11. Leachco admits that at various times Podsters® were sold at the named retail chains, not all of which are currently distributing Podsters®. Leachco denies all remaining allegations contained in Paragraph 12 of the Complaint not specifically admitted herein.

12. Leachco admits the allegations contained in Paragraph 13 of the Complaint.

13. Leachco admits the allegations contained in Paragraph 14 of the Complaint.

14. Leachco admits the allegations contained in Paragraph 15 of the Complaint.

15. Leachco admits the allegations contained in Paragraph 16 of the Complaint.

16. Leachco admits the allegations contained in Paragraph 17 of the Complaint.

17. Leachco admits the allegations contained in Paragraph 18 of the Complaint.

18. Leachco admits the allegations contained in Paragraph 19 of the Complaint.

"The Podsters' Defects Create a Suffocation Hazard"

19. The allegations contained in Paragraph 20 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations in Paragraph 20 of the Complaint.

20. Leachco is without information sufficient to form a belief about the broad allegations contained in Paragraph 21 of the Complaint and on that basis denies the same.

21. Leachco is without information sufficient to form a belief about the broad allegations contained in Paragraph 22 of the Complaint and on that basis denies the same.

22. Leachco admits that some caregivers may ignore the warnings on the Podster®. Leachco denies all remaining allegations contained in Paragraph 23 of the Complaint not specifically admitted herein.

23. Leachco denies the allegations contained in Paragraph 24 of the Complaint.

24. Leachco denies the allegations contained in Paragraph 25 of the Complaint.

25. Leachco denies the allegations contained in Paragraph 26 of the Complaint.

26. Leachco denies the allegations contained in Paragraph 27 of the Complaint.

27. Leachco denies the allegations contained in Paragraph 28 of the Complaint.

28. Leachco denies the allegations contained in Paragraph 29 of the Complaint.

29. Leachco denies the allegations contained in Paragraph 30 of the Complaint.

30. Leachco denies the allegations contained in Paragraph 31 of the Complaint.

31. Leachco denies the allegations contained in Paragraph 32 of the Complaint.

32. Leachco is without information sufficient to form a belief about the allegations contained in Paragraph 33 of the Complaint and on that basis denies the same.

33. Leachco is without information sufficient to admit or deny the allegations contained in Paragraph 34 of the Complaint and on that basis denies the same.

"Fatal Incidents Caused by the Podsters"

34. Leachco denies the allegations contained in Paragraph 35 of the Complaint.

35. Leachco denies the allegations contained in Paragraph 36 of the Complaint.

36. Leachco is without sufficient knowledge or information to admit or deny the allegations contained in Paragraph 37 of the Complaint, and therefore denies these allegations.

"The Substantial Risk of Injury Posed by the Podsters"

37. Leachco denies the allegations contained in Paragraph 38 of the Complaint.

38. Leachco denies the allegations contained in Paragraph 39 of the Complaint.

39. Leachco denies the allegations contained in Paragraph 40 of the Complaint.

40. Leachco denies the allegations contained in Paragraph 41 of the Complaint.

41. Leachco denies the allegations contained in Paragraph 42 of the Complaint.

"Legal Authority Under the CPSA"

42. The allegations contained in Paragraph 43 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations contained in Paragraph 43 of the Complaint.

43. The allegations contained in Paragraph 44 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations contained in Paragraph 44 of the Complaint.

44. The allegations contained in Paragraph 45 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations contained in Paragraph 45 of the Complaint.

45. The allegations contained in Paragraph 46 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations contained in Paragraph 46 of the Complaint.

46. The allegations contained in Paragraph 47 of the Complaint are legal conclusions to which no response is required. To the extent a response is required, Leachco denies the allegations contained in Paragraph 47 of the Complaint.

"Count I"

47. Leachco repeats and restates its answers, denials, and defenses to Paragraphs 1 through 47 and incorporates each by reference as if fully set forth herein.

48. Leachco admits the allegations contained in Paragraph 49 of the Complaint.

49. Leachco denies the allegations contained in Paragraph 50 of the Complaint.

50. Leachco denies the allegations contained in Paragraph 51 of the Complaint.

51. Leachco denies the allegations contained in Paragraph 52 of the Complaint.

"Relief Sought"

Leachco denies that CPSC is entitled to the "Relief Sought" including the relief set forth in paragraphs A through D, inclusive of subparts. Leachco further denies all allegations contained in the Complaint not specifically admitted herein.

ADDITIONAL DEFENSES

By asserting the matters set forth below, Leachco does not allege or admit that it has the burden of proof and/or the burden of persuasion with respect to any of these matters.

FIRST ADDITIONAL DEFENSE

The Complaint fails to state a claim upon which relief can be granted, or upon which relief can be granted against Leachco.

SECOND ADDITIONAL DEFENSE

The Complaint fails to identify a "defect" in the Podster® products within the meaning of 15 U.S.C. § 2064(a)(2) and (b)(3), and 16 C.F.R. § 1115.4.

THIRD ADDITIONAL DEFENSE

The Complaint fails to identify a "substantial product hazard" within the meaning of 15 U.S.C. § 2064(a)(2) and (b)(3), and 16 C.F.R. § 1115.4.

FOURTH ADDITIONAL DEFENSE

The Complaint fails to identify a "substantial risk of injury to the public" within the meaning of 15 U.S.C. § 2064(a)(2) and (b)(3) if used properly or under reasonably foreseeable misuse.

FIFTH ADDITIONAL DEFENSE

The Complaint fails to identify a risk of injury that outweighs the utility to a consumer of the product for parents to use while the infant is awake and supervised by an adult.

SIXTH ADDITIONAL DEFENSE

The alleged injuries were caused by the acts or omissions of third-persons or entities over which Leachco had no control.

SEVENTH ADDITIONAL DEFENSE

The alleged injuries were caused or contributed to, directly and proximately, in whole or in part, by misuse, unauthorized use, unintended use, unforeseeable use and/or improper use of the product at issue.

EIGHTH ADDITIONAL DEFENSE

The Complaint may be barred by the doctrine of estoppel, waiver and/or laches.

NINTH ADDITIONAL DEFENSE

Leachco reserves the right to amend this Answer to add additional defenses if they become apparent from further discovery.

WHEREFORE, Respondent, Leachco, requests the entry of an Order:

A. Dismissing this case;

B. Awarding to it its costs and expenses, including attorneys' fees; and

C. Granting it such other and further relief as may be justified.

Respectfully submitted,

Cheryl A. Falvey

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CERTIFICATE OF SERVICE

I hereby certify that on March 2, 2022, a true and correct copy of the foregoing Answer to Complaint was served by U.S. Mail, first-class and postage prepaid, on the Secretary of the U.S. Consumer Product Safety Commission, and all parties and participants of record in these proceeding in the following manner:

Original and three copies by U.S. Mail, first-class and postage prepaid, and one copy by electronic mail, to the Secretary of the U.S. Consumer Product Safety Commission, Alberta Mills:

Alberta Mills
Secretary
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
301-504-7479
amills@cpsc.gov

As no Presiding Officer has been appointed as of this date, one copy by U.S. Mail, first-class and postage prepaid to the Presiding Officer in the care of Secretary Mills at the above address. One copy by electronic mail to:

Robert Kaye
Assistant Executive Director
Office of Compliance and Field Operations
U.S. Consumer Product Safety Commission
4330 East West Highway
Bethesda, MD 20814
rkaye@cpsc.gov

One copy by U.S. Mail, first-class and postage prepaid, and one copy by electronic mail to Complaint Counsel:

Mary B. Murphy, Director
Leah Ippolito, Supervisory Attorney
Brett Ruff, Trial Attorney
Rosalee Thomas, Trial Attorney
Division of Enforcement and Litigation

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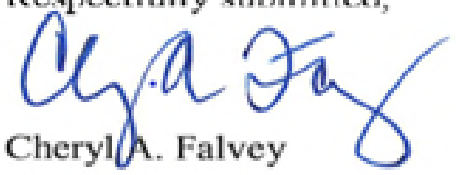
rthomas@cpsc.gov

Respectfully submitted,



Cheryl A. Falvey

Exhibit Z

United States
CONSUMER PRODUCT
SAFETY COMMISSION

Whether At Home or Traveling for the Holidays CPSC Reminds Parents to Keep Babies' Sleep Space Safe

Release Date: November 10, 2022

CPSC Joins Members of Congress, Safety Advocates at Chicago Lurie Children's Hospital

WASHINGTON, D.C. – With the holiday season fast approaching and families preparing to gather, the U.S. Consumer Product Safety Commission (CPSC) is teaming up with members of Congress and safety advocates to remind adults to keep the little ones safe – whether at home or at grandma's house – by always creating a safe sleep space.

Chair Alex Hoehn-Saric joined pediatric experts from Lurie Children's Hospital and American Academy of Pediatrics (AAP), child safety advocates from Kids in Danger (KID), Safe Kids Worldwide, and Consumer Federation of America, and Members of Congress to raise awareness of the best safe sleep practices for babies and highlight new laws and regulations aimed at creating a safer marketplace to keep all babies safe.

"I'm excited to be working alongside these trusted collaborators to expand our reach and provide parents, grandparents, and caregivers with the best safe sleep

practices for their babies during the holidays and all year," said CPSC Chair Alex Hoehn-Saric. "Together we can reduce these tragic deaths and injuries and create a safer marketplace."

This event was held following a year of aggressive Congressional and CPSC action to protect babies from product hazards. These steps include:

- **Infant Sleep Products Rule.** CPSC's Infant Sleep Products Rule went into effect in June 2022, and requires all new infant sleep products to have a sleep surface angle of 10 degrees or lower and to meet at least one of the existing standards for sleep products: bassinets and cradles, play yards, or cribs.

Since the rule went into effect, CPSC has sent more than 125 letters to businesses to alert them of their obligation to comply with the new requirements; and, in more than 70 instances, specific infant sleep products were identified that could be subject to the rule. Subsequently, 26 products were removed from sale, helping to protect consumers. Additionally, CPSC has recently issued a notice to one firm, Dock-a-tot, for manufacturing a non-compliant infant sleep product after June 23, 2022, an apparent violation of the ISP rule.

- **Safe Sleep for Babies Act.** CPSC has written to retailers, including e-commerce platforms, urging them to comply with the requirements of the Safe Sleep for Babies Act, which was enacted into law this summer, and goes into effect on November 12th. The Act bans padded crib bumpers and inclined sleep products, regardless of date of manufacture. Last week, CPSC wrote to 45 retailers urging them to comply with these requirements with respect to crib bumpers, and CPSC will be monitoring the market for inclined products.
- **Additional safety measures.** In addition to these steps forward on

infant sleep products, major steps were taken to improve the marketplace for baby safety. Congress recently enacted **Reese's Law**, aimed at protecting children from hazardous button cell batteries. CPSC also issued final rules establishing safety standards for crib mattresses, magnets, window coverings, and clothing storage units.

"Being a new parent can be hard enough and keeping our newborns safe is a goal we all share. Thanks to the dedication of my colleagues, the dynamic leadership of U.S. Consumer Product Safety Commission Chair Alex Hoehn-Saric, and the urgency to protect our children, President Biden was able to sign into law multiple pieces of legislation that will protect babies and promote safe sleep practices," said Congresswoman Jan Schakowsky. "Nearly 200 deaths have been linked to crib bumpers and infant inclined sleep products. Thanks to the Safe Sleep for Babies Act, which I introduced with Rep. Tony Cárdenas, these dangerous products will be banned, providing families with the peace of mind they deserve when purchasing new products for their newborns."

"I'm glad CPSC Chair Alex Hoehn-Saric will be traveling to Chicago to raise awareness around the dangers families may not be aware of during the holiday season," said Congresswoman Robin Kelly. "Recent CPSC actions against infant sleeping products have been key to ensuring businesses are removing harmful products and babies are kept safe. Additionally, while the recent passage of my bill, Reese's Law, will help ensure future products with button batteries are safer; many homes have remotes, holiday decorations, and toys that contain button batteries and can be easily opened, and pose life threatening injuries if the batteries are ingested."

CPSC's latest nursery product injury and death report shows most nursery-product infant deaths occurred in a cluttered sleep space, when soft bedding was added to

the cribs, playpens/play yards or bassinets/cradles. On average there are almost 100 infant deaths annually in unsafe sleep environments involving nursery products. CPSC is reminding caregivers to follow these practices to keep babies' sleep space safe:

1. *Back to Sleep:* Always place the baby to sleep on their back to reduce the risk of sudden unexpected infant death syndrome (SUID/SIDS) and suffocation.
2. *Bare is Best:* Always keep the baby's sleep space bare (fitted sheet only) to prevent suffocation. Do not use pillows, padded crib bumpers, quilts or comforters.
3. Transfer the baby to a firm, flat crib, bassinet, play yard or bedside sleeper if they fall asleep in a swing, bouncer, lounger, or similar product.
4. Inclined products, such as rockers, gliders, soothers, and swings should never be used for infant sleep, and infants should not be left in these products unsupervised, unrestrained, or with soft bedding material, due to the risk of suffocation.

RECALLS: Always check to see if any purchased baby nursery products have been recalled, which includes any secondhand products. Remember, babies rely on adults to keep them safe. **Sign up today at CPSC.gov.**

FOR MEDIA:

For b-roll of a safe sleep environment click here.

For more tips on baby safety, recalled baby products and to view CPSC's newest baby safety public service announcement, visit CPSC's Safe Sleep and Crib Safety Education Center here.

Release Number

23-039

About the U.S. CPSC

The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public from unreasonable risk of injury or death associated with the use of thousands of types of consumer products. Deaths, injuries, and property damage from consumer product-related incidents cost the nation more than $1 trillion annually. CPSC's work to ensure the safety of consumer products has contributed to a decline in the rate of injuries associated with consumer products over the past 50 years.

Federal law prohibits any person from selling products subject to a Commission ordered recall or a voluntary recall undertaken in consultation with the CPSC.

For lifesaving information:

- Visit CPSC.gov.
- Sign up to receive our e-mail alerts.
- Follow us on Facebook, Instagram @USCPSC and Twitter @USCPSC.
- Report a dangerous product or a product-related injury on www.SaferProducts.gov.
- Call CPSC’s Hotline at 800-638-2772 (TTY 301-595-7054).
- Contact a media specialist.

Exhibit AA

US Department of Health and Human Services National Institutes of Health

SAFE TO SLEEP®

NIH Eunice Kennedy Shriver National Institute of Child Health and Human Development

Safe Sleep Environment for Baby

A safe sleep area can help reduce baby's risk for Sudden Infant Death Syndrome (SIDS) and other sleep-related deaths, such as from accidental suffocation.

What does a safe sleep environment look like?

A safe sleep environment for baby is:

- Firm (returns to its original shape quickly if pressed on)
- Flat (like a table, not a hammock)
- Level (not at an angle or incline) and covered only with a fitted sheet

Learn more about safe sleep surfaces and other features of a safe sleep environment.

You can find examples and images of safe sleep areas on our Flickr page. Babies should never sleep on an adult bed, couch, or armchair by themselves, with others, or with pets. Couches and armchairs are particularly dangerous when an adult falls asleep on them while feeding or comforting baby.[1]

Why does baby's sleep surface have to be firm, flat, and level?

Although adults may prefer soft surfaces for sleep, research shows that babies who sleep on top of soft surfaces or with items are at higher risk of SIDS and other sleep-related death. Soft surfaces, like couches, sofas, waterbeds, memory foam, air or pillow-top adult mattresses, quilts, blankets, and sheepskins are not safe for babies to sleep on.

Learn more about other sleep-related deaths including entrapment, suffocation, and strangulation.

Sleeping under quilts, blankets, sheepskins, and other soft coverings also increases the risk of sleep-related infant death from suffocation and strangulation.

Sleep surfaces with one end higher than the other are not safe for babies to sleep on, because baby's body can slide down and their head can slump forward. This can cause positional asphyxia, which is when baby's body position gets in the way of their breathing.

Similarly, sleep surfaces that elevate both baby's head and feet, like a hammock, also increase the risk for positional asphyxia. Sitting with the head down and the chin on or near the chest could block baby's airway and cause suffocation.

For these reasons, baby's sleep surface should be firm (returns to its original shape quickly if pressed on), flat (like a table, not a hammock), and level (not at an angle or inclined).

Can I put a pillow, blanket, or a favorite toy in baby's sleep area?

Even though a crib with nothing in it except a fitted sheet covering the mattress may seem bare, it is the safest option for baby.

Things in the sleep area can pose dangers for baby, especially if they are:

- Soft or squishy (e.g., pillows, stuffed toys, crib bumpers)
- Under or on top of baby (e.g., comforters, quilts, blankets, positioners)
- Non-fitted, even if they are lightweight, small, or "tucked in" (e.g., loveys/cloths, non-fitted sheets, tucked-in blankets)
- Weighted (e.g., weighted blankets, weighted swaddles)

Research also links crib bumpers and bedding other than a fitted sheet covering the baby's mattress to serious injuries and deaths from SIDS, suffocation, entrapment, and strangulation.

Keeping these things out of baby's sleep area is the best way to avoid these dangers.

Is it safe for my baby to sleep in a car seat or stroller?

Car seats, strollers, and sitting devices are not recommended as baby's regular sleep or nap space. If baby falls asleep in a sitting or carrying device, move them to their regular sleep space as soon as possible.

Learn more about safe sleep surfaces and other features of a safe sleep environment.

HANDOUT

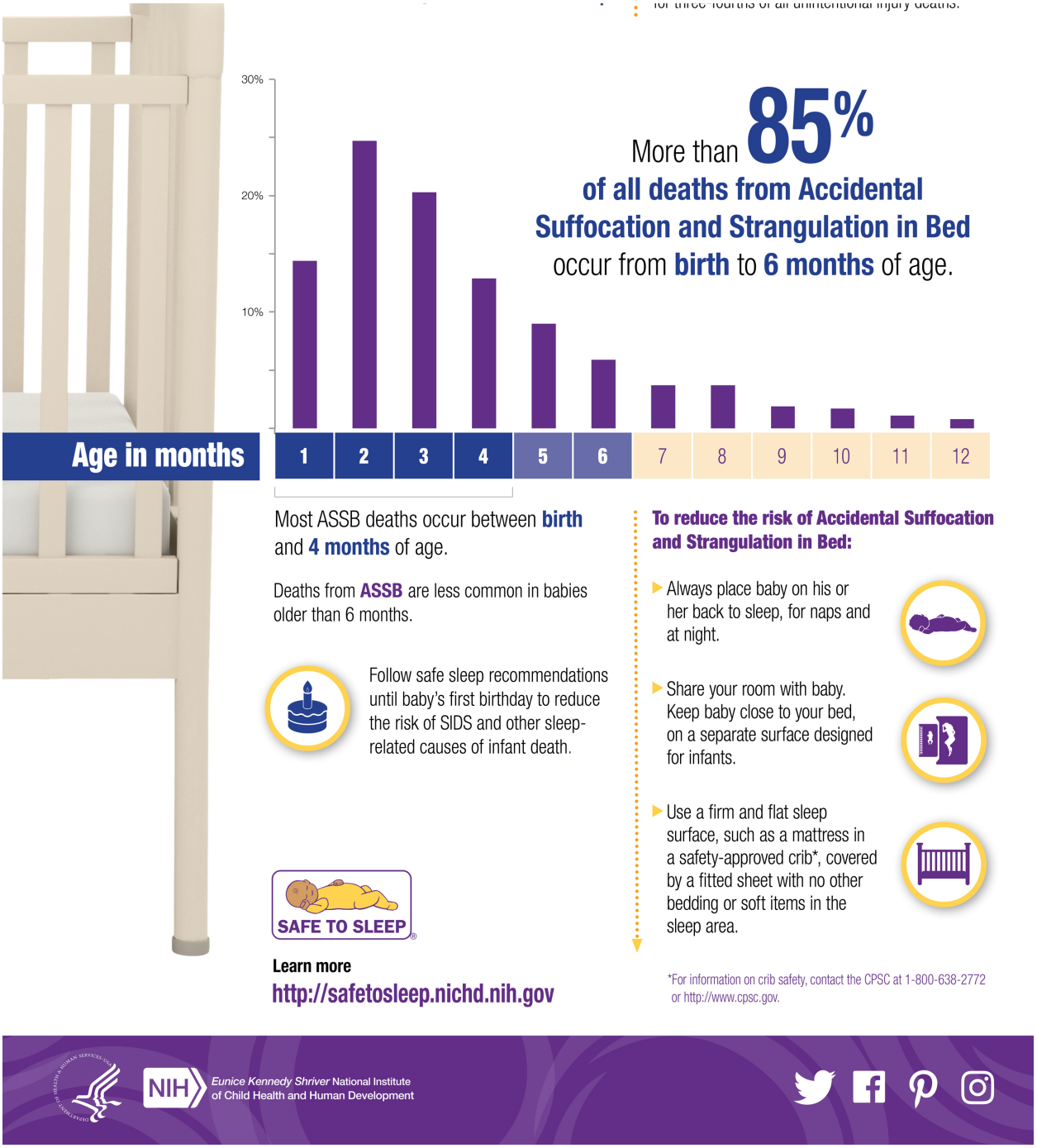
What does a safe sleep environment look like? Reduce Baby's Risk of Sleep-Related Death

This 1-page handout shows a safe infant sleep environment and summarizes ways to reduce baby's risk of sleep-related death. (Available in sets of 50 sheets)

ORDER **OPEN PDF (1.68 MB)**

Accidental Suffocation and Strangulation During Infant Sleep

Accidental Suffocation and Strangulation in Bed, or ASSB, occurs when something limits a baby's breathing, like when soft bedding or blankets are against their face or when a baby gets trapped between two objects, such as a mattress and wall. Among babies, accidental suffocation is responsible for three-fourths of all unintentional injury deaths



Accidental Suffocation and Strangulation During Infant Sleep

OPEN PDF (345 KB) **OPEN JPEG (3.9 MB)**

Text alternative

Copy and paste the code below to embed this infographic.

```
<a href="https://safetosleep.nichd.nih.gov/resources/social-digital"><img src="https://safetosleep.nichd.nih.gov/sites/default/files/inline-images/ASSB_timeline_infographic_625_2.jpg" width="625"
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What is room sharing, and how do I do it?

Room sharing means that baby sleeps in the same room as parents or adults, near or next to the adult bed, but in a separate sleep space that is made for infants (crib, bassinet, or portable play yard).

Research shows that room sharing reduces the risk of SIDS and sleep-related infant deaths. It is safer than bed sharing and is safer than having baby sleep in their own room.

Some data suggest that room sharing reduces the risk of SIDS by as much as 50% compared with sharing an adult bed with baby or sleeping in a separate room from baby.[2] Room sharing without bed sharing also reduces the risk of suffocation, strangulation, and entrapment, any of which can occur when a baby sleeps in an adult bed.

Room sharing also makes feeding, comforting, and monitoring the baby easier. For example, keeping a baby in a safety-approved crib* next to the adult bed makes it easier to check on baby without having to get fully out of bed. An infant sleep space next to mom's side of the bed also means she can breastfeed without having to go in another room.

What should I do if I fall asleep while feeding or comforting baby in my bed?

If you fall asleep while feeding or comforting baby in your bed, put them back into their own sleep area, like a bassinet, next to your bed as soon as you wake up.

You should also think about how tired you are before you bring baby into your bed to feed or comfort. If there's a chance you may fall asleep, remove all items and bedding from your side of the bed before adding baby to the bed. Removing pillows, blankets, and unfitted sheets from the area reduces the risk of suffocation and strangulation for baby.

Learn more about ways to practice safe sleep when breastfeeding.

Safe Sleep for Your Baby (60 seconds)

This short video describes ways to reduce the risk of SIDS and other sleep-related causes of infant death.

Text Alternative

Won't I be able to better protect my baby from SIDS by bed sharing with them/having them sleep in my bed?

Bed sharing—when baby shares a sleep surface with an adult, other child/children, or pet—is not recommended, because it increases the risk for SIDS and sleep-related death. Babies should not share an adult mattress, couch, or armchair with others, or with pets.

Many people think they will be able to hear or sense SIDS before it happens and take action to save baby. But SIDS is not associated with sounds or movements, meaning there is usually nothing to hear or sense.

Bed sharing can also be very risky for baby in certain situations. Room sharing without bed sharing is the safest option.

Learn more about safe sleep surfaces and other features of a safe sleep environment.

* The Consumer Product Safety Commission has more information on crib safety at https://www.cpsc.gov/SafeSleep.

Citations

1. Hauck, F. R., Herman, S. M., Donovan, M., Iyasu, S., Merrick Moore. C., Donoghue, E., et al. (2003). Sleep environment and the risk of sudden infant death syndrome in an urban population: The Chicago Infant Mortality Study. *Pediatrics, 111*(Suppl 1), 1207–1214. Retrieved May 3, 2021, from https://pubmed.ncbi.nlm.nih.gov/12728140/.
2. Moon, R. Y., & American Academy of Pediatrics Task Force on Sudden Infant Death Syndrome. (2016). SIDS and other sleep-related infant deaths: Evidence base for 2016 updated recommendations for a safe infant sleeping environment. *Pediatrics, 138*(5), e20162940. Retrieved May 3, 2021, from https://pubmed.ncbi.nlm.nih.gov/27940805/.

Exhibit BB

United States
Consumer Product Safety Commission

Injuries and Deaths Associated with Nursery Products Among Children Younger than Age Five

November 2022

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Directorate for Epidemiology
Division of Hazard Analysis
U.S. Consumer Product Safety Commission
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This report was prepared by the CPSC staff. It has not been reviewed or approved by, and may not necessarily reflect the views of, the Commission.

Table of Contents

Executive Summary

U.S. Consumer Product Safety Commission (CPSC) staff presents in this report statistics regarding injuries and deaths associated with nursery products among children younger than the age of 5 years, based on the most recently available information.[1]

Emergency Department-Treated Injuries:

- In 2021, there were an estimated 53,000 emergency department-treated injuries associated with (*i.e.,* in use at the time of incident), but not necessarily caused by, nursery products among children younger than 5 years of age. This translates to an injury rate of an estimated 281 injuries per 100,000 children under the age of 5 years.[2] The increase from the total 2020 injury estimate is statistically significant and is presumed to reflect a reduction in emergency department avoidance due to COVID-19 that was apparent in 2020.[3]

- High chairs, cribs/mattresses, infant carriers, and strollers/carriages were associated with 63 percent of the total estimated injuries. Falls were the leading cause of injury; and the head, followed by the face, was the body part injured most frequently. A diagnosis of internal organ injury, contusion/abrasion, or laceration was associated with most of the injuries.

- A trend analysis based on the 3 years from 2019 through 2021 does not show any statistically significant trend in the injury estimates. A longer-term trend analysis over the period 2017 through 2021 does not show any statistically significant trend either.

- A review of the estimated injuries by victims' demographic characteristics shows that:
  - For 2019–2021, on average, race information is known in about 60 percent of the injuries, while ethnicity information is known in about 44 percent of the injuries.
  - Where information is available, the injury and population distributions by race appear to be closely aligned for each year from 2019 through 2021.
  - Ethnicity data are insufficient to allow for presentation of any estimates.

[1] Not all these incidents are addressable by an action the CPSC could take; however, it was not the purpose of this report to evaluate the addressability of the incidents, but rather, to update estimates of emergency department-treated injuries and to quantify the number of fatalities reported to CPSC staff.
[2] The population data for the denominator is available at the U.S. Census Bureau website: https://www.census.gov/data/datasets/time-series/demo/popest/2020s-national-detail.html; Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2020 to July 1, 2021 (NC-EST2021-AGESEX-RES); last revised June 30, 2022.
[3] Schroeder, T. and Cowhig, M., "Effect of Novel Coronavirus Pandemic on 2020 NEISS Estimates", March-December, 2020

Fatalities:

- CPSC staff has reports of 443 deaths during the 3-year period from 2017 to 2019—an annual average of 148 deaths among children younger than age 5—associated with (*i.e.,* in use at the time of incident), but not necessarily caused by, nursery products.

- Cribs/mattresses, playpens/play yards, bassinets/cradles, infant carriers, and inclined infant sleep products were associated with 82 percent of the fatalities reported.

- Causes of death included positional asphyxia, strangulation, and drowning, among others. In some instances, the fatalities were attributed to the product; in other cases, the fatalities resulted from a hazardous environment in or around the product, or a combination of contributions.

CPSC staff has evaluated the incidents characterized in the annual reports on nursery products for many durable infant and toddler products, along with other reported incidents, to assess the efficacy of voluntary standards. These evaluations have supported the staff's work with standards development organizations to refine these standards, and likewise, supported staff briefing packages for notices of proposed rulemaking (NPRs) and final rules under section 104 of the Consumer Product Safety Improvement Act of 2008 (CPSIA).[4] Early in fiscal year (FY) 2022, the Commission issued a final rule establishing a new standard for Crib Mattresses, which took effect August 15, 2022. The final rule for Infant Sleep Products became effective on June 23, 2022. The Commission also issued revised rules on Infant Swings, Carriages and Strollers, High Chairs, Baby Changing Products, Infant Bath Tubs, Frame Carriers, Slings, and Bouncer Seats in FY 2022.

[4] There is much overlap between the products covered by this report and the products subject to rules issued under section 104 of the CPSIA. However, this report covers some nursery products that may not fall within section 104 and some products that are not currently regulated under section 104.

Introduction

This report presents nursery product-related injury estimates for 2021,[5] as well as comparisons with historic injury estimates. Detailed information on deaths associated with nursery products that reportedly occurred during the 3-year period from 2017 to 2019, is also presented. Note that reporting is ongoing, and the number of reported fatalities for the period of time in this report may change as new reports are received.

Nursery Product-Related Emergency Department-Treated Injury Estimates

An estimated 53,000 nursery product-related injuries among children younger than 5 years old were treated in U.S. hospital emergency departments (ED) in 2021. Table 1 shows the estimated injuries and the corresponding injury rates for the latest 3 years, as well as the annual averages for this 3-year period. Staff did not observe a trend in injury estimates over the 2019 through 2021 period (p-value= 0.732). The attached Appendix provides annual estimates for 2017 through 2021, as well as more detail about the data-selection processes.

Table 1

Estimated Emergency Department-Treated Injuries to Children Under Age Five: 2019–2021

Calendar Year	Estimated Injuries	Estimated Injury Rates per 100,000 Children[2]
2019	60,600	310
2020	44,600	231
2021	53,000	281
2019 – 2021 Average	52,700	274

Source: NEISS, CPSC.
Note: Estimates rounded to the nearest 100. The average calculation is based on unrounded injury estimates.

Falls were the leading cause of all nursery product-related injuries reported through NEISS for 2021, like previous years. About 68 percent of the total injuries involved the head and the face, which were the body parts injured most frequently. Internal organ injuries, contusions/abrasions, or lacerations were the diagnoses in about 66 percent of the NEISS-reported injuries.[6] Approximately 93 percent of the injuries were treated and released; about 3 percent of the injuries required hospitalization; and 2 percent of the injuries were treated and transferred to a different hospital. These proportions have remained steady over the years; for example, both in 2020, as well as in 2019, 93 to 94 percent of the estimated injuries were treated and released. Any deaths reported through NEISS are included in the fatality discussion that follows.

[5] The source of the injury estimates is the National Electronic Injury Surveillance System (NEISS), a statistically valid surveillance system for collecting injury data. NEISS injury data are gathered from the emergency departments of hospitals selected as a probability sample of all the U.S. hospitals with emergency departments. The surveillance data gathered from the sample hospitals enable CPSC staff to make timely national estimates of the number of injuries associated with specific consumer products.
[6] Beginning in 2018, two diagnoses codes and two injured-body-parts codes are available in NEISS. To date, these newly introduced codes remain uncoded for more 80 percent of the injury reports. They were not used in this analysis.

Table 2 shows the breakdown of injury estimates by different product categories for 2021, along with the injury estimates for 2019 and 2020, for comparison purposes. As in 2020, there were more than 30 product codes associated with the injury estimates in 2021. The associated products have been aggregated into 13 product categories that align with standards development activities as in 2020. The top four categories: high chairs, cribs/mattresses, infant carriers, and strollers/carriages were associated with 63 percent of the total estimated injuries.

There was a statistically significant increase from an estimated total of 44,600 ED-treated injuries in 2020, to 53,000 injuries in 2021. This likely reflects a reversal of the reduction in emergency department avoidance due to COVID-19 that was apparent in 2020.[7] After the lifting of restrictions related to the COVID-19 pandemic, parents/caregivers were probably more likely to take young children to hospital EDs again following an injury. As a result, between 2020 and 2021, increases were observed in every product group except two. Three of the increases, annotated with a "**" in Table 2, were statistically significant (p-value < 0.05). The only product groups showing a decrease were the high chairs and baby walkers/jumpers/exercisers categories.

Table 2

Estimated Emergency Department-Treated Injuries to Children Under Age Five By Type of Nursery Product: 2020–2021

PRODUCT CATEGORY	ESTIMATED EMERGENCY DEPARTMENT-TREATED INJURIES		
	2019	2020	2021
TOTAL	60,600	44,600	53,000
High Chairs	12,000	10,200	10,100
Cribs/Mattresses	11,800	8,700	9,900
Infant Carriers (Excludes Motor Vehicle Incidents)	7,700	5,900	6,900
Strollers/Carriages	7,200	5,100	6,600
Changing Tables**	3,400	2,600	3,800
Baby Gates/Barriers	3,000	2,500	3,400
Baby Bouncer Seats**	2,800	1,300	2,500
Portable Baby Swings**	2,000	1,200	2,100
Playpens/Play Yards	2,400	1,500	2,100
Baby Walkers/Jumpers/Exercisers	3,000	2,200	1,800
Bassinets/Cradles	---[8]	---	1,200
Baby Bottles/Warmers/Sterilizers	1,300	---	---
Baby Baths/Bath Seats/Bathinettes	---	---	---
Other[9]	1,300	1,400	1,500

Source: NEISS, CPSC. Estimates are rounded to the nearest 100. The injury estimates may not add up to the total due to rounding.
Note: '**' indicates statistically significant increase from 2020 to 2021 (p-value<0.05).

[7] Schroeder, T. and Cowhig, M., "Effect of Novel Coronavirus Pandemic on 2020 NEISS Estimates", March-December, 2020
[8] '---' represent estimates that do not meet the NEISS reporting criteria, which require estimates to be 1,200 or greater, sample sizes to be 20 or larger, and the coefficients of variation to be 33 percent or lower.
[9] In both 2020 and 2021, the "Other" category included: pacifiers/teething rings, diapers (excluding diaper rash cases), potty chairs/training seats, and harnesses. In 2020, the "Other" category also included diaper pails and safety pins while in 2021, it included night lights, plastic nipple guards, and baby rattles.

Table 3 shows the breakout of injury estimates by race for each year from 2019 through 2021. Over the 3-year time frame, on average, the victim's race was unspecified for 40 percent of the estimated nursery product injuries. White children made up 45 percent of victims under the age of 5; Black/African American children made up 10 percent of victims, and children of other races made up less than 5 percent of victims. When considering only the injuries where race was known, on average, 75 percent were White (compared to 70 percent of the population for that age), 17 percent were Black (compared to 16 percent of the population for that age), and 3 percent were Asian (compared to 6 percent of the population for that age). As Table 3 shows, the distribution of estimated injuries by race has not changed much year-over-year during the period 2019 through 2021. However, due to the high proportion of the data with race information unspecified, this finding should be interpreted with caution.

Staff explored the injury data for information on ethnicity of victims. Although NEISS is equipped to capture such information, for the period 2019 through 2021, for nursery product injuries among children under 5 years of age, the ethnicity is unspecified for most of the data.

Table 3

Distribution of Population[2] and Estimated Emergency Department-Treated Injuries by Race[10] Among Children Under Age Five: 2019–2021

Race	2019		2020		2021	
	Percent of		Percent of		Percent of	
	Estimated Injuries	Population	Estimated Injuries	Population	Estimated Injuries	Population
White	75%	70%	74%	70%	76%	69%
Black/African American	19%	16%	18%	16%	15%	16%
Other[11]	4%	6%	3%	6%	6%	6%
Asian	1%	6%	4%	6%	3%	6%
American Indian/Alaska Native	1%	2%	1%	2%	1%	2%
Native Hawaiian/Pacific Islander	<0.5%	<0.5%	<0.5%	<0.5%	<0.5%	<0.5%
Total	100%†	100%	100%‡	100%	100%ᵟ	100%

Source: NEISS, CPSC. Percentages may not add up to 100, due to rounding.
Note: †This accounts for 58 percent of total estimated ED-treated nursery product-related injuries in 2019 for children under 5.
‡This accounts for 60 percent of total estimated ED-treated nursery product-related injuries in 2020 for children under 5.
ᵟThis accounts for 60 percent of total estimated ED-treated nursery product-related injuries in 2021 for children under 5.

[10] Where information is available in NEISS. See notes below Table 3 for information on the percentage of unknown in each year.
[11] Other: By NEISS definition, this category includes any race not explicitly listed in Table 3, or when more than one race is indicated.

Deaths Associated with Nursery Products

Although all the Commission's databases are used to identify nursery product-related deaths, death certificates are a major source of information for this analysis. At the time of the data extraction for this analysis, the Commission's death certificates database was at least 93 percent complete through 2019. The deaths reported here are from 2017 through 2019, the latest 3-year time frame with sufficiently available information, like previous annual reports.[12]

Table 4 provides a summary of nursery product-related reported deaths (total and average annual) for 2017 through 2019, along with data previously reported for 2016 through 2018, for comparison purposes. Reporting is ongoing, and the number of reported fatalities may change. Moreover, these reports are anecdotal and do not constitute a statistical sample or a complete count of nursery product-related deaths. As such, CPSC staff strongly discourages drawing any inferences based on the year-to-year increase or decrease shown in the reported data.

CPSC staff has received reports of a total of 443 deaths associated with nursery products—an annual average of 148 deaths—during this period. About 31 percent (137 total, or an annual average of 46) were associated with cribs/mattresses. Bassinets/cradles accounted for 16 percent (71 total, or an annual average of 24) of the reported deaths. Playpens/play yards were also associated with 16 percent (a total of 70 or an annual average of 23) of the reported deaths, while infant inclined sleep products were associated with 11 percent (a total of 48 or an annual average of 16) of the reported deaths. Infant carriers accounted for 9 percent (a total of 38 or an annual average of 13) of the reported deaths. The remaining 79 reported fatalities were associated with a range of products, including baby bath/bathinettes, baby bouncer seats, baby gates/barriers, infant portable swings, changing tables/pads, high chairs, infant strollers/carriages, baby walkers/jumpers/exercisers, and a variety of other sleep-products (*e.g.*, in-bed sleepers and toddler beds), seating products (*e.g.*, floor seats), and miscellaneous products.

For certain incident scenarios in which direct product involvement or failure was not evident, consultation with staff from the CPSC's Directorate for Engineering Sciences was necessary to determine the most appropriate product category in which to place the fatalities. Details of the methodology are provided in the attached Appendix.

[12] These deaths do not constitute a statistical sample of known probability and do not necessarily include all nursery product-related deaths that occurred during the 2017–2019 period. However, they do provide at least a minimum number for deaths associated with nursery products during that time. Furthermore, the number of reported incidents may change should staff receive additional reports. In addition, the number of fatalities for each product/group of products presented in this and previous annual nursery product reports are not expected to match the number of fatalities presented in any rulemaking packages on the same product/group of products because of the difference in the data-inclusion criteria applied. See Methodology section of the Appendix for the process used in this report.

Table 4

Reported Deaths Among Children Under Age Five by Type of Nursery Product

PRODUCT CATEGORY	TOTAL DEATHS		AVERAGE ANNUAL DEATHS	
	2016-2018	2017-2019	2016-2018	2017-2019
TOTAL	*389*	443	*130*	148
Cribs/Mattresses[13]	*127*	137	42	46
Bassinets/Cradles	*63*	71	21	24
Playpens/Play Yards	73	70	24	23
Infant Inclined Sleep Products[14]	*26*	48	*9*	16
Infant Carriers (Excludes Motor Vehicle Incidents)	31	38	10	13
Baby Baths/Bath Seats/Bathinettes	*11*	17	*4*	6
Baby Bouncer Seats	11	11	4	4
Baby Gates/Barriers	9	10	3	3
Portable Baby Swings	9	6	3	2
Changing Tables	5	3	2	1
High Chairs	1	3	<1	1
Strollers/Carriages	3	3	1	1
Baby Walkers/Jumpers/Exercisers	1	1	<1	<1
Other[15]	19	25	6	8

Source: CPSC epidemiological databases: Consumer Product Safety Risk Management System (CPSRMS) and NEISS from 2017 to 2019, for reported deaths.
Deaths for 2016-2018, which are shown in italics, represent changes since publication of the previous annual report, due to availability of additional information.
Note: The average annual deaths do not add up to the total due to rounding.

A closer look at the top five product categories with the largest numbers of reported deaths provides some insight into the hazard patterns. Between 2017 and 2019, these product categories were associated with 82 percent of the reported fatalities; for the earlier period (2016 through 2018), they also accounted for 82 percent of the total reported fatalities.

Between 2017 and 2019, 137 deaths were associated with cribs/mattresses. This total includes one additional fatality in 2018, for which additional information became available since publication of the previous annual report. About 73 percent of these deaths were associated with a cluttered sleep environment (the presence of extra bedding in the crib, such as pillows, blankets, and/or

[13] Certain items, such as nursing pillows and lounger pillows, are usually placed within other products, such as cribs, bassinets, and play yards. Any report involving these items was categorized with the product in which they were located, to avoid double counting.
[14] Beginning with the annual report published in 2018, the Infant Inclined Sleep Products group is presented in a row of its own in Table 4. These products come with one or more inclined sleep surface adjustment positions for the seat back that are greater than 10 degrees, but do not exceed 30 degrees. Some specific examples are infant hammocks, recliner seats, and nappers. These products are subject to the safety standard for Infant Sleep Products that the Commission published on June 23, 2021, which became effective since June 23, 2022 (86 FR 33022).
[15] Of the 25 deaths in this category from 2017 through 2019, 14 deaths were associated with products used in the sleep environment that are not among the product categories listed in Table 4. Among the 14, a toddler bed (product code 4082) was involved in 2 deaths; portable youth bedrails (product code 4075) were involved in 2 deaths; and in-bed sleepers were involved in the remaining 10 deaths. As of June 23, 2022, the in-bed sleepers are subject to the safety standard for Infant Sleep Products (86 FR 33022).
In addition to the 14 deaths, there were 4 asphyxiation deaths—1 in an unspecified infant seat, 1 on a baby bottle nipple and 2 on a pacifier; 4 drowning deaths, where an infant was left unattended on a non-bathing infant floor seat (product code 4074) in a water-filled tub; and 3 deaths in a rocker, where two unrestrained infants were found rolled over in a prone/sideways position, and another infant was found “slumped” in a supine position.
See https://www.cpsc.gov/s3fs-public/Nursery-Products-Annual-Report-2021.pdf p.10, for a list of products associated with deaths in the “Other” category in 2016−2018.

comforters, among others) that led to asphyxiation of the infant. Approximately 8 percent of the 137 deaths resulted from a range of hazards associated with the crib, including incomplete assembly; missing, broken, or nonfunctioning components; ill-fitting mattress; or ineffective crib repairs. Some of these incidents occurred in, or on, older, reassembled, recalled, or secondhand cribs. The remaining crib fatalities involved the presence of hazardous crib surroundings. Examples include strangulations from nearby cords or strings; suffocations from small objects located in/near the crib; asphyxiations due to co-sleeping with other children in the crib; entrapments between crib rail and a tied-down cover (*e.g.*, a twin mattress); entrapments between crib rail and a picture frame; and in one case, an electrocution when the infant touched a power outlet from inside his crib.

Between 2017 and 2019, staff identified 71 deaths associated with bassinets/cradles. This total includes one new fatality in 2018, for which additional information became available since publication of the previous annual report. Most of these deaths were associated with extra bedding, with pillows involved in many of the suffocation deaths. A few of the bassinet-related deaths involved product failure and/or the presence of hazardous surroundings around the bassinet.

Playpens/play yards were associated with 70 deaths between 2017 and 2019. Most of the deaths were due to asphyxiation, where the infant suffocated on a blanket/pillow/other soft bedding placed inside the play yard. The presence of a hazardous environment in or around the product, such as makeshift covers (*e.g.*, cardboards) used on top of play yards to contain the infant, use of ill-fitting, non-original mattresses and sofa cushions in the play yards, or co-sleeping arrangements with other infants in the play yard, were associated with some of the deaths. A few of the fatalities involved faulty products.

Between 2017 and 2019, infant inclined sleep products were associated with 48 deaths. This total includes 1 additional fatality in 2018, for which additional information became available since publication of the previous annual report. These products come with one or more inclined sleep surface adjustment positions for the seat back that are greater than 10 degrees, but do not exceed 30 degrees. All but one of these 48 fatalities happened in deep-seated recliner seats with rocking features; 1 fatality occurred in an inclined sleeper attachment that was placed in a crib. Some of the decedents were placed prone in the product, on soft bedding; some of the decedents were found to have rolled over, either completely or partially, ending up in a compromised position that resulted in asphyxiation deaths; a couple of the fatalities described the decedent as being found in a chin-to-chest position. These products are subject to the safety standard for infant sleep products that the Commission published on June 23, 2021, which became effective as of June 23, 2022 (86 FR 33022).

Finally, 38 deaths associated with infant carriers were identified during the period 2017 through 2019. Placing the infant in the carrier in a hazardous manner was the most common scenario. Examples include an infant partially restrained in the seat with shoulder straps only, who slid forward in the seat and strangled at the chest clip; a fatality resulting from an unattended and unrestrained infant, sometimes sleeping on top of a soft blanket in the seat, who managed to get into a compromised position; a fatality resulting from a carrier tipping over when placed on a nonrigid surface, trapping the infant inside; an infant positioned improperly in a carrier on the caregiver's body, which led to suffocation; and an infant left unsupervised for an extended period in a vehicle with the windows rolled up, resulting in death due to hyperthermia.

In conclusion, the hazard patterns described indicate that although a nursery product was involved, many of the fatalities were associated with how the product was used, including putting the product in a hazardous situation, and/or using it in a hazardous manner.

Appendix

Methodology

ED-Treated Injuries (In-Scope Data):

- Database: NEISS from 01/01/2021 through 12/31/2021 (2017 through 2020 NEISS analytical datasets from previous years were used for comparison purposes); date of extraction was 05/19/2022.
- Product codes: 1500–1599, excluding 1550.[16] When multiple nursery products were coded as involved in an injury report, staff identified a "primary" product code based on the narrative description and used that for classification in this analysis.
- Age of victim: 0 through 4 years.
- Screened to ensure that no motor vehicle incidents were included.
- All cases of diaper rash (identified as side-effects of antibiotics use or exposure to prolonged moisture) were excluded.

Beginning with the 2016 report (using 2015 NEISS data), the injury estimates in annual reports on nursery products are based on non-incidental, emergency department-treated injuries. The association of an incident/injury with a nursery product is incidental if the occurrence of the incident/injury is considered *not dependent* on the presence of that nursery product in the incident scenario. The exclusion of incidental injury cases aligns more closely with the way CPSC staff has prepared the CPSIA section 104 rulemaking packages for the Commission. Now that most of the nursery products discussed in this report have a mandatory rule in place, staff believes that annual estimates based on the non-incidental data will provide a better tool for gauging the efficacy of the various standards.

Examples of Additional Screenings (Applied to In-Scope Data to Arrive at Non-Incidental Data):

- If the official diagnosis indicated that no injury had been sustained, the case was excluded.
- If the product's involvement was incidental, such as a child being stung by a bee, or getting bitten by a dog while in an infant stroller, the case was excluded.
- If a child suffered a medical crisis while seated in a high chair (*e.g.*, choking on food), or gained access to adult medication by climbing on a crib, the case was excluded.
- If a child was injured by other young children (*e.g.*, pulled out of an infant swing by a young sibling), the case was excluded.

All ED-treated injury estimates/analyses in this report are based on non-incidental data.

Deaths:

- Databases: CPSRMS and NEISS from 01/01/2017 through 12/31/2019; date of extraction was 08/08/2022.

  Information available from CPSRMS and NEISS on incidents that have not been investigated is often incomplete or provides insufficient information on the hazard scenario. If these incident reports are investigated later, or as other associated reports come in, the

[16] Product code 1550 (*Infant and Toddler Play Centers excluding Jumpers, Bouncers, and Exercisers)* represents a toy, not a nursery product.

initial information is corroborated or contradicted, and the fatality numbers reported may change.

- Product codes: 1500–1599, excluding 1550[16]; 4074 for *children's chairs*, 4075 for *portable youth bed rails,* and 4082 for *toddler beds*.
- Age of victim: 0 through 4 years.
- Screened to ensure no duplicates were included; all records of the same incident that were reported through different data sources were associated and included as a single report.
- Miscoded products were recoded correctly. A common example was a play yard miscoded as a crib, but was counted as a play yard for this report.
- As with the emergency department-treated injuries, deaths involving certain products were grouped together. For instance, baby baths and bathinettes were counted together with bath seats; exercisers were counted with baby walkers and jumpers; and as noted earlier, any extra-bedding-in-crib incidents were counted with cribs, while incidents with extra bedding in a play yard were counted with play yards.
- Staff carefully screened to determine whether cases were in scope or out of scope. An example of an out-of-scope case would be an incident where no direct or circumstantial information was available to determine *how* the death occurred, or if Sudden Infant Death Syndrome was the only information available from the official report(s). These criteria differ from the inclusion criteria used in various rulemaking packages prepared by CPSC staff. In the latter, *all* data are included, but such incidents may be classified differently; for example, the incidents could be classified into "non-product-related" or "no information" categories, as appropriate (and are excluded from the data-based evidence used for rulemaking purposes). As such, the number of fatalities for each product/group of products presented in this and previous annual nursery product reports are not expected to match the number of fatalities presented in any rulemaking packages on the same product/group of products.

  In some cases that were considered in scope, the death was not associated directly with the nursery product. However, hazards in the vicinity of the product, often created inadvertently by caregivers, led to the deaths. For instance, extra bedding inside the crib, or plastic bags that were within easy reach of the crib, have led to some deaths. These deaths have been included with crib deaths. Similarly, clutter and extra bedding inside the play yard, or placement of the play yard within easy reach of a window blind cord, have led to some fatalities. These have been counted with play yard deaths. While these deaths may not be due to product failure only, they highlight some common misconceptions and oversights, poorly drafted instructions, or warnings, and/or foreseeable use patterns for these products. Therefore, these deaths were included.

  Staff excluded any report to the CPSC of a nursery product-related incident that occurred outside of the United States.

Historical Data

Based on the non-incidental data only, trend analysis for 2019–2021 shows no statistically significant trend (p-value=0.732). Additionally, when historical data from 2017 and 2018 are included, the 2017–2021 data do not show any statistically significant trend either (p-value=0.347).

Table 5 and Figure 1 present the 5-year injury estimates covering 2017 through 2021, based on ED-treated, non-incidental data on nursery products. Figure 2 presents the corresponding 5-year estimated injury rates per 100,000 children under age 5.

Table 5

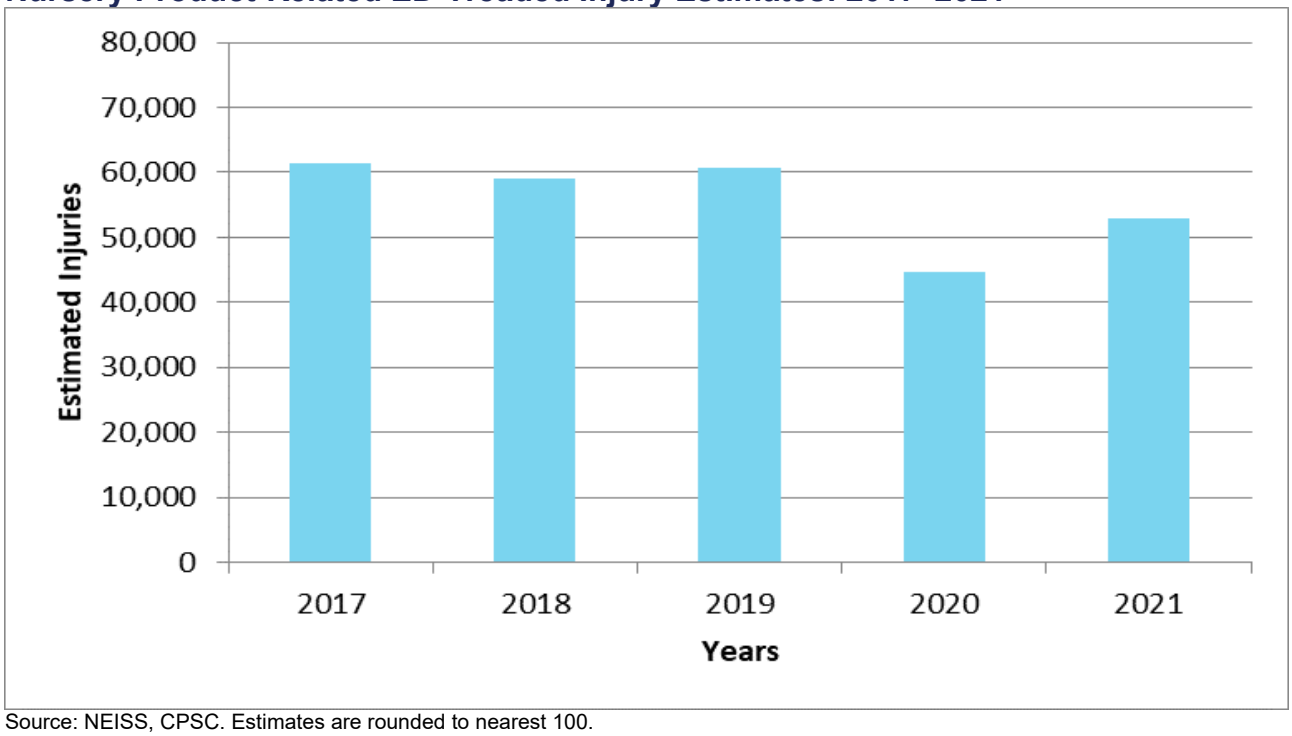
Nursery Product-Related ED-Treaded Injury Estimates: 2017–2021

Calendar Year	Estimated Injuries	95% Confidence Interval
2017	61,400	42,700 – 80,100
2018	59,000	38,400 – 79,600
2019	60,600	38,000 – 83,200
2020	44,600	26,800 – 62,300
2021	53,000	34,900 – 71,000

Source: NEISS, CPSC. Estimates rounded to nearest 100.

Figure 1

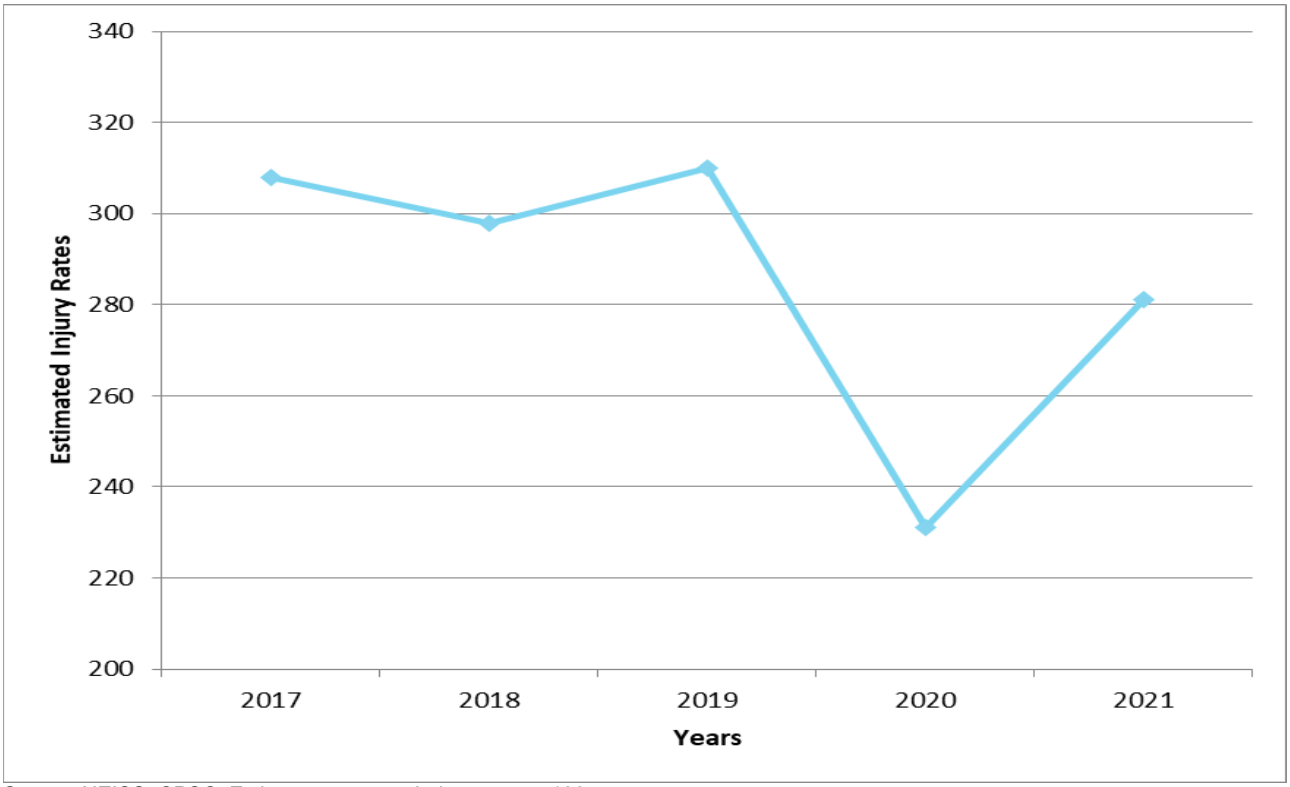
Nursery Product-Related ED-Treaded Injury Estimates: 2017–2021



Source: NEISS, CPSC. Estimates are rounded to nearest 100.

Figure 2

Nursery Product-Related ED-Treaded Estimated Injuries per 100,000 Children Under 5 Years: 2017–2021



Source: NEISS, CPSC. Estimates are rounded to nearest 100.
The population data for the denominator is from U.S. Census Bureau website (same as footnote 2): https://www.census.gov/data/datasets/time-series/demo/popest/2020s-national-detail.html; Annual Estimates of the Resident Population by Single Year of Age and Sex for the United States: April 1, 2020 to July 1, 2021 (NC-EST2021-AGESEX-RES); last revised June 30, 2022.

With the completion of this report, analyses of non-incidental hospital ED-treated injury data are now available for the seven years, 2015 through 2021. As analyses are completed for additional years, staff anticipates presenting 10- and 15-year trends in the future.

Exhibit CC

CONSUMER PRODUCT SAFETY COMMISSION

IN RE LEACHCO, INC.	CPSC Docket No. 22-1 HON. MICHAEL G. YOUNG PRESIDING OFFICER

ORDER ON PREHEARING SCHEDULE

This matter, having come before me on the Parties' Joint Proposed Revised Prehearing Schedule, dated September 14, 2022, and for good cause having been found to adopt the proposed schedule, on this 16th day of September, 2022,[1]

IT IS HEREBY ORDERED THAT the following deadlines are established:

Event	Deadlines
Responses to First Set of Requests for Production of Documents and First Set of Interrogatories, including revised privilege log(s)	October 3, 2022
Last day to serve any written discovery requests	February 2, 2023
Fact Discovery closes (pending motions to compel)	March 20, 2023
Responses to Expert Interrogatories under 16 C.F.R. § 1025.31(c)(4)(i)(A) and Expert Witness Direct Testimony under 16 C.F.R. § 1025.44(b) and Discovery Deadline (pending motions to compel)	April 28, 2023
Motions for Summary Decision	June 9, 2023

[1] The hearing in this matter was originally scheduled for June 5, 2023. After the hearing date was set, the parties were engaged in a discovery dispute, and new counsel entered an appearance on behalf of Respondent. The parties volunteered to work cooperatively on a new schedule and to commit to the efficient resumption and completion of discovery, and proposed a new hearing date of August 14. In light of the significant pretrial activities, the appearance of new counsel, and the justification provided by counsel for the new date, I have determined that the requested hearing date is appropriate.

Responses to Motion for Summary Decision	June 23, 2023
Prehearing Briefs	July 7, 2023
Witness and Exhibit Lists, Stipulations, and Prehearing Motions, including Motions in Limine	July 14, 2023
Hearing (estimate two weeks)	August 7, 2023
Post-hearing briefs (16 C.F.R. § 1025.46)	50 days after hearing
Replies to post-hearing briefs (16 C.F.R. § 1025.46)	15 days after briefs

MICHAEL G. YOUNG
Administrative Law Judge
Federal Mine Safety and Health Review Commission[2]

[2] The Administrative Law Judges of the Federal Mine Safety and Health Review Commission are authorized to hear cases pending before the Consumer Product Safety Commission pursuant to an Interagency Agreement effective for a period beginning February 25, 2022.