



# **Infant Deaths in Inclined Sleepers: Fisher-Price's Rock 'n Play Reveals Dangerous Flaws in U.S. Product Safety**

*Prepared for Chairwoman Carolyn B. Maloney*

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## **EXECUTIVE SUMMARY**

This staff report presents findings from the Committee on Oversight and Reform’s investigation into the design, safety, and recall of infant inclined sleep products. The Committee launched this investigation in August 2019 following media reports that dozens of infants died in inclined sleep products because of inadequate safety research and product designs that conflicted with longstanding guidelines on safe infant sleep. The first inclined sleeper on the market was the Rock ‘n Play Sleeper, which was released by Fisher-Price, a wholly-owned subsidiary of Mattel, in October 2009.<sup>1</sup>

As part of its investigation, the Committee obtained thousands of documents from five manufacturers of infant inclined sleep products. The Committee conducted interviews with current and former Fisher-Price employees and officials at the Consumer Product Safety Commission (CPSC), the agency responsible for oversight of consumer products, including infant inclined sleepers.

The Committee’s investigation revealed that Fisher-Price failed to ensure the Rock ‘n Play was safe before bringing it to market, ignored critical warnings from pediatricians, parents, and foreign regulators that the product was dangerous, and continued to market it for overnight sleep despite clear evidence that this put infants at risk of serious harm or death. The investigation also showed that Fisher-Price and other manufacturers of infant inclined sleepers operate with inadequate oversight, and that CPSC lacks the necessary authority to protect infants from potentially deadly products.

Fisher-Price’s poor safety practices and lack of meaningful oversight allowed the Rock ‘n Play to stay on the U.S. market for a total of 10 years, during which time more than fifty infants died using the product—while the company raked in at least \$200 million in revenue.<sup>2</sup>

## **FINDINGS**

### ***1. Fisher-Price Failed to Ensure the Rock ‘n Play was Safe, Ignored Warnings That it was Dangerous, and Marketed it for Overnight Use Despite Risks***

The Committee’s investigation shows that Fisher-Price did not take adequate steps to ensure its product was safe before bringing it to market, ignored warnings and evidence that the product may be unsafe, and marketed the Rock ‘n Play for overnight sleep despite evidence that sleeping at an incline could put infants at risk of serious harm or death. The investigation found:

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<sup>1</sup> An inclined sleeper is a product designed for infants and marketed for all-night sleep. The sleeper holds the infant on its back at a thirty-degree angle, such that the infant’s feet are at a downward slope from the infant’s head. The name “sleeper” is given to a device in which a caregiver can be expected to leave a child without direct supervision while the child sleeps.

<sup>2</sup> *New Evidence Shows More Infant Deaths Tied To Inclined Sleepers Than Previously Reported*, Consumer Reports (Mar. 11, 2020) (online at [www.consumerreports.org/child-safety/new-evidence-shows-more-infant-deaths-tied-to-inclined-sleepers-than-previously-reported/](http://www.consumerreports.org/child-safety/new-evidence-shows-more-infant-deaths-tied-to-inclined-sleepers-than-previously-reported/)).

- Although Fisher-Price marketed the Rock ‘n Play for overnight sleep, at the time it was brought to market in October 2009 there was no independent research, or even internal company research, showing that it was safe for babies to sleep at an angle. On the contrary, research showed that sleeping on an angle was unsafe.
- In three separate instances from August 2008 through February 2009, Fisher-Price’s internal Safety Committee warned about the need to research the positioning of infants in the Rock ‘n Play, finding the product was “unacceptable” without such research. The company never completed any research establishing that it was safe for infants to sleep at an angle before bringing the product to market.
- Before bringing the Rock ‘n Play to market, the company consulted only one doctor about the safety of the novel product for infant sleep. This individual was not a pediatrician and was later accused of practicing medicine without a license and using unsafe practices. A Fisher-Price executive told Committee staff that consulting even one doctor was not the company’s regular practice when introducing new infant products and confirmed this consultation was “extraordinary.”
- Fisher-Price tested only 62 infants using the product before it was released to the public, and no medical doctors were involved in analyzing the results of the tests. 4.7 million Rock ‘n Play units were sold before the product was recalled due to the risk of injury or death.
- The Rock ‘n Play became a wildly successful product for Fisher-Price, bringing in millions of dollars in sales every year. But documents obtained by the Committee show that Fisher-Price became aware of serious concerns about the Rock ‘n Play soon after its launch, including from regulatory bodies in Australia and Canada, pediatricians in the United States, and from consumers who were concerned the product was not safe for overnight sleep. For example:
  - In 2010, the Australian consumer protection agency privately warned Fisher-Price that the product’s use for sleeping “is at odds with widely accepted and promoted best practices.”
  - In 2011, the Canadian government banned the company from marketing the Rock ‘n Play as a sleeper due to safety concerns, prompting Fisher-Price to stop selling the product in Canada.
  - Also in 2011, a UK midwives organization warned that the Rock ‘n Play “***must not be*** used as infant cot ...because babies must always sleep flat on their backs.” A Fisher-Price executive complained the feedback was “very limiting” and said “this may put an end to our ability to sell the product in the UK.”

- In 2012, Fisher-Price was notified that a 15-week old infant died in the Rock ‘n Play, and that a two-month old “had stopped breathing” while in the Rock ‘n Play, but was revived.
- In 2013, a board-certified pediatrician wrote to Fisher-Price, “I am concerned that parents are using this product as a routine sleeping area for their babies. This is unsafe.”
- The company’s market research in 2017 showed that some consumers had similar concerns, with one mother warning, “It is obviously very unsafe. Babies need a flat surface to sleep on, no incline! It should absolutely not be marketed as a sleep space.”
- Internal documents show that the company conducted market research to determine how sales might be affected if the Rock ‘n Play were no longer marketed as a “Sleeper,” but instead as a “Soother.” The research showed that new mothers were more interested in purchasing the product when it was marketed as a Sleeper, indicating that the product could be used for nighttime sleep. The company opted not to change its marketing tactics in the United States or other countries where it sold the product.

## ***2. CPSC Does Not Have Adequate Regulatory or Enforcement Powers to Protect the Public***

The Committee’s investigation revealed grave flaws in the U.S. consumer product safety system, in which manufacturers are largely left to police themselves. Fisher-Price was permitted to conduct unregulated research into the safety of its own products, help develop the industry’s voluntary standards to govern those same products, and override attempts by CPSC to release important safety information about their product to the public.

- Fisher-Price was not required to submit *any* data or evidence to CPSC showing that the angle of the Rock ‘n Play was safe for overnight sleep before releasing it to the public, despite the fact that it was the only inclined product designed for infant sleep on the market at the time.
- CPSC has never issued a safety standard governing infant inclined sleep products. Instead, the Rock ‘n Play fell under a voluntary standard created by the non-governmental ASTM International. Fisher-Price led the committee that generated the standard, and CPSC had no power to approve or reject the standard.
- Even though Fisher-Price and CPSC were aware of injuries and deaths in the Rock ‘n Play as early as 2012, CPSC first expressed concern to Fisher-Price that the product was unsafe in February 2018. Even after that warning, the Rock ‘n Play was not recalled until more than a year later in April 2019.

- In early 2018, CPSC employees became alarmed when they compiled data for CPSC commissioners showing there were 15 infant deaths associated with the Rock ‘n Play, with one writing, “Holy cow! We need to discuss this. When the Commission sees this they are going to flip.”
- In 2019, after Fisher-Price failed to present data demonstrating that the Rock ‘n Play was safe, CPSC hired a medical expert to evaluate the risk of infants rolling over and suffocating in inclined sleep products. The expert’s report found that the Rock ‘n Play and similar products were unsafe for infant sleep. This was the first time such research had been conducted, either by CPSC or manufacturers, in the nearly ten years the product had been on the market.
- For nearly a year while CPSC’s research was ongoing, the public was not informed about the risks posed by the Rock ‘n Play. Because of laws preventing CPSC from disclosing information provided by manufacturers, CPSC could not publicly release any information about the deaths or injuries associated with Rock ‘n Play or institute a recall without engaging in costly and drawn out litigation or administrative proceedings. In April 2019, CPSC finally informed Fisher-Price that a public statement was necessary due to “the need to warn the public quickly because infants may be in danger of death when they roll over in the Rock ‘n Play.”
- The Rock ‘n Play was only recalled after CPSC inadvertently disclosed data to *Consumer Reports* in early 2019 about infant deaths associated with the Rock ‘n Play. *Consumer Reports* informed CPSC and Fisher-Price that it intended to publish the data, and within days Fisher-Price decided to recall the Rock ‘n Play. Documents obtained by the Committee show that CPSC and Fisher-Price were not planning to recall the Rock ‘n Play prior to the report published by *Consumer Reports*. The product might still be on the market today were it not for CPSC inadvertently disclosing data in violation of the restrictive laws protecting manufacturers.

The Committee strongly recommends reforms to empower CPSC to take more decisive action to prevent dangerous products from coming to and staying on the market. CPSC is unique among federal safety agencies for the limited power it holds to disclose safety information without manufacturer consent. Manufacturers are private companies driven by profit, and they have an obvious financial incentive to keep their products on the market. They should not be empowered to determine whether these products are safe for the public.

Consumer product manufacturers hold too much power and regulators not nearly enough. In the case of the Rock ‘n Play, this resulted in dozens of infant deaths. The Committee’s investigation makes clear that consumer protection laws, especially with respect to products for infants, must be strengthened.

## TABLE OF CONTENTS

<b>I.</b>	<b>BACKGROUND .....</b>	<b>1</b>
A.	Fisher-Price’s Novel Inclined Sleep Product Conflicted with Existing Guidelines and Research on Infant Sleep .....	1
B.	Fisher-Price Was Not Required to Prove the Rock ‘n Play Was Safe Before Selling It and Fended Off New Regulations.....	2
C.	Fisher-Price Was Heavily Involved in Creating the Weak Voluntary Standards Governing Its Own Product .....	3
<b>II.</b>	<b>FISHER-PRICE DEVELOPED THE ROCK ‘N PLAY WITHOUT ADEQUATE RESEARCH AND IGNORED WARNINGS ABOUT ITS SAFETY.....</b>	<b>4</b>
A.	Fisher-Price’s Product Development Process Skipped Needed Safety Analysis .....	4
B.	Fisher-Price Ignored Repeated Warnings That the Rock ‘n Play Was Unsafe.....	11
<b>III.</b>	<b>CPSC’S RESPONSE WAS HAMPERED BY LACK OF ENFORCEMENT TOOLS .....</b>	<b>19</b>
A.	CPSC Has Little Power to Prevent Dangerous Products from Being Released on the Market.....	19
B.	Deaths Associated with the Rock ‘n Play Raised Serious Concerns at CPSC .....	20
C.	Fisher-Price Pushed Back Against Concerns That the Rock ‘n Play Was Unsafe .....	24
D.	CPSC Contracted with an Outside Doctor to Evaluate the Risk of Infants Sleeping at an Incline.....	25
E.	Fisher-Price Recalled Rock ‘n Play After CPSC Action and Negative Press Attention .....	27
F.	Many Daycare Centers Remained Unaware of the Recall for Months.....	30
G.	Lack of Oversight of Infant Products is an Industry-Wide Problem .....	30
<b>IV.</b>	<b>POLICY RECOMMENDATIONS .....</b>	<b>32</b>

## I. BACKGROUND

### A. Fisher-Price's Novel Inclined Sleep Product Conflicted with Existing Guidelines and Research on Infant Sleep

The Rock 'n Play was developed and sold by Fisher-Price, a wholly-owned subsidiary of Mattel and one of Mattel's top-performing brands.<sup>3</sup> The two entities share key personnel, with some individuals employed by both entities. Mattel employees were in key positions of control throughout the development process for the Rock 'n Play.<sup>4</sup>

When the Rock 'n Play was launched in 2009, prevailing medical science held that infants should sleep flat on their backs on a firm surface. For decades, pediatricians and medical experts have recognized that infants need to be in a safe position while sleeping. During the early 1990s, pediatricians were concerned about the high number of infants dying from Sudden Infant Death Syndrome (SIDS), which occurs when infants die without explanation and is associated with sleep. Research at the time found that if infants slept on their stomachs, they were at least twice as likely to die of SIDS.<sup>5</sup> As a result, the National Institute of Child Health and Development—part of the National Institutes of Health—and the American Academy of Pediatrics (AAP)—a widely respected organization comprised of 67,000 pediatricians—started the “Back to Sleep” campaign to educate parents and encourage them to put their babies to sleep on their backs.<sup>6</sup>

A 2005 Policy Statement by the AAP stated that infants should be placed wholly on their back for sleep, and that a “firm crib mattress, covered by a sheet, is the recommended sleeping surface.”<sup>7</sup> The guidelines did not address the safety of infants sleeping at an angle because at the time, there were no inclined infant sleep products on the market. The design of the Rock 'n Play, which is positioned on an incline, did not conform to the 2005 standard.

Publicly available studies warned that it is unsafe for infants to sleep in car seats, which have a slightly steeper angle than the Rock 'n Play. In 2006, a study in the British Medical Journal warned that infants sleeping in car seats could suffer potentially life-threatening breathing problems. The same year, the AAP cautioned parents: “Don't leave your baby unattended in a car safety seat,” and “When your baby falls asleep in her car safety seat, it can be

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<sup>3</sup> Mattel, Inc., *Form 10-Q* (Apr. 29, 2021) (online at <https://investors.mattel.com/static-files/d9559138-6338-409a-9857-52427d0214ee>).

<sup>4</sup> While this report references Fisher-Price rather than Mattel, Mattel was at all times in control of all key decisions made about the development, safety monitoring, and recall of the Rock 'n Play.

<sup>5</sup> American Academy of Pediatrics, *Reducing Sudden Infant Death With “Back to Sleep”* (online at [www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/7-great-achievements/Pages/Reducing-Sudden-Infant-Death-with-Back-to-.aspx](http://www.aap.org/en-us/advocacy-and-policy/aap-health-initiatives/7-great-achievements/Pages/Reducing-Sudden-Infant-Death-with-Back-to-.aspx)) (last visited May 28, 2021).

<sup>6</sup> *Id.*

<sup>7</sup> *AAP Releases New Guidelines on Preventing SIDS*, American Family Physician (Dec. 1, 2005) (online at [www.aafp.org/afp/2005/1201/p2368.html](http://www.aafp.org/afp/2005/1201/p2368.html)).

tempting to bring her inside and leave her alone in the seat, but this can be unsafe.” AAP stated that the “best place for your baby to sleep is on her back in a safe crib.”<sup>8</sup>

**B. Fisher-Price Was Not Required to Prove the Rock ‘n Play Was Safe Before Selling It and Fended Off New Regulations**

When Fisher-Price released the Rock ‘n Play in October 2009, it was the only infant inclined sleep product on the market. The company aggressively marketed the new product, emphasizing that babies could sleep all night in the Rock ‘n Play. At the time it was launched, the Rock ‘n Play fell under CPSC’s new mandatory standard for bassinets and cradles, but that standard was silent on the appropriate angle for a baby to sleep. Fisher-Price was not required to provide any information to CPSC or any third party showing that it was safe for babies to sleep at an incline before bringing the product to market.

In 2010, CPSC proposed a standard that would limit the angle for infant sleep products to five degrees.<sup>9</sup> Since the Rock ‘n Play would not meet the new mandatory standard, Fisher-Price submitted a letter to CPSC requesting that the standard be revised to accommodate the design of the Rock ‘n Play. Fisher-Price wrote that the new standard would “inadvertently prohibit[...] products that do not present the risks at which the rule is aimed” and serve a segment of the market that “reasonably desire[s] an inclined sleep position for their infants.”<sup>10</sup> CPSC then decided to exclude inclined sleepers from the new mandatory standard. CPSC failed to put in place any alternative regulatory requirements or safety oversight for the Rock ‘n Play.

In an interview with Committee staff, CPSC General Counsel Gib Mullan confirmed that Fisher-Price was free to market the Rock ‘n Play without any oversight of its safety:

Q: [W]hen the Rock ‘n Play was introduced on the market, it was really the only product of its kind being marketed for overnight sleep. In that case, would the manufacturer have to attest to the safety of the product for overnight sleep to the CPSC?

...

A: [N]o, they would not have to.<sup>11</sup>

Mr. Mullan also confirmed that CPSC does not conduct its own safety review of products being released before they are launched. As a result, when deciding whether a product is safe to release on the market, even a product for infants and children, manufacturers are largely left to police themselves.

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<sup>8</sup> *Car Seat Safety: Watch Infants*, WebMD (Dec. 7, 2006) (online at [www.webmd.com/parenting/baby/news/20061207/car-seat-safety-watch-infants#2](http://www.webmd.com/parenting/baby/news/20061207/car-seat-safety-watch-infants#2)).

<sup>9</sup> 75 Fed. Reg. 22303.

<sup>10</sup> Mattel\_HCOR\_001785 at 1.

<sup>11</sup> Committee on Oversight and Reform, Transcribed Interview of Duane Boniface (Sept. 9, 2020).



**C. Fisher-Price Was Heavily Involved in Creating the Weak Voluntary Standards Governing Its Own Product**

When CPSC decided to exclude inclined sleepers from the new mandatory standard for bassinets and cradles, CPSC wrote to Fisher-Price saying that because inclined sleepers would be “out of scope” for the new standard, they “should be in another or new ASTM standard.”<sup>12</sup> ASTM International is a non-governmental organization that develops voluntary standards for thousands of consumer products. ASTM standards are developed within committees that often include manufacturers, consumer safety advocates, testing labs, and other parties with interest in the standards being developed. The resulting standards are entirely voluntary.

The committee charged with developing the new standard for infant inclined sleepers was led by Mike Steinwachs, a Fisher-Price engineer, giving the company a central role in setting the safety standard for its own product. According to ASTM bylaws, no more than 50% of a committee can be comprised of employees of the manufacturers who created the product in question.<sup>13</sup> Other committee participants, such as consultants for manufacturers and testing labs, may rely heavily on manufacturers for business, but do not count towards the 50% limit on manufacturer representatives. As a result, manufacturers often have an outsized influence on the voluntary standards that govern their own products.<sup>14</sup>

CPSC representatives were recently given the power to vote on the approval of final voluntary standards developed by ASTM committees. However, Duane Boniface, CPSC Assistant Executive Director of the Office of Hazard Identification and Reduction, made clear in an interview with Committee staff that CPSC still lacks the power to overrule inadequate safety standards:

Q: Before you were able to vote, if the CPSC did have concerns, could the committee ultimately move forward, despite those concerns?

A: Yes. And they can do that even with our ability to vote.<sup>15</sup>

Mr. Boniface told Committee staff that the ASTM standards process allows medical professionals to provide their perspective, but does not require it. The process also does not empower medical professionals to veto or strike down rules that are not supported by safety data:

Q: But there’s no sort of special requirement for infant products, you know, for overnight sleep that you consult outside pediatricians or anything like that?

A: No. So the consultation there would, again, be at the voluntary standards

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<sup>12</sup> Mattel\_HCOR\_003884.

<sup>13</sup> *Regulations Governing ASTM Technical Committees*, ASTM (Sept. 2020) (online at [www.astm.org/Regulations.html#s8.1](http://www.astm.org/Regulations.html#s8.1)).

<sup>14</sup> Briefing from Nancy Cowles to Staff, Committee on Oversight and Reform (Aug. 5, 2020).

<sup>15</sup> Committee on Oversight and Reform, Transcribed Interview of Duane Boniface (Sept. 9, 2020).

meetings and then through part of the rulemaking process.<sup>16</sup>

As a result, even though the standards process is intended to provide a forum for experts, consumer advocates, and medical professionals to provide input, manufacturers have a great deal of power to override their views and set the standards that will govern their own products.

ASTM did not release a voluntary standard for infant inclined sleepers until May 2015—nearly five years after the Rock ‘n Play was released—which was then revised in January 2017.<sup>17</sup> The voluntary standard required that the seat back angle not exceed thirty degrees, the exact angle of the Rock ‘n Play.<sup>18</sup> CPSC officials told the Committee that ASTM does not have a written rationale for the angle limit being set at thirty degrees, but “discussions early on in the development of the standard focused on car seat limits set at 45 degrees, so with a ‘safety factor,’ ASTM set the limit at 30 degrees.”<sup>19</sup> That rationale echoes the justification for determining the angle of the Rock ‘n Play provided in litigation by Fisher-Price employees.<sup>20</sup>

## **II. FISHER-PRICE DEVELOPED THE ROCK ‘N PLAY WITHOUT ADEQUATE RESEARCH AND IGNORED WARNINGS ABOUT ITS SAFETY**

### **A. Fisher-Price’s Product Development Process Skipped Needed Safety Analysis**

As a household name in the baby business, Fisher-Price relies on its reputation as a company that manufactures safe and reliable products. An internal presentation from 2016 stated that the company has “nearly 100% brand awareness globally” and is the “#1 most trusted and loved brand by moms.” The presentation asserted, “Research has always been at the heart of product development at Fisher-Price.”<sup>21</sup>

The idea for the Rock ‘n Play Sleeper was born in 2008 by a Fisher-Price industrial designer named Linda Chapman. Ms. Chapman recalled that when her son was a baby, he had trouble sleeping. At the time, around 1999 or 2000, her son’s pediatrician recommended that he try sleeping with his head at an incline. Although it was subsequently disproved, some pediatricians believed at the time that keeping babies’ heads at an angle could prevent acid reflux. In 2008, Ms. Chapman felt that there was still no product on the market that allowed babies to sleep at an incline, and she pitched the idea for the Rock ‘n Play to her supervisor at

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<sup>16</sup> *Id.*

<sup>17</sup> 82 Fed. Reg. 16963.

<sup>18</sup> Consumer Product Safety Commission, *Proposed Rule: Safety Standard for Infant Sleep Products* (Nov. 12, 2019) (84 FR 60949) (online at [www.federalregister.gov/documents/2019/11/12/2019-23724/safety-standard-for-infant-sleep-products](http://www.federalregister.gov/documents/2019/11/12/2019-23724/safety-standard-for-infant-sleep-products)).

<sup>19</sup> Email from Christopher Hudgins, Consumer Product Safety Commission, to Staff, House Committee on Oversight and Reform (Sept. 14, 2020).

<sup>20</sup> *While They Were Sleeping*, Consumer Reports (Dec. 30, 2019) (online at [www.consumerreports.org/child-safety/while-they-were-sleeping/](http://www.consumerreports.org/child-safety/while-they-were-sleeping/)).

<sup>21</sup> Mattel\_HCOR\_022328 at Slide 5.

Fisher-Price.<sup>22</sup> The Rock ‘n Play was designed as a free-standing bassinet that holds an infant on its back at a thirty-degree angle, so the infant’s feet are at a downward slope from the infant’s head.



Ms. Chapman is not a doctor, and she said in a deposition that it is “not [her] job to look at the laws” and regulations regarding safe sleep, or to consult current guidelines from pediatricians to determine whether a product is safe. Chapman stated that she trusted that others within the company would do their due diligence to determine whether the product was in fact safe for infants to sleep.<sup>23</sup>

Once the idea for the Rock ‘n Play had been proposed, the company set about building a prototype. Kitty Pilarz, Fisher-Price’s Vice President of Product Safety and Regulatory Compliance, confirmed in an interview with Committee staff that Fisher-Price did not consult any medical doctors about the safety of the product before building the prototype.<sup>24</sup> In fact, she could only recall one instance, when the company was developing a weighted blanket for a baby, in which Fisher-Price consulted a medical doctor before designing a prototype. Ms. Pilarz stated that in that instance, Fisher-Price “consulted with some medical experts to get their feedback because [the product] was unique.”<sup>25</sup> Inexplicably, Fisher-Price did not have the same concern about the Rock ‘n Play, the only product of its kind at the time it was launched, and one that Fisher-Price consistently called “innovative” in internal and external-facing documents. For example, an August 2011 Fisher-Price presentation discussing baby gear sales strategies said that “innovation wins,” citing the Rock ‘n Play Sleeper as an example. On another page of the presentation discussing ways to expand growth, the presentation advised: “Gain consumer insights to create new categories i.e. Rock ‘n Play Sleeper.”<sup>26</sup>

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<sup>22</sup> Deposition of Linda Chapman, *Goodrich v. Fisher-Price, Inc.*, No. 1:16-cv-03116 (N.D. Ga. 2016).

<sup>23</sup> *Id.*

<sup>24</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>25</sup> *Id.*

<sup>26</sup> Mattel\_HCOR\_5750, at Slide 7.

Fisher-Price included this graphic in its marketing pieces describing the story behind the Rock ‘n Play and calling it “an innovative product” and a “lifesaver”.<sup>27</sup>



Documents and interviews show that Fisher-Price did not undertake any independent research to confirm that the Rock ‘n Play’s thirty-degree angle was medically safe, and instead relied on knowledge about existing inclined products that were not intended for sleep, such as car seats. The company ultimately consulted only one doctor who did not specialize in pediatrics to evaluate the safety of inclined sleep. The Committee’s investigation confirmed that Fisher-Price does not have any internal policies requiring that pediatricians review products designed for infant sleep.

### ***Internal “Hazard Analysis” Process Did Not Establish the Product’s Incline was Safe***

After the prototype was built, Fisher-Price began what it calls its “hazard analysis process,” which is intended to identify potential safety hazards with products in development and work to fix them. This process is led by the Safety Committee, which includes approximately eight members.<sup>28</sup> Although none of the eight members of the Safety Committee is a pediatrician or has any medical expertise, the group was tasked with determining whether the positioning of newborns in the Rock ‘n Play Sleeper was medically safe.<sup>29</sup> With an incline of thirty degrees, the design of the Rock ‘n Play was a marked departure from infant sleep products on the market at the time, which were generally flat or had an incline under ten degrees. In three separate hazard analysis reports, from August 2008 through February 2009, the Safety Committee highlighted the need to research the positioning of infants in the Rock ‘n Play. For example, an October 6, 2008, Safety Audit Report for the Rock ‘n Play found the product to be

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<sup>27</sup> Mattel\_HCOR\_005103, at 1.

<sup>28</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>29</sup> *Id.*

“Unacceptable” until two action items were completed. The first action was, “Must assure proper infant position.”<sup>30</sup>

	<b>Fisher-Price</b> Product Integrity <b>SAFETY AUDIT REPORT</b> ISSUED BY KP _____	SAR No: 22660 Project Number: 201581 Product Number: Intro Year: 2010 Product Name: ROCKING HAMMOCK AgeGrade/Developmental Level:
<b>CONCLUSION:</b> <input type="checkbox"/> ACCEPTABLE w/ execution of action items. <input type="checkbox"/> CONDITIONALLY ACCEPTABLE - follow-up Safety Audit meeting required after execution of following:  <input checked="" type="checkbox"/> UNACCEPTABLE - the following aspect of the product must be changed:		Safety Audit Date: 10/6/2008
<b>DESCRIPTION OF PRODUCT CONCEPT:</b> Infant folding hammock		
<b>SPECIAL PACKAGING INFORMATION OR PRODUCT LABELING REQUIRED (LHAMA)</b> TBD		
<b>ACTION ITEMS:</b> 1. Must assure proper infant position. 2. Compare to existing bassinets, gliders.		

Ms. Pilarz, who served as Chair of the Fisher-Price’s Safety Committee for two decades, told Committee staff that despite this warning, at the time the Rock ‘n Play was launched, the company had done no research showing that the product’s thirty-degree angle was safe for sleep. Ms. Pilarz stated that this was not unusual:

Q: Did you see any research specifically into the 30-degree angle indicating that it was safe?

A: I can’t say I’ve seen research like that. Typically, at least in my experience, you don’t see research saying things are safe. You know, people research things that are not safe.<sup>31</sup>

Ms. Pilarz said Fisher-Price was not concerned by the lack of affirmative research showing that a 30-degree angle was safe:

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<sup>30</sup> Mattel\_HCOR\_001677, at 1 (emphasis added); Mattel\_HCOR\_001669; Mattel\_HCOR\_001644.

<sup>31</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

Again, because it's unlikely you would find research of that nature, we relied on the research that was available showing where angles had been a problem, like car seats, and on our own background with respect to angles in children's products and what angles are appropriate, as well as the knowledge we've gained through participating in standards development to – to feel comfortable with the angle.<sup>32</sup>

None of the five Fisher-Price employees interviewed by the Committee could articulate a reason why Fisher-Price chose thirty degrees as the angle for the Rock 'n Play, other than in reference to other products that were not intended for overnight sleep.<sup>33</sup>

### ***Fisher-Price Only Consulted One Doctor—Who Was Not a Pediatrician***

Fisher-Price consulted only one medical doctor regarding the safety of the Rock 'n Play—a family medicine doctor named Dr. Gary Deegeer. Dr. Deegeer is not a pediatrician. Dr. Deegeer's medical license expired in 2015, and the Texas Medical Board subsequently filed a cease and desist order against him for practicing medicine without a license and for conducting unsafe practices.<sup>34</sup>

The company did not formally consult any pediatricians.<sup>35</sup> When asked in an interview whether Fisher-Price considered consulting a pediatrician for a product intended for infants, Ms. Pilarz said, "I did place a call to my own pediatricians, but I ... don't think they ever called me back."<sup>36</sup> Ms. Pilarz also confirmed that it was an "extraordinary" step for Fisher-Price to consult even one medical doctor about the safety of a product, even a product designed for infant sleep:

Q: During the design process for the Rock 'n Play, did you consult any medical doctors about the design?

A: Yes.

Q: How many?

A: One.

Q: And is it general practice to only speak to one doctor about a product for infant sleep?

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<sup>32</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>33</sup> During her interview, Ms. Pilarz mentioned that Fisher-Price had, at one time, released an inclined bassinet on the market. However, she could not recall any details about the product or whether it had informed Fisher-Price's decision to settle on a 30-degree angle for the Rock 'n Play.

<sup>34</sup> *Fisher-Price Invented a Popular Baby Sleeper Without Medical Safety Tests and Kept Selling It, Even As Babies Died*, Washington Post (May 30, 2019) (online at [www.washingtonpost.com/business/economy/how-fisher-price-invented-a-popular-baby-sleeper-without-safety-tests-and-kept-it-on-the-market-even-as-babies-died/2019/05/30/78c2707a-7731-11e9-b3f5-5673edf2d127\\_story.html](https://www.washingtonpost.com/business/economy/how-fisher-price-invented-a-popular-baby-sleeper-without-safety-tests-and-kept-it-on-the-market-even-as-babies-died/2019/05/30/78c2707a-7731-11e9-b3f5-5673edf2d127_story.html)).

<sup>35</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>36</sup> *Id.*

A: Speaking to a doctor is not really the general practice in the product development process.

Q: I see. So that was an extraordinary thing to consult a medical doctor for the Rock ‘n Play?

A: Correct. You know, it’s happened other times, but it’s not part of the standard product development process.<sup>37</sup>

Documents obtained by the Committee show that Fisher-Price employees consulted Dr. Deegear numerous times from December 2008 to August 2009 about the safety of the design of the Rock ‘n Play. In some of these conversations, Dr. Deegear expressed views at odds with prevailing research about safe sleeping environments for infants. For example, in a February 2009 email summarizing her conversation with him, Ms. Pilarz wrote:

Dr. Deegear stated pediatricians recommend babies with reflux sleep at 30 degrees, this is just fine, or sleep in a car seat overnight for months or even a year. The Back to Sleep campaign places children on their backs, and elevated positions of the head is fine.<sup>38</sup>

Dr. Deegear’s assertion that infants can sleep in a car seat “for months or even a year” directly contradicted pediatricians’ recommendations. When asked about the statement, Ms. Pilarz said that Dr. Deegear was simply relaying what he thought pediatricians were recommending:

Q: Do you see anything wrong with Dr. Deegear’s statement that pediatricians recommend that infants can sleep overnight in a car seat for months or a year?

A: I’m aware of incident data associated with infants sleeping in car seats if the car seat tips over. So, you know, I wouldn’t consider it safe for a baby to sleep overnight in a car seat – in many applications.

Q: So did—did it raise any concerns for you that Dr. Deegear was making the statement that pediatricians say babies can sleep in a car seat overnight for months or a year?

A: I am concerned about the practice of a baby sleeping in a car seat, but I—I believe that’s a true statement he made, that some pediatricians do recommend that babies be placed at an angle, such as a car seat.<sup>39</sup>

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<sup>37</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>38</sup> *Id.*

<sup>39</sup> *Id.*

Ms. Pilarz said that Fisher-Price did not consult any pediatricians to confirm whether Dr. Deegeear's statement was correct.<sup>40</sup> In an August 2009 call, just two months before the Rock 'n Play was released, Fisher-Price asked Dr. Deegeear about the concern that an infant could slide down in the seat and become "scrunched up." A Fisher-Price employee summarized his response as follows:

He did not see this as an issue and stated that babies spend their entire time in the womb in a scrunched-up position. The folds of fat will limit potential chin excursion. He stated that unless there is some type of anatomical variation or physical predisposition, a scrunched up occupant should not be compromised in any way.<sup>41</sup>

**From:** Taft, Joel <Joel.Taft@Fisher-Price.com>  
**Sent:** Wednesday, August 19, 2009 10:37 AM  
**To:** Snyder, Tim; Steinwachs, Mike; Chapman, Linda; Moulin, Margo; Dzialga, Dan  
**Cc:** Taton, Justin; Pilarz, Kitty  
**Subject:** Rock & Play Sleeper

Here are my notes from today's conference call with Dr. Deegeear regarding the Rock & Play Sleeper:

I first explained the changes that were made to the product since the last version he'd seen: relaxed footrest angle, increased seat back angle, and addition of a barrier at the top of the seat back (head dam).

Dr. Deegeear's overall impression was that the changes were an improvement to the product. He stated that an infant would have to be at least 3 months old before they would begin to arch their backs and push up the seat back. He stated that they would be very persistent in their efforts and would not stop until they wore themselves out. He liked the head dam but thought the transition from the seat back to the head dam could be a little more substantial. He suggested that a cut-out or depression in the head area would increase the margin of safety and make it that much more difficult for an arching infant to defeat the head dam. He also suggested that we could use a stretchy-type mesh material in the foot-rest area to make it more difficult for the occupant to push. However, Dr. Deegeear reiterated his previous conclusion that even if a child were to push themselves out of the seat, the limited fall height would not result in a significant injury; likely outcome would be bruises and abrasions. He also stated that if a child were to get their head over the edge of the top of the seat he did not believe there was any potential for neck impingement or suffocation.

Dr. Deegeear was concerned that a caregiver may place a child in the seat backwards which would increase the chances for the occupant to push themselves out of the seat and there would also be inadequate head support in this position. He suggested that we add some type of pictogram to the product to indicate proper orientation of the occupant.

I also asked Dr. Deegeear to comment on the situation where an unrestrained smaller infant slides down the seat such that they become "scrunched-up" in the seat. He did not see this as an issue and stated that babies spend their entire time in the womb in a scrunched-up position. The folds of fat will limit potential chin excursion. He stated that unless there is some type of anatomical variation or physical predisposition, a scrunched up occupant should not be compromised in any way.

Ms. Pilarz informed Committee staff that she thought Dr. Deegeear's statement was "unusual," but Fisher-Price did not do any independent research or consult any pediatricians to determine whether the statement was correct.<sup>42</sup> Ms. Pilarz said Fisher-Price stands by the decision to consult Dr. Deegeear about the safety of the Rock 'n Play.<sup>43</sup>

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<sup>40</sup> *Id.*

<sup>41</sup> Mattel\_HCOR\_001661 (emphasis added).

<sup>42</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>43</sup> *Id.*



### ***Child Development Research Was Not Supervised by Medical Doctors***

Ms. Pilarz explained that before products are released on the market, Fisher-Price conducts tests in its play lab, and has parents take the products home and report back with any issues they encounter.<sup>44</sup>

According to Ms. Pilarz, the play lab is “a special facility where [Fisher-Price] bring[s] parents in, and we evaluate various features of the product.” She stated that parents are present for parts of testing for infant products, where Fisher-Price evaluates “how babies fit in products, how easy it is for parents to take babies in and out of products. We sometimes study the assembly methods or verify our instruction sheets by actually watching people assemble the products.”<sup>45</sup> The employees monitoring the play lab typically have advanced degrees in child development, which enables them to determine what age is appropriate for the products being tested. However, Ms. Pilarz explained that these employees do not have any expertise about the medical safety of the products:

Q: And so they would be able to tell you what age is appropriate for products. They do not have medical expertise about the safety of a product. Is that accurate?

A: Yeah, I’m not aware that anybody has medical training.<sup>46</sup>

For in-home tests, parents would take the product home, observe their children using the product, and answer a series of questions the following day. In 2009, a total of 62 infants were tested at home using the Rock ‘n Play. There was no further in-home testing until 2012, when an additional six infants were tested.<sup>47</sup> Ms. Pilarz told the Committee that because the Rock ‘n Play was a sleep product, testing 62 infants in 2009 was actually more testing than was typical. Fisher-Price sold approximately 4.7 million Rock ‘n Play Sleepers before the product was recalled in 2019.<sup>48</sup>

### **B. Fisher-Price Ignored Repeated Warnings That the Rock ‘n Play Was Unsafe**

The Committee’s investigation showed that shortly after releasing the Rock ‘n Play, Fisher-Price was made aware of multiple indications that the Rock ‘n Play was unsafe, including statements from international regulatory bodies that the Rock ‘n Play was not safe for infant sleep, warnings from pediatricians, and concerns expressed by their own customers. Despite these warnings, the company chose to continue selling the Rock ‘n Play and marketing it as a sleep product for infants.

### ***Foreign Regulators and Experts Raised Major Safety Concerns about the Rock ‘n Play***

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<sup>44</sup> *Id.*

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> Mattel\_HCOR\_010337.

<sup>48</sup> *Fisher-Price Recalls Rock ‘n Play Sleepers Due to Reports of Deaths*, CPSC (Apr. 12, 2019) (online at [www.cpsc.gov/Recalls/2019/fisher-price-recalls-rock-n-play-sleepers-due-to-reports-of-deaths](http://www.cpsc.gov/Recalls/2019/fisher-price-recalls-rock-n-play-sleepers-due-to-reports-of-deaths)).

The Rock ‘n Play was released in the United States in October 2009. Within a year, the product was a clear commercial success. Fisher-Price sought to build on the success by selling the Rock ‘n Play in international markets, but almost immediately confronted safety concerns in Australia, Canada, and the United Kingdom.

1. Australian regulators told Fisher-Price the Rock ‘n Play was not safe for sleep.

In May 2010, less than a year after the Rock ‘n Play was released in the United States, regulators with the Australian Competition and Consumer Commission (ACCC) contacted Fisher-Price, stating that they understood that Fisher-Price was looking to begin selling the Rock ‘n Play in Australia. In response, Fisher-Price sent the ACCC a sample Rock ‘n Play. Several weeks later, in a June 18, 2010, email to Fisher-Price, the Australian regulator expressed serious concerns about the Rock ‘n Play:

The main concern with the Fisher Price Newborn Rock n Play Sleeper is that its promotion is at odds with widely accepted and promoted best practices that these types of products should not be used as an infant bedding alternative. Infants should not be left in these types of products without constant supervision and we recommend that the packaging and promotion be amended accordingly.<sup>49</sup>

Despite the strong concerns from Australian regulators, Fisher-Price continued to sell the Rock ‘n Play in Australia for another year, until June 2011.<sup>50</sup>

2. Health Canada blocked Fisher-Price from marketing the Rock ‘n Play as a sleeper in Canada.

Fisher-Price tried to sell the Rock ‘n Play in Canada but was informed that the product did not meet regulations for bassinets set by Canada’s national health agency, Health Canada. Ian Johnston, who at that time was the Senior Manager for International Marketing with Fisher-Price, described Health Canada’s concerns in his interview with Committee staff:

To my recollection, it was—the product was new, and it didn’t fall within the guidelines. And because there were no standards specific to this type of product, they were interpreting it very specifically as a bassinet and, I believe, the interpretation of “back to sleep.” And there were concerns—my understanding, there were concerns about that.<sup>51</sup>

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<sup>49</sup> Email from Australian Competition and Consumer Commission to Fisher-Price (June 18, 2010) (online at <https://foi.accc.gov.au/sites/foi.accc.gov.au/files/repository/ACCC%20FOI%20request%2025-2020%20-%20Document%203.pdf>).

<sup>50</sup> Email from John Karam, Mattel, to Pauline Ng, Australian Competition and Consumer Commission (Jan. 23, 2013) (online at <https://foi.accc.gov.au/sites/foi.accc.gov.au/files/repository/ACCC%20FOI%20request%2025-2020%20-%20Document%2011.pdf>).

<sup>51</sup> Committee on Oversight and Reform, Transcribed Interview of Ian Johnston (Sept. 25, 2020).

As a result of Health Canada's concerns, Fisher-Price revised the Canadian label for the Rock 'n Play to read, "This product is not intended to replace a crib or bassinet for prolonged periods of sleep" and "NEVER leave child unattended."<sup>52</sup> Officials at Health Canada also informed Fisher-Price that it would be required to market the Rock 'n Play as a Soother rather than a Sleeper.<sup>53</sup> To assess the impact of the change, Fisher-Price conducted a market research study with 327 expectant mothers, half of whom already had an older child and half of whom were having their first child. The study found that "[p]renatal moms previously unfamiliar with the Rock 'n Play who saw the product positioned as a Sleeper (original) expressed significantly higher rates of purchase interest than moms who saw either of the alternate positions as a Soother."<sup>54</sup>

Mr. Johnston explained to the Committee that once Fisher-Price could no longer market the Rock 'n Play as a Sleeper, it ultimately decided not to sell the Sleeper in Canada at all:

A: The research that was done, as I recall, supported the sleep benefit as one of the key, if not the key, one of the many key benefits of the product. And so we felt it was important to have that to differentiate that within the marketplace in the U.S. market and felt the same for Canada.

Q: I see. So without the sleeping component to differentiate the product, Fisher-Price did not think it would do well in Canada. Do I have that right?

A: Yeah, I guess that's a fair statement.<sup>55</sup>

According to internal documents, Fisher-Price decided on July 19, 2011, no longer to sell the Rock 'n Play in Canada.<sup>56</sup>

**3. United Kingdom medical professional organization strongly advised against using the Rock 'n Play for overnight sleep.**

In May 2011, Fisher-Price encountered an obstacle to selling the Rock 'n Play in the United Kingdom. In a May 16, 2011, email, Mr. Johnston sent a report on the Rock 'n Play from the UK Royal College of Midwives, a professional organization for midwives, to Kitty Pilarz and Mike Steinwachs, a Senior Manager for Quality Engineering with Fisher-Price. The report from the Royal College of Midwives, in which four midwives, two mothers, and two women without children all evaluated the safety of the Rock 'n Play, flagged four safety concerns:

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<sup>52</sup> Mattel\_HCOR\_040225, at 2.

<sup>53</sup> *While They Were Sleeping*, Consumer Reports (Dec. 30, 2019) (online at [www.consumerreports.org/child-safety/while-they-were-sleeping/](http://www.consumerreports.org/child-safety/while-they-were-sleeping/)).

<sup>54</sup> Mattel\_HCOR\_004127, at Slide 2.

<sup>55</sup> Committee on Oversight and Reform, Transcribed Interview of Ian Johnston (Sept. 25, 2020).

<sup>56</sup> Mattel\_HCOR\_040225.

- (1) “this would *not be suitable for a new born infant* as babies *cannot* be placed in a semi-prone [face down] position;”
- (2) “this should not be used for infants under six weeks;”
- (3) “the lying surface is not suitable as an infant cot—and ***must not be*** used as infant cot to sleep next to mother’s bed because babies must always sleep flat on their backs;” and
- (4) “**Unreservedly**—this product must only be used for no more than two hours in a day and for the purpose of play/interaction with parents/siblings etc.”<sup>57</sup>

In his email forwarding the report, Mr. Johnston wrote to Ms. Pilarz and Mr. Steinwachs that it is “very limiting in what they say is the appropriate use for the product ... I think this may put an end to our ability to sell the product in the UK as I understand this organization carries quite a bit of weight.”<sup>58</sup> Mr. Johnston told the Committee that Fisher-Price did not consider marketing the Rock ‘n Play differently in the UK to accommodate the concerns voiced by the Royal College of Midwives. Mr. Johnston told Committee staff that despite this warning, the “positioning and the benefits” of the Rock ‘n Play had “proven successful here in the U.S., and there wasn’t a desire to change that.”<sup>59</sup>

#### 4. Fisher-Price continued to seek expansion into international markets.

According to internal Fisher-Price documents, the concerns expressed by the ACCC, Health Canada, and the UK Royal College of Midwives did not trigger any additional safety reviews of the Rock ‘n Play within Fisher-Price. None of the Fisher-Price employees interviewed by the Committee could cite any additional research conducted as a result of the safety concerns raised by international regulators.

A 2013 Fisher-Price business development presentation shows that in the United States, Rock ‘n Play sales were increasing every year, and that the company anticipated sales would continue to grow. In 2011, Fisher-Price generated roughly \$10 million in Rock ‘n Play sales. By 2013, the company was projecting annual sales revenue would more than double, to \$26.3 million.<sup>60</sup>

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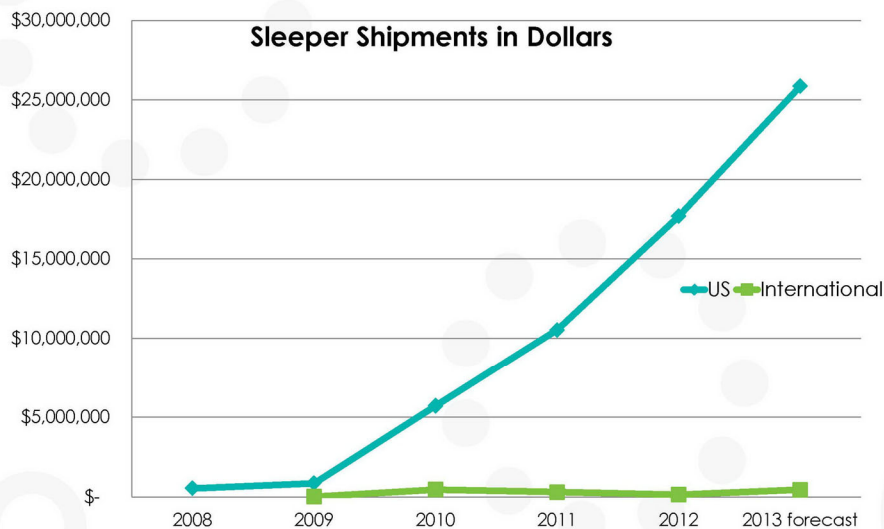
<sup>57</sup> Deposition of Catherine Pilarz, *Goodrich v. Fisher-Price, Inc.*, No. 1:16-cv-03116 (N.D. Ga. 2016). (emphasis in original).

<sup>58</sup> Deposition of Catherine Pilarz, *Goodrich v. Fisher-Price, Inc.*, No. 1:16-cv-03116 (N.D. Ga. 2016).

<sup>59</sup> Committee on Oversight and Reform, Transcribed Interview of Ian Johnston (Sept. 25, 2020).

<sup>60</sup> Mattel\_HCOR\_005762, at Slide 5.

## Sleepers State of the Business



**\$26.3 MM  
2013  
Forecast**

Mattel – Confidential Information – May Include Trade Secrets – For Internal Use Only

With international sales near flat, Fisher-Price sought to expand sales internationally, despite concerns in foreign markets about the safety of the Rock ‘n Play. However, the same 2013 business development presentation noted, “Outside the US, inclined sleeping faces regulatory and perception hurdles.”<sup>61</sup>

<sup>61</sup> Mattel\_HC0R\_005762, at Slide 7.

## 2015 Sleepers Product Strategies & Tactics

### Key Strategies

- 1) Leverage expertise in incline sleepers
  - Establish presence in new sub-segment
- 2) Solidify strength in sleeper/bassinet category in the US
- 3) Expand sleepers internationally

### Key Insights

- New moms are looking for a solution to help baby sleep
- Some babies sleep more comfortable at an incline
- Moms like the rocking feature of the sleeper and wish it rocked automatically
- Space saving features including size and fold are important
- Outside the US inclined sleeping faces regulatory and perception hurdles

### *Fisher-Price Received Death and Injury Reports for the Rock ‘n Play*

Around the same time that regulators in Canada and Australia and a professional organization in the United Kingdom were expressing concerns about the safety of the Rock ‘n Play, Fisher-Price was also made aware of injuries and deaths associated with the product. On October 26, 2012, a consumer reported to Fisher-Price that a year earlier, in October 2011, her two-month-old son “had stopped breathing” while in the Rock ‘n Play. The consumer believed that “due to the slant in the product ... his head may have been positioned in his chest at the time.” She picked him up and he began breathing again. This consumer called Fisher-Price because she was preparing for a new baby and “loved using the sleeper for convenience purposes but was nervous about using this one for her new baby.” The consumer wanted to know whether any changes had been made to the Rock ‘n Play since she had used it in 2011. Internal Fisher-Price notes show that the company told the consumer that some newer models had added padding, but no major changes had been made. Fisher-Price then offered her a refund for the Rock ‘n Play, and the consumer shipped it back to the company. In June 2013, an employee wrote: “No further contact. Closing case.”<sup>62</sup>

Less than two months later, on December 7, 2012, Fisher-Price received a report of a 15-week old infant who had died in the Rock ‘n Play in September 2011. The report explained that no specific cause of death was found during the autopsy, and SIDS was ruled as the cause of death. After receiving the report, Fisher-Price attempted to follow up with the consumer twice,

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<sup>62</sup> Mattel\_HCOR\_005920, at 3.

once via email and once via phone. When the company received no further contact from the consumer, it closed the case on January 14, 2014.<sup>63</sup>

According to interviews with Fisher-Price employees, both of those incidents would have been reviewed by the Product Integrity team and the Safety Advisory Panel.<sup>64</sup> The Safety Advisory Panel would then determine whether there was a safety concern with the product that needed to be addressed. There is no evidence that Fisher-Price raised any concerns internally about the safety of the Rock ‘n Play as a result of these two early incidents, and Fisher-Price took no action to warn or inform parents about the incidents.

### ***Independent Pediatrician Told Fisher-Price the Rock ‘n Play Was “Unsafe”***

In February 2013, Dr. Roy Benaroch, a board-certified pediatrician, wrote an email to Fisher-Price expressing concerns about the safety of the Rock ‘n Play. He wrote: “I am concerned that parents are using this product as a routine sleeping area for their babies. This is unsafe.” He pointed Fisher-Price to the 2011 safe sleep guidelines from the American Academy of Pediatrics and explained how the Rock ‘n Play violated multiple aspects of those guidelines.<sup>65</sup>

Nearly three weeks later, after a follow-up email from Dr. Benaroch, Fisher-Price responded: “The Rock ‘n Play Sleeper complies with all applicable standards. We encourage consumers who have questions or concerns about providing a safe sleeping environment for their babies to discuss these issues with their doctors or pediatricians.”<sup>66</sup> In interviews with Committee staff, Fisher-Price employees could not explain why they would encourage consumers to discuss safe sleeping environments with their pediatricians when the company itself had not consulted any pediatricians, and in fact did not address the clear, science-based warning from Dr. Benaroch. Ms. Pilarz told Committee staff that she did not believe that Dr. Benaroch was completely familiar with the features of the product and asserted that he may have only viewed it online. In crafting a response to Dr. Benaroch, Fisher-Price consulted its legal team, but did not have anyone with any medical training review his concerns.<sup>67</sup>

### ***Moms Told Fisher-Price the Rock ‘n Play Was Not Safe for Overnight Sleep***

As early as 2017, Fisher-Price began to hear concerns from consumers that the Rock ‘n Play was not safe for overnight sleep. In a December 2017 market research report, Fisher-Price reported the results of its qualitative research with mothers who were planning to or were currently sharing a bed with their babies. As part of the research, Fisher-Price asked mothers about their impressions of products from several different manufacturers. For the Rock ‘n Play,

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<sup>63</sup> Mattel\_HCOR\_005926.

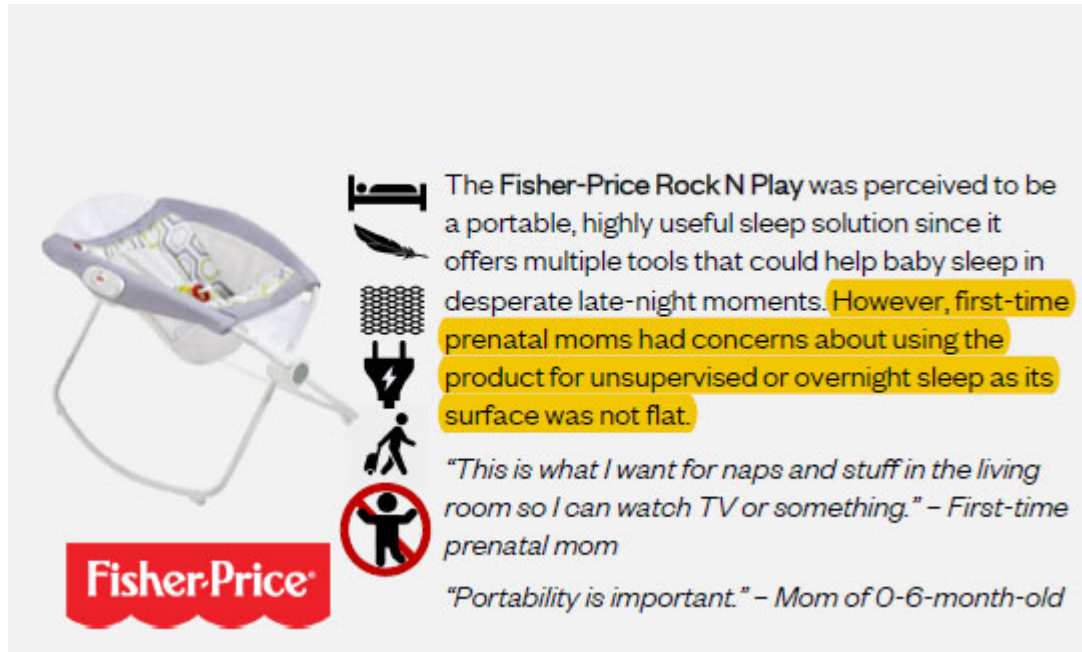
<sup>64</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>65</sup> Mattel\_HCOR\_001634.

<sup>66</sup> Mattel\_HCOR\_001735.

<sup>67</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

prenatal moms had “concerns about using the product for unsupervised or overnight sleep as its surface was not flat.”<sup>68</sup>



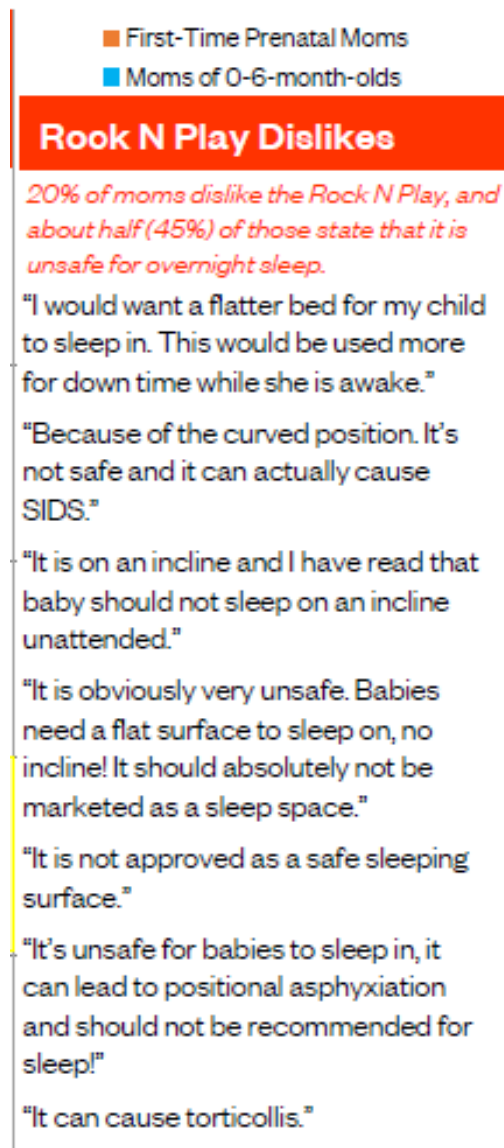
In May 2018, Fisher-Price’s marketing team circulated another report on consumer insights about the Rock ‘n Play, which also pulled data from market research with mothers who were planning to or currently shared a room with their babies. The research found that 20% of moms disliked the Rock ‘n Play, and about half of those stated that it was unsafe for overnight sleep. The presentation included strong statements from consumers about their safety concerns with the Rock ‘n Play:<sup>69</sup>

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<sup>68</sup> Mattel\_HCOR\_016058, at Slide 8 (emphasis added).

<sup>69</sup> Mattel\_HCOR\_036439.





Ian Johnston, the former Senior Manager of Global Brand Marketing with Fisher-Price, told the Committee that the marketing team would have shared these types of concerns with the safety or engineering teams working on the Rock 'n Play, but he could not recall if the specific concerns outlined in this presentation were shared with anyone else at the company. He also said he did not recall any conversations within the company about these concerns other than with the marketing and design teams.<sup>70</sup>

### III. CPSC'S RESPONSE WAS HAMPERED BY LACK OF ENFORCEMENT TOOLS

#### A. CPSC Has Little Power to Prevent Dangerous Products from Being Released on the Market

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<sup>70</sup> Committee on Oversight and Reform, Transcribed Interview of Ian Johnston (Sept. 25, 2020).

The Consumer Product Safety Act (CPSA) was passed in 1972 and established the Consumer Product Safety Commission.<sup>71</sup> Section 2 of the CPSA states that “an unacceptable number of consumer products which present unreasonable risks of injury are distributed in commerce,” and that “the public should be protected against unreasonable risks of injury associated with consumer products.”<sup>72</sup>

Over the ensuing years, it became clear that CPSC did not have adequate enforcement authority to carry out these goals, with particular concern about the lack of oversight for children’s products. Millions of toys were recalled due to excessive levels of lead, and millions of cribs were recalled for failing to provide a safe sleep environment for children.<sup>73</sup> In 2008, Congress passed the Consumer Product Safety Improvement Act (CPSIA), which allows CPSC to promulgate mandatory standards for durable infant products.<sup>74</sup>

After Congress passed the CPSIA, CPSC began enacting mandatory standards for certain categories of products, including infant sleep products. The law requires that these standards are “substantially the same as” applicable voluntary standards, and permits more stringent requirements only if the Commission concludes such requirements would further reduce the risk of injury associated with the product.

However, the process for enacting a mandatory CPSC standard can take years. As a result, products can be released on the market that are only required to meet a voluntary standard set by ASTM, or in the case of some products, no standard at all. When the Rock ‘n Play was recalled—after 10 years on the market—CPSC still had not promulgated a mandatory standard for infant inclined sleep products. Instead, the only available U.S. standard was the voluntary inclined sleep standard set by the ASTM committee led by a Fisher-Price employee. Inclined sleepers are a clear example of why the mandatory rulemaking process at CPSC is inadequate to mitigate the risk of unsafe products being on the market for years.<sup>75</sup>

## **B. Deaths Associated with the Rock ‘n Play Raised Serious Concerns at CPSC**

In early 2018, the number of deaths associated with the Rock ‘n Play raised alarms at CPSC. Despite officials’ concern, the public remained in the dark about safety issues involving the product for another year while CPSC communicated with Fisher-Price about the fatalities and requested more information.

### ***CPSC Requested a Full Report on the Rock ‘n Play from Fisher-Price***

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<sup>71</sup> 15 U.S.C. §§ 2051–2089.

<sup>72</sup> 15 U.S.C. §§ 2051(a).

<sup>73</sup> *The Consumer Product Safety Improvement Act Fact Sheet*, Consumer Federation of America (online at <https://consumerfed.org/pdfs/CPSIA-fact-sheet-8-5-13.pdf>).

<sup>74</sup> 15 U.S.C. § 2056(a).

<sup>75</sup> Consumer Product Safety Commission, *Proposed Rule: Safety Standard for Infant Inclined Sleep Products* (Apr. 7, 2017) (online at [www.federalregister.gov/documents/2017/04/07/2017-06875/safety-standard-for-infant-inclined-sleep-products](http://www.federalregister.gov/documents/2017/04/07/2017-06875/safety-standard-for-infant-inclined-sleep-products)).

Federal law requires a manufacturer that has obtained information that reasonably supports the conclusion that one of its products fails to comply with applicable rules, regulations or standards, contains a defect which could create a substantial product hazard, or creates an unreasonable risk of injury or death, to provide that information to CPSC.<sup>76</sup> Pursuant to that requirement, Fisher-Price provided CPSC with reports of 15 fatalities associated with the Rock ‘n Play, which occurred over a period from September 2011 to January 2018. On February 6, 2018, CPSC wrote privately to Fisher-Price requesting a “full report” to “assess accurately the potential hazard, if any, presented by” the Rock ‘n Play.<sup>77</sup>

Fisher-Price provided a report to CPSC ten days later, on February 16, 2018. In the report, Fisher-Price told CPSC that it was aware of 14 fatalities associated with the Rock ‘n Play and gave a description of each.<sup>78</sup> The report asserted, “The hazard patterns, including extra bedding and infants rolling over into a prone position, indicated that, although a nursery product was involved, many of the fatalities were not caused directly by failures of the product.” Fisher-Price also reported that it was aware of 8 incidents in which infants in the Rock ‘n Play “stopped breathing, turned color, or exhibited some kind of distress.”<sup>79</sup> Despite those deaths and injuries, Fisher-Price concluded:

Fisher-Price does not believe that the information in its possession reasonably supports the conclusion that the product is defective, presents a substantial product hazard or an imminent hazard, or creates an unreasonable risk of injury. Further, Fisher-Price denies that this information in any way supports the contention that the product caused or contributed to any death or bodily injury.<sup>80</sup>

The company’s report included an incident report dated December 22, 2017, less than two months before the date of Fisher-Price’s submission to CPSC. The incident report discussed an infant who died in the Rock ‘n Play after his parents used it as directed, placing their son on his back with the restraints. In the morning, his parents found him face-down in the Rock ‘n Play, having suffocated. When asked how the company could conclude that the Rock ‘n Play did not create an unreasonable risk of injury less than two months after receiving this report, Ms. Pilarz told Committee staff that while they could not eliminate the possibility that the infant’s death had been caused by the Rock ‘n Play, and CPSC’s investigation was ongoing, the “information in [the] report does not lead to the conclusion that the product caused the death.” In particular, she said police had interviewed the parents and thought the child may not have been wearing a restraint.<sup>81</sup>

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<sup>76</sup> 15 U.S.C. § 2064(b).

<sup>77</sup> Mattel\_HCOR\_007782.

<sup>78</sup> Although CPSC had mentioned 15 fatalities in its request for a full report, Fisher-Price stated that one of the fatalities had been erroneously attributed to the Rock ‘n Play when it was in fact connected to another product. Mattel\_HCOR\_006006.

<sup>79</sup> Mattel\_HCOR\_006006.

<sup>80</sup> *Id.*

<sup>81</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

On February 16, 2018, the same day Fisher-Price submitted its full report to CPSC, CPSC employees privately discussed the number of deaths associated with the Rock ‘n Play while preparing a briefing report for CPSC commissioners on new cases involving consumer product hazards. Carol Cave, CPSC’s Deputy Director of Compliance, wrote to Sharon White, a member of CPSC’s Defects Investigation Division: “The Rock and Play sleeper case shows 15 deaths. Is that accurate?” Ms. White responded that CPSC had recently received two additional death reports, bringing the total number of deaths associated with the Rock ‘n Play to 17. Ms. Cave then wrote: “Holy cow! We need to discuss this. When the Commission sees this they are going to flip.”<sup>82</sup>

**To:** White, Sharon <[SWhite@cpsc.gov](mailto:SWhite@cpsc.gov)>; Latkowski, Liliana <[LLatkowski@cpsc.gov](mailto:LLatkowski@cpsc.gov)>; Rauchschwalbe, Renae <[RRauchschwalbe@cpsc.gov](mailto:RRauchschwalbe@cpsc.gov)>  
**Cc:** Simmons, Scott <[SSimmons@cpsc.gov](mailto:SSimmons@cpsc.gov)>; Kaye, Robert <[RKaye@cpsc.gov](mailto:RKaye@cpsc.gov)>; Rose, Blake <[BRose@cpsc.gov](mailto:BRose@cpsc.gov)>  
**Subject:** RE: Tasks - Please approve EXC Commission Briefing Report 02-15-2018

Holy Cow! We need to discuss this. When the Commission sees this they are going to flip. Do we have define injury scenario? Are the deaths attributed to SIDS or other items that may be in the actual product?

I see this is an RP report? Did they really report?

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**From:** White, Sharon  
**Sent:** Friday, February 16, 2018 10:09 AM  
**To:** Cave, Carol <[CCave@cpsc.gov](mailto:CCave@cpsc.gov)>; Latkowski, Liliana <[LLatkowski@cpsc.gov](mailto:LLatkowski@cpsc.gov)>; Rauchschwalbe, Renae <[RRauchschwalbe@cpsc.gov](mailto:RRauchschwalbe@cpsc.gov)>  
**Cc:** Simmons, Scott <[SSimmons@cpsc.gov](mailto:SSimmons@cpsc.gov)>; Kaye, Robert <[RKaye@cpsc.gov](mailto:RKaye@cpsc.gov)>  
**Subject:** RE: Tasks - Please approve EXC Commission Briefing Report 02-15-2018

Hi Carol,

Yes. When I opened the case, we had 15 infant deaths involving this product. However, I recently received 2 additional death reports. The deaths occurred in 2017. So, today, we have a total of 17 infant deaths associated with this product. I updated the injury data in DCM to reflect this number.

Sharon

On March 14, 2018, a member of CPSC’s Compliance Division drafted a list of questions for the agency’s technical staff as part of its investigation into the safety of the Rock ‘n Play. One of the questions was, “Does the design of the product (i.e. the incline or ‘ledge’ below an infant’s feet) impact an infant’s ability to roll over?”<sup>83</sup> Robert Kaye, CPSC’s Director of the Office of Compliance and Field Operations, told the Committee that neither CPSC nor Mattel had ever looked into that question before.<sup>84</sup>

### ***The Public Remained in the Dark About Rock ‘n Play Deaths***

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<sup>82</sup> CPSCOLAIS000012806, at 4.

<sup>83</sup> CPSCOLAIS000013576, at 1.

<sup>84</sup> Committee on Oversight and Reform, Transcribed Interview of Robert Kaye (Sept. 16, 2020).

Although Fisher-Price confirmed to CPSC that it was aware of 14 deaths as of February 2018, the public remained unaware of the risks of the product, and Fisher-Price continued to sell the Rock ‘n Play for newborns.

On May 31, 2018, CPSC issued a safety alert warning consumers that babies had died in inclined sleep products and urging parents to use the restraints when putting their infants in those products.<sup>85</sup> However, because of limitations on CPSC’s authority, the alert did not mention the Rock ‘n Play or Fisher-Price. Under Section 6(b) of the CPSA, CPSC cannot disclose any information provided by a manufacturer in its full report “unless the Commission has sued the manufacturer, has accepted a voluntary corrective action plan from the firm, has the firm’s permission to release the information or the Commission publishes a finding that public health and safety requires public disclosure.”<sup>86</sup>

Section 6(b) also prevents CPSC from publicly releasing *any* information that would identify a manufacturer without first providing the manufacturer with a summary of the information to be released. The manufacturer then has the opportunity to comment on the summary provided by CPSC; if the information is ultimately disclosed, CPSC must include the comments provided by the manufacturer if so requested. Before publicly releasing any information, CPSC also must ensure that the information is “accurate,” “fair in the circumstances,” and “reasonably related to effectuating the purposes” of the CPSA.<sup>87</sup> Even then, if the manufacturer objects to the release of the information at issue, it can sue in court to enjoin its release.<sup>88</sup>

The statute preventing CPSC from releasing important public safety information is a unique limitation that is not imposed on other federal regulatory agencies. David Friedman, a former Acting Administrator of the National Highway Traffic Safety Administration (NHTSA), said of Section 6(b), “The gag that 6(b) places on CPSC is a dangerous anomaly among federal safety agencies.” He noted that NHTSA was “able to call for the recall of millions of deadly Takata airbags because we had the freedom to share what we knew. But CPSC can’t do that.” Eliot Kaye, a current commissioner and former chairman of CPSC said during a 2019 congressional hearing, “We need the anti-consumer safety and anti-transparency requirements of Section 6(b) ... to be eliminated.” He continued, “People die because of Section 6(b). It is that simple.”<sup>89</sup>

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<sup>85</sup> *CPSC Consumer Alert: Caregivers Urged To Use Restraints With Inclined Sleep Products*, Cision PR Newswire (May 31, 2018) (online at [www.prnewswire.com/news-releases/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products-300657677.html](http://www.prnewswire.com/news-releases/cpsc-consumer-alert-caregivers-urged-to-use-restraints-with-inclined-sleep-products-300657677.html)).

<sup>86</sup> Consumer Product Safety Commission, *CPSA Section 6(b) FACT SHEET* (online at [www.cpsc.gov/s3fs-public/pdfs/blk\\_pdf\\_CPSA6bFactSheet.pdf](http://www.cpsc.gov/s3fs-public/pdfs/blk_pdf_CPSA6bFactSheet.pdf)).

<sup>87</sup> 15 U.S.C. § 2055(b)(1).

<sup>88</sup> 15 U.S.C. § 2055(b)(3).

<sup>89</sup> *Decades-Old Law Hides Dangerous Products and Impedes Recalls*, Consumer Reports (Apr. 30, 2019) (online at [www.consumerreports.org/product-safety/decades-old-law-hides-dangerous-products-and-impedes-recalls/](http://www.consumerreports.org/product-safety/decades-old-law-hides-dangerous-products-and-impedes-recalls/)).

C. **Fisher-Price Pushed Back Against Concerns That the Rock ‘n Play Was Unsafe**

On March 23, 2018, CPSC and Fisher-Price had a phone call to discuss “reports of infants turning over in Rock ‘n Play Sleeper.” On March 27, 2018, Kitty Pilarz, Fisher-Price’s Vice President of Product Safety and Regulatory Compliance, wrote to CPSC:

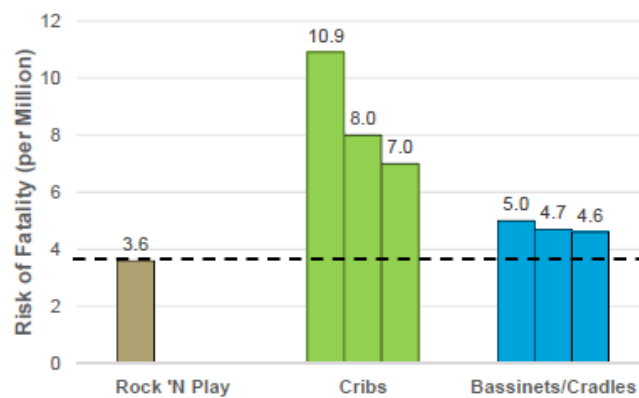
We agree with your suggestion that we should meet with CPSC staff and discuss our perspective. We believe the Rock ‘n Play Sleeper does not present a substantial product hazard. We are working with outside experts related to the reports of infants turning over to supplement our existing analysis.<sup>90</sup>

On April 6, 2018, Fisher-Price met with CPSC to explain why it believed that the Rock ‘n Play was safe. In preparation for the meeting, Fisher-Price hired a consulting firm called Exponent to evaluate the safety of the Rock ‘n Play from a statistical perspective and develop an analysis comparing the risk of fatality from the Rock ‘n Play to the risk with other products. Exponent’s analysis asserted that there was a lower risk of fatality with the Rock ‘n Play than with cribs and bassinets.<sup>91</sup>

## Comparative Risk Analysis



Risk of fatality within a Rock N’ Play is less than the risk of fatality for infants within Cribs and Bassinets/Cradles



27

Confidential Sensitive Business Document. Confidential Treatment Requested. Submitted Under Section 15(b).

<sup>90</sup> CPSCOLAIS000013338, at 4.

<sup>91</sup> Mattel\_HCOR\_010337.

Robert Kaye, CPSC’s Director of the Office of Compliance and Field Operations, told the Committee that CPSC “did not agree with their analysis” and thought the data presented by Fisher-Price was not useful because it was not an “apples-to-apples comparison.”<sup>92</sup> Kaye stated:

[T]hey used certain sales data for cribs that we thought greatly understated the number of cribs that were out there and that children were sleeping in because cribs are handed down, they’re sold as secondhand. We thought the crib number was greatly underestimated.

Mr. Kaye also noted that “some of the raw data on the number of deaths in the products we didn’t think was a clear comparison, particularly when you took into account the age range that we were most concerned about.”<sup>93</sup>

In the same presentation, Fisher-Price also presented data from a testing observation it conducted with 11 infants who ranged in age from 3.8 months to 7.6 months. Fisher-Price concluded based on that experiment that there was “[m]ore spontaneous rolling ... observed in the crib environment.”<sup>94</sup> Putting aside the extremely small sample size, the age range also excluded infants under 3 months—the age range for which the Rock ‘n Play was specifically targeted in marketing. The presentation from Fisher-Price’s consultant concluded:

Reported fatalities in the Rock ‘n Play were associated with other known risk factors (i.e. soft bedding and pre-existing medical conditions) or had insufficient information to determine if additional risk factors existed and no evidence that the product caused the death.<sup>95</sup>

**D. CPSC Contracted with an Outside Doctor to Evaluate the Risk of Infants Sleeping at an Incline**

After being presented with Fisher-Price’s analysis, CPSC did not believe it had enough data on the risks associated with the Rock ‘n Play to determine whether there was a substantial product hazard.<sup>96</sup> The Commission decided to contract with Dr. Erin Mannen, a biomechanics researcher and Assistant Professor of Orthopaedic Surgery at the University of Arkansas for Medical Sciences, to conduct a study into whether infants sleeping at an incline increases the risk that they will roll over and suffocate. Dr. Mannen selected a team of six co-investigators, including a pediatric pulmonologist, pediatric spine surgeon, pediatric orthopaedic surgeon, pediatric psychologist, and two biomechanics researchers. Dr. Mannen and her team issued a final report on September 18, 2019, which concluded that none of the inclined sleep products evaluated were safe for infant sleep. The study further stated, “It is likely that in incidents where

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<sup>92</sup> Committee on Oversight and Reform, Transcribed Interview of Robert Kaye (Sept. 16, 2020).

<sup>93</sup> *Id.*

<sup>94</sup> Mattel\_HCOR\_010337, at Slide 36.

<sup>95</sup> Mattel\_HCOR\_010337 at slide 42.

<sup>96</sup> Committee on Oversight and Reform, Transcribed Interview of Robert Kaye (Sept. 16, 2020).

babies were found deceased in the prone position, that an accidental roll occurred, and after some amount of struggling, the baby was fatigued and could no longer move into a position to prevent suffocation.” The study included the following key findings:

- Inclined surfaces and incline sleep products resulted in significantly higher muscle activity of the turn core muscle (abdominals), which may lead to quicker fatigue and suffocation if an infant is in a prone position in an incline sleep product.
- Muscle synergies (*i.e.*, how muscles work together) are significantly different in inclined sleep products. If an infant rolls from supine (face up) to prone in an inclined sleep product, it is likely the first time the baby has experienced the position and the demands the position requires of the muscles.
- Some inclined sleep products require greater neck and trunk adjustments during prone positioning, indicating that infants may struggle to adjust their posture to enable breathing and attempt to self-correct if a roll from supine to prone occurs.
- Prone lying in the incline sleep products puts infant at higher risk of suffocation as evidenced by oxygen saturation results.
- Some evidence was found that supports the idea that the inclined sleep products make the babies roll more easily from supine to prone. The flexed trunk and ease of head lifting during supine lying in an inclined sleep product may indicate that supine to prone rolling is achieved more easily.
- If babies roll from supine to prone in an inclined sleep product, then, due to the high musculoskeletal demands necessary to maintain safe posture to prevent suffocation, babies would fatigue faster than they would on a stable, flat surface.<sup>97</sup>

The Mannen Study provided critical data about the safety of the Rock ‘n Play and other inclined sleepers, which manufacturers had never bothered to generate. According to CPSC, the Mannen Study cost \$248,000.<sup>98</sup> That is a tiny fraction of the \$35 million in global sales that Fisher-Price earned from the Rock ‘n Play in 2017, according to an internal presentation obtained by the Committee.<sup>99</sup> In the ten years that the Rock ‘n Play was on the market, it generated at least \$200 million in revenue for Fisher-Price.<sup>100</sup>

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<sup>97</sup> Consumer Product Safety Commission, *Supplemental Notice of Proposed Rulemaking for Infant Sleep Products* (Oct. 16, 2019) (online at [www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts\\_10\\_16\\_2019.pdf](http://www.cpsc.gov/s3fs-public/SupplementalNoticeofProposedRulemakingforInfantSleepProducts_10_16_2019.pdf)).

<sup>98</sup> Email from Chris Hudgins, Consumer Product Safety Commission, to Staff, Committee on Oversight and Reform (Sept. 14, 2020).

<sup>99</sup> Mattel\_HCOR\_005807, at Slide 11.

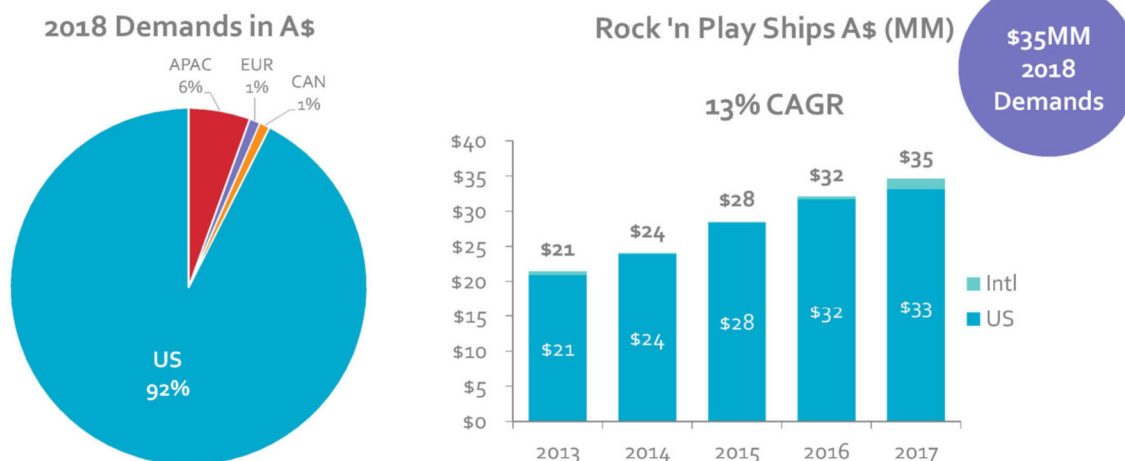
<sup>100</sup> *Id.*; Mattel\_HCOR\_005762.





## Sleepers –FP Global State of the Business

Growth in the US is being driven by the ARNP



Mattel – Confidential Information – May Include Trade Secrets – For Internal Use Only

### E. Fisher-Price Recalled Rock ‘n Play After CPSC Action and Negative Press Attention

On April 1, 2019, CPSC sent Fisher-Price a letter notifying the company that CPSC would be releasing a press alert regarding the Rock ‘n Play. The press alert warned consumers “not to use the Fisher-Price Rock ‘n Play for infants 3 months or older, or as soon as an infant exhibits rollover capabilities, whichever is earlier.” The alert would also inform consumers that CPSC was “aware of 10 infant deaths in the Rock ‘n Play that have occurred since 2015, after the infants rolled from their back to their stomach or side. All 10 infants were 3 months or older.”<sup>101</sup> While regulations would ordinarily require that Fisher-Price be provided 15 days to comment on the press alert, CPSC invoked a rule allowing a shorter period of notice if required by public health and safety. Fisher-Price was provided 24 hours to comment on the press alert “based on the need to warn the public quickly because infants may be in danger of death when they roll over in the Rock ‘n Play.”<sup>102</sup>

Ms. Pilarz told the Committee that CPSC’s letter was “unexpected.” She said it was “hard to understand” because Fisher-Price and CPSC had been “working on an ASTM standard. No further questions came from CPSC for many months [after CPSC’s conversations with Fisher-Price in 2018], and then, all of a sudden, it was an emergency to take some action.”<sup>103</sup>

<sup>101</sup> Mattel\_HCOR\_014817, at 3.

<sup>102</sup> Mattel\_HCOR\_014817, at 1.

<sup>103</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

When asked why the Commission had acted so suddenly, Robert Kaye told the Committee that it was a “confluence of events.” First, Dr. Mannen’s study had yielded some preliminary findings that indicated inclined sleepers could be unsafe. Second, CPSC had received additional reports of infants dying while in the Rock ‘n Play, beyond the 17 deaths already reported to the agency. And third, CPSC had inadvertently disclosed incident data for the Rock ‘n Play to *Consumer Reports*.<sup>104</sup> In early 2019, CPSC sent *Consumer Reports* data requested by the publication, including data about injuries and deaths associated with consumer products. However, CPSC failed to redact the names of manufacturers and products, as required by Section 6(b) of the CPSA. CPSC requested that *Consumer Reports* destroy the data, but *Consumer Reports* refused. Through its analysis of CPSC data, *Consumer Reports* found that at least 29 fatalities were tied to the Rock ‘n Play. *Consumer Reports* contacted CPSC for comment on its story on April 1, 2019.<sup>105</sup> CPSC sent its letter with a proposed press alert to Fisher-Price the same day.

In response to CPSC’s proposed press alert, on April 4, 2019, Fisher-Price sent back a revised draft of the alert. Among other changes, Fisher-Price proposed saying that an infant should stop using the Rock ‘n Play when it “exhibits rollover capabilities,” rather than when they reach 3 months of age.<sup>106</sup> On April 5, 2019, CPSC ultimately issued the alert warning consumers to stop using the Rock ‘n Play when infants are three months old or begin exhibiting rollover capabilities, mentioning 10 infant fatalities tied to the Rock ‘n Play since 2015.<sup>107</sup>

*Consumer Reports* contacted Fisher-Price for comment on its investigation between April 1 and April 3, 2019.<sup>108</sup> On April 4, 2019, the same day that Fisher-Price sent its comments on CPSC’s press alert, Fisher-Price informed CPSC that it would like to conduct a fast-track recall of the Rock ‘n Play.<sup>109</sup> When asked why Fisher-Price decided to issue a fast-track recall on the same day that the company sent comments on the press alert, Ms. Pilarz told Committee staff that the company was “still trying to process where CPSC was going, and we were trying to keep up with the very fast pace. And we had some internal discussions that maybe instead of issuing that safety alert, we would take a more proactive approach by doing this fast track recall.”<sup>110</sup>

In an email, Fisher-Price informed CPSC what the recall would include:<sup>111</sup>

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<sup>104</sup> Committee on Oversight and Reform, Transcribed Interview of Robert Kaye (Sept. 16, 2020).

<sup>105</sup> *While They Were Sleeping*, Consumer Reports (Dec. 30, 2019) (online at [www.consumerreports.org/child-safety/while-they-were-sleeping/](http://www.consumerreports.org/child-safety/while-they-were-sleeping/)).

<sup>106</sup> Mattel\_HCOR\_009815; Mattel\_HCOR\_009817.

<sup>107</sup> Consumer Product Safety Commission, *CPSC Alert: CPSC and Fisher-Price Warn Consumers About Fisher-Price Rock ‘n Play Due to Reports of Death When Infants Roll Over in the Product* (Apr. 5, 2019) (online at [www.cpsc.gov/Newsroom/News-Releases/2019/CPSC-ALERT-CPSC-and-Fisher-Price-Warn-Consumers-About-Fisher-Price-Rock-N-Play-Due-to-Reports-of-Death-When-Infants-Roll-Over-in-the-Product](http://www.cpsc.gov/Newsroom/News-Releases/2019/CPSC-ALERT-CPSC-and-Fisher-Price-Warn-Consumers-About-Fisher-Price-Rock-N-Play-Due-to-Reports-of-Death-When-Infants-Roll-Over-in-the-Product)).

<sup>108</sup> *While They Were Sleeping*, Consumer Reports (Dec. 30, 2019) (online at [www.consumerreports.org/child-safety/while-they-were-sleeping/](http://www.consumerreports.org/child-safety/while-they-were-sleeping/)).

<sup>109</sup> Mattel\_HCOR\_009895, at 2.

<sup>110</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>111</sup> Mattel\_HCOR\_009895, at 2.

[A] joint press release, asking consumers to contact us and we will provide a new warning label, to be applied by the consumer in a more conspicuous location. The label wording will be in accordance with the roll over label developed by CPSC staff that is currently out for ballot to be incorporated in ASTM F3118.

Ms. Pilarz explained that Fisher-Price's proposal would have stopped sales of new Rock 'n Play units, but would only send modified warning labels to consumers who already owned the Rock 'n Play rather than instructing them to immediately stop use of the product.<sup>112</sup>

CPSC informed Fisher-Price that it did "not agree on your proposed remedy with regard to the warnings. We would need to continue negotiations on the remedy and including a refund option."<sup>113</sup>

Had Fisher-Price not initiated a voluntary fast-track recall after it was contacted by *Consumer Reports*, CPSC would have had very limited options for recalling the Rock 'n Play. Mr. Kaye told Committee staff that even after officials at CPSC became urgently concerned about the safety of the Rock 'n Play based on Dr. Mannen's preliminary findings, CPSC could not have unilaterally ordered a recall. He described the two options available to CPSC if the manufacturer does not voluntarily institute a recall:<sup>114</sup>

Recalls are instituted by companies, and the only way that we can compel a company to institute a recall is to either take them through our administrative process, which is an administrative litigation process that results in a Commission order, which is appealable, or where we believe a hazard is imminent we have certain statutory authority to go directly to Federal court.

Mr. Kaye agreed that neither option would be a quick solution.<sup>115</sup> As a result, dangerous products can remain on the market for much longer if manufacturers resist a recall.

On April 5, 2019, CPSC confirmed that Fisher-Price would be ready to submit a corrective action plan (CAP), which would have to be approved by CPSC.<sup>116</sup> The CAP details the remedial action taken by the manufacturer—in this case a recall. However, CAPs are voluntary, are not public, and are not binding on the manufacturer.<sup>117</sup> If manufacturers do not abide by the plan, CPSC would be left with the same time-consuming options to compel a recall it would have without a CAP.

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<sup>112</sup> Committee on Oversight and Reform, Transcribed Interview of Catherine Pilarz (Aug. 13, 2020).

<sup>113</sup> Mattel\_HCOR\_009895, at 1.

<sup>114</sup> Committee on Oversight and Reform, Transcribed Interview of Robert Kaye (Sept. 16, 2020).

<sup>115</sup> *Id.*

<sup>116</sup> Mattel\_HCOR\_009895.

<sup>117</sup> Committee on Oversight and Reform, Transcribed Interview of Robert Kaye (Sept. 16, 2020).

Fisher-Price and CPSC negotiated the terms of the CAP. On April 12, 2019, CPSC sent over its “best and final” draft, including a clean and tracked version, and requested that Fisher-Price sign it.<sup>118</sup> The tracked changes version of the CAP sent by CPSC makes clear that Fisher-Price was still seeking to avoid admitting that there was a substantial product hazard with the Rock ‘n Play, and wanted CPSC to emphasize that it had not found a substantial product hazard. CPSC refused.<sup>119</sup>

8. Reservation of Rights: The submission of this CAP does not constitute an admission by Fisher-Price that either reportable information or a substantial product hazard exists. ~~The CPSC has made no finding that the Subject Product contains a substantial product hazard.~~ CPSC reserves the right to seek broader corrective action if it becomes aware of new facts or if this CAP does not sufficiently protect the public.

The CAP established how Fisher-Price would be required to notify consumers of the recall and required that Fisher-Price provide monthly reports to CPSC on the status of the recall.<sup>120</sup>

On April 12, 2019, CPSC announced the recall of the Rock ‘n Play, stating that “over 30 infant fatalities have occurred in Rock ‘n Play Sleepers, after the infants rolled over while unrestrained, or under other circumstances.”<sup>121</sup>

#### **F. Many Daycare Centers Remained Unaware of the Recall for Months**

Although CPSC publicized the recall and Fisher-Price agreed to notify consumers through its website, social media, and traditional media, a study found that daycare centers were still unaware of the recall months after it had been issued, putting more infants at risk. In April 2020, the Public Interest Research Group (PIRG) released the results of a survey of 376 licensed childcare facilities in three states about whether they were still using inclined sleepers. One in ten facilities caring for children under one year old said they were still using sleepers, and many were unaware of any recalls or safety issues.<sup>122</sup> Since the recall of the Rock ‘n Play, CPSC has received dozens of new reports of fatalities associated with inclined sleep products.<sup>123</sup>

#### **G. Lack of Oversight of Infant Products is an Industry-Wide Problem**

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<sup>118</sup> Mattel\_HCOR\_010043.

<sup>119</sup> Mattel\_HCOR\_010048.

<sup>120</sup> Mattel\_HCOR\_010045.

<sup>121</sup> Consumer Product Safety Commission, *Fisher-Price Recalls Rock ‘n Play Sleepers Due to Reports of Deaths* (Apr. 12, 2019) (online at [www.cpsc.gov/Recalls/2019/fisher-price-recalls-rock-n-play-sleepers-due-to-reports-of-deaths](http://www.cpsc.gov/Recalls/2019/fisher-price-recalls-rock-n-play-sleepers-due-to-reports-of-deaths)).

<sup>122</sup> *Day Cares Used Dangerous Infant Sleepers After Recall*, New York Times (Apr. 18, 2020) (online at [www.nytimes.com/2020/04/18/parenting/baby/rock-n-play-day-care.html](http://www.nytimes.com/2020/04/18/parenting/baby/rock-n-play-day-care.html)).

<sup>123</sup> Consumer Product Safety Commission, *Proposed Rule: Safety Standard for Infant Sleep Products* (Nov 12, 2019) (84 FR 60949) (online at [www.federalregister.gov/documents/2019/11/12/2019-23724/safety-standard-for-infant-sleep-products](http://www.federalregister.gov/documents/2019/11/12/2019-23724/safety-standard-for-infant-sleep-products)).

Although the Committee’s investigation focused on Fisher-Price’s Rock ‘n Play, the lack of oversight of consumer products—particularly products intended for infants and children—is an industry-wide problem. After the Rock ‘n Play was released in 2009, numerous other manufacturers released similar products. Shortly after *Consumer Reports* published its 2019 investigation into the Rock ‘n Play, it found that inclined sleepers made by another manufacturer, Kids II, were associated with four infant fatalities. Kids II recalled its inclined sleepers on April 26, 2019, citing five infant fatalities associated with the products.<sup>124</sup> Kids II did not produce any documents to the Committee indicating that it had conducted original research into the safety of inclined sleep for infants.

The case of Dorel, another manufacturer of inclined sleepers, is particularly illustrative of how the current system is failing. Dorel recalled its inclined sleeper models on July 31, 2019. Dorel told the Committee that it was not aware of any infant deaths associated with its sleepers but recalled the products out of an abundance of caution. In response to the Committee’s requests, Dorel could not identify any documentation of discussions with internal or external doctors, scientists, consultants, or experts regarding the safety and design or design of inclined sleep products. The company explained:

Dorel did not discuss or consult directly with any physician, scientist, consultant or expert regarding the safety or design of the Dorel inclined sleepers. Dorel designs its products to meet ASTM specifications. ASTM specifications for children’s products such as inclined sleepers are developed with the input of the medical, scientific and engineering community. **It is standard practice in our industry and other consumer product industries to do this, relying on the expertise of ASTM International.**<sup>125</sup>

As noted above, the ASTM standards process is largely driven by manufacturers. Manufacturers sit on the ASTM committees that create standards for their own products, and they often hold a great deal of sway over other committee members.

CPSC never promulgated a final mandatory standard for inclined sleepers before they were recalled. After the recall, the agency proposed a new rule limiting the angle of any inclined sleep products to ten degrees, essentially banning infant inclined sleep products.<sup>126</sup> This is a step in the right direction, but further steps are needed to strengthen oversight of the industry as a whole.

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<sup>124</sup> *Kids II Recalls Infant Sleepers Linked to Infant Deaths*, Consumer Reports (Apr. 26, 2019) (online at [www.consumerreports.org/recalls/kids-ii-inclined-sleeper-recall-rocking-sleepers-linked-with-infant-deaths/](http://www.consumerreports.org/recalls/kids-ii-inclined-sleeper-recall-rocking-sleepers-linked-with-infant-deaths/)).

<sup>125</sup> Letter from Dorel Juvenile Group, USA to Chairman Elijah E. Cummings, Committee on Oversight and Reform (Sept. 5, 2019) (emphasis added).

<sup>126</sup> Consumer Product Safety Commission, *Proposed Rule: Safety Standard for Infant Sleep Products* (Nov. 12, 2019) (84 FR 60949) (online at [www.federalregister.gov/documents/2019/11/12/2019-23724/safety-standard-for-infant-sleep-products](http://www.federalregister.gov/documents/2019/11/12/2019-23724/safety-standard-for-infant-sleep-products)).

#### **IV. POLICY RECOMMENDATIONS**

To correct the problems discussed in this report and strengthen oversight of potentially dangerous consumer products, significant legislative reforms are needed. CPSC should be empowered to take more decisive action to prevent dangerous products from coming to and staying on the market. Among other potential reforms, the following changes could help protect American consumers from dangerous products:

- Repeal Section 6(b) of the CPSA and establish a publicly available, national database that includes data on all known serious injuries and deaths associated with consumer products, identified by manufacturer, product name, and date.
- Remove administrative barriers for CPSC to issue and enforce a mandatory recall if CPSC determines that a product poses an imminent danger of serious injury or death.
- Require manufacturers to submit a report to CPSC demonstrating the safety of any new durable infant or toddler product that falls outside mandatory standards already promulgated by CPSC. The report must affirmatively establish that the design is safe through studies or consultation with relevant experts. The product may not be released until CPSC concludes that the product is safe.
- Require that all licensed care facilities for children register with CPSC, providing contact information that CPSC can use to notify the facilities in the event of a recall.