

## CPSC FOIA 19-F-00215 Production Part I of III pp 1-255 of 765

	CONTENTS OF CASE NO. CA120159	file Fisher-	MER/PRVLBI COMMENTS: _OVERRUL _EXCISION _ DO NOT F Pure	R NOTIFIED AM 9/18/13  YES NO ED; ATTACHED (6) 6) IS/FOIA EXS 3/15 (5) RE-NOTIFY RE-NOTIFY  ROCK-N-Play Sleep	
(b)(4); (b)(3):CPSA Section 6(a)					
(b)(4); (b)(3):CPSA Section 6(a)					

- JC 2
- 2. **Consumer Contact:** Include the toll-free 1-800 number, time period and website address for consumers.
- 3. Description: Include the number of patterns and color palettes in which all RNP Sleepers are sold.
- 4. Remedy: Include the website address at which consumers can find cleaning and care instructions.
- 5. **Sold at:** Include the big box stores nationwide in which the RNP Sleepers are sold. On a list not to be included on this press release, include small boutiques at which these are sold. Also include online locations at which products are sold. Include if all models have been sold to date by inserting November 2012 after "to".
- 6. Photos: See instructions re jpgs to submit.

If you have any questions please feel free to contact me. Our offices will be closed for the national holiday, Veteran's Day, on Monday. We look forward to your response on Tuesday.

Terri

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone; 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Moore, Kelly

Sent: Friday, October 19, 2012 9:52 AM

To: Pilarz, Kitty

Cc: Schoem, Marc; Murphy, Mary; Dan.Dzialga@Fisher-Price.com; Tarnoff, Howard; Nelson, Theresa

Subject: RE: Rock and Play Sleeper

Kitty,

(b)(4); (b)(3):CPSA Section 6(a)		

Best regards, Kelly

Kelly M. Moore Trial Attorney Acting Team Lead, Children's Safe Sleep Team Office of the General Counsel, Division of Compliance U.S. Consumer Product Safety Commission 4330 East West Hwy, Room 703H Page 3

Bethesda, MD 20814 (301) 504-7447

From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com]

Sent: Friday, October 12, 2012 9:43 AM
To: Moore, Kelly; Nelson, Theresa
Cc: Schoem, Marc; Murphy, Mary
Subject: FW: Rock and Play Sleeper

Dear Kelly and Terri,

(b)(4); (b)(3):CPSA Section 6(a)

Here is our communication plan.

		,

	•	
	(b)(4); (b)(3):CPSA Section 6(a)	
1.		
2.		
3.		
T.		
4.		

Best regards, Kitty

Confidential treatment requested
Submitted under section 15b
Kitty Pilarz
Senior Director, Mattel Product Safety
Fisher-Price
636 Girard Avenue
East Aurora, New York 14052
716-687-3343

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Consumer Product Safety Commission

Bethesda, Maryland 20814

4330 East West Highway

MEETING ATTENDANCE RECORD

1 psc #834 19012 Location: Date:

Project: Fisher Price Rock N Play Sleeper Purpose: FIRM + CPSC Staff

				$\rightarrow$								<b>—</b>	—	•••••	 
E-mail			VOP. X93 On Up LYX	Kmwre@cox An	inathson@cox.gov	Isattamen @ cocc. col	o,o,o					merophy age go	VOCHSMan PO COX 8. 9.0V		
Fax			301 504 0359		37-504-0079	(30) 504 - 0079									,
Phone		4001	301 504 4359	301 504 7447	301-584-7043	(301) 504-7238 1						301 504 7809	301-504-7686		
Organization	(PSC	(Psc	SCN WCND RESC	CPSC	(K)	CPSC	Fisher Price	F. PRICE (ICTM)	MATTER (FISHER-PRICE	Colding Scalle UP	Fisher Ale	CPSC	CBe		
Name (PLEASE PRINT)	Telli Nolson	reve Thomas	Frency of anchischmonths Cose	Kelly Moore	JOANTY MATRIESIN	Lori Saltzman	Hitty Pilarz	Kell (2/13	DAVID Krowbit	Cheal Possenbi	DANIEL DEMICE	MARY MURPHY	Fab Chriman		

(b)(6)





Best regards, Kelly

Cheryl,
(b)(4); (b)(3):CPSA Section 6(a)

Page 10

## Nelson, Theresa

From:

Cheryl Possenti [cpossenti@goldbergsegalla.com]

Sent:

Monday, July 23, 2012 3:48 PM

To:

Nelson, Theresa; Moore, Kelly; Thomas, Treye

Cc:

Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject:

RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Hi, Terri,

Per your request, in addition to Dr. Gots and me, the following people will be attending the meeting on Tuesday, August 14, 2012 at 1:30 p.m.

David M. Kosnoff
Vice President
Product Quality & Regulatory Compliance
Mattel, Inc

Kitty Pilarz Senior Director Mattel Product Safety

Daniel A. Dzialga, Esq. Senior Counsel Fisher-Price, Inc.

Would you please let us know the members of the CPSC staff who will be attending?

Thank you very much.

Cheryl

Submitted Under Section 15(b)
Confidential Treatment Requested



New York: London Philadelphia: Princeton Hartford Buffalo Rochester Syracuse: Albany: White Plains: Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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Privileged Attorney-Client Communication / Attorney's Work Product

Page 12

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Monday, July 23, 2012 11:35 AM

**To:** Cheryl Possenti; Moore, Kelly; Thomas, Treye **Cc:** Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject: RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Cheryl,

We look forward to meeting with you and staff from the firm, on Tuesday, August 14<sup>th</sup> at 1:30 pm. Our staff will be available at the meeting for Dr. Got's presentation. Could you please send me a list of individuals and their titles who will be in attendance from the firm?

Thanks, Terri

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Monday, July 23, 2012 10:26 AM

**To:** Nelson, Theresa; Moore, Kelly; Thomas, Treye **Cc:** Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject: RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Hi Terry,

Thank you very much. We would be able to meet at 1:30 p.m. on Tuesday, August 14, 2012, if that is convenient for you and the other staff members.

)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)		

We look forward to meeting with you and other members of the staff to share this information and to discuss these issues.

Best regards,

Cheryl



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
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Privileged Attorney-Client Communication / Attorney's Work Product

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

**Sent:** Wednesday, July 18, 2012 11:07 AM **To:** Cheryl Possenti; Moore, Kelly; Thomas, Treye **Cc:** Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject: RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Cheryl

Our staff would prefer to meet with you and your staff on Tuesday, August 14<sup>th</sup> in the afternoon after 1:00 pm (EST). Please let me know an exact time and we will plan accordingly.

We plan to postpone our Preliminary Determination Panel until after our meeting with you on that date. Can you email me a copy of Dr. Got's additional study which you plan to present, for our review prior to the meeting?

Terri

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Monday, July 16, 2012 4:01 PM

To: Nelson, Theresa; Moore, Kelly; Thomas, Treye

Cc: Pilarz, Kitty; Dzialga, Dan

Subject: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Hi, Terry, Kelly and Trey,

Attached is a letter that is being sent by fax and overnight mail. We look forward to hearing from you.

Best regards,

Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested



New York London: Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany: White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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Nelson, Theresa	To Price March 8
Subject: Location:	Conf.Call with Fisher Price - mold re Pock N Play sleeper Am715 Rm 715
Start: End:	Thu 3/8/2012 3:00 PM Thu 3/8/2012 4:00 PM
Recurrence:	(none)
Meeting Status:	Meeting organizer
Organizer: Required Attendees:	Nelson, Theresa Thomas, Treye; Moore, Kelly; Johnson, Dominique; Matheson, Joanna; Kameros, Andrew; Wanna-Nakamura, Suad; Tarnoff, Howard; Schoem, Marc
The purpose of this meeting the second of the second	ng is two-fold:
(b)(4); (b)(3):CPSA Section 6(a)	
2)	
Terrin Cold with Fisher Kilty Palay. Dr Dots Cheryl Pos	Dant K.

Page 20

(b)(5)

Nelson, Theresa Rock N Play Sleeper call w/FP Subject: Location: 715 Mon 2/27/2012 2:00 PM Start: Mon 2/27/2012 3:00 PM End: Recurrence: (none) Status call ofthe frem in **Meeting Status:** Accepted Moore, Kelly Organizer: Nelson, Theresa; Schoem, Marc; Thomas, Treye Required Attendees: Tarnoff, Howard; Murphy, Mary Optional Attendees: 0 bConference: 6 **Call Handling Mode:** CallHandleReminderEnable: FP participants - Kitty Pilary, Chenley P. Kitty Pour D. CallHandlingCanceled: strinviteCode: When: Monday, February 27, 2012 2:00 PM-3:00 PM (GMT-05:00) Eastern Time (US & Canada). Where: 715 \*~\*~\*~\*~\*~\*~\*~\* PARTICIPANTS - To Join Meeting Dial appropriate Access Number Press 1 to "Attend the Meeting" Enter Press #

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## Consumer Product Safety Commission

4330 East West Highway

Bethesda, Maryland 20814

# MEETING ATTENDANCE RECORD

Date: 2-16-2012

Location: CASC - Betheson, MD

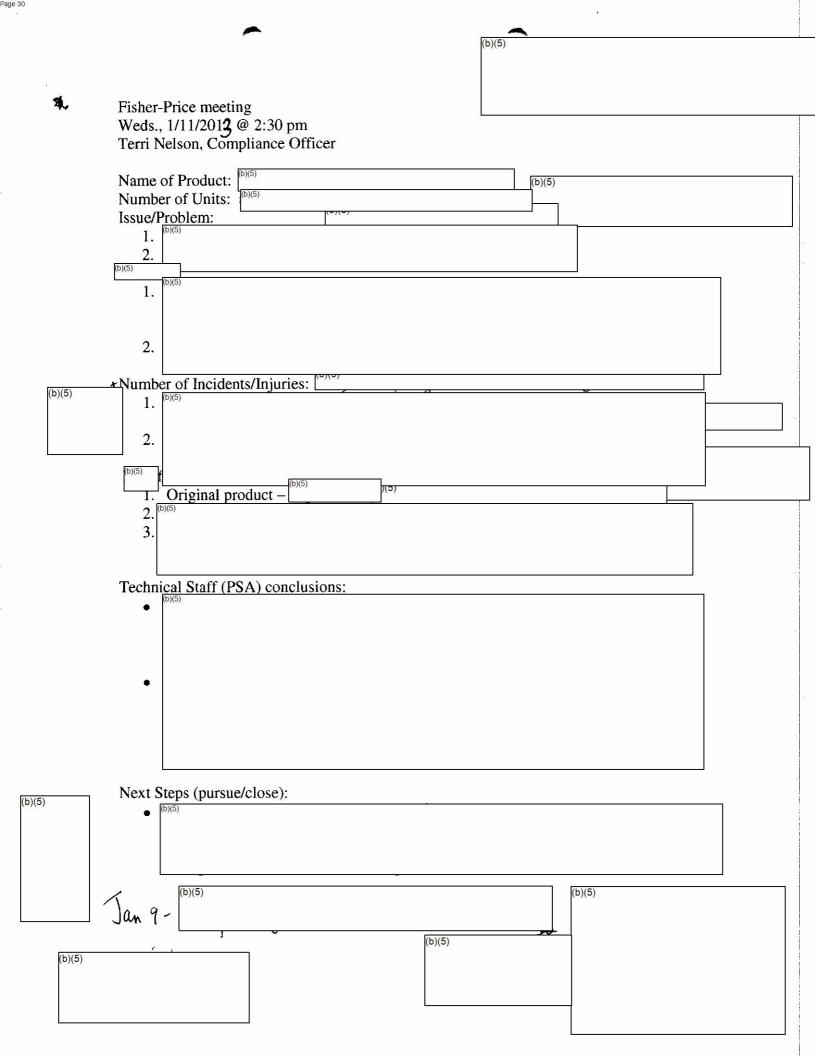
Project: Fisher Price Rock N Play Sleyer

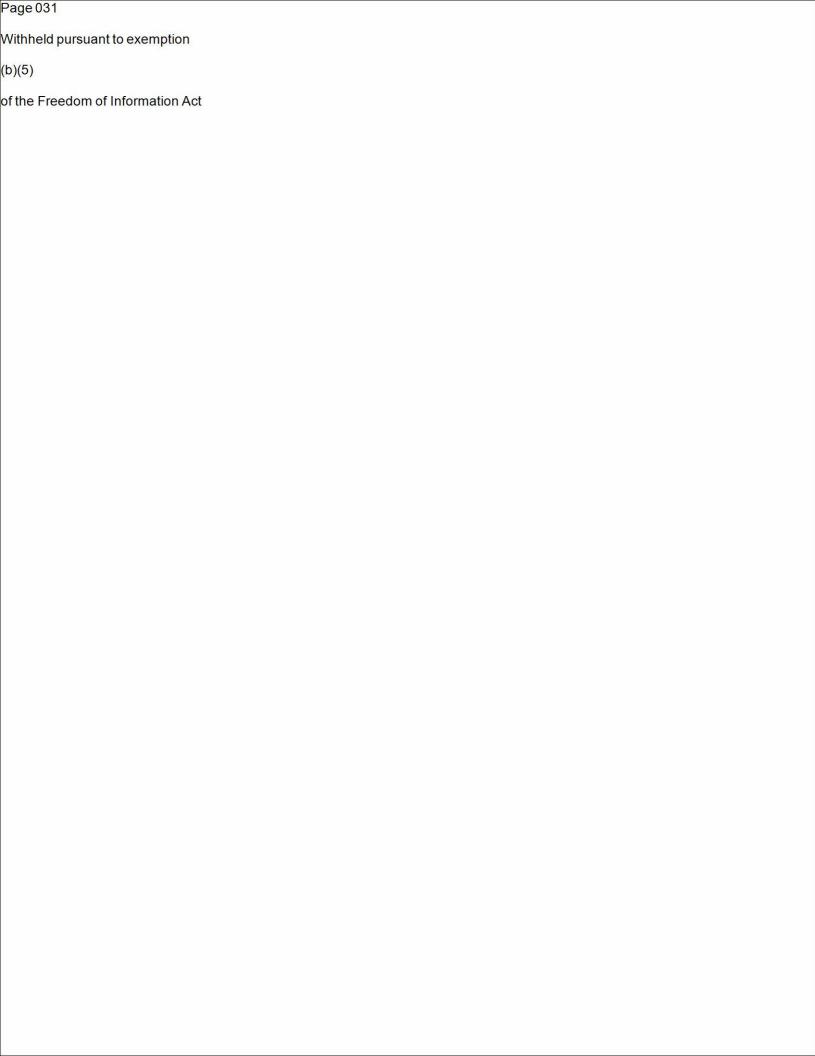
Purpose: neeting with Fisher Price staff

E-mail	fnelson(5 cpsc.gov	2							
Fax									
Phone									
Organization	CPSC								
Name (PLEASE PRINT)	Teni Nelson								

Fisher Price - CRSC 2/16/12

Norme Fram Phone # JIM WALTER MATTEL Kithy Pilava Mattel DAVID KUSNOFF MATTEL Chery Possenti Goldberg Sigalla LLN RUNALD E. GOTS 10 m DAVIEL DZIALGA MATTEL Daminique Johnson CRSC/HS 27597 Treye Thomas Terri Welson CPSC, X 7738 Opsc ×7509 Helly Moore CPSC x7447 Tought lands CESC XZID MARC Schoem C/S C 2012012250 Jano Matheron CPSC Ats x 7043 mary freg OGC CPSC x 7809















From:

Pilarz, Kitty [Kitty.Pilarz@Fisher-Price.com]

Sent:

Wednesday, December 21, 2011 5:14 PM

To:

Page 37

Nelson, Theresa

Cc: Subject: Thomas, Treye; Moore, Kelly RE: CPSC Rock N Play Sleeper - mold issue

Hi Terri,

Please use this call in information:

PARTICIPANTS - To Join Meeting

Dial appropriate Access Number (b)(6

Press 1 to "Attend the Meeting"

Enter (b)(6)

Press #

State your name

Press #

I will be joined by Jerry Miller and Cheryl Possenti, our attorney from Goldberg Segalla. Dan is not available for the call.

Kitty Pilarz

Senior Director, Mattel Product Safety

Fisher-Price

636 Girard Avenue

East Aurora, New York 14052

(b)(6)

**From:** Nelson, Theresa [mailto:TNelson@cpsc.gov] **Sent:** Wednesday, December 21, 2011 4:02 PM

To: Pilarz, Kitty

Cc: Thomas, Treye; Moore, Kelly

Subject: RE: CPSC Rock N Play Sleeper - mold issue

Kitty

Yes, 11:00am (ET) tomorrow is fine for the conference call. Do you want to send us a call in number? Both Kelly Moore and Treye Thomas will be in on the call as well.

Also, how is the report being sent today?

Thanks, Terri

From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com]

Sent: Wednesday, December 21, 2011 1:35 PM

To: Nelson, Theresa; Moore, Kelly

Cc: Dzialga, Dan

Subject: RE: CPSC Rock N Play Sleeper - mold issue

Hi Terri,

We will be sending our report to you today. Would you be available at 11:00 tomorrow for a conference call?

Page 38

### Best regards, Kitty

Kitty Pilarz
Senior Director, Mattel Product Safety
Fisher-Price
636 Girard Avenue
East Aurora, New York 14052
716-687-3343

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Friday, December 09, 2011 1:48 PM

To: Pilarz, Kitty; Moore, Kelly

Cc: Dzialga, Dan

Subject: RE: CPSC Rock N Play Sleeper - mold issue

Thanks Kitty - We'll look forward to your report and the conference card. We will contact Dan after Monday.

Terri

**From:** Pilarz, Kitty [Kitty.Pilarz@Fisher-Price.com] **Sent:** Friday, December 09, 2011 12:18 PM

To: Nelson, Theresa; Moore, Kelly

Cc: Dzialga, Dan

Subject: RE: CPSC Rock N Play Sleeper - mold issue

Hi Terri,

(b)(4); (b)(3):CPSA Section 6(a)

# Best regards, Kitty

Confidential treatment requested Submitted under section 15b

Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052

(b)(6)

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Monday, December 05, 2011 1:21 PM

To: Pilarz, Kitty; Moore, Kelly

Cc: Dzialga, Dan

Subject: CPSC Rock N Play Sleeper - mold issue

#### Kitty

Thank you for taking the time this morning to discuss the mold issue on this product which concerns both your firm and the Commission. We look forward to hearing your timeframe on when we can meet within the next two weeks to discuss this issue together. As we confirmed in our phone call, our primary focus will be to determine how much time will be needed by the firm to obtain preliminary test designs and testing procedures that will assist us in a decision on corrective action with this infant product.

In the meantime, we will need you to continue sending us any additional reports of mold (b)(4), (b)(3).CPSA Section 6(a)

(b)(4); (b)(3):CPSA Section 6(a)

. Also, how many units of this product has the firm replaced to consumers

due to mold, up to this date?

Thank you for your cooperation,

Terri

#### Terri Nelson

Compliance Officer Office of Compliance & Field Operations U.S. Consumer Product Safety Commission Phone: 301-504-7509 or 1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

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From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com]

Sent: Tuesday, November 29, 2011 10:25 PM

To: Moore, Kelly; Nelson, Theresa

Cc: Dzialga, Dan Subject: Mold Reports Importance: High

Dear Terri and Kelly,

As you requested, attached are the reports of mold on the Rock and Play Sleeper that we submitted to CPSC last week. I will send you a meeting notice for Monday shortly.

Best regards, Kitty

<<Rock n Play Mold 15(b) November 23 2011.xls>>

Confidential treatment requested

Submitted under section 15b

Kitty Pilarz

Senior Director, Mattel Product Safety

Fisher-Price

636 Girard Avenue

East Aurora, New York 14052

716-687-3343

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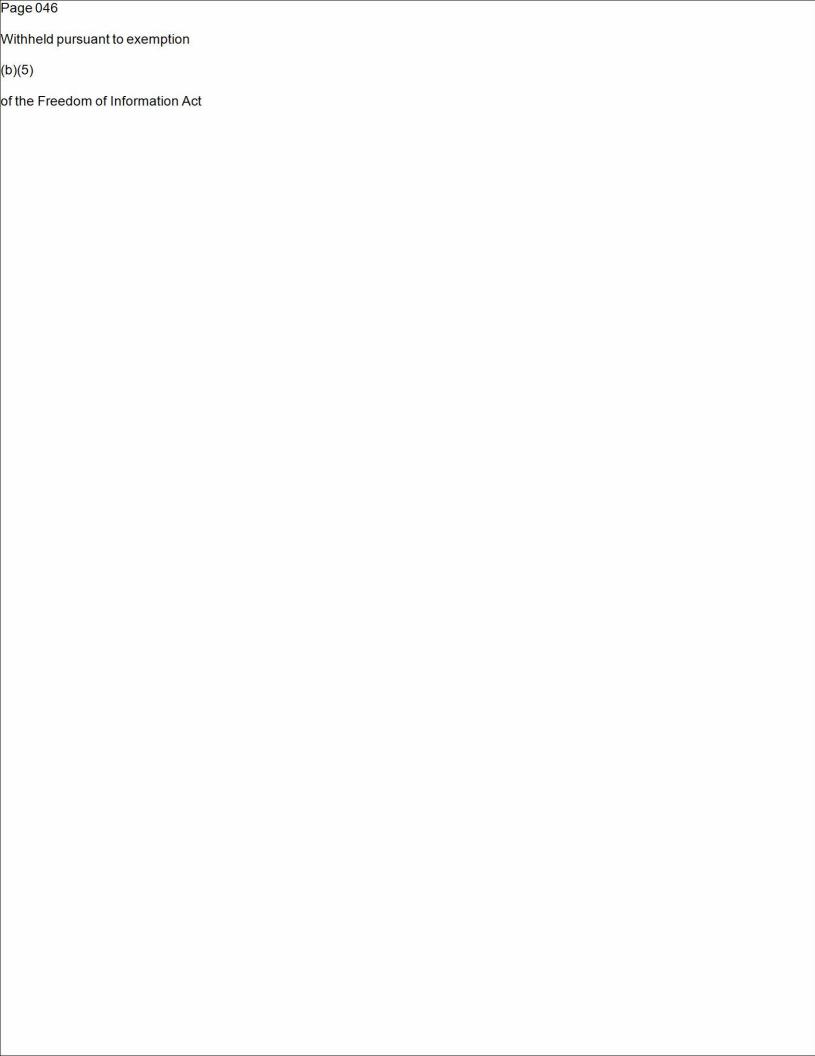
Nelson, Theresa	
From: Sent: To: Cc: Subject:	Nelson, Theresa Wednesday, November 09, 2011 4:42 PM 'Pilarz, Kitty' Moore, Kelly Rock 'N Play Sleeper (PI110066)
Attachments:	mold I90355.pdf
Kitty,	
Thank you for taking	the time to speak with us vesterday regarding our concerns with the
mold issue for this p	noduct.
100 C	
	our next conference call with you next Monday, November 14th at nine the firm's findings.
Terri	
Clearinghouse, since	0906CCC1997 is being mailed to you after review from the CPSC the size of the file could not be emailed. This incident relates to an the severe brachycephaly and plagiophaly and was not previously sent to

From: Sent: To: Cc:	Pilarz, Kitty <kitty.pilarz@fisher-price.com> Monday, November 12, 2012 5:54 PM Nelson, Theresa; Cheryl Possenti (cpossenti@goldbergsegalla.com) Tarnoff, Howard; Rauchschwalbe, Renae; Thomas, Treye; Schoem, Marc; Moore, Kelly;</kitty.pilarz@fisher-price.com>
Subject:	Fest, Don RE: Rock and Play Sleeper press release
Dear Terri,	
(4); (b)(3):CPSA Section 6(a)	
Confidential treatment reques	sted
Submitted under section 15b	
Kitty Pilarz Senior Director, Mattel Prod Fisher-Price 636 Girard Avenue East Aurora, New York 140 716-687-3343	
<b>Sent:</b> Friday, November 0 <b>To:</b> Pilarz, Kitty; Cheryl Po	ossenti (cpossenti@goldbergsegalla.com) ichschwalbe, Renae; Thomas, Treye; Schoem, Marc; Moore, Kelly
as discussed in the ema	draft copy of the recall press release on the Rock 'N Play (RNP) Sleeper for your review ill below from Kelly Moore. Please return with your comments by COB on Tuesday,
	need to reach an agreement on the release date with you and our Office of ollowing items need to be addressed in the attached draft:

Best regards, Kitty  Confidential treatment requested  Submitted under section 15b  Kitty Pilerz  Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052  From: Moore, Kelly Imalito:KMoore@cpsc.gov) Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper  Kitty,  Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  We look forward to reviewing your communications plan. When it will be available?  Thanks, Kelly  From: Pilarz, Kitty [mailto:Kity.Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,  Butt. Bostor/Schoen Roc.	
Confidential treatment requested  Submitted under section 15b  Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052  Senior Moore, Kelly Imailto: Kitoore@cpsc.gov) Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper  Kitty,  Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  We look forward to reviewing your communications plan. When it will be available?  Thanks, Kelly  From: Pilarz, Kitty [mailto:Kitty,Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,	(b)(4), (b)(3) CPSA Section 6(a)
Confidential treatment requested  Submitted under section 15b  Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052  Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper  Kitty,  Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  Sent: Thanks, Kelly  From: Pilarz, Kitty [mailto:Kitty,Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,	
Confidential treatment requested  Submitted under section 15b  Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052  Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper  Kitty,  Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  Sent: Thanks, Kelly  From: Pilarz, Kitty [mailto:Kitty,Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,	Rest regards. Kitty
Submitted under section 15b  Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052  From: Moore, Kelly [mailto:KMoore@cpsc.gov] Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper  Kitty,  Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  We look forward to reviewing your communications plan. When it will be available?  Thanks, Kelly  From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,	
Kitty Pilarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052  ***  From: Moore, Kelly [mailto:KMoore@cpsc.gov] Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper  Kitty,  Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified.  ***  We look forward to reviewing your communications plan. When it will be available?  Thanks, Kelly  From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,	Confidential treatment requested
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Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper  Dear Terri,	
Dear Terri,	5 · · · · · · · · · · · · · · · · · · ·
	Subject: Rock and Play Sleeper
	Dear Terri.







The N Play

From:

Cheryl Possenti <cpossenti@goldbergsegalla.com>

Sent:

Monday, November 19, 2012 5:05 PM

To:

Page 47

Nelson, Theresa

Cc:

Schoem, Marc; Moore, Kelly; Thomas, Treye; Rauchschwalbe, Renae; Tarnoff, Howard;

Pilarz, Kitty; Kosnoff, David M.; Dzialga, Dan

Subject:

Rock 'N Play Sleeper CONFIDENTIAL

Attachments:

Theresa Nelson 111912 - #954650.PDF; Rock n Play Sleeper Safety Alert - #954594.PDF;

Rock n Play Sleeper Press Release - #954595.DOC

Dear Terry,

(b)(4); (b)(3):CPSA Section 6(a)

We look forward to working with you toward accomplishing the mutual goals of Fisher-Price and the staff.

Best regards,

Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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Privileged Attorney-Client Communication / Attorney's Work Product







Page 051 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act

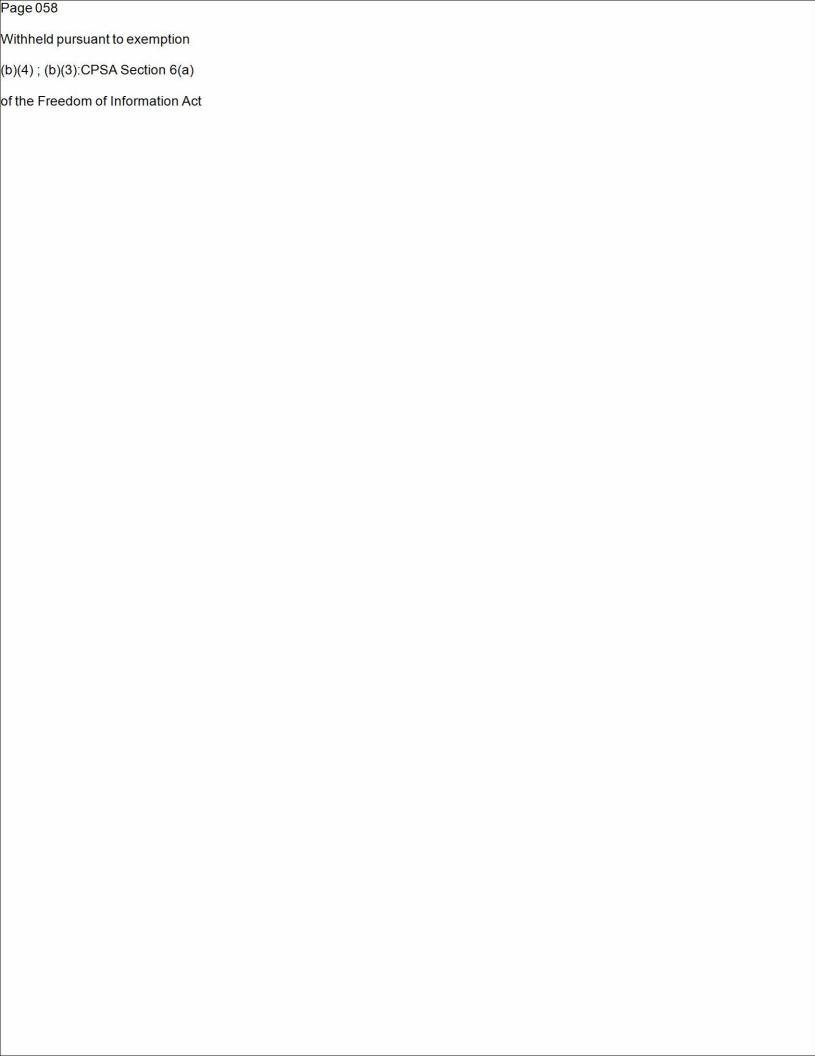
Page 052	
Withheld pursuant to exemption	
(b)(4); (b)(3):CPSA Section 6(a)	
of the Freedom of Information Act	

Page 053 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 054 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act





Page 057 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act



From:

Pilarz, Kitty <Kitty.Pilarz@Fisher-Price.com>

Sent:

Wednesday, December 21, 2011 4:05 PM

To:

Nelson, Theresa

Subject:

CONFIDENTIAL: Fisher-Price - Full 15(b) Report - Newborn Rock 'n Play Sleeper

**Attachments:** 

DOC.PDF

Hi Terri,

Attached is our full report on the Newborn Rock 'n Play Sleeper. The hard copy with all the attachments is being sent to you today by overnight delivery.

Best regards, Kitty

Confidential treatment requested <<DOC.PDF>>

Submitted under section 15b

Kitty Pilarz

Senior Director, Mattel Product Safety

Fisher-Price

636 Girard Avenue

East Aurora, New York 14052

716-687-3343

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Page 061 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act

### Page 62

Nelson, Theresa

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-	re	311	n:

Moore, Kelly

Sent:

Friday, October 19, 2012 9:52 AM

To:

Pilarz, Kitty

Cc:

Schoem, Marc; Murphy, Mary; Dan.Dzialga@Fisher-Price.com; Tarnoff, Howard; Nelson,

Theresa

Subject:

RE: Rock and Play Sleeper

Kitty,

Any communication plan that merits discussion needs to include a recall press release. We have been very clear on this point. Mold in an infant's breathing zone is not acceptable. Parents must be told to inspect their products to ensure that their product is not affected. If mold is found, Fisher-Price should replace the affected product as it has been doing on a case-by-case basis for some time. It is not only appropriate but essential for the message to be communicated to the public at large. Many recall press releases contain information that is instructional in nature; this is no barrier to issuing a recall press release. We will draft a proposed release and send it to you in the next few days for review.

Best regards, Kelly

Kelly M. Moore
Trial Attorney
Acting Team Lead, Children's Safe Sleep Team
Office of the General Counsel, Division of Compliance
U.S. Consumer Product Safety Commission
4330 East West Hwy, Room 703H
Bethesda, MD 20814
(301) 504-7447

From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com]

Sent: Friday, October 12, 2012 9:43 AM To: Moore, Kelly; Nelson, Theresa Cc: Schoem, Marc; Murphy, Mary Subject: FW: Rock and Play Sleeper

Dear Kelly and Terri,

Here is our communication plan.

(b)(4); (b)(3):CPSA Section 6(a)

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-	(b)(4); (b)(3):CPSA Section 6(a)
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	Confidential treatment requested
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	Submitted under section 15b
	Submitted under Section 13b
	Vias. bil
	Kitty Pilarz
	Senior Director, Mattel Product Safety
	Fisher-Price
	636 Girard Avenue
	East Aurora, New York 14052
	(b)(6)

From: Moore, Kelly [mailto:KMoore@cpsc.gov] Sent: Wednesday, October 10, 2012 4:15 PM To: Pilarz, Kitty Cc: Schoem, Marc; Nelson, Theresa; Murphy, Mary Subject: RE: Rock and Play Sleeper Kitty, Thank you for your response. At the outset, we all agree that we need to cast a wide net to communicate the message to consumers and, to that end, we support your use of the forms of media you identified. (b)(4); (b)(3):CPSA Section 6(a) (b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b) We look forward to reviewing your communications plan. When it will be available? Thanks, Kelly From: Pilarz, Kitty [mailto:Kitty.Pilarz@Fisher-Price.com] Sent: Tuesday, October 09, 2012 10:51 AM To: Nelson, Theresa Cc: Schoem, Marc; Moore, Kelly Subject: Rock and Play Sleeper Dear Terri,

1. 2.

3.

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Best regards, Kitty

Confidential treatment requested
Submitted under section 15b

Kitty Pílarz
Senior Director, Mattel Product Safety
Fisher-Price
636 Girard Avenue
East Aurora, New York 14052
716-687-3343

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\*\*\*\*\*!!! Unless otherwise stated, any views or opinions expressed in this e-mail (and any attachments) are solely those of the author and do not necessarily represent those of the U.S. Consumer Product Safety Commission. Copies of product recall and product safety information can be sent to you automatically via Internet e-mail, as they are released by CPSC. To subscribe or unsubscribe to this service go to the following web page: <a href="https://www.cpsc.gov/cpsclist.aspx">https://www.cpsc.gov/cpsclist.aspx</a> \*\*\*\*\*!!!

From:

Moore, Kelly

Sent:

Thursday, October 04, 2012 2:03 PM

To:

cpossenti@goldbergsegalla.com

Cc:

Nelson, Theresa; Thomas, Treye; Murphy, Mary; Schoem, Marc; Kitty.Pilarz@Fisher-

Price.com; Dan.Dzialga@Fisher-Price.com

Subject:

Fisher-Price Rock N Play

**Attachments:** 

Mold Response to Fisher Price Letter Oct 4.pdf

Cheryl,

Thank you for your letter dated Sept. 21, 2012. Our technical staff has prepared the attached to address some issues that you raised and provide the additional sources of information that you requested. We look forward to talking with you shortly.

Best regards,

Kelly

Kelly M. Moore
Trial Attorney
Acting Team Lead, Children's Safe Sleep Team
Office of the General Counsel, Division of Compliance
U.S. Consumer Product Safety Commission
4330 East West Hwy, Room 703H
Bethesda, MD 20814
(301) 504-7447

# Response to Fisher Price Letter Summary of Mold Data Review

Page 67

(b)(4); (b)(3):CPSA Section 6(a)	
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(b)(4); (b)(3):CPSA Section 6(a)		

(b)(4); (b)(3):CPSA Section 6(a)		
(5)(1), (5)(6).51 57 5561611 5(4)		

(b)(4); (b)(3):CPSA Section 6(a)		

# List of relevant studies

o)(4); (b)(3):CPSA Section 6(a)
()(4), (0)(3)(2)(3) Section ((a)

# Federal agency action on mold

(b)(4); (b)(3):CPSA Section 6(a)				

<sup>&</sup>lt;sup>3</sup> http://www.cdc.gov/mold/basics.htm

# **Nelson, Theresa**

From:

Cheryl Possenti <cpossenti@goldbergsegalla.com>

Sent:

Page 73

Wednesday, October 03, 2012 4:49 PM

To:

Nelson, Theresa

Cc:

Pilarz, Kitty; David.Kosnoff@Mattel.com; dan.dzialga@fisher-price.com; Moore, Kelly FW: Call-in # for conf.call on Thurs. 10/4 @ 3:pm EST w/CPSC -RE: Rock 'n Play Sleeper

Subject:

**CONFIDENTIAL PI110066** 

Hi, Terri,

Kitty and I look forward to speaking with you tomorrow at 3:00 p.m.

(b)(4); (b)(3):CPSA Section 6(a)

Thank you very much.

Best regards,

Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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Privileged Attorney-Client Communication / Attorney's Work Product

From: Nelson, Theresa [mailto:TNelson@cpsc.gov] Sent: Thursday, September 27, 2012 8:10 AM

To: Cheryl Possenti

Cc: 'Kitty.Pilarz@Fisher-Price.com'; 'David.Kosnoff@Mattel.com'; 'dan.dzialga@fisher-price.com'; Moore, Kelly

Subject: Call-in # for conf.call on Thurs. 10/4 @ 3:pm EST w/CPSC -RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066

# Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commissio

Phone: 301-504-7509 or 1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Friday, September 21, 2012 4:57 PM

To: Nelson, Theresa

Cc: Thomas, Treye; Moore, Kelly; Schoem, Marc; Pilarz, Kitty; Dzialga, Dan; Kosnoff, David M.

Subject: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Hi, Terry,

Please see the attached letter asking for information and requesting a call. Hard copies are being sent out today.

Thank you very much for your courtesies.

Best regards,

Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested

<image001.jpg>
Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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# Nelson, Theresa

Best regards,

From:	Nelson, Theresa				
Sent:	Wednesday, October 03, 2012 5:12 PM				
To:	'Cheryl Possenti'				
Cc:	Pilarz, Kitty; David.Kosnoff@Mattel.com; dan.dzialga@fisher-price.com; Moore, Kelly				
Subject:	RE: Call-in # for conf.call on Thurs. 10/4 @ 3:pm EST w/CPSC -RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066				
Cheryl,					
I will be providing you with that information tomorrow morning. It is being routed for approval at this time.					
Other staff that will be available for the conference call tomorrow include: Treye Thomas, Joanna Matheson, Dominique Johnson, Kelly Moore, Marc Schoem and Mary Murphy.					
We look forward to speaking with you.					
Regards, Terri					
Terri Nelson  Compliance Officer  Office of Compliance & Field Operations  U.S. Consumer Product Safety Commission  Phone: 301-504-7509 or  1-800-638-8095 ext. 7509					
Fax: 301-504-0359 tnelson@cpsc.gov					
SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx					
From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com] Sent: Wednesday, October 03, 2012 4:49 PM To: Nelson, Theresa Cc: Pilarz, Kitty; David.Kosnoff@Mattel.com; dan.dzialga@fisher-price.com; Moore, Kelly Subject: FW: Call-in # for conf.call on Thurs. 10/4 @ 3:pm EST w/CPSC -RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066					
Hì, Terri,					
Kitty and I look forward to speaking with you tomorrow at 3:00 p.m.					
Thank you very much.					
mank you very much					

Page 76

Submitted Under Section 15(b) Confidential Treatment Requested



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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Privileged Attorney-Client Communication / Attorney's Work Product

From: Nelson, Theresa [mailto:TNelson@cpsc.gov]
Sent: Thursday, September 27, 2012 8:10 AM

To: Cheryl Possenti

Cc: 'Kitty.Pilarz@Fisher-Price.com'; 'David.Kosnoff@Mattel.com'; 'dan.dzialga@fisher-price.com'; Moore, Kelly

Subject: Call-in # for conf.call on Thurs. 10/4 @ 3:pm EST w/CPSC -RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066

The call in information is as follows:

representation of the control of the

Toll Free:			
Participar	nt Passcode:	(b)(6)	

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or

Phone: 301-504-7509 or 1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Nelson, Theresa

Sent: Wednesday, September 26, 2012 9:53 AM

To: 'Cheryl Possenti'

Cc: Kitty.Pilarz@Fisher-Price.com; David.Kosnoff@Mattel.com; dan.dzialga@fisher-price.com

Subject: RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Cheryl

Yes, I'll get back to you with a call-in number shortly.

Terri

# Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Wednesday, September 26, 2012 9:37 AM

To: Nelson, Theresa

Cc: Kitty.Pilarz@Fisher-Price.com; David.Kosnoff@Mattel.com; dan.dzialga@fisher-price.com

Subject: Re: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Hi Terry

We can confirm. Thank you. Can we call you?

Cheryl

Cheryl A. Possenti, Esq.
Partner
Goldberg Segalla
NY • PA • NJ • CT • UK
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**From:** Nelson, Theresa **To:** Cheryl Possenti

Cc: Kitty Pilarz; David M. Kosnoff; Daniel A. Dzialga

**Sent:** Wed Sep 26 08:53:08 2012

Subject: RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Cheryl,

Next Thursday, October 4<sup>th</sup> at 3:00pm EST, works for us. Please confirm.

Thank you, Terri

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or

Phone: 301-504-7509 or 1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Wednesday, September 26, 2012 7:33 AM

To: Nelson, Theresa

Cc: Kitty Pilarz; David M. Kosnoff; Daniel A. Dzialga

Subject: Re: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Hi, Terry,

We are not available October 1 between 2:00 and 4:00 however we can be available October 4 at either 11:00 a.m. or 3:00 p.m. Please let us know if either of these times work for you.

Best regards,

Cheryl

Confidential treatment requested Submitted under Section 15(b)

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
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On Sep 25, 2012, at 8:08 AM, "Nelson, Theresa" <TNelson@cpsc.gov> wrote:

#### Thanks Cheryl

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

#### SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Monday, September 24, 2012 6:44 PM

To: Nelson, Theresa

Cc: Thomas, Treye; Moore, Kelly; Schoem, Marc; Kitty.Pilarz@Fisher-Price.com; dan.dzialga@fisher-

price.com; David.Kosnoff@Mattel.com

Subject: Re: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Hi Terry

Thank you. I will check and get back to you as soon as possible

Cheryl

Confidential treatment requested Submitted under section 15(b)

Cheryl A. Possenti, Esq.
Partner
Goldberg Segalla
NY • PA • NJ • CT • UK
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Buffalo, NY 14203
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http://www.goldbergsegalla.com

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Privileged Attorney-Client Communication / Attorney's Work Product

**From**: Nelson, Theresa **To**: Cheryl Possenti

**Cc**: Thomas, Treye; Moore, Kelly; Schoem, Marc; 'Pilarz, Kitty (<u>Kitty.Pilarz@Fisher-Price.com</u>)'; 'Dzialga, Dan (<u>Dan.Dzialga@Fisher-Price.com</u>)'; 'Kosnoff, David M. (<u>David.Kosnoff@Mattel.com</u>)'

**Sent**: Mon Sep 24 17:51:58 2012

Subject: RE: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Cheryl

I'm not able to schedule your requested phone conference for this Thursday, due to multiple conflicts on our end. Would your staff be available on Monday, October 1<sup>st</sup> for an hour between 2:00-4:00pm EST?

# Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Nelson, Theresa

Sent: Monday, September 24, 2012 1:37 PM

To: Cheryl Possenti (cpossenti@goldbergsegalla.com)

Cc: Thomas, Treye; Moore, Kelly; Schoem, Marc; Pilarz, Kitty (<u>Kitty.Pilarz@Fisher-Price.com</u>); Dzialga,

Dan (<u>Dan.Dzialga@Fisher-Price.com</u>); Kosnoff, David M. (<u>David.Kosnoff@Mattel.com</u>)

Subject: FW: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Cheryl

Thank you for the attached submission to our request on September 6, 2012 for a corrective action proposal. I am checking on staff's availability for a phone call for Thursday, September 27<sup>th</sup> and will get back to you by COB today.

Terri

# Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commissio
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Friday, September 21, 2012 4:57 PM

To: Nelson, Theresa

Cc: Thomas, Treye; Moore, Kelly; Schoem, Marc; Pilarz, Kitty; Działga, Dan; Kosnoff, David M.

Subject: Rock 'n Play Sleeper CONFIDENTIAL PI110066

Hi, Terry,

Please see the attached letter asking for information and requesting a call. Hard copies are being sent out today.

Thank you very much for your courtesies.

Best regards,

# Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested

<image001.jpg>
Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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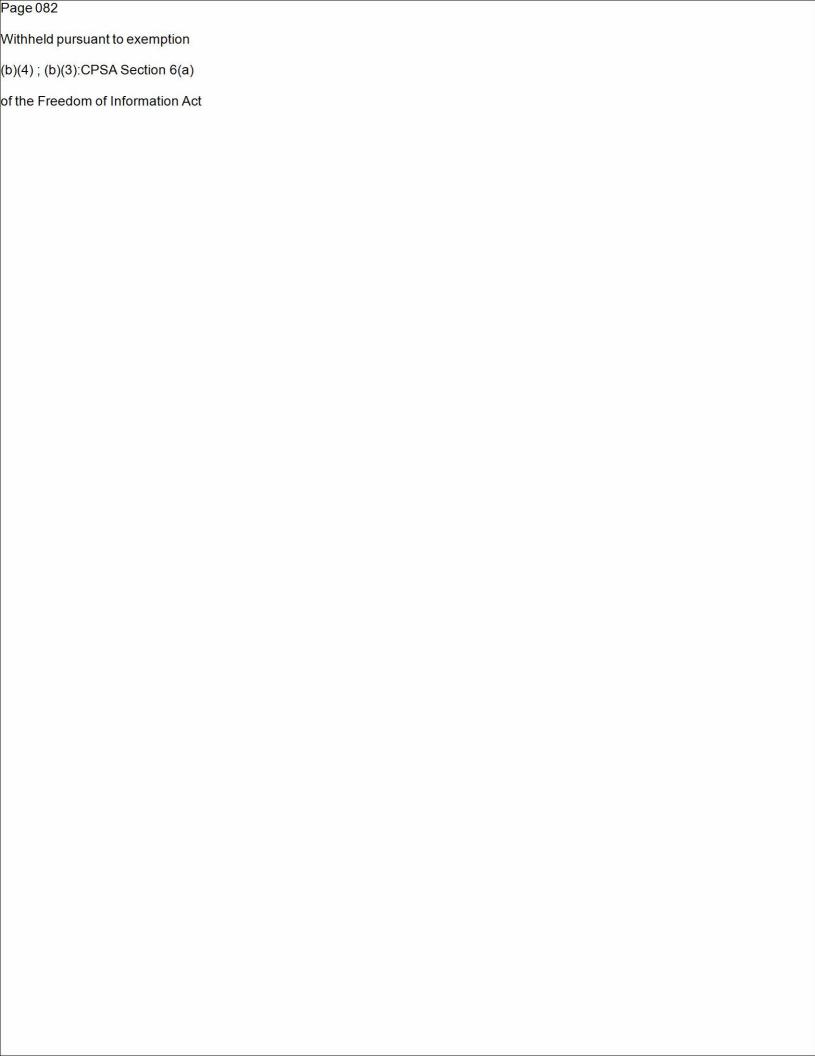
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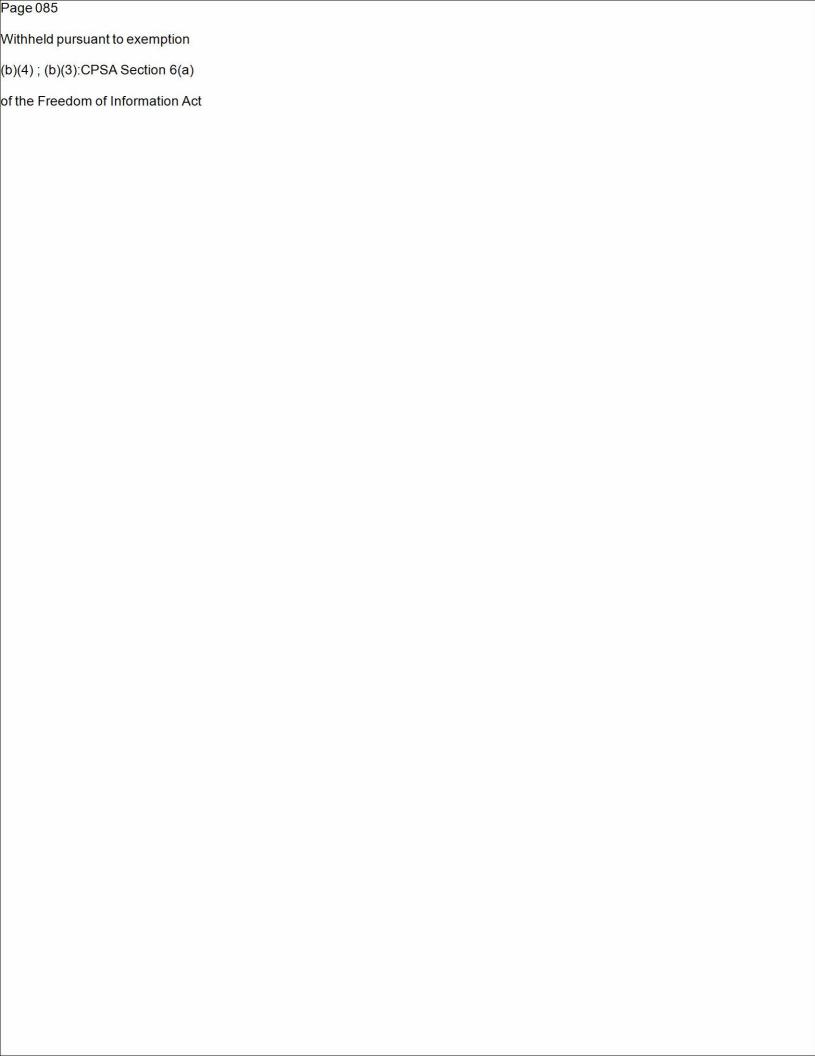
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Page 087 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act



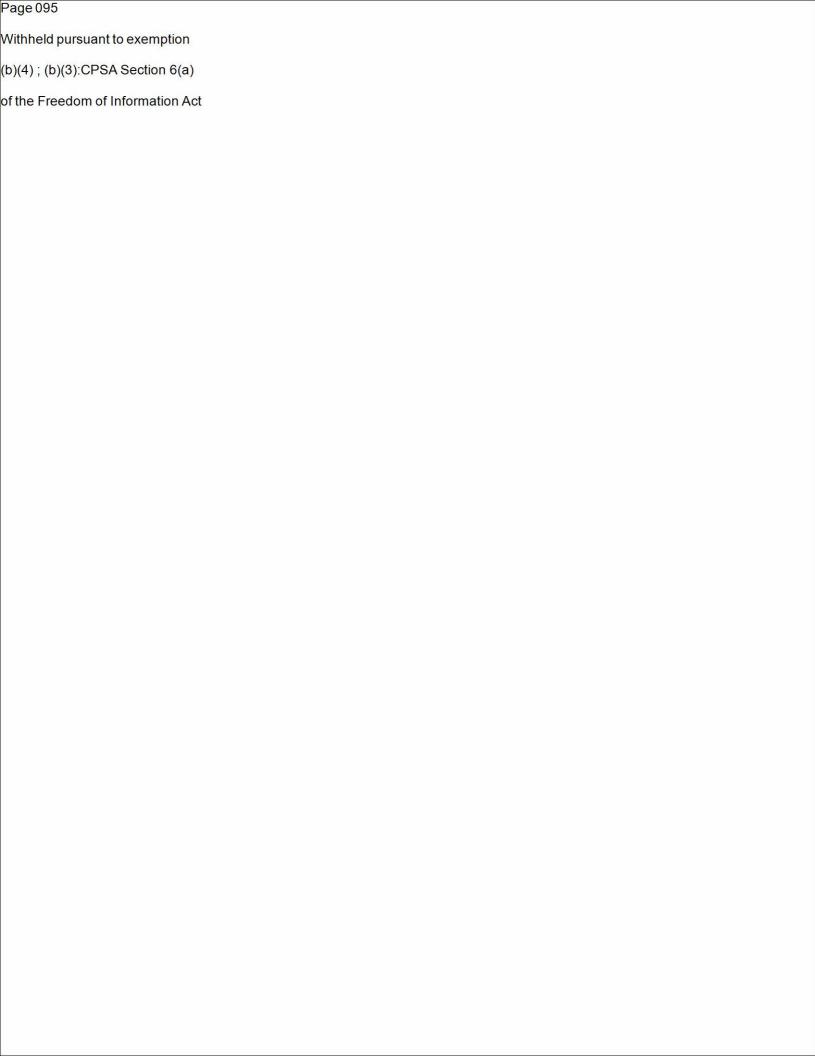




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Page 093 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 094 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act





Page 097 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act





Page 100 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 101

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(b)(4); (b)(3):CPSA Section 6(a)

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Page 102 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 103

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Page 105 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 106 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act

	From: Sent: To: Cc: Subject: Cheryl,	Moore, Kelly Wednesday, August 08, 2012 2:49 PM Cheryl Possenti Pilarz, Kitty; Dzialga, Dan; Schoem, Marc; Murphy, Mary; Nelson, Theresa; Thomas, Treye RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL			
(t	D)(4); (b)(3):CPSA Section 6(a)				
	,				
	Best regards,				
	Kelly				
	Kelly M. Moore Trial Attorney Acting Team Lead, Children's Safe Sleep Team Office of the General Counsel, Division of Compliance U.S. Consumer Product Safety Commission 4330 East West Hwy, Room 703H Bethesda, MD 20814 (301) 504-7447				
From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com] Sent: Monday, July 23, 2012 10:26 AM To: Nelson, Theresa; Moore, Kelly; Thomas, Treye					
	Cc: Pilarz, Kitty; Działga, Dan; Sc Subject: RE: Fisher-Price Rock 'r	n Play Sleeper PI11066 CONFIDENTIAL			
	Hi Terry,				
	Thank you very much. We would be able to meet at 1:30 p.m. on Tuesday, August 14, 2012, if that is convenient for you and the other staff members.				
	(b)(4); (b)(3):CPSA Section 6(a)				

We look forward to meeting with you and other members of the staff to share this information and to discuss these issues.

Best regards,

Cheryl



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
665 Main Street / Suite 400
Buffalo, NY 14203
716.566.5444/FAX 716.566.5401
cpossenti@goldbergsegalla.com
http://www.goldbergsegalla.com

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From: Nelson, Theresa [mailto:TNelson@cpsc.gov]

Sent: Wednesday, July 18, 2012 11:07 AM

**To:** Cheryl Possenti; Moore, Kelly; Thomas, Treye **Cc:** Pilarz, Kitty; Dzialga, Dan; Schoem, Marc

Subject: RE: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

#### Cheryl

Our staff would prefer to meet with you and your staff on Tuesday, August 14<sup>th</sup> in the afternoon after 1:00 pm (EST). Please let me know an exact time and we will plan accordingly.

We plan to postpone our Preliminary Determination Panel until after our meeting with you on that date. Can you email me a copy of Dr. Got's additional study which you plan to present, for our review prior to the meeting?

Terri

### Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext. 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

From: Cheryl Possenti [mailto:cpossenti@goldbergsegalla.com]

Sent: Monday, July 16, 2012 4:01 PM

To: Nelson, Theresa; Moore, Kelly; Thomas, Treye

Cc: Pilarz, Kitty; Dzialga, Dan

Subject: Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

Hi, Terry, Kelly and Trey,

Attached is a letter that is being sent by fax and overnight mail. We look forward to hearing from you.

Best regards,

Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested



New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
Partner
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## Nelson, Theresa

From:

Cheryl Possenti <cpossenti@goldbergsegalla.com>

Sent:

Monday, July 16, 2012 4:01 PM

To:

Nelson, Theresa; Moore, Kelly; Thomas, Treye

Cc:

Pilarz, Kitty; Dzialga, Dan

Subject:

Fisher-Price Rock 'n Play Sleeper PI11066 CONFIDENTIAL

**Attachments:** 

Letter to CPSC staff requesting conference 71612 - #898073.PDF

Hi, Terry, Kelly and Trey,

Attached is a letter that is being sent by fax and overnight mail. We look forward to hearing from you.

Best regards,

Cheryl

Submitted Under Section 15(b) Confidential Treatment Requested

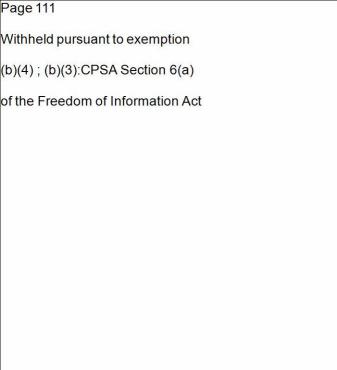


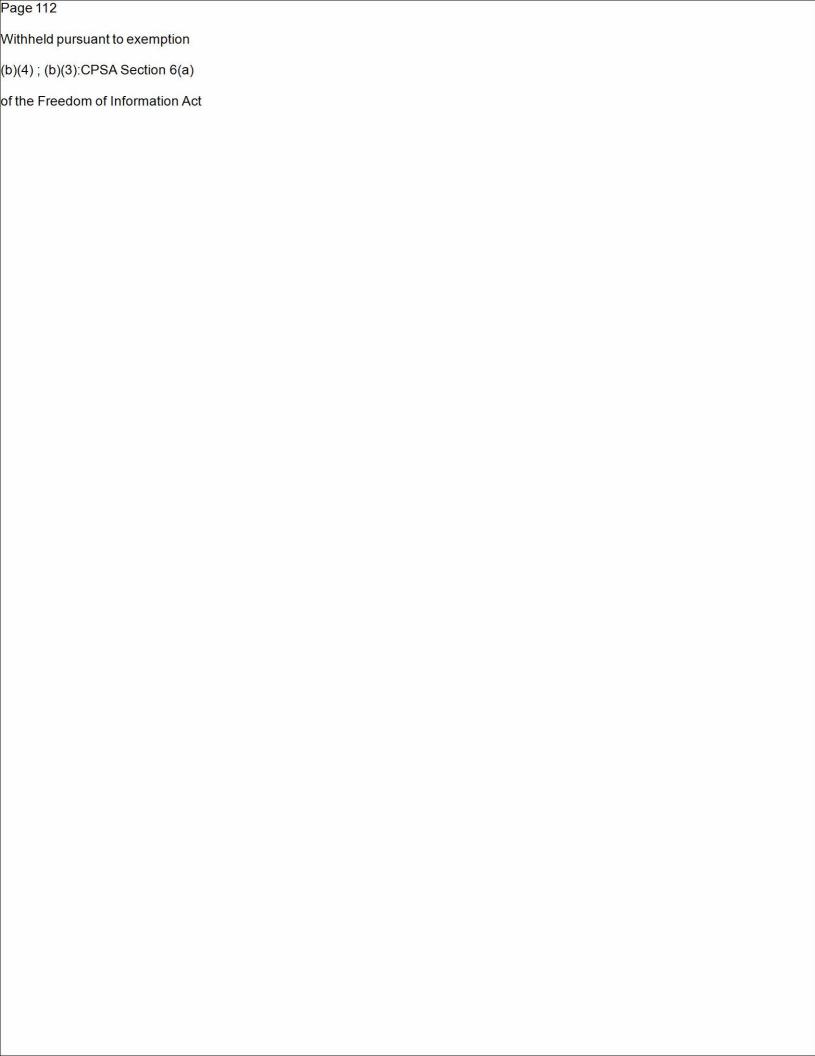
New York London Philadelphia Princeton Hartford Buffalo Rochester Syracuse Albany White Plains Garden City

Cheryl A. Possenti, Esq.
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Page 114
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Page 115 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act

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Non Responsive Record	
of the Freedom of Information Act	

Page 118
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Non Responsive Record
of the Freedom of Information Act

## Nelson, Theresa

Page 119

From: Sent: To: Cc: Subject:	Cheryl Possenti <cpossenti@goldbergsegalla.com> Wednesday, March 07, 2012 7:34 AM Nelson, Theresa; Moore, Kelly; Thomas, Treye Kitty Pilarz; David M. Kosnoff; Dan Dzialga Fwd: Rock 'n Play sleeper CONFIDENTIAL</cpossenti@goldbergsegalla.com>
	Hi, Terry, Kelly and Treye,
	We have obtained the following information in response to your email describing additional information requested by the technical staff.
	(b)(4); (b)(3):CPSA Section 6(a)
	We hope this information is helpful. If you have any questions or need further information, please let me know.
	Cheryl
	Submitted Under Section 15(b)
	Confidential Treatment Requested
	<image004.jpg></image004.jpg>
	Cheryl A. Possenti, Esq.
	Partner
	665 Main Street / Suite 400

Buffalo, NY 14203

Page 120 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 121 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 122 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 123
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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act

Page 137
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Page 138

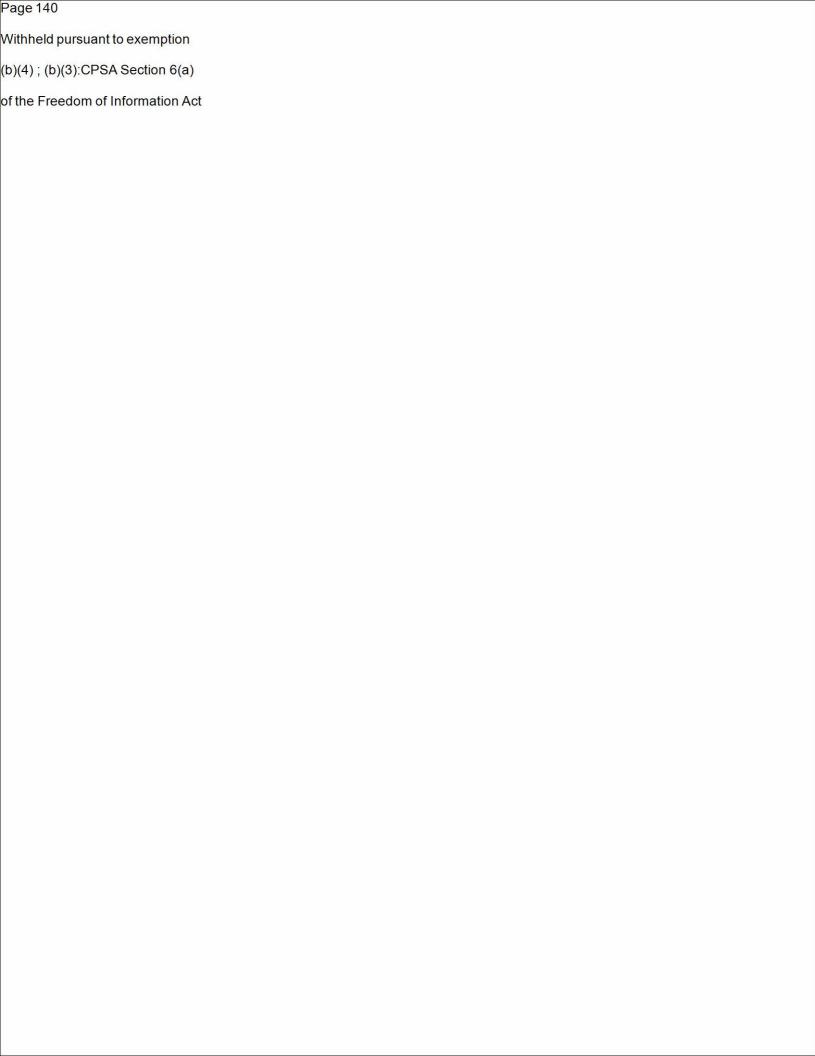
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of the Freedom of Information Act

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# U.S. CONSUMER PRODUCT SAFETY COMMISSION BETHESDA, MD 20814

Kelly M. Moore, Trial Attorney Office of the General Counsel Division of Compliance Tel: (301) 504-7447 Fax: (301) 504-0121 Email: kmoore@cpsc.gov

## Via E-Mail

February 15, 2012

Ms. Kitty Pillarz Senior Director, Mattel Product Safety Fisher-Price 636 Girard Avenue East Aurora, New York 14052

Re: Fisher-Price Rock N Play Sleeper CPSC File No. PI110066

Dear Kitty,

(b)(3):Exemption 3 for fairness; (b)(3):CPSA Section 6(b)

Thank you for forwarding the BV reports. I have sent them on to our technical staff for review.

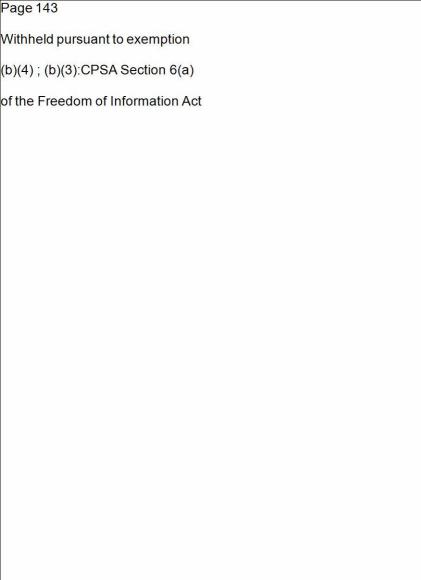
Kitty Pillarz Fisher-Price Page 2

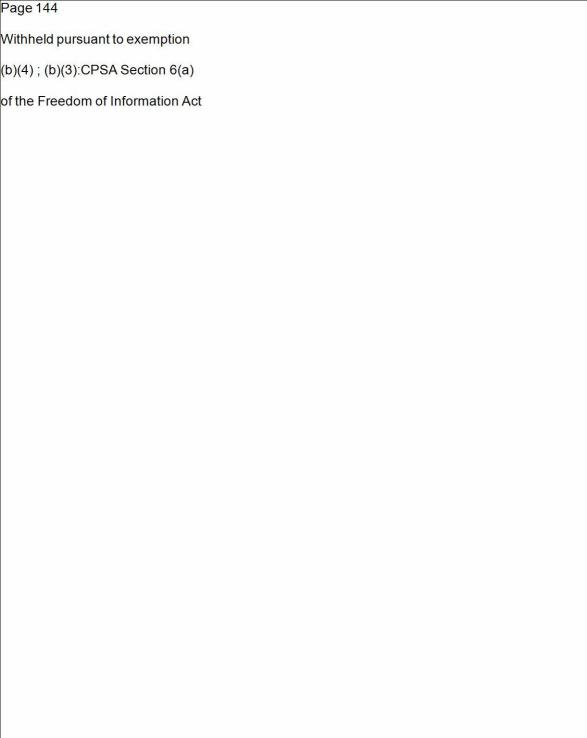
(b)(3):Exemption 3 for fairness; (b)(3):CPSA Section	on 6(b)		

Sincerely,

Kelly M. Moore

<sup>&</sup>lt;sup>1</sup> See, the head padding in models #X2897 and #W9443.





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Page 147 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 148 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 149 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 150 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 151
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of the Freedom of Information Act

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Page 155 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 156 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 157 Withheld pursuant to exemption (b)(4); (b)(3):CPSA Section 6(a) of the Freedom of Information Act Page 158

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of the Freedom of Information Act

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of the Freedom of Information Act

Page 164

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of the Freedom of Information Act

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of the Freedom of Information Act

Page 184

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of the Freedom of Information Act

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of the Freedom of Information Act

Page 188

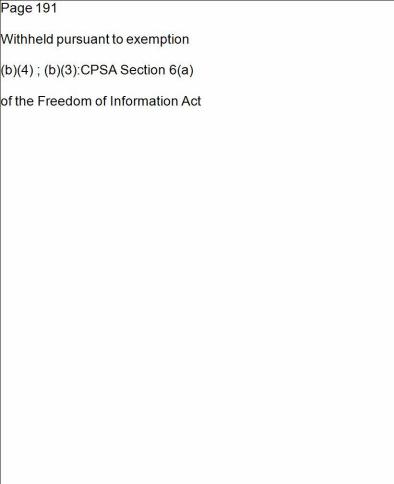
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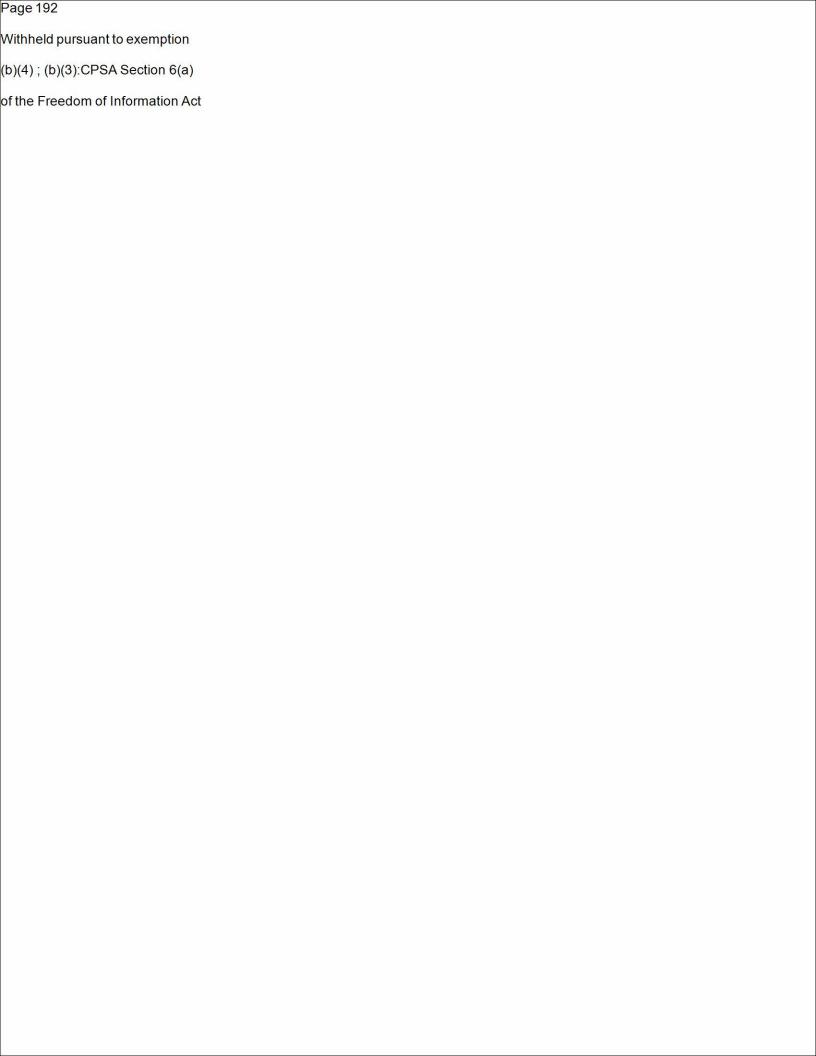
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of the Freedom of Information Act

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of the Freedom of Information Act

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of the Freedom of Information Act



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## Nelson, Theresa

From:

Nelson, Theresa

Sent:

Thursday, August 04, 2011 5:16 PM

To:

'Pilarz, Kitty'

Cc:

Moore, Kelly

Subject:

CPSC update re Rock N Play Sleeper

Attachments:

04269000.pdf; 05242557 61.pdf

Kitty,

Our staff is currently reviewing the Full Report information sent on July 22<sup>nd</sup>, but I wanted to forward you the attached incidents received by the Commission within the last two weeks.

The first IDI (# 110426CNE9000) attached, is the final report from the incident #I090528A which I had sent the Firm on April 25, 2011 with the Full Report request. This consumer wishes her identity to remain confidential. In the second IDI (#110524CCC2557) attached, the consumer's name is identified as per her consent. This consumer's complaint does not appear to have been received by the Firm according to their Full Report.

Our the sample of the Rock 'N Play Sleeper model R6070 is currently being assessed by our technical staff. Were there any changes (besides fabric color) made in the production of models V9102, V9196 and V9197?

Please let me know if you have any questions.

Terri

## Terri Nelson

Compliance Officer
Office of Compliance & Field Operations
U.S. Consumer Product Safety Commission
Phone: 301-504-7509 or
1-800-638-8095 ext, 7509

Fax: 301-504-0359 tnelson@cpsc.gov

SIGN UP FOR RECALL NOTICES: http://www.cpsc.gov/cpsclist.aspx

I. Task Number 110426CNE9000 3. Office Code		2. In	ventinator's ID			
110426CNE9000		2. In	ventinotorio ID			
3. Office Code	1. Task Number 110426CNE9000		2. Investigator's ID 9088		EPIDEMIOLOGIC (b)(5)	
	4. Date of Accide		ate Initiated YR MO DAY		INVESTIGATION REPORT	( )
840	2010 07 01	20	011 04 26		(b)(5)	
5. Synopsis of Accider A four month old male		<b>UPC</b> th plagiocephaly		of playpen/s	vieeper use.	
7. Location (Home, Sc 1 - HOME 10A. First Product	hool, etc)	8. Ci (b)(6	(1)		9. State CA 10C. Model Number	
1537 - Bassinets Or C		E ROCK N PLAY	R6070			
11A. Second Product	CA 90245-5012	11B. Trade/Br	and Name	1-1-1-1	11C. Model Number	
0 11D. Manufacturer Nai NONE	me and Address	NONE			NONE	
12A. Hispanic or Latin	o 12B. Race	1 - White			12C. Race Source	
2 - No	Other:				1 - Respondent-Self/Family	
13. Age of Victim 204	<b>14. Sex</b> 1 - Male		<b>15. Disposition</b> 1 - Injured, not Ho	osp.	16. Injury Diagnosis 71 - Other/NS/No inj	
17. Body Part(s) Involved 75 - HEAD	18. Respond		19. Type of Invest 2 - Telephone	igation	20. Time Spent (Operational / Travel) 6 / 0	
		2. Case Source	Case Source 23. Sa - Consumer Complaint		ample Collection Number	
24. Permission to Disc	close Name (Non	NEISS Cases C	Only)		**************************************	
0-20-1 Doc	● No	<u></u>	Yes for Manuf.		● Verbal ○ Written	
O Yes		201 20	U-4. 40 40 HUGS ALLER V	27 Region	al Office Director	
Yes  25. Review Date  05/13/2011	<b>26. Reviewed B</b> 9003	у		Dennis R i		

Page 214

Page 215

Doc No: I1090528A

Issue: 51

09/14/2010

Name = (b)(6)

Address = (b)(6)

City = (b)(6)

State :

Zip = (b)(6)

Email = (b)(6)

Telephone = (b)(6)

Name of Victim =

Victim's Address =

Victim's City =

Victim's State =

Victim's Zip =

Victim's Telephone =

Incident Description = Hello,

We bought the Fisher Price Newborn Rock-N-Play Sleeper and we feel it contributed significantly to his plagiocephaly (flat head). He is now in physical therapy three times a week and a \$3,800 corrective helmet. While I think the rocker is a great idea, and I can see how it is helpful for babies with acid reflux, I would never have used it as an overnight sleeper knowing what I now know. The packaging says it is approved as an overnight sleeper, so that's how we used it - but at the newborn stage all they do is sleep. In hindsight, I think the backing is too hard, which put too much pressure on his malleable little skull. Perhaps our son was more at risk than other kids (the therapists say torticollis can exacerabte turning to one side, and he was a left-handed thumb sucker), but I do believe the rocker needs additional warnings or perhaps releassified as an infant seat or extra padding added to the hard back. Also, when we took the cover off to wash it, we noticed black spots -- my husband thought it was mold, but I thought it might have been from our toddler who loved to put crayons behind the liner and watch them drop out the bottom. Anyway, I just wanted to add my experience with this product in case you are receiving other complaints from consumers. Many thanks for your time.

Victim's age at time of incident 4 mmulio Victim's sex = Date of incident = Product involved = infant sleeper Product brand name/manufacturer = Fisher Price Newborn Rock-N-Play Sleeper Manufacturer street address = Place where manufactured (City and State or Country) = Product model and serial number, manufacture date = R6070 Product damaged, repaired or modified = If yes, before or after the incident = Description of damage, repair or modification = Date product purchased = 3/10/2010 Product involved still available = yes Have you contacted the manufacturer = no If not, do you plan to contact them = yes Name Release = Do not release name

## 11090528A

If you have any changes, additions, or comments you wish to make concerning your attached report, please make them in the space below.

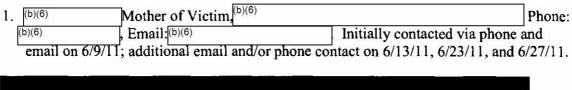
I confirm that the information in the attached report (including any changes, additions, or comments I have made) is accurate to the best of my knowledge and belief.

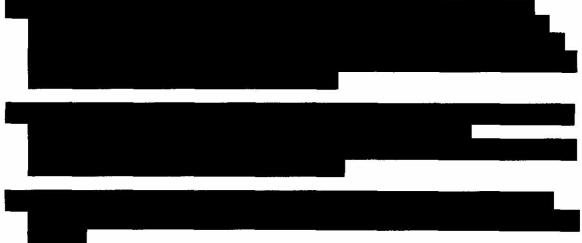
	(b)(6)		1 7
	Śighature	<del></del> -	9 24 2000 Date
X	I request that you do not release my name.		
	You may release my name to the manufactu you not release it to the general public.	ırer bu	t I request tha
	You may release my name to the manufactu	irer an	d to the public

<sup>3</sup> .						(b)(5)
1. Task Number	2	. Invest	igator's ID	194,10	<u> </u>	
110524CCC2557			471	range .		EPIDEMIOLOGIC
3. Office Code	4. Date of Accid	ent 5	. Date I	nitiated		INVESTIGATION
	YR MO DA			MO DAY		REPORT 6
810	2010 12 01		2011	06 09		
6. Synopsis of Accide	An an an and a said	pRE material texts are	tor at lame	7084834185		No to seld that South that South that South that
naps and overnight sle	ep everyday from ed with torticollis i	zero to six m until four mon	onths o	ld. The tort	icollis was	ed in the sleeper at victim's home for sevident at three weeks old but ween the sleeper and the torticollis
7. Location (Home, Sc	nool, etc)	8	. City			9. State
1 - HOME	-34	(	(b)(6)			ОН
10A. First Product		10B. Trade	/Brand	Name		10C. Model Number
1537 - Bassinets Or C	radies	NEWBOR	N ROCK	( 'N PLAY S	LEEPER	R6070
11A. Second Product	<u> </u>	11B. Trade	/Brand	Name		11C. Model Number
0		NONE				NONE
11D. Manufacturer Nar NONE	ne and Address					
I2A. Hispanic or Latino	12B. Race	1 - White				12C. Race Source
1 - Yes	Other:	e.V				1 - Respondent-Self/Family
3. Age of Victim 206	14. Sex 2 - Female		15. Disposition 1 - Injured, not Hosp.			16. Injury Diagnosis 71 - Other/NS/No inj
17. Body Part(s) Involved 75 - HEAD 18. Respondent 1 - Victim/Complainant			19. Type of Investigation 1 - On-Site		estigation	20. Time Spent (Operational / Travel) 30.5 / 2.25
21. Attachment(s) 9 - Multiple Attachments  22. Case Sc 07 - Consu				olaint		23. Sample Collection Number
4. Permission to Disc	lose Name (Non	NEISS Case	s Only)		PRO NICES	
O Yes	O No		● Y	es for Man	uf. Only	◯ Verbal ● Written
5. Review Date	Review Date 26. Reviewed By			• -	27. Re	egional Office Director
07/11/2011	9071				Denn	nis R. Blasius
28. Distribution Nelson, Theresa					29. So	ource Document Number (b)(5)

## **IDENTITY OF RESPONDENTS**

The respondents in this investigation are:





This is a copy of your Report to the U.S. Consumer Product Safety Commission submitted on 5/23/2011

Incident Detai	Is
Document Number:	11150455A
Report Number:	20110523-D10B6-2147478897
Report Submitted Date:	5/23/2011
Who You Are:	Consumer
	My daughter has been using the Fisher Price Rock and Play Sleeper for nighttime and naptime sleep for 6 months, since she came home from the hospital. The product is marketed to parents as "meeting industry safety standards for bassinets" and the packaging includes a photo of a mom in bed with her infant beside her in this product. After just 3 weeks of overnight use my daughter developed torticollis (a tightening of the neck muscles). She was not diagnosed until 4 months (but it is visible in pictures at 3 weeks) and we did not make the connection to this product until she was 6 months old, at which time we ceased using the product. Torticollis develops after use with this product because it forces the child to turn her head to one side. I made the connection to this product after reading numerous reviews on Amazon.com of many other parents reporting the same condition after repeated nighttime use. Treatment of this condition requires months of physical therapy and has delayed my daughter's physical development. My daughter has also developed a flat head that has been shaped by the hard plastic backing of the product. While hers is not severe, many of the Amazon.com reviewers report severe flat head problems.
	12/20/2010 This is an estimate
Incident Location:	Home/Apartment/Condominium $-\frac{(b)(6)}{}$ United States This is my home address
Victim Details	
First Name:	(b)(6)
Last Name:	
lnjury Information:	Injury, Seen by Medical Professional
Victim is of Hispanic/Latino origin?	Yes
Race:	White
Other Race/Ethnicity:	
Information:	Respondent - Self/Family
My Relationship to Victim:	My Child
Gender:	Female
Age when incident occurred:	0 Years 1 Months
Address:	(b)(6)
E-mail:	
Phone Number:	
Product Detai	ls

CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Publicly Available Consumer Product Safety Information Database on SaferProducts.gov, particularly with respect to information submitted by people outside of CPSC.

Product nighttime sleeper (like a bassinet) and playtime seat (link to product on Amazon.com: Description: http://www.amazon.com/Fisher-Price-Newborn-Rock-Sleeper-Yellow/dp/B002M77N22)

Product Baby Category:

Product Type: Nursery Equipment & Supplies

Brand Name: Fisher Price Manufacturer/Private Flsher Price

Labeler Name:

Model Name or Newborn Rock 'n Play Sleeper, Model No. R6070

Number:

Serial Number:

Manufactured:

Manufacturer

Date Code:

Manufacturer Not specified

Address:

Manufacturer Website URL:

Manufacturer

Phone Number:

Retailer: Babies R Us

Retailer State: Ohio

#### Additional Details

Purchase Date: 10/1/2010 This date is an estimate

I still have the Yes product in my possession.

The product No was damaged before the incident.

The product No was modified before the incident.

Have you No contacted the manufacturer?

If not, do you Yes plan to contact them?

Explanation: I plan to contact the manufacturer to make them aware of the damage their product design is doing to many children, not just mine.

Your Contact Information

First Name: (b)(6)

CPSC does not guarantee the accuracy, completeness, or adequacy of the contents of the Publicly Available Consumer Product Safety Information Database on SaferProducts.gov, particularly with respect to information submitted by people outside of CPSC.

Last Name:	(b)(6)	
Address:		United States
E-mail		
Phone Number:		
Consent		
May we include your Report, including any documents or photographs that you have attached to your Report, but without your name and contact information, in CPSC's Public Database?	Yes, you may include my Report with any attach	nments on SaferProducts.gov.
May we release your name and contact information to the product manufacturer / private labeler identified in your Report?	Yes, you may release my name and contact info	ormation to the product manufacturer/private
I certify that I have reviewed the Report and that the information provided in this Report is true and accurate to the best of my knowledge, information, and belief.	Yes	

OMB Control Number 3041-0146

SENDER: COMPLETE THIS SECTION	COMPLETE THIS SECTION ON DELIVERY		
<ul> <li>Complete items 1, 2, and 3. Also complete Item 4 if Restricted Delivery is desired.</li> <li>Print your name and address on the reverse so that we can return the card to you.</li> <li>Attach this card to the back of the mailpiece, or on the front if space permits.</li> <li>Article Addressed to:</li> </ul>	A. Slanature  X (b)(6)  D. Agent  □ Addressee  C. Date of Delivery  (b)(6)  D. Is delivery address different from item 1? □ Yes  If YES, enter delivery address below: □ No		
Fisher-Price, Inc. 636 Girard Avenue East Aurora, NY 14052	3. Service Type Certified Mail		
2. Article Number	Testificial Delivery (Extra 1 de)		
- 7010 1870 0003 4106 208	1 PT 11 000 102595-02-M-1540		

# PIII addo 102595-02-M-1540

TRANSMISSION VERIFICATION REPORT

TIME

: 04/25/2011 10:46 : COMPLIANCE FIELD OPS

NAME FAX

TEL SER.# : 000K9N178939

3015040060 3015040060

DATE,TIME FAX NO./NAME DURATION PAGE(S) RESULT MODE

04/25 10:38 917166873599 00:08:10 OK STANDARD

ECM



## U.S. CONSUMER PRODUCT SAFETY COMMISSION OFFICE OF COMPLIANCE AND FIELD OPERATIONS BETHESDA, MD 20814 FAX: 301-504-0359

## **FAX**

ro: Kitty Pilarz	From: Terri Nelson
ro: Kitty Pilarz Fax: 716 687-3599	Pages + Cover: 34
'hone:	Date: 4/25/11
Re:	_ CC:
Facsimile Transmission Only	Confirmation by U.S. Mail
Comments:	
Kitty- Please See	attacked letter and
Kitty Please See attachments (2	incident reports). This
kitty- Please See attachments (2 well also be	entireled letter and insident reports). This sent were certified man

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4706	Postage	\$	7.N.		
<b>-</b>	Certified Fee	}			
0003	Return Receipt Fee (Endorsement Required)		Postmark * Here		
	Restricted Delivery Fee (Endorsement Required)				
1,870	Total Postage & Fees	\$			
7010	Sent To Street, Apt. No.; or PO Box No.	PIIIOO	do		
	City, State, ZIP+4				
	PS Form 3800, August 2	006	See Reverse for Instructions		



## U.S. CONSUMER PRODUCT SAFETY COMMISSION OFFICE OF COMPLIANCE AND FIELD OPERATIONS BETHESDA, MD 20814

FAX: 301-504-0359

## FAX

To: Kitty Pilarz	From: Terri Nelson
Fax: 716 687-3595	Pages + Cover: 34
Phone:	Date: 4/25/11
Re:	_ CC:
Facsimile Transmission Only	Confirmation by U.S. Mail
Comments: Kitty- Please See	attacked letter and
attachments (2	entident reports). This cent were certified much
well also be a	ent men certified much
today. Pluse	- entet me of you Love
ang questions.	Thank you
0 /	Deni Kelson
	301-504-7509

Note: If all pages are not received, or you have problems with this transmittal, please contact the person above.

This message is intended for the use of the individual or entity to which it is addressed and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this message is not the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone, and return the original message to us at the above address on the U.S. Postal Service. Thank you



# U.S. CONSUMER PRODUCT SAFETY COMMISSION 4330 EAST WEST HIGHWAY BETHESDA, MD 20814

Office of Compliance and Field Operations Defect Investigations Division Email: <a href="mailto:tnelson@cpsc.gov">tnelson@cpsc.gov</a>

Page 226

Theresa Nelson Compliance Officer Tel: 301-504-7509 Fax: 301-504-0060

Certified Mail/Telecopy (716) 687-3599

April 25, 2011

Ms. Kitty Pilarz
Senior Director, Mattel Product Safety
Fisher-Price, Inc.
636 Girard Avenue
East Aurora, NY 14052

Re:

CPSC File No. PI110066

Fisher-Price, Inc. Rock 'N Play Sleeper Model Number: R6070

Dear Ms. Pilarz:

(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

Enclosed are one Incident Report (currently being followed up with an In-Depth Investigation) and one In-Depth Investigation and for your review.

Enclosed for your information (or you can access the information on line at the links provided) are the Consumer Product Safety Act ("CPSA") and the Commission's regulation titled "Substantial Product Hazard Reports" (16 C.F.R. Part 1115). These documents explain the law, the Commission's authority, and the Commission's policies regarding products that may present substantial product hazards. They also explain the Firm's rights and obligations under the CPSA. Since your report concerns a product intended for use by children, please refer also to the Federal Hazardous Substances Act (FHSA).

One of the responsibilities of the Office of Compliance and Field Operations staff is to determine preliminarily whether a defect is present in a product and, if so, whether that defect

Page 2 PI110066

rises to the level of a substantial risk of injury to children under section 15(c) of the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. § 1274(c).

#### **Information Requested**

For the Commission staff to assess accurately the potential hazard, if any, presented by the Subject Product, the Firm must provide the "full report" information and documents required by 16 C.F.R. § 1115.13(d) (1-14). Please provide that information and those documents to the extent applicable to the Subject Product and the reported problem or issue, and in your response, please reference each regulation subsection number (1-14). This request is not limited by a date range and includes all versions, model numbers, and similarly engineered designs of this product. If a similarly engineered product was rebranded, cosmetically changed, or provided a new model number, this request is inclusive of all such products.

In addition to providing the information requested above, please also submit the following relating to the Subject Product:

- 15(a) All documents, records, and information (including electronic mail and other electronic documents, records, and information) pertaining to the reported problem or issue and comprising or relating to the following: all oral and written consumer, dealer, distributor, retailer, and other complaints and claims; all warranty and insurance claims, reports, and forms; and all reports of incidents, property damage, and injuries. <sup>1</sup>
  - Your response must include all court complaints and other documents initiating lawsuits, and all documents and records concerning the resolution of all complaints, claims, incidents, and lawsuits.
  - ii. For each telephone or other oral complaint, claim, and report identified above, include the date and contents.
  - iii. If any of the documents and records requested above are unavailable, identify them, state the reason they are unavailable, and provide a summary containing the names, addresses, and

<sup>&</sup>lt;sup>1</sup> This request for information is intended to be construed as broadly as possible and if the Firm is in doubt about whether to include an item in its response, CPSC staff expects that the Firm will include the item. The words "and" and "or" shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive. The word "including" shall be construed to mean without limitation. The words "any" and "all" shall be construed so as to make the request inclusive rather than exclusive. This construction is particularly important when the Firm provides CPSC staff with its responsive materials in regards to consumer reports, complaints, and injuries in addition to all legal claims, complaints, lawsuits, etc. as set forth in 16 CFR §1115.13(6) and (10) in addition to its answers and responsive materials to questions 15(a) and 15(d)-(f) of this Full Report Request.

telephone numbers of the consumers, dealers, distributors, and retailers, or of their attorneys, as applicable.

- 15(b) A list of all countries other than the United States to which the Firm distributes or distributed the Subject Product, and the number of Subject Products shipped or distributed to each country.
- 15(c) All premarket and postmarket test reports, analyses, and evaluations related to the reported problem or issue.
- 15(d) A list of all modifications made to the product including all structural and functional modifications to the product, modifications made in response to any safety concerns, modifications made to address, in part or in whole, the reported problem or issue, and modifications made to address, in part or in whole, consumer incident reports to the Firm.
- 15(e) All engineering drawings, engineering change notices, requests for engineering changes, and material specifications related to the modifications outlined above.
- 15(f) All internal Firm documents, records, and information (including electronic mail and other electronic documents, records, and information) pertaining to the modifications outlined above.
- 15(g) All UPC codes for all models involved.
- 15(h) A list by consumer name and address of which consumer incident samples were returned to the Firm and which consumer incident samples are currently in the possession of the Firm. Provide one returned consumer sample of each model involved that exhibits the best or most severe examples of the reported problem or issue. Consumer incident samples returned to the Firm from the date of this letter are not to be destroyed and the Firm is to update CPSC staff when additional consumer incident samples are received.
- 15(i) One sample of each model involved, including the retail packaging and all instructions. If there is a proposed correction for the reported problem or issue, provide samples of the proposed correction with all instructions proposed to be given to consumers. If there is a cost associated with these samples, notify us prior to sending the samples.
- 15(i) Country of manufacture.
- 15(k) Full name, address, and telephone number of each foreign manufacturer.

Page 4 PI110066

### **Information Disclosure**

Section 6(b)(5) of the CPSA, 15 U.S.C. § 2055(b)(5), prohibits the Commission from releasing information submitted under section 15(b) of the CPSA unless a remedial action plan has been accepted in writing, a complaint has been issued, the submitting person consents to such release, or the Commission publishes a finding that the public health and safety require such release.

If the Firm submits any information that it considers to be a trade secret, or confidential commercial or financial information, it must mark it "confidential" in accordance with section 6(a)(3) of the CPSA, 15 U.S.C. § 2055(a)(3). The Commission may not disclose to the public trade secret information or proprietary commercial or financial data. If the Firm does not request confidential treatment at the time of its submission, or within ten days thereafter, the staff will assume that it does not consider information in the submission to be a trade secret or otherwise exempt from disclosure under section 6(a) of the CPSA and under the Freedom of Information Act, 5 U.S.C. § 552(b)(4).

#### **Continuing Obligations**

The Firm has a continuing obligation to supplement or correct its "full report" and any other information it provides, including the information submitted in response to the above requests. If, for example, after submitting its report and information to the Commission, the Firm receives or learns of information concerning complaints, claims, incidents, or injuries that the Firm did not report, or other information that affects the scope, prevalence, or seriousness of the reported problem, issue, or potential defect or hazard, the Firm must immediately report that information to the Office of Compliance and Field Operations.

In addition, until this matter and any related matters are resolved, there will remain the possibility of further enforcement action, including reasonably anticipated litigation. Therefore, the Firm must abide by the continuing legal obligation to preserve all information, documents, records, and samples, now in existence or created hereafter, related to the Subject Product.

#### **Due Date and Contact Information**

The Office of Compliance and Field Operations requests that the Firm respond in writing and in full by providing all requested documents, records, information, and samples within ten working days of your receipt of this letter. Please reference the file number stated above in your response. If you seek assistance or if you have any questions, you may contact me at 301-504-7509. Please address your correspondence to the following: Office of Compliance and Field Operations, U.S. Consumer Product Safety Commission, Room 824, 4330 East West Highway, Bethesda, MD 20814-4408. The Office of Compliance telefax number is (301) 504-0060.

Page 5 PI110066

Thank you for your cooperation in this matter.

Sincerely,

Theresa Nelson Compliance Officer Defect Investigations Division

#### Enclosures/Links:

Consumer Product Safety Act - http://www.cpsc.gov/about/cpsia/legislation.html 16 C.F.R. Part 1101, Information Disclosure - - http://www.cpsc.gov/ABOUT/guide.html Part 1115, Substantial Product Hazard Reports --

http://www.cpsc.gov/BUSINFO/frnotices/fr06/E611758.pdf

Part 1116, Section 37 Reports -- http://www.cpsc.gov/BUSINFO/cpsa37.pdf

Recall Handbook - http://www.cpsc.gov/businfo/8002.html

Recall Checklist - http://www.cpsc.gov/businfo/recallcheck.pdf

In-Depth Investigation# 101221CNE0795 Lead plague play
Incident Report # 11090528A - full fur surpe

Doc No: I1090528A

09/11/2010 17:44:34

Name =

City = Santa Clarita
State = California
Zip =

Name of Victim =
Victim's Address =

09/14/2010 (b)(5)

Incident Description = Hello,

Victim's City =
Victim's State =
Victim's Zip =
Victim's Telephone =

We bought the Fisher Price Newborn Rock-N-Play Sleeper and we feel it contributed significantly to his plagiocephaly (flat head). He is now in physical therapy three times a week and a \$3,800 corrective helmet. While I think the rocker is a great idea, and I can see how it is helpful for babies with acid reflux, I would never have used it as an overnight sleeper knowing what I now know. The packaging says it is approved as an overnight sleeper, so that's how we used it - but at the newborn stage all they do is sleep. In hindsight, I think the backing is too hard, which put too much pressure on his malleable little skull. Perhaps our son was more at risk than other kids (the therapists say torticollis can exacerabte turning to one side, and he was a left-handed thumb sucker), but I do believe the rocker needs additional warnings or perhaps releassified as an infant seat or extra padding added to the hard back. Also, when we took the cover off to wash it, we noticed black spots — my husband thought it was mold, but I thought it might have been from our toddler who loved to put crayons behind the liner and watch them drop out the bottom. Anyway, I just wanted to add my experience with this product in case you are receiving other complaints from consumers. Many thanks for your time.

Issue: 51

Victim's age at time of incident = Victim's sex = Date of incident = Product involved = infant sleeper Product brand name/manufacturer = Fisher Price Newborn Rock-N-Play Sleeper Manufacturer street address = Place where manufactured (City and State or Country) = Product model and serial number, manufacture date = R6070 Product damaged, repaired or modified = If yes, before or after the incident = Description of damage, repair or modification = Date product purchased = 3/10/2010 Product involved still available = yes Have you contacted the manufacturer = no If not, do you plan to contact them = yes Name Release = Do not release name

DocNo: I1090528A 09/11/2010 17:44:34

#### Email =

Name of Victim =
Victim's Address =
Victim's City =
Victim's State =
Victim's Zip =
Victim's Telephone =

Incident Description = Hello,

We bought the Fisher Price Newborn Rock-N-Play Sleeper and we feel it contributed significantly to his plagiocephaly (flat head). He is now in phyiscal therapy three times a week and a \$3,800 corrective helmet. While I think the rocker is a great idea, and I can see how it is helpful for babies with acid reflux, I would never have used it as an overnight sleeper knowing what I now know. The packaging says it is approved as an overnight sleeper, so that's how we used it - but at the newborn stage all they do is sleep. In hindsight, I think the backing is too hard, which put too much pressure on his malleable little skull. Perhaps our son was more at risk than other klds (the therapists say torticollis can exacerabte turning to one side, and he was a left-handed thumb sucker), but I do believe the rocker needs additional warnings or perhaps relcassified as an infant seat or extra padding added to the hard back. Also, when we took the cover off to wash it, we noticed black spots -- my husband thought it was mold, but I thought it might have been from our toddler who loved to put crayons behind the liner and watch them drop out the bottom. Anyway, I just wanted to add my experience with this product in case you are receiving other complaints from consumers. Many thanks for your time.

Victim's age at time of incident = 4 years
Victim's sex =
Date of incident =
Product involved = infant sleeper
Product brand name/manufacturer = Fisher Price Newborn Rock-N-Play Sleeper
Manufacturer street address =
Place where manufactured (City and State or Country) =
Product model and serial number, manufacture date = R6070
Product damaged, repaired or modified =
If yes, before or after the incident =
Description of damage, repair or modification =
Date product purchased = 3/10/2010
Product involved still available = yes
Have you contacted the manufacturer = no

## 11090528A

If you have any changes, additions, or comments you wish to make concerning your attached report, please make them in the space below.

I confirm that the information in the attached report (including any changes, additions, or comments I have made) is accurate to the best of my knowledge and belief.

	Signature Date
X	I request that you do not release my name.
	You may release my name to the manufacturer but I request that you not release it to the general public.
	You may release my name to the manufacturer and to the public

•			
Doc No: <b>I10C0687A</b>	Issue: 13	12/21/2010	(h)/E)
12/18/2010 13:51:43			(b)(5)
Name = (b)(6)  Address = (b)(6)  City = (b)(6)			
State = Tennessee Zip = [b)(6) } Email = (b)(6) } @gmail.com			
Telephone = (b)(6) Name of Victim = (b)(6)			
Victim's Address = (b)(6) Victim's City =((b)(6)			
Victim's City = (5)(5) Victim's State = Tennessee Victim's Zip = (5)(6)			
Victim's Telephone =			
Incident Description = My son was in his Ro hardwood floor. He has a bump and scratch concussion.	ck and Play, he was to on the side of his her	ouckled in. Somehow he fell out of in o ad. We are watching for any signs of a	on to the

Victim's age at time of incident = 4 months
Victim's sex = male
Date of incident = 12-18-2010
Product involved = Rock and Play Sleeper
Product brand name/manufacturer = Fisher Price
Manufacturer street address = 636 Girard Avenue
Place where manufactured (City and State or Country) =
Product model and serial number, manufacture date =
Product damaged, repaired or modified = no
If yes, before or after the incident =
Description of damage, repair or modification =
Date product purchased = March 2010
Product involved still available = yes
Have you contacted the manufacturer = no
If not, do you plan to contact them = yes
Name Release = Do not release name

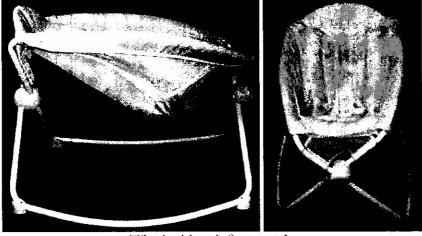
1. Task Number		2	lavantiga (	!- ID	4 60	
101221CNE0795			2. Investigator's ID			EPIDEMIOLOGIC
		Agricus India.	Date Initia			INVESTIGATION REPORT
810 2010 12 18			2010 12			
6. Synopsis of Accider	nt or Complaint	UP	C			
A female consumer pur him in the seat with the and fell from the seat.	three-point waist	restraint. While	e she was	out of the to his hea	bedroom, the injuries	d daytime use. She buckled infant got out of the restrain s have healed.
				(1	o)(5)	
7. Location (Home, Sci	hool, etc)	8. (	City	402(2)	E1 - 0000 II	9. State
1 - HOME	3	(b)(				TN
10A. First Product		10B. Trade/E	Brand Nan	ne		10C. Model Number
1549 - Other Baby Ca	rriers	FISHER PR	ICE ROCK	'N PLAY		R6070
11A. Second Product 1807 - Floors Or Floor 11D. Manufacturer Nar	100	11B. Trade/Brand Name UNKNOWN			11C. Model Number UNKNOWN	
12A. Hispanic or Lating 2 - No 13 Age of Victim 204	o 12B. Race Other: 14. Sex 1 - Male	1 - White		position ared, not H	OSD.	12C. Race Source 1 - Respondent-Self/Fam 16. Injury Diagnosis 53 - Cont./Abras.
	381 G. 854		w gaunga			
17. Body Part(s) Involved 75 - HEAD 18. Respondent			Monay Analysis		20. Time Spent (Operational / Travel)	
[ MITTER 1980] - 이번 전 전시되었다고 있다고 있다고 되었다. [ 1980] - 1		<b>2. Case Sour</b> d 07 - Consumer	Complai	b)(5)	23. Sa	mple Collection Number
24. Permission to Disclose Name (Non NEISS			/ L			
Yes	O No	(	Yes	or Manuf.	- ;	○ Verbal ● Written
25. Review Date 01/25/2011	<b>26. Reviewed B</b> y 8978	y	_	2	27. Regional Dennis R. B	l Office Director
28. Distribution Nelson, Theresa	2		****		29. Source D 110C0687A	Document Number

This In-Depth Investigation (IDI) was initiated in response to an internet complaint filed on the CPSC website. The complaint involved a four month old child falling from an infant seat. On January 5, 2011, the following information was obtained from an onsite interview with the complainant.

The complainant is a twenty-three year old female. She lives with her twenty-four year old husband and five month old son/victim. Her son was born on 2010. He was four months old at the time of the incident in December 2010. He is approximately twenty-six inches tall and weighs approximately 15.5 pounds. In December 2010, he was approximately twenty-four inches tall and approximately twelve pounds. He is healthy, active and is meeting his developmental milestones. He suffers from acid reflux and has to take medication to treat the symptoms.

The family lives in a two-story home inside a residential neighborhood. The home has three bedrooms and is approximately 3,000 square feet. The bedrooms have hardwood flooring. The incident occurred in an upstairs bedroom. The PSI could not photograph the incident bedroom because the complainant had guests sleeping inside the room.

The product involved is an infant seat designed for nighttime and daytime use. It has a metal tube X-frame base and is designed to rock slightly forward and backward. The seat has a plastic support insert that inclines. The seat also has a three-point waist restraint and a removable yellow-colored washable fabric. The product measures approximately 32"L x 37" W x 21"H and can fold flat for storage or transport (See Attachment 2 for photographs).



[The incident infant seat.]

In March 2010, the complainant received the infant seat as a baby shower gift from her mother. The product was purchased from a chain baby retail website. The product required minor assembly prior to the first use. The complainant read and understood the owner's manual and used all the required parts for the seat. She does not know the location of the original owner's manual. The PSI downloaded an online version of the manual (See Attachment 3).

She started using the infant seat after her son's birth. The incline of the seat helped with his acid reflux symptoms. She estimated the daily usage was approximately eight hours with nighttime usage and naps. The product was used indoors by her son and was never repaired, altered, or subjected to rough use.

On December 18, 2010, the infant seat was located in an upstairs bedroom. At approximately 20:30 hours, she put the victim in the seat and buckled the three-point waist restraint. She recalls the restraint was not loose. The victim was wearing a diaper and a one piece pajama set with footies. He did not have a blanket or pillow in the seat. She left the bedroom when he fell asleep in the seat. She does not recall him having trouble with his acid reflux symptoms the night of the incident.

Around 22:00 hours, she checked on the victim and he was still sleeping in the seat. Around midnight, she and her husband were in the den and heard the victim crying. When she entered the bedroom, she saw the victim lying on the hardwood floor under the infant seat. His head was facing the foot of the seat and his feet were near the top.

She reports the product was in its original position and was not flipped or overturned. The waist restraint was still buckled. She never heard the victim land on the floor. The product is approximately twenty-one inches in height, so the distance from the seat to the hardwood floor would be no more than twenty-one inches.

She has never seen the victim try to get out of the infant seat. He is capable of holding his head up unsupported, rolling over, and pushing his chest up. At the time, he could not stand, crawl, or pull-up on furniture. She thinks he used his feet to push-up in the seat and was able to rollover the side or fall from the top of the seat. She believes the product would be safer if the seat had shoulder restraints in conjunction with the waist restraint.

After the incident, she called the child's pediatrician and was told to watch for signs of a concussion. The only visible injury was a minor scratch on top of the child's head that went to his mouth and a contusion on his head. The injuries have healed. The PSI was not able to get a photograph of the victim's face. She reports the victim has no health complications associated with the fall.

She has not contacted the manufacturer to report the incident but plans too. She signed an authorization release giving the CPSC permission to release her information the manufacturer only (See Attachment 4).

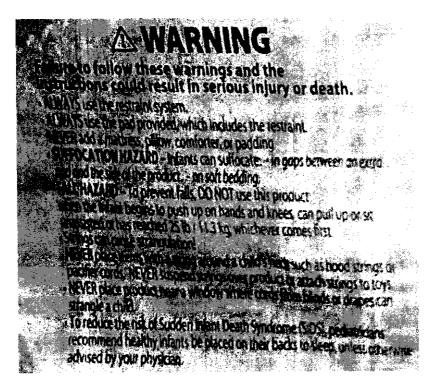
#### PRODUCT IDENTIFICATION:

Page 237

The product involved in this IDI is a **Fisher-Price Rock'n Play Sleeper**, model R6070. The Universal Product Code is 746775014582. The manufacturer is Mattel Inc. located at 333 Continental Boulevard El Segundo, CA 90245-5012. The product was purchased from the Babies "R" Us internet website. The infant seat is approximately \$50.

The product is a nighttime sleeper and/or daytime seat. It has a metal tube X-frame base and is designed to rock slightly forward and backward. The seat has a plastic back support insert that inclines. The seat also has a three-point waist restraint and a removable yellow-colored washable fabric. The product measures approximately 32"L x 37" W x 21"H and can fold flat for storage or transport. The incident product was photographed and not collected.

The manufacturer's suggested weight limit is twenty-five pounds. The firm suggests consumers use the product from birth until the child is able to pull-up or sit unassisted. The product has labeling on the frame that reads, "R6070 FISHER PRICE, INC. A SUBSIDARY OF © 2008 MATTEL, INCO EAST AURORA, NY 14052 CHINA PATENT PENDING." Labeling on the fabric reads as follows:



## CONTACT WITH RETAILER:

Item was purchased from the internet.

#### **ATTACHMENTS:**

- 1. Contacts
- Photographs (16)
   Manual
- 4. Name Release form

Attachment 1

CONTACT LIST

IDI 101221CNE0795

Complainant- (b)(6)	
(b)(6)	
Tel: (b)(6)	
E-mail: (b)(6)	- Contacted on 12/29/2010

 $www.babiesrus.com-used\ for\ product\ information.$ 

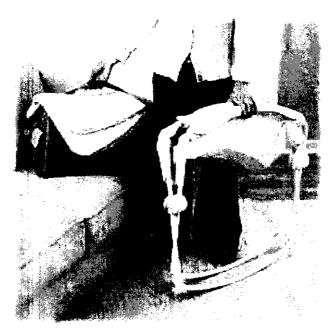


Photograph 1: The manufacturer's photograph of Fisher Price Rock and Play Sleeper.

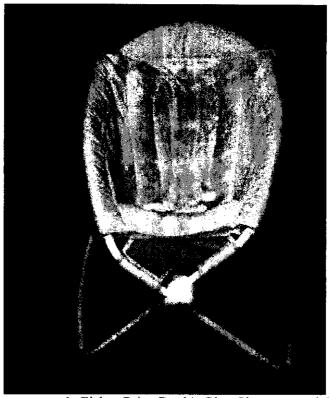


Photograph 2: The manufacturer's photograph of infant usage.

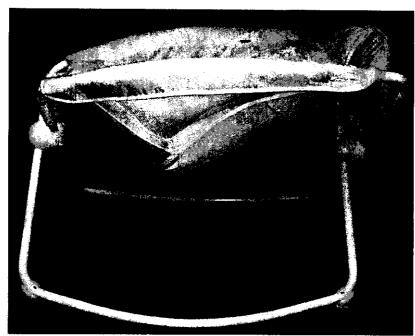
age 243



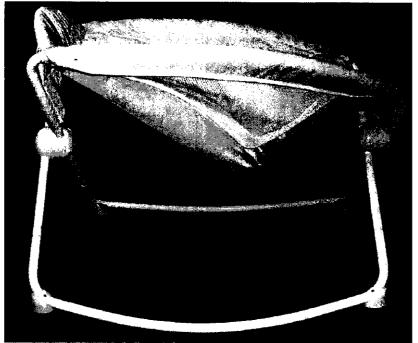
Photograph 3: The manufacturer's advertisment of versatility.



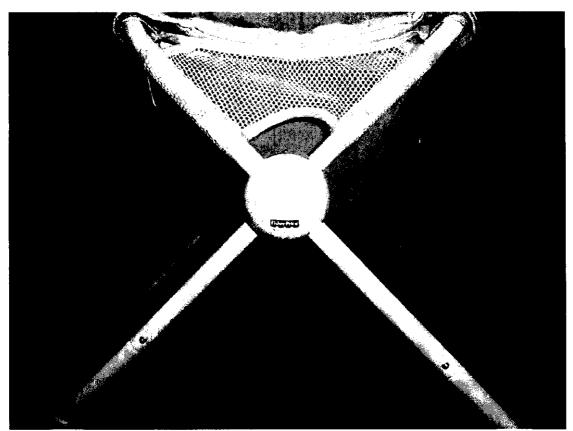
Photograph 4: The consumer's Fisher Price Rock'n Play Sleeper, model R6070. The PSI could not photograph the bedroom where the incident occurred because the consumer had guests visiting that were sleeping inside the room.



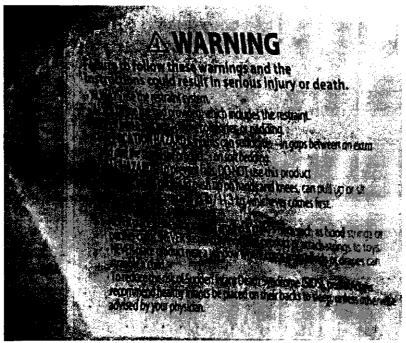
Photograph 5: The side view of the infant seat.



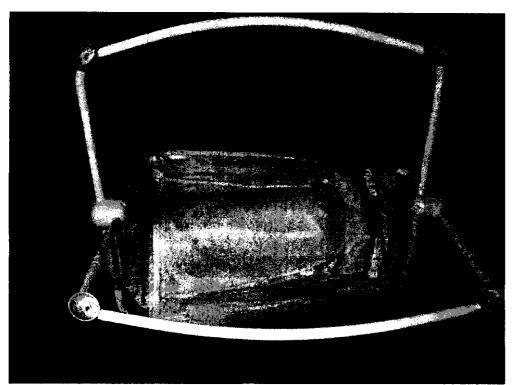
Photograph 6: Opposite view of the seat.



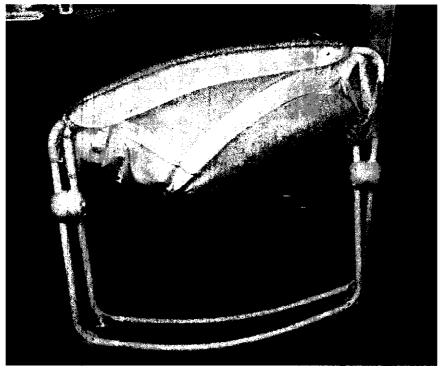
Photograph 7: The fold button reads, "Easy Fold Fisher Price." The consumer pushes both plastic buttons on either side to fold the product.



Photograph 8: Labeling at the head of the product.



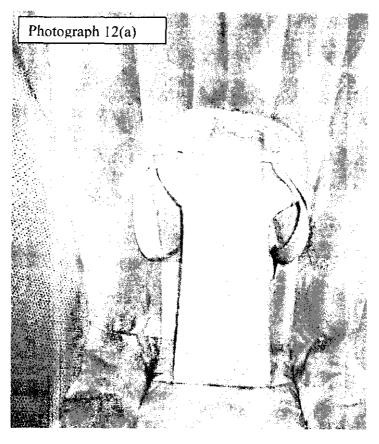
Photograph 9: The bottom of the seat.

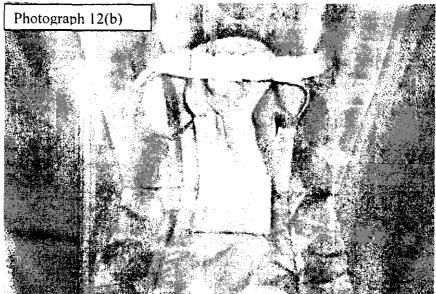


Photograph 10: The product folded.

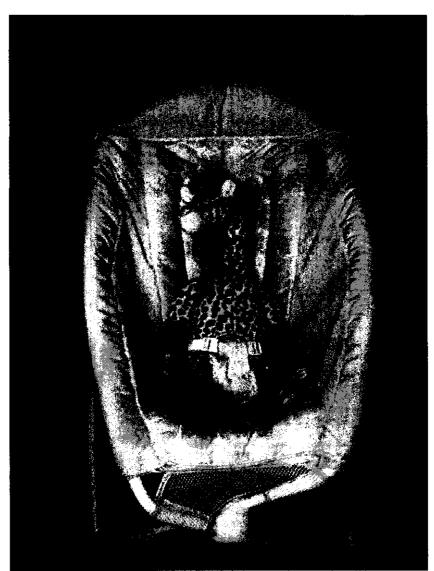


Photograph 11: The seat area.

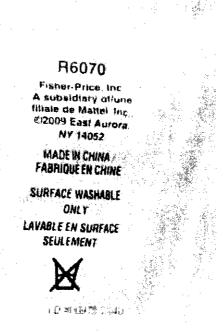




Photograph 12 (a-b): The three-point restraint for the infant's legs. The seat does not have a shoulder restraint.

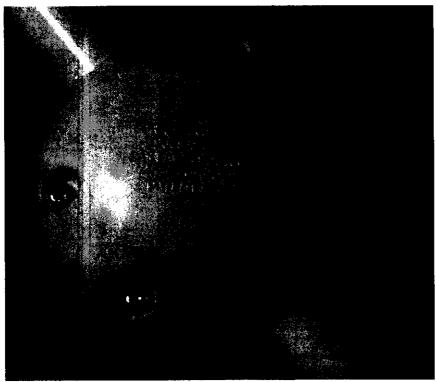


Photograph 13: The PSI could not photograph the infant inside the product because he was sleeping. The complainant reports the giraffe is approximately the same height as her son.



Photograph 14: Labeling on the seat insert.

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Photograph 15: Labeling reads, "R6070 FISHER PRICE, INC. A SUBSIDARY OF © 2008 MATTEL, INC. EAST AURORA, NY 14052 CHINA PATENT PENDING."

## **U.S. Consumer Product Safety Commission**

#### **AUTHORIZATION FOR RELEASE OF NAME**

Thank you for assisting us in collecting information on a potential product safety problem. The Consumer Product Safety Commission depends on concerned people to share product safety information with us. We maintain a record of this information, and use it to assist us in identifying and resolving product safety concerns.

We routinely forward this information to manufacturers and private labelers to inform them of the involvement of their product in an accident situation. We also give the information to others requesting information about specific products. Manufacturers need the individual's name so that they can obtain additional information on the product or accident situation.

Would you please indicate on the bottom of this page whether you will allow us to disclose your name? If you request that your name remain confidential, we will of course, honor that request. After you have indicated your preference, please sign your name and date the document on the lines provided.

	I request that you do not release my name. My identity is to remain confidential.
7-	You may release my name to the manufacturer but I request that you do not release it to the general public.
(b)(6)	You may release my name to the manufacturer and to the public.
(Signature)	1-3-1\ (Date)

CPSC Form 322

#### DRAFT - FOR OFFICIAL USE ONLY

CONSUMER PRODUCT SAFETY COMMISSION	PSA No:	0481.12			
PRODUCT SAFETY ASSESSMENT	CASE No: P1110066				
TECHNICAL EVALUATION	REQUESTER:	(b)(6)			
DIVISION FOR HEALTH SCIENCES	SAMPLE No:				
DRAFT - FOR OFFICIAL USE ONLY - DRAFT	CPSC SEAL:				
	IDI No:				
FIRM: Fisher-Price, Inc.					
PRODUCT: Fisher-Price Rock 'n Play Sleeper		_			
POTENTIAL HAZARD: Concern of infant's developing head plagiocephaly and/or neck torticollis from sleeping in product. Also development of mold in plastic liner could be harmful to infants					
INCIDENTS: see below review		3			
REQUEST: Provide a written report assessing the mold issue with this product as it relates to current research and literature. Also include staff's assessment of the firm's study disputing the hazards of mold in this product.					
PREPARED BY: Treye Thomas, PhD, Toxicologist, 504-7738	301- DATE: 4/	24/2012			
REVIEWED BY: Jason R. Goldsmith, Ph.D., Physiologist	DATE: 4/	24/2012			

## Assessment of Mold Hazards - Fisher-Price Rock 'n Play Sleeper

### Background

The Newborn Rock 'n Play Sleeper is an elevated rocking seat for newborns. The seat is inclined and has a plastic insert within its fabric and mesh seat sling to provide support to the infant. A separate, removable, machine washable soft goods pad is provided for the seat. The seat also includes a 3-point restraint strap and is intended for infants up to six months of age. Between April 2010 and February 1, 2012, there have been 57 total reports to CPSC involving the Rock 'N Play sleep/recliner by Fisher Price. Within this total, caregivers reported infants using this product developed head flatness, often diagnosed as plagiocephaly and/or neck tortilcollis in 32 of the total incidents. Also, caregivers reported black mold growing between the plastic liner and washable pad in 19 of the total reports received (b)(5)

## DRAFT – FOR OFFICIAL USE ONLY

#### Summary

Health Sciences (HS) staff have conducted a preliminary assessment of available data to determine whether the Fisher-Price (FP) Rock 'n Play (RNP) Sleeper presented a health hazard based on the presence of mold. In making this assessment, staff evaluated the FPprovided data to ascertain whether mold can grow on the product, and reviewed available published literature regarding the potential health effects of mold, and whether mold is likely to cause health effects in infants who sleep on the product. Attachment 1 provides a summary of available data on the potential health effects of mold.

Mold is a fungus that is found in both indoor and outdoor environments. The number of species of fungi is unknown; however, it is estimated to be in the range of tens of (b)(5)thousands to hundreds of thousands, and mold exposure has been associated with a variety of health effects, including irritant and allergic reactions, such as asthma and other respiratory conditions<sup>1</sup>. Available data indicates that exposure to dampness and mold in buildings poses significant public health and economic risks in the USA. Of the 21.8 million people reported to have asthma in the USA, approximately 4.6 (2.7-6.3) million cases are estimated to be attributable to dampness and mold exposure in the home<sup>2</sup>. The national annual cost of asthma that is attributable to dampness and mold exposure in the home is estimated to be \$3.5 billion (\$2.1-4.8 billion).

Federal agencies, including the Centers for Disease Control and Prevention (CDC) and the Environmental Protection Agency (EPA), have issued warnings and guidance documents on the dangers of mold in the home and strategies to reduce mold exposures, particularly to children. Although these recommendations largely focus on mold in interior spaces (for example a home or office environment), there is no reason to assume that remediation is not appropriate for consumer products that are found to have mold growth. Consumer exposure to mold on a product may be more frequent and direct than exposures that might occur in a building setting, making remediation even more important for products with mold contamination.

Fisher-Price provided two sources of data on mold and other microbial contamination of RNP sleepers: (b)(4); (b)(3):CPSA Section 6(a); (b)(3):CF

(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)

(b)(5)

<sup>1</sup> http://www.epa.gov/mold/index.html

<sup>&</sup>lt;sup>2</sup> Mudarri D, Fisk WJ. 2007. Public health and economic impact of dampness and mold. Indoor Air 17(3): 226-235.

<sup>3</sup> http://www.cdc.gov/mold/basics.htm

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(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)	
(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)	
(b)(4); (b)(3):CPSA Section 6(a); (b)(3):CPSA Section 6(b)	Ц
>: g	1
Upon reviewing these studies, HS staff concludes (b)(5)	
	th control
	1
Conclusion (b)(5)	

<sup>4</sup> Meeting between CPSC staff and Fisher-Price staff

Mendell et.al. (2011). Respiratory and Allergic Health Effects of Dampness. Mold, and Dampness
Related Agents: A Review of the Epidemiologic Evidence. Environmental Health Perspectives 119:748-756.

<sup>756.

&</sup>lt;sup>6</sup> Full maturation of the lungs doesn't occur until 6 to 8 years of age, and maturation of the immune system not until puberty. Current research suggests that due to environmental exposure, abnormalities of lung structure and function already exist in infants who will subsequently develop asthma, a major public health problem.

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of existing respiratory illnesses. This is of particular concern given the duration of time the infant may be in contact with this product and the vulnerability of this population.