

**JOHNSON & JOHNSON'S RECALL OF CHILDREN'S  
TYLENOL AND OTHER CHILDREN'S MEDICINES  
AND THE PHANTOM RECALL OF MOTRIN  
(PART 2)**

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**HEARING**

BEFORE THE

**COMMITTEE ON OVERSIGHT  
AND GOVERNMENT REFORM  
HOUSE OF REPRESENTATIVES  
ONE HUNDRED ELEVENTH CONGRESS**

SECOND SESSION

SEPTEMBER 30, 2010

**Serial No. 111-111**

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**JOHNSON & JOHNSON'S RECALL OF CHILDREN'S TYLENOL AND OTHER CHILDREN'S MEDICINES AND THE PHANTOM RECALL OF MOTRIN (PART 2)**

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**THURSDAY, SEPTEMBER 30, 2010**

HOUSE OF REPRESENTATIVES,  
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM,  
*Washington, DC.*

The committee met, pursuant to notice, at 10:07 a.m. in room HVC-210 Capitol Visitor Center, Hon. Edolphus Towns (chairman of the committee) presiding.

Present: Representatives Towns, Cummings, Kucinich, Clay, Watson, Norton, Van Hollen, Issa, and Chaffetz.

Staff present: John Arlington, chief counsel—investigations; Kevin Barstow, investigative counsel; Kwame Canty, senior advisor; Linda Good, deputy chief clerk; Carla Hultberg, chief clerk; Marc Johnson and Ophelia Rivas, assistant clerks; Chris Knauer, senior investigator/professional staff member; Steven Rangel, senior counsel; Leneal Scott, IT specialist; Christopher Staszak, investigative counsel; Gerri Willis, special assistant; Ashley Wilson and Alex Wolf, professional staff members; Lawrence Brady, minority staff director; John Cuaderes, minority deputy staff director; Jennifer Safavian, minority chief counsel for oversight and investigations; Adam Fromm, minority chief clerk and Member liaison; Kurt Bardella, minority press secretary; Benjamin Cole, minority policy advisor and investigative analyst; Seamus Kraft, minority director of new media and press secretary; Justin Franco, minority press assistant and clerk; Tom Alexander, minority senior counsel; Ashley Callen and Sery Kim, minority counsels; and Christopher Bright and Molly Boyd, minority professional staff members.

Chairman TOWNS. The committee will come to order.

Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines and the Phantom Recall of Motrin.

Good morning, and thank you all for being here. This is our second hearing on the disturbing recall of children's medicine by Johnson & Johnson. At our first hearing, we learned that J&J's April 30th recall of children's Tylenol, children's Motrin, children's Benadryl and Tylenol Infants' Drops was the largest recall of children's medicine in history. More than 135 million bottles of children's medicines were recalled.

We also learned that there wasn't just one recall. We heard testimony about rolling recalls, a phantom recall, a plant shutdown and management firings. Since then we have obtained additional docu-

ments which raise troubling questions about both the accuracy of J&J's earlier testimony and the extent of the phantom recall.

When Johnson & Johnson learned it had a problem with one of its adult Motrin products in 2008 and 2009, the company hired contractors to go into stores and buy the product off the shelves—without saying it was a recall—so that the public and the news media would not know what was really happening. When J&J was asked about this phantom recall at our first hearing, and about the behavior of its contractors, we were basically told that J&J did not know what the contractors were doing.

However, documents subsequently obtained by the committee show that J&J dictated how the phantom recall would be carried out. Internal emails and other documents indicate that J&J clearly knew what it was doing and why.

For example, referring to the problems with Motrin that resulted in the phantom recall, one McNeil executive said, “We are just trying to prevent a recall and a lot of expended dollars.” In another email, a McNeil executive referred to the phantom recall and said, “This was a major win for us, as it limits the press that will be seen.”

Finally, it appears the president of the company gave the go-ahead for the phantom recall, saying, “let’s make this happen as soon as possible.”

Perhaps we can clear up this apparent discrepancy between J&J's testimony in May and the documents that have come to light since that time. J&J has said the FDA knew about and approved the phantom recall. But FDA says that isn't true. Both sides will have an opportunity to tell their side of the story today.

But even if the FDA was technically aware of it, that does not excuse what Johnson & Johnson did. Johnson & Johnson had both the legal and moral obligation to do the right thing and they did not.

There are also new questions. Our investigation has uncovered documents that show J&J hired the phantom recall contractors to perform work related to children's Tylenol. In light of what we know now about the phantom recall of adult Motrin, I think J&J has a duty to fully explain how it handled problems with children's medicine.

Finally, the troubling issues about rolling recalls and phantom recalls that this hearing examines makes one point very, very clear: Even if the FDA had been notified about the Motrin problem, the agency did not have the legal authority to order a recall. This needs to be rectified. The FDA needs mandatory recall authority, which we have been pushing for. I think most people would be surprised to learn that the FDA, the agency that is responsible for ensuring drug safety, has no power to order a company to recall its defective drugs.

This is why I introduced a bill that would give the FDA mandatory recall authority. Hopefully, we can avoid future phantom recalls and empower the FDA to take action to protect the American people. Both Johnson & Johnson and the FDA will be asked questions today. And I hope they are prepared to give us the answers that we need to make certain that the drugs that are on the shelf are safe.

On this note, I yield 5 minutes to the gentleman from California,  
the ranking member, Congressman Issa.  
[The prepared statement of Hon. Edolphus Towns follows:]



**OPENING STATEMENT**

**CHAIRMAN EDOLPHUS TOWNS  
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM**

**September 30, 2010**

**"Johnson & Johnson's Recall of Children's Tylenol and other  
Children's Medicines and the Phantom Recall of Motrin"  
(Part 2)**

Good morning and thank you for being here.

This is our second hearing on the disturbing recall of children's medicine by Johnson and Johnson.

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We also learned that there wasn't just one recall. We heard testimony about rolling recalls, a phantom recall, a plant shut-down, and management firings.

Since then, we have obtained additional documents which raise troubling questions about both the accuracy of J&J's earlier testimony and the extent of the "phantom recall."

When Johnson & Johnson learned it had a problem with one of its adult Motrin products in 2008 and 2009, the company hired contractors to go into stores and buy the product off the shelves – without saying it was a recall – so that the public and the news media wouldn't know what was really happening.

When J&J was asked about this phantom recall at our first hearing and about the behavior of its contractors, we were basically told that J&J didn't know what the contractors were doing.

However, documents subsequently obtained by the Committee show that J&J dictated how the phantom recall would be carried out. Internal emails and other documents indicate that J&J clearly knew what it was doing and why.

For example:

Referring to the problems with Motrin that resulted in the phantom recall, one McNeil executive said, "we are just trying to prevent a recall and a lot of expended \$."

In another email, a McNeil executive refers to the phantom recall and says, "this was a major win for us as it limits the press that will be seen."

Finally, it appears the president of the company gave the go-ahead for the phantom recall, saying: "Let's make this happen asap."

Perhaps we can clear up this apparent discrepancy between J&J's testimony in May and the documents that have come to light since.

J&J has said the FDA knew about and approved the phantom recall, but the FDA says that isn't true. Both sides will have an opportunity to tell their sides of the story today.

But even if the FDA was technically aware of it, that does not excuse what Johnson & Johnson did. Johnson & Johnson had both the legal and moral obligation to do the right thing, and they did not. And the FDA does not have the legal authority to force a recall.

There are also new questions. Our investigation has uncovered documents that show J&J hired the phantom recall contractors to perform work related to Children's Tylenol. In light of

what we now know about the phantom recall of adult Motrin, I think J&J has a duty to fully explain how it handled problems with children's medicine.

Finally, the troubling issues about rolling recalls and phantom recalls that this hearing examines makes one point very clear: Even if the FDA had been notified about the Motrin problem, the agency did not have the legal authority to order a recall.

This needs to be rectified. **The FDA needs mandatory recall authority.**

I think most people would be surprised to learn that the FDA – the agency that is responsible for ensuring drug safety – has no power to order a company to recall its defective drugs. This is why I introduced a bill that would give the FDA mandatory recall authority. Hopefully we can avoid future phantom recalls and empower the FDA to take action to protect the American people.

Both Johnson & Johnson and the FDA will be asked questions today and I hope they are prepared to give us the answers we need.

###

**From:** Quinn, Frank [MCCUS] <FQuinn@its.jnj.com>  
**Sent:** Thursday, January 29, 2009 7:04 PM (GMT)  
**To:** Carrillo, Eddie [MCCPR] <ECarrill@its.jnj.com>; Homer, Haans [MCCPR] <HHomer@its.jnj.com>  
**Cc:** Huss, Michael [MCCUS] <Mhuss@its.jnj.com>  
**Subject:** RE: Motrin

---

should have the report today.

-----Original Message-----

**From:** Carrillo, Eddie [MCCPR]  
**Sent:** Thursday, January 29, 2009 1:16 PM  
**To:** Homer, Haans [MCCPR]  
**Cc:** Quinn, Frank [MCCUS]; Huss, Michael [MCCUS]  
**Subject:** RE: Motrin

Thanks to all. We are just trying to prevent a Recall and a lot of expended \$. That's why your quick response will be appreciated.

Eddie

-----Original Message-----

**From:** Homer, Haans [MCCPR]  
**Sent:** Thursday, January 29, 2009 1:59 PM  
**To:** Carrillo, Eddie [MCCPR]  
**Cc:** Quinn, Frank [MCCUS]; Huss, Michael [MCCUS]  
**Subject:** RE: Motrin

Eddie

I will request Frank Quinn to help us with this report. I believe it usually takes a couple days to compile.

Frank, we will need the First Consignee report for the Motrin. Please let us know how soon you think we can get the information.

**Part Number:** 4816800

**Description:** MOTRIN IB CAPLET 8 VIAL

**Batches:** SCH003 & SCH004

**Haans Homer**

Production Planning Manager | McNeil Healthcare, LLC. | P-787.733.7605 | C-787.604.7653 | F-787.733.7670 | [hhomer@its.jnj.com](mailto:hhomer@its.jnj.com)

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-----Original Message-----

**From:** Carrillo, Eddie [MCCPR]  
**Sent:** Thursday, January 29, 2009 1:23 PM  
**To:** Homer, Haans [MCCPR]  
**Subject:** FW: Motrin

Haans, as you see below, Bob is requesting me the list of customers who received the lots of Motrin that we talked about yesterday (SCH003 & SCH004). Can you please check today and let me know.

Thanks

-----Original Message-----

**From:** Miller, Bob [MCCUS]  
**Sent:** Thursday, January 29, 2009 11:54 AM  
**To:** Carrillo, Eddie [MCCPR]; OPaels, Paul [MCCUS]

---

**From:** Benedict, Gary [MCCUS] [GBened1@its.jnj.com]  
**Sent:** Thursday, May 28, 2009 9:41 AM  
**To:** Figus, Daniel [MCCUS]  
**Subject:** FW: Market withdrawal of Motrin 8's

fyl

**From:** Parziale, Carolyn [MCCUS]  
**Sent:** Thursday, May 28, 2009 9:29 AM  
**To:** Benedict, Gary [MCCUS]  
**Cc:** DiPaolo, Paul [MCCUS]; Luther, Peter [MCCUS]; Miller, Bob [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]  
**Subject:** RE: Market withdrawal of Motrin 8's

Gary,

Just a clarifying point, in order to gain a significant cost avoidance, we intend to use CLS (Carolina Logistics) to make the 2<sup>nd</sup> phase of the store visits. GQA partnered with J&J SLC to create the relationship & CLS did a great job in completing the first Phase of this soft withdrawal. I can try to negotiate with them on price once we have the full store list, based on volume.

Carolyn

**From:** Benedict, Gary [MCCUS]  
**Sent:** Thursday, May 28, 2009 8:30 AM  
**To:** Luther, Peter [MCCUS]; Miller, Bob [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** RE: Market withdrawal of Motrin 8's

Bob...I spoke to Dan Figus this morning and can offer the following perspective to help figure out what we need to do.

- Sales had provided contact list for the majority of the stores. Hopefully, this information has been passed on to Stericycle to begin activities.
- We are still working to get contact list for small group of stores where we're having difficulty getting information from convenience distributors. Peter, for background, this recall is for a convenience channel code and it's been a challenge to secure full list of stores but should have everything this week.

Kathy, can you comment on Bob's concern about not being able to get PO from marketing?

**From:** Luther, Peter [MCCUS]  
**Sent:** Wednesday, May 27, 2009 10:03 PM  
**To:** Miller, Bob [MCCUS]; Benedict, Gary [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** RE: Market withdrawal of Motrin 8's

Group,

Where is the miss here? Given our current financial situation, I hope we're not going to really double our cost to do this. Let's make this happen ASAP.

Thanks,

MCNEIL HC 8309

**From:** Miller, Bob [MCCUS]  
**Sent:** Wednesday, May 27, 2009 9:51 PM  
**To:** Benedict, Gary [MCCUS]; Luther, Peter [MCCUS]; Mahony, John [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** Market withdrawal of Motrin 8's

Gary

As you know we have negotiated an agreement with FDA not to formally conduct a recall for Motrin 8's but rather conduct a "soft market withdrawal". This was a major win for us as it limits the press that will be seen. We had committed to FDA to complete this withdrawal by July 15<sup>th</sup>. There has been continuing issues trying to get a PO from the marketing group which is now putting our ability to meet the July 15<sup>th</sup> timeframe in jeopardy. At the same time as we delay this work the cost to complete the work continues to increase because of the fact that the outside resource will now need more resources to expedite the work. We can NOT extend our commitment date to FDA. It is now estimated that this will cost approx. \$400K which is approximately 2x that which was originally quoted. We need to start this work ASAP. If I we are unable to get a PO by Friday, we will issue the PO from QA and then back charge to marketing. Please let me know how you want to proceed or how we can get the PO. Carolyn Parziale is leading this effort and should be your POC for any questions you have. Please let me know if you have any questions.

Bob

**From:** Parziale, Carolyn [MCCUS]  
**Sent:** Thursday, July 2, 2009 1:12 PM (GMT)  
**To:** DiPaolo, Paul [MCCUS] <PDipaolo@its.jnj.com>  
**Subject:** FW: Change in Visit Request & SOW

---

Paul,  
I think we can get the mix we want.....Rob is working it and within budget.  
Carolyn

---

**From:** Parziale, Carolyn [MCCUS]  
**Sent:** Thursday, July 02, 2009 9:02 AM  
**To:** 'Small, Rob'  
**Cc:** Harper, Amanda  
**Subject:** RE: Change in Visit Request & SOW

Rob,  
The key here isn't the number as much as the mix, so I think if you can get the right mix (store types & regions) any number around 400 will be just fine!

---

**From:** Small, Rob [mailto:Rob.Small@inmar.com]  
**Sent:** Wednesday, July 01, 2009 5:04 PM  
**To:** Parziale, Carolyn [MCCUS]  
**Cc:** Harper, Amanda  
**Subject:** RE: Change in Visit Request & SOW

OK - I have the schedule back and we do have some options. There are 224 stores scheduled from 7/3 through 7/8. The problem is all but 80 will be done by Friday.

The geographic coverage is fair:

- CA
- TN
- GA
- IL
- MN
- WV
- WI
- FL
- OH
- IN
- MI

We're missing the Gulf Coast area, northeast, and really have CA as the only west coast work remaining.

---

We do have another convenience store project happening next week (7/6-7/10) though that has nearly complete geographic coverage. We could add this project to some of those stores if needed.

So the question is, would the 80 - 224 stores + 50 in other channels suffice given the states listed?

If not, we can add on additional locations from the other project.

Either way we will fall within the original budget, which accounted for 400 stores total.

We could create a mix of 400 stores inclusive of all channels and geographic regions and stay within budget if that were your preference.  
(something like 200 convenience, 75 grocery, 50 mass, 75 drug)

MCNEIL\_0022012

**Rob W. Small**  
Director of Field Operations & Transportation

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O: 336-631-7847  
C: 336-418-5496  
rob.small@inmar.com  
<http://www.inmar.com>

*Please consider the environment before printing this email.*

---

**From:** Parziale, Carolyn [MCCUS] [mailto:CParzla@ts.nj.com]  
**Sent:** Wednesday, July 01, 2009 12:11 PM  
**To:** Harper, Amanda; Small, Rob; Berdel, Joseph [MCCUS]  
**Cc:** DiPaolo, Paul [MCCUS]; Baller, Lorraine [MCCUS]  
**Subject:** Change in Visit Request & SOW

Amanda and Rob,

QA management has asked that if CLS can switch gears a bit and add the Liquids search, to the entire back end of the Motrin search and add some mass retailers to the visit list. That would mean that for the remaining stores on the Motrin intended visit list we would ask that the CLS reps. look for Liquids products as well, and report on any findings (they report total number of bottles found of the identified products we indicated, from the lot no. list we previously provided).

In addition, can you look at a few (approx. 50) mass retail stores, in locations that are common to the ones you are already visiting for Motrin?

Bottom line, we will not visit the 400 stores initially requested for just liquids, rather we will add onto the Motrin visits a Liquids check and add 50 mass retail store visits in locations that are common to the Motrin check areas. These locations would be selected by CLS from the list issued by Lorraine.

I would need to know if that can still be accomplished within the initial estimate costs and I will need to revise the SOW.

Joe,

It seems like I will need to revise the SOW (or modify the original), I will call you regarding managements new thinking.

Carolyn

Lorraine,

Thanks very much!

---

**From:** Baller, Lorraine [MCCUS]  
**Sent:** Wednesday, July 01, 2009 11:35 AM  
**To:** Parziale, Carolyn [MCCUS]  
**Cc:** amanda.harper@inmar.com  
**Subject:** FW:

Carolyn/Amanda,

Here are our master customer lists for Target, WalMart and CVS. You can query by city/state to match where we still need to go for Motrin to see if there is a Walmart/Target/ CVS store in that area to check as well. I am still waiting to get the Walgreens data and

MCNEIL\_0022013

will pass that on once I receive.

Thanks

**Lorraine K. Bailer**

*Supply Chain Director Analgesics/Peds/Specialty/JJ MCP*

**McNeil Consumer Healthcare**

215-273-7163 Office

215-273-4015 Fax

*lbailer@lts.nj.com*

---

**From:** Ault, Matt [SLCUS]  
**Sent:** Wednesday, July 01, 2009 10:38 AM  
**To:** Bailer, Lorraine [MCCUS]  
**Subject:**

<< File: storeReport.xlsx >> << File: WM Store\_DC\_JNJDC\_3\_11\_09.xls >>

Target & WalMart

CVS

<< File: StoreMasterdownload 6-11-09.xls >>

Matt Ault  
OTC/Nutritionals GBU Supply Logistics Manager  
Johnson & Johnson Sales and Logistics Co. LLC  
Phone: 908-904-3141  
Cell: 267-994-6106  
Email: mault@lts.nj.com  
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<http://ljab2.eu.nj.com/portal/ljab2/slcople-na/supplylogistics>

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September 18, 2009



Dear Healthcare Professional:

I am writing to inform you that, in consultation with the U.S. Food and Drug Administration (FDA), McNeil Consumer Healthcare is voluntarily initiating a recall of certain lots of Children's and Infants' TYLENOL® products that were manufactured between April 2008 and June 2008. The full list of recalled product lots is below.

The company has implemented this recall because examination of bulk raw material detected that one of the inactive ingredients did not meet internal testing requirements. Specifically, the gram-negative bacteria *Burkholderia cepacia* (*B. cepacia*) was detected. The portion of raw material in which the bacteria was found was isolated and was not used in the production of any finished product. However, it was decided, as a precaution, to recall all product that utilized any of the raw material manufactured at the same time as the raw material that tested positive for the bacteria. Please note: No bacteria has been detected in finished product and the finished product has met all specifications.

A review of the relevant published scientific literature regarding *B. cepacia* indicates that while ingestion of contaminated pharmaceutical product is not known to be a route of transmission of *B. cepacia* infection, infection has been reported following the use of contaminated pharmaceutical products such as mouthwashes and nasal sprays. Adverse health consequence of *B. cepacia* infections could be potentially severe especially in high-risk patients, such as those with underlying pulmonary disease, cystic fibrosis or compromised immune systems.

McNeil has conducted an assessment of post-marketing safety surveillance data and did not identify any safety signals or batch-related safety concerns for Infants' and Children's TYLENOL® products over the time period, starting with the introduction of these batches, in or around April 2008.

McNeil is advising parents and caregivers who have administered affected product to their child or infant and have concerns to contact their healthcare providers. Parents and caregivers can find the lot numbers on the bottom of the box containing the product and also on the sticker that surrounds the product bottle. If your patients determine that they have affected product, they can contact our Customer Care Center at 1-800-962-5357 and we will send them a coupon for a new bottle.

If you have any questions, please call our Medical Affairs Department at 1-800-962-5357 (available Monday-Friday 8 a.m. to 8 p.m. Eastern Time).

Sincerely,

Edwin K. Kuffner, MD  
Vice President, Medical Affairs  
McNeil Consumer Healthcare

Recalled Products - Full List			
UPC #	Code #	Lot #	Product Description
300450391049	3910400	SBM041, SBM067, SCM037, SDM027, SEM109	Children's TYLENOL® Plus Cold MS Suspension 4 oz. Grape
300450296047	2960400	SBM042, SCM015, SCM036, SDM034	Children's TYLENOL® Suspension 4oz. Grape
300450407047	4070400	SBM043, SBM044, SCM029	Children's TYLENOL® Suspension 4oz.

			Bubble Gum
300450493040	4930400	SBM045, SCM011, SCM030, SDM035	Children's TYLENOL® Suspension 4oz. Strawberry
300450122407	1224000	SBM064, SCM033, SDM020	Infants' TYLENOL® Grape Suspension Drops 1/4oz.
300450186157	1861500	SBM065, SCM005, SCM006, SDM032	Infants' TYLENOL® Suspension 1/2oz. Cherry
300450166043	1660400	SBM066, SCM068	Children's TYLENOL® Dye Free Suspension 4oz. Cherry
300450123046	1230400	SBM068, SCM035, SCM070, SCM080, SDM005	Children's TYLENOL® Suspension 4oz. Cherry
300450249043	2490400	SBM069, SBM070, SCM081, SDM006	Children's TYLENOL® Plus Cough & Runny Nose 4oz. Cherry
300450122155	1221500	SCM012, SCM087, SDM007, SDM068	Infants' TYLENOL® Suspension Drops 1/2oz. Grape
300450386045	3860400	SCM013, SCM014, SCM069	Children's TYLENOL® Plus Flu 4oz. Bubble Gum
300450387042	3870400	SCM016, SFM024	Children's TYLENOL® Plus Cold Suspension 4oz. Grape
300450247049	2470400	SCM017	Children's TYLENOL® Plus Cough/ST Suspension 4oz. Cherry
300450122018	1220100	SCM082, SDM039, SDM040	Infants' TYLENOL® Suspension Drops 1oz. Grape
300450167019	1670100	SCM083, SCM084, SDM008	Infants' TYLENOL® Dye Free Suspension 1oz. Cherry
300450123015	1230100	SDM084	Children's TYLENOL® Pediatric Suspension 1oz. Cherry
300450186300	1863000	SDM038, SDM009	Infants' TYLENOL® Suspension Drops 1oz. Cherry
300450390042	3900400	SDM033	Children's TYLENOL® Plus Cold/Allergy 4oz. Bubble Gum
300450122100	1221000	SDM078	Infants' TYLENOL® Drops 1oz. Grape
350580144183	1221800	SCM034	Infants' TYLENOL® Grape Suspension Drops H/G 1/2oz.
350580123034	1230300	SDM028	Children's TYLENOL® Suspension 4oz. Cherry, Hospital Govt.



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Head & Body | Arthritis | Sore & Allergy | Cold & Flu | Pain & Sleeplessness | Children | Our Products

News & Offers

Important News

PRINT EMAIL

September 24, 2009

- ▶ Important information about the recall of certain product lots of TYLENOL® Extra Strength, TYLENOL® PM and Children's TYLENOL® Metaways products - July 8, 2010
- ▶ Information about the recall of certain TYLENOL® Extra Strength Rapid Release Gels - June 15, 2010
- ▶ Information about the recall of certain Infant's TYLENOL® and Children's TYLENOL® products - April 30, 2010
- ▶ Information about the recall of certain Children's TYLENOL® products - March 28, 2010
- ▶ Information about the recall of certain infant's TYLENOL® products - March 20, 2010
- ▶ Certain TYLENOL® products recalled - January 15, 2010
- ▶ TYLENOL® Arthritis Pain 100 Count with EZ-OPEN CAP recalled - December 2008
- ▶ Unlabeled TYLENOL® Arthritis Pain Recall - November 2008
- ▶ Recall on certain Children's and Infant's TYLENOL® products - September 24, 2009
- ▶ Information about other recalls

You may have heard that McNeil Consumer Healthcare (the makers of TYLENOL®) is voluntarily recalling certain lots of Children's and Infant's TYLENOL® liquid products that were manufactured between April, 2008 and June, 2009. All products manufactured met Internal specifications. However, the company is implementing this recall because during this period, an unused portion of one inactive ingredient did not meet all quality standards. Therefore, as a precautionary measure, it was decided to recall all Children's and Infant's TYLENOL® liquid products listed below, which were made during 934 time.

Parents and caregivers who have questions or concerns should contact their child's health care provider or our consumer call center at 1-800-882-5357 (available Monday-Friday 9 a.m. to 6 p.m. Eastern Time). Consumers can find the lot numbers on the bottom of the box containing the liquid product and also on the sticker that surrounds the product bottle. The lot numbers of the affected products are listed below.

These actions do not apply to Children's TYLENOL® Metaways and Junior Strength TYLENOL® Metaways. The voluntary recall applies only to select lots of Children's and Infant's TYLENOL® liquid products.

Recalled Products - Full List

Lot #	Product Description
SBM041, SBM067, SCM037, SDM027, SEM109	Children's Tylenol Plus Cold MS Suspension 4 oz, Grape
SBM042, SCM015, SCM036, SDM034	Children's Tylenol Suspension 4oz, Grape
SBM043, SBM044, SCM028	Children's Tylenol Suspension 4oz, Bubble Gum
SBM045, SCM011, SCM030, SDM036	Children's Tylenol Suspension 4oz, Strawberry
SBM064, SCM033, SDM020	Infant's Tylenol Grape Suspension Drops 1/4oz.
SBM066, SCM005, SCM008, SDM032	Infant's Tylenol Suspension 1/2oz, Cherry
SBM068, SCM096	Children's Dye Free Suspension 4oz, Cherry
SBM069, SCM035, SCM070, SCM080, SDM005	Children's Tylenol Suspension 4oz, Cherry
SBM069, SBM070, SCM081, SDM008	Children's Tylenol Plus Cough & Runny Nose 4oz, Cherry
SCM012, SCM067, SDM007, SCM068	Infant's Tylenol Suspension Drops 1/2oz, Grape*
SCM013, SCM014, SCM069	Children's Tylenol Plus Flu 4oz, Bubble Gum
SCM016, SFM024	Children's Tylenol Plus Cold Suspension 4oz, Grape
SCM017	Children's Tylenol Plus Cough/ST Suspension 4oz, Cherry
SCM082, SDM039, SDM040	Infant's Tylenol Suspension Drops 1oz, Grape
SCM083, SCM084, SDM069	Infant's Tylenol Dye Free Suspension 1oz, Cherry
SDM064	Children's Tylenol Pediatric Suspension 1oz, Cherry
SDM038, SDM069	Infant's Tylenol Suspension Drops 1oz, Cherry
SDM033	Children's Tylenol Plus Cold/Allergy 4oz, Bubble Gum
SDM070	Infant's Tylenol Drops 1oz, Grape
SCM034	Infant's Tylenol Grape Suspension Drops 1/4Oz 1/2oz.
SCM039	Children's Tylenol Suspension 4oz, Cherry Hospital Oint.

\*This product may be contained in certain JOHNSON'S® Baby Relief Kits. Please check the lot number on the Tylenol bottle in your kit to determine if it is included in this recall.

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7050 Camp Hill Road • Fort Washington, PA 19034

May 29, 2009

Executive Summary:

Microcrystalline Cellulose and Carboxymethylcellulose Sodium NF, Avicel RC-591, vendor lot# DN08819021 and McNeil lot # 8M11418 was tested for Microbial Limits on 04/07/08. Microorganisms were isolated from the enrichment broth from the E. coli test on 04/10/08. On 04/14/08 the growth was identified as Burkholderia cepacia. It should be noted that Avicel RC-591 is tested for microbial limits as per McNeil specifications, but is not required as per USP.

Avicel RC-591, vendor lot# DN08819021 was manufactured from 2/1 to 2/2/08 and consists of 120 drums for a total of 9600 kg.

On 04/15/08, this QN was initiated and the microbiology lab contacted QA to have batches 8M11418 and 8M11210 blocked in SAP. Both batches have the same vendor lot DN08819021 and were currently in McNeil inventory. Lot 8M11418 has not been used for manufacturing. The following lots were not in inventory but are from the same vendor lot that is impacted, 8M10725, 8M10731, and 8M10903. These lots were used in manufacturing, with the exception of 8M10731, which was rejected due to defective drum liners. Based on this event Plant QA Management, T. Bauer (QA/QC Site Leader), J. Hayes (Associate Director QA), R. Jerez (Manager QA) and D. Bonilla (Microbiology Manager) had made the decision to temporarily hold the distribution of all finished goods that used this material and are under direct control (materials located at Fort Washington plant or Satellite Warehouse). Below is the breakdown of receipts and drum numbers of Avicel RC-591 at the Fort Washington Plant:

1. 8M10725 - Drums: 91-95, 101-105, and 111-120 (Received 2/15/08)
2. 8M10731 - Drums: 16-35 (Received 2/15/08) \*Rejected at Incoming due to defective liners.
3. 8M10903 - Drums: 6-15, and 36-45 (Received 3/3/08)
4. 8M11210 - Drums: 1-5, 46-50, and 66-75 (Received 3/24/08)
5. 8M11418 - Drums 76 to 90 and 96 to 100 (Received 4/7/08) \* Rejected after investigation.

1. Vendor Investigation

FMC Polymer, located in Newark, DE, supplies Microcrystalline Cellulose and Carboxymethylcellulose Sodium NF, Avicel RC-591 (Avicel.) They state that the process is not a sterile operation. Some parts of the manufacturing process are confidential, but a review of the general process shows it to be hostile to potential microbial growth. It is a continuous, closed process which begins with a city water wash of the raw material, followed by a rinse of 1 – 2 pH acid. As the pulp is further processed, it is rinsed several times with USP water at 110°C. FMC protocols and cleaning procedures are in-place to minimize the risk and exposure when equipment is opened for cleaning. The supplier also employs change-over procedures which involve a purging step of transferring and packaging material through equipment as a precautionary measure. Batch records were reviewed and no atypical activity was reported during the manufacture and packaging of this vendor lot. FMC has not received any related complaints for Avicel® RC-591 lot in question (Lot DN08819021.) During our vendor investigation, FMC did share that they had recovered Burkholderia cepacia from the E. coli test in drum sample 56. Per previous agreement with McNeil, FMC would reject only for the presence of the family of Enterobacteriaceae. As precautionary measure drums 51 to 65 were rejected by FMC, but not communicated to McNeil until after the investigation.

**OBJECTIVE**

To visit all the stores on your schedule; locate, and purchase all of the **MOTRIN® IB Caplet 8ct Vial** product in the store, bagging the product by-store (with receipt), boxing-up multiple stores worth of product and returning to the manufacturer as outlined later in these instructions. Also, to complete the required paperwork as noted below.

Lot Codes are purchased - we will record Lot Code of



ATTN: [Redacted]

**PROCESS**

WIS has been asked by CSCS (our client) on behalf of Johnson & Johnson to purchase all **MOTRIN® IB Caplet 8ct Vial** in the stores you have been scheduled for. You will quickly enter each store, find ALL of the Motrin product described, make the purchase transaction, secure the receipt, and leave.

You should simply "act" like a regular customer while making these purchases. **THERE MUST BE NO MENTION OF THIS BEING A RECALL OF THE PRODUCT!** If asked, simply state that your employer is checking the distribution chain of this product and needs to have some of it purchased for the project.

With your purchase, ask for a bag for the product so you can keep the product from each visit separate with the corresponding receipt in a box in your car.

Immediately after each purchase and while in your car, fill out the attached **Product Purchase & Ship Instructions Form** and place it in the bag that contains that stores product with your receipt. You will need a copy of this form for each store you visit.

Next, fill out the **WIS Daily Activity Sheet** with your information from this individual store. You will add information to this form after each stop. You will use this form the entire day; a different one each day.

Proceed to the next stop on your schedule.

Repeat the above process for each visit.

BE AWARE THAT SOME LOCATIONS, POSSIBLY MANY OF THEM, WILL NOT HAVE ANY OF THIS MOTRIN PRODUCT. IF YOU CANNOT FIND THE PRODUCT, ASK THE STORE IF THEY CARRY ANY OF IT. IF NOT, THANK THEM AND LEAVE. YOU MUST STILL FILL OUT THE Product Purchase & Ship Instructions Form and the WIS Daily ACTIVITY SHEET FOR EVERY VISIT, EVEN IF YOU FIND NO PRODUCT. Simply enter zeros for product purchased.

Mr. ISSA. Thank you, Mr. Chairman. And thank you for holding this important second hearing on the failure of FDA regulators, FDA regulators of the Johnson & Johnson failure to protect the American people.

I think it is critical for us today to understand that Johnson & Johnson and its subsidiaries do not get a pass for failing to meet the high standards expected of their company through their long history. That failure will mar Johnson & Johnson's image for many years to come. No matter how much they correct it, they will live with the repercussions of their failures.

But the American people will also, at the end of these hearings, recognize that government has failed to do its job. FDA's explanation appears to include seemingly false statements to this committee in April of this year. Given the documents received by the committee, it demonstrates the FDA was in fact aware of Johnson & Johnson's quiet recall of Motrin products, something they led us to believe they were not.

Even if we gave them additional authority for mandatory recalls, if they were complicit in a silent recall, then to what end would that new authority be? Mr. Chairman, fundamental concerns of this committee are making government do its job. In the case of the FDA, that means making sure that those who regulate our food and drug supply are careful, thorough and honest. Regrettably, the pattern emerging at FDA is one of carelessness, deficiencies and untruthfulness.

Now that this committee has sufficient evidence of FDA failure, we must be committed to following up that investigation and its needed reforms. New authority may be part of it. But no amount of authority makes up for failure to do the job you already have authority for and responsibility.

Mr. Chairman, there are differences in views today on where this committee should focus its oversight. Well-intentioned men and women on both sides of a partisan aisle often disagree, with the best of intentions. When we find agreement on our oversight responsibility, we should pursue them together. That is the case with the FDA, and many other issues before this committee.

In 2007, White House Chief of Staff Rahm Emanuel, then-Congressman from Chicago and head of the Democratic Congressional Campaign Committee, described the important role that this committee plays to ensure responsibility and accountability of government. He said "We, the Democratic Party, want to be the party that is fettering out waste and fraud, and the Oversight Committee is the point of the spear for us."

Similarly, this committee's former chairman, my colleague from California, Mr. Waxman, noted that Congress does not always fulfill its duty to the American people to provide oversight of the administration. He said, "Congress has failed to meet this constitutional oversight responsibility. On issue after issue, the Congress has failed to conduct meaningful investigations of significant wrongdoing."

I happen to agree with Mr. Waxman and Mr. Rahm Emanuel. These are constitutional obligations and we must vigorously meet those responsibilities.

Fortunately, the chairman and I are pursuing a common investigation. It leads us to two sides and two failures. The public has a right to know how Johnson & Johnson got to this point; how they are going to get their reputation back, by earning it with high quality products that meet or exceed all standards. That is important, and it should be bipartisan.

Mr. Chairman, today we also have to remember that our first part of our name, Government Oversight Reform Committee, implies exactly what it means. We are overseeing government. Yes, we are also seeing when government fails in its interaction with business. We must, though, remember that our authority is to oversee and then reform.

I for one, in 2005, had the opportunity to oversee the Mineral Management Service and show that they were a dysfunctional organization, too cozy with those that they oversaw. Unfortunately, in the years that followed, we didn't have reform. And in 2010, the American people paid a high price for that failure to reform.

When it comes to the FDA, we have seen the same thing, at least in this circumstance. We cannot fail to do that reform. We cannot wait for the American people to pay with their lives.

With that, I yield back.

Chairman TOWNS. I thank the gentleman for his statement. I want you to know that we are going to live up to our name, Oversight and Government Reform. I want you to know that.

Now I call on the gentleman from Maryland for 3 minutes, Congressman Cummings.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. Mr. Chairman, I thank you for convening this very important followup hearing to consider the safety of medications for children and families. I am extremely troubled by what appears to be an egregious pattern of behavior on the part of Johnson & Johnson and their subsidiary, McNeil Consumer Healthcare.

As I listened to Mr. Issa, I must say that I am also, I think we need to reserve judgment. Because the FDA, the Principal Deputy Commissioner Sharfstein, will be testifying. And I know him to be a very, he was head of Baltimore's health department and I can think of no one with more integrity and who puts more effort into protecting the safety of our fellow citizens.

Now, the Johnson & Johnson Web site states that "The values that guide our decisionmaking are spelled out in our credo. Put simply, our credo challenges us to put the needs and well-being of the people we serve first." Living these values, McNeil Consumer Healthcare and Johnson & Johnson were lauded for their efforts recalling Tylenol and temporarily stopping advertising when lives were on the line due to cyanide contamination in 1982.

The recent events could not be more different. One day after our last hearing, GlaxSmith Brands recalled PediaCare because the products were manufactured by McNeil Healthcare, even though McNeil officials had said that they did not manufacture products for other companies. Yet, it doesn't stop there. In June and July 2010, McNeil Healthcare twice expanded their original January 15, 2010 recall because of TBA contamination, a pesticide and flame retardant.

Why exactly were these items not identified 6 months prior in the original recall? Perhaps most disturbing, McNeil's consumer healthcare and Johnson & Johnson conspired to put profits first. There is no other conclusion that simply can be drawn. McNeil hired contractors to simply act like regular customers when conducting a soft market withdrawal of tainted Motrin from over 4,000 convenience stores in more than 40 States. Any product that needs to be recalled through a phantom or regular recall should not be in the hands of consumers and is probably unsafe.

Revealing the true motivation for these events, McNeil President Peter Luther wrote on May 27, 2009, "Given our current financial situation, I hope we are not going to really double our costs to do this. Let's make this happen as soon as possible." Minutes later, J&J vice president for sales, Gary Benedict, responded via email that he wanted more information on the situation that day.

These actions clearly show that McNeil and Johnson & Johnson knew the product was not safe and that they chose to make profits their first consideration over the safety of their constituents. With that, I look forward to the testimony, Mr. Chairman. And I yield back.

Chairman TOWNS. Thank you very much. I thank the gentleman from Maryland for his statement.

I now yield 3 minutes to the gentleman from Utah, Congressman Chaffetz.

Mr. CHAFFETZ. Thank you. Thank you, Mr. Chairman, for calling this hearing and thank you all for being here today.

Obviously, the American people rely upon the FDA to make sure that our country and our people and our children are safe and secure. We also rely upon big brand names, people like McNeil and Johnson & Johnson to provide good, quality products that families, mothers can use with their children.

Yet despite the hearing earlier this year, there are some very concerning issues that have come to light. I am very disappointed that the FDA has evidently not given us access to the people on the ground in Puerto Rico in particular that have first-hand knowledge of what is happening. I simply do not understand why the San Juan district director is not made available as she would provide the most, the best, most comprehensive type of information given the direct nature in which she has been involved. And I think we need to further explore that, Mr. Chairman.

Then within Johnson & Johnson, I want to read some quotes from emails. If you spend time in your testimony giving us platitudes and reading things that some corporate communications person wrote, I think you are going to see a frustrated group of members. When we read quotes, and these are quotes from within Johnson & Johnson to other Johnson & Johnson employees: "FDA is really bending the rules in this case, the Motrin caplet case, because of the fact that we stopped distribution a while ago." In another email, "Regarding FDA documents, all my conversation with the FDA director, Ms. Torres, here in Puerto Rico, have been off the record since I cannot quote her. This happens due to my good relationship with her. That's why we are doing something very different."

In another email, "The district director is already sticking her neck out, as her boss in Washington is more in favor of a recall." We need some answers from Johnson & Johnson, and we need some answers from the FDA. Because the candor has not been there. It has not been there.

This committee has an obligation to the American people to get to the bottom of this. And there is some funny business happening here, and nobody is happy about it. Please, don't just read some testimony that gives us platitudes. Answer these questions. They are serious. And there are millions of Americans that are relying upon the answers to these questions.

But based on the evidence that we are starting to see more and more of, it looks like there was much too much of a cozy relationship that does not give the confidence to the American people to buy your products and to insist and make sure that the FDA is actually doing its job.

I yield back.

Chairman TOWNS. I would like to thank the gentleman from Utah for his statement.

I now yield 3 minutes to the gentleman from Ohio, Congressman Kucinich.

Mr. KUCINICH. Thank you, Mr. Chairman.

I want to associate myself with the remarks of Mr. Chaffetz. We don't know if it is in this case, but there are so many areas where regulators and the regulated have a cozy relationship, which works to the detriment of the American people. We need only to look to the BP Oil catastrophe to have that underlined boldly.

And sadly, there are many other examples. We will find out if that is the case here.

But I want to caution some of my colleagues about how we define the work of this committee. Because on one hand, some of my colleagues would reject a beneficial role for government in people's lives. And on the other hand, when a regulatory agency does attempt to assert government responsibility for corporate misconduct, that is not recognized. This committee is not just oversight of the government, it is oversight of misconduct in the private sector. And there is plenty, rather, it is oversight of corporate conduct in the private sector. And there is plenty of misconduct in the corporate sector.

Now, why does it happen? Well, it happens for a lot of reasons, mostly greed. Why doesn't the government always come forward quickly and call corporations on it? There are a lot of reasons why that happens. One of the reasons is because corporations assert enormous influence on this government because of their campaign contributions. That is the clear fact, incontrovertible evidence to that effect.

So we have a problem with the system. Within the context of the system, the American people have a problem in being able to trust corporations, and in this case, Johnson & Johnson is going to have to answer a lot of serious questions about why they should continue to merit the public's trust, when apparently they concealed from public awareness information that was vital to protecting people's health.

Finally, Mr. Chairman, I understand the bill that you are preparing for this Congress. I think we should start also considering another dimension of corporate responsibility, and that is that if we are able to establish that a corporation knowingly avoided their responsibility to inform the public about a material matter that could create serious injury or death, that corporation's corporate charter should be canceled, and that we should instruct the Justice Department to take steps to do just that, in cooperation with the attorneys general in various States. If you have any conduct that hurts people, and people rely on you to do the right thing, and you don't do the right thing, you should actually be put out of business.

Thank you, Mr. Chairman.

Chairman TOWNS. I thank the gentleman from Ohio for his statement.

Now we will turn to our first panel. Our first witnesses are Mr. William Weldon and Ms. Colleen Goggins. William Weldon is the chairman and chief executive officer of Johnson & Johnson. Ms. Colleen Goggins is worldwide chair of the Johnson & Johnson Consumer Group. She also testified at the committee's first hearing. Welcome, both of you.

It is committee policy that all witnesses are sworn in. So if you would stand and raise your right hands, while I administer the oath.

[Witnesses sworn.]

Chairman TOWNS. Let the record reflect that the witnesses answered in the affirmative. You may be seated.

The rule is here that of course you have 5 minutes to give a summary. We have your statement for the record. And of course, there is a light that comes on and when you have 1 minute left, the yellow light comes on. Then of course at the end is a red light and the red light of course mean stop.

Mr. Weldon, if you would start and then after that, you, Ms. Goggins.

**STATEMENTS OF WILLIAM C. WELDON, CHAIRMAN AND CHIEF EXECUTIVE OFFICER, JOHNSON & JOHNSON; AND COLLEEN GOGGINS, WORLDWIDE CHAIRMAN, CONSUMER GROUP, JOHNSON & JOHNSON**

**STATEMENT OF WILLIAM C. WELDON**

Mr. WELDON. Chairman Towns, Congressman Issa and members of the committee. I am Bill Weldon, chairman and chief executive officer of Johnson & Johnson.

I appreciate the opportunity to appear before you today to describe our efforts to address the serious quality issues at McNeil Consumer Healthcare.

As you know, I was unable because of back surgery to testify at the committee's hearing in May. I was grateful for the opportunity to meet with both the chairman and Congressman Issa shortly afterwards to discuss our response to the recalls.

It is essential that we work closely with Congress, the FDA and others to restore the public's confidence in McNeil Consumer Healthcare's products. Mr. Chairman, I know that we let the public

down. We did not maintain our high quality standards. And as a result, children do not have access to our important medicines.

I accept full accountability for the problems at McNeil, and I will take full accountability for fixing these problems.

After we found a substantial quality issue at McNeil, we instituted a broad precautionary recall of all liquid children's products manufactured in Fort Washington. And even though our medical experts and the FDA agreed that the health risk was remote, we believed it was the right thing to do for patients.

We also commenced a complete re-examination of McNeil's manufacturing processes. We are working hard to restore the public's trust and confidence in Johnson & Johnson and to strive to ensure that something like this never happens, ever again.

I have spent my entire professional career at Johnson & Johnson. I was honored to be appointed chairman and chief executive officer in 2002. I am very proud to lead Johnson & Johnson and our dedicated, hard-working professionals. We are working hard to bring our important pediatric products back to the market responsibly.

Indeed, I am pleased to announce that consumers will soon begin to see McNeil liquid pediatric products back on the shelves. During the week of October 4th, we will begin shipping one of McNeil's children's medicine products to our customers. Although available only in limited quantities at first, almost 1 million bottles, these will be available for release next week. We expect to distribute a total of 4 million bottles in the United States by the end of the year.

As Colleen Goggins testified in May, it is important for consumers to know that the April 2010 recall was not undertaken on the basis of reports of adverse medical events. When we first found the issues that led to the April 2010 recall, we stopped shipping the products, shut down the plant and issued a broad precautionary recall of all liquid medicines. We have kept McNeil's Fort Washington facility shut down and we are completely revamping the facility to bring both equipment and procedures up to the high standards that we set for ourselves around the world.

The facility will not reopen until we are confident that we can make McNeil products to the high quality standards that the public, Congress and the FDA rightfully expect of us. Across McNeil, Johnson & Johnson is investing more than \$100 million on facilities, equipment and other improvements.

McNeil retained an independent third-party consultant with expertise in manufacturing and quality systems. McNeil also appointed a new vice president of quality assurance, a new vice president of operations, a new plant manager at Fort Washington, and a new head of quality for the Fort Washington plant.

Since the hearing in May, these efforts have accelerated. As Ms. Goggins promised during the May hearing, we submitted a comprehensive action plan to the FDA in July. We have established new quality officers for each of our three business segments. Quality and manufacturing report to a single point, with oversight of our operating companies. This person reports directly to me.

I have also personally visited many of our manufacturing facilities to reinforce the importance of quality.

In your letter inviting me to testify, you raised questions about the recall of two lots of eight-caplet Motrin vials. The documents that we provided to the committee show that McNeil informed FDA officials about our plans for an in-store assessment and then a retrieval of any of the eight-caplet Motrin vials that remained available for sale. I do think the McNeil personnel were trying to be transparent with the FDA. McNeil also notified its customers that it would be sending in personnel to remove the products.

Nonetheless, based on what I have learned since the May hearing, including the points that this committee brought to light, it is clear to me that in retrospect, McNeil should have handled things differently. And going forward, if similar situations arise, they will be handled differently.

Mr. Chairman, I am committed to working cooperatively with the committee and the FDA to get the McNeil products back on the shelves for the people who rely on them. We look forward to earning back the trust of all those who have depended upon Johnson & Johnson to take care of themselves and their families for decades. I would be happy to answer your questions.

[The prepared statement of Mr. Weldon follows:]



Testimony of  
Mr. William C. Weldon  
Chairman and Chief Executive Officer, Johnson & Johnson  
before the  
Committee on Oversight and Government Reform  
U.S. House of Representatives  
September 30, 2010

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Chairman Towns, Congressman Issa, and Members of the Committee, my name is Bill Weldon, and I am the Chairman and Chief Executive Officer of Johnson & Johnson. I appreciate the opportunity to appear before you today to describe our efforts over the last several months to address the serious quality issues at McNeil Consumer Healthcare. McNeil is one of the approximately 250 companies in the Johnson & Johnson family of companies.

As you know, I was unable – because of back surgery – to testify at the Committee’s hearing in May. I was grateful for the opportunity to meet with both the Chairman and Congressman Issa, shortly after recovering from surgery, to discuss our response to the recalls. Over the past several months, we have kept you informed about the progress we have been making and the milestones that have been achieved, as well as the challenges that we continue to confront. It is essential that we work closely with Congress, the FDA, and others to restore the public’s confidence in McNeil Consumer Healthcare’s products. This Committee has played an important role in focusing attention on the McNeil issues.

Mr. Chairman, I know that we let the public down. We did not maintain our high quality standards, and as a result, children do not have access to our important medicines. I accept full accountability for the problems at McNeil, and I will take full accountability for fixing them.

After we found a substantial quality issue at McNeil, we instituted a broad and precautionary recall of all liquid children’s products manufactured in Fort Washington, which we did in the interest of protecting consumers. Although our medical experts and the FDA agreed that the health risk was remote, we believed the right course of action was to proceed with a broad precautionary recall and commence a complete reexamination of McNeil’s manufacturing processes. We recognized then, and we recognize now, that we need to do better, and we will work hard to restore the public’s trust and faith in Johnson & Johnson, and strive to ensure that something like this never happens again.

I have spent my entire professional career at Johnson & Johnson. I started with the company in 1971 – right out of college. I began in the sales force before moving into an executive position. I was honored and humbled to be appointed, in 2002, Chairman and Chief Executive Officer of the company. I am very proud to lead Johnson & Johnson, its family of

companies, and its more than 100,000 employees. Our employees are some of the most dedicated, hard working, and committed professionals in the industry. I have given them my personal commitment that we will do whatever is necessary to address the quality concerns at McNeil, bring our important pediatric products back to the market responsibly, and restore the public's confidence in our products.

Indeed, I am pleased to announce that consumers will soon begin to see McNeil liquid pediatric products back on shelves. During the week of October 4, we will begin shipping one of McNeil children's medicine products to our customers. Although it will be available only in limited quantities at first, we have been able to achieve this step by working closely with the FDA and our Canadian affiliate. Almost 1 million bottles will be available for release next week, and we expect to distribute a total of 4 million bottles in the United States by the end of the year.

It is critical that the public have accurate information about what transpired at McNeil and how we came to have a string of product recalls. As Colleen Goggins testified in May, it is important for consumers to know that the April 2010 recall was not undertaken on the basis of reports of adverse medical events. We recalled these products because of Johnson & Johnson's commitment to consumers and its belief that the serious manufacturing issues it uncovered needed to be addressed even though the health risks to consumers were remote.

Today, I would like to describe for the Committee Johnson & Johnson's efforts to address the quality issues that it found at McNeil, and then address two issues raised in your letter inviting me to testify today.

**A. Actions Taken To Fix the Problems at McNeil**

After we first found the issues that led to the April 2010 recall, we stopped shipping the products, shut down the plant, and issued a broad precautionary recall of all liquid medicines made at Fort Washington. During the hearing in May, Ms. Goggins described the many steps that Johnson & Johnson and McNeil then took to address the issues that led to the recall. First and foremost, we kept McNeil's Fort Washington facility shut down, and we are completely revamping the facility to bring both equipment and procedures up to the high standards that we set for ourselves around the world.

When complete, it is fair to say that the Fort Washington facility will represent the state-of-the-art in medicine production. The facility will not open until we are confident that we can make McNeil products to the high quality standards that the public, Congress, and the FDA rightly expect from us. Across McNeil, Johnson & Johnson is investing more than \$100 million on facilities, equipment, and other improvements to our operations.

Even before the April 2010 recall, McNeil began working with an independent, third-party consulting firm with expertise in manufacturing and quality systems. This third-party expert has assisted McNeil in identifying issues with, and improving, McNeil's manufacturing methods, supply chain management, and overall quality practices. As Ms. Goggins testified, McNeil also made significant organizational changes in the quality and operations leadership on the management team in all McNeil facilities. Already by May, McNeil had appointed a new vice president of quality assurance, appointed a new vice president of operations, appointed a

new plant manager at Fort Washington, and appointed a new head of quality for the Fort Washington plant.

Since the hearing in May, these efforts have only accelerated. We have undertaken significant improvements at McNeil's facilities. We have taken further actions more broadly across McNeil. As Ms. Goggins promised during the May hearing, we submitted a "Comprehensive Action Plan" to the FDA in July. The Comprehensive Action Plan, which applies to all the manufacturing facilities McNeil operates to supply the U.S. market, addresses governance and management controls, training programs, process assessments, and process improvements. We have brought in outside experts to examine our production and quality practices, and they are examining and validating the way we make our products. We have called on our internal experts and brought them into the effort to improve quality across McNeil's facilities. We have improved our supply chain management and oversight to address issues identified in our overall review. And perhaps most importantly, we have committed to regular and detailed communications with the FDA throughout the implementation of the plan. We have been consistently meeting the remediation milestones we set for ourselves with the FDA.

In addition, I have been traveling around the country visiting Johnson & Johnson's manufacturing sites and speaking with the employees on the front lines of our production facilities. Soon, I will be visiting our manufacturing sites around the world. Our employees must know, as I have told them in these meetings, that Johnson & Johnson is dedicated to manufacturing products to the highest standards. As trusted partners in our manufacturing process, I have stressed to our employees the importance of identifying and reporting any issues that they may observe at their facilities.

Finally, Mr. Chairman, we have completed the organizational restructuring of our quality and operations responsibilities across Johnson & Johnson. We began this reorganization prior to the events at McNeil, and those events highlighted the need for clear and effective oversight of our companies' operations. Under the reorganization, we have established new chief quality officers for each of our three business segments – consumer, pharmaceutical, and medical devices. The quality operations in each of the business segments now report to a chief quality officer for the company. Quality and manufacturing report to a single point, with oversight of our operating companies. This person reports directly to me.

#### **B. The Retrieval and Subsequent Recall of Motrin Products**

Mr. Chairman, at the May 27 hearing, and again in your recent letter to me, you raised questions about what you described as a "phantom recall" of two lots of 8-caplet Motrin vials that were distributed to certain retail establishments, primarily gas stations and convenience stores. Since that hearing, when the Committee raised this issue with us for the first time, we have provided the Committee with thousands of documents and information about the retrieval of Motrin products that took place in 2009.

Based on what I have learned since the May hearing about the way the Motrin retrieval was handled, including the points that this Committee brought to light, it is clear to me that in retrospect, McNeil should have handled things differently. And going forward, if similar situations arise, they will be handled differently.

As an initial matter, it is important to keep in mind that the Motrin retrieval and subsequent recall were not prompted by safety concerns about the product. Rather, the caplets were found not to dissolve as quickly as intended. McNeil reported this dissolution issue to the FDA, and made plans to assess how much, if any, of the product in question was still in stores. At the time the quality issue arose, McNeil reasonably believed that a small amount of these 8-count vials remained in convenience store locations. The company elected to use a third-party contractor, called Inmar, to visit stores and, if the Motrin product in question was found in a store, to purchase and destroy the product. In a March 23, 2009, field alert, which is a formal notice to the FDA, McNeil stated that "a third party has been contracted to perform an in store assessment. . . . If this assessment confirms that there is no product from [the affected Motrin batches] at the store level, a recall will be considered not necessary due to unavailability in the market; otherwise a recall of these Motrin batches will be recommended to be performed." There were additional communications, as I understand it, between the FDA district office personnel and McNeil from April to July 2009.

On April 21, 2009, McNeil submitted a field alert stating that "a statistical sampling of approximately ten (10) percent of all stores across the US that received these batches were visited (250 stores out of 2000). The assessment performed demonstrated that, on a statistical basis, a low amount of product (approximately 1% of the batches) is potentially still at the retail level. The product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found." On May 5, 2009, McNeil informed its customers that it would "send in our own teams to remove the specific product lots from those retail outlets and reimburse the outlets for the cost of the product removed."

In July 2009, after the retrieval had already been completed, and about two months after the April 21 field alert to the FDA, the FDA informed McNeil that the retrieval should be treated as a formal recall. McNeil appropriately agreed to the FDA's request and submitted the necessary recall documentation to the FDA.

In response to the Committee's requests, we produced to you internal McNeil correspondence, correspondence with the FDA, and the formal notices sent to the FDA reflecting McNeil's communications with the agency regarding the use of a third-party contractor to purchase and remove the Motrin products from the retail locations. The documents that we provided to the Committee show that McNeil informed FDA officials about McNeil's plans for an in-store assessment and then a retrieval of any of the 8-caplet Motrin vials that remained available for sale. McNeil believed that this was an expeditious way to remove the remaining caplets from the convenience store shelves.

I believe that McNeil acted with good intentions, and I do not view the use of a contractor to retrieve product, by itself, as inappropriate. The retrieval of product in this case was targeted and very comprehensive. But this episode was not a model for how I would like to see Johnson & Johnson companies approach problems with defective product when they arise, and I can assure the Committee that we are taking stock of the lessons learned.

**C. The Children's Tylenol Assessment and September 2009 Recall**

Mr. Chairman, your letter to me about today's hearing included a document – apparently an internal e-mail from a contractor – referencing a potential for a recall involving Children's Tylenol. As this is not a Johnson & Johnson or McNeil document, I cannot speak to it specifically. I can, however, tell you that in the summer of 2009, McNeil contracted with Inmar to assist with a recall that was announced publicly on September 24, 2009. The FDA was informed that McNeil would use Inmar to assist with the recall. The FDA specifically approved visits to retailers, and it approved communications to retailers that described the use of contractors to purchase and remove the recalled products. Prior to the recall, in July 2009, as I understand it, McNeil requested that Inmar conduct an in-store assessment to determine the extent to which product from the affected lots – which had been produced many months earlier – remained in the marketplace. A document provided to the Committee shows that Inmar confirmed to McNeil that no product would be purchased during this assessment.

Importantly, the issue that prompted the discussion and eventual recall in September 2009 presented only a remote risk to patient safety. The September 2009 voluntary recall was undertaken out of an abundance of caution because objectionable bacteria had been found in raw material that was rejected and not used in production. McNeil tested the raw materials, and no raw materials that tested positive for objectionable bacteria were ever used in production. In addition, McNeil tested its final products for bacteria and has not identified any products placed on the market that contained objectionable bacteria. Subsequently, McNeil tested retained samples, which also tested negative for objectionable bacteria. Indeed, the McNeil liquid products are specifically designed to resist bacteria, with both a low water activity level and a preservative system that preclude bacteria growth.

Finally, your letter asks whether this contractor document is related to the April 2010 recall. As best we are able to determine, it is not. The recall conducted in April 2010 was undertaken by McNeil because of issues identified regarding particles in April 2010, as described in Ms. Goggins' testimony last May. The contractor document appears to be related to the recall conducted in September 2009.

\* \* \*

I would like to close my testimony by noting my appreciation for Ms. Goggins' leadership of Johnson & Johnson's consumer group. As you know, she has announced that she will retire from Johnson & Johnson next year. During this busy and important time at Johnson & Johnson, she has demonstrated strong leadership as we work to address the quality issues that led to the recent recalls. I am grateful for her long service to the company.

Mr. Chairman, our efforts to assess and improve the quality issues we found at McNeil began many months ago. We have made considerable progress, and we are working quickly to resolve any outstanding issues and resume production of our children's liquid products. As you know from our several personal meetings, I am committed to working cooperatively with the Committee and the FDA to get the McNeil products back on the shelves for the people who rely on them. We look forward to earning back the trust of all those who have depended upon Johnson & Johnson to take care of themselves and their families for decades.

I would be happy to answer your questions.

Chairman TOWNS. Thank you very much, Mr. Weldon, for your statement.

Ms. Goggins.

#### STATEMENT OF COLLEEN GOGGINS

Ms. GOGGINS. Chairman Towns, Congressman Issa and members of the committee, I am Colleen Goggins, the worldwide chairman of the Consumer Group of Johnson & Johnson.

I appreciate the opportunity to appear before you today, as I did in May, to discuss our efforts to address the quality and process issues at McNeil Consumer Healthcare.

Because my May testimony contains considerable detail concerning McNeil and the recent recalls, I will be brief in my testimony today.

Since my prior appearance before this committee, we have continued to work very hard to address the problems at McNeil. As Mr. Weldon stated, McNeil submitted to the FDA a comprehensive action plan [CAP], in July. The CAP applies to all the manufacturing facilities McNeil operates to supply the U.S. market, not just the Fort Washington facility that remains closed. The CAP is part of our ongoing dialog with the FDA to improve product quality, improve quality systems and enhance training.

Under the CAP, we have engaged leading experts on manufacturing processes, and we have also dedicated Johnson & Johnson's own experts to our efforts at McNeil.

Mr. Chairman, I understand from your letter inviting me to appear today that you have questions concerning my testimony about the Motrin caplets recall in 2009. I regret if my testimony created any confusion. And I hope that I can clear up any confusion today.

By way of background, I learned that the committee was interested in the Motrin recall for the first time during the morning session of the May hearing. We quickly gathered what information we could prior to my testimony in the afternoon. And during my testimony, we committed to providing additional information to the committee, which we have now done.

At the hearing in May, I told the committee that I believed there had been discussions with the FDA about our plans for the third-party contractor in connection with the Motrin caplets. I believe that the documents we have now obtained and provided to the committee reflect these discussions and McNeil's efforts to be transparent and act in good faith with the agency.

As I tried to make clear in my testimony, I had no knowledge at the time of the May hearing of any instructions that may have been given to any contractor. Since the May hearing, the company located and provided the committee a copy of instructions given by McNeil to its contractor on the Motrin matter. In those instructions, McNeil directed the contractor to purchase the product without engaging in discussions with store personnel.

Having now seen those documents, I believe McNeil should have handled things in a more straightforward manner with the retail stores. We as a company have learned from this process and appreciate the committee's help in highlighting these concerns.

As I said at the outset, we have committed to deal aggressively and effectively with the quality and process issues we have at

McNeil. Although we still have work to do, I do believe we are living up to that commitment. I would be happy to answer any questions you or the other committee members might have.

[The prepared statement of Ms. Goggins follows:]



Testimony of

Ms. Colleen A. Goggins  
Worldwide Chairman, Consumer Group, Johnson & Johnson

before the

Committee on Oversight and Government Reform  
U.S. House of Representatives

September 30, 2010

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Chairman Towns, Congressman Issa, and Members of the Committee, I am Colleen Goggins, the Worldwide Chairman of the Consumer Group of Johnson & Johnson. I appreciate the opportunity to appear before you today, as I did in May 2010, to discuss our efforts to address the quality and process issues at McNeil Consumer Healthcare. Because my May 2010 testimony contains considerable detail concerning McNeil and the recent recalls, I will be brief in my testimony today.

Since my prior appearance before this Committee, we have continued to work very hard to address the problems at McNeil. In July, McNeil submitted to the FDA a “Comprehensive Action Plan” (CAP). The CAP applies to all the manufacturing facilities McNeil operates to supply the U.S. market – not just the Fort Washington facility that remains closed. The CAP is part of our ongoing dialogue with the FDA to improve product quality, improve quality systems, and enhance training. Under the CAP, we have engaged leading experts on manufacturing processes, and we have also dedicated Johnson & Johnson’s own experts to our efforts at McNeil.

We are committed to dealing aggressively with the quality and process issues at McNeil, and I believe we are living up to that commitment, although we recognize we still have work to do. As you heard from Mr. Weldon, our employees have dedicated themselves to addressing the quality concerns at McNeil. Johnson & Johnson has directed new personnel and additional resources to the efforts at McNeil. And as Mr. Weldon said, we are working very hard to bring the pediatric products back to the market.

Mr. Chairman, let me address a question you raised in your letter inviting me to appear today. When I testified in May, the Committee asked about McNeil’s use of a contractor in 2009 in connection with the two lots of 8-caplet Motrin vials determined to have a dissolution issue. I learned that the Committee was interested in this issue for the first time during the morning session of the hearing in May. Based on the information available at the time, I informed the Committee that the FDA was told of McNeil’s plans for Motrin, and I committed to provide the Committee with further information relating to this issue.

Since the May hearing, the company has provided documents to the Committee that reflect discussions with the FDA, including an April 21, 2009, field alert submitted to the FDA’s

San Juan office. That field alert notified the FDA that McNeil had hired a contractor to visit retail outlets and remove any product still found in stores by July 15, 2009. Based upon this and other documents, I continue to believe that the FDA was informed of McNeil's plans.

At the hearing, I also stated that I had no personal knowledge of statements reflected in excerpts from a subcontractor's document shown to me during the hearing, which I had never before seen. As I understand it, neither McNeil nor Johnson & Johnson had seen these instructions prior to the hearing. Since the hearing, the company located and provided to the Committee a copy of instructions issued by McNeil to its contractor on the Motrin matter. At the time of the hearing in May, I had no personal knowledge of and had not seen the contractor or McNeil instructions. Since then, however, I have reviewed the McNeil instructions to the contractor that instructed the contractor to purchase the product without engaging in discussions with the store personnel. Based on what I have learned since May, I believe that McNeil should have handled things differently. We, as a company, have learned from this process.

Finally, Mr. Chairman, I recently announced that I will retire from Johnson & Johnson early next year. I have been thinking about retiring for some time, as I have spent nearly 30 years with the company and almost 10 years in my current position. With the McNeil remediation plan in place, I announced my retirement now in order to ensure an orderly transition at this critical time for the company. Even after I retire, I have committed to the company that I will be available for anything they need, and I extend the same commitment to the Committee.

Mr. Chairman, I would be happy to answer any questions that you or the other Committee Members may have for me.

Chairman TOWNS. Thank you very much.

Let me thank both of you for your statements, and of course, for being here.

Let me begin with you, Mr. Weldon. In your prepared statement to the committee, you talk about a March 23, 2009 field alert that was sent to the FDA about the defective Motrin. This is the product that was taken off the shelves during the phantom recall.

That field alert says a third party has been contracted to perform an in-store assessment. That does not say anything about contractors going into stores and not communicating about a recall and buying all the affected products. Then on April 1, 2009, just about a week after McNeil told the FDA it would perform an assessment, a McNeil executive emailed your contractors with instructions for the phantom recall. And those instructions say, "purchase all of the product," and "do not communicate to store personnel any information about this product." We also have an email dated April 16, 2009, where an employee of one of your contractors informs McNeil that the phantom contractors had already completed 250 visits to stores.

Mr. Weldon, don't these documents show that the phantom recall had already been performed in over 200 stores before you made any mention to the FDA about these, the defective Motrin?

[The information referred to follows:]



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McNeil Healthcare, LLC • P.O. Box 2009, Las Piedras, Puerto Rico 00771-2009

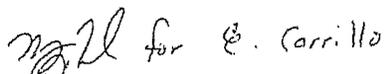
March 23, 2009

Ms. Maridalia Torres  
U. S. Food and Drug Administration  
466 Fernández Juncos Ave.  
San Juan, Puerto Rico 00901-3223

Ms. Torres:

Attached please the third follow-up to the Field Alert Report (FAR) for Motrin Caplets submitted on November 26, 2008.

Cordially,

  
Eddie Carrillo  
Quality Site Leader

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>NDA-FIELD ALERT REPORT</b>		TO: (NAME AND ADDRESS OF DISTRICT) Ms. Maridalia Torres, District Director FDA - San Juan District Office 466 Fernández Juncos Ave. San Juan, PR 00901-3223	
TYPE OF REPORT <input type="checkbox"/> Initial <input checked="" type="checkbox"/> Follow-Up <input type="checkbox"/> Final			
In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:			
1. NDA/ANDA - ANTIBIOTIC FORM 5/6 NO. 19-012 Motrin Caplets		2. NDC No. 50580-110-68	
3. GENERIC NAME OF DRUG PRODUCT Ibuprofen		4. TRADE NAME (if any) OF DRUG PRODUCT Motrin Caplets	
5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009		6. FEI 2650141	
7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S) Motrin Tablets - Ibuprofen 200mg - 8 count vials			
8. LOT NUMBER(S) SHC003			
9. EXPIRATION DATE(S) OF DRUG PRODUCTS 03/2011			
10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER November 21, 2008			
11. HOW WAS PROBLEM DISCOVERED During the routine stability testing (3-month interval)			
12. STATE PROBLEM(S) Dissolution failure during the 3-month interval stability testing Actual results: - S1 = Average: 72% (min. 64%) - S2 = Average: 71% (min. 64%) - S3 = Average: 71% (min. 58%)  Specification S1 = Each unit NL T Q + 5, Q = 80% S2 = Average of S1 + S2 is equal to or greater than Q. No unit less than Q-15% S3 = Average of S1+S2+S3 is equal to or greater than Q. Not more than 2 units less than Q-15%. No unit less than Q-25%			
13. PROBABLE CAUSE(S) OF PROBLEM(S) Investigation is in progress.			
14. CORRECTIVE ACTION(S) TAKEN (if any) TO PREVENT RECURRENCE OF PROBLEM(S) Remaining inventory in the distribution centers has been placed on hold.			

## 15. REMARKS

- \* This batch (SHC003), along with two others, was placed on stability in order to fulfill the marketed product stability requirements for new packaging codes (8 and 10 count vials). The other two batches are showing satisfactory dissolution results at S1 stage.
  - \* On October 23, 2008 a communication was issued in order to discontinue the sale of this product display due to low volume sales.
  - \* The retain samples of the finished product batch SH003 were tested and the results were within specifications (average 98, range 82-106, n=12)
  - \* Bulk retained sample of batch SCH003 was tested and result confirmed initial out of specification result.  
Average = 76%, Range 65 - 99 (n=24)
  - \* Fresh stability samples of lot SHC003 were tested in our Fort Washington affiliate and results passed dissolution specifications at S2.  
Average = 80%, Range 71-94% (n=12)
  - \* Fresh stability samples of lot SHC003 were tested in Las Piedras facility and the S1 results confirmed initial out of specification  
Average = 74%, Range 69-79% (n=6)
  - \* Temperature and humidity assessment to the stability chamber and retention room were performed and no atypical value was observed.
  - \* Retain bulk samples of four associated granulation batches were tested. Only compression lot (SDA0000807) failed dissolution S3 criteria. Result obtained for this batch was:  
Average = 60%, Range 49-71% (n=24)
  - This additional bulk batch, which failed dissolution, was packaged also in vial and was already on hold in the distribution center. Investigation is ongoing to understand the cause of these out of specification results. The other three batches were within specification.
  - \* Assay, IB related compound Isobutylacetophenone, and Impurities results of stability batch SCH003 for the three month interval are well within specification.
  - \* During a detailed assessment of the manufacturing records from granulation step for the compression batch of packaging lot SCH003 a downtime of 1 hour and 25 minutes during drying was observed. This downtime is allowed by procedure, however it was found to be an atypical situation. Various other lots from 2006 through 2008 having similar and longer downtime during the granulation drying process were assessed. One lot on Stability was made using granulation having a similar downtime as SCH003. The stability results thru eighteen (18) months of storage are well within specification. In addition, retain samples from three batches made with granulation having longer drying downtime than that of SCH003 was assessed, one from each assessed years was identified. Retain bulk of these three batches were tested for dissolution and S1 results were well within specifications.  
Lot MDAD002299 : Average = 100%, Range 97-102% (n=6)  
Lot PHA0002970 : Average = 101%, Range 99-102% (n=6)  
Lot SHA0000372 : Average = 100%, Range 99 - 101% (n=6)
  - \* A medical assessment was requested and it concludes that the use of Motrin IB caplets from these lots is not likely to cause an increased risk of serious adverse health consequences.
  - \* Up to this point, although more investigative work is being performed, it is considered that this event is isolated to the original vial batch number SCH003 and batch SCH004 which a result not meeting S3 dissolution specification was observed during retained bulk testing. Batch SCH004 was also packaged in vials. All remaining inventory of these two batches and other batches in this product code are currently on hold in our distribution centers. As stated before, this product code was discontinued.
- A Health Hazard assessment was performed and it concludes that the Motrin IB caplets from these lots are not likely to cause an increased risk of serious adverse health consequences.
- Two experimental batches have been manufactured re-creating the downtime specified above and have been packaged in bottles and vials. These will be placed in accelerated stability condition in order to assess the process downtime hypothesis.
- As stated above, this Motrin product line was discontinued on October 23, 2008, due to low sales. Remaining inventory in the Distribution Centers and Packaging Contractor of Motrin batches SCH003 and SCH004 were placed on hold in November 2008. It is expected that none of these affected lots are available at the store level. A review of our complaint history indicates that neither affected lot has had a complaint registered against it from November 1<sup>st</sup>, 2008 through March 19, 2009. This finding further supports the hypothesis that neither of these lots are available at the store level.
- In order to confirm that neither affected lots is available at the store level, a third party has been contracted to perform an in store assessment. A statistical sampling of twenty-five (25) percent of all stores across the US that received these batches will be visited. If this assessment confirms that there is no product from batches SCH003 and SCH004 at the store level, a recall will be considered not necessary due to unavailability in the market; otherwise a recall of these Motrin batches will be recommended to be performed. The assessment is expected to be completed by April 15, 2009.

NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.

REPORTING ESTABLISHMENT	
NAME AND MAILING ADDRESS <i>(include ZIP Code)</i> McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009	
NAME AND TITLE OF AUTHORIZED REPRESENTATIVE Eddie Carrillo	TELEPHONE <i>(include Area Code)</i> 787-733-7651
SIGNATURE OF AUTHORIZED REPRESENTATIVE <i>Eddie Carrillo</i>	DATE SUBMITTED 3/23/2009

**Harper, Amanda**

**From:** Vandermolen, Lily [MCCUS] [LVanderm@its.jnj.com]  
**Sent:** Wednesday, April 01, 2009 2:56 PM  
**To:** Small, Rob  
**Cc:** Parziale, Carolyn [MCCUS]; Harper, Amanda; Figus, Daniel [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy; Davey, Frank [MCCUS]; Degen, Jenna [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** RE: Lot Number Info  
**Attachments:** Motrin Vial Audit Letter.docx; PRODUCT PURCHSHIP FORM.docx

Team,

Attached are the final, approved documents for the audit. Please distribute both documents to your field team ASAP.

The goal is to meet the 4/15 drop dead date to report back to the FDA on our audit and sales data findings. Per offline conversations, in-store audits should be complete by that time and reporting of the attached audit report would be processed and tracked daily, such that we should have an accurate account of the number of stores with product. The processing of the actual product will likely conclude later this month.

Please call with any questions.

Thank you!

lv.

-----Original Message-----

**From:** Small, Rob [mailto:Rob.Small@lnmar.com]  
**Sent:** Wednesday, April 01, 2009 1:14 PM  
**To:** Vandermolen, Lily [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; Harper, Amanda; Figus, Daniel [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy  
**Subject:** Re: Lot Number Info

Understood. That's perfect, thank you.

Sent from my mobile device.  
 Rob Small

On Apr 1, 2009, at 12:52 PM, "Vandermolen, Lily [MCCUS]" <LVanderm@its.jnj.com> wrote:

Team,

This should not be an issue. Auditors should BUY ALL Motrin 8ct Vial product in the store. There were only 2 lots used to produce the product and these are the 2 lots we've highlighted. No need to look for lot codes until after they've left the store. We're just asking the team to indicate on the form how much of each lot was purchased as the FDA will want counts in case we do end up having to do a recall. The product will be processed and tracked accordingly, but it'll be good to have another data point to compare to for final reporting.

Still tracking down approvals on the documents. We are working hard to get this back to the team today so we can stay on track to an 4/15 completion.

Please let me know if you have any other questions.  
 Thanks,  
 lv.

-----Original Message-----

**From:** Small, Rob [<mailto:Rob.Small@inmar.com>]

**Sent:** Wednesday, April 01, 2009 12:21 PM

**To:** Parziale, Carolyn [MCCUS]; Harper, Amanda

**Cc:** Figus, Daniel [MCCUS]; Vandermolén, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy

**Subject:** RE: Lot Number Info

This adds a new dynamic that we need to discuss. If the product is in dispensers we will have to remove all of the products and physically review them. This will take time and may draw suspicion to what we are doing.

Some stores will not care, others will ask specifically what we are doing. Initially we were going to buy all products as mystery shoppers. We will need to clarify to the field what the response will be if the store asks questions as we are reviewing products searching for specific lot codes.

Some typical responses:

"We are looking at packaging changes/conditions of the product and will be purchasing some samples."

"We are conducting random quality and/or packaging checks."

Thanks

**Rob W. Small**

Director of Field Operations & Transportation

<image001.jpg>

Inmar

CI.S Supply Chain Services

2601 Pilgrim Court

Winston-Salem, NC 27106

O: 336-631-7647

C: 336-416-5496

[rob.small@inmar.com](mailto:rob.small@inmar.com)

<http://www.inmar.com>

*Please consider the environment before printing this email.*

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**From:** Parziale, Carolyn [MCCUS] [<mailto:CParzia@lts.lni.com>]

**Sent:** Wednesday, April 01, 2009 12:01 PM

**To:** Harper, Amanda

**Cc:** Figus, Daniel [MCCUS]; Vandermolén, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley;

Barnes, Amy; Small, Rob  
**Subject:** RE: Lot Number Info

Amanda,

Only the 2 effected lots should be purchased.

Carolyn

-----Original Message-----

**From:** Harper, Amanda [<mailto:Amanda.Harper@inmar.com>]  
**Sent:** Wednesday, April 01, 2009 11:44 AM  
**To:** Parziale, Carolyn [MCCUS]  
**Cc:** Ficus, Daniel [MCCUS]; Vandermolen, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy; Small, Rob  
**Subject:** RE: Lot Number Info

Thank you, Carolyn.

One more clarification. When our Field Agents go into the stores, they are to purchase all of the product fitting the description given in the form or are they only to purchase the two specified lots?

Also, wanted to let the team know I will be out of the office after 1 today. Please send any updates to Ashley Kerman, Rob Small, and myself so that we can ensure everything is covered with no delay.

Thanks again!

Amanda

Amanda Harper

Client Development Manager

<image001.jpg>

CLS Reverse Logistics

2601 Pilgrim Court

Winston-Salem, NC 27106

336-631-7619 (p)

336-407-3327 (cp)

336-770-1939 (f)

[amanda.harper@inmar.com](mailto:amanda.harper@inmar.com)

<http://www.inmar.com>

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**From:** Parziale, Carolyn [MCCUS] [mailto:CParzia@its.ini.com]  
**Sent:** Wednesday, April 01, 2009 11:28 AM  
**To:** Harper, Amanda  
**CC:** Figus, Daniel [MCCUS]; Vandermolen, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kernan, Ashley; Barnes, Amy; Small, Rob  
**Subject:** Lot Number Info

Amanda,

I received your voice mail and the folks from Mkt are actively working towards the Legal approval.

The lot numbers for the materials are SHC003 & SHC004.

Lily will send the final format for the checklist I don't have the final version at this moment.

Carolyn

\*\*\*\*\*  
The information contained in this e-mail is privileged and confidential information intended only for the use of the individual or entity to which it is addressed. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, copy or taking action in reliance upon this e-mail is strictly prohibited. If you have received this e-mail in error, please immediately notify the sender and then delete this e-mail in its entirety.  
\*\*\*\*\*

CONFIDENTIAL  
AI0000266



McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034

April 1, 2009

TO: Inmar Field Analysts

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. is requesting a store audit for the following product:

<u>Product Code #</u>	<u>UPC #</u>	<u>Lot #'s</u>	<u>Product</u>
48168	300450481689	SHC003 and SCH004	MOTRIN® IB Caplet 8ct Vial

A listing of stores to audit is attached. This audit should begin as soon as possible and be complete by Friday, April 10, 2009. Please refer to the Product Purchase & Ship Instructions attached to this letter for all required information and instructions. It is not necessary to alert the stores of the audit. Do not communicate to store personnel any information about this product. Simply visit each store, locate the product and, if any is found, purchase all of the product.

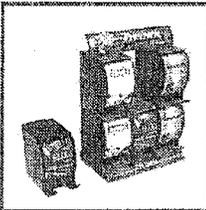
It is not necessary to check for any other product. Only the product code and lots indicated above.

If you have any questions, please contact your Inmar Representative, Amanda Harper at (336) 631-7619 or (336) 407-3327.

Thank you for handling.

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

CONFIDENTIAL  
AI0000267

<small>Field Analyst Name:</small>	<small>Location Name:</small>	<small>Time of visit:</small>
<small>Address:</small>		<small>City, State, Zip:</small>
<b>Product Purchase &amp; Ship Instructions</b>		
<p>1. Locate and purchase <b>ALL</b> MOTRIN® IB Caplet 8ct Vial products. (see pictures/details below)  <b>UPC # 300450481689</b> from lots SHC003 and SHC004,  <b>are the ONLY products you are to purchase.</b></p> <p>2. <b>DO NOT</b> communicate to store personnel any information about this product. Just purchase all available product. If you are questioned by store personnel, simply advise that you have been asked to perform an audit and refer them to Amanda Harper at (336) 831-7619.</p> <p>3. Save receipt from your purchase and submit with your expense report. Send a copy of the receipt from each store back with this report to Josh Brown in the Winston-Salem office. Email a copy of this report to Josh within 24 hours of visit.</p> <p>4. Send another copy of this report with your shipment. Send to:</p> <p style="margin-left: 40px;">CLS          10400 Marina Drive          Suite 115          Olive Branch, MS 38554          P: 662-690-7985</p> <p>5. You may place multiple location envelopes in a shipping box, just be sure to place reports and location contents into separate bags or envelopes inside of box.</p> <p>6. Ship via &lt;&lt;Carrier Name&gt;&gt; using account number &lt;&lt;Account Number&gt;&gt;.</p> <p>7. Be sure to place RMA # XXXXXXX clearly on the outside of the shipping container.</p> <p>8. Complete the following:</p> <p><input type="checkbox"/> We have checked for stock of MOTRIN® IB Caplet 8ct Vials -- product code 48168, UPC # 300450481689, lots SHC003 and SHC004.</p> <p><input type="checkbox"/> We did not find any MOTRIN® IB Caplet 8ct Vials -- product code 48168, UPC # 300450481689, lots SHC003 and SHC004.</p> <p><input type="checkbox"/> We purchased the following number of packages of MOTRIN® IB Caplet 8ct Vials, product code 48168, UPC # 300450481689 accordingly:</p> <p style="margin-left: 40px;">Lot SHC003 _____ (# of packages)      Lot SHC004 _____ (# of packages)</p>		
<div style="display: flex; justify-content: space-around;"> <div style="text-align: center;">  <p><small>Product Code 48168, UPC # 300450481689 ONLY</small></p> </div> <div style="text-align: center;">  <p><small>DISPLAY EXAMPLES</small></p> </div> </div>		
<small>Incar Field Analyst Signature:</small>		<small>DATE:</small>

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Formatted: Bullets and Numbering

**Joyner, Sarah**

**From:** Joyner, Sarah  
**Sent:** Monday, April 27, 2009 8:54 AM  
**To:** 'Parziale, Carolyn [MCCUS]'  
**Cc:** Kerman, Ashley; Barnes, Amy; Huggins, Terri; Vandermolten, Lily [MCCUS]; Atkins, Sara; Harper, Amanda  
**Subject:** RE: J&J Motrin update  
**Attachments:** J&J Field Store list.xls

Here is the spreadsheet with the store added that replaced one that was closed. It is the last line on the spreadsheet.

Final totals are:

- 595 units were purchased.
- o 238 Units - SHC003
  - o 40 Units - SHC004
  - o 317 Units - SHC002 & SHC042 (Other Lots)

Thanks and have a great day!

**Sarah G. Joyner**  
 Manager-Recall Services



Inmar  
 CLS Reverse Logistics  
 2501 Pilgrim Court  
 Winston-Salem, NC 27106  
 Phone: 336.631.7738  
 Fax: 336.499.8601  
 Email: [sarah.joyner@inmar.com](mailto:sarah.joyner@inmar.com)  
*Please consider the environment before printing this email.*

**From:** Parziale, Carolyn [MCCUS] [mailto:CParzia@its.jnj.com]  
**Sent:** Thursday, April 16, 2009 1:23 PM  
**To:** Joyner, Sarah  
**Cc:** Kerman, Ashley; Barnes, Amy; Huggins, Terri; Vandermolten, Lily [MCCUS]; Atkins, Sara; Harper, Amanda  
**Subject:** RE: J&J Motrin update

Sarah,  
 Yes, please add it, thanks!  
 Carolyn

-----Original Message-----  
**From:** Joyner, Sarah [mailto:Sarah.Joyner@inmar.com]  
**Sent:** Thursday, April 16, 2009 12:13 PM  
**To:** Vandermolten, Lily [MCCUS]; Parziale, Carolyn [MCCUS]

**CONFIDENTIAL**  
**AI0000481**

Cc: Kerman, Ashley; Barnes, Amy; Huggins, Terri; Atkins, Sara; Harper, Amanda  
Subject: J&J Motrin update

Hi Lily and Carolyn,

Attached please find the most recent update for the Motrin site visit project. Below is a brief summary to date:

The Field Staff has completed 250 of 250 visits. (100% Complete)  
1 of the stores in Colorado could not be found. See comments highlighted in yellow on the spreadsheet. The Field Rep substituted with another store but I do not have the form yet to include the details. Once we get that form, do you want us to add it to the spreadsheet?

- 583 units have been purchased.
- o 226 Units - SHC003
  - o 40 Units - SHC004
  - o 317 Units - SHC002 & SHC042 (Other Lots)

Please let us know if you have questions or concerns.

---

**Sarah G. Joyner**  
Manager-Recall Services



Inmar  
CLS Reverse Logistics  
2601 Pilgrim Court  
Winston-Salem, NC 27106  
Phone: 336.631.7738  
Fax: 336.499.8601  
Email: [sarah.joyner@inmar.com](mailto:sarah.joyner@inmar.com)

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.....

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.....

Mr. WELDON. Yes, it does, sir. May I offer some thoughts on this?  
Chairman TOWNS. Delighted.

Mr. WELDON. I think your comments are absolutely accurate and correct. And I think this is one of the areas where we have benefited by the guidance of the committee. If you look at the document in March, we were notifying the FDA that we were going to go and audit stores. When we went out in April, April 1st, I think it was, to your reference, we audited stores and also purchased product.

April 21st, I think we notified the FDA of exactly what we had done and what we were planning on doing and completing this by July 15th, I think it was. Unfortunately, we did not notify the FDA that we would be purchasing this product. That was a mistake we made. We firmly admit that. We also hope that people would understand that if we went into an account and there was a minimal amount of product there, and it did not present a safety hazard to anybody, but actually did not dissolve and give pain as quickly as we would like it to have been, as it should have, we would take that product off the market.

We made a mistake. We should have notified them that we would be taking these products, if it was small amounts, off the shelves. So you are absolutely correct that we made a mistake. But we feel we did keep people informed as to the actions we were taking.

Chairman TOWNS. Thank you very much. I really appreciate your explanation.

Ms. Goggins, when you testified before this committee 4 months ago, you indicated that Johnson & Johnson did not intend to hide anything about the phantom recall, and that Johnson & Johnson did not know what the phantom contractors were doing.

You also said that the affected Motrin was sparsely distributed. However, we now have documents that show McNeil wrote instructions for the phantom recall. And it is clear that McNeil's executives were fully aware of the phantom recall while it was going on.

We also know that the phantom recall was not sparse, because it involved at least 40 States. Can you explain this discrepancy?

[The information referred to follows:]

2801 Mr. CUMMINGS. And when do you expect that to reopen?

2802 Ms. GOGGINS. I don't know, sir. What I can tell you is  
2803 that we will not reopen that plant until we meet our own and  
2804 the public's and the FDA's standards for high quality and  
2805 safety.

2806 Mr. CUMMINGS. Thank you very much.

2807 Thank you, Mr. Chairman.

2808 Chairman TOWNS. Thank you very much. I thank the  
2809 gentleman from Maryland.

2810 I want to, Ms. Goggins, go back to this contractor  
2811 business. Now, the contractors, what were they contracted to  
2812 do and who contracted them? Explain all this to me, because  
2813 it is just not clear to me.

2814 Ms. GOGGINS. I can tell you what I know, and then I  
2815 promise you I will come back to you with more information.  
2816 The product in question is sparsely distributed, as I  
2817 understand it, primarily in gas stations. So I think the  
2818 idea was to go in and identify how much product there was on  
2819 the shelves. But beyond that, I don't know, sir. We did  
2820 contract them, but, as I said, I am told that we contracted  
2821 them in discussions and with the knowledge of the San Juan  
2822 office of the FDA.

2823 Chairman TOWNS. So I guess what I am saying, were they  
2824 instructed to go out and buy if they found--

2825 Ms. GOGGINS. I can't answer that, sir, nor can I answer

2826 the question of what they are alleged to have said. I don't  
2827 know the answers to that.

2828 Chairman TOWNS. Well, I would like for you to get back  
2829 to us on that, because these contractors, I just find this  
2830 very disturbing.

2831 Ms. GOGGINS. As do I.

2832 Chairman TOWNS. Okay. So, in other words, you don't  
2833 know who actually contracted them or what their role and  
2834 responsibility was? You don't know any of that at this time?

2835 Ms. GOGGINS. I know only that I imagine we contracted  
2836 them, sir, and we did so, as I am told, with the knowledge of  
2837 the FDA.

2838 Chairman TOWNS. Were they instructed to do certain  
2839 things?

2840 Ms. GOGGINS. I can't tell you right now what they were  
2841 instructed to do or not, sir.

2842 Chairman TOWNS. The quality control, do you have the  
2843 same amount of people in the quality control unit today as  
2844 you had four years ago or three years ago or eight years ago?  
2845 What is the situation with quality control?

2846 Ms. GOGGINS. I believe that, at the Fort Washington  
2847 plant, our headcount is basically flat. I do know that  
2848 between 2006 and 2009 we increased our spending 17 percent,  
2849 and I know that we have increased it again this year.

2850 Chairman TOWNS. This document, that was actually just

2247 extensively; we take samples from the beginning, the middle,  
2248 and the end of manufacturing, and we make sure they are  
2249 within specification. They were. We released them to the  
2250 marketplace. When the FDA raised its concerns, we tested the  
2251 last batch which we had in our possession. We actually  
2252 tested 1,200 bottles, and not one of the 1,200 bottles was  
2253 over the specified amount of active ingredient.

2254 Chairman TOWNS. So was that a yes or no?

2255 Ms. GOGGINS. I am sorry. That is that no product with  
2256 excess acetaminophen entered the marketplace, to the best of  
2257 our knowledge in testing.

2258 Chairman TOWNS. But it was actually found in the  
2259 medicine, so that would be a yes.

2260 Ms. GOGGINS. It was found, but it was rejected, sir. It  
2261 never reached the marketplace.

2262 Chairman TOWNS. Would you agree that these quality  
2263 control issues are totally unacceptable?

2264 Ms. GOGGINS. I would absolutely agree with that, yes,  
2265 sir.

2266 Chairman TOWNS. Did you have contractors go back to  
2267 stores and buy medicine, instead of recalling the medicine?

2268 Ms. GOGGINS. Let me explain that, sir. I think it is  
2269 very important. There has been a lot of misinformation about  
2270 the entirety of this recall, and I am glad you raise that  
2271 issue right now, because I think there is misperceptions.

2272 We did have a Motrin dissolution issue in 2009. It was  
2273 for a small product that was distributed in gasoline  
2274 stations. We discussed with the San Juan district of the FDA  
2275 this issue. We talked to them about hiring a third-party  
2276 contractor to go to see the breadth of the distribution of  
2277 these products. So we were in discussions with them. They  
2278 knew that we had hired this third party, and the third party  
2279 did go out to make an inventory, and we discussed that with  
2280 the San Juan office of the FDA. So there was never any  
2281 intent to mislead or hide anything from anyone.

2282 Chairman TOWNS. So the San Juan office of the FDA were  
2283 aware of the fact that you were going out to purchase--

2284 Ms. GOGGINS. That is correct, sir. We were in  
2285 discussions with them.

2286 Chairman TOWNS. Let me make sure that I understand. Now,  
2287 you went out and you purchased them, but the FDA was aware of  
2288 the fact that you were going to do it?

2289 Ms. GOGGINS. Let me see if I can explain what happened.

2290 Chairman TOWNS. Yes, help me.

2291 Ms. GOGGINS. We had a Motrin product where the  
2292 dissolution profile, or how it is solubilized, wasn't in  
2293 specification. It is a small product; it sold primarily in  
2294 gas stations. We discussed this issue with the San Juan  
2295 office of the FDA and we agreed or we offered to have a  
2296 contract force go out and identify how much of this was in

2297 the marketplace. The FDA was aware that we were doing that  
2298 in San Juan and we did that. I can't tell you about the  
2299 behavior of these contractors in the market or what they said  
2300 or didn't say or how they acted, but clearly FDA was aware of  
2301 this and there was no intent, obviously, to mislead or hide  
2302 anything.

2303 Chairman TOWNS. In other words, for the contractors to  
2304 go in and say do not mention the fact that this is a recall?  
2305 You know nothing about any of that?

2306 Ms. GOGGINS. I know nothing about that, sir. I know  
2307 only that we were in discussions with the FDA in San Juan  
2308 over the product issue and how we were planning to handle it  
2309 with a third-party contractor.

2310 Chairman TOWNS. Do you have any kind of documents or  
2311 anything that might be able to confirm what you are saying?  
2312 Because the FDA is saying that they learned of this later on.  
2313 If you were in discussions with them, why wouldn't they know  
2314 it immediately?

2315 Ms. GOGGINS. Chairman Towns, I can't answer that  
2316 question. What I can do is I promise you to get back to you  
2317 with the kind of documentation what we have regarding this  
2318 issue. In fact, I would welcome the opportunity.

2319 Chairman TOWNS. Well, I would like for you to do that  
2320 for me because--

2321 Ms. GOGGINS. I would be happy to.

**Harper, Amanda**

**From:** Vandermolen, Lily [MCCUS] [LVanderm@its.inj.com]  
**Sent:** Wednesday, April 01, 2009 2:56 PM  
**To:** Small, Rob  
**Cc:** Parziale, Carolyn [MCCUS]; Harper, Amanda; Figus, Daniel [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy; Davey, Frank [MCCUS]; Degen, Jenna [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** RE: Lot Number Info  
**Attachments:** Motrin Vial Audit Letter.docx; PRODUCT PURCHSHIP FORM.docx

Team,

Attached are the final, approved documents for the audit. Please distribute both documents to your field team ASAP.

The goal is to meet the 4/15 drop dead date to report back to the FDA on our audit and sales data findings. Per offline conversations, in-store audits should be complete by that time and reporting of the attached audit report would be processed and tracked daily, such that we should have an accurate account of the number of stores with product. The processing of the actual product will likely conclude later this month.

Please call with any questions.

Thank you!  
 lv.

-----Original Message-----

**From:** Small, Rob [mailto:Rob.Small@intrmar.com]  
**Sent:** Wednesday, April 01, 2009 1:14 PM  
**To:** Vandermolen, Lily [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; Harper, Amanda; Figus, Daniel [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy  
**Subject:** Re: Lot Number Info

Understood. That's perfect, thank you.

Sent from my mobile device.  
 Rob Small

On Apr 1, 2009, at 12:52 PM, "Vandermolen, Lily [MCCUS]" <LVanderm@its.inj.com> wrote:

Team,

This should not be an issue. Auditors should BUY ALL Motrin 8ct Vial product in the store. There were only 2 lots used to produce the product and these are the 2 lots we've highlighted. No need to look for lot codes until after they've left the store. We're just asking the team to indicate on the form how much of each lot was purchased as the FDA will want counts in case we do end up having to do a recall. The product will be processed and tracked accordingly, but it'll be good to have another data point to compare to for final reporting.

Still tracking down approvals on the documents. We are working hard to get this back to the team today so we can stay on track to an 4/15 completion.

Please let me know if you have any other questions.  
 Thanks,  
 lv.

-----Original Message-----

**From:** Small, Rob [<mailto:Rob.Small@inmar.com>]

**Sent:** Wednesday, April 01, 2009 12:21 PM

**To:** Parziale, Carolyn [MCCUS]; Harper, Amanda

**Cc:** Figus, Daniel [MCCUS]; Vandermolen, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kernan, Ashley; Barnes, Amy

**Subject:** RE: Lot Number Info

This adds a new dynamic that we need to discuss. If the product is in dispensers we will have to remove all of the products and physically review them. This will take time and may draw suspicion to what we are doing.

Some stores will not care, others will ask specifically what we are doing. Initially we were going to buy all products as mystery shoppers. We will need to clarify to the field what the response will be if the store asks questions as we are reviewing products searching for specific lot codes.

Some typical responses:

"We are looking at packaging changes/conditions of the product and will be purchasing some samples."

"We are conducting random quality and/or packaging checks."

Thanks

**Rob W. Small**

Director of Field Operations & Transportation

<image001.jpg>

inmar

CI.S Supply Chain Services

2601 Pilgrim Court

Winston-Salem, NC 27106

O: 336-631-7847

C: 336-416-5496

[rob.small@inmar.com](mailto:rob.small@inmar.com)

<http://www.inmar.com>

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---

**From:** Parziale, Carolyn [MCCUS] [<mailto:CParzia@lts.lni.com>]

**Sent:** Wednesday, April 01, 2009 12:01 PM

**To:** Harper, Amanda

**Cc:** Figus, Daniel [MCCUS]; Vandermolen, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kernan, Ashley;

Barnes, Amy; Small, Rob  
**Subject:** RE: Lot Number Info

Amanda,

Only the 2 effected lots should be purchased.

Carolyn

-----Original Message-----

**From:** Harper, Amanda [<mailto:Amanda.Harper@inmar.com>]  
**Sent:** Wednesday, April 01, 2009 11:44 AM  
**To:** Parziale, Carolyn [MCCUS]  
**Cc:** Figus, Daniel [MCCUS]; Vandermolten, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kerman, Ashley; Barnes, Amy; Small, Rob  
**Subject:** RE: Lot Number Info

Thank you, Carolyn.

One more clarification. When our Field Agents go into the stores, they are to purchase all of the product fitting the description given in the form or are they only to purchase the two specified lots?

Also, wanted to let the team know I will be out of the office after 1 today. Please send any updates to Ashley Kerman, Rob Small, and myself so that we can ensure everything is covered with no delay.

Thanks again!

Amanda

Amanda Harper

Client Development Manager

<image001.jpg>

CLS Reverse Logistics

2601 Pilgrim Court

Winston-Salem, NC 27106

336-631-7619 (p)

336-407-3327 (cp)

336-770-1939 (f)

[amanda.harper@inmar.com](mailto:amanda.harper@inmar.com)

<http://www.inmar.com>

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**From:** Parziale, Carolyn [MCCUS] [mailto:CParzia@its.ini.com]  
**Sent:** Wednesday, April 01, 2009 11:28 AM  
**To:** Harper, Amanda  
**Cc:** Figus, Daniel [MCCUS]; Vandermolen, Lily [MCCUS]; Martina, Aubrey [MCCUS]; Kermañ, Ashley; Barnes, Amy; Small, Rob  
**Subject:** Lot Number Info

Amanda,

I received your voice mail and the folks from Mkt are actively working towards the Legal approval.

The lot numbers for the materials are SHC003 & SHC004.

Lily will send the final format for the checklist I don't have the final version at this moment.

Carolyn

.....  
The information contained in this e-mail is privileged and confidential information intended only for the use of the individual or entity to which it is addressed. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, copy or taking action in reliance upon this email is strictly prohibited. If you have received this e-mail in error, please immediately notify the sender and then delete this e-mail in its entirety.  
.....



McNeil Consumer Healthcare, 7050 Camp Hill Road, Fort Washington, PA 19034

April 1, 2009

TO: Inmar Field Analysts

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc. is requesting a store audit for the following product:

<u>Product Code #</u>	<u>UPC #</u>	<u>Lot #s</u>	<u>Product</u>
48168	300450481689	SHC003 and SCH004	MOTRIN® IB Caplet 8ct Vial

A listing of stores to audit is attached. This audit should begin as soon as possible and be complete by Friday, April 10, 2009. Please refer to the Product Purchase & Ship Instructions attached to this letter for all required information and instructions. It is not necessary to alert the stores of the audit. Do not communicate to store personnel any information about this product. Simply visit each store, locate the product and, if any is found, purchase all of the product.

It is not necessary to check for any other product. Only the product code and lots indicated above.

If you have any questions, please contact your Inmar Representative, Amanda Harper at (336) 631-7619 or (336) 407-3327.

Thank you for handling.

McNeil Consumer Healthcare Division of McNEIL-PPC, Inc.

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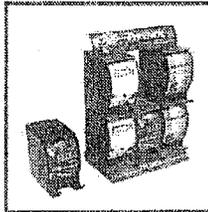
Field Analyst Name:	Location Name:	Time of visit:
Address:		City, State, Zip:
<b>Product Purchase &amp; Ship Instructions</b>		
<p>1. Locate and purchase <u>ALL</u> MOTRIN® IB Caplet 8ct Vial products. (see pictures/details below)  <b>UPC # 300450481889 from lots SHC003 and SHC004,</b>  <b>are the ONLY products you are to purchase.</b></p> <p>2. <b>DO NOT</b> communicate to store personnel any information about this product. Just purchase all available product. If you are questioned by store personnel, simply advise that you have been asked to perform an audit and refer them to Amanda Harper at (336) 831-7619.</p> <p>3. Save receipt from your purchase and submit with your expense report. Send a copy of the receipt from each store back with this report to Josh Brown in the Winston-Salem office. Email a copy of this report to Josh within 24 hours of visit.</p> <p>4. Send another copy of this report with your shipment. Send to:</p> <p style="padding-left: 40px;">C.I.S.          10400 Marina Drive          Suite 115          Olive Branch, MS 38654          P: 662-890-7985</p> <p>5. You may place multiple location envelopes in a shipping box, just be sure to place reports and location contents into separate bags or envelopes inside of box.</p> <p>6. Ship via &lt;&lt;Carrier Name&gt;&gt; using account number &lt;&lt;Account Number&gt;&gt;.</p> <p>7. Be sure to place RMA # XXXXXXX clearly on the outside of the shipping container.</p> <p>8. <u>Complete the following:</u></p> <p><input type="checkbox"/> We have checked for stock of MOTRIN® IB Caplet 8ct Vials -- product code 48188, UPC # 300450481889, lots SHC003 and SHC004.</p> <p><input type="checkbox"/> We did not find any MOTRIN® IB Caplet 8ct Vials -- product code 48188, UPC # 300450481889, lots SHC003 and SHC004.</p> <p><input type="checkbox"/> We purchased the following number of packages of MOTRIN® IB Caplet 8ct Vials, product code 48188, UPC # 300450481889 accordingly:</p> <p>Lot SHC003 _____ (# of packages)      Lot SHC004 _____ (# of packages)</p>		

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Product Code 48188; UPC # 300450481889 ONLY



DISPLAY EXAMPLES

Team Field Analyst Signature:	DATE:
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Ms. GOGGINS. I am sorry, sir, it contained at least 46, you said?  
Chairman TOWNS. Forty States.

Ms. GOGGINS. Forty States, I am sorry, thank you. When I testified in May, sir, what I was aware of at the time was, as I said, we verified that the FDA was aware that we were as of, the SN1 office of the FDA was aware that we had hired contractors and we were going into stores and we were retrieving product. We have since determined that was since the April 21st filing of the field alert report.

At the time, I was not aware of any retrieval actions going on, I don't believe, and I had not seen any instructions to contractors until the excerpted instructions, I think, were exhibited that day during the hearing.

To Mr. Weldon's point, I think that we would agree that were we to do this over, we would certainly be more transparent, particular with the store personnel. But I don't believe there was ever any intent to mislead or deceive the FDA, sir.

Chairman TOWNS. When you say they were notified, what process did you use to do that?

Ms. GOGGINS. To the point that Mr. Weldon made, and I believe in our testimony, the FDA was notified by a field alert report submitted on April 21st. And I believe there was ongoing correspondence between that date and the agreed-to date for the termination of that work, which was July 15th.

Chairman TOWNS. Thank you very much. My time is expired.

I now yield 5 minutes to the gentleman from California, the ranking member, Congressman Issa.

Mr. ISSA. Thank you, Mr. Chairman.

I am going to continue along that line, because our documents appear to be again, a little different than what I am hearing. I have a McNeil document dated March 23, 2009, to Ms. Torres. But very clearly it says, "attached please find the third followup to the field alert report for Motrin caplets submitted November 26, 2008."

So now, really, the FDA was well informed November 26, 2008, is that correct?

Ms. GOGGINS. Yes, the first field alert report was filed in November 2008.

Mr. ISSA. So let's put it in perspective, Mr. Weldon had said. There was a stealth recall, phantom recall, remaining product purchased back because it was less than effective as prescribed. And I understand that's just as good a reason to get something off the market as anything else. But it was not something that you took it and you were poisoned, you took it and you were hurt. But you took it and your headache didn't go away, right? That is pretty much it. OK.

So this product that the FDA is aware doesn't work, dissolve, do its job properly, the FDA is aware of it November 26th. So you have pieces of November, all of December, all of January, all of February, almost all of March. And then in April, March, April, the product is actually removed.

So in retrospect, one, it should have been removed quicker once you knew it didn't work. Two, Mr. Weldon, you have already said, and so have you, Ms. Goggins, that if you had to do it over again, you would do it in a more general recall way. But I am trying to

understand why the FDA was so slow in going through to make a decision and why, in earlier testimony, they sort of say, well, we didn't find out, we didn't know, when in fact they knew for month after month and emails show that there was dialog.

I am going to ask you two a tough question. Because although I am very disappointed in Johnson & Johnson, I said it in the first hearing, I say it again, this is not what we expected from a company with your history. But it happened. You didn't do your job well in a number of quality areas.

Let me ask you, is your relationship ordinarily supposed to be so cozy as to have months of discussion and informal back-channel and then be allowed to have, if you will, an undocumented recall? Is that what should be happening? Is that what we should expect from the FDA or tolerate? Both of you, please.

Mr. WELDON. Congressman Issa, I think my response to that would be that, I asked the same question about our organization. Is there a way we could do this faster? It seemed like exactly the same question you are asking, it seemed like it took a protracted period of time. And I think in the future, we try and accelerate that, to see if we can do it faster, to get the product off the market.

As far as relationships and things like that, I think it is important that there is dialog between the FDA, in this case, and our company to ensure that we are doing the right thing. So I can't comment exactly on the discussions that went on, or the relationship. But I think it is very important and very normal that there would be a dialog before action is taken.

Mr. ISSA. I am going to followup with another question, because you can never take a CEO out, once he has been one. When I looked at your reorganization, your July plan, I begged two questions. First of all, you have single line accountability from quality to quality to you. Should have been that way to begin with.

But in our research, there was a period of time at McNeil where they were clearly trying to cost down QC. Today, who controls the decision of how much money the QC portion of any of your companies can spend? In other words, who is responsible for making sure they are fully funded and not part of an edict to lower costs?

Mr. WELDON. Congressman, respectfully, I would like to maybe clarify one point. We have gone back and looked at the period between 2006 and 2009. And at best, the cost on quality at McNeil were flat. Actually, they increased during that period of time. And the head count was constant also. There was not a reduction.

Mr. ISSA. That came out in the first hearing. What I am looking at is in your plan going forward. Because our responsibility is to fix the FDA going forward, but it is also to have confidence in companies like yours. Who determines if there are sufficient funds today? Does a plant manager, a division CEO, chief operating officer, chief financial officer? If the quality control people do not believe they have the resources, whether it is a new tool, advanced technology in the production line or actual personnel, how is that done today so that we can know that those cost efficiencies are not being looked at by somebody far away and too many chains between them?

Mr. WELDON. Yes, sir, that would be determined by the quality people directly to the individual who reports to me and myself. And

we have let it be known that we will not get in the way of cost. We want to make sure we are investing appropriately in quality and that decision will be made directly up to and including myself.

Mr. ISSA. OK, and then if you can, quickly, Fort Washington, when it reopens, tell me how it is going to be different, different in a way that the American people can believe in product that eventually comes from there.

Mr. WELDON. Sir, I would like to say we are working closely with the FDA, external consultants and our own people to invest, as I mentioned, \$100 million across the McNeil facilities. We are going to make that the start of the art facility. It will not be opened up until we are sure it is state-of-the-art. I would like to say it will be the best in the world. That is what we would like it to be.

But I guarantee it will be state-of-the-art and people can have the highest degree of confidence. We will not ship a product out of there until we have been able to satisfy the expectations of the people who will use our products.

Mr. ISSA. Thank you. Thank you, Mr. Chairman.

Chairman TOWNS. I recognize the gentleman from Maryland for 5 minutes.

Mr. CUMMINGS. Mr. Weldon, on August 19th, in an online article in Fortune Magazine suggested that McNeil had exceptional quality control measures until 2002, the year you assumed the position of chairman and chief executive officer. The article suggests that the cost-cutting had a significant impact on the quality control staff and procedures across the company. Are you familiar with that article?

Mr. WELDON. Yes, sir.

Mr. CUMMINGS. Further, the article is critical of your ability to manage the consumer products business we are discussing today. Is it possible that cost-cutting contributed to the culture that created the quality issues?

Mr. WELDON. Sir, I do not believe the cost-cutting contributed to this.

Mr. CUMMINGS. Well, do you think the cost-cutting, do you think the cost-cutting culture may have inadvertently created a situation in which phantom recalls and processes that did not put consumer safety first could occur?

Mr. WELDON. No, sir. Could I elaborate on that?

Mr. CUMMINGS. I only have 5 minutes. I do want you to answer, though, briefly.

Mr. WELDON. OK, I said no, sir, I do not believe, I do not believe that cost-cutting nor financials were put ahead of the quality for patients at any of our facilities.

Mr. CUMMINGS. Mr. Weldon, in your testimony you stated that McNeil believed that the phantom recall was an expeditious way to remove the remaining caplets from the convenience store shelves. If the product was not good enough or safe enough to sell, why would it be good enough for consumers to keep it in their homes, in their medicine cabinets?

Mr. WELDON. Sir, first of all, I think we had looked at this closely and determined there was no risk, no safety hazard, no risk to patients who consumed these products. We thought it was a way to expeditiously get the product out of the market. And I think it

was in May that we sent a letter to the customers, notifying them of this action and telling them that we wanted to remove the products that were in the facilities.

Mr. CUMMINGS. Why do you think they conducted this phantom recall?

Mr. WELDON. Sir, that I can't address. I would not quite characterize it that way. But I do believe that we kept people informed. I think that we just talked about the document in April, in March saying that we were going to be acquiring or retrieving the product during that period of time.

But shortly thereafter, we notified the FDA of our actions, our intent, and that we would have this product off the market in July. And we executed against that plan.

Mr. CUMMINGS. I notice that Mr. Issa spent some time I guess sort of halfway complimenting you on making changes. I think Ms. Goggins talked about changes that you all had made. And you have made some significant changes, have you not?

Mr. WELDON. Yes, sir, and I think it is the guidance of the committee that has helped us see some of the changes and some of the issues that we really did need to make at the Fort Washington facility. And we have taken it beyond that to help ensure that we have actually learned and grown and continue to learn across Johnson & Johnson.

Mr. CUMMINGS. Well, let me ask you this question about how much you have learned and grown. Mr. Weldon, both you and Ms. Goggins have stated that you have addressed the issues with McNeil Consumer Healthcare by changing the senior leadership. Yet Mr. Peter Luther, you know him?

Mr. WELDON. Yes, sir.

Mr. CUMMINGS. The current president of McNeil, remains in place. It seems disingenuous to suggest that you changed leadership to fix the problem, when key people involved in the decisions to conduct the phantom recall, and I know you don't call it a phantom recall, I call it a phantom recall, remain in place. Can you comment on whether Mr. Luther is competent to do what is needed to fix the problem, when he was involved in the problem originally?

Mr. WELDON. Yes, sir, and I do appreciate the way you refer to the recall. I appreciate that.

Mr. Luther has been a long-serving Johnson & Johnson employee. He has been a good employee for a very extended period of time. Mr. Luther also is very committed to improving and revamping the facility, and he is very committed to doing that. We are looking forward to the results of what he is doing. So yes, I think Peter Luther is a good employee who will contribute to rectifying this problem.

Mr. CUMMINGS. And so the same folk that were around when the problem took place, you then put it in their hands to fix the problem, is that it? And I think you said, in a very, very sincere way, that you were looking to get the public's trust. And we all know in order to get the public's trust, you need people in place that people trust, the consumers trust. To me, that doesn't make very much sense, and then put the person who was in charge when the problem came up back in charge. You follow me?

Mr. WELDON. Yes, I do, sir, and think we all, as I said, share accountability in this. I think that Mr. Luther was in charge, but I think that you can see that there were many changes that were taken that were in the quality area, the manufacturing area, to ensure that we have the best representation.

As I said, Mr. Luther has been a long-serving employee who has done a very good job for us. But he is also committed to and has been very instrumental in making sure that we are revamping and improving the facility. So I think there is accountability that is shared across the organization. I think that the players that we needed to replace have been replaced.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Chairman TOWNS. Thank you very much.

I now yield 5 minutes to the gentleman from Utah, Congressman Chaffetz.

Mr. CHAFFETZ. Thank you, Mr. Chairman.

Ms. Goggins, with the Motrin phantom or silent recall or retrieval, was it McNeil's understanding that until July 2009, the FDA was not requesting a recall? Is that correct?

Ms. GOGGINS. Yes, that is our understanding, sir.

Mr. CHAFFETZ. Had the FDA wanted or even suggested a recall at the time a problem was discovered, would you have issued a recall?

Ms. GOGGINS. In fact, I believe that the FDA told us in that time period that they wanted to classify our retrieval as a recall and we filed the forms almost immediately.

Mr. CHAFFETZ. What percentage of the product shipped was actually recalled? Do you have any idea?

Ms. GOGGINS. I am estimating it is about 1 percent of the product shipped was recalled, sir.

Mr. CHAFFETZ. Mr. Weldon, you said in your testimony that the right thing to do was an imperative for you. I am having a hard time with the directive from the CEO's office and the way you feel personally with what happened on the ground. Were any of the personnel fired, relieved of their duties, dismissed, demoted? What happened to all these employees that were involved here from your operation?

Mr. WELDON. I can't comment. I know some people have been relieved of their responsibilities and there are some new people in the facilities, yes. But I don't know all the direct information.

Mr. CHAFFETZ. Ms. Goggins.

Ms. GOGGINS. Yes, to elaborate on Mr. Weldon's point, we have a new, at McNeil we have a new head of manufacturing, we have a new head of quality. And the two largest plants that we have, our Las Piedras plant and our Fort Washington plant. We have new people both in manufacturing and—

Mr. CHAFFETZ. Was anybody fired?

Ms. GOGGINS. Yes. Yes, that is my point.

Mr. CHAFFETZ. Mr. Weldon, I believe you when you personally say you want to do the right thing. But I have a hard time rectifying what was actually happening on the ground within your organization. You said you wanted to take personal responsibility for it.

Let me read this excerpt from March 24, 2009 emails from Paul DePaulo, and pardon if I am mispronouncing these names, to Dan-

iel—I can't pronounce his last name, Fegas, I guess is his name. "The FDA is really bending the rules in this case, the Motrin caplet case, because of the fact that we stopped distribution a while ago." Doesn't that imply that there was some encouragement from Johnson & Johnson to bend the rules?

Mr. WELDON. Again, I can't directly know what was meant by that. It says, the email says exactly what it says. I think that what we are looking at here is the ability to dialog and make the right decisions.

Mr. CHAFFETZ. And you say that, but then when you say the FDA is really bending the rules, and that is coming from a Johnson & Johnson employee to another Johnson & Johnson employee, it doesn't look as if you are doing "the right thing" to do.

Let me read another email. "Regarding FDA documents," this is from Eddie Carillo to Carolyn Prezalli, again, I am slaughtering their names, "Regarding FDA documents, all my conversation with the FDA director, Ms. Torres, here in Puerto Rico, have been off the record, since I cannot quote her. This happens due to my good relationship with her, and that's why we are doing something very different."

Is that inappropriate mode of conduct? I mean, does this regularly happen above and beyond this one instance, where you are having off the record discussions? That the relationship is so cozy? Is this common practice? Is this something you condone? Is this an exception?

Mr. WELDON. No, we don't condone it, sir. I can't comment for the conversation that go on across the organization. What I can comment on is that we would like to have, and I think we have worked cooperative, and I think with the FDA, to ensure that we have a dialog to make sure that the right things are done for the patients and to make sure we are behaving in a proper way.

As far as being able to comment as to whether, on specific emails, no, sir, I can't comment on those.

Mr. CHAFFETZ. Help me understand, for the record, moving forward, Johnson & Johnson's commitment on what is the proper way.

Mr. WELDON. Johnson & Johnson's commitment on what is the proper way, to continue to dialog with the FDA and to ensure that we are looking out for the rights, for the best interests of patients. Sir, if I could elaborate for a little bit, I think that we try and establish ourselves, I think there is a reference that the chairman made earlier on to our credo. And our credo, our first responsibility is to the people who use our products. I stated, and I would state again that we have let them down. There is absolutely no doubt we let them down. This was not one of our best moments.

We are going to fix it, and improve up on it. And we are stressing, as I said also, I have gone out to our facilities, I have talked to our people and I have talked to our leadership to ensure that we continue to reinforce the responsibility we have to the people who use our products. There is absolutely nothing more important than ensuring the safety of our products and the quality of our products.

So going forward, we are committed to doing the right thing for patients.

Mr. CHAFFETZ. Thank you. And thank you, Mr. Chairman, my time is expired. I will yield back.

Chairman TOWNS. Thank you.

I now yield 5 minutes to the gentleman from Ohio, Congressman Kucinich.

Mr. KUCINICH. Thank you very much, Mr. Chairman.

The committee has documents that demonstrate that on September 18, 2009, there was a letter to health care professionals, like physicians, explaining the recall of children's and infants' Tylenol. On the third line of the second paragraph of this particular document, B. cepacia is clearly mentioned. It mentions that children with underlying pulmonary disease, cystic fibrosis or compromised immune systems are at high risk.

Then there was another document dated September 24, 2009, just 6 days later, that describes the recall of children's and infants' Tylenol, it is from Tylenol.com, it is directed at the public. But there was no mention of B. cepacia and no mention of any conditions a child might have, like cystic fibrosis, that would make him more vulnerable.

Now, this would make sense, if a patient had to go to their doctor to get the medicine. But because a doctor would have a chance to convey the hazard to a patient, but this was an over the counter drug. Now, and apparently, they kept the public out of the loop.

So follow this pattern. We have McNeil knowing a product was defective, they kept it away from public knowledge. They hired phantom contractors who purchased the product but did not inform store personnel. As a matter of fact, their contractors were told, don't tell the store personnel. Inform the doctors, don't inform the public.

Mr. Chairman, what we have here, I think, is a pattern of concealment. Now, one of the things I am concerned about, with all due respect to Mr. Weldon, your testimony presentation has all the earmarks of coaching from the spin doctors who help corporate executives put a good face on misconduct. To say, OK, admit, throw yourself on the mercy of the court, we did wrong. But wait a minute. There is a pattern of concealment here. You can't call that pattern a mistake. A person can make a mistake once. But if you keep making the "mistake" over and over and over, then somebody has to ask, well, it is just the way you do business, or the way you did business.

Now, Ms. Goggins, I was present at your testimony the last time, and there is a transcript of your testimony. And I listened carefully when you said at the time of the hearing that you weren't aware of any retrieval actions. I have here a memo, which the chairman alluded to in his opening statement, which is to Gary Benedict, from Bob Miller. And listen to this memo.

"Gary, as you know, we've negotiated an agreement with the FDA not to formally conduct a recall for Motrin 8s, but rather conduct a 'soft market withdrawal.' This was a major win for us, as it limits the press that we'll be seeing. We had committed to FDA to complete this withdrawal by July 15th. There have been continuing issue trying to get a PO, purchase order, from the marketing group, which is now putting our ability to meet the July 15th timeframe in jeopardy. At the same time as we delay this work, the cost

to complete the work continues to increase because of the fact that the outside resource," that is the people involved in this recall, the phantom recallers, "will now need more resources to expedite the work. We cannot extend our commitment date to FDA. It is now estimated this will cost approximately \$400,000, which is approximately two times what was originally quoted."

And then Peter Luther has an answer here, he says, "Group, where is the miss here? Given our current financial situation, I hope we're not going to really double our costs to do this. Let's make this happen ASAP."

Now, Ms. Goggins, since you are the head of this consumer group, are you trying to lead this committee to believe that you knew nothing about it? Apparently, from this memo, there was widespread discussion within your organization about phantom recall, about the cost of the recall, about not being able to get cooperation from the marketing people. You are at the top of this group and you knew nothing about it? Really? I am not talking about what is on the record here. Are you saying that no one ever talked to you about it? Not only do you have no recollection, you are sure that no one talked to you about it?

Please help us.

Ms. GOGGINS. Yes, I will, thank you for the opportunity. As I said in my opening testimony—

Mr. KUCINICH. No, answer my question. Not your opening testimony. What is the answer to my question?

Ms. GOGGINS. I did not know at the time that I testified in May. I have since learned from looking at documents that there was a retrieval going on. I did not know that at the time of my testimony in May, I don't believe.

Mr. KUCINICH. Mr. Chairman, I have to tell you, this testimony is lacking in credibility in light of this particular document. Thank you, Mr. Chairman.

Chairman TOWNS. I now recognize the gentlelady from Washington, DC, Congresswoman Norton.

Ms. NORTON. Thank you, Mr. Chairman.

I have a question about children's medicine. We have a McNeil document that shows that a contaminant was discovered in April 2008. And another document that shows that more than 8 million bottles had been shipped starting in March 2008. So when you put these two documents together, doesn't this mean that although your company recalled 8 million bottles of the children's medicine in 2009, that the fact is that you had discovered the problem at least a year earlier in 2008?

Mr. WELDON. May I comment on that?

Ms. NORTON. Yes, Mr. Weldon, this is a question for you.

Mr. WELDON. Thank you.

I would like to maybe clarify the record in terms of what exactly took place. And we are talking about the B. cepacia, the potential bacterial contamination of the product. Just to maybe shed a little light on it, the way we manufacture our product is we order product from, let's say raw materials from suppliers, we then test those raw materials. We manufacture product, we test the product and then we release the product.

What happened in this case is we had done that and in a batch of raw materials that came from a supplier, we detected B. cepacia. We eliminated that from our manufacturing, we want to be clear that none of that was used in any product that was manufactured or left our facility.

We went back and checked for B. cepacia, we went back and checked the product. We wanted to make sure there was no risk as we saw to anybody that was there, anybody that would consume this product.

The following year, I think you said in 2009, the FDA came to inspect our facility. And they found exactly what we had done. And they said there could be a risk that there is B. cepacia in the product, in the product that was delivered that was gone out. We had never used, I want to be clear, we had never used the raw materials that had B. cepacia. We felt confident in the work we had done that there was no B. cepacia in the products that we released.

Ms. NORTON. Do you believe in 2008 that those 8 plus million bottles that had been shipped starting in 2009, which your own document says get consumed very quickly, that you believe that none of this contaminant made its way into those 8 million bottles?

Mr. WELDON. That is correct. Because the raw material that had B. cepacia we did not use to manufacture any product. We eliminated that.

The FDA's position, and in discussion we said fine, was that possibly there could have been in some product. So we recalled the product. But we were confident in the manufacturing process, the checks that we use, and then we have a thing called retain samples, where we take these and put them aside, of the products that are manufactured. We went and checked that, after we brought product back, we went and checked those retained samples. And there was no trace of B. cepacia.

But to protect patients, and as a precautionary measure, and I think we also mentioned this in the communications that went out to the customers that we had, we said that there was a product there that had, that we did not know had any problems. We had worked closely with the FDA on this, to take the product off the market. And we have no, today we still have no, we do not feel, and we have no indication that any product that was ever shipped had B. cepacia.

But because of the product we did not use, the raw material, there was a concern there could have been a potential risk. So we accepted that and withdrew the product. But we have never confirmed that there was any B. cepacia in any of the products we released. And it was never used, I am stressing, the raw material that had B. cepacia in it, was never used to manufacture a product that was shipped out of the facility.

Ms. NORTON. In any of those 8 million?

Mr. WELDON. In any of those 8 million, yes, ma'am.

Ms. NORTON. Mr. Weldon, let me ask you another question. Is it not true that 8-count vials of Motrin tablets can no longer be found on store shelves because you no longer make them?

Mr. WELDON. That is correct. To the best of my knowledge, it is correct.

Ms. NORTON. But isn't it commonly known that Motrin tablets were removed from store shelves because the product was defective?

Mr. WELDON. Yes, ma'am. Once again, to clarify, we identified there was never a health risk to patients. What we found is that the product dissolved more slowly than we would have liked it to dissolve and it was supposed to dissolve. So we went out and took the products off the shelf, that is correct.

Ms. NORTON. Well, I wonder if you could explain this guidance given to Johnson & Johnson, we have another document here, given to Johnson & Johnson and to McNeil employees in an internal email to tell customers that the product is not on the shelves because your company no longer makes it. Here is the email. It says the recall and the consumer will not know that we recalled it, a candid response to the customers is that we no longer make the 8-count vial.

Mr. WELDON. Yes, I am not familiar with that specific document, and I am not sure if it refers to, it was referring to notifying our own internal employees that we no longer made it.

Ms. NORTON. It tells your employees what to tell the customers.

Mr. WELDON. And that is correct. Again, I don't see the document, I don't know, but we no longer make that product, that is absolutely correct.

Ms. NORTON. You do have the document before you, though, I understand. The document says, unfortunately, the consumer Q&A form doesn't apply to the Motrin products, since it isn't a recall and the consumer will not know that we recalled it. It is only two lots of the product, you say. They simply won't be able to find it on the shelf. They will not know we recalled it. They simply will not know they are not able to find it on the shelf. Our candid response to the consumers is that we no longer make the 8-count vial.

Mr. WELDON. Could I take a moment and just read this?

Ms. NORTON. Please.

Chairman TOWNS. Then I will give the gentlewoman additional time.

Ms. NORTON. Thank you, Mr. Chairman. I thought he had the document and had looked at it.

Mr. WELDON. I did, I just wasn't aware of it. I apologize.

It says, it refers to a consumer Q&A that I am not aware of. But it does say that the response to the consumer is that we no longer make the 8-count vial. That is correct. We no longer make it.

Ms. NORTON. Is that the response under all circumstances, it should have been made, no recall, we just don't make it?

Mr. WELDON. No, ma'am. I think there are some lessons that we have learned, and I think you all have helped us with this. I think some of the wording that we have used and the directions we have given have been inappropriate. I cannot comment on this specifically, but I can assure you that we would be much more transparent with our customers and the people that would have our products in the future.

Ms. NORTON. Well, understand that there is a difference between telling a consumer you no longer make a product, which may simply mean you decided to move onto another product, and telling the consumer that the product has been recalled, so that the consumer

may know to look himself or herself for the product and all that goes along with recalled products.

Mr. WELDON. Yes, ma'am, and I do appreciate your comments. I do think in May we did send out an announcement saying that we were going to be taking these products off the shelves. But I think your point is well taken. Thank you.

Chairman TOWNS. The gentlewoman's time has expired.

I now yield 5 minutes to the gentleman from Missouri, Congressman Clay.

Mr. CLAY. Thank you, Mr. Chairman. Thank you, Ms. Goggins and Mr. Weldon, for being here.

There were repeated instances of alarming problems with Johnson & Johnson's children's medicine from 2008 to 2010. And in April 2008, McNeil began receiving reports that an uncharacteristic odor in its products was causing nausea, stomach pain, vomiting and diarrhea. FDA found that McNeil's initial investigation into these complaints was unjustifiably delayed and terminated prematurely. Over 100 additional complaints later, McNeil did not discover the root cause of the contamination until September 2009.

Why did it take so long to figure out the cause of the contamination?

Mr. WELDON. Yes, sir. This was an area where we have learned a very important lesson. And as you said, in 2008, there were adverse events reported that we knew, and it had to do with the aroma in the product and then some reported cases of nausea and vomiting. We investigated that to see if there was a microbial content or any content in the product. We found that there was not. And we saw that the adverse events fell off.

So we knew that there was, at that point we identified that there would be no harm to patients. There was some gastric distress but no serious adverse events. The adverse events fell off.

They came back in September, I guess in 2009, I am not sure exactly the date. We then investigated it, and I think worked closely with the FDA to identify. And I have to say, it was a very complex issue to identify a product called TBA. What had happened is this is a preservative. There is a preservative put on wooden pallets that can migrate into packaging material. It was something that has been very hard to identify and determine.

Now, I also want to be clear: we should have determined the root cause in 2008. I do not want to defend our inaction there. I think the FDA pointed that out correctly to us, and we appreciate that.

What we did do, though, in working closely with the FDA, was able to identify this. It was a very, very difficult initiative that needed to be undertaken and we were able to determine it. I think as the FDA said, this actually helped to lead to some new guidance documents from the FDA for everybody to benefit by.

So I do not want to make any excuses for what we should have done in 2008, which was to have determined the root cause. As a corporation, we know today if we have adverse events we need to investigate. We investigate them thoroughly until we determine the root cause. And that is exactly what happened in this instance. We did not, and the FDA was absolutely correct in pointing that out to us. And we did identify it ultimately. It was a very, very scientifically challenging exercise. But that is no excuse. We did ulti-

mately determine it, and I think in combination with the FDA, I think it is something that will benefit many people.

Mr. CLAY. But Mr. Weldon, it leached through the——

Mr. WELDON. Yes, that is correct. What happens is, they put a preservative on a wooden pallet, which materials are shipped on. And the preservative can actually break down and actually, as you, the words you described are very accurate, leach into the packaging material. And that packaging material then, when you put the product in it and you ship the product out, can actually cause this musty odor, this smell. And I think it was something, again, I want to say that I think it was a combination of people working closely together to determine this. And I think ultimately a guidance document has gone out that will help many people in this area.

Mr. CLAY. Thank you for that response, Mr. Weldon. Regulations require drug makers to submit field reports within 3 working days of receipt of information concerning any bacteriological contamination or any significant physical or other change or deterioration in its drug products. Yet, when McNeil began receiving consumer complaints in 2008, McNeil did not alert FDA. Further, when McNeil had test results confirming the contamination, these results were not shared with FDA. Why didn't McNeil share this information with FDA as required?

Mr. WELDON. I cannot comment on that. I am not, I just can't comment. I am not aware of that specific example.

Mr. CLAY. Ms. Goggins, can you explain it?

Ms. GOGGINS. I don't know which incident you are referring to. Are you referring to the B. cepacia, sir, or what are you referring to?

Mr. CLAY. OK, here, your FDA regulations require.

Ms. GOGGINS. Right, absolutely.

Mr. CLAY. Well, let's go back to the first instance. Did you report it within 3 days?

Ms. GOGGINS. Mr.——

Mr. CLAY. You can twist my words if you like. But you still can't get around the fact that you didn't follow the rules that you are required to. You can twist my words if you want. But why didn't you report it within 3 days?

Ms. GOGGINS. I wasn't trying to twist your words, sir, I apologize.

Mr. CLAY. OK, well, do you understand the question now?

Ms. GOGGINS. I do understand the question, and I don't, to Mr. Weldon's point, we are aware of the regulations for the FDA, and you are absolutely right, we are supposed to report these within 3 days to the FDA.

Mr. CLAY. And you didn't.

Ms. GOGGINS. I don't know which incident you are talking about. If we did not, sir, we should have.

Mr. CLAY. Well, any of the incidents. You didn't report it in a timely fashion, within 3 days.

Mr. WELDON. Sir, if——

Mr. CLAY. So why didn't you?

Mr. WELDON. That I——

Mr. CLAY. Simple question.

Mr. WELDON. That I cannot answer. I would say, though, in all instances, in some instances, I know that we did, I don't know the

specific instance. If we did not, it was a mistake on our part and we should have, you are absolutely correct.

Mr. CLAY. My time is expired, I yield back.

Chairman TOWNS. The gentleman's time is expired.

Before we let you go, there are some terms, actually phrases that have been used. I want to make certain that the committee understands. You used the term "soft market" withdrawal. What does that really mean? Soft market withdrawal.

[The information referred to follows:]

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**From:** Benedict, Gary [MCCUS] [GBened1@its.nj.com]  
**Sent:** Thursday, May 28, 2009 9:41 AM  
**To:** Figus, Daniel [MCCUS]  
**Subject:** FVV: Market withdrawal of Motrin 8's

fyi

**From:** Parziale, Carolyn [MCCUS]  
**Sent:** Thursday, May 28, 2009 9:29 AM  
**To:** Benedict, Gary [MCCUS]  
**Cc:** DiPaolo, Paul [MCCUS]; Luther, Peter [MCCUS]; Miller, Bob [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]  
**Subject:** RE: Market withdrawal of Motrin 8's

Gary,

Just a clarifying point, in order to gain a significant cost avoidance, we intend to use CLS (Carolina Logistics) to make the 2<sup>nd</sup> phase of the store visits. GQA partnered with J&J SLC to create the relationship & CLS did a great job in completing the first Phase of this soft withdrawal. I can try to negotiate with them on price once we have the full store list, based on volume.

Carolyn

**From:** Benedict, Gary [MCCUS]  
**Sent:** Thursday, May 28, 2009 8:30 AM  
**To:** Luther, Peter [MCCUS]; Miller, Bob [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** RE: Market withdrawal of Motrin 8's

Bob...I spoke to Dan Figus this morning and can offer the following perspective to help future out what we need to do.

- Sales had provided contact list for the majority of the stores. Hopefully, this information has been passed on to Stericycle to begin activities.
- We are still working to get contact list for small group of stores where we're having difficulty getting information from convenience distributors.. Peter, for background, this recall is for a convenience channel code and it's been a challenge to secure full list of stores but should have everything this week.

Kathy, can you comment on Bob's concern about not being able to get PO from marketing?

**From:** Luther, Peter [MCCUS]  
**Sent:** Wednesday, May 27, 2009 10:03 PM  
**To:** Miller, Bob [MCCUS]; Benedict, Gary [MCCUS]; Mahony, John [MCCUS]; Widmer, Kathy [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** RE: Market withdrawal of Motrin 8's

Group,

Where is the miss here? Given our current financial situation, I hope we're not going to really double our cost to do this. Let's make this happen ASAP.

Thanks,

MCNEIL HC 8309

**From:** Miller, Bob [MCCUS]  
**Sent:** Wednesday, May 27, 2009 9:51 PM  
**To:** Benedict, Gary [MCCUS]; Luther, Peter [MCCUS]; Mahony, John [MCCUS]  
**Cc:** Parziale, Carolyn [MCCUS]; DiPaolo, Paul [MCCUS]  
**Subject:** Market withdrawal of Motrin 8's

Gary

As you know we have negotiated an agreement with FDA not to formally conduct a recall for Motrin 8's but rather conduct a "soft market withdrawal". This was a major win for us as it limits the press that will be seen. We had committed to FDA to complete this withdrawal by July 15<sup>th</sup>. There has been continuing issues trying to get a PO from the marketing group which is now putting our ability to meet the July 15<sup>th</sup> timeframe in jeopardy. At the same time as we delay this work the cost to complete the work continues to increase because of the fact that the outside resource will now need more resources to expedite the work. We can NOT extend our commitment date to FDA. It is now estimated that this will cost approx. \$400K which is approximately 2x that which was originally quoted. We need to start this work ASAP. If we are unable to get a PO by Friday, we will issue the PO from QA and then back charge to marketing. Please let me know how you want to proceed or how we can get the PO. Carolyn Parziale is leading this effort and should be your POC for any questions you have. Please let me know if you have any questions.

Bob

Mr. WELDON. Mr. Chairman, I have no idea what soft market withdrawal is. I have heard the term.

Chairman TOWNS. It is used in the memos and the emails that we received.

Mr. WELDON. I am not familiar with the term. I do not know what it means.

Chairman TOWNS. Ms. Goggins, do you know what it means?

Ms. GOGGINS. No. We don't use that term regularly, so I have not heard it before this instance.

Chairman TOWNS. Why would the employees use it? Maybe it is the same thing as phantom recall. I am just trying to figure this out. Because you have seen it, you have heard it. What do you think it means? We don't know.

Ms. GOGGINS. I agree with you, I think the language is very unfortunate. It is terminology we don't use. I also don't think it reflects accurately our priorities and the fact that we try to put safety of patients first. I think the use of language is unfortunate.

Chairman TOWNS. Do you want to comment, Mr. Weldon?

Mr. WELDON. I think, Mr. Chairman, the comment that I would make is that I think we have learned a lot of lessons through this unfortunate situation. I have said to you and to Mr. Issa and to the committee that we have learned and benefited by being here. I think we have discussed and can show you the changes we have made, the comments we are making, the resources we are investing, the people we are putting into roles. I can only assure you that we will do everything in our power to never let this happen again.

I think that the characterization of phantom, soft, all kinds of things, I cannot explain to you. I wish I could, and I think many people use many different terms. What I can assure you is that we are committed to ensuring to resolve these problems, to fix these problems and to make sure that we are giving the highest quality products to patients.

As I said earlier, and I will tell you very honestly that the FDA and Johnson & Johnson, the people at McNeil, have worked so closely together that we will be able to deliver some of these products in the market next week. And that is much faster than we ever thought we could have done. Our own internal expectation was that it would have been much later.

Now, we are not able to fulfill the whole market. But I think because of the efforts that we have made collectively, we are going to be able to get these products back into the market for people that need them. And that is our single greatest concern.

I can only commit to you, we will do the best we possibly can and we will do everything we can to ensure this never happens again.

Chairman TOWNS. Mr. Weldon, let me thank you for coming to testify. The gentleman from Ohio.

Mr. KUCINICH. Mr. Chairman, with the unanimous consent of the committee, I have a followup question to Ms. Goggins to try to square this testimony that she just gave, based on committee documents that I have just received.

Chairman TOWNS. Let me just say that before I recognize the ranking member, let me just say that I will give you 2 minutes to raise the issue and the question.

Mr. KUCINICH. I appreciate the indulgence of my colleagues.

Chairman TOWNS. The gentleman is recognized.

Mr. ISSA. Mr. Chairman, thank you. As we go to the second panel, I would ask, because of the gravity of this hearing, of the failures at J&J and the corrective action that we are expecting you to do, plus the likelihood that we are going to have followup questions for you in writing, if you would both do the fairly extraordinary thing of remaining here through the FDA testimony as principals. We do believe that what you are doing is essential. We are obviously interested enough, even after the House is adjourned, to hold this hearing, because this is important that the American people know we are getting it right.

So I would only ask that you do the followup written questions, and of course, yield back so the other gentleman can ask his.

Chairman TOWNS. I thank the gentleman. And I also agree with the fact that we would really appreciate if you would stay and hear the testimony of FDA.

The gentleman from Ohio.

Mr. KUCINICH. Thank you very much, Mr. Chairman. The committee produced a document here to Colleen Goggins from, among others, Peter Luther and Bob Miller, relating to the final remediation plan for the children's Tylenol. Now, on the document that I raised the question on, my last question, I pointed out that Bob Miller and Peter Luther were involved in a communication involving Motrin. And for some reason, Ms. Goggins, who was in the loop on the children's Tylenol, would lead this committee to believe that on something that apparently had wide circulation within her organization, she didn't know anything about it.

Now, Mr. Chairman, one of two things have happened here. Either she was out of the loop on that, and if she was, a pattern of concealment from her needs to be further investigated, or the other part is that Ms. Goggins, you are not telling the truth. Now, would you like to respond to why you were kept in the loop on this, but you weren't kept in the loop on the children's Tylenol issue, but you were, as you say, were kept out of the loop or imply that you were kept out of the loop on the Motrin issue. Could you square the discrepancy there on your inter-office communications?

Ms. GOGGINS. Yes, I will. I was not in the loop, as you put it, on the Motrin recall. But I was in the loop on the children's Tylenol recall.

Mr. KUCINICH. Why?

Ms. GOGGINS. That is because we received a 483 with a number of observations regarding the issue of the children's recall in June of that year. So it was brought to my attention.

Mr. KUCINICH. But why? Were you concerned about that after you found out?

Ms. GOGGINS. I was very concerned.

Mr. KUCINICH. Who kept you out of the loop? And why were they in the loop and you weren't? Because you're the head of the consumer products.

Ms. GOGGINS. I was not in the loop, as you say, for the Motrin recall until I came to the committee, and then I went back and looked at the documents after my testimony. On the children's Tylenol recall, which happened when, we received the FDA 483 in

June 2009, I was made aware of that. I was very displeased with that, and I maybe inserted myself in the loop, if you will.

Mr. KUCINICH. Thank you.

Mr. Chairman, I am going to ask you to direct staff to call some of the people on this list who were involved in these communications because we may find out something that will be of benefit to the work of this committee.

Chairman TOWNS. Without objection, so ordered.

Let me thank the two of you. Thank you, again, Mr. Weldon, for coming, and for your testimony. I want to thank you, Ms. Goggins, for coming back. I really appreciate it, because as you can see, there is a concern here. We also want to make certain that when medication is on the shelf, that it is safe. We have that obligation and responsibility. So thank you again. We hope that you will remain and hear the testimony of FDA. Thank you for your testimony.

We now will move to our second panel.

Dr. Joshua Sharfstein is the Principal Deputy Commissioner at the Food and Drug Administration. It is committee policy, Dr. Sharfstein, that we swear all of our witnesses in. So if you would stand and raise your right hand.

[Witness sworn.]

Chairman TOWNS. Thank you. Let the record reflect that he answered in the affirmative. You may be seated.

Dr. Sharfstein, you have 5 minutes to deliver your testimony, which will allow the Members an opportunity to raise questions with you. So you may proceed.

**STATEMENT OF JOSHUA M. SHARFSTEIN, M.D., PRINCIPAL DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION**

Dr. SHARFSTEIN. Thank you very much, Mr. Chairman, Mr. ranking member, members of the committee. I am Dr. Joshua Sharfstein, the Principal Deputy Commissioner of the FDA.

Thank you for the opportunity to testify today.

I would like to provide a brief update on FDA's investigation of the serious quality lapses at McNeil and then address the phantom recall. First, FDA has continued to investigate whether any serious illnesses or deaths have been linked to the recall. Since the last hearing, FDA has looked into adverse events reported to FDA and McNeil citing the product subject to the recalls. This investigation covers over 2,400 reports received by FDA for the 2-year period preceding the recall as well as for the 2-month period immediately afterward. We did not, in this process, establish any direct link to a serious adverse event, including death, in the recalled product.

Second, FDA has worked with McNeil to improve the two facilities at the center of the previous recalls. In Puerto Rico, as has been mentioned, FDA became aware that McNeil had received reports of products from its Las Piedras facility having a musty, moldy odor, and McNeil did not conduct a timely investigation of the issue or file timely reports. After FDA personnel urged McNeil to do more, the firm identified the cause of the odor to be a chemical called 2,4,6-Tribromoanisole [TBA], a pesticide used to treat wooden pallets. FDA issued McNeil a warning letter very quickly on January 15, 2010, related to this failure, and FDA since then

has issued guidance letters to industry. Subsequent investigations by customers have led to additional recalls and McNeil has informed us that the firm has stopped using the wooden pallets, cleaned its facilities and increased its oversight and qualification standards of its suppliers. FDA is currently conducting a followup inspection of the facility.

In Pennsylvania, FDA found that the facility in Fort Washington had not conducted adequate investigations of product problems and complaints. During the April 2010 inspection, the firm announced it would stop manufacturing liquid products and conduct a major recall, as you know, because of excessive particulate matter, potency variability and possible microbial contamination. Subsequently, the firm held a series of meetings with FDA and identified many corrective actions the company would take. These corrective actions include ceasing all manufacturing and renovation of the Fort Washington facility, remediating the quality systems and using a third-party expert consulting firm to review all aspects of the firm's manufacturing and quality changes. We are continuing to review and provide feedback to the company.

In addition, since the last hearing, third, all facilities associated with McNeil have been inspected at least once within the last year. FDA has found inspectional deficiencies of varying degrees of seriousness in all of these facilities. One common concern the agency has found is the failure to investigate and correct product problems in a prompt and thorough manner. McNeil has responded to these observations with a large-scale corrective plan. FDA is currently reviewing and investigating this plan to ensure that corrective actions are actually effective.

Fourth, FDA has had continued discussions with Johnson & Johnson, the parent company of McNeil, to address the breakdown in leadership and oversight that led to these serious compliance problems. We recognize the company is taking agency concern seriously, and many changes have been made. We intend to keep a close eye on these facilities until the company earns our confidence back.

In February 2010, FDA called an extraordinary meeting with the senior executives of Johnson & Johnson. At that meeting, the agency discussed a number of serious compliance problems at McNeil. More broadly FDA confronted these executives about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency and safety of its products.

As part of that meeting, the agency raised concerns about what has been called the phantom recall of sub-potent Motrin tablets in the spring of 2009. FDA raised this concern because it seemed strange and concerning that the company had paid a contractor to go into retail stores across the country to purchase all available product, while acting like a regular customer, and not disclosing what was going on.

In the summer of 2009, the agency told the company to register a real recall. Over the last several months, the committee has investigated this event further, using its authority to gather additional information from the company and the agency. Because of this committee's investigation, we understand much more about these events. My understanding comes from documents that have

been provided to the committee by McNeil and FDA. I have not had access to all the relevant materials gathered in a related criminal investigation.

Based on what we know now, the phantom recall raises important questions for Johnson & Johnson, FDA and Congress. The current voluntary system of drug recalls depends on companies providing accurate and complete information to the agency and recalling adulterated or otherwise violative products in a prompt and appropriate manner. As you and other members of the committee have stated, the new documents raise serious questions about whether the company's actions have met this standards.

But regardless of the behavior of the company, it is FDA's job to do everything possible to protect the public. It was clear in November 2008 that the Motrin lots did not meet specifications. Yet the actual recall did not happen until early August of the following year. This took too long. Part of this delay can be attributed to several months spent checking whether or not any remaining product was on the shelves.

Then in April 2009, the company sent a report to FDA indicating it was purchasing product from the shelves of retailers. This communication did not fully disclose the likely scale of the action or the way that the company was intending to proceed. In other words, it did not disclose the phantom part of the phantom recall. From this point, it took until July for the FDA to tell the company should be conducted. In July, FDA not only instructed the company that it should be registered as a recall, but then went on to confront the senior executives at Johnson & Johnson about what happened. In my opinion, however, the message that was delivered should have been delivered sooner by FDA.

FDA has no legal authority to require a manufacturer to recall a drug product that is unsafe or is not in compliance with current good manufacturing process. The recall system depends on full and open disclosure, trust, and the industry's acceptance of its responsibilities. FDA urges and expects firms to notify the agency when it is initiating a recall, but firms have no legal requirement to provide this type of notification. If a firm does initiate a drug recall, the agency does not have the authority to approve the manner in which the firm conducts the recall, or to direct the firm to adopt a different recall strategy.

Although the agency is able to accomplish most drug recalls with the cooperation of the drug manufacturer, there are instances in which firms are reluctant or unwilling to conduct a recall, or to do so in a timeframe that FDA believes is necessary and appropriate to protect public health. If a firm refuses to recall, FDA can pursue a remedy in Federal court, like a seizure, but this can be time-consuming and cumbersome. Under current authorities, when a product has already been widely distributed to hundreds of retail stores, the agency would have to undertake hundreds of separate seizures in order to ensure that all violative product has been removed from the market.

Mr. ISSA. Mr. Chairman, could I ask unanimous consent that the entire statement be placed in the record so we can get to Q&A? We have received it.

Chairman TOWNS. Without objection, your entire statement will be included in the record. So if you just would summarize.

Dr. SHARFSTEIN. Sure, I am sorry. I just have two more sentences.

The events of the phantom recall raises important questions about the current voluntary recall system. In this case, if FDA had the authority simply to order a recall to be done in the right way, I do not believe these events would have occurred.

Thank you for the opportunity to testify today, and I am ready for questioning.

[The prepared statement of Dr. Sharfstein follows:]



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Silver Spring, MD 20993

**STATEMENT OF**  
**JOSHUA M. SHARFSTEIN, M.D.**  
**PRINCIPAL DEPUTY COMMISSIONER**  
**U.S. FOOD AND DRUG ADMINISTRATION**  
**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**BEFORE THE**  
**COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM**  
**U.S. HOUSE OF REPRESENTATIVES**  
**HEARING ON**  
**"JOHNSON & JOHNSON'S RECALL OF CHILDREN'S**  
**TYLENOL AND OTHER CHILDREN'S MEDICINES & THE**  
**PHANTOM RECALL OF MOTRIN (PART 2)"**

September 30, 2010

RELEASE ONLY UPON DELIVERY

**Introduction**

Mr. Chairman and Members of the Committee, I am Dr. Joshua M. Sharfstein, Principal Deputy Commissioner of the Food and Drug Administration (FDA or the Agency), an agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the McNeil Consumer Healthcare, LLC (McNeil) recalls and the Agency's role with respect to recalls.

In May, your Committee's hearing focused on the serious quality lapses at two McNeil production facilities, which led to several large recalls of over-the-counter (OTC) medications for children and adults. Today, I would like to provide a brief update on FDA's investigation of these problems and then address what some have called the "phantom recall."

First, FDA has continued to investigate whether any serious illnesses or deaths have been linked to the recalls. Since the last hearing, FDA has extensively investigated adverse events reported to FDA and McNeil citing the products that were subject to the recall. This investigation, which covers over 2,400 reports received by FDA for the two-year period immediately preceding the recall, as well as for the two-month period immediately following the recall, does not, overall, establish a direct link to any serious adverse event, including death, and a recalled product.

Second, FDA has worked with McNeil to improve the two facilities at the center of the previous recalls.

- In Puerto Rico, FDA became aware that McNeil had received reports of products from its Las Piedras facility having a musty, moldy odor and that McNeil did not conduct a thorough, timely investigation of the issue or file timely reports. After FDA personnel urged McNeil to conduct a more complete investigation, the firm identified the cause of the odor to be a chemical, called 2, 4, 6-Tribromoanisole or TBA, a pesticide used to treat wooden pallets. FDA issued McNeil a warning letter on January 15, 2010, related to their failure to conduct a thorough, timely investigation of the issue. Since that time, FDA issued guidance and a letter to industry explaining the potential for TBA contamination, inspectional guidance to ensure coverage of the potential for TBA contamination from treated wooden pallets, and a letter providing guidance to specific customers who used components that may have been exposed to TBA. Subsequent investigations by customers contacted by FDA led to additional recalls. McNeil has informed us that the firm has stopped using wooden pallets, cleaned its facilities, and increased its oversight and qualification standards of its suppliers, and FDA has reviewed and commented on these changes. FDA is currently conducting a follow-up inspection of the facility.
- In Pennsylvania, FDA found that McNeil's facility in Fort Washington had not conducted adequate investigations of product problems and complaints. During the April 2010 inspection, the firm announced that it had stopped manufacturing liquid products and would conduct a recall of liquid products associated with excessive particulate matter, potency variability, and possible microbial

contamination. Subsequent to the inspection, the firm held a series of meetings with FDA and identified a series of corrective actions that the company would take across all McNeil facilities. These corrective actions included ceasing all manufacturing and renovation of the Fort Washington facility, remediation of its quality systems, and using a third-party expert consulting firm to review all aspects of the firm's manufacturing and quality changes. FDA is continuing to review and provide feedback to the company concerning these remedial actions.

Third, FDA has inspected additional McNeil facilities in the time since the last hearing. This includes facilities associated with McNeil in Lancaster, Pennsylvania; Lititz, Pennsylvania; and Guelph, Ontario, Canada. As I just mentioned, FDA is currently conducting a follow-up inspection of McNeil's facility in Las Piedras, Puerto Rico. All facilities associated with McNeil have been inspected at least once within the last year. FDA has found inspectional deficiencies of varying degrees of seriousness at all of these facilities. One common concern the Agency has found across these facilities is the failure to investigate and correct product problems in a prompt and thorough manner. McNeil has responded to these observations with a large-scale corrective action plan. FDA is currently reviewing and investigating this plan to ensure that corrective actions are actually effective.

Fourth, FDA has had continued discussions with Johnson & Johnson, the parent company of McNeil, to address the breakdowns in leadership and oversight that led to these serious compliance problems. We recognize that the company is taking the Agency's concerns

seriously, and many changes have been made. FDA intends to keep a close eye on these facilities until the company earns back our confidence.

In February of this year, FDA called an extraordinary meeting with senior executives of Johnson & Johnson. At that meeting, the Agency discussed a number of serious compliance problems at McNeil. More broadly, FDA confronted these executives about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency, and safety of its products.

As part of that meeting, the Agency raised concerns about what some have called the "phantom recall" of subpotent Motrin tablets in the Spring of 2009. FDA raised this concern because it seemed strange that the company had paid a contractor to go into retail stores across the country to purchase all available product while acting like a regular customer, and not disclosing whether it was a recall. In the Summer of 2009, the Agency told the company that a real recall needed to occur.

Over the last several months, the Committee has investigated this event further, using its authority to gather additional information from the company and the Agency.

Because of this Committee's investigation, we now understand much more about the events. My understanding comes from documents that have been provided to the Committee by McNeil and FDA. I have not had access to all of the relevant materials gathered in the related criminal investigation.

Based on what we now know, the “phantom recall” raises important questions for Johnson & Johnson, FDA, and Congress.

The current voluntary system of drug recall depends on companies providing accurate and complete information to the Agency, and recalling adulterated or otherwise violative products in a prompt and appropriate manner. As you and other members of the Committee have stated, the new documents raise serious questions about whether the company’s actions met this standard.

Regardless of the behavior of a company, it is FDA’s job to do everything possible to protect the public. It was clear in November 2008 that the Motrin lots did not meet specifications. Yet the actual recall did not happen until early August of the following year. This took too long. Part of this delay can be attributed to several months spent checking whether or not any remaining product was on the shelves. Then, in April 2009, the company sent a report to FDA indicating that it was purchasing product from the shelves of retailers. This communication did not fully disclose the likely scale of the action or the way that the company was intending to proceed. From this point, it took until July for FDA to tell the company that a recall should be conducted. In my opinion, that message should have been given sooner.

FDA has no legal authority to require a manufacturer to recall a drug product that is unsafe or is not in compliance with current Good Manufacturing Practice. The recall

system depends on full and open disclosure, trust, and the industry's acceptance of its responsibilities to protect the public from violative products.

FDA urges and expects firms to notify the Agency when initiating a drug recall, but firms have no legal requirement to provide this type of notification. If a firm does initiate a drug recall, the Agency does not have legal authority to approve the manner in which the firm conducts the recall or to direct the firm to adopt a different recall strategy.

Although the Agency is able to accomplish most drug recalls with the cooperation of the manufacturer, there are instances in which firms are reluctant or unwilling to conduct a recall, or to do so in the time frame that FDA believes necessary and appropriate to protect public health. If a firm refuses to recall violative product, FDA may pursue a remedy in Federal court, such as a seizure, but this can be time-consuming and cumbersome. Under current authorities, when the product has already been widely distributed to hundreds of retail stores, the Agency would need to undertake hundreds of separate seizures in order to ensure that all violative product has been removed from the marketplace.

The events of the "phantom recall" raise important questions about the current voluntary recall system. In this case, if FDA had the authority simply to order a recall to be done in the right way, I do not believe these events would have occurred.

Thank you for the opportunity to testify today, and I look forward to your questions.

Chairman TOWNS. Thank you very much. Let me thank you for your statement, Dr. Sharfstein.

Let me begin by asking, did the FDA approve Johnson & Johnson's phantom recall of Motrin?

Dr. SHARFSTEIN. No. To start, the FDA doesn't approve recalls. It is in the discretion of the company.

But the second thing, I think, that is very important, is the phantom part of the phantom recall. And this was part of my testimony previously. It relates to the fact that there were contractors going out telling people to act like regular customers and not really tell the truth about what they are doing in the stores. Based on what I know, based on the documents that I have reviewed, I don't see any indication that FDA was aware at the time that those types of activities were going on or approved.

Chairman TOWNS. Are you familiar with the soft market withdrawal term?

Dr. SHARFSTEIN. I am not familiar with that term.

Chairman TOWNS. When Johnson & Johnson sent the FDA a letter April 2009, talking about buying defective Motrin, why didn't the FDA become concerned and take action right away? What led to the delay?

[The information referred to follows:]



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McNeil Healthcare, LLC • P.O. Box 2009, Las Piedras, Puerto Rico 00771-2009

April 21, 2009

Ms. Maridalla Torres  
Director, San Juan District Office  
U. S. Food and Drug Administration  
466 Fernández Juncos Ave.  
San Juan, Puerto Rico 00901-3223

Ms. Torres:

Attached please the Final Report to the Field Alert Report (FAR) for Motrin  
Caplets submitted on November 26, 2008.

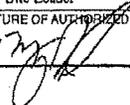
Cordially,

A handwritten signature in black ink, appearing to read "MPujals", is written over a light blue circular stamp.

Mayra Pujals  
Quality Site Leader

Attachment

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION <b>NDA-FIELD ALERT REPORT</b>		TO: (NAME AND ADDRESS OF DISTRICT) Ms. Mirkalila Torres, District Director FDA - San Juan District Office 466 Fernández Juncos Ave. San Juan, PR 00901-3223	
TYPE OF REPORT <input type="checkbox"/> Initial <input type="checkbox"/> Follow-Up <input checked="" type="checkbox"/> Final			
In accordance with Section 314.81 (b)(1)(i) and (ii) of the New Drug Application Regulations (21 CFR 314) promulgated under the Federal Food, Drug and Cosmetic Act, as amended, the following information is herewith submitted:			
1. NDA/ANDA - ANTI-BIOTIC FORM #/6 NO. 19-012 Motrin Caplets		2. NDC No. 30580-110-68	
3. GENERIC NAME OF DRUG PRODUCT Ibuprofen		4. TRADE NAME (if any) OF DRUG PRODUCT Motrin Caplets	
5. FIRM NAME AND ADDRESS WHERE PROBLEM OCCURRED McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009			6. FEI 2650141
7. DOSAGE FORM, STRENGTH AND PACKAGE SIZE(S) Motrin Tablets - Ibuprofen 200mg - 8 count vials			
8. LOT NUMBER(S) SHC003 and SHC004			
9. EXPIRATION DATE(S) OF DRUG PRODUCTS 03/2011			
10. DATE WHEN NOTIFIED ABOUT PROBLEM(S) OR WHEN PROBLEM(S) FIRST BECAME KNOWN TO APPLICATION HOLDER November 21, 2008			
11. HOW WAS PROBLEM DISCOVERED During the routine stability testing (3-month interval)			
12. STATE PROBLEM(S) Dissolution failure during the 3-month interval stability testing (Lot SHC003) Actual results: - S1 = Average: 72% (min. 64%) - S2 = Average: 71% (min. 64%) - S3 = Average: 71% (min. 58%)  Specification S1 = Each unit NLT Q + 5, Q = 80% S2 = Average of S1 + S2 is equal to or greater than Q. No unit less than Q-15% S3 = Average of S1+S2+S3 is equal to or greater than Q. Not more than 2 units less than Q-15%. No unit less than Q-25%			
13. PROBABLE CAUSE(S) OF PROBLEM(S) Investigation is in progress.			
14. CORRECTIVE ACTION(S) TAKEN (if any) TO PREVENT RECURRENCE OF PROBLEM(S) Remaining inventory in the distribution centers has been placed on hold.			

16. REMARKS	
<p>As stated in the previous Field Alert Report follow-up issued on March 23, 2009, in order to confirm the availability of Motrin batches SHC003 and SHC004 at the retail level, a statistical sampling of approximately ten (10) percent of all stores across the US that received these batches were visited (250 stores out of 2000). The assessment performed demonstrated that, on a statistical basis, a low amount of product (approximately 1% of the batches) is potentially still at the retail level. The product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.</p> <p>A Health Hazard assessment has indicated that the use of Motrin IB capsules of the above batches is not likely to cause an increased risk of serious adverse health consequences. In addition, a review of our complaint history indicates that neither affected lots have had complaints registered against them from November 1, 2008 through April 13, 2009.</p>	
NOTE: SEPARATE NARRATIVE REPORTS MAY BE ATTACHED IF DESIRED.	
REPORTING ESTABLISHMENT	
NAME AND MAILING ADDRESS (include ZIP Code)	
McNeil Healthcare, LLC PO Box 2009 Las Piedras, PR 00771-2009	
NAME AND TITLE OF AUTHORIZED REPRESENTATIVE	TELEPHONE (include Area Code)
Mayra Pujals Quality Site Leader	787-733-7656
SIGNATURE OF AUTHORIZED REPRESENTATIVE	DATE SUBMITTED
	4/21/2009

Dr. SHARFSTEIN. I think that is a very fair question for the committee to ask. That report disclosed that McNeil was retrieving product that failed specifications. And removing the product was the right thing for McNeil to be doing. But what it didn't say in that report was that they were, all it said was we are going to retrieve it from the shelves, or however they phrased it. It didn't say that they would be telling people to act like regular customers or not disclosing the facts when they were asked about what happened when they went out.

I think that in part because there was limited information, that might have contributed to the delay. But I also think that FDA should have been asking questions right away, and figured out what the agency eventually figured out, that this really did need to be registered as a real recall.

Chairman TOWNS. What went wrong that caused Johnson & Johnson's recall of 135 million bottles of children's medicine? Is the FDA satisfied with what Johnson & Johnson is doing to solve the problem? Are you satisfied with Johnson & Johnson?

Dr. SHARFSTEIN. What went wrong there is sort of the notes and the music. The notes are the specific details and the inspectional observations. The fact that there were batches that were super-potent or batches that may have had particles or an issue with how they investigated and responded to potential bacterial contamination.

But the music is that the company had an inadequate quality system. And that you could see in multiple facilities. FDA is both responding to the notes and the music, you have heard from the testimony there are major changes at McNeil. FDA has been very involved in ensuring that those are the right kinds of changes. And FDA is committed to making sure when this facility is up and running that it is in compliance.

So we are comfortable with where things are now. We appreciate the commitment of McNeil and Johnson & Johnson's leadership to fixing the problem. But this was a very serious problem, and we are not going to take anything for granted.

Chairman TOWNS. Right.

Let me ask, does FDA need more enforcement authority or funding to be able to respond to issues like the Johnson & Johnson recall? This bothers me in terms of, for something like this to happen. We are concerned about safety. Does FDA need additional authority? What is the problem?

Dr. SHARFSTEIN. I think there are a couple of things. This is to be put in the context that FDA did identify these lapses before there was a serious health consequence. We are not finding that there are serious illnesses or deaths linked to this problem. And the agency, through its inspections and through multiple meetings with the company, and aggressive, extraordinary meetings with the company, has brought about tremendous change in this area.

Having said that, all of us want to prevent these things and we want to be responding much faster in some cases even than what happened here. And I think that issues of resources and authority are very fair questions. I testified that if FDA had had mandatory recall authority, I think things would have gone a lot different.

Chairman TOWNS. Now how are you working with Johnson & Johnson to correct this and to make certain it doesn't happen again?

Dr. SHARFSTEIN. How are we working?

Chairman TOWNS. Yes.

Dr. SHARFSTEIN. It is both at the individual facility level and at the corporate level. So we are helping them with individual quality issues that they had, as well as how they structure their quality program to make sure that the kinds of lapses that they had don't happen again.

Chairman TOWNS. On that note, my time is expired and I now yield 5 minutes to the gentleman from California.

Mr. ISSA. No, let Mr. Chaffetz go ahead.

Chairman TOWNS. Five minutes to the gentleman from Utah.

Mr. CHAFFETZ. Thanks, Mr. Chairman.

Thank you, Doctor, for being here. Ms. Torres, can you help explain to me, what is her current status? Did she get fired? Has she been demoted, did she get promoted, what is her current status?

Dr. SHARFSTEIN. I understand she is still the district director in San Juan, Puerto Rico.

Mr. CHAFFETZ. So you found that she has done nothing inappropriate, she acted just the way she should have, you are totally comfortable with the way she acted?

Dr. SHARFSTEIN. No, I would say that this is a matter that is under investigation. We are looking at what happened here. As I testified, things should have happened sooner on FDA's part. It is something that we are looking at. And based on what we find and conclude, that could lead to different changes at FDA.

Mr. CHAFFETZ. Is there an opportunity for this committee to interact with her? Is there any reason there is a hesitation on the part of FDA to make her available for questioning by the committee?

Dr. SHARFSTEIN. Well, as you know, I think that, I know at least the minority staff had requested to speak with her. And FDA declined. FDA declined at the instruction of the Department of Justice, because she is a witness, a central witness, in a related criminal investigation.

Mr. CHAFFETZ. When you say related criminal investigation, is that related to Johnson & Johnson in this case or related to some other group or product?

Dr. SHARFSTEIN. I believe it is related to this.

Mr. CHAFFETZ. Related to this. Is it your common practice or recommendation to not make field staff and people who are closest to these situations available to the committee?

Dr. SHARFSTEIN. My view, as a former staff member of this committee, is that Congress should get as much information as possible.

Mr. CHAFFETZ. So is it your personal recommendation that she should be made available?

Dr. SHARFSTEIN. Well, but I also recognize the importance of the integrity of a criminal investigation.

Mr. CHAFFETZ. Why would a criminal investigation be slowed down by her appearing before this committee, or even simply meet-

ing with staff from both the Republican and Democratic sides of the aisle?

Dr. SHARFSTEIN. I don't think that is a judgment that FDA should make. What we did is we turned to the Department of Justice and their career prosecutors and we got instructions from them. They said basically that it would be a problem. That is why. But I am not a lawyer, I don't know these cases, so I can't really comment. But basically we are relying on the Department of Justice.

Mr. CHAFFETZ. I think there is a frustration, if I can express it, at least from this Member, that she should be made available, the other staff that are there in the field office should be made available, in the spirit of full disclosure and what is happening. I am a bit troubled by this Elaine, and again, I am slaughtering people's names here, Elaine Bobo, is that how you pronounce her name? She is the FDA spokesperson. Very recently she said, it appeared in the Wall Street Journal, Associated Press and Reuters, "Any effort to suggest that the FDA had knowledge of the phantom recall is based on quoting documents selectively and out of context and ignores other evidence as to what occurred. McNeil's own written account of its communications with the FDA does not support the conclusion that McNeil disclosed the activities associated with its phantom recall to the FDA."

I have a problem believing that. And I am troubled when the FDA puts out such a dramatic statement. And yet, we have a whole host of information here that suggests otherwise.

Dr. SHARFSTEIN. I would be happy to try to clarify that and explain.

Mr. CHAFFETZ. Sure.

Dr. SHARFSTEIN. What I believe people were alleging, or there were questions coming to the agency, was that we knew about the surreptitious nature of the recall, the phantom part of the phantom recall, that people were out there acting like regular customers, not telling the truth when asked. There isn't, in anything that I have seen or anything before the committee, evidence that FDA knew about that. And so I think that is what she was responding to.

Mr. CHAFFETZ. When we use the term recall, that has some very specific implications. It is a term, right? It is a very specific term that has a great deal of definition to it in the world of FDA and certainly the companies that you interact with. So if a company came and said, we are conducting a recall, you would have a pretty good sense of what they are going to do, right? Am I off base in saying that?

Dr. SHARFSTEIN. Not all recalls are the same. They then have to file a form, which goes through all the specifics, and there can be a fair amount of variability in a recall.

Mr. CHAFFETZ. So I am looking at this field action report, which is dated April 21, 2009. And part of what was submitted said, the product from the subject lots found in the stores was removed during the visits. Visits to the remaining retailers will be completed by July 15, 2009, to remove any product from the subject lot that is found. It didn't say they were doing a recall, it said they were going back, and I am not trying to excuse their action, we just heard testimony from them saying we didn't do this right.

Dr. SHARFSTEIN. And I want to be clear. FDA was informed of exactly that on April 21st.

Mr. CHAFFETZ. Then how does the FDA spokesperson come out and say, we didn't know anything about this?

Dr. SHARFSTEIN. I think the difference is that what she was referring to, what she is saying FDA didn't know, and I still don't see any evidence of, is didn't know about the surreptitious, lying part of the recall.

Mr. CHAFFETZ. It wasn't a recall.

Dr. SHARFSTEIN. Well, the event. And that is still not in the documents, where people are being instructed to say things that aren't true.

Mr. CHAFFETZ. We all agree. But what my concern is—

Dr. SHARFSTEIN. And that is not in that document.

Mr. CHAFFETZ. What I would appreciate your looking back and considering is that the FDA's statement was very strong, saying, oh, no, you cannot construe—there was evidence that you should have looked deeper into that. When they say they are not doing a recall, then I think the FDA has some obligation to probe a little bit further, maybe ask a few questions. And you admitted that they came to the party late in this regard.

Let me read a couple quick quotes, Because I cited them earlier. This is from internal J&J documents. "FDA is really bending the rules in this case because of the fact that we stopped distribution a while ago." So for the FDA to go take a real strong stance and say, oh, we knew nothing about this, but then we have documents back from March 24, 2009 saying the FDA is really bending the rules.

Dr. SHARFSTEIN. Here is what I can explain I think that one means, because I am familiar with that. That was referring to the fact that we weren't ordering a recall without even a check. That is my understanding of that document. When he says because, basically a product that is violative and on the market should be recalled.

But the company came to us and said, we don't think any is out there. They said that to us, even though their own documents here indicate, I believe, that they knew there was some out there. But they said very specifically, and in fact if you look at the March 23rd FAR, they were saying, there is none out there, there is none out there. They used that argument. And FDA's district office said, well, if there is none out there, you don't need to do a recall. He interpreted that as bending the rules, but in fact, our regulations permit if there is none out there not to have a recall.

Mr. CHAFFETZ. Mr. Chairman, let me just make this last comment and I will yield back. I think it is irresponsible for the FDA to put out a public statement when the documentation shows that it wasn't a "recall," that there is a criminal investigation in place, that there are internal documents that demonstrate there were many discussions with the FDA. I think you have plenty of reasons to not attack the committee for the testimony that we were able to draw out during the previous testimony, but you essentially came out just a couple, literally days ago, and attacked the credibility of what this committee is trying to do. And really what we are

trying to do is inform the public and let them participate in this and come to their own conclusion.

There was plenty of evidence from multiple sources that did not warrant the strong statement that came from the FDA. That is part of my point. I would appreciate your consideration in looking into that moving forward.

I yield back the balance of my time.

Chairman TOWNS. I thank the gentleman for his questioning. I now yield to the gentleman from Maryland, Congressman Cummings.

Mr. CUMMINGS. Thank you very much. First of all, I want to thank the gentleman who just asked questions. I thought he asked a great set of questions. As I was looking at the document that he was referring to, Dr. Sharfstein, there is a sentence here that said, "the assessment performed demonstrated that on a statistical basis, a low amount, approximately 1 percent of the batches, is essentially still at the retail level." Are you familiar with that?

Dr. SHARFSTEIN. Yes.

Mr. CUMMINGS. What did that say to you all? So you didn't think it was that much out there?

Dr. SHARFSTEIN. That is correct. In fact, the month before, in the March version of the same document, it actually said it is expected that none of the affected lots are available at the store level. And at the same time, there are several documents that have emerged through the committee's investigation that they were expecting to find more. And in fact, they found more. And I will read you one of the emails that was on April 16th, prior to the submission of that. It said, "we found 264 units of the impacted lots, which would project there is potentially 5,280 units across the 5,000 stores, or 6.3 percent of the total product manufactured and shipped."

Now, it goes on to say why she thinks—

Mr. CUMMINGS. But this was not information that you all had at the time?

Dr. SHARFSTEIN. As far as I can see in the documents, this information was not shared with the FDA.

Mr. CUMMINGS. Dr. Sharfstein, buried in the field alert report dated April 21, 2009, there is a brief statement that "The product from the subject lots found in stores was removed during the visits." How would the FDA normally interpret a statement like that? And how would most companies normally remove product from stores if they were conducting a product recall? And how would the FDA and general public be informed?

Dr. SHARFSTEIN. I think that is an excellent question. I spoke last night to the head of enforcement in the Office of Regulatory Affairs at FDA. He said that he had looked at that report and that line. He said it was an unremarkable line. That is the kind of thing that companies do as part of recalls, they go out and they get the product.

But what is remarkable is the phantom part, that they were concealing it when they went out. That is not in there. He said, that is remarkable. What is in the report is not remarkable.

Mr. CUMMINGS. So let me make sure I know what you are talking about. As you heard, McNeil instructed their contractor, Inmar, to "simply act like a 'regular customer' while making these pur-

chases.” They are also told “there must be no mention of this being a recall of the product.”

So when you say you didn’t know about the phantom part, that is what you mean?

Dr. SHARFSTEIN. That is exactly right.

Mr. CUMMINGS. I see. So just for clarification, then, you thought they, apparently there is a situation where something was not dissolving properly and no one was under the impression, that is FDA, that it could be harmful to somebody that would buy it, is that a fair statement?

Dr. SHARFSTEIN. Not pose a safety problem, but it wouldn’t necessarily be as effective as it should be.

Mr. CUMMINGS. Say that again?

Dr. SHARFSTEIN. We didn’t think that it caused a safety problem.

Mr. CUMMINGS. Right.

Dr. SHARFSTEIN. We agreed that it might not be as effective as it should be, because it was less medicine in the pill, basically.

Mr. CUMMINGS. Did you know they were going into 40 States to do this phantom recall?

Dr. SHARFSTEIN. All we knew, I don’t know if I can answer that completely, other than to point to that document, that is what we were told, that they were going to retrieve it. But I think that what is clear, and this is where I believe that FDA could have done better, is that document doesn’t say a whole lot. We should have been asking questions, then, to really understand more. We eventually did ask those questions, we eventually did find out about the phantom part of the recall. Then the agency called the company to account for it, and that is why we are here.

Mr. CUMMINGS. Dr. Sharfstein, let me ask you this. So you are admitting that the FDA did not do all it should have done, is that right?

Dr. SHARFSTEIN. That is correct.

Mr. CUMMINGS. But we don’t want to take light off of the fact that McNeil and J&J could have done better, too, is that right?

Dr. SHARFSTEIN. I think fundamentally, the responsibility is with the company to have handled their quality problems in a much different way. And FDA did respond and did identify these problems. I think we always have to ask ourselves whether we could have done so faster.

Mr. CUMMINGS. And that leads me to my final question, how do we know that we now have an FDA and a Department that deals with this that would deal with it differently and would deal with it in a way that would cause that trust to come to citizens of our country who might be buying the product?

Dr. SHARFSTEIN. That is a fair question. I think I would point in part to all the work that we have done with these companies since this came to light. And I would also say that Dr. Hamberg, the Commissioner and I are absolutely committed to strengthening the enforcement and the oversight of FDA. I actually invited here today our new head of enforcement, Dara Corrigan, a former acting HHS inspector general. This is her first week on the job, and I asked her to come to understand what had gone on in this case and the need, as she works and establishes leadership over this part of FDA, the need for us to do everything we can.

Mr. CUMMINGS. Could she raise her hand, so we will at least know who you are talking about? There you are. Welcome, congratulations.

Thank you, Mr. Chairman.

Chairman TOWNS. Let me also welcome you. Thank you.

I now yield 5 minutes to the gentlewoman from Washington, DC, Congresswoman Norton.

Ms. NORTON. Thank you, Mr. Chairman.

Dr. Sharfstein, I was really interested in Mr. Weldon's answer to my question regarding the children's medicines and the 8 million bottles. I would like your opinion. This was my question to him, predicated on the McNeil documents that showed contamination growth identified in children's medicine in April 2008. And I wanted to know from him whether or not he should have recalled, not in 2009, but earlier. And he indicated that they had looked at those samples and that there was no contaminant in those samples. Is that your view?

Dr. SHARFSTEIN. It is true, it basically relates to what I would call a super-lot of this substance, meaning a huge batch, and the sub-lots. So the super-lot was known to have some contamination in it. I understand that the company knew that this certain sub-lots that were contaminated, they didn't use. Other sub-lots they tested and didn't find a problem and they used those.

But FDA's view was that testing alone is not, doesn't give you enough confidence of safety if the whole super-lot has had a problem.

Ms. NORTON. So what should be done?

Dr. SHARFSTEIN. So what should have been done was basically recall it. And that is why it eventually got recalled. But this isn't just FDA's view, this is what we believe that their good manufacturing practices required. And it relates to the concept that you can't test quality into something. If you know that something is of poor quality, you can't keep testing it to find the little part to use. If there is a problem overall, you can't use it.

Ms. NORTON. And I would think especially with children's medicine of various kinds. I must say that what it does show is that a company will act, I think quite normally, absent regulations. It will draw the presumption in favor of itself. I noticed that on page 5 of your own testimony you say something that I would regard as a truism: the current voluntary system of drug recall depends on companies providing accurate and complete information to the agency and recalling adulterated or otherwise violative products in a prompt and appropriate manner.

The voluntary system would assume all that to be the case. But I must say that it makes the same kind of assumption that was made for 10 years about the financial system, that voluntarily letting them go without regulations will do it. And the same way, this voluntary recall notion is not only an oxymoron, I don't see how we can continue to abide it and expect companies to act any way but the way people do, to protect themselves, to protect their shareholders. The only way to pierce that is with some kind of form of regulation. If we haven't learned that from financial reform, and now we have to learn it from children's medicine, we will never learn it.

I want to ask you about the phantom recall of defective Motrin. Do you believe, Dr. Sharfstein, that the companies adequately informed FDA about the defective Motrin issues beginning in November 2008?

Dr. SHARFSTEIN. We knew there was a defective Motrin issue, the company did inform us that there was a defective Motrin issue November 2008. I do not think that we were adequately informed about what the company knew about whether it was still on the shelves. Because at the same time the company was telling FDA they didn't think any was on the shelves, they were internally expecting to find some on the shelves. So I don't think that was adequate information to the agency. I think that may have been one of the contributing factors to the delay.

Ms. NORTON. And of course, although they have a duty to do that, since it is only a voluntary duty, there was nothing you could do about it.

Dr. SHARFSTEIN. And I also don't believe, based on the information that I have available, that the company informed FDA about the phantom part of the phantom recall, the surreptitious nature, the act like a regular employee, don't tell people what you are doing, part of the recall. I do not see in any of these documents that FDA was informed about that at that time.

Ms. NORTON. I see my time is expired. Thank you, Mr. Chairman.

Chairman TOWNS. I now yield 5 minutes to the gentleman from California, the ranking member of the committee, Congressman Issa.

Mr. ISSA. Thank you, Mr. Chairman.

Doctor, I earlier in my opening statement referenced your old boss, Mr. Chairman Waxman. Because I do think that he was right when he said that we had a constitutional obligation and we weren't meeting it. But I want to be true to his words and ask you, it is hard to get a notebook like this, four inches thick. This is the record of your agency's inspections without shutting down that plant. Now, you are coming here today and you are saying, I need new authority, I need mandatory recall authority. You may get it.

But you had the ability to shut down the factory. Any time you found anything, you could pull the switch and shut them down. This is how many times you visited and visited and visited under Chairman Waxman's tenure, your working on the committee.

But more importantly, under the Bush administration, this was not dealt with. Of course, it was the same people. Under your administration, this was not dealt with. This was the record of failure before we got to the recall.

Now, you haven't been on the job more than about 2 years, but I assume you have read your regulatory procedure manual, 7-3, which talks about your recall procedures, statutory recall procedures? OK. Let's go through it by the numbers and make sure we understand. Your people in Puerto Rico were participants in a stealth recall. The evidence shows that they understood product was being taken.

I will agree with you, subject to criminal investigation that is going on, that they may not have known that it was being bought without saying that in fact it was being recalled. But of course, re-

member, your people had agreed that it wasn't a recall, and yet they were agreeing that it was going to be removed from the shelves.

So while the FDA was aware product was being assessed and removed from the shelf, they were not asking for a recall. They were not in fact doing what they already have a responsibility, according to your manual, which was to agree to public statements, etc.

Now, if they didn't have the right to do a recall but they knew product was being recalled, then they did not participate in how that recall that wasn't a recall was going to be done. In fact, if anything, while they knew that product was being removed by a third party contractor, they didn't ask, they didn't tell, like the three monkeys that you see, hear no evil, see no evil, speak no evil. They failed to do their job, because they had an obligation and a manual that told them how to do that.

Isn't that correct, that the fact that they didn't know how it was being removed and didn't ask, and did not assert any of the procedures in your manual?

Dr. SHARFSTEIN. Let me thank you for your questions and I respect the importance of oversight.

Mr. ISSA. And I would like a yes or no on that. Did they in fact, according to the evidence, know product was being removed from the shelf and did not assert, in any documents you have, remember, because of the criminal investigation, we are almost opaque relative to the FDA.

Dr. SHARFSTEIN. The FDA did assert that this needed to be a recall in July. But it did not happen before that. And one of the things—

Mr. ISSA. But they were informed that product was being removed from the shelf. That is in the email. Your people—no, wait a second—that your people did a press release, a press statement, implying that we weren't doing our jobs and we were misleading the public, when in fact, you may not have known what was being said as they purchased the product, but your people knew they purchased the product, and there was ongoing dialog into that extent. Isn't that true?

Dr. SHARFSTEIN. It is true that we knew they were purchasing the product. That was—

Mr. ISSA. OK, so now you know there is a recall going on. Purchasing back the product is a recall, isn't it? Call it whatever you want, isn't it a recall?

Dr. SHARFSTEIN. It is a component of a recall.

Mr. ISSA. OK, so they are purchasing back the product. You are not doing a public statement to encourage people to return product so it can be bought back at those consumer areas. You are not doing any of the things that are in your manual. And yet you want us to believe it is all Johnson & Johnson.

Dr. SHARFSTEIN. That is not what I—

Mr. ISSA. Now, wait a second. Johnson & Johnson made bad product. They made product that was not working up to its standard. But yet you want us to believe that it is all their fault—

Dr. SHARFSTEIN. No.

Mr. ISSA [continuing]. And that Ms. Torres, who is still on the job but under criminal investigation, is in fact somehow to be given

a pass here and you are to be given new authority, when I have four inches of authority that you didn't assert.

Dr. SHARFSTEIN. With all respect, that is not what I testified. I did not testify this was all Johnson & Johnson's fault. In July—

Mr. ISSA. Well, what changes have you made or are you prepared to make at FDA to prevent this from happening again at the other 14 plants in Puerto Rico, 35 plants in Puerto Rico?

Dr. SHARFSTEIN. Can I finish my previous thought?

Mr. ISSA. Please.

Dr. SHARFSTEIN. FDA identified the problem and in July was very clear with the company. What I testified was—

Mr. ISSA. No, no, in July, no, they were told by the company of this problem prior to that in the whole process.

Dr. SHARFSTEIN. FDA instructed the company to register this as a recall in July.

Mr. ISSA. That is 6 or 7 months after they were aware of the problem and after it was all removed from the shelf.

Dr. SHARFSTEIN. And I testified that instruction should have come earlier. But it was because of that instruction that it got into the FDA enforcement bulletin.

Mr. ISSA. Isn't it true that it is not on your Web site today, that it is not a listed recall?

Dr. SHARFSTEIN. That is not true.

Mr. ISSA. We looked for it, we could not find it. Would you please make it available to the committee?

Dr. SHARFSTEIN. I can give it to you right now, if you want it. It is in the enforcement report of November 25, 2009.

Mr. ISSA. No, I asked about your Web site, where you list public recalls.

Dr. SHARFSTEIN. This is on, I have a printout that looks like it is from a Web site right here, listing it. I am happy to show it to you. It sure looks like a printout from a Web site.

Mr. ISSA. I am sorry, but we do have, we will provide you with our Web site that it is supposed to be on that it is not on, and we can compare that for the record later.

Dr. SHARFSTEIN. I was given the report printed out from a Web site. So we will figure out what is going on there.

FDA realizes that it has a critical responsibility, not just for the facilities in Puerto Rico, the facilities elsewhere in the United States, but all around the world that are shipping drugs and other things into our country. This is extremely important. That is why the commissioners made a priority of enforcement, and that is why we are pleased that there is an entire business within the private sector to train companies to meet FDA's specifications for compliance. It is both an FDA responsibility, it is also a corporate responsibility. We have to do everything we can in a changing and very difficult environment to protect the public.

Mr. ISSA. Mr. Chairman, I know my time is expired. So for the record, I would like a complete answer to this. And that is, since the discovery of this pesticide used on the wood, and you testified that in fact, if you will, they had failed to meet the responsibility, would you explain for the record why you did a notification to the industry of a new, novel problem after the fact that was discovered by Johnson & Johnson, reported by Johnson & Johnson and fixed

by Johnson & Johnson, if you will, and yet you put it out to an industry that was completely unaware of it, and you want us to believe that somehow it was a failure of a company, when in fact it was a discovery not previously known by any of the manufacturers in the industry?

I would like that completely answered for the record, Because I find an inconsistency between your implying that a terrible thing to discover had happened, but that somehow you guys were the cure rather than in fact, all you did was take their work and publicize it to an industry that otherwise would not have been made aware of it. I yield back.

Dr. SHARFSTEIN. I would be happy to answer that question initially, but I will leave it to you.

Chairman TOWNS. There will not be a second round, so maybe you could answer it at this time, even though your time has long, long expired. But you can answer it at this moment.

Dr. SHARFSTEIN. It is OK, it is what I deserve for having been on the committee as staff. Many minutes of questions.

What FDA objected to with respect to the smell and the TBA was not so much that there was a new problem that the company found, but they had identified a problem and not reported it for quite some time. And then it was the FDA pushing them to investigate it further that led them to discover the problem.

So if the company had come to us and said, we have found a problem, we would be saying, that is terrific, you found a problem that may be applicable in other places, thanks for having a system that finds that. Instead, there were problems, many months went by before a report came into FDA. When that happened, we felt the company wasn't pursuing it diligently enough. FDA was on top of it.

And as a result of that, we got those recalls. We learned and we informed the rest of the industry so that we could be on top of an emerging problem. I think it speaks to a bigger point.

Mr. ISSA. Mr. Chairman, I appreciate his answer and I think it is a good one. But it flies in the face of, when you discover new science, the expectation that you are going to report it within 3 days in a meaningful way begs the question of, if the FDA can't even make up its mind on the July report that they are still evaluating, 60 days later, and say that they are not prepared to talk about, I am seeing a pattern that we expect corporations to respond to new science discoveries in 3 days and then so that everyone knows.

It is very clear that we do need to have reporting. I think Johnson & Johnson appropriately was wrong not to at least give a heads up. But let's be honest. This was new science that needed discovery, that has benefited all the industry so that we make better product. And I think 3 days is a nice time to say, oh, we found something you might be interested in—

Mr. CUMMINGS. Mr. Chairman, regular order. Mr. Chairman, regular order.

Chairman TOWNS. Let me just say this. Based on what the gentleman is saying, it seems like he wants to support my legislation. [Laughter.]

I yield to Ms. Watson for 5 minutes.

Ms. WATSON. I do hope that is so.

Dr. Sharfstein, Johnson & Johnson has described, as our chairman has rightfully dubbed the phantom recall of the adult Motrin products as merely an assessment to determine how much product was in circulation. However, we knew this is not accurate because they proceeded to remove the product from the stores without informing customers or retailers of the defective product.

Is this a typical kind of thing that happens, and what steps should have Johnson & Johnson taken when they discovered the dissolution problem with the Motrin? Is this something that occurs often?

Dr. SHARFSTEIN. This is a very unusual set of circumstances. That is why, when FDA really understood what was going on, there was an extraordinary meeting with the parent company, Johnson & Johnson, to express concern about it.

To your point, what should happen is when there is a product that is out of specification, there is a prompt notification to the agency and a recall, an official, registered recall. In this case, because they had stopped selling it before, they made the case to the agency that there wasn't out there and there might not need to be a recall. Although as I said, I am concerned, based on some of the documents the committee has found, that wasn't necessarily a fair representation to the agency. Because they seemed to know that there was stuff out there. That was one of the steps that led this to take a lot longer than it should have.

But I also acknowledge that FDA could have done more to make this happen sooner.

Ms. WATSON. During our previous hearing on this subject, it was reported that from January 1, 2008 through April 30, 2010, that 775 adverse events had been reported for children who took the recalled products. At the time, the FDA could not confirm whether or not there was a direct causal link between these events and the recalled drugs.

But I think it is important that we fully investigate the effects these contaminated or super-potent drugs could have on children. So has the FDA been investigating the adverse events report and if so, how? Would you elaborate a bit?

Dr. SHARFSTEIN. Sure. I believe that there was a team in the Office of Surveillance and Epidemiology that pulled all the adverse events for the recalled products for 2 years prior to the recall and then 2 years after and reviewed them, and did not find that there was evidence establishing a link. That was one of the things that was done.

In other specific cases, FDA actually went out, where there was a coroner, for example, who had a sample, and was concerned. We tested the sample and we didn't find it in any of the samples.

So everything that we could do we have done to try to assess this. There is a very small risk, but we did not see evidence in these reports that there were serious illness or death.

Ms. WATSON. Do you have any reasons to believe that these adverse events were related to the recalled medications? What are the most common adverse events that children have experienced because of the use?

Dr. SHARFSTEIN. Most of the adverse events are because of the medications themselves. We couldn't find any adverse events related to the problems in production. Each of those different kinds of medicines has their own series of adverse events that are on the label. Some medicines might make a child jittery, potentially. There are a list of things that could happen. Those are the kinds of reports that we got.

In other cases, people might take, mistakenly, an overdose, too much of a medicine and have an adverse event related to that. But that is not because of the quality problem in production. That just happens. All medicines carry risks.

So those are the kinds of things that were being reported to the agency, not things that we could track to the quality problems that were at issue.

Ms. WATSON. In my last 30 seconds, I am addressing the Chair. Mr. Chair, does your bill address this kind of thing, what are the adverse effects and how typical?

Chairman TOWNS. Yes.

Ms. WATSON. Would your bill address that, is there a provision?

Chairman TOWNS. It will address it. It also is still open for amendment and suggestions.

Ms. WATSON. Very good.

Chairman TOWNS. We need co-sponsors.

Ms. WATSON. I yield back. You will have one.

Chairman TOWNS. Thank you very much. Let me thank the gentlelady for her comments.

And let me just say to you, Dr. Sharfstein, thank you so much for your testimony. I also want to thank Mr. Weldon and Ms. Goggins for staying and listening to your testimony. I think you are the appropriate person to do this, because you are a pediatrician, aren't you?

Dr. SHARFSTEIN. I am.

Chairman TOWNS. So you are the right person to talk to in reference to this issue. I want to thank you for that.

I also want to let the Members know that the record will be open for several days. We have not come up with the amount of days but there are certain questions, of course, that Members wanted to submit for the record. Of course, we will leave it open to get those questions.

Again, I want to thank you for being here. I want to thank all the Members for their participation. On that note, the committee stands adjourned.

[The prepared closing statement of Chairman Edolphus Towns follows:]

### Closing Statement

At the outset of today's hearing, Johnson & Johnson specifically confirmed that they did not inform the FDA about the phantom recall.

J&J also admitted that they made a mistake in the way they handled the defective Motrin.

Nevertheless, the testimony today, combined with the testimony at our first hearing, indicates some very serious problems – both with the way Johnson & Johnson viewed its responsibility to the public and with its day-to-day relationship with the FDA.

Mr. Weldon testified that J&J tries to work cooperatively with the FDA. On its face, that sounds positive. But there is often a thin line between "working cooperatively" and having a "cozy relationship."

The documents we have seen in this case indicate that this line may have been crossed – early and often.

But it is all too easy for J&J to say, "If the FDA had asked us to conduct a recall, we would have done it."

On the contrary, the evidence indicates J&J did everything it could to avoid a formal recall. In short, J&J tried to pull a fast one on the American public, but they got caught.

Judging from the Members' questions today, I think it is fair to say this will not be the last word on this investigation. We look forward to full cooperation from J&J and the FDA as we move forward.

While I understand that the Justice Department has initiated a criminal investigation related to some of these matters, we are not aware of any reasons why our investigation should not move forward. We intend to continue our investigation and interview some additional key witnesses.

Thank you.

[Whereupon, at 12:20 p.m., the committee was adjourned.]  
[Additional information submitted for the hearing record follows:]

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December 15, 2010

**By Electronic Mail**

Christopher Staszak  
Investigative Counsel  
Committee on Oversight and Government Reform  
U.S. House of Representatives  
2157 Rayburn House Office Building  
Washington, D.C. 20515

Re: Chairman's Letter of December 7, 2010

Dear Chris:

On behalf of Johnson & Johnson ("J&J") and McNeil Consumer Healthcare ("McNeil"), this letter responds to the December 7, 2010, letter from Chairman Towns to William C. Weldon, J&J's Chairman and Chief Executive Officer, and Colleen Goggins, J&J's Worldwide Chairman, Consumer Group. In that letter, the Chairman submitted three additional questions to Mr. Weldon and Ms. Goggins for the record in the hearing entitled "Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines and the Phantom Recall of Motrin (Part 2)," which was held on September 30, 2010. As requested, the text of each of the Chairman's questions has been included along with each response.

**1. How many bottles/packages of children's medicine were included in the Johnson & Johnson/McNeil September 2009 recall of children's medicine? Please include medication that was purchased by customers, medication that was shipped to retail outlets and medication that was shipped to wholesalers.**

As reflected in a report submitted to the FDA in August 2009 (previously produced to the Committee labeled MCNEIL\_0024681 - MCNEIL\_0024695), the "[a]mount of product distributed" from the impacted lots in the September 2009 recall was 7,983,648 bottles. *See* MCNEIL\_0024689. The report also provides a breakdown by "[Percentage] of Product Distributed" from the impacted lots to government, wholesale, and various retail accounts. *See id.* To the best of our knowledge, the 7,983,648 bottles include all bottles from the impacted lots that either were purchased by consumers, shipped to retail outlets, or shipped to wholesalers. *See id.*

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Christopher Staszak  
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Across all of the impacted product lots in the September 2009 recall, the total “[a]mount of product manufactured” was just over 8.1 million bottles. *See* MCNEIL\_0024691. This is because one impacted lot, SFM024, representing slightly more than 119,000 bottles, was destroyed and not distributed. *See* MCNEIL\_0024689.

**2. One of the documents Johnson & Johnson provided to the Committee (Bates stamp McNeil\_0022013) indicates that at the same time contractors were buying Motrin without disclosing to the public or to store personnel that there was a problem with the medication, those contractors were also performing a service for Johnson & Johnson/McNeil related to children’s medicine. Please describe in detail all services any third party performed for Johnson & Johnson/McNeil in connection with the September 2009 recall of children’s medicine.**

**Did the same contractors who surreptitiously purchased Motrin perform work related to children’s medication at the same time those contractors were performing the Motrin “phantom recall”? If so, please describe in detail what work those contractors performed with respect to children’s medication.**

In spring 2009, McNeil contracted with Inmar, Inc. (“Inmar”), a third-party contractor, to conduct an in-store assessment on certain lots of Motrin®. While we understand the Committee’s concerns on this issue, and McNeil would proceed differently today, McNeil informed the FDA of its actions regarding Motrin® and kept the FDA apprised of those actions over a period of several months in 2009. As a part of these communications, McNeil told the FDA that “a third party ha[d] been contracted to perform an in-store assessment,” and later, that “[v]isits to the remaining retailers will be completed by July 15, 2009 to remove any product from the subject lots that is found.” *See* MCNEIL HC 7298; MCNEIL HC 7306. McNeil also notified key customers that the Motrin® caplets “d[id] not meet [its] performance standards,” and the company would “send in [its] own teams to remove the specific product lots” from retail outlets. *See* MCNEIL HC 7336.

In July 2009, McNeil requested that Inmar conduct an in-store assessment to determine the extent to which certain lots of Infants’ and Children’s Tylenol liquid products remained in the marketplace, as most of the lots in question had shipped in 2008. For the purpose of this assessment, Inmar visited 398 stores, including some that were part of the Motrin® project. McNeil asked Inmar to undertake the Tylenol liquids assessment project because the company was in communication with the FDA about a possible recall, and in the course of these kinds of discussions, FDA often asks for estimates of how much affected product remains on store shelves. To the best of our knowledge, based on the information currently available, Inmar did not

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purchase product from the affected lots during this assessment. A document provided to the Committee demonstrates that Inmar confirmed to McNeil that “No Product w[ould] be purchased” during this assessment. *See* MCNEIL\_0021325.

Later in the summer of 2009, McNeil contracted with Inmar to assist with a recall of certain lots of Infants’ and Children’s Tylenol liquid products. This recall was implemented, in close consultation with the FDA, in September 2009. The FDA was informed on August 19, 2009, that McNeil would use Inmar to assist with the recall. *See* MCNEIL\_0024944. Initially, Inmar assisted the recall at the wholesale level by issuing recall notification mailings to wholesalers. When McNeil voluntarily extended the recall to the retail level at the end of August 2009, McNeil specifically informed the FDA that Inmar would be visiting retailers to remove and purchase affected Tylenol product, and received the agency’s approval. McNeil’s communication letters to retailers were approved by the FDA, and directed managers to inform stores that “Inmar representatives will be visiting . . . [to] remove and purchase affected product.” *See* MCNEIL\_0027171.

Over the course of this liquids recall, McNeil used another third party, the Lancaster County Solid Waste Authority (“LCSWA”), to assist in the transport and destruction of product from the affected lots that was returned through the recall effort. The FDA was informed that LCSWA was destroying product from the affected lots that was returned to McNeil.

To the best of our knowledge, Inmar and LCSWA were the principal third parties that were utilized to assist the actual, physical recall and destruction of product from the affected lots.

**3. Who provided McNeil/Johnson & Johnson with the inactive ingredient that was found in April 2008 to be contaminated with B. cepacia? Where was that inactive ingredient manufactured?**

The inactive ingredient that McNeil received, tested, and found to contain B. cepacia in April 2008 was Avicel RC-591, a suspending agent used in some infants’ and children’s liquid products. The Avicel was provided to McNeil by FMC BioPolymer, one of McNeil’s raw materials suppliers. FMC manufactured the Avicel in its Newark, Delaware plant.

As stated in the written testimony before the Committee on September 30, 2010, the issue that prompted the discussion and eventual recall in September 2009 presented only a remote risk to patient safety. The September 2009 voluntary recall was undertaken out of an abundance of caution because objectionable bacteria had been

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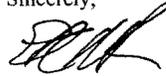
Christopher Staszak  
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found in raw material that was rejected and not used in production. McNeil tested the raw materials, and no raw materials that tested positive for objectionable bacteria were ever used in production. In addition, McNeil tested its final products for bacteria and has not identified any products placed on the market that contained objectionable bacteria. Subsequently, McNeil tested retained samples, which also tested negative for objectionable bacteria. Indeed, the McNeil liquid products are specifically designed to resist bacteria, with both a low water activity level and a preservative system that preclude bacteria growth.

\* \* \*

Please contact either of us if you have any questions.

Sincerely,



Ethan M. Posner  
Robert K. Kelner

cc: Sery E. Kim, Counsel, Minority Staff  
Carla Hultberg, Chief Clerk

EDOLPHUS TOWNS, NEW YORK  
CHAIRMAN

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ONE HUNDRED ELEVENTH CONGRESS

**Congress of the United States**  
**House of Representatives**

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December 7, 2010

Mr. William C. Weldon  
Chairman and Chief Executive Officer  
Ms. Colleen Goggins  
Worldwide Chairman, Consumer Group  
Johnson & Johnson  
One Johnson & Johnson Plaza  
New Brunswick, NJ 08933

Dear Mr. Weldon and Ms. Goggins:

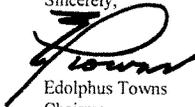
Thank you for appearing before the Committee on Oversight and Government Reform on Thursday, September 30, 2010, at the hearing entitled "Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines and the Phantom Recall of Motrin (Part 2)." We appreciate the time and effort you gave as a witness before the Committee.

Pursuant to the Rules of the Committee on Oversight and Government Reform, attached are additional questions for the hearing record. In preparing your answers to these questions, please include the text of the Member's question along with your response.

Please provide your response to these questions by December 15, 2010. Your response should be addressed to the Committee office at 2157 Rayburn House Office Building, Washington, DC 20515. Please also send an electronic version of your response by e-mail to Carla Hultberg, Chief Clerk, at [carla.hultberg@mail.house.gov](mailto:carla.hultberg@mail.house.gov) in a single Word or WordPerfect formatted document.

Thank you for your prompt attention to this request. If you need additional information or have other questions, please contact Carla Hultberg at (202) 225-5051.

Sincerely,

  
Edolphus Towns  
Chairman

Attachment

**Questions for Mr. William C. Weldon, Chairman and Chief Executive Officer  
Johnson & Johnson and Ms. Colleen Goggins, Worldwide Chairman,  
Consumer Group, Johnson & Johnson  
From Rep. Edolphus Towns,  
Committee on Oversight and Government Reform  
Hearing entitled, "Johnson & Johnson's Recall of Children's Tylenol and  
other Children's Medicines and the Phantom Recall of Motrin (Part 2)."**

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1. How many bottles/packages of children's medicine were included in the Johnson & Johnson/McNeil September 2009 recall of children's medicine? Please include medication that was purchased by customers, medication that was shipped to retail outlets and medication that was shipped to wholesalers.
  
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