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JOHNSON & JOHNSON'S RECALL OF CHILDREN'S TYLENOL AND OTHER CHILDREN'S MEDICINES

HEARING

BEFORE THE

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED ELEVENTH CONGRESS

SECOND SESSION

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JOHNSON & JOHNSON'S RECALL OF CHILDREN'S TYLENOL AND OTHER CHILDREN'S MEDICINES

THURSDAY, MAY 27, 2010

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

The committee met, pursuant to notice, at 10:04 a.m., in room 2154, Rayburn House Office Building, Hon. Edolphus Towns (chairman of the committee) presiding.

Present: Representatives Towns, Cummings, Kucinich, Tierney, Clay, Watson, Connolly, Quigley, Norton, Davis, Speier, Issa, Westmoreland, Bilbray, Jordan, Chaffetz, Luetkemeyer, and Cao.

Staff present: John Arlington, chief counsel—investigations; Kevin Barstow, investigative counsel; Adam Hodge, deputy press secretary; Carla Hultberg, chief clerk; Marc Johnson and Ophelia Rivas, assistant clerks; Jenny Rosenberg, director of communications; Leneal Scott, IT specialist; Christopher Staszak, senior investigative counsel; Ron Stroman, staff director; Gerri Willis, special assistant; Alex Wolf, professional staff member; Lawrence Brady, minority staff director; John Cuaderes, minority deputy staff director; Rob Borden, minority general counsel; Adam Fromm, minority chief clerk and Member liaison; Kurt Bardella, minority press secretary; Stephen Castor, minority senior counsel; and Ashley Callen, minority counsel.

Chairman TOWNS. The committee will come to order.

Good morning and thank you for being here.

Any time we give our children or grandchildren medicine, like this bottle of Children's Tylenol that was included in the recall, we expect it to be safe and we expect it to help the children get better, not create problems for them.

When questions are raised about whether children's medicine is safe, parents need immediate answers. Almost every household in this country has these children's products in their medicine cabinets. And everyone has the same question this morning: Are these products safe, and what are we doing to ensure safety and to make certain that this does not happen again?

While we do not want to cause unnecessary alarm, we also cannot ignore the troubling facts before us.

Less than a month ago, a Johnson & Johnson company known as McNeil Consumer Healthcare recalled over 40 variations of children's medicine, including such widely used products as Children's

Tylenol, Children's Motrin, Children's Benadryl and Tylenol Infants' Drops.

This recall was carried out because of production problems at McNeil that affected the quality, purity and potency of the medicine. McNeil received dozens of consumer complaints about foreign particles in children's medicine, which were later confirmed by McNeil.

In addition, tests at the plant show that three batches of Infant's Tylenol were found to be "super potent," meaning that they contained an overdose of the active ingredient.

McNeil's production of children's medicine was shut down by the company and a month later it still is shut down. The FDA is currently investigating any possible links between the recalled medicine and adverse health effects on children who took that medicine.

The FDA is also currently reviewing reports of children who died to determine if there is any connection between those deaths and this recall. At this point, the FDA is not aware of any connection between the recalled medicine and the death of any child.

One document the committee received from the FDA refers to the case of a 1½-year-old girl who died. That document reads, "coroner's office called to report the death of a 1½-year-old female that is suspected to be related to a Tylenol product."

Just last night, the committee obtained from the FDA even more disturbing information. According to an FDA document, McNeil knew there was a potential problem with one of its Motrin products that was on the market in 2008, but rather than issue a public recall, McNeil allegedly sent contractors out to stores to buy the product back and told the stores "not to mention" a recall.

After the FDA confronted McNeil about this, McNeil officially enacted a recall on the affected products.

If true, this "phantom recall" attempt by McNeil could have endangered the public and warrants further investigation by this committee.

We need to know what health risks are associated with this recall. We need to know whether this is an isolated issue, or part of a widespread problem with the safety and production of children's medicine at McNeil. We need to know what Johnson & Johnson is doing to get to the bottom of this. And we need to know what the FDA is doing to ensure the safety of children's medicine and whether the FDA has the resources it needs to carry out its mission.

Both Johnson & Johnson and the FDA will be asked very difficult questions today and I hope they are prepared to give us the answers that will assure safety of these medications.

This is our first hearing on this issue, but there may be more. We will follow this road until we have all the answers and the questions raised by the American people are answered.

There is nothing this committee will investigate that is more serious than the health of our children. I can assure you that, as chairman of this committee, and I know on this matter I also speak for the ranking member when I say this, we will use all of our authority to find out what went wrong and do everything that we can to ensure that it does not happen again.

[The prepared statement of Chairman Edolphus Towns follows:]

STATEMENT OF
CHAIRMAN EDOLPHUS TOWNS

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

"Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines."

May 27, 2010

Good morning and thank you for being here.

Any time we give our children or grandchildren medicine, we expect it to be safe and we expect it to help our children get better.

When questions are raised about whether children's medicine is safe, parents need immediate answers. Almost every household in this country has these children's products in their medicine cabinets. And everyone has the same questions: Are these products safe, and what are we doing to ensure safety in the future.

While we do not want to cause unnecessary alarm, we also cannot ignore the troubling facts before us.

Less than a month ago a Johnson & Johnson company known as McNeil Consumer Healthcare recalled over 40 variations of children's medicine, including such widely used products as Children's Tylenol, Children's Motrin, Children's Benadryl and Tylenol Infants' Drops.

This recall was carried out because of production problems at McNeil that affected the quality, purity and potency of the medicine. McNeil received dozens of consumer complaints about foreign particles in children's medicine, which were later confirmed by McNeil.

In addition, tests at the plant show that three batches of Infant's Tylenol were found to be "super potent," meaning that they contained an overdose of the active ingredient.

McNeil's production of children's medicine was shut down by the company and a month later it is still shut down. The FDA is currently investigating any possible links between the recalled medicine and adverse health effects on children who took that medicine.

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Just last night, the Committee obtained from the FDA even more disturbing information. According to an FDA document, McNeil knew there was a potential problem with one of its Motrin products that was on the market in 2008, but rather than issue a public recall,

McNeil allegedly sent contractors out to stores to buy the product back and told the stores "not to mention" a recall.

After the FDA confronted McNeil about this, McNeil announced a recall of the affected products.

This "phantom recall" warrants further investigation by this Committee. Who at McNeil and Johnson & Johnson knew about this scheme? How high up in the corporate suite was this scheme hatched? Is this a standard operating practice for McNeil?

We need to know what health risks are associated with this recall. We need to know whether this is an isolated issue, or part of a widespread problem with the safety and production of children's medicine at McNeil. We need to know what Johnson & Johnson is doing to get to the bottom of this. And we need to know what the FDA is doing to ensure the safety of children's medicine and whether the FDA has the resources it needs to carry out its mission.

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

This is our first hearing on this issue, but there may be more. We will follow this road until we have all the answers the American people deserve.

There is nothing this Committee will investigate that is more serious than the health of our children. I can assure you that as Chairman of this Committee – and I know that I also speak for the Ranking Member when I say this – we will use all of our authority to find out what went wrong and do everything we can to ensure that it doesn't happen again.

Thank you.

###

Chairman TOWNS. On this note, I yield 5 minutes to the ranking member of the committee, Congressman Issa, from the great State of California. Mr. Issa.

Mr. ISSA. Thank you, Mr. Chairman. And you are right, you speak for both of us when you say we will use all efforts of this committee and all power of this committee to ensure this does not happen again.

Johnson & Johnson has owned the McNeil Consumer Healthcare Division since 1959, so for, one, from this day forward, I will say Johnson & Johnson and not talk about a subsidiary that has been owned by a company for so long.

Before I came to the Congress, I was a manufacturer. I understand ISO 9001; certainly a good, but lesser standard than what we expect medical items and food items to be held to. But there is no question that my manufacturing techniques were less than I would have expected if I were going to put a product in my mouth.

Producing electronics, you want it to work and you want it to work reliably. You want it to work consistently and you want it to never hurt anyone. But my company knew that we would produce a product that from time to time would be installed poorly. We knew that from time to time we would have a bad transistor, resistor, or diode. We did not produce to aviation specs because, to be honest, an alarm going off because of a malfunction was less of a problem.

But today we are talking about a market leader, a leader who had so much confidence of the American people that we never question their products or their services; whose creed was all about safety and reliability. And they have disappointed us.

We are not the committee of manufacturing. We are not the committee of jurisdiction directly over healthcare products or, for that matter, any of the manufacturing sector in this country. That is for other committees. What we are is the committee that oversees Government's overseeing of its responsibility.

Today we have before us the FDA. And much like the National Transportation Safety and other parts of the Department of Transportation, we have an agency who has done their job. They have delivered report after report of problems and they have come to a final conclusion before coming to this committee of a massive recall.

So like Akio Toyoda, we would hope that Johnson & Johnson comes ready to say this is a mistake that will not happen again; that the company will in fact change how it does business so significantly as to never be before us again.

But as to the FDA, I am encouraged that they have done their job, but I am disappointed that it took so long. As with the national transportation questions that we had before Secretary LaHood, today I will be interested to know what changes at FDA would allow for, if you will, shortcuts to this conclusion. How do we find that a manufacturing technique that is below standard is corrected more quickly? How do we ensure that there are no backdoor or, if you will, unannounced recalls? And how do we ensure that the FDA has all of the authority and financing that it needs to ensure the American people that not just a 120-year-old company, well regarded and able to pay for all the cost of their mistakes, but that

every piece of over-the-counter or prescription medicine or, for that matter, food, whether domestic or foreign import, as so much is today, is safe?

I am deeply concerned, Mr. Chairman, that Johnson & Johnson is the tip of the iceberg. If one of the most reliable and responsible organizations in America and a company with great connections to the community can fail us, then what about those aspirins and other products that are more and more being imported from outside our country, from factories that are harder to reach and people who do not even speak our language when we go to inspect them?

So although today is about Johnson & Johnson, and I hope the second panel does their job of explaining why they will not be in front of us again, I am most interested in the first panel. What do we need to do, as the Committee on Oversight and Government Reform, to ensure that you are able to do your job worldwide, safely, so the American people can sleep knowing that these kinds of medicines, no matter where they are made in the world, will be absolutely safe from this day forward?

I thank the chairman and yield back.

[The prepared statement of Hon. Darrell E. Issa follows:]

EDOLPHUS TOWNS, NEW YORK
CHAIRMAN

DARRELL E. ISSA, CALIFORNIA
RANKING MINORITY MEMBER

ONE HUNDRED ELEVENTH CONGRESS

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Statement of Rep. Darrell Issa, Ranking Member

"Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines."

May 27, 2010

Thank you, Mr. Chairman, for holding today's important hearing about the recall of medicines produced by Johnson & Johnson and its subsidiary, McNeil Consumer Healthcare, for use by children and infants.

In Washington, there are many different perspectives, and often we find ourselves divided along partisan lines. But today, we are not considering tax policy, or defense policy, or federal spending, or the size of government. Today, we are considering a matter that is neither Republican nor Democrat, conservative or liberal.

Today, we are talking about the safety and protection of the nation's children. And on that issue, Mr. Chairman, there is no divide.

It is unacceptable for any company that wishes to sell its products in U.S. markets to cut corners in product safety. Already this year we've had one major hearing to expose the breakdowns in consumer safety regulations that allowed Toyota Motor Corporation's faulty braking mechanisms to go undetected and uncorrected.

But it is a moral outrage for a company specifically marketing its products for children to allow a culture of neglect and irresponsibility to taint the medicines that parents and physicians trust to help children get well. In fact, when a parent gives her child a Tylenol Product or other children's medicine produced by Johnson & Johnson, they are relying on the 120 year old reputation of a company who claims that it puts "the needs and well-being of the people we serve first."

The Johnson & Johnson credo – which is prominently displayed on their corporate promotional material – states that the "first responsibility" of the company is "to the mother and fathers . . . who use our products and services." The credo also states that "in meeting their needs everything we do must be of high quality . . . [and at] reasonable prices."

These values are commendable, but I'm afraid that their implementation is not. In fact, the reason the federal government takes such a keen interest in consumer safety is because regulators serve as a check – forever making sure that cost-saving and reduced quality never trump safety concerns. In the last months, it has become apparent that Johnson & Johnson – and its subsidiary McNeil Consumer Healthcare – have failed to fulfill its promises and have threatened the health and well-being of our nation's most vulnerable through corporate carelessness. I am particularly interested in Johnson & Johnson's plan to revamp it entire children's over the counter product line from production to point of sale. It is my hope that the company will step up to the plate, take responsibility and formulate a plan to regain its status as a trusted brand of over the counter products.

Today's hearing, Mr. Chairman, and every hearing of this nature, provides the opportunity for us to remind every company and every regulator that the people's representatives will continue to watch out for their interests, hold accountable those who violate their trust, and work diligently to prevent threats to their health, safety and security.

Thank you.

Chairman TOWNS. I would like to thank the gentleman from California for his statement and, of course, I want you to know that I agree with you.

I would like to just recognize the Brooklyn Friends School who is here. Thank you very much for joining us this morning.

Mr. ISSA. Could you please stand up? You can't be recognized when you are—there we go.

Chairman TOWNS. Brooklyn Friends School. Thank you so much for joining us this morning.

We turn now to our first witness. Dr. Joshua Sharfstein is the Principal Deputy Commissioner of the Food and Drug Administration. He is our witness today from the FDA, but he is accompanied by Deborah Autor and Michael Chappell, who will not be making opening statements, but are here to provide any additional expertise that may be helpful to the committee. Deborah Autor is the Director of the Office of Compliance at the Center for Drug Evaluation and Research at the Food and Drug Administration and Michael Chappell is the Acting Associate Commissioner for Regulatory Affairs at the FDA.

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. You may be seated.

Let the record reflect that the witnesses answered in the affirmative.

Dr. Sharfstein, being the only person making opening statements, let me start with you.

STATEMENT OF DR. JOSHUA M. SHARFSTEIN, PRINCIPAL DEPUTY COMMISSIONER, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY DEBORAH M. AUTOR, DIRECTOR OF THE OFFICE OF COMPLIANCE, CENTER FOR DRUG EVALUATION AND RESEARCH, FOOD AND DRUG ADMINISTRATION, AND MICHAEL A. CHAPPELL, ACTING ASSOCIATE COMMISSIONER FOR REGULATORY AFFAIRS, FOOD AND DRUG ADMINISTRATION

Dr. SHARFSTEIN. Great. Mr. Chairman and members of the committee, thank you for having this hearing. I am Joshua Sharfstein, the Principal Deputy Commissioner of the U.S. Food and Drug Administration. I am a pediatrician and I am the former Health Commissioner of Baltimore, MD.

I want to talk to you about what happened at McNeil, what FDA has done, and I want to answer your questions.

I am joined, as you mentioned, by Deb Autor, who is also a former prosecutor at the Department of Justice and a finalist for the Service to America medal; and by Mike Chappell, who is a 38-year veteran of FDA.

The FDA has authority over drug manufacturing both to enforce general good manufacturing practice requirements and to require companies to comply with their own rules.

McNeil Consumer Healthcare makes a variety of over-the-counter products for the U.S. market from four manufacturing facilities in the United States and Canada. Over the last several

years, FDA has had growing concerns about the quality of the company's manufacturing process, reflected in unsatisfactory inspections and recalls. FDA inspected the company's facilities with an increased frequency and, in February 2010, the agency convened the management of its parent company, Johnson & Johnson, to express concern about a pattern of noncompliance. This is a story of an agency that identified a problem, confronted a company, and eventually forced major changes to protect the public.

I would now like to walk you through some of the key events.

Prior to 2009, FDA investigators identified several problems with good manufacturing practices at facilities run by McNeil. These problems included laboratory controls, equipment cleaning processes, and a failure to investigate identified problems. The company generally fixed these problems and the agency inspected the firm regularly.

At its Fort Washington facility, McNeil makes a wide variety of over-the-counter products, including a large number of over-the-counter liquid products for children.

In May and June 2009, FDA identified several violations, including McNeil's failure to meet its own standard for quality in one of its ingredients in over-the-counter liquids. McNeil's standard for this ingredient, known as microcrystalline cellulose, required that there be no gram negative bacteria. McNeil purchased the cellulose in partial lots that had not tested positive for this objectionable bacteria, but the vendor had tested other partial lots from the same master lot and had found a certain bacteria called Burkholderia cepacia. According to its standards, McNeil should not have used any of the partial lots from this master lot.

In reviewing the situation, FDA scientists at the time concluded that the risk to the public was remote. All of the drugs that were used had tested negative for the bacteria, all the final product had tested negative, and FDA agreed with the company's assessment that this bacteria would be very unlikely to grow in the final product.

Yet, because the company had not kept to its standard, it represented a significant violation of manufacturing processes and the company initiated a recall of almost 8 million bottles of finished product.

A few months later, in Puerto Rico, where McNeil makes a large number of over-the-counter pills for the U.S. market, FDA became aware that the company had received reports of products from this facility having a musty odor. Yet, McNeil had not fully investigated these reports for about a year and did not notify FDA, despite the requirements that such reports be referred to the agency within 3 days.

FDA inspectors urged McNeil to conduct a complete investigation, which eventually identified the source of the odor to be a chemical called TBA, which was in the air because of a pesticide used on the wood of the pallets to store empty medication bottles. McNeil initiated a series of recalls as the scope of the problem became clear.

The risk to the public by this problem included potential temporary non-serious reactions, including nausea, stomach pain, vomiting, and possibly diarrhea. Very little is known about this chemi-

cal called TBA, but in the small quantities transferred to the products, it was not thought to pose a serious risk for long-term health problems.

On January 15, 2010, FDA issued a warning letter expressing serious concerns about the company's control over the quality of its products and the company's failure to aggressively investigate and correct quality problems. FDA noted in this public warning letter that neither upper management at Johnson & Johnson nor McNeil had assured timely investigation and resolution of the issues.

On February 19, 2010, in the wake of that warning letter, senior compliance staff from FDA's Center for Drug Evaluation Research and the field organization called a meeting with senior officials from McNeil and its parent company, Johnson & Johnson. Attendees included the president of McNeil, the company group chairman for over-the-counter drugs at Johnson & Johnson, as well as a number of quality assurance executives from both companies.

This was an extraordinary meeting. FDA requested that senior officials from Johnson & Johnson attend the meeting over the heads of the McNeil executives so that they would be on notice regarding FDA's rising concerns about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency, and safety of its products. FDA raised concerns about multiple recalls based on the recent inspections and expressed concern that there was a pattern of failure to report material information to FDA in a timely manner. FDA told the company that significant immediate steps were needed to address issues of compliance and quality.

We learned that the company was taking major steps to address these issues, but we told them we would not take their word for it; they would expect close oversight ongoing.

In April, FDA returned to McNeil's facility in Fort Washington. This was an inspection that was scheduled sooner than usual because of the history of compliance problems.

Days before the inspectors arrived, McNeil shut down manufacturing because of particulates found in a number of liquid medications, including acetaminophen, cellulose, nickel, and chromium. We identified a range of violations, including failure to meet its own specifications for bacteria and particulates and, for one Tylenol product, the possibility of higher than expected concentrations of Tylenol.

In reviewing the situation, FDA scientists concluded the risk posed to the public by these problems was remote. We did not find evidence that McNeil used raw materials that its tests found to be positive for bacterial contamination and that all finished lots tested negative. The particulates would be expected to pass through the gastrointestinal tract. And while there was a potential for higher concentrations of Tylenol per dropper, none of the final products tested with high levels.

Although the public health risk from these quality problems is low, these problems should never have occurred, and the manufacturing failures at the facility that caused them were unacceptable. Following requirements assures that products are consistent in their safety and effectiveness, and failure to follow these proce-

dures risks more serious problems and undermines consumer confidence.

On April 30th, McNeil announced a voluntary recall of over 136 million bottles of liquid infants' and children's products.

The agency is now closely monitoring the implementation of a corrective action plan that includes changes to McNeil's quality system, organizational changes, and senior management oversight.

FDA will take steps to ensure that when this facility begins to manufacture again, it will be able to produce safe products. We are also considering additional enforcement actions against the company, which may include seizure, injunction, and criminal penalties.

I wanted just to say one word about adverse events. It is understandable that many Americans, hearing about these large recalls, are wondering whether or not their children were put at risk. In assessing this question, FDA considers two sources of information: first, our assessment of the manufacturing problems themselves and, second, adverse event reports to the agency.

As I discussed earlier, FDA analyzed the various manufacturing problems. Based on the circumstances in each case, our experts believed the risk for any child in the United States was remote.

We also looked and are looking at adverse event reports reported to the agency. We receive these reports and often request and review medical records, coroner's reports, and other supplementary data sources.

In one case we had a report of a 6-year-old child where the child died as a result of an infection from Burkholderia cepacia, the same bacteria that was found in the lot of the ingredient. FDA actually got hold of the medications used by this child and tested them, and we conducted extra inspections to see whether there was a connection between this death and the product. In fact, all the samples tested negative and FDA believes that there was not a connection in that particular case.

When we have adequate information, we review the reports to determine what role, if any, the medication played in the development of an adverse event. We can find the medication had no role in the adverse event, that the activity as a drug could cause a serious side effect, or that a quality problem may have contributed to the outcome.

So far, FDA does recognize that some of the reports may reflect the side effects of the medications, but we have no cases with evidence that a product quality problem contributed to a significant adverse health outcome for children. We are continuing to receive information about certain cases and we will update the public and the committee should our assessment change.

Let me close by noting that every investigation presents an opportunity for FDA to improve our effectiveness in protecting public health. In this case, we have learned more about the importance of corporate structure for compliance. When we do not get a response that we are comfortable with from a subsidiary, FDA will not hesitate, as we did not in this case, to go over their heads to the corporate parent. FDA will be developing new procedures to use what we learned at one facility in guiding our inspections of other facilities run by the same company.

We have also gained experience with two issues that we are working on at the agency: how to improve our recall process and how to strengthen enforcement. FDA Commissioner Dr. Margaret Hamburg has called for FDA's enforcement to be vigilant, strategic, quick, and visible. A range of activities are underway at the agency to bring this vision to reality, including strengthening our criminal enforcement of FDA's laws. We will continue to work with Congress to secure additional authority to assist us.

Let me just mention in this regard we believe that transparency in our enforcement activities is very important, both so people can see what we are doing and to make sure that we are accountable. As part of our new program performance effort at FDA, called FDA-TRACK, we are going to be posting monthly the numbers of different kinds of enforcement actions that FDA is taking, and as part of our transparency task force we have proposed making public every inspection, when it is happening and what the outcome of that inspection is, and we are getting public comment on that.

I would end by saying that this episode reminds us that a vigilant FDA is essential to drug safety in the United States. FDA inspectors identified serious problems at McNeil, called the company to account, and forced major changes to protect the public. On behalf of the many FDA staff who worked on and are continuing to work on this issue, I appreciate the opportunity to make this statement and I look forward to your questions.

[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 REPERSENTATIVES

HEARING ON

"JOHNSON & JOHNSON'S RECALL OF CHILDREN'S TYLENOL AND OTHER CHILDREN'S MEDICINES"

May 27, 2010

RELEASE ON UPON DELIVERY

Introduction

Mr. Chairman and Members of the Committee, I am Joshua M. Sharfstein, M.D., Principal Deputy Commissioner, U.S. Food and Drug Administration (FDA or the Agency), which is an Agency of the Department of Health and Human Services. Thank you for the opportunity to discuss the Agency's regulation of drug manufacturing, our oversight of McNeil Consumer Healthcare, LLC (McNeil), and lessons learned from the ongoing investigation into quality concerns at McNeil.

FDA Oversight of Drug Manufacturing

Under the Federal Food, Drug, and Cosmetic Act, FDA is charged with, among other things, ensuring that drugs marketed in the United States are safe and effective, and are manufactured in accordance with current Good Manufacturing Practice (cGMP).

The cGMP regulations for drugs contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The regulations are intended to ensure purity, potency, and quality of drug products, and to prevent unsafe products from reaching consumers.

Under the cGMP regulations, each manufacturer sets specifications for its own products for such factors as potency, stability and purity, and puts in place a quality system that

ensures those specifications are met. Critical to the cGMP process is that a company must meet its own standards.

A violation of cGMP does not necessarily mean that a product is hazardous to the public. It does indicate, however, a breakdown in a manufacturer's quality system and is an indication that a company needs to take effective steps to fix the problem promptly.

FDA inspects facilities to ensure compliance with cGMP standards. These inspections occur on average for domestic facilities every two to three years. We increase the frequency of inspections for facilities when warranted by past problems or by products that are difficult to manufacture or are especially high risk.

When on site, FDA inspectors identify gaps in manufacturing standards and discuss with companies how they can fix them. Firms may choose to recall products when there are cGMP violations, especially when those violations have a significant impact on product quality or safety.

For drugs, patterns of non-compliance or non-compliance that put the public's health at risk leads to appropriate enforcement action by the Agency, including warning letters, seizures, injunctions and criminal prosecution.

Oversight of McNeil Consumer Healthcare, LLC (McNeil)

McNeil makes a variety of over-the-counter (OTC) products for the U.S. market from four manufacturing facilities in the United States and Canada. Over the last several years, FDA has had growing concerns about the quality of the company's manufacturing process. These concerns have led to a number of unsatisfactory inspections and consumer recalls. FDA has inspected the company's facilities with an increased frequency, and in February 2010, the Agency took the extraordinary step of convening a meeting with the management of the parent company, Johnson & Johnson, to express concern about a pattern of non-compliance.

Prior to 2009. Before 2009, FDA investigators identified several problems with cGMP compliance at facilities run by McNeil. These problems included laboratory controls, equipment cleaning processes, and a failure to investigate identified problems. The company generally fixed the specific problems, and the Agency inspected the firm regularly.

Spring/Summer 2009. At its Fort Washington facility, McNeil makes a wide variety of OTC products, including a large number of OTC liquid products for children.

In May and June 2009, FDA identified several cGMP violations, including McNeil's failure to meet its own standard for quality in one of the ingredients in OTC liquids.

McNeil's standard for this ingredient, known as microcrystalline cellulose, required that there be no gram negative bacteria. McNeil purchased the cellulose in partial lots that had not tested positive for this objectionable bacteria. The vendor tested other partial lots from the same large master lot and found a certain gram negative bacteria called *B. cepacia*. According to cGMP standards, McNeil should not have used any partial lots from this master lot.

In reviewing the situation, FDA scientists concluded that the risk to the public was remote. All of the drums used tested negative for the bacteria *B. cepacia*, all of the final product tested negative, and FDA agreed with the company's assessment that this bacteria would be very unlikely to grow in the final product.

Yet, because the company had not kept to its standard, it represented a cGMP violation, and the company initiated a recall of almost eight million bottles of finished product in August 2009.

Fall 2009. At its Las Piedras, Puerto Rico, facility, McNeil makes a large number of OTC pills for the U.S. market.

In the fall of last year, FDA became aware that McNeil had received reports of products from this facility having a musty odor. Yet, McNeil had not fully investigated these

reports for about a year and did not notify FDA despite the requirement that such reports be referred to the Agency within three days.

FDA inspectors urged McNeil to conduct a complete investigation, which eventually identified the source of the odor to be a chemical, called 2,4,6-Tribromoanisole or TBA, which was in the air because of a pesticide used on the wood of the pallets used to store empty medication bottles. McNeil initiated a series of recalls as the scope of the problem became clear.

The risk posed to the public by this problem included potential temporary, non-serious gastrointestinal reactions – including nausea, stomach pain, vomiting, or diarrhea. Very little is known about the chemical TBA, but in the small quantities transferred to the products, it is not thought to pose a serious risk for long-term health problems.

On January 15, 2010, FDA issued a warning letter to McNeil expressing serious concerns about the company's control over the quality of its drugs and the company's failure to aggressively investigate and correct quality problems. This letter identified significant violations of the cGMP regulations. FDA noted that neither upper management at Johnson & Johnson nor at McNeil assured timely investigation and resolution of the issues.

January and February 2010. In early 2010, FDA conducted focused inspections of McNeil at both the Las Piedras and Fort Washington facilities to follow up on a reported

problem. The report identified a 6-year-old child who died. Prior to his death, the child had been given several products manufactured by McNeil at these facilities. FDA tested the products the child had taken for potential contamination, and all results were negative. Based on the results of the testing and the results of the inspection, FDA did not find evidence to link the products to the child's death.

February 2010. On February 19, 2010, senior compliance staff from FDA's Center for Drug Evaluation and Research and from FDA's field organization met with senior officials from McNeil and its parent company, Johnson & Johnson. Attendees included the President of McNeil, the Company Group Chairman for OTC at Johnson & Johnson, as well as a number of Quality Assurance executives from both companies.

This was an extraordinary meeting. FDA requested that senior officials from Johnson & Johnson attend the meeting so they would be on notice regarding FDA's rising concerns about whether McNeil's corporate culture supported a robust quality system to ensure the purity, potency and safety of its products. FDA also raised concerns about Johnson & Johnson's oversight of McNeil due to recent multiple recalls of McNeil products and recent warning letters FDA had issued to both McNeil and its parent company, Johnson & Johnson. Based on the Fort Washington and Las Piedras inspections in 2009 as well as the firm's recent compliance history, FDA expressed its significant concern that there was a pattern of conduct including failure to report material information to FDA in a timely manner, miscalculating and/or misstating risks and benefits of their products, and reactive vs. proactive approaches to product quality problems. FDA told the company's

leadership that significant, immediate steps were needed to address issues of compliance and quality, especially in investigating product quality issues so that the company could take preventive action to avoid problems.

The Agency learned that McNeil was taking several major steps to address these issues, including implementing management reporting structure changes, hiring new managers, and engaging a third party manufacturing consultant. FDA indicated that it would continue to monitor closely and consider further action, and that it was concerned about whether the company's corporate culture was appropriately focused on product quality issues.

April 2010. In April, FDA inspectors returned to McNeil's Fort Washington facility. This inspection was scheduled sooner than usual due to McNeil's recent history of compliance problems, including numerous recalls and cGMP deficiencies discovered in the June 2009 Fort Washington inspection, which had a significant impact on the scheduling of the April 2010 inspection.

Days before the inspectors arrived, McNeil shut down manufacturing because of manufacturing issues, including particulates found in a number of liquid medications. These particulates included acetaminophen, cellulose, nickel, and chromium. FDA inspectors identified a range of cGMP violations. These included the company failing to meet its own specifications for bacteria and particulates and, for one Tylenol product, the possibility of higher than expected concentrations of Tylenol per dropper.

In reviewing the situation, FDA scientists concluded that the risk posed to the public by these problems was remote. FDA did not find evidence that McNeil used raw materials that its tests found to be positive for bacterial contamination and all lots of finished product were tested by McNeil and found negative for bacterial contamination. The particulates would be expected to pass through the gastrointestinal tract. While there was a potential for higher concentrations of Tylenol per dropper, none of the final products released for sale tested with high levels. In addition, the increase in potency would not be expected to cause adverse effects.

Although the public health risk from these quality problems is low, these problems should never have occurred, and the cGMP failures at the facility that caused them were unacceptable. Following cGMP requirements assures that products are consistent in their safety and effectiveness and failure to follow those procedures undermines consumer confidence. On April 30, 2010, McNeil announced a voluntary recall of over 136 million bottles of liquid infants' and children's products.

Next Steps in FDA Oversight of McNeil

Based on the pattern of concerns found at McNeil's facilities, FDA is working with the company to address its systemic quality issues. The Agency is closely monitoring the implementation of a corrective action plan developed by McNeil that includes significant

enhancements to its quality system, organizational changes, and senior management oversight.

FDA will continue to investigate issues related to the Fort Washington facility including oversight related to renewal of manufacturing operations at that facility, to evaluate the facility's suppliers, and evaluate the compliance of all other McNeil facilities. FDA will also take steps to help ensure that when the facility begins manufacturing again it will be able to produce safe products. FDA is also considering additional enforcement actions against the company for its pattern of non-compliance which may include seizure, injunction or criminal penalties.

Adverse Event Evaluation

It is understandable that many Americans, hearing about these large recalls, would wonder whether or not their children were put at risk. In assessing this question, FDA considers two basic sources of information – first, our assessment of the manufacturing problems themselves, and second, adverse event reports to the Agency.

As I discussed earlier, FDA analyzed the various manufacturing problems. Based on the circumstances in each case, our experts believe the risk for any child in the United States was remote.

FDA has also looked at adverse events reported to the Agency. FDA receives these reports and often requests and reviews medical records, coroner's reports, and other supplementary data sources.

When we have adequate information about a case, the Agency reviews these reports to determine what role, if any, the medication played in the development of an adverse event. We can find that the medication likely had no role in the adverse event, that the medication's activity as a drug could have caused a serious side effect, or that a quality problem may have contributed to the outcome.

All drugs have side effects, and some of the McNeil reports may reflect the side effects of OTC medications. Other reports appear unrelated to the medications.

So far, FDA has no cases with evidence that a product quality issue contributed to a significant adverse health outcome. We are continuing to receive information about certain cases and we will update the public and the Committee should our assessment change.

Lessons Learned

Every investigation presents an opportunity for FDA to improve our effectiveness in protecting the public health. One lesson to be drawn from the McNeil story is that it is important for the Agency to even more fully consider the corporate structure when

investigating and enforcing the law. FDA will be developing new procedures to use what we learn at one facility in guiding our inspections of other facilities run by the same company.

FDA is also using these events as part of an ongoing review of our recall process. FDA has already made significant changes to its approach to recalls when there are urgent, life-threatening product quality concerns. For example, in recent months, FDA has moved aggressively to support several urgent food recalls. FDA is now looking at our process for clear expectations and standards with respect to other types of recalls, such as those undertaken by McNeil.

We will continue to work with Congress to secure additional authorities that could assist us in assuring product quality and acting more quickly when product quality issues occur. FDA will also be considering enforcement actions in this case as part of the Agency's ongoing changes in enforcement. FDA Commissioner Dr. Margaret Hamburg has called for FDA's enforcement to be "vigilant, strategic, quick, and visible." A range of activities are underway at the Agency to bring this vision to reality, including strengthening our criminal enforcement of FDA's laws.

As we continue these efforts, as well as our other regulatory work, we will focus on entire companies and their systems in addition to focusing on specific violations, individuals, and sites, much as we are doing in the McNeil situation.

Conclusion

Thank you for the opportunity to explain FDA's oversight of drug manufacturing and our engagement with McNeil. I look forward to your questions.

Chairman TOWNS. Thank you very much, Dr. Sharfstein, for your statement. Let me just begin by saying this. Does the FDA need more enforcement authority or funding to be able to respond to issues like this recall?

Dr. SHARFSTEIN. Thank you. I think that it is instructive to think about the food safety bill a little bit, because in the food safety bill there are some provisions that Congress is looking at granting the FDA over food that we don't currently have over drugs, and those include authority to require certain types of quality systems and preventive controls, mandatory recall authority, access to records by companies, and civil money penalties.

So those are some areas where we don't have a position at this point, it hasn't worked its way through the system. With respect to drugs, I would point those out, that those are in the food safety bill. The administration is supporting those for foods.

Chairman TOWNS. Let me ask this. Can you say with complete certainty that no children who took the medicines that were recalled last month were harmed by them?

Dr. SHARFSTEIN. No, I cannot say that with complete certainty. I think we are continuing to get information and there were remote risks that were potentially possible. But from what we know, we do not have evidence at this point of children who did have serious problems. But because there was a remote risk, it was the right thing to do the recall.

Chairman TOWNS. But are you still looking to see in terms of whether or not this occurred?

Dr. SHARFSTEIN. That is correct, we are. And there are certain reports that we have gotten that we are in the process of thoroughly reviewing.

Chairman TOWNS. How serious were the problems at McNeil's plant in Fort Washington that the FDA most recently discovered? How serious were they?

Dr. SHARFSTEIN. I think as manufacturing problems go, they were serious. There was a range of different problems. They had not responded to the complaints that they had gotten of particulates in the product; they had missed the fact that some of their ingredients came from a lot that had had contamination, even though the previous year they knew this to be an issue. There were a wide range of findings that indicated to us that there were serious manufacturing quality problems at the facility.

Chairman TOWNS. What went wrong that caused one of the largest makers of children's medicine to recall millions? Was it quality control? What do you think might have happened here?

Dr. SHARFSTEIN. I think that is a great question and it can be answered at different levels. I think one level you answer it is exactly like you said, it is quality control, that there were quality control problems. At another level you have to ask why, why did a company with a reputation and record of McNeil and Johnson & Johnson have those quality control problems?

And we think it is a very important question for you to be looking at. It is something we need to understand better. We think it may relate to the corporate compliance and corporate structure. And we note that the company has made major changes in that

when we confronted them with the very serious compliance problem that they were having.

Chairman TOWNS. Could you sort of describe to us what you are doing now to work with Johnson & Johnson to make sure that they correct the problems that exist?

Dr. SHARFSTEIN. Sure. Well, this facility in Fort Washington is now not manufacturing. There is a complete plan for standing it back up that the company is going to be presenting to FDA. I think it is fair to say that we have very good cooperation from the company now; that they are really looking for the agency's seal of approval before they get going, and I am sure you will hear that from them on the next panel. In addition to what we are working on there, we are also reviewing the record and considering whether other types of enforcement action are appropriate.

Chairman TOWNS. Dr. Sharfstein, tell me what the FDA believes McNeil did as described in these FDA documents that we received.

Dr. SHARFSTEIN. Can you say that again? I am sorry.

Chairman TOWNS. On the screen there, Doctor.

Dr. SHARFSTEIN. Oh, I see.

Chairman TOWNS. On the screen.

Dr. SHARFSTEIN. What do we believe actually happened here?

Chairman TOWNS. Yes.

Dr. SHARFSTEIN. This is something that is troubling to the agency. I am not sure we know the complete full story, but basically there was a problem with how Motrin tablets dissolve and whether or not patients would get the right dose. The company notified FDA that they were going to be evaluating whether there was product on the shelves to recall.

Then we were alerted, I believe, by one of the State Boards of Pharmacy that instead of just looking to see whether or not there was medication to recall, the company had a contractor that was going out and trying to buy up all the medicine when they went into the store, and the information said 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 your employer is checking the distribution chain of this product and he needs to have some of it purchased for the project.

I don't think we really fully understood exactly what was going on. It was troubling to us and, when FDA found out about this, we insisted that an actual recall occur. And we did think that it reflected poorly on the company, and it was one of the things that FDA brought to their attention during this extraordinary meeting that happened in February.

Chairman TOWNS. Thank you. After the recall, FDA recommended consumers buy drugstore alternatives for their children. The vast majority of those drugstore products are made by Perrigo, a company in Michigan that had ongoing quality control problems. When was the last time FDA inspected the plant in Michigan that makes infants' and children's problems? Do you know when it was inspected last?

Dr. SHARFSTEIN. I do. I may ask Deb Autor to answer that because she oversees the compliance efforts at the Center for Drugs. I believe there were several inspections in the last couple years.

Ms. AUTOR. I don't have the exact dates here, but there have been several inspections in the last few years. I believe there have been two in 2010, but I would have to double-check those facts.

Chairman TOWNS. But you agree with the fact there have been some issues with quality control?

Ms. AUTOR. Yes, there have been some issues at Perrigo.

Chairman TOWNS. OK, on that note, I yield to the ranking member for 5 minutes.

Mr. ISSA. Thank you.

Ms. Autor, I would like to followup. Is it appropriate for the FDA to recommend an alternative at all? Basically, if you say don't do that or, baby doctor, if you prefer, isn't it really appropriate for the FDA to simply deal with its knitting and say don't take that, and not intervene in alternatives?

Dr. SHARFSTEIN. Well, the challenge is——

Mr. ISSA. I know there is an irresistible urge to answer people's questions; I am in that business. But isn't it in fact inappropriate for any government entity to make a recommendation unless it is an authorized recommendation? It doesn't appear as though there is any mandate for that.

Dr. SHARFSTEIN. I think that Dr. Hamburg and I see FDA as a public health agency that has to be responsive to the needs of clinicians and patients, and it very frequently happens that there is a shortage of one medication, and we have a whole shortage team that works with manufacturers and professional societies to give recommendations in the event of a shortage for what can be used as an alternative. I think it is wrong to say this brand is the right one to use, but when people don't know what is available, for the FDA to say we want you to know this medication is available and is a potential alternative, I think that is information that the clinical community really wants to hear from FDA.

Mr. ISSA. And I have no problem with the clinical community. When you speak doctors to doctors, I certainly appreciate that. My only question was where is the line. I think all of us want to know where is the line when it is ultimately to the public, to the uninformed public. As you said, a brand name would be inappropriate, but a chemical description, I gather, is what you are saying would be appropriate, which would cover potentially multiple brands?

Dr. SHARFSTEIN. Right.

Mr. ISSA. OK.

Ms. Autor, one that I know falls more squarely on you, in this case, I don't want you to say you have an investigation or you don't, but is there a potential criminal liability for some of the acts that went on?

Ms. AUTOR. I think what I can say at this point is that the Center for Drugs has referred this to FDA's criminal investigative unit, and then they have to judge where to go from there.

Mr. ISSA. OK. I will take that as a yes, that there is at least the potential, and that everyone who is out there providing food and drugs should be aware that the scenario we just saw in the future, or perhaps in this case, could lead to criminal actions or indictments. At least not saying in this case, but that should be fair warning to people who are watching this hearing.

Ms. AUTOR. And I think, as Dr. Sharfstein said, the agency is working to increase our enforcement on the criminal side and to connect carefully what we do on the criminal side with what we do on the civil side so that we can maximize the effectiveness of those tools.

Mr. ISSA. Yes, Doctor.

Dr. SHARFSTEIN. I think that is an excellent point. We very much want to send that message. Dr. Hamburg, the Commissioner, gave a major address on enforcement, where she called on companies to make sure they had excellent compliance programs, and just this week someone sent me an email about a course and report that is being marketed, where it says bigger, tougher, faster, preparing for the new FDA. When the inspector comes calling, will you be ready?

And it is all about sending a message to industry. This is within industry they are marketing this, that FDA is significantly strengthening its oversight and companies have to learn how to put quality systems in place. This is the kind of thing we like to see. We don't like to see these kinds of recalls; we like to see compliance. That is our goal. And seeing the industry really coming together, getting the message, that is very important to us.

Mr. ISSA. Now, Doctor, your being here today goes far beyond the McNeil division of Johnson & Johnson, so let me ask a slightly different question. In the ordinary course, you try to visit facilities here in the United States once every 2 years. But, more and more, non-prescription drugs are being produced in China and other very far away places, and those places, in many cases, have a standard of simply lying on their paperwork. We have had that in a number of other areas.

How do you propose that the FDA be able to ensure that a foreign manufacturer in a country where we have a fairly opaque ability to go beyond what the papers presented at the factory, that we can rely on those test results and, as such, the medicine that comes from them?

Dr. SHARFSTEIN. It is an excellent question. The safety of imports is extremely important to us, and Dr. Hamburg has raised these very similar sorts of concerns in some major speeches, and we had a hearing in the Energy and Commerce Subcommittee on health not too long ago, where this got a fair amount of attention. It is a concern for us and there are certain things that we need to be able to do better. Included among those is holding each person in the supply chain accountable, and there are some tools that would allow us to do that. In addition, we need to significantly expand our coordination with other agencies.

We now have two foreign offices in China that coordinate with other agencies. For example, if Australia does an inspection that we have confidence in, then we can go to another plant in Australia and can have confidence in that inspection. We also need to strengthen and work——

Mr. ISSA. So what you are saying is part of your procedure would be to learn to inspect the inspectors, to qualify countries or inspection techniques so that we can be somewhat reciprocal.

Dr. SHARFSTEIN. That is absolutely true both for our major partners in the developed world, but also we want to strengthen the indigenous inspecting capacity, and there is a big effort to do that in

countries like China and India. So it is a very complex problem and there are a lot of solutions.

Mr. ISSA. Let me just ask one final question. And if it goes long, I would ask that it be answered for the record. Every day, 45-foot, 53-foot containers of non-prescription drugs come in the country. Currently, our import authorities open only a fraction of those containers and, when they do, they open them to see if it is an aspirin, and not much more.

Do you believe here today that the Congress should begin creating both the authority and the mandate for at least sample inspection of 100 percent of these types of imports if they come from countries that you have not certified the certifiers?

Dr. SHARFSTEIN. I believe that Congress and the FDA need to work together to really address the question of import safety. I am not sure 100 percent testing is the answer. I think we need to have 100 percent accountability across the supply chain and a strong import border presence, but it has to be addressed comprehensively.

Mr. ISSA. OK. I would like you to answer for the record, then, the key question of if it comes from a country in which you have not achieved that level of confidence, no part of the supply chain can change the fact that if any one of those bottles is bad and there has been no sampling, you will not have that public confidence.

So I would like you to tell us how you are going to get that confidence if you didn't get it in the country of origin and now it is sitting in a container in the United States or going through the supply chain. And I ask you to answer that for the record.

Dr. SHARFSTEIN. Happy to do that.

Mr. ISSA. Thank you.

Thank you, Mr. Chairman.

Chairman TOWNS. The gentleman's time has expired.

I now yield 5 minutes to the gentleman from Maryland, Mr. Cummings.

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

Dr. Sharfstein, it is very good to see you again. And I say this without reservation: When you served as the Health Commissioner for Baltimore, where I live, you did an outstanding job. You did it with excellence and integrity. And I have full faith and confidence in you. So I wanted to say that before I got into these questions.

Dr. SHARFSTEIN. OK. Thank you.

Mr. CUMMINGS. There appears, Dr. Sharfstein, as I listen to your testimony, that McNeil was involved in a culture of mediocrity. It seems that the FDA had one standard and McNeil had another, and I am trying to figure out where the two meet. In other words, it sounds like the standard at McNeil, they said, OK, we got a little taint here, a little problem there, but we will still mix it up, it will be all right. FDA says, no, that is not good enough. And then you said something that was very interesting. You said there might be a need to take further action. You said further action may be required.

I am trying to figure out how that all comes together. When you have a company that seems to be, over and over again, be it by negligence, intent, greed, or whatever, skirting the system, but you have the FDA saying we have this standard, how does that work? How does that come together? You follow what I am saying?

Dr. SHARFSTEIN. Sure. Absolutely. And there is a real parallel to Baltimore because in Baltimore we inspected restaurants at the Health Department, and we would sometimes find problems, and there is always a balance between cooperation, working cooperatively with the business, and taking action; and most of the time we would find a problem and the business would jump and fix it, and then we were done.

But every so often there was a restaurant that we would have a significant problem with and we eventually got to the point where, for some people, we took away their license to run a restaurant in Baltimore, their ability to do that. It is a balance.

And I think if you look at this experience with McNeil, you see that. FDA is pointing things out, McNeil is sort of correcting them, waiting a little bit of time in some cases to tell us about problems, and over time FDA is ratcheting up the oversight like we would do in Baltimore, where we would say, wait a second, this should have been corrected in a restaurant, and we are going to have to go back again, and eventually we are going to have to bring them in and eventually we are going to bring them to the administrative judge. That is basically what FDA is doing.

And the story of this whole episode is that FDA increased the pressure, brought in the corporate executives and wound up forcing, I think you will hear, very major changes in the company's approach to quality.

We are going to use this as an opportunity to see what we can improve. But I think overall it is a tough balance that the FDA has to strike.

Mr. CUMMINGS. Let me ask you this. In your testimony you state that in February 2010 FDA took the extraordinary step, you said, of meeting with the management of Johnson & Johnson to express your concern about a pattern of noncompliance. Why was this meeting considered so extraordinary?

Dr. SHARFSTEIN. What was extraordinary about it were two things. First of all, we went over the heads of the whole company. McNeil is a pretty big company, but we went to the actual corporate central head of the entire major company to express this concern. That is one reason why it is extraordinary.

The second thing is usually we meet about specific problems, and this was a meeting about a culture of compliance, that we had seen so many problems at different facilities, and problems that really concerned us, that we really were calling them on their whole quality system, and it led to major changes, I think you will hear, at the company. People were moved in their positions or removed from their position. They have a whole new layer, I believe you will hear. And I think those were the two things that made it extraordinary, that we went over their heads and that we talked about the culture of compliance at the company, not just individual problems.

Mr. CUMMINGS. Now, how did Johnson & Johnson react to what you said? They were present at the meeting, were they not?

Dr. SHARFSTEIN. They were, yes.

Mr. CUMMINGS. OK. What was their reaction?

Dr. SHARFSTEIN. My understanding is they took it quite seriously. They heard that this was not a usual kind of meeting for the FDA to have. They had gotten one of the fastest warning letters

ever from what happened in Puerto Rico. We issued a warning letter and the warning letter itself mentioned the fact that there was a failure of oversight by not just McNeil and Johnson & Johnson. And I think, based on the changes they committed to at that point, we got the sense that they had heard our concern, although we made it very clear that we weren't going to take their word for it.

Mr. CUMMINGS. And what does all of this say about a corporation? Apparently, you have gone pretty far with this corporation. What does this say about this corporation? Have you drawn a conclusion?

Dr. SHARFSTEIN. Well, you know, most of the companies that FDA deals with do comply, and there are some great examples out there of terrific compliance programs. This is a company that had a major problem with compliance, and it was a problem that crossed different domains, different facilities, and was a systematic problem at the company. That is something FDA needs to be able to identify and address with the company, with its senior leadership, and we have to be willing, and I think in this case I think we did, really, call them to account for it.

Mr. CUMMINGS. Thank you, Mr. Chairman.

Chairman TOWNS. Thank you. Thank you very much.

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

Mr. CHAFFETZ. Thank you.

Thank you all for being here. In a moment, Ms. Goggins, from Johnson & Johnson, is about to testify, and in her written testimony she says, "The health risks due to consumers from the recalled products were remote." Is that true or false, from your opinion?

Dr. SHARFSTEIN. I think that is also FDA's understanding right now.

Mr. CHAFFETZ. Next thing she says, "Second, McNeil has no indication of a serious adverse medical event caused by any of the issues referenced in the recalled announcement." In your opinion, is that accurate?

Dr. SHARFSTEIN. Well, I can't speak to what McNeil knows. FDA does not have evidence of that kind of severe event, although we are continuing to investigate certain cases.

Mr. CHAFFETZ. She says, "Third, no raw materials that tested positive for objectionable bacteria were ever used in the manufacture of McNeil's pediatric products." Is that true?

Dr. SHARFSTEIN. I would say that is sort of true, maybe with an asterisk.

Mr. CHAFFETZ. Sort of true?

Dr. SHARFSTEIN. Yes. I would say——

Mr. CHAFFETZ. What is sort of true?

Dr. SHARFSTEIN. You know, with a footnote, the footnote being they did use raw materials from lots that had tested positive. There were some negative tests for the parts of those lots that they used, but FDA does not consider that an adequate assurance of safety.

Mr. CHAFFETZ. "And, finally, McNeil rejected the products that it found had excess active ingredient." Would you agree with that statement or disagree with that statement?

Dr. SHARFSTEIN. Again, I would say I agree with a footnote. When they knew those particular lots had excess ingredients, they rejected it. But I think we felt that they didn't test other parts of that area to be sure that there wasn't a problem, another ingredient that was shipped.

Mr. CHAFFETZ. Now, my understanding is——

Dr. SHARFSTEIN. Let me just see if Deb wants to clarify that?

Ms. AUTOR. Yes. Just to clarify that, with the potency issue, what happened was that McNeil made a change in their manufacturing process, the size of the vat they were using, without testing whether the product would adequately mix once that change was made. So they produced 11 batches using that new process.

Three of them tested to be super-potent. They threw away those three, but, from our perspective, there is no assurance that the other eight wouldn't have the same potency issues. They did some testing, they didn't find potency, but, because the process hadn't been tested, there was potential that there were potency problems in the other batches even though they hadn't tested that way.

Mr. CHAFFETZ. I appreciate the efforts of the FDA and I love the fact that they are ahead of the ball, but having found no serious adverse reaction, is the FDA overreacting to this? I mean, there are 775 serious side effects, so where in the spectrum is this in what you are usually dealing with? How severe is this problem?

Dr. SHARFSTEIN. Well, let me answer that in a couple ways. The side effects were reported about the medications, and we think that some of them were linked to the actual medications used, not the quality problems. And I think the number of adverse events we probably have to separate a little bit from the quality problems.

We consider these quality problems to be quite significant, and we want to fix them before it becomes a point where we are counting the problem in hospitalizations and injuries, instead of in bottles recalled.

Mr. CHAFFETZ. What is a mom supposed to do? You have had hundreds of millions of products recalled. How many of those have actually made it beyond the store shelf and actually into somebody's cupboard and they are sitting the? What is a mom supposed to do at home?

Dr. SHARFSTEIN. We had some in our house. I think we recommend that people throw out the ones that they have. You can find out which ones they are from the Web site and other information, and that they can go to the store and get alternatives.

Mr. CHAFFETZ. So if you have any of these products on your shelf, you are supposed to actually go back to the store? When you say the Web site, how does that work? Is there a lot number on the bottom that they can go check on the FDA Web site?

Dr. SHARFSTEIN. There is, yes. McNeil has actually set up a phone number for people to call to get instructions. They may answer better how they are handling that part of it, but there are instructions for people to be able to turn back their medication.

Mr. CHAFFETZ. And, finally, were any of you at those meetings in February?

Dr. SHARFSTEIN. I think that Ms. Autor was the one who called for the meeting, but I don't think any of us were at the meeting.

Mr. CHAFFETZ. OK.

All right, thank you, Mr. Chairman. Yield back.

Chairman TOWNS. Thank you very much.

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

Mr. KUCINICH. Thank you.

Dr. Sharfstein, in your testimony you reference a 2010 report which identified a 6-year-old child who died. Now, prior to the child's death, according to this report, the child had been given several products manufactured at the facilities in question. Did any of those products that the child took contain a harmful bacteria?

Dr. SHARFSTEIN. No, as far as we know. Those were tested, and we did not see any of the bacteria.

Mr. KUCINICH. And what was the cause of death?

Dr. SHARFSTEIN. I want to be sure whether we have this. I think there that is still an open coroner's investigation, so I am not sure they have a final cause of death. It may have been infection.

Mr. KUCINICH. When was the death?

Dr. SHARFSTEIN. January.

Mr. KUCINICH. Have you seen an toxicology screens from this autopsy report? Have you seen the autopsy report?

Dr. SHARFSTEIN. I am not sure that we have the final autopsy report. If the coroner's investigation is open, we probably don't have the final report. I understand that there was this bacteria found in multiple tissues.

Mr. KUCINICH. Which bacteria was found in multiple tissues?

Dr. SHARFSTEIN. Burkholderia cepacia.

Mr. KUCINICH. And was that bacteria found in any of the samples that the FDA picked up of the products that were recalled?

Dr. SHARFSTEIN. No. No. That bacteria was not found in the products that this child apparently consumed; it was not found in any finished product that we know of. But it was the same bacteria that was involved in the ingredient issue that the company had.

Mr. KUCINICH. So does the FDA have a pathologist on its staff?

Dr. SHARFSTEIN. I couldn't tell you 100 percent.

Mr. KUCINICH. Do you outsource pathology reviews?

Dr. SHARFSTEIN. Well, we do have medical officers who would be qualified to review pathology reports.

Mr. KUCINICH. Are they certified in terms of pathology? Are they pathologists or do they just review pathology reports?

Dr. SHARFSTEIN. I would have to get back to you on that exact question. But we do have people who are qualified to review pathology and judge whether or not we are concerned about a link between a product and a particular death.

Mr. KUCINICH. Why was the report even included in testimony if it doesn't seem to rise to the level of significance, according to your answers here?

Dr. SHARFSTEIN. Well, I used it as an example of how seriously we take reports like this. I mean, we went out, we tested the products. We actually went back and reviewed the records again at each of the facilities that were involved, because they had taken products from the two facilities. It is really two lines of evidence that we use: one is our assessment of the manufacturing problem and the other is a thorough investigation of the adverse event reports that we get, and that was an example of one.

Mr. KUCINICH. When is something, by your consideration, the result of an adverse event that is well understood to be a contraindication of taking of a drug and, on the other hand, an adulterated product? How do you make the distinction?

Dr. SHARFSTEIN. It is a good question. It partly depends on the specific situation. So, for example, in some of the cases that were reported, there were toxic levels of the medicine, a variety of medicines, and there was a history of the child maybe getting extra doses. That is a known problem for certain over-the-counter medicines.

Mr. KUCINICH. When will you get the autopsy report on this 6-year-old child who died? Do you expect to get it?

Dr. SHARFSTEIN. Will we? Oh, yes, I believe so.

Mr. KUCINICH. Can you share it with this committee?

Dr. SHARFSTEIN. I am sure we would do that, yes.

Mr. KUCINICH. And could I ask you, to your knowledge, does anyone who is at the FDA, have they ever gone over and worked for Johnson & Johnson or McNeil? Is there anybody over there at Johnson & Johnson or McNeil who used to work for the FDA?

Dr. SHARFSTEIN. I couldn't say for sure, but I would guess probably there are people who have.

Mr. KUCINICH. And is there anyone who used to work at Johnson & Johnson or McNeil who now works for the FDA?

Dr. SHARFSTEIN. I don't know that for sure, but it is possible.

Mr. KUCINICH. OK.

Thank you, Mr. Chairman. No further questions.

Chairman TOWNS. Thank you. Thank you very much.

I now yield 5 minutes to the gentleman from Ohio, Mr. Jordan.

Mr. JORDAN. Thank you, Mr. Chairman.

I want to thank you all for being here with us today.

Just to be clear for the record and kind of picking up where Mr. Chaffetz was, the cause and effect, has there been any determination that any adverse event was caused by product from McNeil or Johnson & Johnson?

Dr. SHARFSTEIN. By the product, not the product quality issue? Yes, I believe that there are adverse events that are known to be caused by the product. There are a lot of adverse events that happen in medicine, and often they are linked to the actual pharmaceutical itself because all medicines have risks and benefits. But not anything linked to the product quality issues that we are talking about here.

Mr. JORDAN. OK. I just wanted to be clear on that. Have you looked at any of the recalled product? Have you tested that to see if there is the bad stuff in there, any of the product that has been taken off the shelf?

Dr. SHARFSTEIN. We did in the course of some of these investigations of individual adverse events, but generally, other than that, we generally don't do that.

Mr. JORDAN. And why not? I mean, in this situation why not?

Dr. SHARFSTEIN. Well, we believe that if there needs to be a recall because of the testing that has been done demonstrates a problem, then it should just be recalled, there is no need for us to do it.

Mr. JORDAN. No need to check it out? OK. If I follow the time line right, you did the warning letter in January, you had the inspection of the Pennsylvania facility, I believe, in April, and then you have had the recalls and the stoppages and everything else. And you had the meeting where it seemed like you indicated at that meeting, though you all weren't there, that you felt that it was positive and productive.

I mean, I contrast what we are hearing about here and what we have seen with, frankly, what we are hearing about in the Gulf Coast with MMS, I guess it is, the Mineral Management Service, and their relationship with the industry. It seems to me this process is working much better than what we are seeing and hearing about in another area of government. Do you think the process is working appropriately?

Dr. SHARFSTEIN. I think, as I testified, if you look at what happened here, you had a team, actually both part of Mr. Chappell's organization and Ms. Autor's organization, career inspectors that at FDA who are very vigilant with this company, identified the problem, called them to account, and it led to major changes to protect the public.

Mr. JORDAN. OK. OK.

Mr. Chairman, I yield back. Thank you.

Chairman TOWNS. I thank the gentleman for yielding back.

I now yield to the gentlewoman from Washington, DC, Ms. Eleanor Holmes Norton, 5 minutes.

Ms. NORTON. Thank you very much, Mr. Chairman.

Dr. Sharfstein, listening to your testimony and the action taken, I want to commend you for what looks like effective action by an administrative agency. I would like to ask you about this notion of super-potency. I think about when my kids were young. If I had read that something I was giving them was found by FDA to have something called super-potency, I would have been immediately fearful. I would like to know what it takes for a product to be super-potent, and as a physician, former Public Health Commissioner, whether you think such potency could result in health effects at some later point. What does it mean?

Dr. SHARFSTEIN. Sure.

Ms. NORTON. How did it manifest itself?

Dr. SHARFSTEIN. It is an excellent question. There is a range of the amount of material in a drug that we expect to be in a particular dose, and in this case I think it was up to about 108 percent we expect to be there. And when they tested certain lots, they found up to 124 percent of what they were expecting. So let's say there is supposed to be 100 milligrams in there. Any particular lot we would say it is acceptable, it doesn't have to be exactly milligrams, it could be up to 108. But what they found was up to 124. Now, they threw out those lots, but we weren't assured that some of the ones that did ship were OK because of what Ms. Autor said about their new process.

So what happened was, both at FDA and at the company, we looked, we assessed whether or not this problem, if it had been there—we don't have proof that anything shipped that was super-potent, but if it had been there, would that have posed a risk; and that evaluation was done by physicians within FDA and by doctors

within McNeil, and for a number of reasons the conclusion was this would not have posed a risk.

It is a relatively small increase; it was one formulation, actually, of the dropper for little babies. And Tylenol and acetaminophen is actually something that, particularly in adults, you can get into trouble and people get liver problems if they get overdoses on. But there are a number of reasons why, for babies, actually, babies are much less likely to get that problem, and it turns out it has to do with the way that the chemicals metabolize in children's livers.

So that gives you one margin of safety, and then you have a whole other margin of safety because 20 percent isn't a real big increase in the scheme of toxicology that you are looking for two or three times the dose to start to get into trouble. So, for all those reasons we felt that the risk was very, very low of a problem.

Ms. NORTON. That is comforting, particularly since we know adults get in trouble with these medicines in adult doses, and we know these effects can be different. I have to ask you, though, as a physician, these medicines for children and infants are very controversial. I am looking at an ad for one of them, and it says infant's, pediatricians' choice. Are these effective enough to take the risk? Every time a child has a sniffle, we ought to run for one of these infant doses of medicines that weren't even available until fairly recently?

Dr. SHARFSTEIN. Well, I think for particularly small babies it is important for patients to talk with their doctors about the use of medications. Congressman Cummings knows that I personally have a history with some of these products of concern, about whether they should be used for young children, and I petitioned the agency, as the Health Commissioner of Baltimore, about them, and I am recused from that issue at FDA now. But I do think that it is important for patients to talk to a doctor about the use of medicines. I certainly use Tylenol and ibuprofen, acetaminophen for children.

Ms. NORTON. For infants?

Dr. SHARFSTEIN. For infants under certain circumstances. But it really is something that, as a doctor, I would say, particularly to parents of small babies, that it is very important that we be in touch. If you are giving medicine because you are worried about your child, I would say I want to know about it so we can decide whether that was the right response.

Ms. NORTON. Dr. Sharfstein, let me ask you about a statement in your statement. I am looking at page 10. You say FDA is considering additional enforcement actions against the company for its pattern of noncompliance, which may include seizure, injunction, and criminal penalties. These are nuclear penalties. Does FDA need more effective penalties? I don't think you are going to go around seizing companies, or even seizing large batches, and I don't think you are going to be quick to run to court to get injunctions. And we have not seen criminal penalties yet. Do you have the graduation of penalties necessary to be effective here beyond the effectiveness you have already shown?

Dr. SHARFSTEIN. I think that is a very fair question to ask. I will point out that in the food safety bill Congress is looking at giving

FDA the ability to assess civil money penalties, which would be one of those graduated steps.

Ms. NORTON. So you have no such authority now?

Dr. SHARFSTEIN. I believe not.

Ms. AUTOR. Not for drugs, no.

Ms. NORTON. That is authority you would like to have?

Dr. SHARFSTEIN. You know, that position is sort of working its way through the process, but the administration supports that for food.

Chairman TOWNS. The gentlewoman's time has expired.

Before I go on, I just want to clear up something, Dr. Sharfstein. When my staff and the ranking member's staff, earlier this week, they were told that the recall consisted of 6 million bottles. I believe you said 136 million bottles? What number are we using here?

Dr. SHARFSTEIN. I understand that there was a recall of about 6 to 8 million bottles last year, in 2009. That was the 2009 recall. But this recall was much bigger, over 100 million bottles. That is my understanding.

Ms. AUTOR. This recall was over 136 million bottles. The recall last year relating to the chemical contamination that Dr. Sharfstein mentioned, by our numbers, was over 60 million; and then the year before, the recall relating to the potentially contaminated raw material was 8 million bottles.

Dr. SHARFSTEIN. That wasn't the year before, it was a couple months before.

Ms. AUTOR. Yes, I am sorry, a couple months before, in August 2009.

Chairman TOWNS. Thank you very much for correcting the record.

I now yield 5 minutes to Mr. Luetkemeyer of Missouri.

Mr. LUETKEMEYER. Thank you, Mr. Chairman.

As I have been listening to the discussion this morning, it seems to me that we have a situation where we have gone through this and we had a 6-year-old that passed away, but it wasn't necessarily due to the drugs that were in question here today. Your own FDA report indicates that the recalled drugs pose a remote potential problem for serious health problems, but yet McNeil found their own problems. One of your comments a while ago, Doctor, indicated that the operations were not up to McNeil's standards. Can you elaborate on that just a little bit? They have their own set of standards and you have FDA standards?

Dr. SHARFSTEIN. That is correct.

Mr. LUETKEMEYER. Are their standards higher than your standards or lower than your standards?

Dr. SHARFSTEIN. Well, part of what good manufacturing practices are is that a company has to set its own standards. So that is something every company has to do.

Mr. LUETKEMEYER. Are they higher than FDA standards or lower than FDA standards?

Dr. SHARFSTEIN. Well, part of FDA's standards is for the company to sort of work together. So part of FDA's standards are for the company to set standards for its product.

Mr. LUETKEMEYER. OK. So it seems as though we have a problem here. McNeil, correct me if I am wrong, they did the recall on their own, is that correct?

Dr. SHARFSTEIN. That is correct. We do not have mandatory recall authority.

Mr. LUETKEMEYER. So they found the problem, they realized they had a problem, and they went out and did the recall on their own. So it would appear to me that we have a situation where it looks like we have a sloppy shop that found they were doing poor work, and they are going to try to correct it themselves, and you are working with them to do that, is that correct? Is that pretty well framing it?

Dr. SHARFSTEIN. I think that is basically true. I think that what was particularly troubling in this story to FDA is that there was a pattern of FDA finding out about things late. People were complaining that the products smelled bad for a year before they told FDA about it, and it turned out there was a chemical coming in through the pallet. And it should not have taken a year, it should have taken 3 days for us to hear about it.

And the recall in 2010, part of that recall was related to something that happened in 2009 that the company should have been able to figure out. So I do think that, particularly over this period, I believe that the company has gotten the message from FDA and I believe that they are really improving, and I think you will hear about that. But I do believe FDA's oversight was very important to that.

Mr. LUETKEMEYER. Have you found any problem with co-dosing or taking more than the prescribed amount with the people that you have had complaints with? Has that been a problem at all with regards to some of the drugs you looked into with this group?

Dr. SHARFSTEIN. Well, these are over-the-counter, so they are generally not prescribed. I do think, in general, for these types of medicines, you know, overdosages are just generally an issue, but nothing that I know for this that would make it a particular issue.

Mr. LUETKEMEYER. OK. But my question is, as you are looking at some of the adverse events that you were describing here, are in those events any instances of co-dosing? Are there instances of over——

Dr. SHARFSTEIN. Oh, absolutely. Yes.

Mr. LUETKEMEYER. OK. Are those things, then, that are part of whenever you get your little labeling and you get your little pamphlet that goes along with your drugs, is that information in there? Because these are over-the-counter drugs, an individual has to read it themselves to be able to see that they are not going to interact with something inappropriately. Is that information there? Were these drugs something that were not part of the prescription that was released along with the drug itself?

Dr. SHARFSTEIN. No, I think that, in general, the drugs are labeled with their ingredients, and people should be able to see those. It is complicated for some of these products because they may have multiple ingredients and people may not immediately realize that if they are giving one medication and another, that they actually have the same underlying ingredients; and that kind of

confusion has been one of the issues in this field, and I think it is something that FDA is working with the industry on.

Mr. LUETKEMEYER. So you are looking at further labeling or further advertisement about this?

Dr. SHARFSTEIN. You know, I probably shouldn't go further, because this is the area that I am recused from, in part, because of the petition that I wrote when I was the Baltimore City Health Commissioner. But FDA is looking at the labeling and the appropriate handling of this class of medicines in the cough and cold arena.

Mr. LUETKEMEYER. OK, with these adverse events, were any of them with regards to taking more than the prescribed amount of this medication?

Dr. SHARFSTEIN. More than the labeled amount? I believe yes.

Mr. LUETKEMEYER. OK. So between the two of them, co-dosing and taking more than suggested, what percentage of the total number of adverse events would you apply to those different groups?

Dr. SHARFSTEIN. I would have to get back to you on that, I couldn't answer that.

Mr. LUETKEMEYER. I see my time has expired. Thank you, Mr. Chairman.

Chairman TOWNS. Thank you very much.

I now yield 5 minutes to the gentleman from Virginia, Mr. Connolly.

Mr. CONNOLLY. I thank the Chair and I certainly welcome all of the concerns of members of the committee about this tragedy. It is too bad not everybody on the committee could find their way to voting to give FDA mandatory recall authority, and that is, I think, the crux of what we are talking about here today.

Mr. Chairman, this committee has held many important and groundbreaking hearings in its history, none more important than this. Why? Because 37 children are dead due to a tainted product, a product that parents relied on; a product they trusted to be safe both because of the brand name and the expectation that the FDA ensured its safety through Federal regulatory and oversight statutes. Whoever is responsible, everyone involved failed those 37 families in a profound and tragic way, including us.

This story is part of a much broader and equally tragic pattern characterized by anti-government rhetoric, laissez-faire laws and policies, and deliberate non or lax enforcement of existing laws and regulations, especially during the Bush administration.

In the last 6 weeks we have witnessed the unfolding drama of multiple examples of the effects and consequences of this laissez-faire philosophy of government:

A mine tragedy in West Virginia, with a number of deaths, and one prominent advocate of the laissez-faire approach actually reacting by stating sometimes accidents happen, even though there is strong evidence lax mine safety enforcement had something to do with that tragedy.

The BP oil well, which has spilled at least four times the oil leaked in Exxon Valdez, was exempted from regulation by the Minerals Management Service from the normal National Environmental Policy Act regulations. Result: an oil slick the size of Rhode

Island and Delaware combined, threatening the single largest fishery and source of seafood in the United States.

No need for health insurance reform? Tell that to the breast cancer victims who were systematically targeted by the largest insurer in the United States for recision of all coverage.

And what could go wrong with lax enforcement of oversight on Wall Street? The steepest recession in 80 years, 8.5 million Americans losing their jobs, the largest Government bailout in American history, and the loss of $17.5 trillion, that is trillion with a T, worth of aggregate worth in the United States.

And now 37 children dead because a contaminated product could not be detected and mandatorily recalled by the regulatory agency in question in a timely fashion.

There is certainly a difference between these two philosophies of government. One offers protections to the public through reasonable regulation and strict oversight enforcement, and the other leads us tragically, as we have seen in these last few weeks, to nothing short of the law of the jungle.

I yield back.

[The prepared statement of Hon. Gerald E. Connolly follows:]

Opening Statement of Congressman Gerald E. Connolly

"Johnson and Johnson's Recall of Children's Tylenol and other Children's Medicine"

Thursday, May 27th 2010

Thank you, Chairman Towns for shining a spotlight on this recall of pediatric medicine, which is a prime example of the need for balanced public safety regulation. This is the largest FDA recall of children's medicine in American history. Though the recall is only a month old and investigations are ongoing, these tainted medicines could be related to the deaths of 37 children that are currently under investigation by the FDA. While the full extent of this health threat will not be fully known until the investigation is complete, unprecedented amounts of tainted medicine were distributed, potentially threatening every American family that has purchased pediatric medicines recently.

It is equally clear, and more germane for members of Congress, that more robust regulation, such as mandatory recall authority such as that contained in the Food Safety Enhancement Act, could help prevent distribution of unsafe products like these medicines.

Johnson & Johnson's own company documents report receiving 109 samples following complaints submitted by consumers. These samples contained insects, syringe caps, hair, glass, yeast, grease, fingernails, wood, and a safety pin. In interviews with Committee staff, Johnson & Johnson quality control representatives claimed that consumers placed these items in the medicine bottlesJohnson & Johnson may claim that their subsidiary, McNeil, was solely responsible for endangering the public. McNeil's Vice President for Quality Assurance reported not to the McNeil president, but directly to Johnson & Johnson. This was not a case of a rogue subsidiary.

Johnson & Johnson's egregious behavior is more extraordinary because the FDA tried to intervene to protect public health. In September of 2009 the FDA found bacteria in children's medicine at a plant in Pennsylvania. In January, 2010 FDA sent a Warning Letter to warn of problems at a McNeil plant in Puerto Rico, yet McNeil has delayed sharing test results with FDA. Unfortunately, FDA simply doesn't have the robust authority that would allow them to shut down operations like McNeil in time to protect public health. The House has now authorized mandatory recall authority for the FDA, though that bill failed the initial suspension vote because of opposition from one party.

Today I am sure we will hear outrage over this case from both sides of the aisle. Tomorrow, some members of Congress will come to the floor of the House and rail against government regulation of Wall Street, government regulation of greenhouse gas pollution, or government regulation of avaricious insurance companies. As this hearing reminds us, the benefits of the profit motive can only be enjoyed when government establishes fair, clear rules of the game. Otherwise private companies will sacrifice public welfare for short term profit maximization, just as McNeil did by failing to take adequate steps to ensure their medicines were safe, just as health insurance companies did by cancelling coverage for women who had breast cancer, just as Wall Street investors did by scamming our constituents with credit default swaps and other exotic financial instruments.

When some members of Congress expressed concern about the Bush Administration's decision to place industry at the helm of the Minerals Management Service, advocates of laissez faire claimed that industry representatives were the most knowledgeable and experienced employees. That agency, captured by the industry it was supposed to regulate, exempted the Deepwater Horizon rig from NEPA regulations that could have prevented the largest oil spill in U.S. history. Ironically, NEPA passed Congress and was signed by a Republican President following an oil spill off the California coast. Now, with an oil slick larger than Delaware and Rhode Island combined destroying America's most productive oyster and shrimp fishery, the same opponents of regulation want taxpayers to foot the bill for economic damages caused by BP and Transocean.

When this Congress passed health insurance reform, every single member of the minority party lined up to protect insurance companies' ability to throw women with breast cancer off the insurance rolls. When we responded to America's largest insurance company systematically discriminating against women, others claimed that such elementary consumer protections constituted "socialism" or a "government takeover."

When the House passed regulatory reform to prevent Wall Street from creating another financial crisis, some claimed that such legislation would constitute a "takeover" of Wall Street. Perhaps they have forgotten that such a takeover already occurred, to the benefit of large investment banks, during the Bush Administration. Now those same opponents of any regulation in any circumstances are prepared to sow the seeds of another financial crisis.

Even as we witness an unprecedented oil spill destroy the Gulf Coast the opponents of regulation have introduced a variety of legislation to strip the EPA of regulatory authority over greenhouse gas emissions. They are nothing if not consistent; if Wall Street should manage financial policy, oil companies should decide when to institute basic safety procedures for deep water oil wells, and insurance companies should be able to choose when to cancel coverage, then logically the fossil fuel industry should be able to dictate when it will and won't be regulated, based on the successful record of deregulation in the aforementioned cases. Pharmaceutical manufacturers should decide for themselves when product contamination is a threat to public health and when or if a recall of that product should be initiated.

There is a distinct difference between the two parties, and this fissure—between the laissez faire advocates in the Republican Party and supporters of reasonable regulatory protection in the Democratic Party—separates tectonic plates of public policy. As recent tragic events in West Virginia, the Louisiana coast, the Wall Street meltdown, and now this children's Tylenol recall give evidence, the laissez fare philosophy is nothing more than the law of the jungle, leaving us all utterly exposed to its Darwinian mercies.

Chairman TOWNS. I thank the gentleman for his statement.

I now yield to the gentleman from Georgia, Mr. Westmoreland.

Mr. WESTMORELAND. Thank you, Mr. Chairman.

Dr. Sharfstein, I have seven grandchildren and they spend the night with us on a regular basis, so we have a cabinet full of children's medicine; and my wife and I, after the recall, went and looked and saw that some of it needed to be taken out. Could you tell me who manufactures the CVS brand infant similar medicine or maybe the Wal-Mart equivalent brand?

Dr. SHARFSTEIN. I don't know if I can tell you off the top of my head. I think that there may be a number of manufacturers there. One of them was mentioned earlier that does supply for that market, but there may be more than one.

Mr. WESTMORELAND. Because I know that a lot of times certain companies make all the products and just put different labels on them or have different specs. So you don't know who actually? Since McNeil manufactures or at least has about a 70 percent market share, would we be safe going to buy a CVS or a Wal-Mart, not actually knowing who manufactured it? I mean, do you know that?

Dr. SHARFSTEIN. Well, FDA knows who manufactured it, I just don't know off the top of my head. But I think one of the things we were talking about is that FDA does inspect those facilities too, and FDA has not identified the kinds of problems at those facilities, and that is why they are on the market.

Mr. WESTMORELAND. OK. Do you know how many labels McNeil manufactures for?

Dr. SHARFSTEIN. Yes, we do know that, and we know that all the products of concern have been recalled.

Mr. WESTMORELAND. There has been some question, I guess, about the availability of these products for this, and that is one of the concerns that my wife had was, well, where are we going to get it from; what is it? Is there sufficient amount of product on the market right now to where people can feel comfortable that they would have the medication for the young children?

Dr. SHARFSTEIN. Yes. The drug shortage team at FDA looked at that around the time of this recall and felt like there would be adequate alternatives for the medications that had been recalled.

Mr. WESTMORELAND. And have you put out a list of what those might be or is it anything but?

Dr. SHARFSTEIN. I think that, you know, it is what is available in the stores, because the other ones have been pulled off. We do have a shortage team that is looking to see and even though it looks like there is enough across the country, if there a spot shortage in a particular location, our team can help direct the supplies and work with the companies to direct the supplies to alleviate a spot shortage. That is something that we were concerned about given the fact that the facility is such a large supplier to the market.

Mr. WESTMORELAND. OK.

With that, Mr. Chairman, I——

Mr. ISSA. Would the gentleman yield?

Mr. WESTMORELAND. I will. I yield.

Mr. ISSA. I thank the gentleman.

Doctor, Mr. Connolly seemed to imply that the previous 8 years before you came to this job, that the FDA wasn't doing their job. Do you know of any of that?

Dr. SHARFSTEIN. Well, I think that, as I testified before, we have not identified a case of a serious adverse event linked to these quality problems.

Mr. ISSA. No, that wasn't my question. Mr. Connolly implied that the Bush administration didn't care about safety, that somehow those 8 years were not good. You are heading as a political appointee, but you are heading an organization that, if I understand correctly, is almost all non-political appointees, isn't that correct?

Dr. SHARFSTEIN. That is correct.

Mr. ISSA. So how would you rate the agency, the FDA, at the time you came from a standpoint of professionalism and consistency of inspecting with the intent of food safety, food and drug safety?

Dr. SHARFSTEIN. Well, personally, I have been incredibly impressed with the people at the FDA. There are thousands of professionals with backgrounds in medicine, law, there are inspectors, there are chemists; and the work they do is because they really care about the mission of the agency. I do think that one of the messages that Dr. Hamburg has sent as the Commissioner in the major speeches that she is going to place an emphasis on enforcement and compliance that she believes is very important, and she has really made the pitch to industry that it supports industry when that happens, and that has been something that she has focused on.

Mr. ISSA. Sure. And that probably is very similar to what her predecessor said when they came in. But I just want everyone to understand for the record this is an organization that the vast majority of it is controlled by career professionals, scientists, physicians who do their job and within the limits of the laws and the funding we give them, in fact do the same job whether it is a Republican or a Democratic administration. Isn't that true?

Dr. SHARFSTEIN. You know, I am sitting here with two terrific professionals from the agency who have worked across multiple administrations——

Mr. ISSA. Well, then why don't we go to those two and just answer. Do you see this as a dramatic change in the last 2 years, or is this essentially the same organization it was 2 years ago?

Chairman TOWNS. The gentleman's time has expired. I will yield him an additional minute.

Mr. ISSA. Basically, because the statement was made, I just would like the career professionals to answer if in fact this is substantially the same organization with the same mission and the same level of care.

Ms. AUTOR. I would say that FDA, as you said, has thousands of very hardworking career professionals who did very hard work and do regardless of the administration. I think that we welcome this administration's focus on enforcement and compliance and are glad to see that, and we will continue to do everything we can to ensure the safety, quality, and integrity of the drug supply.

Mr. CHAPPELL. Thank you. I concur in that and also say, as Dr. Sharfstein has said, when Dr. Hamburg arrived and reinforced the

fact that enforcement was one of our major tools, obviously, that was an issue that we have always dealt with and also were encouraged by that.

Mr. ISSA. Thank you.

Thank you, Mr. Chairman.

Chairman TOWNS. The gentleman's time from Georgia has expired.

I now yield to the gentlewoman from California, Congresswoman Watson.

Ms. WATSON. Thank you so much Mr. Chairman. I think this is a very crucial and essential hearing that you are having today, and we all are concerned about the 775 adverse effects that have been reported through Dr. Sharfstein's office and the deaths that have occurred because of some of the products that can be purchased over the counter. And this is directed to you, Doctor.

According to McNeil, no raw material that tested positive for objectionable bacteria were ever used in the manufacture of their products. However, according to the Form 483 filed after the FDA's April inspection of the Fort Washington facility, the raw material samples pulled from testing are not statistically significant enough to be a representative sample of that total.

So here is the question: What does McNeil need to do to improve their sampling methods and what kinds of bacteria were discovered in the raw materials, and what are the health implications for children and for infants who might have consumed the contaminated products?

Dr. SHARFSTEIN. Sure. I am happy to address that. What McNeil needed to do, and what they eventually did, is have a process where if the bacteria was found in any part of a lot of this substance, that they not use the whole lot. What they started to do is they would use part of the lot that tested OK, but the sampling wasn't good enough to assure that. So they have now a new policy they don't take any of the lot, and that is the right policy to have.

Ms. WATSON. Did we pull those products off the shelves, or did they pull them off the shelves?

Dr. SHARFSTEIN. Yes, they did.

Ms. WATSON. OK. And representatives from Johnson & Johnson have stated that McNeil is committed to not restarting operations until it has taken the necessary corrective actions to ensure the safety and quality of their products. What do you think are the most critical changes that McNeil needs to make before the American people can trust the integrity of their medicines again?

Dr. SHARFSTEIN. That is an excellent question. I think there is a broad answer to that question, which is that McNeil needs to put in a very strong quality system that has some very important basic components to it, where not only will things be done correctly, but they have a strong way of catching if there is a problem, investigating what that problem is, and immediately solving that. And that approach is what FDA is going to really insist on to be in place before the facility starts manufacturing again.

Ms. WATSON. I see. Now, do you have the authority to pull these products off the shelves? I wasn't clear with the testimony that preceded.

Dr. SHARFSTEIN. FDA does not have the authority to require recalls. Now, under certain circumstances we can go to court and get seizures and injunctions and other things, but in terms of a mandatory recall authority for drugs, FDA does not have that authority.

Ms. WATSON. The process of going to court is, in some cases, time-consuming.

Dr. SHARFSTEIN. Absolutely.

Ms. WATSON. How can we help with FDA? I have another issue and we had a hearing yesterday that deals with mercury amalgams. I don't want to get into that; that took us 5 hours. But I want to know what authority we can provide to you so that we can take these questionable products off the shelves. Lives are at stake here and you have testified to——

Dr. SHARFSTEIN. Well, one of the things to note is that in the food safety bill Congress is looking to give FDA mandatory recall authority over foods; also authority to put in place, require certain types of preventive standards to prevent problems; access to records, easier access for FDA to records at companies; and civil money penalties.

Ms. WATSON. Let me just interject this question. You are saying authority over foods. Can we add another line saying anything that is ingested or digested through the mouth?

Dr. SHARFSTEIN. I think that would be up to Congress.

Ms. WATSON. That would go beyond just foods.

Dr. SHARFSTEIN. Right. That would be up to Congress.

Ms. WATSON. OK. As a doctor, would that clarify what you need to understand we can do? I want to make it easier for you to indicate.

Dr. SHARFSTEIN. I appreciate the question tremendously.

Ms. WATSON. And we make the policy, so——

Dr. SHARFSTEIN. Right. No, absolutely. The administration hasn't worked out a final position on this with respect to drugs, but the administration does have a position with respect to foods, and these are the types of things that the administration is looking at with respect to foods, and there is no question that it is relevant for drugs.

Ms. WATSON. OK, I am going to have my staff write a letter to you and we are going to suggest this language, and then you can take it the rest of the way.

Dr. SHARFSTEIN. Thank you very much.

Ms. WATSON. Thank you very much. My time is up.

Chairman TOWNS. We will leave the record open for it.

I now yield 5 minutes to the gentleman from California, Mr. Bilbray.

Mr. BILBRAY. Thank you, Mr. Chairman.

Doctor, let me first thank you very much for a very measured response, a very measured and thoughtful approach to this issue. I think it is so quick for us to want to go from one radical extreme to the other, and I appreciate the fact that I think some people would say your experience here, I think your experience in the real world, doing local health gives you that measure of moderation and consistency, and I think that really helps the entire process.

One of the things that I really want to focus on is that we have talked about how do we respond to this and, as you said, we sort

of addressed the issue before it became chronic, before it became a crisis. As we look at the way we can improve this, I have some questions about your auditors when they go in. How do you assign the inspectors to do these inspections for the facilities?

Dr. SHARFSTEIN. They come out of the district office. FDA has a number of district offices around the country and they have a staff of inspectors, so the firms are inspected by their local district office professional inspectors.

Mr. BILBRAY. OK. Does the same inspector go back and inspect these facilities each time, or is there a rotation? Do you know how they allocate personnel toward certain facilities?

Dr. SHARFSTEIN. I am going to maybe ask Mike Chappell, who oversees all the inspectors, to answer that question.

Mr. CHAPPELL. Well, thank you. In response to your question, we make sure that the individuals that conduct these inspections have the proper level of training and experience. Indeed, if they are at a firm where there are some significant problems, they also are able to call upon expertise both within the inspector group and also other places in the agency. We don't have a policy that the same investigator can't go into the same firm; oftentimes they do. But in many of the cases of these large firms, there will actually be a team of inspectors that will go in just due to the sheer size of the firm.

Mr. BILBRAY. So, in other words, you have a policy that you may have an inspector go in with a general oversight, but if he finds specific concerns, he can then call in sort of a delta team that specializes to help him focus on some of the concerns and bring the level of expertise up a little bit on those specific issues?

Mr. CHAPPELL. Yes, exactly. That is exactly it. If there is a specific manufacturing process or a specific issue that we have other people with greater expertise or experience, they are available to be called in for these inspections, yes.

Mr. BILBRAY. Now, when we talk about the inspectors and their relationships with the facility itself, what is the policy and what is the practical application of communication contact with the facility or individuals who operate the facility by the inspectors other than during inspection, other than during the official process of review and inspection of the facilities, as we say, off-campus contacts? What is the policy and what is the reality in what level of contacts off campus or out of the inspection process do these inspectors have with operators or owners of these facilities?

Dr. SHARFSTEIN. I would say that there is quite a lot of communication between the company and its district office, and maybe, Mike, if you want to talk about some of the examples. If they find problems in the facility, for example, it is not during an inspection, there are certain types of problems, they have to notify the district office about.

Mr. CHAPPELL. Just to make sure I understand your question, are you talking about an inspector or investigator that is not conducting an inspection, that has no relationship with that company as it relates to an inspection or investigation?

Mr. BILBRAY. Yes. I am really looking at, Doctor, one side to look through the official communications. But what I am saying is what is the policy about unofficial contacts that may not be directly re-

lated to the responsibility of the inspector to the facility, but outside of official contact? What kind of policy do you have specific to those contacts outside of official——

Dr. SHARFSTEIN. I see. I am sorry, I may have misunderstood the question.

Mr. BILBRAY. That is OK.

Dr. SHARFSTEIN. You are asking about like after-hours contacts, that sort of thing?

Mr. BILBRAY. Right.

Dr. SHARFSTEIN. I thought you meant outside of the inspections, but not outside of the job.

Mr. BILBRAY. I understand that.

Dr. SHARFSTEIN. He means outside the job.

Mike, do you want to?

Mr. CHAPPELL. Well, I can certainly say there is professional integrity that we expect of our investigators, and if they are involved in activities with company officials as it relates to some type of relationship, such as a job seeking, etc., we have standards for that prohibits that kind of activity.

Mr. BILBRAY. OK. I appreciate that.

You know, Doctor, I had the pleasure for a decade of supervising an environmental health department doing this kind of inspection and an Air Resources district doing this kind of inspection, and there are two schools of thought, and I think too often people take the punitive approach that my air district was involved in for too long, rather than a cooperative; and one thing I was very impressed with our environmental health people was they saw their job was to help the private sector stay within the law, stay within the safety boundary, rather than what I ran into with a lot of my air guys that were looking, the cop mentality of trying to catch people crossing the line and being punitive rather than cooperative. And I know people will attack you for trying to work with the private sector at staying within the framework, but I think we all remember busting people or finding fault is not the answer, but to avoid the problem, and I appreciate your efforts.

Chairman TOWNS. The gentleman's time has expired.

Mr. BILBRAY. Mr. Chairman, could I allow the doctor to comment on that?

Dr. SHARFSTEIN. Sure. I would say I absolutely agree with that, and that was the approach we had in Baltimore. It is very important to work cooperatively where you can, and we, in Baltimore, actually had a Web site where we posted common questions so that people could get information. We weren't counting success by the number of closures, but we wanted to have success by compliance; and that is the same thing at FDA. Actually, one of our transparency recommendations parallels that, that FDA should be more aggressive in telling the regulated community about the kinds of problems that we find so that people can correct them in advance, not whether we can find them at every place.

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

Chairman TOWNS. The gentleman's time has expired.

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

Mr. CLAY. Thank you, Mr. Chairman. Let me thank you and the ranking member for holding this hearing on a serious matter of public health and public safety.

Maintaining the highest standard for manufacturing medicine is essential to the safety of the American consumers. Let me ask Dr. Sharfstein. I have two children, 9 and 16. Do you advise me, as well as the rest of the people listening and viewing this hearing, to stay away from these products, from Johnson & Johnson, from Motrin, from Tylenol, and whatever else you found to be problematic?

Dr. SHARFSTEIN. We are advising that people throw out the recalled products, yes.

Mr. CLAY. What about just the brand itself?

Dr. SHARFSTEIN. I don't think we would go that far, because we are looking at each of the different issues at the different facilities. But there is a pretty big list of products that we are staying people to stay away from right now.

Mr. CLAY. You know, looking at the observation from your first report and then from your report in April 2010, it appears that you observed many of the same deficiencies again. Is this a correct assessment?

Dr. SHARFSTEIN. I think that there were some similarities, but we found some new ones in April 2010 that were extra concerning.

Mr. CLAY. In your opinion, how seriously did McNeil take its response to your inspections?

Dr. SHARFSTEIN. I think that what happened over this period is FDA was intensifying its scrutiny and that really culminated in this February meeting, which was an extraordinary meeting with the senior leadership of the parent company, where FDA really said there is a problem of compliance at your company; and our sense is they took that very seriously and have made some major changes to how they oversee quality across this particular company. You know, we wish it hadn't come to that, but I think it was necessary for FDA to really talk to the company about the company's overall compliance problems.

Mr. CLAY. Now, it is my understanding that reports of suspicious odors were made as early as 2008. Is that correct?

Dr. SHARFSTEIN. That is correct.

Mr. CLAY. And how long did it take McNeil to begin a comprehensive response to these complaints?

Dr. SHARFSTEIN. At least a year, I think.

Mr. CLAY. A year?

Dr. SHARFSTEIN. That is correct.

Mr. CLAY. OK. So they didn't take the report seriously. They didn't take the complaint seriously.

Dr. SHARFSTEIN. FDA's view is that they should have reported that to the agency and that they didn't at that time, and then, when they did report it to us, it required a lot of oversight by FDA for them to realize the scope of the problem, and eventually that led to a significant recall. And because of their failures in that regard, FDA sent them a warning letter on January 15th of this year that not only called attention to the problems, but called attention to the failure of corporate oversight.

Mr. CLAY. So, in FDA's opinion, their response was not timely, nor appropriate.

Dr. SHARFSTEIN. That is correct.

Mr. CLAY. Do you believe that Johnson & Johnson's participation in recalling the contaminated product was effective?

Dr. SHARFSTEIN. I believe that they have gone about the recall, particularly this most recent recall, very vigorously, and they have made a lot of information available to the public about it.

Mr. CLAY. What new regulations do you believe should now be enacted to protect American consumers from the contaminated medicines we are investigating today? What else can we do?

Dr. SHARFSTEIN. One of the things we have been talking about are some of the authorities that are being looked at under the food safety bill for food that relate to things like mandatory recall authority, easier access to records to FDA, civil money penalties. Those are things that have been discussed.

Mr. CLAY. Do you believe that contamination of this magnitude has implications for possible terror threats?

Dr. SHARFSTEIN. I don't know if I can answer that question without thinking about it some more. In general, this is really a product quality issue that we see and have seen for a while, and FDA believes it is important, just in general, that products be made according to the best specifications so that they are safe and effective as possible, and it is really product quality that is driving our strong work in this area.

Mr. CLAY. And how often do you check quality with the manufacturers?

Dr. SHARFSTEIN. It depends on the company and it depends on their record. And this is a company that got extra scrutiny from FDA because of our concerns.

Mr. CLAY. Thank you.

I yield back.

Chairman TOWNS. The gentleman's time has expired.

Before we move to the next questioner, let me yield 30 seconds to the gentleman from California.

Mr. ISSA. I thank the gentleman. To clarify the record, I would ask unanimous consent to be able to place in the record a letter from the McNeil Consumer Healthcare Division in which they say call 888–222–6036. I won't put this in the record, but if you do that rather than throwing away medicine, you return it and you are paid $15 on this check. So I would just ask that be placed in the record and that it be clear that the recall does cause this division to pay for healthcare products returned to them.

Chairman TOWNS. Without objection, so ordered.

[The information referred to follows:]

Dear McNeil Consumer,

The Consumer Care Center, on behalf of McNeil Consumer Healthcare, is providing you with the enclosed refund for your purchase of recalled McNeil Consumer Healthcare infants' and children's products.

On behalf of all of us at McNeil, please accept our apologies for any concern and inconvenience this recall caused you. Nothing is more important to us than earning your trust by providing you with the highest quality products.

We are working diligently to ensure that our quality operations meet the high standards that you expect from us and that we expect from ourselves. You will not see our infants' and children's products on store shelves until we can implement our corrective actions in our manufacturing operations.

If you have any further questions or concerns, please call us at 888-222-6036.

Best regards,

McNeil Consumer Healthcare,
Division of McNeil-PPC, Inc.
7050 Camp Hill Road
Fort Washington, PA 19034

Chairman TOWNS. I now yield 5 minutes to the gentlewoman from California, Congresswoman Speier.

Ms. SPEIER. Thank you, Mr. Chairman.

Along those same lines, let me ask FDA do you have this telephone number on your Web site to alert the consuming public that they can contact McNeil and get reimbursed?

Dr. SHARFSTEIN. I believe we do. I believe that we link to all of McNeil's materials.

Ms. SPEIER. Well, I am not talking about linking, but actually having a notice on your Web site to call this number and that you can then get a reimbursement.

Dr. SHARFSTEIN. I would have to——

Ms. SPEIER. And if you don't, I think you should.

Second, I think it is very important for the consumers to be told that they shouldn't throw away these prescription drugs that then get into the water system; that they should properly dispose of them in a manner that will not have it being leached into the water system and then creating more problems down the road.

So I want to talk about the elephant in the room. And I think the elephant in the room is that you don't have recall authority. This has been a voluntary recall by McNeil of 43 of their products, correct? So if they had chosen not to recall those products, you would have had to go to court in order to effectuate that result. Is that correct?

Dr. SHARFSTEIN. And it would have been challenging to do it through court, actually.

Ms. SPEIER. So you probably wouldn't even have been able to do it through the court.

Dr. SHARFSTEIN. We would have had some ability to do some of it through court, but I think in this case McNeil and Johnson & Johnson agreed to do the recall. But I think that part of the issue, if you look across this whole time period, is that from the point of wanting to have a recall, there were some delays, and I think that it is a fair question to ask about mandatory recall authority.

Ms. SPEIER. So you don't have mandatory recall authority. If they had chosen not to recall those products, those products would still be on the shelves today. Is that a fair comment?

Dr. SHARFSTEIN. I think that probably is a fair comment, yes.

Ms. SPEIER. All right, so, Mr. Chairman, I think that is an issue that really needs to be addressed.

Second, if you look at the behavior of McNeil over the course of these 2 or 3 years, it reminds me of a kid in school who continues to get Ds, no one basically takes an action, the kid never goes to the principal's office until 3 years down the road, and very little action occurs. So my question is really about fines. Since your real power is somewhat limited, outside of suggestions and negotiations, what kind of fines can be imposed? Can you close them down for 10 days? What hammers do you have to utilize in your regulatory function?

Dr. SHARFSTEIN. I think I may ask Deb Autor to answer that question. I can tell you we do not have civil money fines for these kinds of violations, so there are criminal penalties that would require going to court to get. But in terms of the ability to assess civil

money penalties, which is part of the food safety bill, we don't have that in this area of drugs.

Ms. SPEIER. OK, maybe that is part of the problem, that getting compliance is more difficult because there is no hammer on any of these companies. There is no downside risk not to ignore what FDA is requiring because you don't have any financial impact.

Dr. SHARFSTEIN. Well, I think the story here is that we got their attention and there were major changes that were made over the course of this process even under the existing law.

Ms. SPEIER. I agree.

Dr. SHARFSTEIN. But having said that, I think you are asking a very fair question, which is, with other tools, could FDA have gotten their attention faster and sooner and had a quicker result. I think those are fair questions to ask. They are being asked in the context of food safety as well.

Ms. SPEIER. And especially since you don't have the power for mandatory recall. How else do you get anyone's attention?

So if Ms. Autor.

Ms. AUTOR. Yes, thank you. Just to add on to what Dr. Sharfstein said, we do not have any civil money penalty authority for violations of good manufacturing practices or drug labeling requirements. And to clarify my answer to Ms. Norton earlier, the only context in which we have civil money penalties for drugs are related to certain application requirements.

Ms. SPEIER. All right.

Ms. AUTOR. So it would be useful to us to have that authority.

Ms. SPEIER. OK, my time is running out.

Cost recovery. A lot of money has been spent investigating inspecting over and over and over again. How much has that cost the taxpayers of this country and are you able to recover the costs associated with that?

Dr. SHARFSTEIN. That is a good question We would have to get back to you on how much money exactly has been spent on it. I think, as we said, there are a number of things that FDA is still considering in terms of enforcement in this situation, and one of our potential options would be to seek to get money back from the company if certain criteria were met, and that is part of the assessment that is probably going on.

Ms. SPEIER. I thank the witnesses. My time has expired.

Chairman TOWNS. The gentlewoman's time has expired.

I now yield 5 minutes to the gentleman from Massachusetts, Mr. Tierney.

Mr. TIERNEY. [Remarks made off mic.]

Chairman TOWNS. Right.

I now yield 5 minutes to the gentleman from Illinois, Mr. Davis.

Mr. DAVIS. Thank you very much, Mr. Chairman. I thank you for holding this hearing.

Dr. Sharfstein, let me ask you when troubles emerge, are found, or concerns raised, are there any remedies that can occur prior to recall?

Dr. SHARFSTEIN. In terms of whether we can fix the manufacturing process before the product gets recalled?

Mr. DAVIS. Yes. I mean, if you find that there is a problem with a product or there are concerns about a product, or allegations of concerns about a product, what happens at that point?

Dr. SHARFSTEIN. I think there is an assessment. In some cases the product may not have left the facility, and you don't have to do a recall at all; it is still there and it just never gets sold. And then there is an assessment, if it has gotten sold, of whether it is something that is significant enough to require a recall. And we have a standard for that and I think one of the things we are going to do is take a look at that. But sometimes, you know, there is a problem and it can be addressed. We look at it, we get more information, and we realize that it doesn't pose any risk at all and there does not need to be a recall, but there will be fixed going forward. So it is kind of a case-by-case determination. But there are sometimes when we don't do a recall.

Mr. DAVIS. In the event that there is just a continuation of production activity that is out of compliance or does not meet specifications or requirements, what can happen to a company?

Dr. SHARFSTEIN. If there is repeated violation, what we have seen so far is we call in the company, we can talk to them; we can send them warning letters; and then they can have other enforcement actions, including court-ordered injunctions, we can seize their products; and then eventually we can refer to criminal investigation and people can be prosecuted criminally.

Mr. DAVIS. Can you think of any instances where that has happened?

Dr. SHARFSTEIN. There have been examples where there has been a quality problem so significant that it has led to that. Recently with a company actually in Massachusetts, there was a major agreement that we reached, that has yet to be blessed by the court, that relates to quality problems and I think well over $100 million is being paid by the company back to the government because of quality problems at their facility.

I think in that case and in this case it is really important to realize the critical role that FDA plays for drug safety; and I think it is important to think of what would have happened in this case had FDA investigators not been on the job, that we could expect that a lot of these problems would not have been caught, that changes at the company would not have been made, and it eventually could get to a situation where there was a very serious risk to the public.

Mr. DAVIS. Thank you very much.

I have no further questions, Mr. Chairman.

Chairman TOWNS. Thank you very much.

Let me just make a quick statement to the Members. We will have votes in just a matter of a few minutes, and what I would like to do is to adjourn and come back 10 minutes after the last vote. I can't say exactly what time it will be because I am not sure as to how long it will take us for the four votes, but we would take a recess and then come back and then do the second panel.

If you would like to, fine.

Mr. ISSA. Thank you, Mr. Chairman.

Just a very, very quick followup. The gentlelady from California, before she leaves, under the previous administration there was an

egregious failure by the FDA, and you probably remember it either from your time on the Hill or when you in Baltimore. We had a spinach problem under the FDA. A bag of spinach coming from a specific location and a specific farm was tainted. That led to a total recall of all spinach. You may not have had authority for mandatory, but the FDA made sure that spinach was dead in America for a period of time.

What are you doing today to ensure, under the food side of food and drug, that if in fact a field of some fresh vegetable is tainted, that only that field, if it can be identified. In this case the bags were numbered; they could have named the manufacturer, or at least the bagger, and they didn't. What are you doing to change that so the next time a bit of food, similar to when beef is tainted and agriculture controls it, that only the actual tainted or likely tainted or possibly tainted is recalled, rather than an entire fresh vegetable segment being off the market for a period of time?

Dr. SHARFSTEIN. That is a good question and that is something that we have thought a lot about. In fact, the transparency report that we just posted has a whole section on the importance of FDA being as transparent as possible about the products that are not affected by recalls. For example, when there was a pistachio recall, FDA linked to an industry Web site of all the brands that were not involved with the particular farm at issue.

Recently, there was a terrible outbreak that was related to Romaine lettuce. FDA worked very quickly with States and localities and the CDC, and we identified a distributor, and we quickly were able to narrow it down so that, when we did do a recall, it was a relatively narrow recall.

There is a balance between the scale of the recall and the timeliness, because you need to move fast because it is often perishable foods that you don't want people to eat. I think we realize that we want to be as absolutely as narrow as we possibly can when we are warning the public about food, and I think that you can look at the Romaine lettuce situation that just happened, that I was quite involved in, as an example of an area where we did our best to narrow it as quickly as possible and, in fact, it was very relatively narrow in how we did it, and we were able to get the products of concern off the market very quickly.

Mr. ISSA. Last question. Do you need any new authority in relation to food, such as, in the case of ground beef, every package of ground beef that is ground outside of the store in which it is sold has a manufacturer's ID, date code, and so on, so that the consumer can make a decision about whether they are covered by a code. In the case of packaged vegetables, that is also true. But in the case of unpackaged vegetables, the master pack may or may not contain sufficient information to find out for sure where it came from. Is that something that you could do within your own rulemaking authority, or does Congress need to act?

Dr. SHARFSTEIN. It sounds like a question I am going to want to get back to you on with a good answer, but——

Mr. ISSA. I think the chairman would appreciate that for the record.

Dr. SHARFSTEIN. But I would say that FDA strongly supports food safety legislation, and we think it is really critical for our abil-

ity to establish the standards that are needed to protect the food supply.

Mr. ISSA. Thank you.

Thank you, Mr. Chairman. I yield back.

Chairman TOWNS. Right. Just before we recess, let me just ask have you checked to see whether or not the quality control staff has been decreased?

Dr. SHARFSTEIN. At McNeil?

Chairman TOWNS. Yes.

Dr. SHARFSTEIN. I believe that one of the things that we are talking to the company about is their quality control staff; what their qualifications are, what kind of plans they are going to put into place. Everything related to the quality control staff FDA is working with the company to make sure it is satisfactory.

Chairman TOWNS. Just before we recess, the gentleman from Maryland, any comments or suggestions?

Mr. CUMMINGS. No, Mr. Chairman. Thank you very much.

Chairman TOWNS. Thank you very much.

We will now recess until 10 minutes after the last vote. Cannot tell you the exact time we will come back because we do not know how fast the votes will move, but this panel is dismissed.

Dr. SHARFSTEIN. Thank you.

[Recess.]

Chairman TOWNS. The committee will reconvene.

Our second witness today is Colleen Goggins, worldwide chairman of the Johnson & Johnson Consumer Group.

It is committee policy that all witnesses are sworn in. Please stand, Ms. Goggins, and raise your right hand.

[Witness sworn.]

Chairman TOWNS. You may be seated.

Let the record reflect that the witness answered in the affirmative.

Ms. Goggins, please give your opening statement.

STATEMENT OF COLLEEN GOGGINS, WORLDWIDE CHAIRMAN, CONSUMER GROUP, JOHNSON & JOHNSON

Ms. GOGGINS. Thank you, Chairman. Chairman Towns, Congressman Issa, and members of the committee. My name is Colleen Goggins, and I serve as the worldwide chairman of the Consumer Group of Johnson & Johnson. In this position, I oversee the products that include the pediatric Tylenol, Motrin, Zyrtec, and Benadryl products that were recalled by McNeil Consumer Healthcare on April 30, 2010. McNeil is a Johnson & Johnson operating company, and I am pleased to testify on behalf of Johnson & Johnson to present our understanding of the events.

All of the Johnson & Johnson family of companies realize that we have a responsibility to provide consumers with the highest quality products possible. We are proud that our products help millions of people around the world improve their health and well-being. In this instance, we have not lived up to that responsibility. The quality issues in this recall are therefore a disappointment to our chairman, Bill Weldon, to me personally, and to the thousands of employees in the Johnson & Johnson family of companies.

The quality and process issues that we found at McNeil, those that led to the recall and others, are unacceptable. On behalf of McNeil and Johnson & Johnson, I apologize to the mothers, the fathers, and the caregivers for the concern and inconvenience caused by the recall. Johnson & Johnson embraces the work of this committee and we hope that today's hearing will be an important step in furthering public understanding of the recall.

Unfortunately, there has been some confusion in the media with respect to this recall. I would like to stress, therefore, four key points that Dr. Sharfstein also reiterated this morning. First, as the FDA noted last month, the health risk to consumers from the recalled products are remote. Second, McNeil has no indication of a serious adverse medical event caused by any of the issues referenced in the recall announcement. Third, no raw materials that tested positive for objectionable bacteria were ever used in the manufacture of McNeil's pediatric products. And, finally, McNeil rejected the products that it found had excess active ingredient and these never reached the marketplace.

Because the McNeil products are used by millions of sick children each year, we receive many questions and reports on possible adverse events. We take all of these very seriously, assess all of them, and specifically investigate all serious adverse event reports, whether or not the events may have been caused by our products. As Dr. Sharfstein indicated, the mere existence of these normal and expected reports does not alter the medical conclusions of the FDA and our doctors that the safety risk from the recalled products is remote.

The recall last month was implemented because of the presence of minute metal particles detected in a small percentage of products. To be clear, these quality issues, including the minute particles, are unacceptable to us. For that reason, McNeil implemented a broad precautionary recall of liquid children's and infants' medicines on April 30, 2010.

Let me address the remote medical risks.

First, with respect to the minute particles, McNeil's health assessment concluded that even if those products were distributed and the particles were ingested, the particles were inert, so small, and so few that they did not present a safety or health risk.

Second, with respect to products with an excess concentration of acetaminophen, which McNeil rejected, McNeil's medical experts confirmed that even ingestion of the maximum labeled dose over an extended period of time, with the highest identified level of excess acetaminophen, would not present a medical concern.

Third, with respect to raw materials, McNeil tested all raw materials and rejected any containers of raw materials that tested positive for objectionable bacteria. No raw materials that tested positive were ever used in production.

Although the medical risks were remote, we recognize that the quality and process deficiencies identified in McNeil's Fort Washington plant must be remedied. My written testimony contains additional details on these points and a summary of the steps that McNeil undertook and is undertaking to act quickly to implement this broad recall and the steps that Johnson & Johnson and McNeil are taking to address quality processes.

In particular, we have made a number of personnel changes and embarked on a comprehensive assessment of McNeil's OTC facilities both before the FDA inspection in April. The Johnson & Johnson parent company is committed to providing McNeil with all the resources and personnel needed to improve quality and to ensure that its product and processes meet the highest standards.

Johnson & Johnson and McNeil take these issues very seriously, and we are committed to taking the steps necessary to bring McNeil's operations back to the level of quality that Johnson & Johnson demands of its companies and that the public rightly expects of us.

Mr. Chairman, I would like to close in the same manner that our chairman, Bill Weldon, concluded his letter to the people who use our products: We will work hard to earn back your confidence. I would now be happy to answer your questions.

[The prepared statement of Ms. Goggins follows:]

Johnson & Johnson

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

May 27, 2010

Chairman Towns, Congressman Issa, and Members of the Committee, my name is Colleen Goggins, and I serve as the worldwide chairman of the consumer group of Johnson & Johnson. In this position, which I have held since June 2001, I oversee all of Johnson & Johnson's consumer products and serve on the company's executive committee. The product lines in the consumer group include household names like Neutrogena, Aveeno, Listerine, Band-Aid, and Neosporin. I also oversee the over-the-counter products within the consumer group, which includes the pediatric Tylenol, Motrin, Zyrtec, and Benadryl products that were recalled by McNeil Consumer Healthcare on April 30, 2010. McNeil is one of the Johnson & Johnson operating companies. I am pleased to testify on behalf of Johnson & Johnson to present our understanding of the events.

All of the Johnson & Johnson family of companies realize that we have a responsibility to provide consumers with the highest quality products possible, and we have worked hard to fulfill that responsibility for more than a century. We are proud that our products help millions of people around the world improve their health and well-being. Across our organization, we believe our first responsibility is to the doctors, nurses, and patients, to mothers and fathers, and all others who use our products and services. In this instance, we have not lived up to that responsibility, and the recall is therefore a disappointment to our Chairman Bill Weldon, to me personally, and to the thousands of employees in the Johnson & Johnson family of companies.

The quality and process issues that we found at McNeil, those which led to the recall and others, are unacceptable. On behalf of McNeil and Johnson & Johnson, I apologize to the mothers, fathers, and caregivers for the concern and inconvenience caused by the recall. Johnson & Johnson embraces the work of this Committee, and we hope that today's hearing will be an important step in furthering public understanding of the recall.

Consistent with our goal of furthering public understanding, it is critical that the public understand that the recall was not undertaken on the basis of adverse medical events. Unfortunately, there has been some confusion in the media with respect to this recall. I would like to stress, therefore, four key points. First, as the FDA noted last month, the health risks to consumers from the recalled products were remote. Second, McNeil has no indication of a serious adverse medical event caused by any of the issues referenced in the recall announcement. Third, no raw materials that tested positive for objectionable bacteria were ever used in the manufacture of McNeil's pediatric products. And finally, McNeil rejected the products that it found had excess active ingredient.

Because the McNeil products are used by millions of sick children each year, we receive many questions and reports on possible adverse events. We take all of these seriously, assess all of them, and specifically investigate all serious adverse event reports, whether or not the events may have been caused by our products. The mere existence of these normal and expected reports does not alter the medical conclusions of the FDA and our doctors that the safety risk from the recalled products is remote.

The recall last month was implemented because of the presence of minute metal particles detected in a small percentage of products. To be clear, these quality issues, including the minute particles, are unacceptable to us. Johnson & Johnson and McNeil take these issues seriously, and we are committed to taking the steps necessary to bring McNeil's operations back to a level of quality that Johnson & Johnson demands of its companies, and that the public rightly expects of us.

A. The Health Risk to Consumers is Remote

McNeil implemented a broad, precautionary recall of liquid children's and infants' medicines on April 30, 2010, because quality process deficiencies produced tiny metal particles in a small amount of product. The recall was not prompted by adverse medical events, nor was it prompted by safety concerns regarding two additional quality issues referenced in the recall notice – excess concentration of active ingredient, and inactive ingredients that did not meet McNeil's testing requirements. Neither of these issues, nor the tiny particle issue, presented anything other than a remote patient safety issue. This conclusion rests on detailed health assessments that were performed by McNeil and shared with the FDA and that included a wide range of possible assumptions.

First, with respect to the minute particles that were discovered in some products, the health assessment concluded that even if those products were distributed and particles were ingested, the health risk was remote. The tiny particles were inert, small, and sparse. The particles did not present a risk for cuts or tears to the gastrointestinal tract, the assessment concluded. Still, the presence of these particles is unacceptable from a quality perspective.

Second, with respect to products with an excess concentration of acetaminophen, which McNeil rejected, McNeil's medical experts confirmed that even ingestion of the maximum labeled dose, over an extended period of time, with the highest identified level of excess acetaminophen would not present a medical concern.

Third, with respect to raw materials, McNeil tested the raw materials and rejected any containers of raw materials that tested positive for objectionable bacteria. 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. 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. McNeil tested these attributes and confirmed that the product killed bacteria.

Even though we were relieved that the medical risks were remote, we recognize that quality process deficiencies are important and must be remedied. Tylenol and the other brand

names produced by McNeil are some of the most trusted names in over-the-counter medicine. Millions of families rely on our products to treat those dearest to them.

B. McNeil Implemented a Broad, Precautionary Recall

McNeil acted quickly to implement a broad recall after its discovery of the fine black particles in a one-ounce bottle of a Tylenol product on a production line of the plant in Fort Washington, Pennsylvania. The products with the fine particles were withheld from distribution, and McNeil commenced an immediate internal investigation.

After receiving the results of an outside laboratory analysis, McNeil issued a field alert to the FDA and suspended production of liquid products on all four of the Fort Washington production lines. This field alert provided details on the particles found and the results of the laboratory tests. This field alert was issued several days before the FDA commenced a site inspection of McNeil's Fort Washington facility. Working closely with the FDA during this inspection, McNeil decided voluntarily to recall all of the unexpired liquid products, even though the just-completed health hazard evaluations concluded the recalled products presented a "remote probability" of a serious adverse medical event.

McNeil's records show that no product packaged after the discovery of the fine black particles was released or distributed into the market.

C. McNeil Acted Rapidly in Pulling Products from Shelves and Informing Consumers and Doctors of the Recall

Immediately upon commencing the recall on April 30, 2010, McNeil acted quickly and decisively to work with wholesalers and retailers to ensure that recalled products were removed from shelves, to inform the public of the recall, and to make sure that parents and caregivers stopped giving the recalled products to children.

Even as McNeil was preparing the materials to announce the recall publicly, its personnel began the process of notifying major retail customers. On April 30, 2010, McNeil's personnel reached out to major customers such as Wal-Mart, Target, CVS, Walgreens, Costco, Sam's Club, Rite Aid, and Kroger. That evening, McNeil began to receive confirmations that retailers were taking action, including confirmation that recall information was received by Duane Reade, Rite Aid, CVS (which indicated that it was already in the process of removing inventory from shelves), Wal-Mart (which indicated that it imposed a "PULL AND HOLD" order), and Family Dollar. To reach smaller retailers, McNeil distributed its notices to wholesalers and brokers that specialize in serving small retail outlets. We understand that substantial amounts of recalled products were removed from store shelves that evening and over the ensuing weekend.

To assist retailers and wholesalers, McNeil prepared and distributed numerous documents for the recall. These included a press release, a warehouse and retail customer letter, a recall authorization form and business reply card, shelf signs in multiple digital formats, health care professional questions and answers, and trade questions and answers. McNeil directed warehouses and retail customers to identify all retail and warehouse inventory of the recalled products, remove them from the shelves, and return them to McNeil. In addition, McNeil requested that retailers institute immediate "stop sell" procedures on the recalled products. The

"stop sell" is designed to prevent the UPC code from an individual product being scanned for sale at a retail register.

McNeil's communications also contained toll-free telephone numbers for the recall shipping coordinator and McNeil's customer service. The questions and answers provided information on identifying the recalled products and returning them to McNeil. Similarly, McNeil distributed question and answer information for pharmacists that contained information on returning the recalled products for a refund.

In parallel to its efforts to inform retail customers and wholesalers of the recall, and to remove the products from store shelves, McNeil worked quickly and broadly to announce the recall to the public, provide information to consumers, and ensure that parents discontinued using the recalled products.

McNeil prepared and distributed a press release that was sent to dozens of media outlets, including major broadcast and print media outlets. Many of these media outlets broadcast the recall widely; some news outlets distributed an e-mail alert on the recall, such as *The New York Times*. McNeil's media tracking indicates that there have been more than 2,300 media stories about the recall and dozens of reports on national broadcast television and cable. In the first three days of the recall, April 30 to May 3, our tracking shows that there were more than 143 million media impressions concerning the recall; and from April 30 to May 21, an estimated 362 million impressions.

The McNeil press release advised parents and caregivers that they should not administer these products to their children. The press release also contained a toll-free telephone number and address of the recall website for further information, and it encouraged parents and caregivers to speak with a doctor or pharmacist about alternative treatments.

McNeil established a website dedicated to the recall (www.mcneilproductrecall.com) where consumers could review the press release, request a refund or coupon, learn more about individual products recalled, and read frequently asked questions. The website contains guidance on obtaining additional information over the phone, through e-mail, or with a call back from a McNeil representative. The website has received approximately 3.5 million unique visitors, and it links to individual product sites that provide detailed information about the individual products recalled, including pictures of the products and UPC bar codes.

In addition, the websites for each of the recalled products – Tylenol, Motrin, Zyrtec, and Benadryl – contain prominent notices about the recall. And the Johnson & Johnson home page contains a dedicated box that links to recall information. McNeil even secured priority placement for recall information on Internet search results on likely recall-related search terms (e.g., Tylenol). A Johnson & Johnson company, BabyCenter, one of the most popular websites for new and expectant parents, communicated recall information though e-mail alerts and banner advertisements.

McNeil also used innovative technologies to distribute information about the recall. On "JNJ BTW," the company's blog, Chairman Bill Weldon posted an open letter to consumers with information on the recall, a link to the recall website, and the toll-free customer service telephone number. The Johnson & Johnson feed on Twitter provided a link to this information as well.

The company used Text4baby, a free mobile information service designed to promote maternal and child health, to distribute recall information.

In its press release McNeil broadly disseminated a toll-free telephone number where consumers could obtain information concerning the recall. The call center provided information about the recalled products, the disposal of recalled products, and a list of recalled products by name and code. Since April 30, 2010, the call center has fielded approximately 280,000 calls, and processed an additional 180,000 e-mails. In addition, McNeil has issued approximately 600,000 consumer refunds.

McNeil also distributed multiple letters to health care providers that provide detailed information about the recall, including a list of recalled products (including samples provided to health care professionals), a toll-free telephone contact number, and website addresses for further information. These letters include instructions to stop use of the recalled products. McNeil also sent e-mail alerts to the American Academy of Pediatrics, the American Association of Family Physicians, the American Association of Poison Control Centers, and the American Pharmacists Association concerning the recall. McNeil posted updated information on websites direct to health care professionals (www.tylenolprofessional.com and www.zyrtecprofessional.com).

McNeil's tracking indicates that distributions to health care professionals of its most recent notice included e-mails to 88,000 professionals who registered for communications; facsimiles to 325,000 locations of health care professionals; an electronic marketing alert to 645,000 health care professionals; and direct mail to 35,000 health care professionals not covered by the e-alerts and facsimiles. McNeil's press release and the letters to health care providers included information on reporting adverse medical reactions to the FDA. Health care professionals were also provided with a toll-free telephone number and website addresses to contact the Medical Affairs Department of McNeil.

D. Johnson & Johnson and McNeil are Committed to Improving Quality

Mr. Chairman, I want to stress that, even before the most recent recall, Johnson & Johnson and McNeil have been working together to improve the quality of McNeil's products. The Johnson & Johnson parent company is committed to providing McNeil with the resources and personnel needed to improve quality, work with the FDA, and ensure that the products meet our high standards. Indeed, over the past several years, McNeil's quality expenditures and investments relating to the Fort Washington plant have increased. Johnson & Johnson and McNeil will expend whatever resources are necessary to ensure that this facility provides, once again, high quality medicines.

We also want the public to understand that McNeil had a very detailed testing and quality assurance process even before the recent recall. The quality process included testing by raw material suppliers prior to shipment to McNeil, additional testing of raw materials upon receipt, numerous product testing cycles during production, and testing of final product samples before shipment to the consumer. For example, McNeil tested the levels of active ingredient from the beginning, middle, and end of the production and manufacturing process. These quality tests found the issues referenced in the April 30 press release, but better procedures were appropriate, as the FDA noted. McNeil has committed that it will not restart operations until it has taken the necessary corrective actions and can assure the quality of its products.

McNeil also has detailed processes for assessing and investigating consumer complaints and reports of possible adverse events from its products. McNeil has dedicated drug surveillance and safety groups that maintain detailed assessments of complaints and adverse event reports. Reports of possible serious adverse events, for example, are reported to the FDA quickly. Although the number of complaints and adverse event reports is very small when compared to the millions of liquid medicines produced by McNeil, the company takes each complaint and report seriously and seeks to investigate each one for potential quality improvements.

I would like to address the steps McNeil is now taking to bring its operation back to a level of quality that Johnson & Johnson demands of its companies, and that the public rightly expects of us.

First, even before the most recent recall was announced, McNeil retained an independent third-party expert to assist the Fort Washington facility in identifying immediate, interim, and long-term corrective actions that it needs to take. The third-party expert is a pharmaceutical consulting firm that has expertise in manufacturing and quality systems methodologies and practices.

Second, McNeil is improving processes and employee training in every part of the manufacturing and quality operations, and deploying new procedures and processes for the conduct of quality investigations.

Third, McNeil has also made significant organizational changes in order to augment the quality and operations leadership on the management team and in all McNeil facilities. McNeil appointed a new vice president of quality assurance, appointed a new vice president of operations, appointed a new plant manager at Fort Washington, and hired a new head of quality for the Fort Washington plant.

McNeil and its outside consultant are in the process of developing a comprehensive action plan on quality improvements, which McNeil will share with the FDA by July 15. The basic elements of the plan include the following:

Governance and Management Controls. Governance during the remediation period will include the establishment of a steering committee, which will include members of senior management, charged with guiding and overseeing remediation efforts across McNeil. Each plant will also have a remediation committee that will be responsible for implementing the plan for that plant and monitoring its effectiveness. Achieving long-term improved management control at each site is critical, and will require an evaluation and restructuring where needed of, among other things, the quality control unit, McNeil's development and manufacturing governance processes, and its quality management systems.

Training and Culture of Compliance. McNeil is committed to reinforcing and enhancing the culture of compliance throughout the company. McNeil has already taken actions to set higher expectations of employees and to increase employee focus on identifying underlying causes and finding lasting solutions to issues that arise during daily operations. Further actions to address the culture of compliance under the comprehensive action plan will include strengthened "good manufacturing practices" training program, the development of a leadership training program and enhanced supervisor training, and the establishment of quality goals for all

employees. McNeil also intends to implement measures to improve communications to and among personnel. Employees will be informed of the status of remediation and ongoing efforts on a regular basis through communications that enlist them in facilitating this transformation.

Full Assessment and Improvements. McNeil will conduct a full assessment of the processes, equipment, and facility in Fort Washington, and will assess McNeil's other facilities as part of the plan. McNeil and Johnson & Johnson are fully committed to providing the training, resources and capital investment needed to provide sustainable improvement of quality systems.

Product Assessments. McNeil will conduct in-depth quality assessments for each product McNeil manufactures to ensure each product's ability to meet specifications throughout its shelf life. Product assessments will review, among other things, testing results, stability data, investigation reports, out of specification findings, rejections, and process changes. McNeil will analyze whether additional controls are needed to support the release of products.

Communication with FDA and Interim Actions. McNeil will update the FDA about its progress implementing the plan at least once a month. McNeil also intends to use the support of a third party in making product release decisions during the first six months of operation. Third-party involvement may include review of investigations, complaints, completed batch records, and changes that have the potential to affect products or processes. McNeil is committed to continuing its cooperative and transparent dialogue with FDA.

* * *

Mr. Chairman, I would like to close in the same manner that our company's chairman, Bill Weldon, concluded his letter to the people who use our products: "We will work hard to earn back your confidence."

Chairman TOWNS. Thank you very much for your statement, Ms. Goggins. Before I begin, I want to say that Johnson & Johnson is a family brand, and the American people have come to rely on that for more than 100 years. Until recently, most people would not think twice about giving their child one of your products. In fact, most Americans have at least one or more of your products in their home. But I have become deeply concerned about your company. Information I have seen during the course of your investigation raises questions about the integrity of the company; it paints a picture of a company that is deceptive, dishonest, and has risked the health of many of our children.

As the ranking member, Mr. Issa, said earlier in his opening statement, I hope that you will be forthcoming today about your company. And on that note, let me just go to a couple questions.

Is it true that excess amount of certain active ingredients were found in your children's medicines?

Ms. GOGGINS. Chairman Towns, it is true that lots of the product were produced with excess amounts of the medicines, but these never reached the marketplace. In fact, as I think Ms. Autor said earlier this morning, we produced something like 10 or 11 lots of product; 3 were rejected on that grounds, the other 7 were tested.

And I should say we test all of our finished products extensively; we take samples from the beginning, the middle, and the end of manufacturing, and we make sure they are within specification. They were. We released them to the marketplace. When the FDA raised its concerns, we tested the last batch which we had in our possession. We actually tested 1,200 bottles, and not one of the 1,200 bottles was over the specified amount of active ingredient.

Chairman TOWNS. So was that a yes or no?

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

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

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

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

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

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

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

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

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

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

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

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

Chairman TOWNS. Yes, help me.

Ms. GOGGINS. We had a Motrin product where the dissolution profile, or how it is solubilized, wasn't in specification. It is a small product; it sold primarily in gas stations. We discussed this issue with the San Juan office of the FDA and we agreed or we offered to have a contract force go out and identify how much of this was in the marketplace. The FDA was aware that we were doing that in San Juan and we did that. I can't tell you about the behavior of these contractors in the market or what they said or didn't say or how they acted, but clearly FDA was aware of this and there was no intent, obviously, to mislead or hide anything.

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

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

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

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

Chairman TOWNS. Well, I would like for you to do that for me because——

Ms. GOGGINS. I would be happy to.

Chairman TOWNS [continuing]. I just find this very, very disturbing, the fact that they went in to purchase the products. FDA is saying they had no knowledge of it and, of course——

Ms. GOGGINS. No more disturbing than I do, sir.

Chairman TOWNS. Right. How can this happen in a company of your size and reputation? I mean, how could something like this happen? Your company has had a longstanding reputation.

Ms. GOGGINS. That is a question that we have been asking ourselves, and what I can tell you is that we think it comes down to a number of factors. It comes down to people and leadership and processes. And what I can tell you is that we have made significant changes in the leadership. We have actually changed six key executive positions: we have changed the head of OTC manufacturing; we have changed the head of OTC quality; we have changed the plant at Fort Washington; we have changed the head of quality at Fort Washington; we have changed the head of quality at our Puer-

to Rico plant; we have changed the head of manufacturing; and we have reassigned people at other levels.

Chairman TOWNS. So all of your quality issues have now been solved?

Ms. GOGGINS. Well, I would not say that, sir. What I would say in addition is that we have undertaken a broad assessment of all of our OTC plants; we have engaged a third-party expert to take a look at our plants and help us do this assessment; and we have committed to the FDA that by July 15th we will have a master plan regarding the remediation of all of our plants as necessary.

Chairman TOWNS. Thank you.

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

Mr. ISSA. Thank you, Mr. Chairman.

Since you patiently sat through the first hearing, you are aware of my line of questioning, so I am going to sort of followup, sort of FDA you.

Ms. GOGGINS. Sure.

Mr. ISSA. You told me, in your testimony and in the chairman's questions, you said basically there was no safety issue in relation to the product that got out of the plant, period. Not the product that may have been multiple times its advertised dosage that remained in the plant as defective material, but the product that got out of the plant, as of right now, the science—both at the FDA and you—consider that there was no health risk from that product. Is that correct?

Ms. GOGGINS. Yes. The FDA and Johnson & Johnson and McNeil is aligned that the risk of a serious health event is remote and, to date, there have been no serious health events associated with any of the reasons for the recall.

Mr. ISSA. OK. So the recall was more about failure to live up to your own standards and, therefore, a recall; and, of course, the potential that if you didn't live up to your own standards, something bad could happen. But the actual product being recalled is not dangerous to the consumer.

Ms. GOGGINS. That is correct.

Mr. ISSA. Now, ma'am, you are very good and scientific. If I understood what you said about the Advil product, the gasoline station——

Ms. GOGGINS. Motrin.

Mr. ISSA. Motrin. Wrong brand. The Motrin. What you have is paper two-packs that they sell at gas stations, and if you take these you are not getting much use out of them because they don't dissolve properly. Is that right?

Ms. GOGGINS. That is correct, yes.

Mr. ISSA. So, in plain English, they simply wouldn't cure your headache, but they wouldn't hurt you.

Ms. GOGGINS. It would take longer to cure your headache, yes, but they would not hurt you, no, sir.

Mr. ISSA. OK, so it is not going to hurt you, just not going to be——

Ms. GOGGINS. That is correct.

Mr. ISSA [continuing]. As good as advertised. And you hired a contractor to try to do it and you have said under oath you did inform the FDA, at least at their local level.

Ms. GOGGINS. Yes.

Mr. ISSA. I was a manufacturer for 20 years. Under ISO 9001, if you find a defect, you do two things: you segregate the defects and, of course, you go through a quality analysis to try to keep that from happening again.

Ms. GOGGINS. Right.

Mr. ISSA. In the case of the Fort Washington facility, if that was where these products were produced that were multiple times their normal dosage—or was it Puerto Rico?

Ms. GOGGINS. That was Fort Washington, sir.

Mr. ISSA. Fort Washington. You segregated the product, is that correct?

Ms. GOGGINS. We did.

Mr. ISSA. You destroyed the product.

Ms. GOGGINS. I believe so.

Mr. ISSA. And what steps were taken to prevent this from reoccurring, if you know?

Ms. GOGGINS. Yes. I honestly don't know the answer to that. What I can tell you is that we had a rigorous testing program to ensure that the products were within specification before they hit the marketplace, and we did go back and we took a look at the last lot that we had in our possession, did extensive testing, 1,200 bottles. I can't answer right now that we did or didn't go back to test the root cause.

Mr. ISSA. Now, some months ago we think famously, but we are in Washington, so our image of what is famous may not be, but we had Akio Toyoda sitting where you are sitting. He made commitments to us that he would use dramatic resources, on a scale not seen before, to change his company to be the leader, not the follower, ahead of, not behind in quality. Can you make that same commitment today on behalf of Johnson & Johnson?

Ms. GOGGINS. Yes, I can, and I think I can give you some points that indicate there we are on the road to doing that.

Mr. ISSA. Please.

Ms. GOGGINS. As I mentioned, we have changed a number of key personnel, both in quality and in our manufacturing organization; we have contracted with an outside expert with pharmaceutical experience to help take a look at our plants independently and determine what needs to be done; we have undertaken on our own an assessment of all of our plants across our North American OTC network; we have made some changes already and, I think most importantly, we have committed to the FDA that we will have a comprehensive plan that we will share with them by July 15th.

Mr. ISSA. Excellent answer. I hope you live up to it. I expect, after 100 years of your company's good reputation, that you have a reason to.

Let me followup with sort of a final line. Again, I said I was a manufacturer. I am not bragging or complaining, but before I could sell to General Motors, Ford, Chrysler, and others, I had to pass independent QS and ISO analysis, and they came back in regularly. So in addition to my own quality folks, in addition to the auto

companies and other companies I supplied to over the years, we had ongoing annual and quarterly independent evaluation. Is there a similar situation or is there a similar capability within your industry and do you employ it?

Ms. GOGGINS. I think there are two ways that we can do that, sir. One is that we can employ the corporate quality resources at Johnson & Johnson, and, in fact, we have brought a lot of those to bear in the current situation; and they take an independent look at our processes at McNeil. And the second thing is, as I have mentioned, we have engaged a third-party expert in manufacturing of pharmaceuticals, manufacturing processes and sites, and we have engaged them to help us take a look at our plants comprehensively.

Mr. ISSA. In closing, I would say that public confidence would be increased, and I hope that you will consider a level of transparency of these independent reviews and, if at all possible, that independent review be ongoing for a period of time. I, for one, applauded the FDA for being diligent in this case. As you can imagine, I am much more concerned about the fact that you test your products three times as to potency and what is in it, while in fact the FDA does not test even once products coming in by the container load from countries and facilities they have no ability to test.

So, Mr. Chairman, I hope that as we followup in this process, that latter will be included in our question of is our food and drug safe under the current law if they are importer. And I yield back.

Chairman TOWNS. I thank the gentleman for his questions.

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

Mr. KUCINICH. I would ask the staff to put the first exhibit up.

Ms. Goggins, you have testified that no raw materials that tested positive for objectionable bacteria were ever used in the manufacture of McNeil's pediatric products. Now, an FDA document, which I have a copy of here, states McNeil's lab determined the presence of B. cepacia, an Avosil raw material to be objectionable, placing the target population at risk if the contaminant was in the product. The product is for use in infants and children; however, the firm knowingly proceeded to partially release some of the remaining raw material, Avosil, which was used to manufacture more product.

What is your response?

Ms. GOGGINS. My response is that is untrue. What I would tell you is that——

Mr. KUCINICH. What is untrue, your testimony or this document from the FDA?

Ms. GOGGINS. My testimony is not incorrect, sir. Let me clarify the issue for you. This is one of the issues that has been in the media and is simply incorrect. It is true that we tested one incoming lot of Avosil, which is an inactive ingredient in our children's products. It tested positive for an objectionable bacteria. We rejected it. We test each of our incoming raw materials; we have tested them all extensively. We have never used a product that tests positive for objectionable bacteria in our manufacturing process.

Further, when our products are manufactured, we test them after manufacturing for the presence of harmful bacteria. We have also had preservative systems and other capabilities in our formulas which would, if a bacteria was in our product, preclude the growth of that bacteria.

We also, then, given the FDA's concerns on this issue, went back, retested, retained products of these products in question. None of them tested positive for this bacteria. We then went back and we tested the preservative systems by inoculating them with bacteria, and the preservative systems killed all the bacteria.

So I feel very confident in saying that we did not knowingly use the products of bacteria and we did not release them into the marketplace.

Mr. KUCINICH. Thank you.

Mr. Chairman, this memo also states at the end of an inspection, an FDA 483 was issued for deficiencies, including failure to reject Avosil raw material after learning of B. cepacia contamination of raw material, Avosil, then it gives the lot number.

I submit this for the record.

Chairman TOWNS. Without objection, so ordered.

[The information referred to follows:]

Food and Drug Administration Establishment Inspection Report

.te Assigned: 09/30/2008 Inspection Start Date: 05/19/2009 Inspection End Date: 06/04/2009

Firm Name & Address: McNeil Consumer Healthcare, Div of McNeil-PPC, Inc. , 7050 Camp Hill Road Fort Washington, PA 19034 US

Firm Mailing Address: 7050 Camp Hill Rd, Fort Washington, PA 19034 United States

FEI: 2510184 **JD/TA:** 11 **County:** MONTGOMERY **Est Size:** 50,000,000 - and over

Phone: (215)273-7000 **District:** PHI-DO **Profiled:** Yes

Conveyance Type: **% Interstate:** 50 **Inspectional Responsibility:** Field

Endorsement

This inspection of a human drug manufacturer was conducted in response to FACTS Assignment ID # 976293, Operation ID # 3853339 as part of the PG 9M FY'09 Drug performance goal under Tier 1 high risk inspectional system. This inspection was conducted in accordance with C.P. 7356.002, Drug Manufacturing Inspections. In addition, the DQRS's were covered during this inspection under C.P. 7356.021, Drug Quality Reporting System NDA Field Alert Reporting.

The previous 2/19/08 inspection resulted in the issuance of the Form FDA-483, Inspectional Observations, regarding investigations, complaints, and manufacturing deviations. One verbal discussion item was noted regarding lack of adequate number of employees trained to perform complaint investigations in a timely manner. A Form FDA-483, Inspectional Observations, was issued to the firm and the inspection was classified VAI.

The current inspection covered the quality and laboratory systems.

At the end of inspection, an FDA 483 was issued for deficiencies including: failure to reject Avicel raw material after learning of B. cepacia contamination of raw material Avicel RC-591 lot #DN08819021 (used to manufacture infant/childrens Tylenol), sampling SOPs lacking sample sizes, missing a 36 month stability test point, incomplete complaint investigations and failure to extend an investigation into related Benadryl lots after a content uniformity failure.

Regarding Avicel, McNeil found the pathogen in Avicel during routine incoming testing of a shipment. McNeil's investigation found that the excipient manufacturer had also isolated the same pathogen during manufacture of the same lot of Avicel. McNeil also knew that the excipient manufacturer had a problem with another gram negative (Enterobacteriaceae), the year prior. McNeil's lab determined the presence of B. cepacia in Avicel raw material to be objectionable, placing the target population at risk if the contaminant was in the product. The product is for use in infants and children. However, the firm knowingly proceeded to partially release some of the remaining raw material Avicel from lot # DN08819021 which was used to manufacture more product.

The firm's management promised a written response within 30 days.

No refusals were encountered during this inspection. DOC sample # 536243 was collected to document the interstate movement of Tylenol Infants' Drop Dye Free Cherry Suspension, Lot # SCM083.

F/U: Refer to compliance branch for warning letter consideration regarding use of contaminated raw material even after determining the presence of a gram negative rod.

Distribution: I: + exhibits: PHI DIB, Compliance Branch, District Files

Endorsement Location: FACTS

Inspector Name	Date & Time of Signature	Supervisor Name	Date & Time of Signature
Vlada Matusovsky	06/12/2009 11:17 AM ET	Anne E Johnson	07/01/2009 11:23 AM ET
Vlada Matusovsky	06/12/2009 11:17 AM ET	Anne E Johnson	07/01/2009 11:12 AM ET

Mr. KUCINICH. Staff, put up the second exhibit.

A 6-year-old boy took medication that was manufactured at your plants in Fort Washington and Puerto Rico. He died this year. He tested positive for B. cepacia. I have a report here which is a McNeil Consumer and Specialty Pharmaceuticals in-house document dated May 10, 2010, where they state that the child was taking medications that were manufactured at Las Piedras plant and Fort Washington plant; that you apparently were in touch with the coroner, who mentioned the child was sick from nausea and vomiting, goes on to give other details; say the child's sputum was tested positive for the B. cepacia complex that is the subject of this.

Do you have any knowledge of that?

[The information referred to follows:]

McNeil Consumer & Specialty Pharmaceuticals, 7050 Camp Hill Road, Fort Washington, PA 19034-2299 (215) 273-7000

TO:	FW-FDA Inspection Related Complaint - January 2010	***DATE:***	May 10, 2010
FROM:	Pragnesh Desai	***COPIES:***	
SUBJECT:	Scribe Notes from 1/28/2010		

Scribe Notes
FDA investigators Julianne McCullough (JM) and Jeen Min (JM) arrived at McNeil approximately 11:00 am on Thursday 1/28/2010. They were met by Paul DiPaolo (PD), he checked their credentials, and escorted them conference room M202. Present in the room were Paul DiPaolo, Timothy Bauer, Jerome Hayes, Rob Jerez, Desiree Ralls-Morrison, Ed Kuffner, Paul D'Eramo, and Pragnesh Desai

Investigator McCullough explained that they were here to review the documents related to batches ADM038, AHM384, and AJM403.

Dr. Kuffner (EK) explained that on 1/27/10, a complaint from California was discussed with R. Fernandez (FDA) [redacted] The child was taking medications that were manufactured at the Las Piedras Plant and Fort Washington plant. EK mentioned that he contacted Coroner's office and discussed with Mr. Johnson who was familiar with the case. The Coroner mentioned that the child was sick for Nausea and Vomiting. When admitted to Lomo Linda Hospital, the child had Pneumonia, Thrombocytopenia, and acute renal failure. T[redacted] mentioned that a written request has been filed and forwarded to the Coroner's office. The post-marketing group is following-up on the request. FDA investigator confirmed the request when asked by EK.

Investigators requested the following list of documents:

- All Packaging and Bulk Batch Records for batches related to ADM038, AHM384, and AJM403
- List of Complaints related to affected batches
- QNs related to affected batches
- List of batches manufactured prior and post affected batches
- Retain Samples for 3 affected batches
- Microbiological and Analytical Testing Results
- Records for Raw Materials and APIs used
- Avicel Records
- Full Distribution List for 1st Consignee

Ms. GOGGINS. Yes, I do, sir.

Mr. KUCINICH. And what is your response?

Ms. GOGGINS. My response is the same as Dr. Sharfstein's, sir, in that we take every adverse medical event seriously. We investigated this. We did discuss this with the coroner. The products, as Dr. Sharfstein said this morning, tested negative for the presence of B. cepacia and, in fact, the products that the young child was administered were not in the investigation of the B. cepacia issue.

Mr. KUCINICH. Are you aware that the Food and Drug Administration official also testified that a coroner's report has not yet been returned on that?

Ms. GOGGINS. Yes.

Mr. KUCINICH. No. 3, I would like the third exhibit put up.

Another 6-year-old boy with cystic fibrosis took Tylenol and tested positive for B. cepacia. As I am sure you know, children with cystic fibrosis are particularly susceptible to B. cepacia, according to the CDC. And I also want to submit this to the record without objection, an establishment inspection report, McNeil Consumer Health Division, where it confirms that a 6-year-old child tested positive for a form of B. cepacia, and it says during the inspection another complaint was received by the FDA; no details were given except there was a death of a baby in reference to the use of concentrated Tylenol infants' drops. This goes to the record.

[The information referred to follows:]

on this lot for packaging line 4. A broken stud was replaced. I spoke to (b) (6) Mechanic Liquid, and he explained the stud was never in contact with the product. He stated once the stud broke the packaging line stops automatically because the line will not fill the bottles without this stub. Once the part was replaced, the lines were flushed as according to their SOP and packaging restarted.

OOS Laboratory Investigations Reviewed

I reviewed an OOS for Dextromethorphan which was found to be positive for Test B (a UV test). (Notification # 9052000028). Mr. Bryant explained the case was closed and found it to be a tester error. A second test was performed on the Dextromethorphan and found to be acceptable. No significant observation to report.

Purified Water System

Ms. Meledez-Figuero explained that the firm's Purified Water System is tested weekly for total count and Pseudomonas. She provided water testing results (Exhibit JM23) for dates: 5/4/09, 5/11/09, 7/27/09, 8/3/09, 6/8/09, 6/15/09, 8/31/09 and 9/8/09. My review of these documents was unremarkable in that there were no apparent deficiencies observed.

F/U for Possible Related Complaints

Ms. Shur and Mr. Kuffner, explained that complaints are trended on a quarterly basis in response to the previous 483 issued in June 2009. The firm provided a list of complaints from the First Quarter (Exhibit JM24) and Second Quarter (Exhibit JM25). During the First Quarter, the firm received 8 complaints. In the Second Quarter, the firm received more than 480 complaints. Ms. Shur pointed out, prior to the recall of the Tylenol, the firm only received 18 complaints. Most of the complaints were received after the recall notice was sent. Of the complaints, there was only one that had any reference to Burkholderia Cepacia, Case # (b) (6) (Exhibit JM26). Mr. Kuffner explained the complaint is unconfirmed and currently open. It was received by the firm on 9/25/09. The patient is a 6 year old child with [redacted] They have tried to contact the Health Care Provider but have not received a response. A letter was sent on 12/18/09 in attempts to contact the HCP and a phone attempt was made on 2/1/10 with no response.

During the inspection another complaint was received by the FDA. No details were given except for there was a death of a baby in reference to the use of Concentrated Tylenol Infant's Drops, lot # AEM103. I reviewed their records for lot # AEM103 and no complaints were received by the firm in reference to this lot.

End Investigator Min.

Mr. KUCINICH. Ms. Goggins, can you tell the American people what they should think when they learn that the FDA found that McNeil knowingly let contaminated raw material into children's medicine and that a contaminant was found in at least two children, one of whom died?

Ms. GOGGINS. As I said, Congressman, we have never used contaminated raw materials in the manufacturing of McNeil pediatric products.

Mr. KUCINICH. Mr. Chairman, that is at variance with the document that we got from the FDA, and I think the committee ought to take further note of that. Thank you.

Chairman TOWNS. Thank you very much. I would like to thank the gentleman for his questions and, of course, we have not made a decision as to what we are going to do from this point on.

I now yield to the gentleman from Maryland, Mr. Cummings.

Mr. CUMMINGS. Mr. Chairman, I would yield to the gentlelady from Washington.

Chairman TOWNS. The gentlelady from Washington, DC, Ms. Norton, is recognized for 5 minutes.

Ms. NORTON. I thank the gentleman for yielding.

I am concerned, Ms. Goggins, about the delay here. I can understand that there could be difficulties in manufacturing, but I believe you need to clarify for the public why a delay doesn't give the appearance of coverup. The FDA, as you know, found, and I am using their words now, that your investigation, or McNeil's investigation was unjustifiably delayed and terminated prematurely.

Now, that is what concerns me, because, apparently, the complaints began with an uncharacteristic bad odor. I can see, given the symptoms that were reported, and we understand those to be nausea and vomiting and diarrhea. When you are talking about children, I can tell you, as somebody who had kids, they all do that anyway. I can understand your thinking that could have had any number of causes. What I don't understand is why any manufacturer hearing, if you will forgive me, that its product stunk wouldn't immediately see that as a justification for investigation. Yet, I understand it took 100 complaints and that you did not discover the contamination until September 2009, although this bad odor began in April 2008.

Why did it take you so long, particularly given the bad odor, which seems to me should have been enough, to find what the root cause of this contamination?

Ms. GOGGINS. Yes. You are referring to the recall that we executed between November and January regarding the contamination by products with TBA. We did receive a number of complaints regarding these products. They were manufactured in our Las Piedras, Puerto Rico facility. The complaints were characterized by the consumers as a moldy and musty odor. We did engage in an investigation of microbiology, because when we get a complaint of musty/moldy, we assume that it is a micro issue. There was no evidence of any kind of a micro issue.

For 6 months we then received no complaints whatsoever, and we thought the issue had gone away. And then in April, I believe, of 2009, the complaints came back, and that is when we realized that we needed to deepen our investigation.

What I guess I would say about this is that this is a very unusual compound; it is not well characterized, it is not well known, it is has not been found in the industry——

Ms. NORTON. Well, did it ever have a bad odor before? Is it that unusual?

Ms. GOGGINS. Not due to this contaminant, ma'am, no. This is a first.

So if I can just continue, please.

Ms. NORTON. Yes.

Ms. GOGGINS. So we found that there was only one lab in the country that we were able to locate that could identify what this was, and there were only two experts in the world that we would identify, one in California and one in France, to characterize this. We finally found what the product was. When we did, in January, we recalled quite an extensive amount of product, about 565 lots of product; and I think we did it out of an abundance of caution. I would add that there has been no adverse medical events due to the trace levels of this contaminant.

Ms. NORTON. Yes, after the fact we are grateful. But, of course, the FDA's concern was in the delay here. We don't know what this might have done had it been something more serious, particularly since the regulations require drug manufacturers to submit field reports within 3 days of receipt of information of bacteria contamination of some kind or, for that matter, of any change or deterioration in a drug product. Apparently, McNeil began receiving complaints in 2008, but you did not follow this 3-day requirement and did not alert the FDA. Why didn't you share this information immediately with the FDA? Indeed, after you had results confirming contamination, you didn't share those results immediately with the FDA.

Ms. GOGGINS. You know, I must say I am sorry, I am not certain of the chronology of these events, but what I can tell you is that——

Ms. NORTON. You began receiving consumer complaints in 2008. And this is why FDA found unjustifiable delay and termination prematurely: you began receiving them in 2008; the regulations require you to report within 3 days of receipt of any information regarding bacterial contamination. Did you believe that you had to have that confirmed in some kind of way before you alerted FDA?

Ms. GOGGINS. I can't tell you when we did or did not alert FDA. What I can tell you is that we did undertake a micro investigation of it, and it was found not to have any micro contamination. Other than that, I can't tell you about the chronology.

Ms. NORTON. Again, I want you to know, Ms. Goggins, the concern here from the point of the consumer——

Ms. GOGGINS. I understand.

Ms. NORTON [continuing]. Is delay. Transparency helps a great deal to ward off the notion of coverup. When FDA finds unjustifiable delay and premature termination of complaints, you say, yes, but we essentially waited to see if it would come back; and when it came back we decided to do it again. That is very troubling.

It seems to me, once you have 100 complaints about a bad odor in something you are selling to the public, you ought to want to tell the FDA immediately and you ought to want to do something very

quickly. It didn't happen very quickly if we are going from April 2008 to September 2009.

Thank you, Mr. Chairman.

Chairman TOWNS. I thank the gentlewoman from Washington, DC.

I now yield 5 minutes to the gentleman from Maryland, Mr. Cummings.

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

Ms. Goggins, tell me, when did you learn that there were serious problems at McNeil? When did you first learn that?

Ms. GOGGINS. I think we became aware, sir, that there were quality issues probably in the first half of 2009.

Mr. CUMMINGS. OK. And, according to our investigation, you all had a major shakeup of McNeil management. I think you have already testified to that, is that correct?

Ms. GOGGINS. We did replace a number of key quality and manufacturing individuals, yes, sir.

Mr. CUMMINGS. And can you tell me what went into that decision? First of all, who made the decision?

Ms. GOGGINS. I was part of that decision, sir, and there were other people who were involved as well. But I was part of that decision.

Mr. CUMMINGS. And why did you make that? What was that decision? How did you come to the conclusion that you had to shake up the management?

Ms. GOGGINS. I think the fact that we were not happy with our quality processes based on some of the things that we saw both in terms of recalls and in terms of some of the FDA observations that we got in a Form 483. And I think we were also concerned about some of the issues that have been raised here today.

Mr. CUMMINGS. When Dr. Sharfstein was testifying, I was trying to get a clarification. You know, it is one thing if you go to McDonald's and you get a sandwich and it has a worm in it, God forbid, and then McDonald's says, you know, what? It is no big deal; it can't do you any harm. That is one standard. But the standard is there should never have been a worm in the sandwich.

I know that is a little extreme for those people who haven't eaten their lunch, but what I am saying to you is that I am wondering if there is a different standard. First of all, it sounds like McNeil didn't even adhere to its own standard, let alone FDA's. Would you agree?

Ms. GOGGINS. I would say, sir, that we have a very high standard, because I think consumers expect a lot of us, and I think we did not adhere to that high standard on the quality standpoint. That is why we enacted this broad recall.

Mr. CUMMINGS. Can we put a pin in that right now? Where you are right there. And should consumers expect the high standard?

Ms. GOGGINS. They should, sir, and our intention is to remediate our plants to the highest possible standards.

Mr. CUMMINGS. Now, Ms. Goggins, can Johnson & Johnson tell the American people today with complete certainty that no children who took these recalled medicines were harmed by them?

Ms. GOGGINS. What I can do is reiterate what Dr. Sharfstein said this morning, that we believe that the risk of a serious medical

event is remote and there have been no serious medical events associated with the reasons for the recall of these products.

Mr. CUMMINGS. Now, you said that you all had some concerns and you heard Dr. Sharfstein's testimony; it sounds like he had some concerns with regard to the way things were going along. It is one thing if it is one incidence, but there is another thing when there appears to be a pattern of these things. Is that one of the things that concerns you?

Ms. GOGGINS. I think the number more than the pattern, sir. There were a different number of plants and different number of products and different number of medicines involved and different number of issues. But the number concerned me, yes.

Mr. CUMMINGS. And what were the top three issues that went into your decision to bring in new management? Just curious.

Ms. GOGGINS. Well, as I said, I think that the——

Mr. CUMMINGS. Give me the top three.

Ms. GOGGINS. Top three?

Mr. CUMMINGS. So the public can hear what went on when you all decided to make this change, so that hopefully they can have some confidence when they buy these products.

Ms. GOGGINS. I think it was the number of quality issues we had, the quality issues themselves, and the fact that the FDA had made observations that we were disappointed in.

Mr. CUMMINGS. Now, would you agree that government has a role in making sure that products that end up in the medicine cabinets of the public are safe?

Ms. GOGGINS. I would. Like most Americans, I have a great deal of respect for the FDA. I think they have an important mission, an important operation, and they have been very professional in their dealings with us, so, yes, I agree with you.

Mr. CUMMINGS. Now, a little bit earlier there was a statement by one of the witnesses from the FDA that this matter had been referred for possible criminal prosecution. Did you hear that?

Ms. GOGGINS. I did, yes.

Mr. CUMMINGS. And are you concerned about that?

Ms. GOGGINS. Sir, my major concern right now is remediating our plants to the highest possible level of quality and getting products back on the marketplace for the consumers who need them.

Mr. CUMMINGS. And the Fort Washington plant, that is basically closed down right now?

Ms. GOGGINS. It is closed down right now, yes.

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

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

Mr. CUMMINGS. Thank you very much.

Thank you, Mr. Chairman.

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

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

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

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

Ms. GOGGINS. I can't answer that, sir, nor can I answer the question of what they are alleged to have said. I don't know the answers to that.

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

Ms. GOGGINS. As do I.

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

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

Chairman TOWNS. Were they instructed to do certain things?

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

Chairman TOWNS. The quality control, do you have the same amount of people in the quality control unit today as you had 4 years ago or 3 years ago or 8 years ago? What is the situation with quality control?

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

Chairman TOWNS. This document, that was actually just brought to my attention, says this: 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. It is a demonstration project and we want to purchase some for the demonstration project.

Is this accurate?

Ms. GOGGINS. As I said, sir, I have no idea. What I can tell you is that I have no idea of whether or not that is true or not, and I also have no idea of the context, sir. I have no idea. All I know is that we did hire a third-party contractor, and I do know that we did it with discussions with the FDA and they were aware of it.

Chairman TOWNS. Well, let me put it this way. If this is true, does it bother you?

Ms. GOGGINS. Again, I don't know the context, sir. I don't know the context. I would have to understand the context. I don't believe there was any intent to mislead or hide anything, so I don't know the answer to that. So I can't answer that.

Chairman TOWNS. I am really trying to finish this, but, I tell you, there are some unanswered questions here that are very troubling.

On that note, I yield to the ranking member, Congressman Issa.

Mr. ISSA. Thank you, Mr. Chairman. First of all, I would like to ask unanimous consent that all Members have 5 legislative days in which to ask additional questions, supplement or provide information.

Chairman TOWNS. Without objection, so ordered.

Mr. ISSA. Thank you.

This email I think speaks for itself. What we don't have here is we don't have the individuals behind that. Can I ask that you use your authority to investigate the email, we will certainly give you a copy if you don't have it, and get back to us in detail with either the individual and statements that they would make for us subject to our interrogatories, if we choose, and at least their side of the story? Because on the face of it all, I look at this and it appears as though people acting on your behalf, working for one of your subsidiaries, did ask for this information, and we would appreciate knowing for sure the individuals, assuming they are still working with you. If they are not, then provide us the information and we will contact them directly.

My understanding from our investigators is that there was a cutback, not on your watch, but at this facility, in 2006, a reshuffling of where quality personnel were located. Do you know anything about that?

Ms. GOGGINS. No, I do not. What I can tell you is what I referenced earlier, that in fact the headcount is flat from 2006 until now, and, in fact, spending was up 17 percent from 2006 to 2009 and is up again this year.

Mr. ISSA. OK. I guess there were a lot of questions about deaths of I hear a number as high as 37. To date, are you involved in any litigation in which you are the defendant, where someone is alleging that your products, those 37, if you will, your Tylenol series products have led to the death or severe injury of some child?

Ms. GOGGINS. Not to my knowledge. But let me just say that I would not necessarily know that, and I would ask you if we could get back to you after we talk to our legal group.

Mr. ISSA. I would appreciate if you would respond in writing.

I guess, last, you use imported products like all companies at times, is that correct?

Ms. GOGGINS. I believe we do, yes.

Mr. ISSA. My understanding is the source of the smelly pallets could well have been imported wood. Is that correct? Or at least not mainland United States.

Ms. GOGGINS. We believe that our supplier of packaging components did use wood from Latin America that was treated with this ingredient, yes.

Mr. ISSA. OK, so I just want you to run us through. I have dealt with import and production from all over the world and in other parts of the world. What did you do after this extensive research, finding only two people in the world that could do it, but you got to the fact that you had a problem? What did you do relative to the vendor for the future? In other words, what corrective action was in your quality loop relative to not having this happen again?

Ms. GOGGINS. One thing, the main thing we did, sir, was not just for the McNeil organization, but for Johnson & Johnson in total,

we mandated that we would only use material that came in on heat-treated wooden pallets, which precludes the use of this fungicide, or plastic pallets, where you don't use it at all.

Mr. ISSA. And I guess last, presently the Federal Government has had a series of problems here in the United States, more of them related to the vitamin industry of imported vitamins from outside the United States, but some related to non-prescription drugs. If you were sourcing vitamins, ingestible products, non-prescription drugs from completely outside of your own production, outside of the United States and outside of factories you control, how often would you test them and how often would you visit the facilities, and what level of transparency would you require in order to bring that product to the American people?

Ms. GOGGINS. You know, what I can do is perhaps draw an analogy to what we do now with raw materials; and I imagine our standards would be exactly the same. We require all of our suppliers to give us a certificate saying that they have tested the product and it meets the specification that is required from them. That being said, when the products arrive at our own facilities, we retest them for identity, for potency, for microbial contamination. Then, when we use them in the final goods, we do test them again.

Mr. ISSA. I would appreciate that. Although we don't make it a practice to look at any one private company when we write legislation, this committee is very interested in the question of drug and food safety, and as imports increase, both raw materials that you may be checking, but finished product that come in from overseas complete in the container, it became apparent in the earlier FDA portion that it is not tested to that level; that the inspection of your facilities seven times in 5 years does not occur in an aspirin factory in China.

So I would appreciate the input you could give as we begin looking at how we should instruct the FDA and other agencies to inspect similar products coming in from around the world where we have no such luxury as to send inspectors seen times in 5 years.

Ms. GOGGINS. We would be happy to provide that.

Mr. ISSA. Thank you.

Thank you, Mr. Chairman. I yield back.

Chairman TOWNS. The gentleman from Maryland is recognized for 5 minutes.

Mr. CUMMINGS. Thank you very much, Mr. Chairman. I won't even take 5 minutes.

I understand that you are basically retraining folks. Is that retraining completed or is that ongoing?

Ms. GOGGINS. No, it is ongoing. We have already started to undertake training programs.

Mr. CUMMINGS. And what kind of things are you emphasizing in this retraining?

Ms. GOGGINS. We are emphasizing a commitment to quality; we are emphasizing adherence to good manufacturing practices and a number of other things. I would say that our program definition isn't complete yet, and one of the things we are doing with the third-party experts we have hired, the independent experts, is we are putting together a comprehensive plan which we will share with the FDA on July 15th.

Mr. CUMMINGS. Now, I am chairman of the committee on the Coast Guard, and one of the things that they do in the Coast Guard is whenever they have a problem, they take that problem and they use it as a learning tool. Is that part of this process?

Ms. GOGGINS. It could well be, sir. It is a good idea.

Mr. CUMMINGS. Yes, it is helpful that way, because I noticed that you ended your testimony saying that you all wanted to make sure you earned the trust of the public. It seems to me that if there is a training process, that in order for it to be effective, not only effective with regard to changes within the corporation, but also effective with regard to the public having confidence, it seems as if you would have to almost certainly show these new folks or the old folks, whoever is there, whoever you are training, what has happened and how those things should not happen again. So I would make that very, very strong suggestion.

I just want to go back. I tell you, I am curious. I wish I could have been a fly in the room when you fired all these people. How many people did you all fire?

Ms. GOGGINS. You know, I can't give you the exact number of people who are no longer in their positions.

Mr. CUMMINGS. But you were there, weren't you?

Ms. GOGGINS. I was not there, no, sir.

Mr. CUMMINGS. Oh, I thought you just told me you were in the meeting.

Ms. GOGGINS. No, no. I was involved in the decision to fire these people, I was not there myself.

Mr. CUMMINGS. Oh. Oh. So you weren't in the room; you helped to give the order.

Ms. GOGGINS. I was part of the discussion, yes, sir.

Mr. CUMMINGS. OK. All right. I am sorry. But were a number of people dismissed?

Ms. GOGGINS. Yes. We have a number of new people in the most senior positions in both our quality and our manufacturing organizations.

Mr. CUMMINGS. And do you know whether a lot of these people are from in-house or a lot of them outside?

Ms. GOGGINS. No, they were all our employees, sir.

Mr. CUMMINGS. They were already employees?

Ms. GOGGINS. They were all our employees.

Mr. CUMMINGS. Is that your normal procedure, when you have a problem, you bring people from within, not anybody from outside?

Ms. GOGGINS. No, we do both. We hire people both inside and outside in different jobs, depending on the qualifications. Then we also bring fresh pairs of eyes in, as we have done in this case, with an independent third-party consultant.

Mr. CUMMINGS. Just one last thing. I asked you about the Fort Washington plant. What are you all doing now to try to reopen it? In other words, what is the process there? First of all, you plan to reopen it, do you not?

Ms. GOGGINS. We do plan to reopen it, yes, sir.

Mr. CUMMINGS. OK. And what is the process there?

Ms. GOGGINS. The process right now, I guess there are two major prongs to the process. One is we are undertaking a massive assessment ourselves of not only the Fort Washington plant, but all the

other plants in our OTC network in North America; and the second is we have brought in this third-party expert who has a lot of pharmaceutical experience to help independently tell us what we should do. Our plan is to combine those two assessments and discuss the master plan for remediation with the FDA by July 15th.

Mr. CUMMINGS. And the last thing, when you all were meeting and firing these people, making the decision to fire them, I take it that this was embarrassing, this is an embarrassing episode to you all, is it not?

Ms. GOGGINS. The entire episode is extremely embarrassing to Johnson & Johnson. We take our commitment to our consumers and quality and safety very seriously, and all of the people of Johnson & Johnson and McNeil are deeply troubled by what has been found and we are all deeply committed to remediating it.

Mr. CUMMINGS. Well, I look forward to seeing the results of your efforts to remediate.

With that, Mr. Chairman, I yield back.

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

Ms. Goggins, and let me just say FDA, what we have heard today is not too reassuring or comforting.

The initial story was bad enough: On April 30th, Johnson & Johnson announced the largest recall of children's medicine in history. But it turns out there wasn't just one recall. What we have heard about today is rolling recalls, a phantom recall, a plant shut down, and management firings.

I think there are still unanswered questions.

J&J told the committee staff that this most recent recall involved only 6 million bottles. That is what they told staff. That's a huge number. But today we learned from the FDA that it was almost 20 times that, namely, 136 million bottles.

J&J testified that there was no attempt to hide anything. But we uncovered a J&J document showing that they told their contractor not to say this is a recall, just buy up everything.

J&J says that none of its contaminated products has had any adverse health effects. But the FDA testified today that the issue of whether any of these products caused deaths is still being investigated.

This is an issue of trust. When parents and grandparents give these medicines to their children, they want to be confident that they are not harmful. Johnson & Johnson has the duty to ensure their safety and the FDA has the duty to enforce that duty.

One thing we know now is that the FDA needs mandatory recall authority. They should not have to persuade a company to recall suspect products. I intend to introduce legislation, Mr. Ranking Member, to give FDA that authority, and I hope you will join me. FDA should also have the power to order a halt in drug production.

At this point, there are still many unanswered questions. We intend to look further. We will hold the record open to get additional information and to have some of the questions that we raised answered and then, based on that, we will make a decision as to what we will do from this point on.

On that point, I yield to the ranking member.

Mr. ISSA. Thank you, Mr. Chairman. I won't have a closing statement. I would just join with you in offering to work on bipartisan legislation to provide FDA additional tools, including mandatory recall capability.

I yield back.

Chairman TOWNS. I thank the gentleman for his statement and his willingness to work along with me.

On that note, the committee now is adjourned.

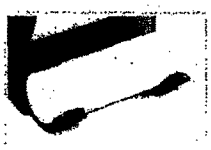
[Whereupon, at 1:57 p.m., the committee was adjourned.]

[Additional information submitted for the hearing record follows:]

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.

[redacted]



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.

May 1, 2010

For Healthcare Professionals and Poison Center Staff Only
Not Intended for Distribution to Patients/Consumers

Some Infants' TYLENOL® recalled products may potentially contain more acetaminophen than is specified on the label. Internal testing of some bottles in certain lots, that were not released to the marketplace, were noted to contain up to 24% more of the active ingredient. We believe it's unlikely that a higher concentration reached the marketplace. Testing of the released batches was within specification but we cannot confirm that all the individual bottles were within specification or that 24% would have been the maximum. While the potential for serious medical events is remote, as a precautionary measure, parents and caregivers should not administer these products to their children.

If you have any questions please call our Medical Affairs Department at 1-866-948-6883 (available Monday-Friday 8 a.m. to 8 p.m. Eastern Time).

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

United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 05/11/2010

COMPLAINT # [redacted]

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
01/27/2010	LOS-DO	PHI-DO	Telephone	Local	Kokiatkulkij,Jinnie	Closed

Complainant Identification

Name	Address
[redacted]	[redacted]5

Phone (W)	Phone (H)	Source POC Name	Source Phone
[redacted]	[redacted]	[redacted]	[redacted]

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 1/27/10, [redacted] Coroner's Office (Deputy Coroner [redacted] called the ONT-RP to report the death of a 1 1/2 y/o female on [redacted] that is suspect to be related to a Tylenol product, "Tylenol Concentrated Infant Drops," Lot # AEM103, purchased during a trip to Idaho btwn 01/13-19/10. The product was purchased from a chain store in Gooding, Idaho. The child had a runny nose & cough for five days prior to going to Idaho. Symptoms appeared less intense upon arrival at home on the 19th. On Wednesday, 1/20/2010, a low grade fever developed & vomiting. Child took a nap & ate toast, drank fluids. On 1/21/10, the child was vomiting and had a low grade fever. By Friday the parents felt the child was still ill because she was clingly. On [redacted] the child was vomiting producing only bile. Parents could not reach their pediatrician and child was taken to [redacted] where the child was diagnosed w/ a viral infection. On [redacted] the child did not have a temperature but was still vomiting, and appeared lethargic and clingly. Severe vomiting at 7:30 PM. Parent took the child to the [redacted] Medical Center. Child was dry heaving. I.V. fluids were administered. The child was received at the ER w/ high heart rate, normal temperature and no urine output. After treatment, the child was released to the parents at 3:00am. The child was sleeping between the parents to keep a closer watch on the child. At 5:30am the child was breathing. At 7:30am the childe was found on her side, there were no obstructions and the child was unresponsive. [redacted] commented the parents indicated the child also received a flu shot. [redacted]s stated Dr [redacted] said there was no medical history, she was a C-section baby with no complications, normal. 2/3 of the medication was said to be remaining. [redacted] Health Dept will test blood culture for B. cepacia.	Death	1/26/2010	

Complaint # [redacted]

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	01/27/2010	Yes	Unknown	Yes		Yes

Remarks
Parents of decedent contact info [redacted]

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in body temperature	CARDIOVASCULAR			
Coughing	RESPIRATORY			
Vomiting	GASTROINTESTINAL	Days		

Health Care Professional

Provider Name	Address	Phone	Occupation
[redacted]	[redacted]		

Hospital Informatio

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
[redacted]	[redacted]		

Product and Labeling

Brand Name	Product Name	Product Cod	Product Description	PAC	UPC Code
Tylenol	Tylenol Concentrated Infant Drops	60LAY01	Acetaminophen (Analgesic);Human - Non/Rx Single Ingredient;NEC	56R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
	AEM103			Yes	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No		

Retail

Name	Address
Ridley's Family Market	1427 Main St. (208) 934-4032(need to verify) Gooding ID

Problem Ingredient Group

Complaint # (b) (6)

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
2510184	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc. 7050 Camp Hill Road Fort Washington Pennsylvania United States 19034	PHI-DO	Own Label Distributor

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Death	On 1/26/10

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Immediate Follow-Up	Kokiatkulkij,Jinnie	01/27/2010

Initial Disposition Remarks

Verify manufacturer, conduct obtain medical records, interview decedent's parents if possible.

Referrals

Org Name	HHS Mail Code

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

Complaint #[redacted]

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
4616319	13	1142170	LOS-DO	LOS-IB-JLS			Canceled	05/06/2010
4626715	12	1144718	PHI-DO	PHI-GRP-05			Completed	03/17/2010
4616094	31	1142657	LOS-DO	LOS-IB-KJ	383652		Completed	03/05/2010
4627131	13	1142170	LOS-DO	LOS-IB-KJ			Completed	03/01/2010
4615410	12	1142430	PHI-DO	PHI-GRP-01			Completed	05/05/2010

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	2510184	7050 Camp Hill Road Fort Washington Pennsylvania United States 19034	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc.	Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
No Action Indicated	Campbell,Karyn M	05/07/2010

Disposition Remarks

Samples and inspection were classified NAI.

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

This is an accurate reproduction of the original electronic record as of 05/10/2010

COMPLAINT # [redacted]

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
11/18/2009	DET-DO	DET-DO	Telephone	Consumer	Richey,Linda R	Awaiting Follow Up Disposition

Complainant Identification

Name	Address
[redacted]	[redacted]

Phone (W)	Phone (H)	Source POC Name	Source Phone
	[redacted]		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Consumer gave her 1 week old infant girl Concentrated Tylenol Infant Drops, (grape flavor 1 ounce bottle). Baby was born [redacted] and had jaundice. Upon leaving hospital, personnel informed mother that she could give the Tylenol to the baby for discomfort and vomiting. Mother gave it to her three times in 5 days. Baby became ill, with symptoms of vomiting, crying, and took her to doctors. Doctor thought it was formula but then sent infant to [redacted] on same day [redacted]. At [redacted] infant was seen and drew blood and did urinalysis. Spinal fluid revealed large amount of white blood cells and they did additional tests to confirm meningitis and could not figure out source of meningitis. Infant was hospitalized for 1 week. Infant had pic line (I.V.) for three additional weeks for the meningitis. Infant is fine but has vomited occasionally. Baby was first breastfed but when baby got jaundice breast milk was fed, then formula so baby got alternate feedings. Infant was first on Enfamil, changed to Similac Advanced Early Shield, then Nutramigen and is now on Enfamil A.R.	Life Threatening Injury/Illness	08/19/2009	Other - identify in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	11/18/2009	Yes	Yes	Yes	Reported to Manufacturer	Yes

Remarks

Meningitis. Mother contacted mfr of Tylenol and was informed that the tylenol had bacteria in it, and could cause meningitis and sent a refund check for tylenol. Lot # has been rubbed off of bottle so unable to determine is this lot was under recall. Incident report with Tylenol #(b) (6) [redacted].

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Vomiting	GASTROINTESTINAL			

Complaint # b) (6)

Health Care Professional

Provider Name	Address	Phone	Occupation
b) (6)			Pediatrician

Hospital Informatio

Hospital Name	Address	Phone	Dates of Stay
b) (6)			b) (6)

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date
b) (6)			b) (6)

Product and Labeling

Brand Name	Product Name	Product Cod	Product Description	PAC	UPC Code
Tylenol	Infant grape flavored	60LAY01	Acetaminophen (Analgesic);Human - Non/Rx Single Ingredient;NEC	41R801	7843738

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
1 Fluid ounces Bottle	SJM089	07/10	8/12/09	Yes	3 times

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
		all	No		1/4 of bottle left

Retail

Problem Ingredient Group

Name	Address
Walmart	100 Sycamore Estates Drive Aurora IN 47001

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
2510184	McNeil Consumer Healthcare, Div of McNeil-PPC, Inc. 7050 Camp Hill Road Fort Washington Pennsylvania United States 19034	PHI-DO	Manufacturer

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	meningitis

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Immediate Follow-Up	Richey,Linda R	11/23/2009

Initial Disposition Remarks

Follow up performed by CIN-DO. Samples in Compliance;

Complaint # [redacted]

Referrals

Org Name	HHS Mail Code

There are no Cosmetics details for this Complaint.

Complaint #

ADVERSE EVENT DETAILS	Product Name Infant grape flavored	Product Code 60LAY01

Birth Date	Age	Gender	Race	Previous Adv Effects of Product?
08/09/2009		Female	Question Not Asked	N/A

Consumption Site	Recommended Dosage/Serving Size	Label Indications for Use
Home	0.4 ml	

Recommended Duration of Use	Product Label Available?	Sample Available?
every 4 hrs 5x max in 24 hrs	Yes	No

Product Ingredients

Duration of Product Used	Frequency of Product Used	How was Product Taken?
First Use	Other	by mouth

Remarks

Symptoms Occurence

Did event abate after stopping use of product?	Did symptoms recur after product reintroduction?	Did symptoms recur after using products with same ingredients?
Yes	N/A	N/A

Did adverse event result in Congenital Anomaly?	Did adverse event require intervention to prevent permanent impairment / damage?
N/A	Yes

Medications / Other Products Used

Medical Test Performed	Results
blood and urinary	

Medical History

Preexisting Conditions	Treatment	Remarks
Measles		

Medical Diagnosis	Medical Treatment
meningitis	

Complaint #[redacted]

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date
4523309	31	1123989	CIN-DO	CIN-GRP-E	585506		Completed	01/05/2010
4511926	13	1123989	CIN-DO	CIN-GRP-E			Completed	01/11/2010
4523309	31	1123989	CIN-DO	CIN-GRP-E	585506		Completed	01/05/2010

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

EDOLPHUS TOWNS, NEW YORK,
CHAIRMAN

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CAROLYN B. MALONEY, NEW YORK
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WM. LACY CLAY, MISSOURI
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STEPHEN F. LYNCH, MASSACHUSETTS
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ONE HUNDRED ELEVENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM
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WITNESS LIST

COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM

Hearing on "Johnson & Johnson's Recall of Children's Tylenol and other Children's Medicines"

Thursday, May 27, 2010

PANEL I

- **Dr. Joshua M. Sharfstein**
  Principal Deputy Commissioner
  Food and Drug Administration

  Accompanied by:

  Ms. Deborah M. Autor
  Director of the Office of Compliance
  Center for Drug Evaluation and Research
  Food and Drug Administration

  Mr. Michael A. Chappell
  Acting Associate Commissioner for Regulatory Affairs
  Food and Drug Administration

PANEL II

- **Ms. Colleen Goggins**
  Worldwide Chairman, Consumer Group
  Johnson & Johnson

○