HEALTH & HUMAN SERVICES

Moderator: Marc Smolonksy
January 15, 2010
12:30 pm CT

Coordinator: Welcome everyone and thank you so much for standing by. At this time all participants are in a listen only mode. During the question and answer session please press star 1 on your phone.

Today's conference is being recorded, if you have any objections you may disconnect at this time and when you do go to questions please introduce yourself by name and organization.

Now I'll turn the meeting over to Marc Smolonsky you may begin.

Marc Smolonsky: Thank you everyone, thank you for participating in the call. I'm Marc Smolonsky, I'm the Associate Deputy Secretary of the Department of Health and Human Services.

I'm joined here with other officials from the department including FDA's Principle Deputy Commissioner Josh Sharfstein, Jesse Goodman, the Acting Chief Scientist of FDA.

Also with us is Linda Birnbaum, the Director of the National Institute of Environmental Health Sciences at the NIH and Robin Ikeda who is the Acting Deputy Director for Non-Communicable Disease, Environmental Health and Injury Prevention from the CDC.

We've asked you to join this call today to talk about the administration's work on health risks, environmental health risks that disproportionably affect children and specifically we want to talk to you about bisphenol-A or BPA.

BPA as you know is a chemical that's been used for more than 40 years in the manufacturing of many products containing hard plastics and epoxy resins including baby bottles and hard plastic sip cups used by infants.

It's also used to produce the lining of metal cans, for example cans of liquid infant formula and trace amounts of BPA has been detected in the food of these containers.

Now under the previous administration the Food and Drug Administration conducted a review of BPA toxicology research and determined at that time that food related products containing BPA were safe.

But thanks to new technology and advances in science we now have new research findings about BPA that shows subtle effects of low doses of BPA in laboratory animals, and this has raised new concerns.

At this time I want to be clear that BPA has not been proven to harm either children or adults. However especially given that children in the early stages of development are exposed to BPA, the data and the new research deserves a closer look.

In fact we need more research to understand the potential health effects of BPA exposure to children. It's one of the reasons the president has asked HHS along with other federal agencies to pull together an inter-agency task force on children's environmental health.

Our role will be to use the expertise we have to drill down on a range of key environmental health questions affecting children, especially questions about BPA.

At HHS through the NIH, the FDA and the CDC, we are investing in important new health studies in both animals and humans to determine the potential health affects of BPA.

And this includes an investment of $30 million funded by the American Recovery and Reinvestment Act supporting research at NIH.

Dr. Sharfstein and Dr. Birnbaum and others are here with me to go over the details of this new research as well as some of the specific work being done by FDA and NIH.

In the meantime while we gather more data, there are simple reasonable steps that we are recommending families and parents can take to minimize exposure to BPA and these recommendations are now on our Website at hhs.gov.

I'll go over just a few of them. Number one, we're recommending that parents follow the recommended guidelines to feed your infant.

The guidelines of the American Academy of Pediatrics which recommend breastfeeding infants for at least 12 months whenever possible since this is the optimal source of nutrition for babies.

But if breast feeding is not an option iron fortified infant formula is the safest and most nutritious alternative. As I mentioned there are small amounts of BPA that have been detected in canned liquid infant formula.

But if canned infant formula is iron fortified it remains nutritious for formula fed babies and good nutrition outweighs at this time the potential risk of BPA exposure.

Parents should not be making any significant changes to a baby's diet without talking to their doctor first. Number two we're recommending that parents throw away scratched baby bottles and cups.

These baby bottles and cups that have scratches may have germs in the indentations that may be contaminated with BPA or may release small amounts of BPA.

We're recommending to pay attention to temperature, the temperature matters. Don't put boiling water or very hot infant formula or other liquids into BPA containing bottles because additional traces of BPA can transfer from the container to the food.

We're also recommending that parents check the labels on the bottles and other containers to see if they're microwave and dishwasher safe. A more complete list if the recommendations as I mentioned is on our Website.

And it includes a list of major manufacturers of baby bottles and cups that have not made BPA containing products since early January 2009.

Again I want to thank you for joining us, I'm now going to turn the call over to Dr. Sharfstein from FDA.

Josh Sharfstein: Thanks Marc, I'm Josh Sharfstein, I'm the Principal Deputy Commissioner of the FDA and I'm glad to have the opportunity to summarize the update on BPA that the agency is releasing today on its Website, 2008 August the FDA published a draft assessment of the safety of BPA in food containers.

This draft assessment was based on a review of traditional toxicological tests which have found BPA to be safe for many years. Soon after the FDA's draft was published, the national toxicology program at the NIH released its assessment of BPA based in part on newer studies that use novel approaches and different end points to evaluate health effects at low doses.

The national toxicology program found "some concern of potential health effects of BPA". The FDA was criticized last year by the agency's external science board for failing to sufficiently consider these newer studies and their results.

Since that time FDA scientists and the center for food safety and applied nutrition have looked at these newer studies. When Dr. Hamburg began as the state commission she asked Dr. Jesse Goodman who is here with me, the Acting Chief Scientist to get the input of experts around the federal government and provide his perspective on BPA.

Our safety assessment of BPA is ongoing. At this time the agency is informing the public that we share the perspective of the national toxicology program of some concern for the health effects of BPA at low doses in the food supply.

Some concern means in part that we need to know more. As the National Toxicology Program included in its review in part, the current literature can not yet be fully interpreted for biological or experimental consistency or for relevance to human health.

That's why the FDA with the support of NIH is partnering with the National Toxicology Program to conduct several key studies on the safety of BPA over the next 18 to 24 months.

These studies which will be conducted at the FDA's National Center for Toxicological Research in Arkansas are intended to answer key questions and clarify uncertainties of the potential risks of BPA.

In the interim, the FDA is taking reasonable steps to help reduce human exposure to BPA.

These steps include supporting the industry's action to stop producing BPA containing baby bottles and infant feeding cups to the US market, facilitating the development of alternatives to BPA for the linings of liquid infant formula cans and supporting efforts to replace BPA or minimize BPA food levels - sorry BPA levels in other food can linings.

FDA is also supporting a shift to a more robust regulatory framework for its oversight of BPA so that the agency will be able to move quickly if necessary if new information becomes known.

Finally the agency is supporting recommendations from the Department of Health and Human Services for sound infant feeding and food preparation practices that can also help reduce exposure to BPA.

FDA is not recommending the families change the use of infant formula or food as a benefit of a stable source of good nutrition outweighs the potential risk from BPA exposure.

Parents considering changing what they feed their infants should speak with their healthcare provider first. The FDA is networking closely with NIH and other government partners and is also seeking further public and external input on the science about BPA.

We'll be opening a public docket soon. The agency will join in supporting an international consultation on BPA safety. We will evaluate all this input as well as new scientific information as it becomes available in determining if and when further action is needed.

Marc Smolonsky: Thank you Josh. Dr. Birnbaum, we'll turn to you for some comments now please.

Linda Birnbaum: Thank you Marc. I'm Linda Birnbaum, Director of the National Institute of Environmental (unintelligible), it's part of NIH. And I'm also Director of the National Toxicology Program which is a cross agency effort involving NIH, CDC and FDA.

There is a growing body of evidence that suggests that bisphenol-A may be a concern and I agree, we do need more research to determine how BPA affects overall human health.

We know that young children are especially vulnerable to the adverse health consequences of a wide variety of environmental exposures including BPA.

Their bodies are rapidly growing and changing and their systems for detoxifying chemicals are immature. (EHS) is investing $30 million for research on BPA and we're working together with other agencies to learn as much as we can as fast as we can and to share that information as quickly as we can.

This $30 million investment includes supporting our existing grant portfolio as well as $15 million from the newly rewarded Recovery Act grant, our in house research and NTP projects at FDA.

Our researchers in government and academia are doing both animal and human studies. And we're placing a special emphasis on critical periods of development.

We're looking at a variety of health effects which might be caused by BPA. I'm glad to tell you that our grantees are working together, talking to one another, sharing resources and forming collaborations, all this will allow for a more comprehensive and integrative assessment of the human health effects of BPA.

It's very important that the scientific and regulatory agencies work together so that all of the available research can and will be considered. We'll continue to communicate the results of our research to regulatory agencies and public health officials as they make decisions on how bisphenol-A will be regulated in the future. Thank you.

Marc Smolonsky: Thank you Linda. We're ready to take questions now please.

Coordinator: Thank you, we'll begin the question and answer session. If you would like to ask a question again please press star 1. Please unmute your phone and say your name clearly when prompted.

We'll introduce you by name. To withdraw a question you can press star 2. We'll wait just a moment, we do have questions coming in.

Our first question comes from Andrea Rock with Consumer's Union, you may ask your question.

Andrea Rock: Yes, you referred to trace levels of the BPA being detected in canned foods. But recent tests conducted by Consumer's Union found that for instance children eating multiple servings per day of canned foods with BPA levels comparable to the ones we found in our tested products would get a dose of BPA approaching levels that have caused adverse affects in animal studies.

So I'm wondering if trace is really a proper term for describing it and if you're going to be offering any kind of cautionary advice for pregnant women or children in terms of reducing BPA exposure in canned foods while you await further evidence?

Josh Sharfstein: I think the - thank you very much, this is Josh Sharfstein from FDA. We appreciate the study that you did and we also appreciate that you've been working with some of the scientists at FDA so we can understand how that was done.

One of the things we are very interested in looking at is exposure data in different ways and that was not - we consider that look ongoing. I don't think - there were a number of questions, I know there have been a lot of discussions in time to understand the approach that you took in that study.

And I think that certainly if we feel like when we've looked at that kids are exposed to canned foods to dangerous levels of BPA that would definitely change our position.

Right now we're not making recommendations about canned foods other than the basic recommendations that are on the HHS Website for appropriate handling of cans.

Andrea Rock: All right, thank you.

Marc Smolonsky: Next question?

Coordinator: Excuse me, the next question comes from Mark Mitchell with CT Coalition for Environmental Justice.

Mark Mitchell: Forgive my voice, I have a cold. We hear from certain infant formula makers that certain types of their products do not contain BPA in their cans and so on.

And I was wondering if there was a plan to make those products known or if there's been confirmation of the testing of those products and if there's a plan to make those products known to the public?

Josh Sharfstein: I think what we understand is that powder formulas that come in cans generally do not have detectable BPA levels. Liquid formulas in cans generally do have small but detectable BPA levels.

So other than that I think if those particular people that are claiming otherwise, I couldn't speak to that right now.

Mark Mitchell: Yeah, I believe that some of the manufacturers said that there's some infant formula, liquid infant formula cans that do not contain BPA. But I can try to get that information.

Josh Sharfstein: Yeah, I think we'd be interested in seeing that. Let me just also point out that one of the things we're interest is in developing alternatives to BPA for infant formula cans.

And you know BPA is in cans in part because it protects the safety of the food inside and it's - we want to move quickly but we also want to be smart and not put infant formula and other critical products at risk for different contamination.

Mark Mitchell: Okay, thank you.

Marc Smolonsky: Next question please.

Coordinator: Next question comes from Diana Zuckerman with National Research Center for Women and Families.

Diana Zuckerman: Yes, thank you. Can you hear me?

Josh Sharfstein: Yep, hi Diana.

Diana Zuckerman: Great, hi. We understand the focus on infants and children and that's very understandable obviously.

But there is evidence that for example breast cancer patients who are exposed to BPA, whether it's through food containers or other exposures that it could undermine the effectiveness of chemotherapy for their breast cancer.

So although the focus right now is on children and infants it seems very important to also look at particularly especially vulnerable adult populations and I was wondering what kind of research you all are doing on that.

Linda Birnbaum: This is Linda Birnbaum. We don't have any research that I know of currently looking at vulnerable adult populations. We are conducting some studies as part of our portfolio where we are looking at potential affects in adults as well as children.

But we have not looked at the kind of population that you are suggesting.

Marc Smolonsky: Okay, can we have the next question please?

Coordinator: Yes, our next question comes from Bill Walker with Breast Cancer Fund, your line is open.

Bill Walker: Thank you very much. Dr. Birnbaum, this is honestly not meant as a nasty question, but just wondering what you would say if people were confused about the difference between what seems to be a very clear statement you made to the Journal Sentinel before the end of the year that there was enough evidence to - (preparence) to take into consideration that they should not be exposing their infants to BPA, and the somewhat more I guess guarded or somewhat more less categorical statements that the FDA and you are making today.

Linda Birnbaum: We do have some concern, which is why we're conducting more research. I think that's the clearest statement we can make.

Coordinator: Okay, our next question comes from Janet Nudelman with the Breast Cancer Fund.

Janet Nudelman: Hi, sorry about the tag team with the Breast Cancer Fund here, I wanted to follow up on one of the last questions that was asked to Dr. Sharfstein about what it would take to shift over the regulatory framework at the FDA vis-à-vis food contact substances.

And whether or not something that Dr. Sharfstein said is that it takes a long time through the rules and the public comment period and I'm wondering if you're working with Senator Feinstein on legislation that would give FDA the authority that it needs to modernize the food contact substance notification program.

So that both the problem of FDA would be - or the problem of BPA would be taken care of as well as possibility of future BPA like chemicals being approved as packaging additives.

Josh Sharfstein: Thank you very much, how many people do you have at the Breast Cancer Fund lined up for questions?

Janet Nudelman: This is it.

Josh Sharfstein: Okay. I think it's a very good question and maybe it will be helpful for me to provide just a little more context on this. Currently BPA is regulated as a food additive which is a very inflexible regulation that has existed for over 40 years.

And under that we don't know at the FDA when people are using products with BPA, we don't know what products it's used in, how it's used,

manufacturer is not required to disclose the existence or nature of the formulations that they're using for BPA.

And if we wanted to change anything, like if we were to decide that it was necessary to revoke a major use of BPA we would have to go through notice and comment rule making.

But since 2000 because of the 1997 Food and Drug amendments law, we've regulated new food contact substances through the food contact notification program.

And with the way this works is that FDA receives notification from each manufacturer of the basis for safe use of the food contact substance detailing the conditions of the substance abuse, allowing the agency and public to know how much is being used and for what application.

We can work with individual manufacturers to minimize exposure of a potential or actual safety concern is identified after approval.

We can require companies to submit additional safety and exposure data, we can require other types of studies and if we are able to reach a conclusion a revocation of one or more approved uses is justified, we can protect the public by revoking the use just through a notice published in the Federal Register.

So FDA is interested in treating BPA within - considering BPA within the modern framework for food contact substances. And I think your question Janet was about how do we get there from here?

And one thing that we can do and we are going to be talking to industry about is we can right now take their voluntary notifications, they can voluntarily move over.

Then we're looking at the question of whether we have the ability to force that switch under our current authority from the old way of doing it to the new way and that may be quite difficult for FDA.

A third way is obviously through legislation and we have had a call with congressional staff today and you know it wouldn't surprise anyone to hear that that question came up.

And I'm sure that will be a topic of discussion.

Marc Smolonsky: Thank you. We have time for one more question please, this will be the last question.

Coordinator: Okay, our next question comes from Catherine Porter with Toronto Star.

Catherine Porter: Hi there. I'm interested - I'm sitting at my desk looking at my SIGG bottle, it's one of the new ones that does not have BPA lining but I was drinking out of the old one while pregnant with my second child.

I'm wondering if you are really concerned about the in utero effects of BPA while you're not alerting pregnant women about drinking out of bottles that have BPA or exposing their in utero children to BPA through food linings.

Josh Sharfstein: I'll give just an overview and then I'm going to ask Dr. Goodman, the Acting Chief Scientist to add his thoughts too. I think that this is challenging because of the level of concern that we have.

You know it's not no concern, it's some concern which is that there's reason why we think both that we need to get more answers as quickly as possible, as Linda Birnbaum said.

And people should take reasonable steps to reduce exposure. So - and those reasonable steps that we support are now on the HHS Website. So that's our position, these are the reasonable steps that we think are appropriate to the level of concern that we have.

We also want to be able to act quickly if necessary as we get results if they are leading us to a conclusion that more steps need to be taken. And I'll ask Dr. Goodman to see if he wants to add anything.

Jesse Goodman: Well I - you know this is Jesse Goodman, I would just say you know we certainly share the concern about development in general, you know pregnancies, infant and young children.

I think it is one of the areas where there's a lot of uncertainty in the science. One thing there of course is that infants may be particularly vulnerable because of the exposures, the potential exposures that have been mentioned.

And also a lot because of their developing system of metabolism in terms of glucuronidation, etcetera. It - so that's sort of why they're particular concern and we're focusing on that but I don't think we're saying that there aren't questions with respect to other areas of development, fetal exposure, etcetera that need to be addressed.

Some of the studies both that I know Dr. Birnbaum's group is funding and also the studies that we're doing collaboratively with them are specifically to

address the issues of the specific types of in utero exposure, whether there are consistent findings or concerns there and sort of address some of these concerns that have been raised.

I think that as we get that information we'll make it available and that you know as people who do that view potential and unknown risks differently, people may make decisions like you're suggesting to reduce their exposure in other ways. So different people approach these different risks differently and we wouldn't argue against somebody doing that but we don't feel the evidence right now is conclusive that we would say to a pregnant woman you need do this.

But you know don't feel that we're disregarding that concern, nor I would say the one that was raised about the issues such as interactions with chemotherapy.

We're really trying to focus on the areas where the concerns such as identified by the NTP are clearest and where we can suggest reasonable things for people to do.

Marc Smolonsky: Okay, that's going to conclude the call, thank you everyone for your participation and I'll remind you that information about this is on our Website at hhs.gov.

Woman: Thank you.

Coordinator: Thank you all for attending today's conference, you may now disconnect.

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