genetic programming; We heard about epigenetics, a new way of changing the way genes function, and then prostate cancer. And I thought I'd show you just briefly what we do. If you look at the prostate as it develops, these glands emerging out of the urethra, what we do is we section the prostate and then scan it into the computer so that the computer actually reconstructs exactly what the prostate looked like in the animal. This is the animal's prostate with the dorsal prostate ducts, the lateral ducts, the anterior prostate. If you just look at conventional histology here, just one section or a cross section of it, you don't really get what happens. And that's the standard in these multi-generation studies.

This is really brought home -- and Dr. Bucher referred to this, here are the actual data -- when Ogura took prostates that had been fed the mothers during pregnancy either a low dose of DES or bisphenol A, and

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he did conventional histology of the kind in a common GLP study, he said you detect no effects. But if you use an immunostain that identifies the basal cell and then that squamous metaplasia, this abnormal cell division, is occurring, you identify an abnormality that is part of the transformation process into cancer.

We also took sections from our reconstruction experiment that we published in PNAS and showed that bisphenol A and these other estrogens were stimulating excessive proliferation -- we call hyperplasia -- of the stem cell, the basal cell that transforms into cancer in adulthood. We then took out the controller cells and put them into cell culture, these mesenchyme cells, and one of the things that we showed, and this is the schematic, is that they actually, as Dr. Bucher mentioned, they lead to an increase in the estrogen receptors in the mesenchyme cells, the androgen receptors. They make this

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more sensitive to male sex hormones. There are a whole series of stimulatory growth factors that are secreted. Basal cells start proliferating and in adulthood they transform into tumors.

So one of the things then is why are there these non-replication studies? I think it's important to note that two of the non-replication studies that the FDA announced for years were the studies that could be used to show that any of the studies that had positive effects were of no value. Particularly George Pauly at the FDA kept coming out with these statements. In fact, the CERHR panel deemed them unusable due to the fact that the DES positive control showed no effects. This was discounted by the FDA report. Whoever wrote that report, I suggest that they talk to Retha Newbold and to NTP who was publishing in the 1980s that doses below .2 micrograms per kilogram DES given during pregnancy would alter subsequent reproductive

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events and there is a substantial article on this. There just seems to be a serious lack of contact with the literature by whoever is responsible for the statements made about this in the report.

So now we're coming to the more current studies, the Tyl et al. studies. And this is the Tyl 2008 study that they so heavily relied on. And one of the things is very clear is that the CD mouse required a very high dose of positive control to show an effect, so it was insensitive. They used outdated assays. Dr. Bucher mentioned that. And I'll show you that they also used some bad dissection technique. And so here are the weights of the control prostates in Dr. Tyl's study that she reports, and she used the 74 milligram prostates as her group that she really looked at.

Here's what Chanda Gupta spent her whole career working on, prostate, and these are one of the data sets that she published in

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1 2000 showing that feeding pregnant females a
2 very low dose of DES, or in this case
3 bisphenol A, she got over a 50 percent
4 increase in prostate weight. But her control
5 weights were 40 milligrams, not 74.
6 Here are data, a number of years
7 ago we were working with other mice, showed
8 that .002 micrograms per kilogram per day of
9 the birth control pill estrogen ethinyl
10 estradiol would stimulate prostate growth,
11 either the main part of the prostate or the
12 anterior part, and notice that our prostates
13 are 40 milligrams, not 75.
14 This is a prostate that's been
15 properly disected out that weighs 40
16 milligrams. It's very difficult to get these
17 things out without loads of fat on them, other
18 organs attached to them. So clearly the 75
19 milligram prostate in the Tyl study either
20 means that the technicians didn't know what
21 they were doing or the animals had prostatitis
22 and were diseased and, regardless the data are

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so flawed that the Tyl study is absolutely unusable as a critique for any other study that looked at the prostate.

The other study that was used by Shelly Tyl and published in 2002 was this was written by the 2001 NTP low-dose peer review report in response to her saying we used these animals because they're the animals we use. And they said we already know these animals are insensitive to estrogen. So they said you really need to demonstrate through a positive control that this is an appropriate modelable animal, that you don't use it just because it's in your lab and you're familiar with it. And if you look at two different kinds of rat, the Sprague-Dawley rat, the special derivative Sprague-Dawley Charles River rats, CDSD rat and another Long Evans rat, they require five to 50 micrograms of the positive control, birth control pill estrogen ethinyl estradiol, to cause an effect and that's between 2,500 and 25,000 times less sensitive than ours.

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1 So you have insensitive animals
2 being used, no positive control as a basis for
3 rejecting experiments, experiments where
4 positive and negative controls didn't show any
5 difference and then insensitive animals and
6 insensitive assays being used. And none of
7 these are being properly discriminated in this
8 FDA report.
9 I want to end up by just briefly
10 showing that there's a literature that
11 nobody's covered that has to do with metabolic
12 events and particularly type 2 diabetes and
13 cardiovascular disease. We have an
14 interesting literature showing that critical
15 antioxidating enzymes are reduced, and this of
16 course leads to oxidative stress and
17 potentially cancer and disease, and this can
18 happen at 0.2 micrograms per kilogram per day
19 by feeding adult rats bisphenol A and then you
20 see the dose response curves. And these other
21 enzymes are antioxidating enzymes. And as Dr.
22 Bucher pointed out but was completely missing

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from the FDA report, it was the consensus of the NIH experts that met at Chapel Hill that it was the membrane-bound receptor that worked to do this. And these are the kinds of cell culture studies with human, rat and mouse cells that have shown effects through this receptor system where estradiol and bisphenol A are operating at at least 100-fold below blood levels present found in people. And it does it through a mechanism that's now been dissected in great detail. We know the non-classical estrogen receptor is activating a system called MAP kinase through what is called the ERK 1/2 pathway. We know it's depolarizing the cell membrane leading to calcium uptake, phosphorylation of a critical transcription factor called CREB and that leads to insulin production. It then leads subsequently to insulin resistance in these animals.

Estradiol and bisphenol A are equally potent and effective in this system at

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a very low dose. In cell culture you can see those lines indicating the human exposure level. Estradiol and bisphenol A both stimulate insulin secretion in mouse pancreatic beta cells at exactly human exposure levels.

A new study was just published where, in human fat cells, at exactly the same dose as in the cell of the mouse pancreas you get suppression of a critical hormone that is required to block inflammation and is associated with obesity, diabetes and cardiovascular disease and exactly that same dose stimulates prostate cancer cells from humans.

So now I'm going to go through the new data that everybody's excited about from Dr. Melzer's group in England. These are data from the National Health Survey. I'll just show you a couple of slides. And they're published in tomorrow's version of JAMA. They represent data from 1,455 people. It's a

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shame Dr. Calafat isn't here. She did the bisphenol A assays that are present in this study.

What these data in the article show is they just looked at adults, not children, but the younger you are, from 18 to 74, the higher your exposure. The fatter you are, the more your exposure. Blacks have the highest level of exposure and the less your income, the higher your exposure.

Some of the data here are very interesting because alkaline phosphatase is an indicator of all kinds of various diseases when it's present in the blood. And gamma-glutamyl transferase in the blood is -- actually in the Framingham longitudinal study -- was predictive of cardiovascular disease and death later on, about 20 years later in life, in a study of over 3,000 people. But what is critical is exactly what I just showed you happened in mice. We see a correlation here between an increase in bisphenol A and an

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increase in insulin, an increase in glucose, and that combination using what is called the HOMA2 measure is an index of insulin resistance. So these people had, for every standard deviation above of the mean increase in bisphenol A, a statistically increased probability of diabetes, heart disease, including heart attack.

So as we heard, you know, the fetus and the newborn is considered to be at greatest harm. Childhood diabetes didn't exist before bisphenol A was used. That doesn't mean bisphenol A is the only factor in it, but it does really ratchet up the need to be taking a look at metabolic effects of bisphenol A in children in relation to childhood diabetes which is now an epidemic.

And this just shows you on the left causal studies that I have here in animals relating bisphenol A at doses far below the proposed NOAEL in the FDA report with diseases in the male, in the female, as

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well as metabolic diseases such as obesity. And these are all substantial human health trends that are a tremendous concern to the public health community.

And as we heard from the FDA officials, safety means there's a reasonable certainty in the minds of competent scientists that substances not harmful under the intended conditions of use. I think that the data that I have presented led me and the other 37 people who signed the consensus statement to say that there was a high level of confidence that at current levels of exposure bisphenol A poses a threat. So clearly the criterion that there has to be reasonable certainty of no harm is untenable given the massive data that we have.

And the last slide is there seems to be an obsessive desire to pay attention to GLP, particularly large animal studies. They made a big deal of how excited they were that Shelly Tyl used 8,000 animals in her first

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1 study and 25 animals a group in the second
2 one. Well that would be rejected by the
3 University of Missouri or any NIH-funded grant
4 as an absolutely unbelievably excessive misuse
5 of animals because what we call power analysis
6 would reveal that those number of animals were
7 in far excess of the number needed to show
8 effects. And that experiment would be
9 disapproved under any NIH guideline being
10 followed. It absolutely violates federal
11 guidelines for conducting research.
12 The FDA is ignoring all of this
13 research, and while it has been doing that,
14 Americans have been at risk for diseases such
15 as diabetes and heart attack. And I would
16 hope that this panel is not, as I heard it
17 seems to be, under some pressure to rush to
18 judgment and reach a decision quickly. This
19 is an extremely difficult literature to go
20 through. As you heard, it's almost 1,000
21 papers. It took us a year to write these
22 reviews. It took the NTP two years. This is

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not something that can easily be done in a short period of time by any group of people, no matter what level of expertise you have. This is a daunting challenge for you. And all of the articles on bisphenol A that I've talked about; and I have PDFs I'm willing to send to any of you. I'm willing to give them to you now on a jump drive or whatever, or a CD. And they're posted as a downloadable document. The reference is in the abstract on the web site shown here.

Thank you for the opportunity to talk.

CHAIRMAN PHILBERT: Thank you for your presentation, Dr. vom Saal.

Given that our time is exhausted for the moment and that public comment is to follow, I'd ask the subcommittee to hold their questions until we meet Dr. vom Saal again on the panel.

So I would ask that the panel adjourn for three to five minutes for a break

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and that we return promptly at ten past 11:00.

I'd also like to assure the public that your time will be preserved for your commentary. Thank you.

(Whereupon, the above-entitled matter went off the record at 11:07 a.m. and resumed at 11:14 a.m.)

CHAIRMAN PHILBERT: Before we get started with the open public hearing, I should point out that we have had more than 200 written comments that were provided to the subcommittee and the rules for the following presentations are three minutes of oral presentation followed by two minutes of questioning.

With that being said and the subcommittee in place, I'd like to invite Dr. Jacob from the Environmental Working Group to take the podium. Thank you.

DR. JACOB: I'd like to start by thanking the subcommittee for this opportunity to present comments on behalf of the

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Environmental Working Group.

There is growing consensus among the scientific community, the medical community and government agencies that current exposures to BPA are harmful. In the next several slides we will present some conclusions from these different groups.

This is the Canadian Minister of Health commenting on the recent BPA assessment completed by the Canadian government. In this assessment, BPA was found to be a chemical of concern and the government proposed measures to ban BPA in baby bottles and decrease BPA contamination of infant formula, from metal cans in order to decrease exposure among vulnerable populations.

In the next slide we have the final assessment from NTP in which they find some concern for effects on the brain, behavior and prostate gland in fetuses, infants and children at current human exposures to bisphenol A. It's been argued

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that some concern is not significant and we'd like to point out that when NTP did an assessment of developmental toxicity of amphetamines, they also found some concern and no one would suggest that unintentional exposures to amphetamines in infants and children is acceptable. So that tells us that this level of concern is significant. When it comes to the health of children, any level of concern is too high.

And here we have a comment from the associate director of NTP following up on their findings. NTP concludes that the possibility that BPA may affect human development can't be dismissed, and yet that's exactly what FDA has done in its draft assessment.

This is part of the Chapel Hill consensus statement that Dr. vom Saal referred to. This is a consensus statement from 38 BPA experts from around the world who reviewed hundreds of articles on BPA toxicity and

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1 issued a consensus statement that was also
2 published in a peer-reviewed journal. They
3 find great cause for concern with regard to
4 adverse effects in humans and correlate this
5 with current health trends.
6 BPA has been linked in lab studies
7 to hyperactivity, breast cancer, prostate
8 cancer, early puberty, infertility, diabetes
9 and obesity. And these are conditions that
10 are common in the U.S. population, and in many
11 cases, on the rise.
12 This is a quote from a letter that
13 the American Academy of Pediatrics wrote to
14 the NTP in support of their findings. The AAP
15 is a group that represents 60,000
16 pediatricians and they're especially concerned
17 about this chemical because their patient
18 population, infants and children, are
19 especially vulnerable to this chemical. AAP
20 questions the validity of any assertion that
21 BPA exposure is safe and especially for
22 vulnerable populations. And yet, that is

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exactly what FDA has concluded as we see in this next slide.

FDA concluded that BPA exposure is safe by relying heavily on two industry-funded studies. The primary reason FDA relied on these two studies is because they follow good laboratory practice, which guarantees that they followed a certain protocol, but doesn't guarantee anything about the quality of these studies. In fact, one of these studies did not include a positive control, so we really don't know the study worked. And most importantly, neither of these studies looked at brain development and behavioral effects, although both the CERHR panel and the NTP raised significant concerns about these end points, prompting the question, how can FDA reassure parents about the safety of this chemical when the studies they rely on don't even look at these relevant points.

CHAIRMAN PHILBERT: One minute. One minute remaining.

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DR. JACOBS: I'll wrap up. And I'll close with, this was a quote from the NIH's scientific program administrator. He was about these two studies in an interview last week, and this was his answer: what you are left with is not much. So basically these two studies don't give us the relevant information. In conclusion, we strongly urge FDA to recognize the credible evidence of the toxicity of this chemical and ban the use of BPA in infant formula, food containers and baby bottles. Thank you.

CHAIRMAN PHILBERT: Thank you very much. We have time for one question.

Hearing none. Thank you. Thank you very much.

Our next presentation is from Dr. Zuckerman from the National Research Center for Women and Families. Thank you.

DR. ZUCKERMAN: The National Research Center for Women and Families is dedicated to improving the health and safety

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of adults and children by scrutinizing and explaining scientific research. I'm also a fellow at the University of Pennsylvania Center for Bioethics. I was trained in epidemiology at Yale, conducted research at Harvard and I've worked on FDA policy issues for 20 years.

The FDA concludes that the BPA in food containers is safe, as you've heard, primarily based on two industry-funded studies. But the FDA report does not consider the weight of the evidence of the hundreds of studies finding reasons for concern. Many of those studies did not follow good laboratory practices because those are industry practices, not university practices. We know that these NIH-funded studies and other federally-funded studies are held to a much higher standard than these good laboratory practices and yet basically they were ignored in the FDA draft report.

In addition the FDA draft report

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uses some questionable data about exposure. On page 7 of the report they admit that they analyzed BPA data based on 14 samples of infant formula, all from Washington, D.C., supermarkets, more than 12 years ago. There's no reason to assume that those levels are representative of infant formula 12 years ago or today. And in fact in a June report, in June memorandum, FDA scientists mentioned other studies finding higher maximum levels of BPA in infant formula. And yet, those maximum levels are not mentioned in the report; basically they're ignored.

The National Toxicology Program concluded that there was some concern, and I want to say that I think that term is misleading. If you look at their report, some concern basically means there is a substantial amount of evidence but it may not be conclusive for a variety of reasons having to do with the quality of the study and the way the studies were analyzed. But there's a huge

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1 difference between there being not conclusive
2 evidence and being able to say we shouldn't be
3 concerned. That's even more true, I think,
4 with some of the other data than the brain
5 development data. But the brain data in
6 particular, there's reason for a great deal of
7 concern, whether you're talking about breast
8 cancer, prostate cancer or neurological
9 development. There's plenty of evidence,
10 plenty of reason for concern; it just may not
11 be conclusive.
12 But as you all know, as scientists, just
13 because the data aren't conclusive doesn't
14 mean that we conclude that a product is safe.
15 And I think that's the big flaw in the FDA's
16 work.
17 The latest research adds to these
18 concerns. Last week, Yale scientists
19 published the first BPA study of primates
20 finding some serious problems with how it
21 affected brain function. A new study
22 published in Environmental Health Perspectives

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1 concluded that BPA could inhibit a key hormone
2 that protects us from diabetes and heart
3 disease. And neither of these studies were
4 published in time to be considered by the FDA
5 draft, but they're both raising very serious
6 questions that need to be considered.
7 The FDA's draft report draws
8 conclusions about safety based on industry's
9 rose-colored glasses and we need you to see
10 more clearly. It's your job to set the FDA on
11 the right path to protect our children and to
12 protect all of us. Since these food
13 containers are not proven safe, the FDA should
14 not be assuring us that they are safe.
15 CHAIRMAN PHILBERT: One minute.
16 DR. ZUCKERMAN: At the very least
17 there should be black-box-type warnings on any
18 food container with BPA so that we can decide
19 if we want to take that chance. But
20 basically, it does feel like there's been a
21 rush to judgment by the FDA and that does none
22 of us any good. We want to know if a product

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is safe. We don't want any assumptions based on wishful thinking that BPA in current levels is safe. And I'd be happy to answer any questions.

CHAIRMAN PHILBERT: Thank you. We have time for one question.

DR. VANDENBERG: You mentioned a study related to exposure that was not referred to by the FDA report. I wonder if you might provide that to the committee, because one of the things we want to make sure of is that we're aware of new studies on exposure which you --

DR. ZUCKERMAN: Okay. Are you talking about the Yale study and the --

DR. VANDENBERG: No. No.

DR. ZUCKERMAN: Okay. You're talking about the exposure levels in infant formula.

DR. VANDENBERG: Correct.

DR. ZUCKERMAN: I'm happy to provide that. I will provide, I think it's

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the June 2nd memorandum, written by an official at the FDA on this topic talking about other maximum levels in other studies by the environmental working group and other groups.

DR. VANDENBERG: We have that one.

DR. ZUCKERMAN: So I'm sure you have that.

DR. VANDENBERG: I just wasn't sure what you were referring to.

DR. ZUCKERMAN: But you're right, because it's not mentioned in the FDA report.

DR. VANDENBERG: Okay.

DR. ZUCKERMAN: Anything else?

CHAIRMAN PHILBERT: Thank you very much.

DR. ZUCKERMAN: Thank you.

CHAIRMAN PHILBERT: Our next presentation is from Dr. Jordan from the Association of Reproductive Health Professionals.

DR. JORDAN: Good morning. My

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name is Beth Jordan. I'm a physician, I'm an internist, and I currently serve as a Medical Director of the Association of Reproductive Health Professionals, ARHP.

For nearly 50 years the ARHP has established itself as a leading source for medical information and information on reproductive and sexual health. ARHP educates health care providers, informs consumers and impacts public policy. Our membership is composed of 11,000 professionals who provide reproductive health services or education, conduct research or influence reproductive health policy.

I come before the BPA subcommittee today to urge you to do two things as you consider the draft assessment of BPA for use in food contact applications: (1) use all existing research on health effects of BPA to make a final determination about its safety; and (2) let any action the FDA takes with regard to BPA be driven by a precautionary

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principle.

The FDA's current draft assessment concludes that BPA is safe. This conclusion is based on two studies, both of which are funded by institutions that have a financial stake in the outcome of the FDA's decision. While the science is still emerging, what's presently known about BPA is worrisome. Human exposure to BPA is widespread. Emerging research reveals that low levels of BPA that were previously thought not to be harmful may now be associated with numerous negative health outcomes.

The scientific community is becoming increasingly concerned about BPA's adverse effects upon humans, particularly women of reproductive age, pregnant women, developing embryos, and young children. These concerns are based on a growing body of toxicology assessments demonstrating that low-dose exposure levels cannot necessarily be deemed safe based on high-dose studies in the

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case of BPA.

Two points are chief among ARHP's concerns about the FDA's current draft assessment:

(1) Safety evaluations of chemicals should take into account the entire existing body of research. To date, over 100 publicly and privately-funded studies have been completed or performed on health effects of BPA exposure. To make a determination, the FDA used two of the 100-plus existing studies, both of which followed good laboratory practices, or GLP, a set of standards commonly used by industry-based researchers. The FDA should strongly consider using the vast body of research available from even non-GLP studies.

(2) The two studies the FDA did use reached its conclusion among the 20 or so industry-funded studies. Currently there is a concern expressed amongst valued scientists that all BPA scientific studies are not

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1 created equal. Of the industry-funded
2 studies, none have found BPA to have any
3 health effects. However, over 100 studies
4 have been conducted by independent NIH-funded
5 scientists on the effects of BPA exposure and
6 all have found health effects. This level of
7 disparity among studies, particularly when
8 sharp contrasts exist along funding lines, is
9 alarming.
10 The FDA should reconsider its
11 current assessment and bring to bear the
12 weight of all existing research on BPA safety
13 to reach its determination. In doing so, the
14 FDA will ensure the public benefits from all
15 we currently know about low-dose chronic
16 exposure to BPA.
17 ARHP supports the use of evidence-
18 based science to inform clinical decision
19 making. Unfortunately, we do not always have
20 the data we want to make the best
21 recommendations for your patients. But
22 absence of a certain kind of evidence does not

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1 necessarily mean evidence of absence of harm.
2 Ethical concerns prevent us from ever being
3 able to conduct randomized double-blind
4 placebo-controlled studies on pregnant women
5 looking at the various effects of various
6 levels of exposure to various toxins. Even
7 when all the existing research on the health
8 effects of BPA is considered, the FDA may not
9 be able to reach a final conclusion on the
10 safety of BPA exposure to the general public.
11 The precautionary principle is
12 generally defined as the following: When an
13 activity raises threats of harm to human
14 health or the environment, precautionary
15 measures should be taken even if some cause
16 and effect relationships are not fully
17 established scientifically. In this context,
18 the proponent of an activity, rather than the
19 public, should be bear the burden of proof.
20 In the face of scientific uncertainty and
21 credible threats of harm, ARHP supports
22 precautionary action form, a government

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recommendation to decrease overall BPA exposure. Thank you.

CHAIRMAN PHILBERT: Thank you. Are there any questions?

Hearing none. Thank you.

Our next presentation is from Ms. Greenspan from Healthy Child Healthy World.

MS. GREENSPAN: Good morning. My name is Nancy Greenspan. I'm here speaking on behalf of Healthy Child Healthy World, which is a non-profit organization and I'm a board member. I'm an economist as well as co-author of several books on child development with Dr. Stanley Greenspan who is an internationally-known child psychiatrist.

There are approximately 4 million live births in the United States. Those babies are the population at greatest risk from BPA, but nowhere in this draft did I find this number. Instead, the draft highlights the average maximum BPA exposure for infants at various ages. This average maximum

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exposure is based on four assumptions and the authors state that, "These assumptions all increase the likelihood that the actual infant exposure to BPA is lower than FDA's estimate." Thus, they claim the exposure estimates to be conservative. In fact, they claim this 17 times in 38 pages. So let's take a look at that.

First, are the exposure estimates accurate? To get this number, the authors divide the overall average BPA exposure separately by the weight of female infants and that of males to derive the daily exposure of each. An artifact of this arithmetic is the unlikely result that the lighter weight females eat more than the heavier male counterparts. As a mother of three, two girls and one boy, I don't think so. Such a fundamental error on the part of the FDA must call into question the accuracy of the entire report.

Next, how sensitive is the margin

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of safety to the maximum average exposure estimate? The FDA says that the margin of safety is 2,066, but we know nothing about the distribution around the average exposure estimate, the skewness. How many babies are above the average? By how much? What if 10 percent of two-month-olds, the group with the highest cumulative estimated daily intake, are in the tail of the distribution and greatly exceed the maximum average exposure? Ten percent of 4 million live births are 400,000 babies. If a baby drinks twice the average amount of formula and so doubles his maximum daily exposure to BPA, the margin of safety becomes 1,033. According to the report, the margin of safety is adequate if it is greater than the uncertainty factor, which in this case is 1,000. That sure is darn close to 1,033.

The purpose of the margin of safety is to safeguard just such a population, but many variables used in the assessment are averages

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with no accompanying standard deviations or distributions.

If the NOAEL is actually a little lower and the infant consumes more than the average and more BPA migrates out of a certain type of bottle or can manufactured in say China, what happens then? If a baby eating double the average cuts the margin of safety in half, how much do these other factors decrease the margin of safety? Where is the sensitivity analysis in this report?

Conclusion. The BPA exposure for infants, the data are not conservative. Proper data analysis might easily show that the margin of safety is not adequate. American children deserve better than the biased and sloppy assessment. Healthy Child Healthy World requests that you answer question 8 of your charge: Did the assessment results objectively and transparently support the conclusion with a resounding no? Thank you very much.

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CHAIRMAN PHILBERT: Thank you. Are there any questions?

No? Thank you very much.

Next presentation is from Ms. Hitchcock from U.S. Public Interest Research Group.

MS. HITCHCOCK: Good morning. I'm Liz Hitchcock and I'm a public health advocate for the U.S. Public Interest Research Group. U.S. PIRG is the federation of state public interest research groups active across the country. We thank the subcommittee for conducting this important public meeting.

I have longer written testimony that I'd be happy to submit for the record, but I'd like to cover three important points at this public meeting.

The hazards of bisphenol A are well-documented and pose a special danger to children. Other countries, a number of states and retailers are acting in the absence of federal action on these chemicals and the

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1 federal government should regulate these and
2 other toxic chemicals to protect our
3 children's health.
4 First, the hazards of bisphenol A
5 are well-documented and pose a special danger
6 to children. We've heard this morning
7 scientists have linked very low doses of
8 bisphenol A to cancers, impaired immune
9 function, early onset of puberty, obesity,
10 diabetes, hyperactivity, among other problems.
11 Our children are receiving doses
12 of bisphenol A along with their milk, formula
13 and juice in their baby bottles and sippy
14 cups.
15 Last year, U.S. PIRG's partner
16 organization, Environment California, tested
17 five of the most popular baby bottle brands on
18 the market. Our researchers found that
19 bottles tested from all five brands leached
20 bisphenol A at levels found to cause harm in
21 numerous laboratory studies. Last April, the
22 National Toxicology Program at NIH

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acknowledged health concerns about children's exposure to BPA. In their final report released earlier this month, they said that current human exposure to bisphenol A is of some concern for effects on the development of the prostate gland, the brain, and for behavioral effects in fetuses, infants, and children, and concluded that the possibility that BPA may affect human development cannot be dismissed.

Second, other countries, a number of states, some manufacturers and retailers are leading the way in taking action on bisphenol A. For example, the Canadian government has declared bisphenol A toxic under Canadian law. There were efforts in at least five state legislatures this year to restrict the use of BPA. There are two bills offered in the Congress to restrict the use of BPA, which U.S. PIRG supports. Walmart announced in May that they would discontinue selling products with the chemical in Canada

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this year and in the U.S. early next year. Nalgene, the maker of this water bottle, announced in April that it would no longer use bisphenol A in these bottles. There are alternatives and the industry is using them.

Given the significant health concerns associated with bisphenol A, a precautionary approach on the part of the Food and Drug Administration makes sense. If there's evidence that these chemicals cause harm, why don't we exercise the good common sense to keep them out of the hands and mouths of our children, especially when we have safer alternatives with which to replace them.

My last point is, of course, that the federal government should regulate these and other toxic chemicals to protect our children's health. Consumers can't be expected to go it alone and we can't just expect that all industry and retailers are going to take the right voluntary steps. FDA should take action based on the weight of

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evidence showing that chemicals like bisphenol A may harm human health.

We urge the subcommittee to take action based on the overwhelming weight of scientific evidence and ban bisphenol A in our food containers. Thank you.

CHAIRMAN PHILBERT: Thank you very much.

Questions? Thank you.

The next presentation is from Dr. Peterson Myers from Environmental Health Sciences.

DR. PETERSON MYERS: Thank you. Good morning. I'm Pete Myers. I'm chief scientist at Environmental Health Sciences in Charlottesville, Virginia.

In June, I offered comments to the CERHR panel that multiple animal experiments published in the peer-reviewed literature show effects on adults at low exposure levels. These included studies that were related to insulin metabolism and showed causation of

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insulin resistance. CERHR chose to ignore these data and my comments.

Then last month, EHP published a new study showing that human tissue exposed to bisphenol A experiences a suppression of the release of adiponectin at .1 and 10 nanomoles per milliliter, well within the range of human exposure. Other longitudinal data looking at the health consequences of suppressed adiponectin release link it clearly to type 2 diabetes, increase in risk of type 2 diabetes and heart attacks.

Now today, we've just learned that JAMA has published the first major epidemiological study of BPA which actually is predicted by the adiponectin results directly and which rests on a significant body of mechanistic literature doing experiments with animals. The JAMA study is cross-sectional; it's not the sort of work that can be used in isolation to infer causality. But given the wealth of mechanistic information about the

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1 underlying mechanisms, it is very clear that
2 the FDA cannot conclude with certainty that
3 BPA is safe. That option is no longer open to
4 you, given these new data.
5 Lastly, I would comment on the
6 reliance by FDA on good laboratory practice
7 studies, GLP, and their reliance on them to
8 reach their conclusion. We had known from
9 CERHR's review and NTP's review that the first
10 three major GLP studies funded by industry
11 were flawed and useless for attempting to set
12 health standards. And now we've learned today
13 from Dr. vom Saal's presentation that the
14 study that's been held up, Tyl et al 2008, the
15 study that's been held up by the FDA as the
16 gold standard is flawed and also useless.
17 That's four out of four. That would suggest
18 that perhaps instead of ignoring hundreds of
19 studies funded by NIH, conducted by world
20 class scientists who have to through very
21 rigorous review processes to get funded, to
22 publish their research and to have their

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research replicated, that instead of ignoring those studies, should ignore GLP studies. Thank you.

CHAIRMAN PHILBERT: Thank you.

Are there questions?

Thank you very much.

The next presentation is from Dr. Melzer from the Peninsula Medical School in the United Kingdom.

DR. MELZER: Thanks very much. I'm Dr. David Melzer. I'm a physician, epidemiologist and public health professor and would like to present the analysis which is being much trailed this morning by various people.

The objective of our analysis was to look at the associations between urinary bisphenol A concentrations in the NHANES study and adult health stages. As has been mentioned this is a cross-sectional study, cross-sectional analysis of data generated at the Centers for Disease Control and Prevention

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in Atlanta and we're very much beholden and appreciative of their release of the data to the scientific community internationally.

The analysis is based on 1,455 adults; that's age 18 to 74, for whom bisphenol A concentrations were available.

This is a simple presentation of age/sex adjusted arithmetic mean urinary bisphenol A concentrations by disease category. We looked at the eight major disease categories in the NHANES study for which there were more than 40 cases. As you can see very clearly, cardiovascular diseases and diabetes stick out. The cases had far higher mean bisphenol A levels than the controls. And similar common diseases like arthritis and respiratory conditions showed no kind of change in mean levels with a control suggesting that these changes are fairly specific for these common disease categories.

In terms of statistical significance, we went onto adjust these models

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for some of the potential confounders that people have talked about, especially for obesity. So we adjusted for both body mass index and waist circumference to be absolutely sure that these weren't obesity-related effects and the associations were still highly statistically significant. Indeed, if you take into account the multiple testing of those eight disease categories, these associations still remain statistically significant. No associations as I mentioned before on full adjustment for any of the other six disease categories.

We also looked at four categories of biochemical change; that is, C-reactive protein representing inflammation, glucose metabolism, especially glucose levels in insulin, liver enzymes and lipids. We found statistically significant increases in three liver enzymes associated with higher urinary bisphenol A concentrations and those associations were also present for clinically

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abnormal levels; that is, taking the clinical cut points, associations were still there for gamma-glutamyl transferase and alkaline phosphatase.

Of course our data is rather limited. even though it's 1,455 people, we don't have that many people with disease. So the nearest we can get to estimating the dose response curve with the liver enzymes and this is the relationship between urinary bisphenol A levels in multiples of standard deviation and the logged gamma-glutamyl transferase levels. And as you see that association is linear against the logged liver enzyme level. so we have a very clear dose response relationship in this data.

CHAIRMAN PHILBERT: One minute.

DR. MELZER: We were asked by the Journal to undertake a series of sensitivity analyses. These included alternative waiting for the complex sampling in the NHANES study, removal of outliers, alternative ways of

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1 dealing with the creatinine adjustment for
2 urine concentration, removing groups; for
3 example, the people with disease and adjusting
4 for alcohol intake as well as adjusting for
5 other phenols in the data set. There were no
6 associations with three other key phenols with
7 estrogenic activity and adjusting the models
8 for them made no difference.
9 Our conclusions therefore are that
10 in the NHANES 2003-4 sample representative of
11 the U.S. adult population, high urinary BPA
12 concentrations are associated with these two
13 common diseases: diabetes and cardiovascular
14 disease and with clinically abnormal liver
15 enzyme levels. The priorities we believe as
16 a research group is to replicate. We have
17 done a partial replication on the younger end
18 of the sample. That's the 10 to 17-year-olds
19 which we are about to submit and that does
20 give some support for the liver enzyme
21 changes. We need to show that these
22 associations are predictive and we need to

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1 understand the mechanisms.
2 I'd like to state that the funding
3 was completely independent and with no
4 conflict of interest reported. I'd like to
5 thank very much the CDC for releasing this
6 wonderful data to the research community
7 internationally.
8 CHAIRMAN PHILBERT: Thank you very
9 much and I apologize for misstating your
10 title.
11 Are there any questions for Dr.
12 Melzer? Dr. Hu?
13 DR. HU: Of course this is where
14 as a molecular epidemiologist I get very
15 excited seeing one of the very first studies
16 of this nature.
17 A key question is, you know, it's
18 a cross-sectional study of course. You have
19 a single measure of urinary BPA and one
20 potential explanation is that somehow urinary
21 BPA at that point in time is an adequate
22 reflection of body burden or exposure that has

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1 happened before and it would seen to me that
2 you could strengthen that assumption if you
3 could show that there was tracking of BPA use.
4 In other words, saying people who had high BPA
5 were using the same kind of, or a portfolio of
6 Nalgene bottles, of this and that, and they
7 would continue those use patterns. Is there
8 any data to support that?
9 DR. MELZER: The Calafat group, in
10 developing the assay, looked at a variation
11 across the day and concluded that a single
12 urine sample was fairly good at placing people
13 in quartile of BPA exposure over a week or so
14 and that's pretty well the only data I've
15 seen.
16 We must bear in mind though that
17 there is a bias towards the null in taking a
18 single sample. So if we took, having a single
19 sample introduced is more variation than you'd
20 expect from multiple samples. If we had
21 multiple samples, we'd expect a stronger
22 association on a weaker one. So the bias in

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1 this case is actually supporting the analysis.
2 CHAIRMAN PHILBERT: Dr.
3 FitzGerald?
4 DR. FITZGERALD: Thank you very
5 much for the very interesting paper.
6 As you mentioned, the
7 cardiovascular conclusions are based on very
8 small numbers of people. And while you have
9 a signal, an apparent signal for coronary
10 heart disease, you've absolutely zero signal
11 for stroke. So did you look for a
12 relationship with blood pressure, which is
13 obviously a more prevalent condition?
14 DR. MELZER: Yes we did and there
15 was no association.
16 DR. FITZGERALD: So have you any
17 thoughts about plausibility around that
18 failure of internal consistency?
19 DR. MELZER: Well, my
20 understanding of the epidemiological risk
21 factors for stroke versus cardiovascular
22 disease is they are rather different.

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cardiovascular disease is much more driven by the lipid and other changes, is my understanding. The numbers are very small. It does need to be replicated as soon as possible. There is another wave of data in NHANES in which BPA is being measured. So I think as a research group we'd say that's the priority, to look at it again.

CHAIRMAN PHILBERT: Other questions?

Thank you very much.

The next presentation is from Ms. Buermeyer from the Breast Cancer Fund.

MS. COLLINSON: Hi. Actually, my name is Ellie Collinson. Nancy Buermeyer was unable to join us, but I'm also speaking on behalf of the Breast Cancer Fund. And I wanted to thank you all for your time and attention to this issue, and for your service for our country's public health.

Breast Cancer Fund is a national organization that focuses solely on preventing

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1 breast cancer by identifying and advocating
2 for the elimination of the environmental links
3 to the disease.
4 Today a U.S. woman's life time
5 risk for breast cancer is greater than one in
6 eight. In 2007, an estimated 240,500 women
7 were diagnosed with breast cancer, invasive
8 and in situ, and 40,500 died of the disease in
9 the United States. Breast cancer is the
10 leading cause of cancer death among U.S. women
11 aged 35 to 44.
12 No more than 10 percent of breast
13 cancers occur in women with a genetic
14 predisposition for the disease. Even when all
15 the traditional risk factors including genetic
16 history, reproductive history, diet, exercise
17 and alcohol are aggregated, more than half of
18 U.S. breast cancer cases remain unexplained.
19 Not surprisingly, an increasing body of
20 evidence is linking synthetic chemicals with
21 the nearly three-fold increase in breast
22 cancer rates in the lat 40 years. Bisphenol

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A is high on our list of chemicals of concern.

A growing body of evidence links exposure to BPA with drastic changes in the development of the reproductive system and mammary glands. BPA mimics estrogen and can have devastating effects at extremely low levels. For example, recent studies at Tufts University found that exposing mice in utero to BPA at doses well below BPA's established safe harbor levels alters mammary gland development in ways associated with the development of breast cancer in both rodents and humans.

BPA has also been linked to early puberty in girls which in turn is linked to an increased risk of breast cancer later in life. Increasing evidence is showing that when it comes to chemicals, it's not just the dose that makes the poison; the timing of exposure also matters. Prenatal, infant, and childhood development are all critical windows of exposure and should be treated with heightened

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concern. Infants and children are not just smaller adults; they are still developing and are changing almost every day. A small dose of a chemical can have a devastating impact one day, where as a few days or weeks later the same chemical may not have the same effect. This is because the endocrine systems of children are incredibly sensitive and are constantly sending signals to the brain and vice versa to direct growth. Endocrine-disrupting compounds like BPA interrupt this chemical conversation and while the effects may not show up for many years, this interruption can set children on a path for later life diseases such as breast cancer.

When it comes to protecting our children, we should be doing everything we can to act on early warnings of harm. Overwhelming evidence has clearly shown that disastrous health effects have occurred from low dose exposure to bisphenol A. As such, we should not be allowing the use of BPA in

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1 containers that come in contact with food or
2 any other product through which a pregnant
3 woman or child may be exposed.
4 On behalf of our over 70,000
5 members throughout the country, we implore
6 this panel to take a more comprehensive
7 approach to reviewing BPA that looks at
8 independent studies, an examination of the
9 low-dose effects of BPA exposure on fetuses
10 and infants, and the relationship between
11 early life exposures to BPA and later life
12 breast cancer and other diseases.
13 Thank you for your time and
14 attention to this critically-important public
15 health issue.
16 CHAIRMAN PHILBERT: Thank you very
17 much.
18 Questions?
19 Thank you.
20 MS. COLLINSON: Thanks.
21 CHAIRMAN PHILBERT: The next
22 presentation is from Dr. Rangan from Consumer

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Reports.

DR. RANGAN: Thank you. Consumer's Union appreciates the opportunity to make comment here today to you. I'm speaking on behalf of not only Consumer's Union, but Consumer Federation of America as well.

My name is Urvashi Rangan; I'm a senior scientist and policy analyst at Consumer Reports. I've been advising our test, reporting and policy action of various risk issues for over a decade. Consumer's Union reaches approximately 20 million people every month with our independent information. We are a non-profit organization whose sole goals since 1936 is to help consumers make the most informed purchasing decisions in the market place.

Our scientists believe that FDA's draft assessment of BPA for use in food contact applications does not do a sufficient job of presenting the evidence and risk posed

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by BPA given the mounting scientific evidence. We believe that materials made from BPA should not be used in any food contact application and should be replaced with safer alternatives. If this were a pre-market approval meeting for whether BPA was safe for use, we'd all be hard-pressed to actually green light this substance at the current time to be used as widespread as it is in the marketplace.

We've had a long history on this issue. We were one of the first organizations to test products for BPA and published our findings of BPA in baby bottles almost a decade ago where we warned consumers then about the potential risks. We've recently tested bottles that came to be BPA free. We've also published advice on how consumers can reduce their direct exposure to BPA and we have long supported strong legislation to ban BPA from children's products and food and beverage containers.

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1 Since our first study, hundreds of
2 studies have been published showing a wide
3 range of effects in animals at low doses.
4 We're seeing the human studies and while the
5 study today correlating or associating BPA
6 exposure with diabetes and cardiovascular risk
7 is a very interesting new study, the data is
8 not new and why the FDA hadn't done this
9 analysis in the first place is definitely of
10 question in our minds. We believe that due to
11 the fact that there are a wide range of
12 adverse effects showing up in animal studies
13 at the levels currently circulating in the
14 U.S. population, we are very concerned that
15 this leaves a very narrow margin of safety.
16 The NOAEL, no observable effect level, of five
17 milligrams per kilogram per day used in the
18 FDA analysis is sorely outdated and based on
19 only a few large-dose studies. We agree with
20 the previous comments here today on the
21 shortcomings of those studies and the need to
22 integrate modern day 21st-Century toxicity

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tests into the calculation of the risk and safety assessment for a very questionable chemical that's on the market today. Traditional linear dose response curves may not simply apply to this chemical. That should not be credence to just assume that this chemical is safe at this time.

In addition, the range of toxic end points considered in this or any safety assessment must be expanded beyond reproductive teratogenic or carcinogenic end points. Toxic end points such as diabetes, cardiovascular risk, asthma, neuro-behavioral effects should be a standard in inclusion in safety risk assessments. We suggest that FDA convene an independent expert panel with representatives from consumer and unbiased scientific groups to discuss how to include these modern day toxicity tests and results into future risk assessments.

I won't be redundant with the GLP studies. We agree with Dr. Vom Saal's

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assessment of those studies and again reiterate that all of the hundreds of other studies also need to be weighted into the calculation of safety and risk from BPA.

One note on infant exposure assessment.

CHAIRMAN PHILBERT: One minute.

DR. RANGAN: We find the assumptions that are being made by FDA to be slightly erroneous. Don't forget after bottles, you have sippy cups where juice, which is acidic, will sit in the sippy cup. So there are many other ways that infants can also be exposed besides the first two months of life and a baby bottle that's only being washed for the first two months. That's erroneous analysis and needs to be cleared up to deal with infant exposures.

The safety of BPA at current exposure levels in the U.S. population simply has not been demonstrated. It's fast clearance rate and yet constant elevated

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levels are reason for concern that people are being exposed to excessive levels that they cannot clear on a daily basis. But the public's hearing contradictory messages from our same government about the level of concern and consumers want to know how they can protect themselves, not be the guinea pig in the experiment.

The FDA depiction of BPA safety is like a picture taken at very low resolution where the finer --

CHAIRMAN PHILBERT: Thank you. You've exhausted your five minutes.

DR. RANGAN: Okay. Thank you.

CHAIRMAN PHILBERT: Thank you very much.

The next presentation is from Ms. Kirsten Stade from Center for Science in the Public Interest.

MS. STADE: My name is Kirsten Stade and I am here representing the Integrity and Science Project of the Center for Science

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in the Public Interest, a non-profit nutrition and health advocacy group.

We are vitally concerned about the safety of packaging used in the nation's food supply, particularly for foods intended for children who are in their most sensitive developmental stages. We are very concerned about the potential health effect of bisphenol A which is widely used in food packaging. Detrimental health effects have now been documented in nearly 200 independent studies and we are concerned because the Food and Drug Administration has largely dismissed these studies in its draft assessment of bisphenol A for use in food contact applications, choosing instead to rely on two studies funded by the very industries that profit from the sale of this chemical.

In the United States bisphenol A is chiefly manufactured by Dow Chemical and Sabic Innovative Plastics. And to reach its conclusion that bisphenol A is safe at current

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levels of human exposure, the FDA relied on two studies funded by subsidiaries of the American Chemistry Council, which is a trade organization that represents both of these manufacturers. Employees of these companies and others that manufacture BPA were also among the co-authors of both these studies.

It is well documented in the scientific literature that there is a funding effect in scientific research. The funding effect has been examined in tobacco research, medical research, nutrition research and environmental research, especially in areas involving exposure to potential toxins. Without exception, this research shows that studies conducted by scientists with employments or other financial ties to industry are much more likely to come up with results that would benefit their employers or funders. Indeed, when it comes to bisphenol A, the effects of conflict of interest on research outcomes have been documented by none

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1 other than Dr. Frederick vom Saal who spoke
2 here today because he is the foremost
3 independently- funded BPA researcher in the
4 nation.
5 In 2005, vom Saal reported in
6 Environmental Health Perspectives a peer
7 review journal published by the National
8 Institutes of Environmental Health Sciences
9 that while a large fraction of independent
10 studies showed toxic effects from BPA,
11 industry-funded studies unanimously reported
12 no effects. Today, of the hundreds of
13 independently-funded studies conducted as of
14 August of this year, 93 percent showed
15 significant health effects from low-dose
16 exposure to bisphenol A. Of the 14 industry-
17 funded studies performed to date, none have
18 showed health effects.
19 The FDA needs to take into account
20 these funding effects when it decides what
21 studies will inform its product safety
22 assessments, especially with respect to a

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1 product as ubiquitous as BPA. Instead, it
2 conducted an imbalanced review of the
3 literature. The resulting white paper issued
4 for this meeting reflects this imbalanced
5 review. The conclusions of the FDA assessment
6 are not only at odds with those of the vast
7 majority of independent studies of BPA, but
8 also with those of all three studies released
9 by the National Toxicology Program over the
10 past year. These studies have come under
11 scrutiny because they were influenced by
12 scientists with financial stake in the
13 production of BPA. And yet even these studies
14 expressed some concern for the developmental
15 effect of this chemical.
16 We hope this committee will reject
17 the conclusions drawn in this draft assessment
18 and order the FDA to conduct a more thorough
19 impartial review of the scientific findings
20 about the health effects of this chemical.
21 The safety of our food supply and the health
22 and safety of our children depends upon it.

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Thank you.

CHAIRMAN PHILBERT: Thank you very much.

Are there questions?

Thank you.

The last presentation in this session is from Tracey Miedema from Stahlbush Island Farms, Inc. and Farmer's Market Foods.

We had some indication that she may not be able to make it here.

If not, that concludes the presentations for this session.

Dr. Pena, are there any housekeeping items?

DR. PENA: No. We'll just reconvene at 1:00 p.m. this afternoon.

CHAIRMAN PHILBERT: Thank you, all, very much.

(Whereupon, the hearing was recessed at 12:03 p.m. to reconvene at 1:00 p.m.)

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A-F-T-E-R-N-O-O-N S-E-S-S-I-O-N

1:03 p.m.

CHAIRMAN PHILBERT: Thank you, ladies and gentlemen. We are reconvened. Before we go any further, I need to read a statement.

Both the FDA and the public believe in a transparent process for information gathering and decision making. To ensure such transparency at the open public hearing session of the advisory committee meeting, FDA believes that it is important to understand the context of an individual's presentation. For this reason, FDA encourages you, the open public hearing speaker, at the beginning of your written or oral statement to advise the committee of any financial relationship that you may have with the sponsors, their products, and if known, their direct competitors. For example, this financial information may include a sponsor's payment of your travel, lodging or any other

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1 expenses in connection with your attendance at
2 the meeting. Likewise, FDA encourages you at
3 the beginning of your statement to advise the
4 committee if you do not have any such
5 financial relationships. If you choose not to
6 address this issue of financial relationships
7 at the beginning of your statement, it will
8 not preclude you from speaking.
9 We're going to move directly into
10 the second session of public statements. And
11 the next speaker will be Dr. Van Miller, BPA
12 Producers and the Polycarbonate/BPA Global
13 Group. Thank you.
14 DR. VAN MILLER: Good afternoon.
15 By way of introduction, I'm a board certified
16 toxicologist and have been practicing in the
17 field of toxicity and risk assessment for more
18 than 25 years. Today I'm here to comment on
19 behalf of the Polycarbonate/BPA Global Group
20 which is comprised of the leading
21 manufacturers of bisphenol A and polycarbonate
22 plastic.

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1 Overall, we agree with FDA's draft
2 assessment. FDA's approach was thorough,
3 objective, transparent and strongly supported
4 by scientific data. The methodology that FDA
5 used to analyze the data applied well-accepted
6 scientific criteria to assess approximately
7 250 scientific research papers, reviews and
8 assessments.
9 As discussed by Dr. Bucher, the
10 National Toxicology Program recently finalized
11 its assessment of BPA. The conclusions are
12 consistent with earlier assessments and these
13 assessments were reviewed and analyzed in
14 FDA's report. We agree with the FDA's
15 assessment that the studies in which NTP's
16 some-concern decision is based are mechanism-
17 driven and suffer from numerous experimental
18 design flaws such that these studies cannot be
19 relied on for regulatory decision making.
20 We also agree with FDA that a
21 guideline study to evaluate potential nervous
22 system and behavioral effects would ad

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1 confidence to the interpretation of existing
2 data. Such a study is underway and we expect
3 to release these results in 2009.
4 Also mentioned earlier was a
5 recent study published by Leranth et al that
6 examines synaptogenic response in
7 ovariectomized monkeys and which was published
8 after the completing of the FDA report. The
9 results reported in this study should not
10 change FDA's conclusions. Among other things,
11 Leranth used a road of exposure, specifically
12 an implanted mini-pump that is not appropriate
13 to risk assessment to humans, because, as
14 mentioned earlier by the FDA, it bypasses
15 first pass metabolism and subsequent
16 excretion. In addition, this study did not
17 measure whether there were actual neuro
18 behavioral impacts such as changed behavior.
19 Evidence of adverse impact is necessary in the
20 use of results of any study in the risk
21 assessment process.
22 This morning you also heard of the

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1 data from a cross-sectional study of BPA that
2 will be published soon. Due to inherent study
3 design limitations, their findings on BPA do
4 not support a cause and effect relationship
5 between BPA and any adverse health effects.
6 With a chemical such as BPA that is rapidly
7 metabolized and eliminated, the CDC's NHANES
8 spot sample data analyzed by Lang show only
9 the exposure on the day of the sample. Thus,
10 the data cannot provide a cause and effect
11 relationship for a health effect developed
12 over a long term such as diabetes or
13 cardiovascular disease.
14 As FDA's robust analysis shows,
15 studies conducted in compliance with
16 international guidelines using validated end
17 points and with good laboratory practices that
18 use the oral route of exposure, provide a
19 strong, appropriate and sufficient basis for
20 the assessment of risk to the human
21 population. Similar studies with the natural
22 hormone estradiol published by Dr. Tyl show

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that the animal species and strains used in these studies are sensitive to the effects of estrogen and that BPA does not mimic estrogen.

In summary, FDA's assessment and the data supporting it allows the FDA to conclude with confidence that: (1) exposure of adults and infants to BPA is low; (2) BPA is readily metabolized in adult and neonatal humans and does not accumulate in fat or other organs; (3) BPA is not a selective reproductive or developmental toxicant; and (4) BPA does not minim estrogen effects either on the time of puberty or in male sexual organ development, including the prostate.

CHAIRMAN PHILBERT: One minute.

DR. VAN MILLER: There is no indication that BPA is a neurotoxicant in standard guideline studies including behavioral measurements from the two-generation study of Ema et al and clinical observations in the multi-generation studies of Tyl.

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1 And last, the appropriate risk
2 assessments using internationally accepted
3 guideline studies meaning the oral route of
4 administration indicate large margins of
5 safety when using FDA's very conservative
6 approaches. Thank you.
7 CHAIRMAN PHILBERT: Thank you very
8 much.
9 We have time for one brief
10 question.
11 Hearing none, thank you very much.
12 The next presentation is from Dr.
13 Janssen from the Natural Resources Defense
14 Council.
15 DR. JANSSEN: Good afternoon. My
16 name is Sarah Janssen. I'm a physician, board
17 certified in occupational and environmental
18 medicine and I have a faculty position at the
19 University of California in San Francisco.
20 I'm also a scientist with Ph.D. training in
21 reproductive biology and I have expertise in
22 endocrine disruption.

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1 I'm here giving comments on behalf
2 of the Natural Resources Defense Council, or
3 NRDC. We are a non-governmental environmental
4 group based in New York and the comments I'm
5 giving, we have no conflicts of interest to
6 report related to bisphenol A.
7 NRDC strongly disagrees with the
8 draft FDA conclusion that current levels of
9 exposure to BPA are safe for human
10 consumption. Scientific experts such as
11 myself who have reviewed the evidence would
12 not agree that BPA meets FDA's definition of
13 safe. Focusing their assessment on only two
14 industry-funded studies, FDA has disregarded
15 a large body of literature, demonstrating a
16 wide array of adverse outcomes from current
17 levels of exposure.
18 A GLP study may meet certain
19 guidelines, but it doesn't mean that the
20 investigators have asked the right question or
21 looked for the right end points. Moreover,
22 FDA has not used an appropriate NOAEL as the

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1 point of departure for margins of safety. The
2 end points chosen should be consistent with
3 the state of current scientific evidence. As
4 examples, in the NTP report BPA was shown to
5 cause neuro-behavioral changes and prostate
6 lesions at doses of equal or great than 10
7 micrograms per kilogram bodyweight per day.
8 This dose is over 500 times lower than the
9 NOAEL chosen by FDA.
10 In my remaining time I want to
11 speak to the relevance and clinical
12 significance of precancerous lesions. Both
13 the EPA cancer guidelines of 2005 and the
14 amended IARC monographs preamble 2006 identify
15 precancerous lesions as relevant to a
16 determination that a substance can cause
17 cancer. And when diagnosed in humans, these
18 precancerous lesions result in immediate
19 medical intervention.
20 Regarding mammary cancer,
21 precancerous lesions including ductal
22 carcinoma in situ have been found after

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1 perinatal exposure to BPA. In women, this
2 pathological diagnosis is recognized as an
3 increased risk for cancer, so much so that the
4 standard of care is a surgical resection
5 followed by radiation and chemotherapy with
6 tamoxifen. Clearly, this is a pathological
7 diagnosis with great public health
8 implications. In addition, a recently
9 published study found when normal human breast
10 tissue was exposed to low environmentally-
11 relevant doses of BPA, there were changes in
12 gene expression consistent with those found in
13 a highly aggressive type of breast cancer
14 associated with poor survival. This study
15 adds further weight of evidence for the
16 ability of BPA to cause mammary tissue changes
17 that are associated with development of
18 cancer.
19 Regarding prostate cancer,
20 perinatal exposure to BPA has been shown to
21 alter prostate development and predispose the
22 prostate to preneoplastic lesions, including

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the development of high-grade PIN lesions. In humans, high-grade PIN lesions are highly predictive of the development of cancer with over one-third to one-half of men on repeat biopsy found to develop cancer.

The relevance of animal models and significance of precancerous lesions for human disease is clear, and as many other speakers have already identified during their comments today, cancer outcomes are just a part of the wide array of adverse effects associated with exposure to BPA.

The conclusions that FDA reaches have the potential to change levels of exposure to a chemical linked to diseases and conditions affecting millions of Americans. We agree that if this were a premarket approval hearing, we would be hard pressed to approve the use of BPA as a food additive.

NRDC believes that BPA should not be approved as a food additive and BPA should be banned from uses for this condition. We

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urge you not to make a rush decision and reject this draft assessment in favor of a report that uses the full range of science, not just industry-funded studies focused on traditional and outdated end points.

CHAIRMAN PHILBERT: One minute.

DR. JANSSEN: Thank you for your time.

CHAIRMAN PHILBERT: Thank you.

Are there any questions?

Thank you very much.

DR. JANSSEN: Thank you.

CHAIRMAN PHILBERT: There's going to be a brief intermission while we make the process more open for our cameras. We're going to turn the podium so that the speakers can be seen. Thank you.

Our next speaker is Ms. Rawlins from the Breast Cancer Action Group in San Francisco. Thank you very much.

MS. RAWLINS: Good afternoon. My name is Rachael Rawlins. I'm an attorney, I'm

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a breast cancer survivor, and I'm another. I'm here today on my own behalf and on behalf of Breast Cancer Action.

Starting about six years before I was diagnosed with very aggressive breast cancer, I stored all my water in a polycarbonate bottle. I filtered it and I stored in my fridge. That was at home. At work, I had one of those five-gallon polycarbonate bottles at my law firm.

I don't know if BPA caused or contributed to my breast cancer, but I do know that there's a study that says that overexposure to BPA could be an underlying factor in the aggressiveness, if not the causality, of breast cancers. I have a copy of that study for you today.

The FDA says that it does not need to fully consider the mammary gland as an end point because the NTP rated the mammary gland as of only minimal concern. Although originally classified as of some concern, the

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1 Science Board voted to change the
2 classification to minimal concern. The vote
3 as to whether it was of some concern or of
4 minimal concern was five in favor of some,
5 seven opposed, with two people noting the lack
6 of clarity as to the distinctions between
7 these categories. Not only are the categories
8 amorphous, but what the FDA seems to be asking
9 throughout the report is how much proof there
10 is of harm, not how much proof there is of
11 safety. This is a clear violation of today's
12 statutory standards.
13 Until 1958, the burden of proving
14 that a food additive was unsafe fell on the
15 government. The Food Additives Amendment Act
16 of 1958 shifted this burden by creating a
17 presumption that a food additive is unsafe
18 until proven otherwise. Now there must be
19 evidence that it is safe. It doesn't really
20 matter if you're not sure if the blood samples
21 finding adult exposures at 500 times the FDA's
22 estimates are sufficient, or if the hundreds

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of low-dose studies are adequate. You simply cannot dismiss the risk. Not only can you not support a finding of safety, but you have evidence of actual harm.

As to specific problems with the study, the study does not consider all food contact sources. Not only did I drink my water from a polycarbonate bottle, but I also had some canned vegetables, some soups, some beans. I also drank wine. I understand from the European study that has a significant amount of BPA. I also ate some pizza. I understand that the pizza cartons, because they're made on recycled paper with ink that came in contact with BPA, that that's another BPA source. The FDA report makes no effort to look at all the sources of BPA exposure from food contact sources or even from other sources. I don't think you can come up with a finding of safety unless you look at the total exposure. A food contact source exposure is not safe in itself if it's putting

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1 you over the top. I think you have to look at
2 the blood levels and the total exposure to
3 decide if BPA is safe in people or not.
4 Not only that, but the statute
5 says you have to consider the cumulative
6 effect, taking into consideration other
7 chemically or pharmaceutically related
8 substances. So you must consider other
9 estrogenic chemicals. I have another study
10 for you here today that shows that when you
11 have different chemicals in combination, even
12 though one particular chemical may be at the
13 no-observed effect level, when you put them
14 together there is indeed an effect.
15 The study also fails to quantify
16 neonatal exposure and fails to consider
17 exposure from breast milk from the heavily
18 contaminated mothers, pump with machines
19 possibly containing BPA and stored in the
20 freezer in polycarbonate bottles. That is the
21 milk that my children drink.
22 The FDA will lose all credibility

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if you refer them this draft study. The breast cancer survivors, the breast cancer advocacy groups and most especially the moms will not stand for this risk. I'll continue to talk to other moms in line at the grocery store, on the gym, on the street, at the bus stop. In this age of the Internet, the studies have and will continue to circulate. The public will not support this decision. There are alternative products and we don't need BPA. Thank you for you time.

CHAIRMAN PHILBERT: Thank you very much.

Questions? Yes?

DR. BUSHNELL: Yes, I have a question regarding the change in the law in 1958, regarding food additives. Does this also apply to food contact substances?

MS. RAWLINS: I believe that it does.

DR. BUSHNELL: Okay.

CHAIRMAN PHILBERT: Yes?

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DR. VANDENBERG: You mentioned some studies. Maybe you're about to hand them to us.

MS. RAWLINS: Yes.

DR. VANDENBERG: I just want to make sure. We've received many, many studies, but if you've got some that we may not have, we'd certainly like to get copies. Maybe that's what you're doing now.

MS. RAWLINS: Yes, this study was referred to by an earlier speaker from NRDC. "It's Bisphenol A Induces a Profile of Tumor Aggressiveness in High-Risk Cells from Breast Cancer Patients." I have five copies of it here.

DR. VANDENBERG: Thank you.

MS. RAWLINS: The other study I have refers to combining ex-estrogens at levels below the individual no-observed effect concentrations, how it dramatically increases steroid hormone action. I just have one copy of this one.

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DR. VANDENBERG: Thank you.

CHAIRMAN PHILBERT: We will make sure that the committee gets copies of those. Thank you very much.

Our next speaker is Ms. Feinberg from For a Better Bronx, SHARE, the New York Breasts and Ovarian Cancer Advocacy Organization.

Is Ms. Feinberg here?

If not, then we'll move on to Ms. Rogers from Reproductive Health Technologies Project. Thank you.

MS. ROGERS: Good afternoon. I want to thank the FDA's Science Board BPA Subcommittee for convening this meeting to discuss BPA for use in food contact applications.

My name is Jennifer Rogers and I am the Programs and Policy Director for the Reproductive Health Technologies Project. RHTP is a national non-profit advocacy organization. Our mission is to advance the

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ability of every woman of every age to achieve full reproductive freedom with access to the safest, most effective and appropriate technologies for ensuring her health and controlling her fertility.

At RHTP our work focuses on a broad range of national public health policies and we've often depended upon the scientific evidence provided by agency reports to help guide our programs and policies.

RHTP does not accept any funding from for-profit companies, drug or device manufacturers.

As mentioned in previous testimonies, BPA is one of the many synthetic endocrine disrupter chemicals. Endocrine disrupting chemicals mimic or block hormones and disrupt the body's normal reproductive functions. A growing body of evidence indicates that endocrine disrupting chemicals, including BPA, are harmful to the developing fetus, infant and child, even at low levels.

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1 Moreover, numerous studies have found that
2 these chemicals are associated with a host of
3 reproductive health problems in both men and
4 women.
5 The FDA plays a critical
6 regulatory role in BPA's use in plastic food
7 containers, bottles, tableware and plastic
8 linings of canned foods. RHTP is concerned
9 with the FDA draft report that has declared
10 BPA safe for the use of these items based
11 exclusively on two studies, both of which are
12 funded by industry, both of which use animal
13 models which have been shown to be non-
14 responsive to estrogen.
15 We understand these two studies
16 are compliant with good laboratory practice,
17 but we question why the FDA has not included
18 hundreds of other high-quality peer-reviewed
19 research published on BPA and its impact on
20 health in this review. Rigorous scientific
21 studies published in reputable and peer review
22 journals should help inform any public health

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1 risk assessment and having included
2 assessments carried about by other federal
3 agencies, including two review completed by
4 the National Institutes of Health. The new
5 study released tomorrow in JAMA underscores
6 this point.
7 Evidence-based peer-reviewed
8 science has long served as the gold standard
9 for policy making and regulatory decisions for
10 many federal agencies, particularly those
11 dealing with chemicals, health and the
12 environment. As a society we have come to
13 depend upon the government to utilize
14 scientific findings to develop sound public
15 policy that advances that the well being of
16 our citizens. Of concern to RHTP and many
17 organizations within and outside the women's
18 health community is the growing trend by the
19 government to manipulate science to advance
20 political or corporate interests over the
21 health and the safety of Americans.
22 We hope as the FDA reviews the BPA

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draft report that the scope of research included and a safety assessment is broadened to take into account the hundreds of research studies published in peer review journals by independent scientists as well as the several reports released from other agencies including the National Toxicology Program that have come to different conclusions on the safety of this chemical. Thank you.

CHAIRMAN PHILBERT: Thank you very much.

Questions from the subcommittee?

Thank you.

Next is Ms. Hughes from the American Nurses Association.

MS. HUGHES: Good afternoon. I'm Nancy Hughes. I am a registered nurse and I am here representing the American Nurses Association, and we welcome this opportunity to comment on the draft assessment of bisphenol A for use in food contact applications that's been issued by the

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subcommittee.

The American Nurses Association is the only full service professional organization that represents the interests of the nation's 2.9 million registered nurses. The ANA is actively engaged in reducing and eliminating toxic products from health care and educating the nation about chemical hazards, utilizing safer alternatives and keeping communities safe. A priority of the ANA is to advocate on behalf of the nursing profession which includes informing regulatory agencies on issues affecting public health.

The FDA safety assessment of BPA is particularly focused on developmental toxicity because of concerns raised by recent assessments including those of the National Toxicology Program, BPA, being an impurity that can be found in everyday food items such as epoxy-based food can liners and polycarbonate baby bottles. In this assessment, the FDA has concluded that an

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1 inadequate margin of safety exists for BPA at
2 current levels of exposure from food contact
3 uses. Thus, the FDA has determined that it
4 will not recommend that anyone discontinue
5 using products containing BPA.
6 The ANA strongly urges the FDA, an
7 agency charged with protecting our health and
8 the health of our children, to reconsider its
9 decision not to take action. The National
10 Toxicology Program, an interagency program
11 with the mission to coordinate, conduct and
12 communicate toxicological research across the
13 U.S. Government, has just released its final
14 report on the potential human reproductive and
15 developmental effects of BPA. The NTP report
16 affirms ANA's serious concerns about the FDA
17 decision.
18 The NTP concludes that there is
19 some concern about BPA effects on brain and
20 prostate development and behavioral effects in
21 fetuses, infants and children. In addition,
22 the NTP associate director has asserted that

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there is considerable uncertainty whether the changes seen in the animal studies are directly applicable to humans and whether they would result in clear adverse health effects and that the possibility that BPA may affect human development cannot be dismissed.

ANA is a firm advocate of the precautionary approach regarding dangers to public health. When an activity raises threats of harm to human health and/or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. This principle includes taking action in the face of uncertainty, and approach that is not evident in this FDA recommendation. ANA supports actions which reduce the use of the toxic chemicals requiring that less harmful chemicals be substituted whenever possible and create more streamline methods for removal of toxic chemicals from use.

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Safer alternatives are available and currently in use. Nalgene, a major manufacturer of plastic water bottles, and Playtex, a producer of many baby products, have announced that they are stopping using BPA. Major retailers such as Walmart and Toys R Us are phasing out the sale of BPA-containing bottles and other baby products. In a landmark decision, the Canadian government is poised to officially list BPA as toxic and is currently planning to ban its use in baby bottles and restrict levels in baby food cans. In addition, there's rising public concern across the U.S. as legislation banning or restricting the use of BPA has been introduced at both the state and federal levels.

Therefore, the American Nurses Association urges the FDA to ban the use of BPA in food, health care and children's products. And we appreciate the opportunity to comment on this important health issue.

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1 CHAIRMAN PHILBERT: Thank you.
2 MS. HUGHES: Thanks.
3 CHAIRMAN PHILBERT: Questions?
4 Thank you very much.
5 MS. HUGHES: Thank you very much.
6 CHAIRMAN PHILBERT: Next is Dr.
7 Wise from the Union of Concerned Scientists.
8 DR. WISE: Good afternoon. My
9 name is Amber Wise and I have a Ph.D. in
10 chemistry. I am here this afternoon to
11 represent the Union of Concerned Scientists,
12 which is a leading science base non-profit
13 working for a healthy environment and a safer
14 world.
15 I'd like to thank the panel for
16 allowing us to comment on this issue today.
17 The Union of Concerned Scientists
18 is troubled that the FDA is basing its
19 conclusions on two studies while downplaying
20 the results of hundreds of other studies that
21 show adverse effects from exposure to BPA. We
22 are calling on the FDA to provide more

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1 transparency into its decision making process
2 to ensure that the full weight of scientific
3 evidence is available to inform our policy
4 makers.
5 We've heard before today and I'm
6 going to say it again: You have concluded in
7 this draft report that "an adequate margin of
8 safety exists for BPA at current levels of
9 exposure." Although you cite only two
10 industry-funded studies that are "pivotal to
11 your safety assessment." Of these two
12 studies, one was never published and therefore
13 not peer reviewed. And the second used a
14 species of rat that is not susceptible to
15 endocrine disrupters and therefore seen by the
16 scientific community as inconclusive. Further
17 in the same letter you also admit that you are
18 aware of the reports from the Environmental
19 Working Group and the Chapel Hill BPA Expert
20 Panel both of which detail exposure hazards
21 and cite hundreds of academic and other peer-
22 reviewed studies suggesting BPA exposure is

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linked to a staggering number of health problems.

In fact, Dr. Twaroski this morning also admitted that to the existence of 8,000 different articles regarding this issue.

The primary method of human exposure to BPA is through food containers and this is the specific topic this panel is charged with addressing. Given that infant and small children's estimated exposure is 13 times higher than adults, as referenced in your draft report, and that a large number of studies have indicated behavioral and developmental disorders, this should cause the FDA to be especially careful in their decisions regarding the safety of this compound in containers designed to hold food for children and infants.

In the written comments that we have submitted I highlighted four recent studies on BPA exposure, three of which were from federal government laboratories; the CDC,

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the NIEHS and the NTP, and the fourth was from the Yale Medical School and published in a highly-regarding scientific journal, PNAS. Certainly these and other studies that we've heard about today merit closer attention in your decision making process as we have invested federal money and time in most of their outcomes.

Given the vast amount of data showing concern for exposure to BPA, the FDA's choice of relying on two industry-funded studies appears to be an example of cherry picking data with a potentially high cost of human health, the very public health you are charged with protecting.

We at the Union of Concerned Scientists are very interested in respecting the scientific process and utilizing the best available science in regulatory and decision making processes and we hope you are too. We call on the FDA to show a detailed account of their decision making process that went into

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identifying these two pivotal studies and why it would be acceptable to ignore or downplay the findings from these vast majority of other researchers. We also call on the FDA to make public any public any dissenting or minority opinions among your own scientific experts on this matter.

We thank you for allowing us the opportunity to speak this afternoon and hope you will take our concerns into consideration.

CHAIRMAN PHILBERT: Thank you very much.

Questions? No?

Just for clarification, because I've heard this in a couple of other comments too, the subcommittee did not write the report. We're constituted to review and provide commentary on the report.

DR. WISE: Okay.

CHAIRMAN PHILBERT: Okay. We're reviewing an FDA report, but your comments are greatly received nonetheless. Thank you very

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much.

The next speaker is Mr. Manuppello from People for the Ethical Treatment of Animals.

MR. MANUPPELLO: My name is Joseph Manuppello and I'll be presenting comments for PETA. PETA is the world's largest animal rights organization with more than 2 million members and supporters worldwide. We appreciate the opportunity to comment today on FDA's draft assessment of bisphenol A.

PETA promotes a precautionary approach to regulation and a human relevant approach to risk assessment. Along these lines two bills addressing BPA regulation have been recently introduced in Congress. Together these would prohibit the use of BPA in children's products and food containers. In addition, the BPA-Free Kids Act would require the CDC to study the health effects of BPA exposure in all age groups and in pregnant women. When introducing the Act, Senator

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1 Dianne Feinstein was quoted as saying, "We
2 cannot let the health of our children hang in
3 the balance while we wait for more studies
4 which could take several years." In fact,
5 history shows repeatedly that critical public
6 health measures have been delayed, often for
7 many years, because of misplaced trust in
8 animal tests.
9 For example, while landmark
10 epidemiological studies by the American Cancer
11 Society in the 1950s linked smoking to cancer,
12 for decades the tobacco industry cited tests
13 showing that animals forced to inhale smoke
14 such as these Beagle dogs did not develop
15 cancer. The story is similar for benzene
16 which was linked to human leukemia as early as
17 the 1920s and for asbestos with numerous
18 epidemiological studies conducted over more
19 than a century demonstrating its adverse
20 respiratory effects.
21 Now with BPA, FDA continues to
22 promote this reliance on animal tests with its

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