DR. vom SAAL: In rats they are suppressed; that's published, significantly. So that if you take a pregnant female rat relative to a non-pregnant female rat and try to model what the fetus is going to get from the non-pregnant female, it's totally different. You get a much longer rate of clearance. The terminal half-life changes quite dramatically.

DR. BENET: I don't recall the exact data, but Ugt levels are different in women than men and they're different in pregnant women than in non-pregnant women. But I don't know the --

DR. vom SAAL: Do you know --

DR. BENET: -- and I don't remember which way.

DR. vom SAAL: Okay.

DR. BENET: But there are a bunch of papers on this. I didn't know I was going to be quizzed.

DR. vom SAAL: Would you be so

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kind as to provide those, if you can?

DR. BENET: I'll see if I can find it, yes.

DR. vom SAAL: I will remind you.

CHAIRMAN PHILBERT: Dr. McCarver?

DR. McCARVER: Since we're still on PK discussion, there's another component that will need to be considered and I suspect FDA will know this when they start doing their PBPK modeling, and that is GFR. As was noted, I think, in some of the documentation, rodents appear to handle this by excretion into the bile and the stool more, whereas humans appear to be virtually 80 to 90 percent into urine. And the GFR does have a developmental ontogency and takes several months to reach adult values of GFR. So that's another factor that's going to have to be handled in terms of the modeling that goes forward.

CHAIRMAN PHILBERT: Are there additional questions from the committee?

DR. BUSHNELL: Yes, and I want to

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1 change the topic a bit. One of the things
2 that we heard a lot from the public commenters
3 was that there are other plastics available.
4 And we're talking about the risk of exposure
5 to BPA, but I am curious to know what would be
6 the consequences and the risks of removing it
7 from our environment. I mean, it's used to
8 seal cans and to keep the food fresher longer
9 sort of thing, so maybe comments from anybody
10 on the panel on this point would be of
11 interest to me.
12 CHAIRMAN PHILBERT: Ms. Lunder?
13 MS. LUNDER: Well, I'd like to
14 bring in the advocacy perspective. Because
15 when we're talking about BPA and talking about
16 mistakenly as a pharmaceutical, it draws into
17 question the cost and the benefit. And the
18 way that I believe FDA evaluates drug safety
19 uses a lot more of those early indications of
20 harm than is being discussed here. And that
21 seems very relevant given that there are
22 alternative formula packaging. Powdered

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formula is acceptable for most children; it's actually cheaper, and that liquid formula is packaged in No. 2 or No. 5 plastic, also sometimes in glass. So there wouldn't necessarily be, you know, huge costs associated with -- we've already seen the baby bottle market shift dramatically away from polycarbonate bottles. So, you know, the safety of adult exposures is one thing, but when infants are assumed to be taking in 12 to 25 times more BPA over six months of their life when it's making up the majority of their diet, I think that immediate precaution is warranted.

If this was a drug and it had some pharmaceutical benefit to children, that would be one thing, but it's detected in 93 percent of the population offering no tangible health benefit. And to me we eclipsed that point of benefit analysis.

CHAIRMAN PHILBERT: Dr. vom Saal and then McCarver.

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1 DR. vom SAAL: There's a paper,
2 2003 Environmental Health Perspectives by
3 Moriyama. And he measured college student
4 urine levels of bisphenol A in the early '90s
5 and then after the Japanese can industry
6 changed the formulation of their cans, and
7 recently we measured cans from Japan. They
8 have a little less than five percent of the
9 release of bisphenol A from comparable cans in
10 the United States. And what Moriyama showed
11 was that after that transition the correlation
12 that had existed between can use and body
13 burden of bisphenol A disappeared, there was
14 no longer any correlation after the change in
15 the lining of the can with the can use and
16 bisphenol A levels and there was a 2.2-fold
17 drop in body burden. That really suggests
18 that cans, at least in that population of
19 Japanese, accounted for more than 50 percent
20 of the body burden of bisphenol A.
21 DR. McCARVER: I really appreciate
22 the complexity of that question. Because I

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1 think as you look at this, this is very tough
2 because we are likely to be taking a compound
3 that we have a lot of data on, we've made a
4 lot of headway with in substituting in some
5 compounds that we have no data or even more
6 limited data only to be back having these same
7 discussions at some point in the future. So
8 I think this is a very weighty question.
9 I also think that it's very
10 critical that we not ban bisphenol A, and I'll
11 be on the record with that. And I don't mean
12 necessarily in foods, but I mean bisphenol A
13 is in a lot of other hard plastics. It does
14 a lot of very good things for us. It's in
15 bicycle helmets that protect children. It's
16 in lots of other things where we need the
17 hardness in order to get the protection. And
18 so I think we have to be balanced in this
19 assessment and step back.
20 Now I do believe that potentially
21 there could be some benefit to changing what's
22 in baby formula. But again, I think that too,

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even that decision has to be looked at very carefully based on the data that are available for the other options, and I don't know that data, so I can't comment.

CHAIRMAN PHILBERT: Thank you.

Dr. Hentges?

DR. HENTGES: I generally agree with what you said. It is a complex question and what is known about the alternatives is not nearly as great as what is known about bisphenol A. So I'll just agree with those comments and not repeat them.

But going back to the can coatings for infant formula in Japan, or just can coatings in general in Japan, by and large epoxy resins are still used as can coatings in Japan. They're not all that different from what is being used here. So they really haven't replaced them. It is quite a big challenge to replace epoxy resin coatings in all cans. That is not an easy thing to do at all. And that doesn't even address the safety

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1 question at all. But just the performance
2 aspect finding something that could be used to
3 replace epoxy resins in the full range of
4 canned foods and beverages and make sure that
5 they work, that's not easy and that has not
6 been done anywhere.
7 CHAIRMAN PHILBERT: John?
8 DR. VANDENBERG: Can I follow-up
9 on that question about that? It seems as
10 though what you're saying is that there is an
11 opportunity to reformulate the epoxy resins
12 that are used in cans. It's being used
13 differently in Japan than it is -- but I'm not
14 sure I'm understanding. Are you saying that
15 that is an option, that you can reformulate?
16 That raises the question then of course
17 whether the study that FDA refers to from '96-
18 '97 is relevant to today's exposures. Has
19 there been a reformulation of what's being
20 used in epoxy resin cans over the last 10 or
21 so years?
22 DR. HENTGES: Well, regarding

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infant formula, focused on that first, if we go from the FDA data, I think that's what you were referring to from '96, and then look at the more recent data from whether it's Environmental Working Group or from Health Canada, the numbers are not all that different. They may vary a little bit, but they're substantially the same.

But then looking at reformulation in general, I'm not sure I can really answer that completely, but I don't think epoxy resins in Japan are all that different from epoxy resin can coatings used here. And again, the epoxy resins are used very widely in Japan, just like they are here and everywhere else around the world.

DR. BUSHNELL: So to clarify, epoxy resins are different from the polycarbonate?

DR. HENTGES: They're chemically totally different, yes.

DR. BUSHNELL: Chemically totally

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1 different. But there is BPA in the epoxy
2 resins? There's contamination?
3 DR. HENTGES: In both cases
4 bisphenol A is used as the monomer or the raw
5 material to make a polymeric material.
6 Polycarbonate plastic is the one that's used
7 for baby bottles and so on. Epoxy resins are
8 widely used as protective coatings for example
9 on cans, but the chemistry is quite different.
10 DR. BUSHNELL: Okay. So the
11 polymers in the epoxies are different?
12 DR. HENTGES: Yes, totally
13 different.
14 DR. BUSHNELL: You don't get
15 degradation hydrolysis of the --
16 DR. HENTGES: Yes.
17 DR. BUSHNELL: Okay. Got it. So
18 would one possible scenario be to have
19 different regulations for baby bottles and
20 infant formula than for cans for adult
21 exposure? I suppose before the JAMA study
22 came out today, there might have been better

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agreement on that, but now there may be some concern for us adults too.

MS. LUNDER: It seems like an immediate -- oh, sorry.

CHAIRMAN PHILBERT: I had recognized Dr. vom Saal a while ago. Do you yield or would you like to be heard now?

DR. vom SAAL: I'll let you go.

CHAIRMAN PHILBERT: Thank you.

MS. LUNDER: It seems like an immediate response to reduce infant exposures as warranted given the considerable scientific uncertainty. As a parent of a three-year-old, my son was fed formula. He's onto other foods, but I never get that chance to protect his body, his young body, from those exposures he might have received from infant formula. I think that there are pressing questions that need to be answered, but the intensity of infant exposure begs immediate action where alternatives exist and are on the market now for alternative packaging.

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DR. vom SAAL: I would like to put the Chair in contact with Japan's leading person who has really worked on this issue for maybe the last 13-14 years, Dr. Koji Arizono, professor at the University of Kumamoto, who when I told him what our data were, such low levels of leaching of BPA from cans brought to me from Japan, he said those are exactly our data because they have a new polyester formulation. It's a trade secret, but I'm sure it's possible to figure out what that is or to find out, and he may have some more information.

CHAIRMAN PHILBERT: That would be very useful information and thank you for that. I suspect I may need a trip to Japan when our report is released.

Dr. McCarver?

DR. McCARVER: If in your deliberations you consider removing the liquid concentrates and liquid formulas off the market, I believe that is a problem. I do not

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1 believe this country should told to go to
2 powdered formula. I believe there are
3 certainly families out there that the risk of
4 incorrect dilution of powder would lead to
5 large electrolyte problems and I do not
6 believe that that is in the best interest of
7 children. Saying that if there's a
8 reformulation to happen on cans, that's a
9 different matter.
10 Similarly I want you to know that
11 there are some specialty formulas that do not
12 exist in powder form. They are only
13 formulated currently in liquid form, so I
14 don't believe that's going to be a quick
15 option for us to take.
16 CHAIRMAN PHILBERT: Thank you.
17 We, despite my best efforts, only have a few
18 minutes left. And I would like to just go
19 down the panel and offer you two minutes in
20 summation to help us address the charge
21 questions.
22 So, Dr. Hentges, if you'd like to

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take the first two minutes without very much forewarning, I'm afraid.

DR. HENTGES: Well, I think in general I would just kind of reiterate some of the comments that were made by John Van Miller in the earlier period. We do generally agree with FDA's draft assessment. We think it is very thorough, very comprehensive and it appropriately focuses on the right health concerns. We didn't really specifically address the research needs, but we do in general agree that additional research is appropriate. We've sponsored research, as you well know, the Tyl studies, and we continue to sponsor research. As John mentioned, we have a DNT study underway right now.

But in general, I think we strongly support the FDA draft assessment. We believe its appropriate and the conclusions are well-founded, well-supported.

CHAIRMAN PHILBERT: Thank you.

Dr. Thayer?

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DR. THAYER: Well, I'm just going to follow up on that comment that came earlier about how do you sort of look at this collection of literature and think about a dose. I just want to offer our observation. And 10 was a value that sort of came out at us. There were three well-conducted oral studies that reported behavioral effects at 10. For the prostate, but of those studies were at 10; one was oral and one was subcu to the neonate. I just wanted to pull that out.

DR. BUSHNELL: That's 10 micrograms per kilogram?

DR. THAYER: Yes.

DR. BUSHNELL: Thank you.

CHAIRMAN PHILBERT: Thank you.

DR. GRAY: I'd just like to thank you all for the opportunity to be here and to answer questions. And if you have any other questions in the future, follow up, be sure to contact me.

CHAIRMAN PHILBERT: Thank you.

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I'd like to reflect that back on all of you. If there is anything that you think that we've missed, or any additional information that you think might be helpful in our deliberations, I encourage you to provide them including contacts in Japan.

Dr. Benet?

DR. BENET: Not to repeat what I said, but the follow-up on the sulfate, knockout animal studies would tell you whether a sulfate is important or not. And pharmacogenomic studies of the Ugts in humans would tell you if a sulfate's not. So those kinds of studies can be carried out and we could find out how important or not important it is.

CHAIRMAN PHILBERT: Dr. McCarver.

DR. McCARVER: I think I can summarize mine fairly quickly. I don't believe the exposure estimates are conservative enough for the reasons I outlined earlier. I do believe that the end point data

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are so complex that it's extremely difficult to sort out. It does depend on whether or not a precautionary principle is being used as opposed to a proven principle. And those may relate again to the regulatory constraints that you're operating under. If you went to a precautionary principle, I would agree with Dr. Thayer that 10 microgram per kilogram would be more in line with a precautionary stance as opposed to a proven stance. And that's a conceptual decision that you will need to make.

I think the studies that are outlined are admirable. I do believe that we must find out which of the isoforms handles this so that we'll be able to do the modeling and I do believe that we're going to be needing to generate some exposure data in babies and, as I mentioned earlier, in premature babies. I thank you for the opportunity to be here.

CHAIRMAN PHILBERT: Dr. vom Saal?

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1 DR. vom SAAL: I also agree with
2 Dr. Thayer about that estimated possible dose
3 of 10 micrograms and that some pharmacokinetic
4 data, particularly information about babies is
5 really badly needed.
6 On the other hand, I presented
7 hundreds of studies just from animals and
8 there's a much greater stack of mechanistic
9 studies. How many more studies do we need to
10 know for you to address the criterion for
11 using bisphenol A in a food contact material,
12 which is that there has to be reasonable
13 certainty that there is no harm under the
14 intended method of use? And I don't see how
15 this call for three or four, five or six more
16 years of research, which is what industry
17 always does, you know, give us another five
18 years, give us another 10 years, then they'll
19 ask for another five years, and you know, we
20 could generate 10,000 studies and there would
21 still be skepticism. I mean, we have hundreds
22 of studies out there and the question you need

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to ask, is there reasonable certainty that there's no harm, given the extensive information that's available? The NIH group and the NTP have really answered that with regard to the current standards that are being proposed by the FDA based on the two Tyl studies, which I go back and I see serious flaws with. Thank you.

CHAIRMAN PHILBERT: Thank you.

MS. LUNDER: Let me be the fourth, I think, to weigh in for really considering the exposures of 10 micrograms per kilogram per body weight per day, five studies looking at the oral route of exposure finding permanent changes either to neurodevelopment or to the prostate. And I definitely see the FDA draft risk assessment as being critically flawed. It proposes some margin of safety that is really indefensible. Whether or not the JAMA study is replicated, the fact is that the exposures in the preliminary findings in adults are 27,000-fold lower than the no-

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1 effect level that FDA is proposing for adults.
2 Also, with the 10 microgram per kilogram per
3 day dosing level, you have infant exposure,
4 high-end infant exposures at a margin of
5 safety of two to five for formula-fed infants
6 in that highest risk group over the first six
7 months of their life.
8 Calling back the issue of cost and
9 benefit, we know that BPA is not critical;
10 it's not serving a health protective benefit.
11 Yes, we wouldn't want to phase out types of
12 formula that are not easily replaced and leave
13 infants stranded. But I think the urgency of
14 those exposures, the fact that liquid formula
15 can be packaged in No. 2 or No. 5 plastics,
16 which at least are things we have known about,
17 may not be quite as potent. Hormone
18 disrupters at low levels as additives in those
19 types of plastics, as we know, the body the
20 evidence suggests for bisphenol A exposures.
21 And in our written comments, we call into
22 question a number of the assumptions FDA used

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to dismiss the low-dose studies. Define emphasis on guideline studies and the fact that that's really reasonable for situations where there might be a conflict of interest or industry-funded studies where there is at least pressure to find and substantiate safety versus academic studies which are peer reviewed, which are reviewed critically for funding and have other sources of validation, as well as issues the FDA raises about short term exposure, small dose groups, small studies and I feel like that it's pretty illogical and inconsistent criteria used to dismiss the weight of evidence from the low-dose academic studies.

So, I thank you guys for the opportunity to participate.

CHAIRMAN PHILBERT: Thank you, all, very much.

Are there any further questions, comments from the subcommittee?

I would like to, before dismissing

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us, thank you all for your participation in this very important meeting. I want you all to know that this subcommittee is dedicated to looking at this matter with all seriousness. We thank you for the information that you've provided and for your time and dedication to this cause.

I would like to thank specifically the presenters this morning from the FDA and from the NTP, the panel for taking time out of your busy schedules to come and be with us, and for my fellow subcommittee members for the enormous time investment that you've already put in, and for the time investment to come.

With that, thank you, all, and have a safe journey home.

(Whereupon, the meeting was concluded at 3:28 p.m.)

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