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MAY 25, 2017**

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PUBLIC MEETING

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THURSDAY, MAY 25, 2017

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FDA

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Wiley Auditorium

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5001 Campus Drive

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College Park, Maryland 20740

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Reported by: NATALIA THOMAS

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A P P E A R A N C E S

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Food and Drug Administration

Center for Food Safety and Applied Nutrition

Director, Office of Cosmetics and Colors

Acting Chief Medical Officer

PUBLIC COMMENTS:

MONICA ENGBRETSON

Cruelty Free International

MEGAN POLANIN, Ph.D.

National Center for Health Research

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1 P R O C E E D I N G S

2 DR. KATZ: Okay. Good afternoon. We'll go  
3 ahead and get started. And I thank everybody for  
4 coming to our Public Meeting in preparation for  
5 the 2017 International Cooperation on Cosmetics  
6 Regulations Meeting which will be held in Brazil  
7 in July of this year.

8 I just would like to give you a few brief  
9 comments before I go ahead and get started.  
10 Basically, if anybody needs to leave the room,  
11 please go up to the back and someone will escort  
12 you to wherever you may need to go. When we're  
13 done with the meeting, again, we'll exit towards  
14 the back.

15 So, let me begin with just a little bit of  
16 some history, and then I will go ahead and begin  
17 my slide presentation. We also have two  
18 presenters that are on our list for today and we  
19 have people who have also opted to call in this  
20 year on WebEx.

21 For those who are on WebEx, just as a

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1 reminder, please make sure that your phone is on  
2 mute.

3 The purpose of the Public Meeting is really to  
4 go ahead and invite the public input on various  
5 topics of interest that may pertain the regulation  
6 of cosmetics. This may also help us in further  
7 discussions at our ICCR meeting that will be held  
8 July 12th through 14th in Brasilia, Brazil.

9 ICCR is a voluntary international group of  
10 cosmetic regulatory authorities that are from  
11 Brazil, Canada, the European Union, Japan and the  
12 United States. These regulatory authorities meet  
13 annually and have dialogues with relevant cosmetic  
14 discussions that are also important to our  
15 cosmetic industry and trade associations and other  
16 political groups.

17 The purpose basically of these meetings is to  
18 help us to develop consensus using the compatible  
19 laws, policy, rules, regulations and directives  
20 that may pertain to all of our governments. The  
21 important thing to keep in mind is that through

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1 all of our discussions, that it's up to each  
2 individual jurisdiction to use the information as  
3 they so please. ICCR does not make or create  
4 regulations, and, in fact, when ICCR's agenda  
5 consists of topics of interest to all the  
6 regulators that would not require implementation  
7 of new regulations in any particular jurisdiction.

8 So, this afternoon, what I'd like to do is to  
9 talk a little bit more about ICCR and its process,  
10 talking a little bit about the history of ICCR and  
11 how it came to be. I'd like to give a brief  
12 summary of what happened in ICCR-10 last year and  
13 talk about some of the upcoming issues for this  
14 year's meeting.

15 This slide is actually an old slide, but it's  
16 relevant because basically it talks about when the  
17 agency first started to deal with international  
18 harmonization. This policy was established back  
19 on October 11th, 1995. Part of the reason for  
20 this was basically to facilitate international  
21 trade and promote mutual understanding, facilitate

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1 exchange of scientific and regulatory knowledge by  
2 foreign government officials to the extent  
3 permissible by law, to accept equivalent standards  
4 compliance activities and enforcement programs of  
5 other countries, if such programs would meet FDA's  
6 level of public health protection and to avoid the  
7 lowering of public health protections. In other  
8 words, to avoid downward harmonization.

9 When the international harmonization efforts  
10 first started to take place, they took place on  
11 the drug and the device side and subsequently  
12 moved to cosmetics after several years. In fact,  
13 the first predecessor of ICCR was CHIC. Some of  
14 you may or may not remember CHIC in the audience.  
15 CHIC was the Cosmetic Harmonization and  
16 International Cooperation.

17 The first meeting of CHIC was held in April of  
18 1999 in Brussels and the host at that time was the  
19 European Union. The participants were Canada, the  
20 EU, Japan, and the United States, and the goal was  
21 to introduce international regulatory schemes,

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1 seeks areas of commonality for regulatory  
2 alignment and develop memorandum of cooperation.

3 CHIC met three more times before deciding it  
4 was time to disband in 2005. And part of the  
5 reason was we felt that the way CHIC was set up  
6 and its memorandum of cooperation, wasn't really  
7 established to try to deal with issues of  
8 relevance to the different jurisdictions. It was  
9 more of a way for us to get to know each other as  
10 regulators and to talk about things possibly of  
11 interest.

12 So, in 2006 ICCR was established and its first  
13 meeting in 2007 in Brussels. Part of the reason  
14 for establishing ICCR, as I mentioned, was  
15 basically for us to develop a cooperation and a  
16 way for us to deal with topics of mutual interest  
17 and really deal with the topics, not just  
18 superficially talk about how each of us regulates  
19 them.

20 The members initially were Canada, the  
21 European Union, Japan, United States, and in July



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1           of 2014, Brazil joined and became the fifth of our  
2           Steering Committee members.

3           We established ICCR with the terms of  
4           reference and we used the voluntary consensus  
5           model. And by this, I mean is that we all need to  
6           reach consensus before we agree to post a document  
7           and that a document is considered complete.

8           We also based the ICCR on ICH, VICH, GHTF  
9           precedents. This was basically to give us, again,  
10          some established way to move forward. The one  
11          difference between us and the others is that we  
12          decided that it was important to have input from  
13          our industry trade association partners, and to  
14          make them a partner at the table even though we,  
15          as the regulators, are the Steering Committee  
16          members.

17          This slide is really just posted to let you  
18          know where we've been over the last ten years or  
19          so. As you can see, the first meeting was in  
20          Brussels. Last year the United States hosted the  
21          meeting, and this year it will be held in Brazil.

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1           The work process is set up and it flows in the  
2           same way every year, we have an annual meeting  
3           with interim teleconferences. And depending upon  
4           what the issues are determine how many  
5           teleconferences we may have during the year, but  
6           we try to at least get together with quarterly  
7           calls. The venue rotates among the five regions,  
8           and as you would notice from the preceding slide,  
9           that you can see each of the five regions takes  
10          their turn.

11           For the United States, before each annual  
12          meeting, we will announce a Public Meeting in the  
13          Federal Register, such as this one. And we  
14          usually try to hold that anywhere from four to six  
15          weeks before the actual meeting. The hosting  
16          country or region chairs the ICCR meeting and it  
17          provides for the secretariat for that year.

18           And the ICCR may constitute a variety of  
19          subsidiary working groups, and some of those  
20          you'll hear about when I tell about the results  
21          from last year.

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1           So, the actual meeting structure has been  
2           fairly constant for the last four or five years.  
3           On the first day it's a regulators-only meeting,  
4           and that's where regulators will meet with each  
5           other, talk about issues that are relevant as for  
6           regulators.

7           The second day is a regulator-plus-industry  
8           meeting, and the third day is a regulator-only  
9           meeting, which, again, is used to talk about which  
10          documents need to be adopted and what the outcomes  
11          were of that meeting.

12          Following the meeting, a press statement that  
13          was developed will get posted.

14          The stakeholder open session is held on day  
15          two of the meeting, and that's where stakeholders,  
16          who desire, may have an opportunity to present.

17          The outcome of ICCR is posted now on our ICCR  
18          website, which has been in existence for about the  
19          last four years. On the website are deliverables,  
20          the accepted documents and we've actually gone  
21          back into time to the first ICCR are posted.

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1           So, this slide shows you the agenda items for  
2           the ICCR-10 that was held last year. I'm not  
3           going to go through each individual item I'm going  
4           to summarize them as I go through what the  
5           outcomes were from each and the meeting itself.

6           With regard to governance, the regulators  
7           provided an update on ICCR expansion and criteria  
8           and process. The outcome was that the ICCR will  
9           remain within the scope of the terms of reference  
10          and that the Steering Committee will continue to  
11          follow a consensus decision-making process.

12          The relevance of this is that as ICCR gets  
13          larger, it's important to keep in mind that we  
14          still believe consensus is the way to go as,  
15          opposed to a plurality or majority.

16          With regard to integrated strategies for  
17          safety assessment of cosmetic ingredients, ICCR  
18          adopted the document called Integrated Strategies  
19          for Safety Assessment of Cosmetic Ingredients and  
20          the terms of reference was posted to the website.

21          With regard to aggregate exposure assessments

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1           for ingredients in personal care products and  
2           cosmetics, a formal presentation was made by  
3           industry and there was no direct outcome from  
4           that.

5           With regard to international standards, ICCR  
6           adopted the International Standards in Cosmetics  
7           Report, and that was posted to the website. And  
8           this is the standard of microbiological standards.  
9           In addition to that, a table of the standards was  
10          posted and it was agreed that it would updated  
11          every three years.

12          With regard to cosmetic preservation, a  
13          “Frequently Asked Questions” document was posted  
14          on the website at the end of November 2016. What  
15          the outcome actually was for 2016's meeting was  
16          that it was translated into 23 different  
17          languages, and that, again, is available on the  
18          website.

19          The agreement was that we would continue to  
20          work on a cosmetic product preservation  
21          infographic and that the work has expanded to

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1 include other communication specialists to make  
2 sure that the infographic really gets across the  
3 message to consumers as well as industry.

4 With regard to microbial contaminants, ICCR  
5 adopted the Microbial Limits - International  
6 Organization for Standardization, ISO-17516, and  
7 that report was also posted to the website.

8 For allergens, ICCR adopted the white paper  
9 "Survey of Approaches Undertaken to Develop Lists  
10 of Potential Allergens in Cosmetics - Allergen II:  
11 Part 1." Next steps were proposed by the work  
12 group as to how to go forward in terms of trying  
13 to identify allergens that are found in cosmetic  
14 products.

15 With regard to traces, that there two white  
16 papers that were adopted. One was "Considerations  
17 on Acceptable Trace Levels of 1,4-Dioxane in  
18 Cosmetic Products," and the other was the  
19 "Recommendations for Acceptable Trace Mercury  
20 Levels in Cosmetic Products."

21 We heard in addition to all of these updates

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1 from observing regulators, and these included  
2 regulators from Columbia, Korea, South Arabia,  
3 Saudi Arabia, South American, and Taiwan.

4 With regard to involvement of interested  
5 parties, the regulators finalized the criteria to  
6 allow interested parties to submit detailed  
7 proposals for work items. And that, again, is  
8 posted on our website.

9 We also put in additional information for new  
10 regulators, international trade associations, NGOs  
11 and academia on the web. Participation, again, is  
12 as observers; and an open session for the  
13 stakeholders, as I mentioned, would occur on day  
14 two of the meeting.

15 This year ICCR will be held in Brasilia. We've  
16 been holding regular teleconferences and work  
17 meetings throughout this year.

18 The agenda itself will continue with  
19 discussions on governance, microbiological  
20 standards, integrated safety strategies for safety  
21 assessment, cosmetic product preservation, and the

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1 Allergen II work group will present their final  
2 report and any new proposed agenda items.

3 This slide is placed here so everyone can have  
4 the access to the International Cooperation on  
5 Cosmetics Regulations website. This website is  
6 kept up to date and any time that there is a new  
7 posting, it will be available there.

8 The website has several of the older documents  
9 that have been posted, in the past, and documents  
10 that will also describe a little bit more about  
11 how ICCR operates.

12 And with that, I'd like to thank you for your  
13 attention and go on to our next speaker, and that  
14 would be Monica Engebretson from Cruelty Free  
15 International.

16 MS. ENGBRETSON: Okay. So you've probably  
17 all been able to read this in the packet by now.  
18 Just a little brief introduction.

19 So we were formally the BUAV and we led a 20-  
20 year campaign working towards a ban on the use of  
21 animals in cosmetic products in the European



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1 Union. We're now working in many countries around  
2 the world to adopt similar regulations. Working  
3 with governments and regulators around the world,  
4 we have people in Brazil, United States and work  
5 with partner organizations in India and Vietnam,  
6 Korea, and many of the other major cosmetics  
7 markets.

8 So, given the remit of the ICCR, we  
9 particularly would like to look at how a non-  
10 animal testing level playing field and harmonized  
11 roles could be good for industry and good for  
12 trade and what we can all do to assist countries  
13 that need support to adopt validated, recognized  
14 alternatives.

15 As people know, the need for animal testing is  
16 rare. Existing ingredients are plentiful, which  
17 already have safety data which are frequently used  
18 just to recombine (ph) to make new products. Non-  
19 animal methods, of course, have been developed.  
20 In the rare case where a -- maybe an alternative  
21 isn't quite developed, those tests are usually not

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1 used for cosmetic purposes. So, all the tests  
2 that are usually used to carry out safety  
3 assessments for consumers have alternatives that  
4 are typically cheaper and often faster and better  
5 able to predict human outcomes than the animal  
6 tests that they replace.

7 In the cases of areas where they are still  
8 being developed, as I mentioned, and validated,  
9 those tests aren't usually used for cosmetics such  
10 as the carcinogenicity test, and that's not  
11 usually carried out for cosmetic products because  
12 of the threshold of toxicological concern, it  
13 doesn't usually rise to the level of needing to  
14 run that test, and that test takes up to two years  
15 to complete and is only about 50 percent  
16 predictive of a human response anyway.

17 Cruelty Free International has a comprehensive  
18 and up-to-date information and analysis available  
19 about the status of the different alternatives and  
20 would like to offer ourselves as a resource for  
21 the ICCR.

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1           The use of non-animal tests has been following  
2           an upward trajectory for at least the last 20  
3           years, and the most significant boost came with  
4           the European Union bans, which came in as a phase  
5           and effect with 2013 being the ban on import or  
6           marketing of any product that's been tested on  
7           animals.

8           In September 2016, an attempt to weaken that  
9           ban was thwarted when the Court of Justice  
10          confirmed that cosmetics containing an ingredient  
11          that was tested outside of the European Union  
12          can't be sold. We were the only NGO that  
13          intervened on that case, so if there's questions  
14          about the details of that, I can get those for you  
15          even though I don't have them right now. That  
16          would be something we can do.

17          But moving on from there, since the European  
18          Union ban came into effect, ten other countries  
19          have adopted some form of regulation. They're all  
20          a little bit a little bit different, but that  
21          resulted in over half of the, you know, global

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1 cosmetics now prohibited animal testing. And so,  
2 of course, once again we would like to look at a  
3 way that a harmonized -- more harmonized schedule,  
4 something closer to the European Union ban across  
5 all markets could be achieved.

6 And we can kind of color Australia pink and  
7 Guatemala pink since the time that this slide was  
8 made.

9 So, there's three issues these are the three  
10 issues that typically come up when talking about  
11 harmonizing regulations: REACH, or how does a  
12 cosmetic testing ban interact with other testing  
13 schemes for chemicals or other products.

14 Innovation, and China. And I'll just go over  
15 these really quickly. So, with REACH, like a  
16 question is if an ingredient is tested under  
17 another testing regime, can like REACH or any  
18 other chemicals, can it be then submitted for  
19 cosmetics. And there's really three options that  
20 each country needs to decide how to handle it.  
21 One would be if it was tested for another regime,

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1 then it can't be used for cosmetics.

2 The other option would be that the results of  
3 the animal test can't be used, even if they've  
4 already been run, they can't be used to determine  
5 safety for cosmetics. You would still have to  
6 submit the non-animal test. Or to say that the  
7 results can be used even if they're because they  
8 were used in another product.

9 The EU Commission position is somewhere  
10 between the second two. It says that the test is  
11 not acceptable if the ingredient was developed  
12 primarily for cosmetics purposes. But if it was  
13 developed for use in another product where the  
14 animal test was used and then later found to be  
15 useful in cosmetics, then they will allow that.

16 Innovation is another common concern. This is  
17 just addressed because only in about three to five  
18 percent of new cosmetics actually have a new  
19 ingredient in them, and many of them have been  
20 tested either in other under other testing regimes  
21 or they can be proven safe by the non-animal

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1           testing methods that already exist. And, of  
2           course, at some point the consumer demand for  
3           innovation is balanced by a consumer demand with  
4           cruelty-free cosmetics, and with innovation, with  
5           the when the cosmetic bans came into place, there  
6           was also a huge boost in the innovation of human  
7           relevant tests. So, the innovation in  
8           alternatives tests and innovation in cosmetics and  
9           meeting consumer demand can really go hand in  
10          hand.

11                   And since the European Union ban, kind of an  
12                   example of this, consumer safety has not been  
13                   jeopardized by the ban and consumers still have a  
14                   lot of products to choose from.

15                   This third point is China, because it is the  
16                   only country that has required animal tests for  
17                   the marketing of cosmetics. But even that is  
18                   shifting and becoming less of a concern, and we  
19                   expect to see a continued lessening of requirement  
20                   from China.

21                   In 2014 there was changes made that would

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1 allow a test to avoid animal testing if the  
2 product is manufactured in the country. And in  
3 2017, just this last March I think it was, there  
4 was a new simplified registration process for  
5 imports that might allow companies to avoid  
6 testing when imported through Shanghai.

7 So once again, we would like to encourage a  
8 robust discussion at the ICCR meeting about what  
9 is needed to move the global regulations in the  
10 direction of non-animal testing and adopt more of  
11 a cruelty-free standard across the board and to  
12 encourage the use of the alternatives. So, three  
13 things that at minimum we think that it might be  
14 used to discuss an actual goal line for the ICCR  
15 because the current position is obviously very  
16 frustrating and confusing for consumers as well as  
17 difficult for industry.

18 Could -- one thing that could be considered is  
19 a mandate on the use of alternatives. That would  
20 be -- so where an alternative has already been  
21 validated by international bodies, doesn't it make

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1           sense that that alternative then is required to be  
2           used before resorting to animal tests?

3                   Three states already have this law in the  
4           United States, California, New Jersey, and New  
5           York. And we think if these modern alternatives  
6           are agreed, shouldn't they then be required to be  
7           used before resorting to the animal test?

8                   The second point that we hope can be discussed  
9           is maybe it's time for a timeline, setting out a  
10          reasonable target for the phasing out of animal  
11          tests. Setting a target gives time for regulators  
12          and industry to adjust and to anticipate what's  
13          coming forward.

14                  So that's the end, and thank you for allowing  
15          me to take some time, and we're here for any  
16          questions you may have. And once again, we hope  
17          that the ICCR meeting will address these issues.

18                  Thank you.

19                  DR. KATZ: Our next speak is Megan Polanin  
20          from the National Center for Health Resource.

21                  DR. POLANIN: Thank you for the opportunity to



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1 speak today. My name is Dr. Megan Polanin. I am  
2 a senior fellow at the National Center for Health  
3 Research.

4 Our research center analyzes scientific and  
5 medical data and provides objective health  
6 information to patients, providers and policy  
7 makers. We do not accept funding from industry so  
8 I have no conflicts of interest.

9 We continue to be concerned about the presence  
10 of endocrine-disrupting chemicals in cosmetics and  
11 their effect on consumers' health. Some hormone  
12 disrupters such as phthalates and parabens are  
13 found in a wide range of cosmetic products.  
14 Others are used in specific cosmetics such as  
15 triclosan in toothpaste and UV filters in  
16 sunscreen.

17 Children and adults are exposed to many  
18 different soaps, creams, and other cosmetic  
19 products every day and, thus, are exposed to  
20 multiple doses of endocrine disruptors.

21 Low molecular weight phthalates such as DEP,

1 DBP, DIBP, and DMP are still found in many  
2 cosmetics. Prenatal exposure and as a young child  
3 are associated with increased behavior problems,  
4 decreased cognitive function and more attention  
5 problems.

6 Parabens are used in cosmetics as  
7 preservatives. They are associated with oxidative  
8 stress, DNA damage of sperm, altered thyroid  
9 hormones, and increased risk of allergies. In  
10 addition, parabens are associated with breast  
11 cancer tumors and their growth. In at least some  
12 cases, the health effects are stronger when  
13 multiple parabens are present such as from use of  
14 several cosmetic products.

15 Phthalates and parabens are found in virtually  
16 all adults. They move into human placenta and  
17 milk where they harm fetal and infant development.  
18 Cosmetics substantially contribute to overall  
19 exposure to endocrine disruptors. A 2016 study of  
20 adolescent girls found that just changing the  
21 cosmetics that they used reduced the amount of

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1 specific phthalates, parabens, and other endocrine  
2 disruptors by 27 to 45 percent. This study needs  
3 to be replicated, but it suggests that cosmetics  
4 provide a substantial exposure at a vulnerable  
5 age.

6 One of the problems with evaluating the impact  
7 of endocrine-disrupting chemicals is that they can  
8 have an impact at very low concentrations and show  
9 a U-shaped dose response. The National Institute  
10 of Environmental Health Sciences has explained  
11 that smaller doses can have stronger effects than  
12 larger doses. This is particularly problematic in  
13 measuring the impact of exposure during critical  
14 developmental windows such as during fetal  
15 development, as a young child, or during puberty.

16 We strongly urge the ICCR to have a thorough  
17 discussion about the issue of endocrine disruptors  
18 in cosmetic products as well as policies to reduce  
19 exposure.

20 Not all phthalates and parabens are endocrine  
21 disruptors, and eliminating all phthalates and

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1 parabens from cosmetics would not eliminate all  
2 exposure. However, changing known or suspected  
3 endocrine-disrupting chemicals to safer  
4 alternatives would substantially reduce overall  
5 exposure for many adults and children. In  
6 products where these chemicals are necessary, they  
7 should be clearly labeled so that consumers have  
8 the option to avoid them. These actions would  
9 reduce the risks of endocrine-disrupting chemicals  
10 on consumers' health.

11 We support the ICCR's attention this year to  
12 two such endocrine disruptors, mercury and 1,4-  
13 dioxane. The Regulators' Industry Traces Working  
14 Group concluded that the maximum allowable mercury  
15 levels in cosmetic products should be kept below a  
16 target level of less than or equal to one parts  
17 per million mercury.

18 In addition, the Trace Elements Working Group  
19 recommended lower levels of 1,4-dioxane in  
20 finished cosmetic products to 25 parts per million  
21 for phase one and 10 parts per million for phase

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1 two. However, 96 percent of products studied were  
2 already at this level and 90 percent had less than  
3 10 parts per million. This recommendation seems  
4 to be based on the status quo rather than sound  
5 science.

6 This issue is similar to the FDA's recent  
7 recommendation for a maximum level of lead in  
8 cosmetic lip products. No research was conducted  
9 to determine whether the FDA's proposed  
10 recommendation is actually safe for consumers, but  
11 instead, the chosen maximum level is consistent  
12 with lip products currently on the market.

13 These recommendations would clearly create a  
14 disincentive for the cosmetic industry to reduce  
15 levels of these toxic chemicals in their products.  
16 Consumers deserve to know about all the chemicals  
17 in cosmetic products so that they can make  
18 informed health decisions for themselves and their  
19 families.

20 The ICCR and FDA have a responsibility to set  
21 high standards for manufacturers so consumers are

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1 no inadvertently exposed to products that harm  
2 them, particularly given that manufacturers do not  
3 have to disclose these toxic chemicals on cosmetic  
4 labels. They have failed to do so. This is  
5 especially discouraging since the ICCR and FDA are  
6 merely making recommendations with no enforcement  
7 mechanisms.

8 In summary, endocrine-disrupting chemicals and  
9 other harmful substances are present in many  
10 cosmetics in the United States. These substances  
11 can harm the health of adults and children and it  
12 is essential for the FDA and the ICCR to consider  
13 the growing evidence for their harm. We urge the  
14 FDA and ICCR to establish high standards for  
15 maximum levels of endocrine disruptors and require  
16 manufacturers to clearly label their presence in  
17 products.

18 Thank you for your time and consideration of  
19 our views.

20 DR. KATZ: I would like to thank everyone for  
21 their time and attention. We have reached the end

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1 of our meeting and of the requested speakers. So  
2 with that, I will say that we're adjourned. And  
3 thank you again for coming.

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CERTIFICATE OF NOTARY PUBLIC

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I, NATALIA THOMAS, the officer before whom the  
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the proceedings were recorded by me and thereafter

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1 reduced to typewriting under my direction; that said  
2 proceedings are a true and accurate record to the best  
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6 further, that I am not a relative or employee of any  
7 counsel or attorney employed by the parties hereto, nor  
8 financially or otherwise interested in the outcome of  
9 this action.

10

*Natalia Thomas*

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NATALIA THOMAS

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Notary Public in and for the

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6/6/2017

*Pamela J alexander*

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DATE

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