



Columbia University  
MAILMAN SCHOOL  
OF PUBLIC HEALTH

DEPARTMENT OF ENVIRONMENTAL HEALTH SCIENCES

May 26, 2015

Elliot F. Kaye  
Chairman  
Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

Dr. Mr. Kaye:

I am attaching a number of letters that my students wrote to you this semester. I thought you would be interested in seeing them. I've attached the assignment I gave them as well. They were asked to review the Chronic Hazard Advisory Panel recommendation that as gestational phthalate exposures are associated with poorer neurodevelopmental test scores, the CPSC should reduce human exposure to DEHP, DBP and DEP. I asked them to write to you regarding what they thought of the CHAP recommendation. As you will see I instructed them that their recommendations should be well supported by their interpretation of the scientific findings and could vary from no action, to additional research, to regulatory actions to reduce prenatal exposures.

  
Robin M. Whyatt, DrPH  
Professor  
Department of Environmental Health Sciences

## Assignment and readings for March 31<sup>st</sup> and April 2<sup>nd</sup> Class

### Background

On August 14, 2008, Congress passed a law, enforced by the Consumer Product Safety Commission (CPSC), that permanently prohibits the sale of any “children's toy or child care article” containing three specified phthalates: (di-(2-ethylhexyl) phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (BBP)). It also prohibited, on an interim basis, “toys that can be placed in a child's mouth” or “child care article” containing three additional phthalates: (diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP)). A “children's toy” is defined under the law as a “consumer product designed or intended by the manufacturer for a child 12 years of age or younger for use by the child when the child plays.” **It should be noted, however, that there were no requirements that CPSC take any regulatory actions to protect the developing fetus from phthalate exposures.**

The law also required the CPSC to convene a Chronic Hazard Advisory Panel (CHAP) to study the effects on children's health of all phthalates and phthalate alternatives used in children's toys and child care articles and to provide recommendations to the Commission regarding whether any phthalates or phthalate alternatives other than those already permanently prohibited should be prohibited. The CHAP released their report on July 2014 and, among other things, concluded that **based on “human data on gestational phthalate exposures and associations with poorer neurodevelopmental test scores, human exposure to DEHP, DBP and DEP metabolites should be reduced”.**

The CPSC is currently in the process of deciding how they will respond to the CHAP recommendations. However, as you will see from the assigned readings, there are substantial inconsistencies in the epidemiologic findings. I will review these data on March 31<sup>st</sup>.

On April 2<sup>nd</sup> we will have a working class. Specifically, working in pairs, you will write a letter to the Commissioner of CPSC advising him on what regulatory actions, if any, you think he should take, based on the experimental and epidemiologic evidence showing associations between gestational phthalate exposures and adverse postnatal cognitive, motor and behavioral development. Your recommendations should be well supported by your interpretation of the scientific findings but also by your own conclusions regarding when precautionary action is appropriate. Your recommendations can vary from no action, to additional research, to regulatory actions to reduce prenatal exposures. The letters should be addressed to:

Elliot F. Kaye  
Chairman  
Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814



## Readings

Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives, July 2014, pages 29-33.

Miodovnik A, Edwards A, Bellinger DC, Hauser R. Developmental neurotoxicity of Ortho-Phthalate Diesters: Review of human and experimental evidence, *Neurotoxicology*, 41: 112-122, 2014

Pam Factor-Litvak, Beverly Insel, Antonia M. Calafat, Xinhua Liu, Frederica Perera, Virginia A. Rauh, Robin M. Whyatt. Persistent Associations between Maternal Prenatal Exposure to Phthalates on Child IQ at Age 7 Years, in press.

Elliot F. Kaye, Chairman  
Consumer Products Safety Commission

Dear Mr. Chairman,

As future public health professionals and constituents, we are writing to urge you, as the Chairman of the Consumer Product Safety Commission, to reduce prenatal exposure to phthalates. We are writing as first year MPH students in Environmental Health Science at Columbia University's Mailman School of Public Health. We have taken a strong interest in learning about the deleterious effects of continuous phthalate exposure on the neurodevelopment of exposed children. Phthalates are ubiquitous; found in other everyday products such as cosmetics and food packaging. Their pervasive presence in American markets equates to widespread exposure and detection in human saliva, urine, amniotic fluid, and breast milk. A developing fetus is just as vulnerable, if not more so, to toxic exposures as children and adults. Therefore, we urge you to implement more regulatory action to expand the requirements to protect against additional phthalates other than the 3 specific phthalates that are already prohibited in children toys.

Phthalates are endocrine disruptors and act by altering hormonal mechanisms in humans including estradiol. They are associated with neurodevelopmental problems as well as impaired genital and pubertal development. Research carried out by prestigious schools of public health at Harvard and Columbia have shown explicit evidence of maternal phthalate exposure during pregnancy and impaired IQ and motor development in children. The developing fetus is particularly vulnerable to exposure to toxicants, and prenatal phthalate exposure to di-n-butyl phthalate (DnBP) and di-isobutyl phthalate (DiBP) has led to an IQ drop of more than 7.6 points. Elevated phthalate concentrations of DiBP and DnBP are also negatively associated with child processing speed, reasoning and working memory. It has been found that urinary phthalate metabolites were connected to elevated levels of aggression, attention problems, conduct issues and depression.

The implications of the proven adverse health outcomes mentioned merit public health concern and substantial legislative action. We strongly recommend that the Consumer Product Safety Commission take the necessary steps to increase the number of phthalates that are banded in consumer products.

Sincerely,

Fatima Riaz

[Redacted signature]

Valorie Richards

[Redacted signature]



April 2, 2015

Dear Chairman Elliot Kaye,

We are current graduate students at Columbia University's Mailman School of Public Health studying for our Master in Public Health in Environmental Health. It has been brought to our attention that the Consumer Product Safety Commission does not currently require any regulation of phthalate exposures to developing fetuses.

We are writing to ask that you work with your colleagues and consider increasing the required regulation of phthalates in order to reduce prenatal exposures. Phthalates, a plasticizer, are found in common household products ranging from insecticides to children's toys, to personal care products.

Given the evidence of epidemiologic and animal studies and wide use of phthalates, we urge the CPSC to take regulatory action on phthalate exposure. We recommend regulatory action for the following reasons:

- The developing fetus is particularly susceptible to the adverse effects of phthalate exposure. Various research has found increased in fetal exposure to phthalate to be associated with decreased mental, motor and behavioral development. This inverse association has been noted in preschool and school aged children.
- School children with lower full-scale IQ were found to have higher prenatal phthalate (di-n-butyl phthalate and di-isobutyl phthalate) exposure than their high IQ classmates.
- Children with higher prenatal phthalate exposure (di-n-butyl phthalate and di-isobutyl phthalate) were also found to have slower processing speed and decreases working memory compared to children with lower prenatal phthalate exposure.

We recommend that the CPSC take action to improve labeling and increase research:

- More research needs to be conducted to evaluate a dose-response relationship to determine if a safe level exists
- As some phthalates appear to have more adverse effects than others, more research needs to be conducted to determine the effects of varying phthalates to determine if there is a safe phthalate.
- Improve labeling standards for consumer products that contain phthalates in order to strengthen awareness of potential fetal exposure

Whereas phthalates are ubiquitous in our environment and evidence regarding the adverse effects of phthalate exposure to developing fetuses and children is recognized, it is in the best interest of the general public to increasing the required regulation of phthalates through increased research and improved labeling.

Thank you for your consideration of our request.

Sincerely,



Cara Smith



Sosy Tatarian

April 14, 2015

Dear Mr. Chairman,

We have read with interest that the Chronic Hazard Advisory Panel (CHAP) has recommended that prenatal exposure to phthalates be reduced, as they are associated with adverse developmental outcomes. We are writing to comment on the recent recommendations of action.

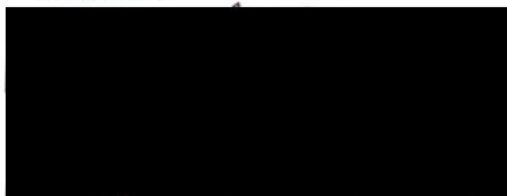
While we realize that more research is needed to address the full extent of the effects of phthalate exposure on neurodevelopment, there are a few areas of evidence that we found to be of particular interest. Prenatal urinary phthalate metabolites concentrations have been shown to be inversely associated with full scale IQ in children at age seven. Similarly, the CHAP report shows that phthalate exposure during pregnancy resulted in poor neurodevelopmental test scores. Studies have also observed antiandrogenic effects in male offspring exposed to phthalates.

Given the ubiquitous nature of phthalates, we feel that greater regulatory action needs to be implemented with an increased focus on prenatal and maternal health outcomes. While the majority of action taken against phthalates currently deals with bans on children's toys, no regulatory action exists which protects the developing fetus from phthalate exposure. There is overwhelming evidence suggesting that the largest phthalate exposure to all subpopulations comes from food, beverages, and drugs via direct ingestion. For this reason, we recommend that the appropriate US agencies take regulatory action to help manage and minimize phthalate exposure from these various sources.

The interim ban suggested by CHAP applies only to toys that can be put a child's mouth. We recommend that this ban be expanded to include all children's toys. Furthermore, we propose that regulatory action be taken against the phthalate metabolites included in this category in the case of personal care products and foods. Collaboration with the Food and Drug Administration regarding food sources of phthalates is also important to reduce exposures. We also recommend that personal care products (i.e. cosmetics, lotions, detergents, etc.) containing phthalates be required to visibly display warning labels that discourage consumption by pregnant and lactating women.

We thank you for your thoughtfulness on this urgent public health issue.

Regards,



Natasha Jhala and Amy Martin  
MPH Candidates, Environmental Health Sciences, 2016  
Columbia University Mailman School of Public Health

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Letter to Consumer Product Safety Commission  
Dear Chairman Elliot F. Kaye,

We are writing this letter to inform Consumer Product Safety Commission about the recent recommendation regarding the prenatal exposure to phthalate. We believe that further researches are needed to justify the regulatory action of phthalate usage. In addition, we should take a precautionous attitude towards the exposure of this class of compound. Prenatal development consists of critical window developments where exposure to teratogen may create birth defect or abnormal growth and development in children. As ubiquitously existing, phthalate can be found in people's daily product from cosmetic products to children toys. In addition, mass production of phthalate without stringent control protocols may lead to leakage of phthalate into surroundings. As a result, human are regularly exposed to multiple phthalates through oral, dermal and inhalation route. Even though many of researches found associations between prenatal exposure to phthalate and defects in neurodevelopmental and reproductive development, there are some inconsistencies among current studies.

Experimental evidence suggests that several phthalates possess antiandrogenic properties and may disrupt endocrine pathways resulting in abnormal reproductive outcomes. Gestation exposure to phthalates and reproductive tract development was explored in a few cohort studies. These studies showed that higher maternal urinary concentration of DEHP, monoethyl phthalate (MEP) and MBP metabolites was associated with the reduction of AGD in male infants. Only one study found no association in boys, however in girls, decreased AGD in relation to amniotic fluid levels of MBP and MEHP was observed. Besides, recent epidemiologic studies reveal a statistically significant association between prenatal exposure to phthalate and altered genital and pubertal development in infants and children.

A wide range of neurodevelopmental outcomes were measured including ADHD, vocabulary scores, withdrawn behavior, PDI or masculine composite scores. Although different neurological test at different childhood ages were done in each publication, the results are inconsistency which make it difficult to compare. However, it is generally observed that poorer test scores were observed and associated with higher urinary levels of some phthalate. There are a wide range of phthalates that are in this list including DEHP, DBP, DMP, BBzP, DiBP and could be more.

Based on the considerable inconsistency among recent researches, it is too early to make a verdict for phthalate and take strong regulations towards the manufacture and marketing of phthalate until additional epidemiology and experimental studies are conducted to justify the further actions. Besides, there are still many uncertainties for phthalate alternatives, which may also need more comprehensive investigations. Any stringent regulation on using phthalate in product manufacturing now could create some adverse consequences such as increasing prices, and spreading fear among users. However, we need to be aware of the potential risk of phthalate. Under this circumstance, we believe that providing information and education to pregnant women and parents, such as community outreaches, social media, and labelling can be one of the more ethical and feasible approaches to deal with the current situation. Future research on phthalate should receive more funding in order to address many of the uncertainties that exist within current researches.





April 14, 2015

Chairman of Consumer Products Safety Commission

Elliot F. Kaye

4330 East West Highway

Bethesda, MD 20814

Dear Mr. Kaye,

We have read with interest that the Chronic Hazard Advisory Panel (CHAP) has recommended that prenatal exposure to phthalates, specifically DEHP, DBP, and BBP be reduced. As graduate students at the Mailman School of Public Health at Columbia University, we would like to express our concern over the hazards over not only infant and child exposure to phthalates, but prenatal exposure as well. It is our understanding that the Consumer Product Safety Commission (CPSC) recently passed a law prohibiting the sale of any "children's toy or childcare article" containing DEHP, DBP, or BBP.


Based on the scarcity of scientific literature linking prenatal phthalate exposure to adverse neurodevelopmental, motor, and behavioral development, there is a clear lack of evidence regarding this issue. We propose that more research be conducted on prenatal exposure to phthalates and their subsequent adverse health effects on infants and children. In addition there have been an adequate number of studies demonstrating an inverse association between DEP and poorer neurodevelopmental test scores. We strongly agree with CHAP's recommendation to reduce human exposure to DEP by prohibiting sales of children's toys or childcare articles with DEP, as it is not currently included in CPSC's current law regarding phthalate exposure from children's toys.


Even though there lacks a clear dose-response between phthalate exposure and adverse health effects, the CPSC should take precautionary actions to not only limit phthalate exposure to infants and children but to limit phthalate exposure to pregnant women in order to protect fetuses. In addition, CPSC should conduct more research in order to determine a safe dose of phthalate exposure in which minimal risks are presented. Until a safe dose is established, limiting phthalate exposure in consumer products to infants, children and pregnant women is necessary to protect the health of the public.

If we do not take precautionary measures to protect fetuses and the lives of future generations of infants and children, we could observe widespread adverse neurological effects in the general population. For example, prenatal DBP phthalate exposure has been linked to lower IQ scores, which could potentially necessitate more intensive school-related assistance to these children who are affected. Studies show that children of mothers exposed to high levels of DBP had IQs that were about 7 points lower than children of mothers who were exposed to low levels of DBP. With a lower IQ, children exposed to phthalates will have a disadvantage in academic and occupational settings. By failing to take regulatory action, children's' potential for success later in life may drastically be compromised.

With this letter, we hope that you can take into consideration our concerns about prenatal exposure to phthalates. We thank you for your initiative in trying to help protect the lives of infants and children and hope that you can also consider the lives of fetuses too.

Sincerely,

  
Alyssa Espiritu  
MPH Candidate - Columbia University,  
Mailman School of Public Health

  
Khristina Ipapo  
MPH Candidate - Columbia University,  
Mailman School of Public Health

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April 2, 2015

The Honorable Elliot F. Kaye  
Chairman  
U.S. Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

Dear Chairman Kaye:

On August 14, 2008 the Consumer Product Safety Improvement Act was passed by Congress. This law is enforced by the Consumer Products Safety Commission (CPSC) to prohibit the sale of any “children’s toy or childcare article” containing three specific phthalates and prohibited three additional phthalates in products that put children at risk. However, the law did not require CPSC to take any regulatory actions to protect the developing fetus from phthalate exposures. It was also required for the Chronic Hazard Advisory Panel (CHAP) to study the effects of phthalates and related chemical alternatives on children’s health. The July 2014 report released by CHAP concluded that “human data on gestational phthalate exposures and associations with poorer neurodevelopmental test scores, human exposure to DEHP, DBP and DEP metabolites should be reduced.”

While presently there is limited epidemiological evidence reporting the impacts of prenatal phthalate exposure on neurodevelopmental outcomes, there is emerging evidence suggesting that some phthalates may result in adverse effects on brain development. Several prospective pregnancy cohort studies and cross-sectional studies have looked at the relationship between urinary phthalate metabolites and neurological tests in children and infants. Overall, those with poorer test scores generally had elevated concentrations of certain phthalates.

Although there is a limited number of studies currently available that show poorer cognitive outcomes in children with exposure to higher prenatal exposure to phthalates, there is still a lot of uncertainty and research gaps. According to Miodovnik et al, these limitations mainly include: the fact that phthalates have weak biological activity, which makes it more difficult to detect slight associations in small population studies. There is also a lot of uncertainty concerning the critical windows of vulnerability during brain development particularly to phthalate toxicity. There are a lot of factors that can contribute to adverse neurodevelopmental outcomes in children. Hence more research needs to be done on phthalates, but phthalates can potentially impact a wide range of downstream developmental processes.

Phthalates are widely used in consumer products and pose pervasive human and environmental exposure. Based on experimental evidence that both low and high level exposure of phthalates may disrupt endocrine pathways resulting in abnormal reproductive outcomes, we express our concern over the prenatal exposure to DEHP, DBP and DEP metabolites. Taking action on phthalate regulation will not only be providing a safer environment, safer consumer products, and a decrease in additional major public health concerns such as obesity, asthma, and breast cancer for our future

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generations. Our future generations should not be the victims of negative externalities caused by the chemical industry's economic interests.

We advise appropriate precautionary action, such as implementation of regulation on products that use phthalates. Particular attention should be focused on industries that produce products used by women of reproductive age, so that precautions can be taken to reduce prenatal exposure to phthalates. Additional research is recommended since uncertainty exists with regards to the critical windows of brain development that are uniquely vulnerable to phthalate toxicity. Research should also focus on the biological activity of phthalates in vivo to find more evidence on the health impacts of phthalates. Studies should also be done to see whether phthalates used in cosmetic products can be substituted with less harmful substances.

We appreciate and acknowledge the CPSC's continuing effort to regulate and protect the general public associated with the use of consumer products. As public health students, we are passionate about protecting everyone from environmental exposures. We believe that the chance to live healthy lives should not be denied to anyone. Should you need help in exploring options to help make this a reality for all, particularly concerning phthalates and prenatal exposure, we would be more than willing to help out.

Sincerely,



Amanda Cheng



Kalon Wang



Chen Chen, MPH, Yameng Luan, MPH  
Department of Environmental Health Sciences  
Mailman School of Public Health, Columbia University

Elliot F. Kaye  
Chairman  
Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

Dear Mr. Kaye,

We have read with interest, that the Chronic Hazard Advisory Panel (CHAP) has been convened to study the effects on children's health of all phthalates and phthalate alternatives used in children's toys and child care articles, which we strongly support because it has been found in both epidemiologic evidence and animal experiments that there is an association between gestational phthalate exposures and adverse postnatal cognitive, motor and behavioral development. We are writing to comment on the recent recommendations on the permanent prohibition of three types of phthalates (DEHP, DBP and BBP) in children's toy and child care articles, and additional three types of phthalates (DINP, DIDP and DnOP) in "toys that can be placed in a child's mouth" or "child care article". We agree with that act, but prenatal exposure to phthalates can cause even more severe outcomes than postnatal exposure. The major problem of phthalates is that everybody is exposed ubiquitously and it is not feasible to protect one population regardlessly of another, so we recommend you take precautionary action to protect pregnant women as well as children.

Though conducted under different conditions, studies on phthalates and neurodevelopmental outcomes have generally shown an inverse association between urinary levels of some phthalates and test scores. The evidence shows that human exposure to DEHP, DBP, DEP, as well as DINP, DIDP and DnOP should be reduced.

Di-2-ethylhexyl phthalate (DEHP) is an organic compound used as plasticizers. It is a widely used compound, accounting for almost 54% of plastic market share. High level of DEHP has been linked with higher nonoptimal reflexes in males, higher somatic complaints in boys, lower internalizing behaviors in girls and higher odds of attention deficit hyperactivity disorder. Dibutyl phthalate (DBP) is also a commonly used plasticizer, and also used as an additive to adhesives or printing inks. DBP has been inversely associated with neurological functions and behaviors, masculine composite scores in boys, and spatial learning and memory. Diethyl phthalate (DEP) is a phthalate ester, often used to bind cosmetics and fragrances. DEP has been associated with disordered cell functions and infant skeletal malformations.

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Diisononyl Phthalate (DINP) has been used in children's toys and child care articles in the past, and urinary metabolites of DINP have been detected from human urine samples. Exposure to DINP can cause reproductive and neurodevelopmental effects, for example, male developmental effects and systemic effects (Liver). Though the current level of DINP is below the 0.1% standard of interim ban, the cumulative risk of DINP with other antiandrogens should also be considered, thus the potential risk should not be ignored. Diisodecyl Phthalate (DIDP) is used in the PVC used to manufacture flooring, film, and coating products. Consumers may also be exposed via food, food packaging, clothing, and children's vinyl toys. DIDP is a potential developmental toxicant, causing supernumerary ribs, and a potential systemic toxicant, causing adverse effects on the liver and kidney. Though not considered as a cumulative risk with other antiandrogens, MOE in human is considered likely to be relatively high. Exposure to Di-n-octyl Phthalate (DNOP) was associated with developmental toxicity, i.e., supernumerary ribs, and may also adverse effects in the liver, thyroid, immune system, and kidney.

Prenatal exposure to DEHP and DBP can also cause adverse neurotoxicological effects. DBP is associated with worse internalized behaviors and less masculinity in boys. DEHP is associated with major depression in girls, worse vocabulary subscale scores in boys and Attention Deficit Hyperactivity Disorder.

As we described above, though few significant adverse effects caused by phthalates have been shown, we cannot assume safety in terms of long term risks. While the studies show only 6-7 point changes in IQ following prenatal exposure, given that everyone is exposed, this can shift the population distribution resulting in the lose of highly intellectual individuals and increased number of children requiring special education and result in a serious burden for the society.

To sum up, we recommend more research on the parts that lacking supportive evidence. For specific types of phthalates, such as DINP, the level of most of current products do not exceed the 0.1% standard, but cumulative risk still exist, so we recommend more strict standards be set. Last but not least, we suggest that not only the six currently banned phthalates in children's toys, but also some these same phthalates should also be banned from consumer products of pregnant women.

Sincerely,  
Chen Chen and Yameng Luan





Elliot F. Kaye  
Chairman  
Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814  
Dear Chairman Elliot Kaye:

We are writing you today in response to the Chronic Hazard Advisory Panel's (CHAP) review of the health of effects of phthalates in children. This 2014 report recommended that human exposure to the phthalate metabolites DiNP, DEHP, DBP and DEP should be reduced considering recent toxicological and epidemiological evidence, specifically concerning the association between prenatal exposure to phthalates and poorer neurodevelopmental test scores in early infancy and childhood.

We commend you for undertaking a thorough review of the health effects of the chemicals in question. We strongly agree with the CHAP recommendations and wish to urge the Consumer Products Safety Commission to take action in responding to this report with the proper legislation, concerning phthalates in question. Though questions still remain on the mechanisms of these effects and more research is necessary in many areas, we believe that there is enough evidence to support regulating phthalate in consumer products now, in order to protect neurological and physical development in US children.

Research findings show exposure to phthalates during pregnancy is associated with a substantial decrease in child IQ. Inverse associations were found between urinary concentrations of MnBP and MiBP and IQ scores on the WISC as well as the psychomotor developmental index. Other significant associations between MBzP and perceptual reasoning have also been seen. We are concerned with the adverse links between prenatal phthalate exposure and cognition that persist into the early school years with potentially meaningful implications for academic performance. Based on these findings, we support CHAP's recommendations to permanently ban DIBP, DEHP, DBP, and DEP metabolites from children's toys and to take action to reduce prenatal exposure to these chemicals.

Apart from intellectual development and academic performance measures, we are also concerned with research that has found associations between prenatal



phthalate exposure and decreased social development. Different projects have found associations between increased phthalate exposure and poorer scores among children, specifically male children, on tests of social development, behavior, and play techniques, including the Social Responsiveness Scale, Behavior Inventory of Executive Function, Behavior Assessment System for Children. Several tests have found an increase in cases of hyperactive behavior, conduct disorders, ADHD, and - most alarmingly - aggressive behavior among male children with increased phthalate exposure. While many of these studies are not prospective in nature and cannot define causality, the findings point towards an alarming likelihood that phthalates are part of the country-wide rise in these behavioral and social disorders and concerns.

Studies have also found association between increased phthalate exposure - specifically to DEHP and DiNP metabolites - during fetal development with shortened anogenital distance, cryptorchidism and hypospadias in male infants. This obviously affects these individuals' future reproductive potentials and increases the likelihood of future health concerns.

Toxic chemicals such as phthalates, and our increased exposure to them, have been linked to a host of health problems including skyrocketing rates of cancer, developmental disabilities, and early puberty. In order to respond to the host of health concerns mentioned above, research needs to be done to pinpoint common exposure routes of fetuses during development. Exposures to phthalates seems almost unavoidable considering the omnipresence of these compounds across a wide scope of various consumer products. To address this broad exposure spectrum, collaboration with the Food and Drug Administration in this research is likely necessary considering phthalates' presence in products across both organizations' jurisdictions. For instance, women are likely exposed to phthalates when receiving medical care before and during delivery, as it is known that PVC's contain a substantial amount of these compounds. While there are multiple exposures outside of the medical care facility, since medical care is increased during the nine month pregnancy term, it is a vulnerable environment for the fetus and the mother.

Moving forward, we believe that the Consumer Products Safety Commission should:

- place the same regulation now in place for children's toys concerning phthalate levels on consumer products commonly used by women of reproductive age
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- expand regulation on both children's toys and consumer products to include CHAP's recommendations on banning DiNP and other phthalate metabolites not currently considered
- phase out flexible PVC's from medical devices and hospital products by collaborating with the Food and Drug Administration
- material substitution and alternatives be made available to the consumers, especially for food packaging, flexible PVC products, cosmetics, and all consumer products
- commission further research on common consumer-driven routes of phthalate prenatal exposure

We reiterate our recommendation that CPSC make these protective and precautionary measures to address threats posed toward children and pregnant women. The research findings are alarming and clear - while the current regulations are a step in the right direction, additional guidelines and restrictions need to be placed to ensure consumer safety.

[REDACTED]  
[REDACTED]  
Hetali Jokhakar

[REDACTED]  
Laura Buckley

Dear Chairman Elliot F. Kaye,

We have read with interest the suggestion of the Chronic Hazard Advisory Panel that outlines the inverse association between phthalate exposure and neurodevelopmental test scores and recommends reducing human exposure to DEHP, DBP and DEP metabolites. In light of recent epidemiological data demonstrating that adverse effects of prenatal phthalate exposure on neurodevelopment persists into school age, the Commission should explore extending their recommendation for the reduction of phthalate exposure to protect the developing fetus. In 2014, PLOS ONE published the first prospective study on associations between maternal prenatal exposure to phthalates and IQ in children at age 7. It found a strong inverse association between prenatal phthalate exposure and IQ. Children of women in the 75th percentile for dibutyl phthalate exposure scored 6.6-7.6 points lower than children of women in the 25th percentile of exposure at age 7, indicating adverse cognitive effects could impact academic performance. While dibutyl phthalates have already been banned in children's toys, we recommend that these chemicals be banned from all consumer products, including personal care products, food containers, medical equipment, adhesives, and others contributing to the ubiquitous maternal exposure present today. To improve the consistency of regulation, CPSC should work in the conjunction with the FDA.

To date, none of the epidemiologic studies have characterized the routes of phthalate exposure or which sources contribute a larger burden to the exposure risk. Considering this information gap, we recommend that the CPSC commission a study to ascertain the sources of exposure, expanding the scope of exposure beyond children's toys to other potential exposure routes for both mother and child including but not limited to baby bottles, baby ointments, cosmetics and personal care products.

States such as California have been more stringently regulating phthalates under Prop 65 through labeling. California Prop 65 was enacted in 1986 and required the Governor of California to publish a list of chemicals that are known to cause cancer, birth defects or other reproductive harm through product labeling. Dibutyl phthalates were added to Prop 65's list of suspected teratogens in November 2006 and DINP was added to the list of chemicals known to cause cancer in December 2013. CPSC should review the measures enacted by states such as California and follow their example to protect human health.

In conclusion, we are advocating for more stringent regulation of phthalates in consumer products, both in terms of the range of phthalates being regulated, as well as the industries bound to the restrictions.

Sincerely,

  
Julia Casciotti and Meghan Kiernan



Elliot F. Kaye  
Chairman  
Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

Dear Mr. Chairman,

We have read with interest the Chronic Hazard Advisory Panel (CHAP) Report on Phthalates and Phthalate Alternative. Dibutyl phthalate (DBP), butylbenzyl phthalate (BBP), and di(2-ethylhexyl) phthalate (DEHP) are permanently prohibited but we think the interim prohibition of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-*n*-octyl phthalate (DNOP) should be made permanent. In addition, the use of Dimethyl phthalate (DMP), Diethyl phthalate (DEP), Diisobutyl phthalate (DIBP), Di-*n*-pentyl phthalate (DPENP), Di-*n*-hexyl phthalate (DHEXP), Dicyclohexyl phthalate (DCHP), Diisooctyl phthalate (DIOP), and Di(2-propylheptyl) phthalate (DPHP) should also be prohibited in consumer products.

While the sale of children's toys containing three phthalates is prohibited, phthalates are found ubiquitously and are a major concern for the public's health. For this reason we believe there needs to be further regulatory action to protect pregnant women and the developing fetus. Women and children are the most vulnerable group to phthalate exposure and the negative health effects of the chemical. Data from NHANES has shown that children ages 6-12 and women of reproductive age have the highest phthalates urine metabolite concentrations.

Brain development during gestation is very sensitive to environmental insults. Mother's exposure to chemicals such as phthalates can have deleterious effects on prenatal development. There is evidence that prenatal phthalate exposure is associated with psychomotor development. A study that addressed prenatal phthalate levels and psychomotor development in infants found that there was an inverse relationship between third trimester phthalates and infants Psychomotor Development Index (PDI) scores. It is important that we not only regulate phthalate exposure to children, but to pregnant women or women expecting to become pregnant.

Prenatal exposure to phthalates can also have effects on the child as they get older. In a study conducted by Factor-Litvak et al. prenatal urinary maternal metabolites were measured among inner-city mothers and a significant inverse association was found between concentrations of di-*n*-butyl phthalate (DnBP) and diisobutyl phthalate (DiBP) and deficits in children's intellectual development at age 7. Another study looked at African-American and Dominican women in the inner-city and measured metabolites during the third trimester of pregnancy and showed a significant decrease in MDI score for girls at age 3 with an increase in DnBP. It is important that we think of the long-term effect that such exposures can have on the health of women and children.

Phthalates can be found in toys, clothing, cosmetics, perfumes, food packaging, building materials, vinyl products, medical devices, lubricating oils, solvents, and detergents. Phthalates are ubiquitous which increases the chance that women and children will be exposed to the chemical on a daily basis. This cumulative effect makes it important that we ban these chemicals from consumer products that women of reproductive age, pregnant women, and children often come into contact with. The negative effects of phthalates on health are clear and it is unacceptable that they are allowed in any products at all. We need to focus on finding acceptable alternatives to phthalates that don't put the public's health at risk.

Thank you,  
Samantha Terrazas & Jalisa Gilmore



Chairman Elliot F. Kaye  
Consumer Products Safety Commission  
4330 East West Highway  
Bethesda, MD 20814

April 13, 2015

Dear Chairman Elliot Kaye,

We respectfully write to request you to take a step further than the recommendations of the Chronic Hazard Advisory Panel (CHAP) to reduce human exposure to di-2-ethylhexyl phthalate (DEHP), dibutyl phthalate (DBP), and benzyl butyl phthalate (DEP) and put into effect, immediately, the complete ban of phthalates in maternal products considering the current research exhibiting only negative side effects.

The epidemiological data is extremely varied between studies due to the lack of a large number of studies specifically studying phthalates and prenatal exposure outcomes. Most studies show that prenatal phthalate exposure plays a role in multiple detrimental health outcomes illustrating negative relationships between maternal phthalate exposure and psychomotor and cognitive development.

The toxicological studies on phthalates are limited in scope but current data has shown that there are a various modes of action whereby phthalates could be affecting physiological development processes and causing neurodevelopmental toxicity. Due to the minimal animal studies, no dose-response can be associated to any health endpoint regulation to ensure the safety of the public.

Based on the evidence, there is a need to further study prenatal phthalate exposure in order to elucidate exact mechanisms, causal agents, and dose-responses contributing to specific developmental health outcomes.

Phthalates are ubiquitous in the environment and all humans have trace amounts of the chemical. Increased research on phthalates for the short term, long term, cumulative, and high dose responses are necessary to deem these chemical agents acceptable for public use.

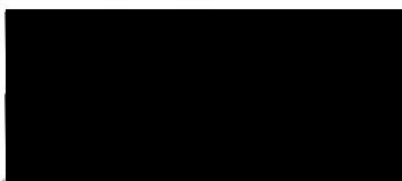
The phthalates reviewed by the CHAP are only a few of the hundreds used in plastic manufacturing and processing. Phthalates may perturb numerous downstream physiologic processes and impact a wide range of health endpoints. When taking all of the following into consideration we think it is clear that phthalates used in maternal products should be completely eliminated for use from both a public health and industry standpoint.

Thank you for considering our request and for your public service. We look forward to your prompt response.

Sincerely,



Richie Evoy



Robyn Lee