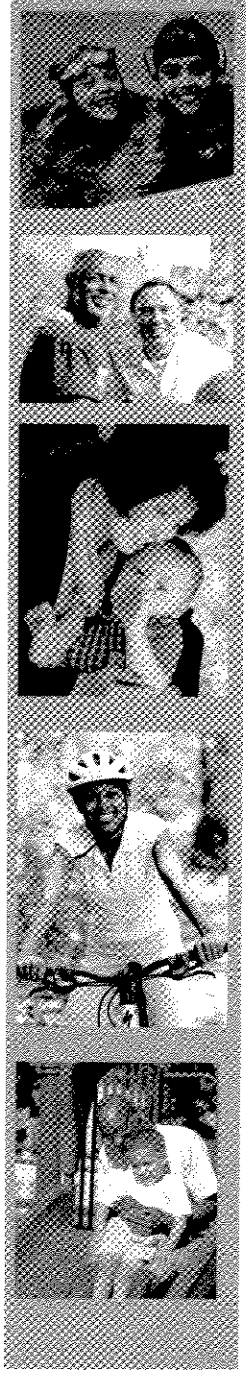
U.S. Consumer Product Safety Commission



TESTIMONY OF DR. MICHAEL BABICH, U.S. CONSUMER PRODUCT SAFETY COMMISSION

SUBMITTED TO THE SUBCOMMITTEE ON CONSUMER AFFAIRS, INSURANCE AND AUTOMOTIVE SAFETY

June 10, 2008

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Testimony of Dr. Michael Babich
Directorate of Health Sciences,
U.S. Consumer Product Safety Commission
June 10, 2008

Good Morning, Mr. Chairman and Members of the Committee:

My name is Dr. Michael Babich, and I am a chemist in the Directorate of Health Sciences at the U.S. Consumer Product Safety Commission (CPSC). I am pleased to come before the Committee today to testify and to answer your questions regarding phthalates and bisphenol A.

Phthalates are chemicals used to soften polyvinyl chloride (PVC) and make it flexible. PVC is found in a number of consumer products. CPSC's regulatory authority over phthalates comes from the Federal Hazardous Substances Act (FHSA), and since the early 1980's, the CPSC has investigated, researched, and monitored phthalates used in consumer products under the agency's jurisdiction.

In regulating a product under the FHSA, the CPSC must consider not only the toxicity of the product under consideration but also the exposure to that product under reasonably foreseeable handling and use. If such a product may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable use by children and is a toy or other article for use by children, it would be considered a hazardous substance and is automatically banned by operation of law. The FHSA does not provide for pre-market approval of consumer products.

In the early 1980's the primary phthalate used in children's products was di-(2-ethylhexyl) phthalate or DEHP. A National Toxicology Program 2-year bioassay indicated that DEHP caused cancer in rodents. Because of concern about these results, the industry removed DEHP from pacifiers, rattles, and teethers. A ban of the use of DEHP in pacifiers, rattles and teethers was subsequently incorporated into ASTM F-963, the voluntary Standard Consumer Safety Specification on Toy Safety. DEHP was replaced with another phthalate, diisononyl phthalate or DINP.

Chronic toxicity studies on DINP were completed by the chemical industry in 1997 and 1998. In 1998 CPSC staff completed a risk assessment on DINP. While staff concluded that few, if any, children were at risk of liver or other organ toxicity from mouthing teethers, rattles, and other PVC toys that contain DINP, staff also indicated that there were a number of uncertainties, primarily regarding exposure. As a result of these uncertainties, a voluntary agreement was reached with industry in December 1998 to stop the use of DINP in teethers, rattles, and pacifiers.

Additionally, CPSC staff at that time recommended that the Commissioners convene a Chronic Hazard Advisory Panel (CHAP) to evaluate whether there are chronic hazards

associated with exposure to DINP and what, if any, risk is posed.[1] The staff further recommended: 1.) that the Commission conduct an extensive observation study of children's mouthing behavior to better understand the exposure issues; 2.) develop a better laboratory method to measure the migration of DINP, and 3.) test additional products intended for children under three years of age to determine if they contain phthalates. The Commission approved all of these staff recommendations.

In its report to the Commission on June 15, 2001, the CHAP concluded that for DINP to pose a risk of injury to young children, they must routinely mouth DINP-plasticized toys for 75 minutes per day or more. For the majority of children, they concluded that exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury and, at the levels to which children were exposed, there was no carcinogenic, reproductive or developmental risks.

CPSC's behavioral observation study took place in 2000 and 2001. It was not completed in time for the CHAP to utilize the results when reaching their conclusions. In the behavioral observation study, trained observers monitored the behavior of 169 children between the ages of 3 and 36 months. The study found that the daily mouthing times of toys and teethers were much lower than expected. Based upon this observation study, staff concluded that it is very unlikely that children will mouth soft plastic toys for the 75 minutes a day that the CHAP identified as a minimum level of concern.

In a separate study, CPSC staff measured the level of migration of DINP from 41 children's products purchased from retail stores. The scientific experiments conducted in this study measured the amount of DINP that would leach from a representative sample of toys when children placed them in their mouths. Taking all of this information together, the CPSC staff estimated that the daily DINP exposure from toys on the market at that time for children up to 3 years of age would not pose a health risk.

In November 1998, a group of organizations petitioned the Commission to ban children's products made from PVC. Based upon the extensive scientific and technical investigations described above, staff concluded in its briefing package to the Commissioners that there is no demonstrated health risk posed by PVC toys or other products intended for children 5 years of age and under, and thus, no justification for banning PVC use in toys and other products for children 5 years of age and under. On February 21, 2003, the Commission voted 3-0 to deny the request to ban PVC in all toys and other products intended for children five years of age and under. A copy of the petition denial letter, Record of Commission Action, and Commissioners' statements are attached.

I would like to note that the legislation currently under consideration by Congress would ban certain phthalates down to 0.1%. Because phthalates are ubiquitous, the level of 0.1% would be a background level and not the result of phthalate being intentionally added to the product. When we tested toys, we found that phthalates were present in the range of 13 to 39%; that is

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[1] A CHAP is an independent panel of seven scientists chosen by the Commission from scientists recommended by the National Academy of Sciences. A CHAP is required under the Consumer Safety Act before the Commission may regulate a chronic hazard.

what is needed to make toys flexible. For toys containing multiple phthalates, it could be extremely difficult to measure down to the level of less than 0.1%.

Also, should DINP be banned in all children's products, manufacturers could choose to use another plasticizer that may or may not be as well characterized toxicologically as DINP. They might choose to use another plastic other than PVC which may release a more toxic chemical and which may or may not be toxicologically characterized. The new plastic may not have the characteristic of flexibility which PVC has and which minimizes the production of small parts that could pose choking hazards.

With regard to bisphenol A, or BPA, this is a chemical used in the manufacture of polycarbonate plastics and epoxy resins. Small amounts of BPA may be released as the plastic or resin breaks down. Examples of consumer products using polycarbonate plastics include eyeglass lenses, protective eyewear, protective gear such as helmets and shin guards, glazing, electronics, compact disks and labware. Epoxy resins are used in paints, coatings, adhesives, and as linings for canned foods.

Polycarbonate used in pacifier shields, helmets, protective gear such as goggles and shin guards, as well as other products, would fall under CPSC's jurisdiction. However, since polycarbonates are expensive, it is our understanding that polycarbonate is used in only those consumer products where there is a need for a very hard, unbreakable, sturdy plastic. Polycarbonate is used in pacifier shields (that prevent the nipple from being swallowed) so that when a child falls, the shield does not shatter, breaking into small parts and injuring the child. There would be no exposure expected from helmets, goggles, other protective gear, compact disks, or electronics. If there is no exposure, there is no health risk. Polycarbonate plays a very important role in its use in helmets and other protective gear. The helmets prevent children from receiving serious head injuries while engaging in many sports. This beneficial use of polycarbonate should be considered when acting to ban bisphenol A from children's products. Such a ban could result in less effective protection of children from head, eye, or bodily injury.

The greatest potential for human exposure to BPA is from food contact items. The recent in-depth peer review conducted by the National Toxicology Program (NTP) Center for the Evaluation of Risk to Human Reproduction (CERHR) stated that diet accounts for the vast majority, 99%, of human exposure. If BPA migrates out of a food contact surface into food, it is considered an unintentional food additive and would be under the jurisdiction of the Food and Drug Administration (FDA).

Thank you for the opportunity to testify today, and I welcome your questions.

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Record of Commission Action
Commissioners Voting by Ballot*

Commissioners Voting: Chairman Hal Stratton
Commissioner Thomas H. Moore
Commissioner Mary Sheila Gall

ITEM:

Petition (HP 99-1) Requesting Ban of Use of PVC in Products Intended for Children Five Years of Age and Under

DECISION:

The Commission voted unanimously (3-0) to deny petition HP 99-1 and issue a denial letter as drafted (copy attached). The petition requests a ban of polyvinyl chloride (PVC) in all toys and other products intended for children five years of age and under and requests that the Commission issue a national advisory warning of health risks associated with soft plastic vinyl toys.

Commissioners Gall and Moore each submitted statements to accompany their votes. The petition denial letter and the Commissioners' statements are attached.

For the Commission:

Todd A. Stevenson
Secretary

* Ballot vote due February 20, 2003

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

Tel: 301 504-7923
Fax: 301 504-0127
Email: tstevenson@cpsc.gov

February 26, 2003

Mr. Jeffrey Becker Wise
Policy Director
National Environmental Trust
1200 18th Street, NW, Suite 500
Washington, DC 20036

Re: Petition Requesting Ban of Use of Polyvinyl Chloride (PVC) in Products Intended for Children Five Years of Age and Under **(briefing package date corrected as noted in bold)**

Dear Mr. Wise:

As requested in your letter of November 19, 1998 I am communicating through you to advise the petitioners that on February 21, 2003, the Consumer Product Safety Commission voted 3-0 to deny the requests from the National Environmental Trust and eleven other organizations that the Commission:

- immediately ban polyvinyl chloride (PVC) in all toys and other products intended for children five years of age and under; and

- issue a national advisory on the health risks that have been associated with soft plastic vinyl toys to inform parents and consumers about the risks associated with PVC toys currently in stores and homes.

The submission from the petitioners gave as the primary reason for these requests the toxicity of diisononyl phthalate (DINP), a plasticizer in PVC, and the toxicity of lead and cadmium in PVC.

The requested ban on PVC in all toys and other products intended for children five years of age and under was docketed as a petition for rulemaking under section 3(j) of the Federal Hazardous Substances Act (FHSA) on December 7, 1998 (Petition No. HP 99-01). 15 U.S.C. §1262(j). The request that the Commission issue a national advisory on the health risks that have been associated with soft plastic vinyl toys was not docketed because it would not require rulemaking to implement.

To take the requested regulatory action, the Commission would have to declare under the FHSA that products containing PVC intended for use by children of five years old and younger were "hazardous substances." This would require the Commission to find that such PVC products met the FHSA's definition of hazardous substance, which requires in this instance not only that the product be toxic, but that it "may cause substantial personal injury or substantial illness during or as a proximate result of any customary or reasonably foreseeable handling or use, including reasonably foreseeable ingestion by children." 15 U.S.C. § 1261(f)(1)(A).

In making a decision whether to grant a petition and commence rulemaking, the Commission is to consider, *inter alia*, the following factors:

- Whether the product involved presents an unreasonable risk of injury
- Whether a rule is reasonably necessary to eliminate or reduce the risk of injury
- Whether failure of the Commission to initiate the rulemaking proceeding requested would unreasonably expose the petitioner or other consumers to the risk of injury which the petitioner alleges is presented by the product

16 CFR § 1051.9

The ban rulemaking would be conducted under section 3(a) of the FHSA.[1] Section 3(a)(2) of the FHSA requires that a rulemaking such as the one requested be conducted in accordance with section 701(e) of the Federal Food, Drug, and Cosmetic Act (FDCA).[2] Under section 701(e), for the Commission to proceed to rulemaking, the petition must set forth "reasonable grounds" for the requested action. The United States Court of Appeals for the District of Columbia Circuit has held that "reasonable grounds" for a petition under the FHSA "are grounds from which it is reasonable to conclude that the Commission would be able to make the findings required to issue the requested rule and to support those findings with substantial evidence on the record."[3]

The Commission considered the petition and the materials submitted with it; the June 15, 2001 final report of the Chronic Hazard Advisory Panel (CHAP) on DINP convened in accordance with sections 28 and 31 of the Consumer Product Safety Act, 15 U.S.C. §§ 2077, 2080; a CPSC staff behavioral observation study to determine how much time young children actually spend mouthing objects and the types of objects they mouth; the November 1997 Commission staff report entitled, *CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products*; the 488 public comments received on the petition; the staff briefing package dated **August 13, 2002**; information presented by the staff during an oral

[1] 15 U.S.C. § 1262(a).
[2] 21 U.S.C. § 371(e).
[3] *Consumer Federation of America v. CPSC*, 883 F.2d 1073, 1076 (D.C. Cir. 1989).

briefing on November 8, 2002; comments received on the staff briefing package; and other information.

The staff briefing package recounts the extensive scientific and technical investigations that have been carried out by the CPSC and others on the issue of PVC in products intended for children and concludes as follows.

> Based upon the scientific data presented in this briefing package, the staff believes that there is no demonstrated health risk posed by PVC toys or other products intended for children 5 years of age and under and thus, no justification for either banning PVC use in toys and other products intended for children five years of age and under or for issuing a national advisory on the health risks associated with soft plastic toys.

Memorandum from Marilyn L. Wind, Ph.D., Deputy Associate Executive Director, Directorate for Health Sciences, to the Commission, *Response to Petition HP 99-1*, **August 13, 2002**, at 16-17.

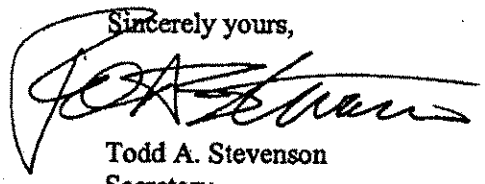
That conclusion is based in part on the finding of the DINP CHAP that, "[f]or the majority of children, the exposure to DINP from DINP-containing toys would be expected to pose a minimal to non-existent risk of injury." *Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP)*, June 2001, Executive Summary item 17. The new data from the recent CPSC behavioral observation study reported in the staff briefing package, which was not available at the time of the CHAP's deliberations, confirm this conclusion and demonstrate that children are exposed to DINP at even lower levels than the CHAP assumed when they reached their conclusion. Further, the recent survey of toys mouthed by children under the age of three also reported in the staff briefing package shows that not all soft plastic toys contain DINP. Therefore, exposure would be even less than the CHAP predicted because children mouth these toys for less time per day than the CHAP estimated, and the average amount of DINP in toys mouthed by children under the age of three is less than the CHAP estimated. If the risk to children under the age of three is not sufficient to warrant action, then based upon the data collected in the staff's behavioral observation study, and the data available in published literature, which indicate that mouthing declines as children age, there is no basis for the findings necessary under the CPSC regulations governing grant or denial of petitions or the FHSA for the Commission to take the requested actions with respect to DINP in PVC toys and other products intended for children five years of age and under.

With respect to lead and cadmium, in November 1997, the Commission staff issued a report entitled, *CPSC Staff Report on Lead and Cadmium in Children's Polyvinyl Chloride (PVC) Products*. That report detailed the results of testing the Commission staff conducted on children's products that Greenpeace had alleged contained hazardous levels of lead and cadmium. Although some of the vinyl products identified by Greenpeace and tested by CPSC

staff contained lead or cadmium, further testing and evaluation revealed that hazardous amounts of lead or cadmium were not released from the products. This means that children would not be exposed to hazardous levels. The report concluded that children would not be exposed to hazardous levels of lead or cadmium when the products are handled or used in a reasonably foreseeable manner. Thus, there is no basis for the findings necessary under the CPSC regulations governing grant or denial of petitions or the FHSA for the Commission to take the requested actions with respect to lead or cadmium in PVC toys and other products intended for children five years of age and under.

In sum, as a result of consideration of the extensive research and analysis summarized herein, the Commission has denied the petition and declined to issue the requested national health advisory.

Sincerely yours,



Todd A. Stevenson
Secretary

Copy to:

Nancy Chuda
Director
Children's Health Environmental Coalition

Mary Ellen Fise
General Counsel
Consumer Federation of America

Rick Hind
Legislative Director
Toxics Campaign
Greenpeace USA

Justine Maloney
Washington Representative
Learning Disabilities Association

Sheila McCarron
Program Director
National Council of Catholic Women

Sammie Moshenberg
Director (Washington Office)
National council of Jewish Women

Philip Clapp
President
National Environmental Trust

Robert K. Musil, Ph.D.
Executive Director
Physicians for Social Responsibility

Jaydee Hanson
Assistant General Secretary
United Methodist Church--
General Board of Church and Society

Pamela Spar
Executive Secretary
United Methodist Church--
Women's Division

Gene Karpinski
Executive Director
U.S. Public Interest Research Group

Ed Hopkins
Vice President
Environmental Working Group

U.S. CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

STATEMENT OF THE HONORABLE MARY SHEILA GALL ON VOTE TO DENY PETITION REQUESTING A BAN OF POLYVINYL CHLORIDE IN TOYS AND PRODUCTS INTENDED FOR CHILDREN FIVE AND UNDER

February 20, 2003

Today I voted to deny a petition submitted by a group of organizations that asked the Commission to ban Polyvinyl Chloride (PVC) in all toys and other products intended for children aged five years and under. The Commission staff gave extensive consideration to the allegations of the petition and thoroughly examined all of the health effects alleged to be caused by children's mouthing of products made of PVC. The staff paid particular attention to products that used diisonyl phthlate (DINP) as a plasticizer. This thorough examination revealed that there is no risk posed by PVC that rises even remotely to that specified by the Federal Hazardous Substances Act (FHSA), the statute under which the Commission regulates this type of risk. Accordingly, the petition must be denied.

The Commission and its staff gave careful attention to the allegations of the petition, as they properly should when claims of detrimental health effects to children are made. A previous Commission staff risk assessment concluded that the lead and cadmium in PVC products posed no risk of injury to children and the petitioners submitted no evidence that called into question the results of that risk assessment. Assessing the risk posed by DINP in PVC involved work beyond that contained in the earlier risk assessment. The Commission went to great lengths to assess all the risks that might be posed by DINP. The staff used a method validated by two international interlaboratory studies of measuring the quantity of DINP that migrates from PVC products. The staff then used that method to estimate the amount of DINP that actually entered a child's body when a PVC product was mouthed. The Commission then convened a Chronic Hazard Advisory Panel (CHAP), which reviewed extensive toxicological data about DINP. The CHAP concluded that for the vast majority of children the exposure to DINP from PVC-containing products posed a minimal to non-existent risk of injury. Data from a subsequent Commission staff study of exposure times of children mouthing products revealed that children were exposed to even less DINP than the CHAP had assumed in making its finding. The chance that children are being injured from mouthing products made from PVC is *de minimus*. There is simply nothing in the record that remotely justifies any finding that PVC products intended for children constitute a hazardous substance within the meaning of the FHSA.

While the Commission has no legal authority to ban PVC products intended for use by children, there is toxicity data showing that it is a carcinogen in rodents, although it is a type of

cancer not usually associated with humans. As least partially in response to these toxicity findings, in 1998 the toy industry and large retail chain stores in the U.S. voluntarily agreed not to sell items made out of PVC designed to be placed in the mouth (e.g., teethers, rattles and pacifiers). The European Union and Japan reached a similar result through their own regulatory processes.

Chronic hazards are among the most technically difficult product-safety problems that the Commission considers. Unlike acute hazards, where the effects occur very quickly and are easily observable, chronic hazards involve health effects that may occur many years after exposure and which may be difficult to trace to exposure to any particular substance. Considerable scientific expertise must be brought to bear on any allegations of chronic hazards and the result must always reflect a judgment call. This may be subject to revision if more is learned about the toxicity or exposure of a specific substance. In the case of PVC, however, consumers may have a high level of assurance that soft plastic products pose no risk to children.

UNITED STATES
CONSUMER PRODUCT SAFETY COMMISSION
WASHINGTON, DC 20207

STATEMENT OF THE HONORABLE THOMAS H. MOORE ON THE PETITION TO BAN POLYVINYL CHLORIDE IN PRODUCTS INTENDED FOR CHILDREN FIVE YEARS OF AGE AND UNDER

February 21, 2003

I am voting to deny the petition to ban polyvinyl chloride in products intended for children five years of age and under. The clear weight of the evidence produced by staff supports the conclusion that children are not at risk from mouthing products currently on the market that contain diisononyl phthalate (DINP). This evidence consists of new exposure studies showing how long children mouth various objects, the migration rates of phthalates from products on the market, an Acceptable Daily Intake that has an extremely large uncertainty/adjustment factor and a scientific consensus that DINP is nongenotoxic and that the cancer caused by peroxisomal proliferation by DINP in the liver of rodents is not relevant to humans. As these are the best and most current scientific opinions, I believe the Commission must bow to that judgment. Our staff has done extraordinary work on this petition—by far the most comprehensive work done to date anywhere in the world. I congratulate them on their achievement. Both their work, and the work of the scientists who participated in the Chronic Hazard Advisory Panel on DINP, should calm parents' fears about the potential harm to young children from children's products currently on the market that contain DINP.

I am concerned, however, that the staff's conclusions could be the basis for industry to use phthalates in products that they have voluntarily agreed not to use them in, namely rattles, teethers and pacifiers. One area in which we do not have concrete information is the migration rate of DINP from these three types of children's products. Our assumption about the migration rate of phthalates from these products could prove to be too low. We also are not completely sure how much phthalates very young children are exposed to from other sources in their environment. This background exposure, coupled with the uncertainty of the rate of migration, made me consider voting to defer action on the petition until we see what happens in the marketplace as a result of the staff's conclusions. If phthalates were to be used in teethers, rattles or pacifiers in the future, the uncertainties mentioned above could cause us to be petitioned again in this area. I decided that I would not vote based on speculation of what might happen. All I can vote on today is the current state of the marketplace and of scientific knowledge, both of which lead to the conclusion that the ingestion of DINP by young children from the children's products on the market poses no risk of harm to America's children.