

# THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg  
*Mayor*

Thomas R. Frieden, M.D., M.P.H.  
*Commissioner*

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nyc.gov/health

TESTIMONY

OF

NANCY CLARK, MA, CIH  
ASSISTANT COMMISSIONER, ENVIRONMENTAL DISEASE PREVENTION  
NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE

BEFORE THE

NEW YORK CITY COUNCIL

COMMITTEE ON HEALTH

On

**INTRO NO 589: BANNING THE SALE OF TOYS, CHILDCARE AND CHILD FEEDING  
PRODUCTS THAT CONTAIN PHTHALATES**

**WEDNESDAY, JUNE 28, 2007**

**250 BROADWAY, 14 FLOOR**

Good afternoon, Chairperson Rivera and members of the Health Committee. My name is Nancy Clark, and I am the Assistant Commissioner of the Bureau of Environmental Disease Prevention at the Department of Health and Mental Hygiene. With me today is Dr. Nathan Graber of the Environmental and Occupational Disease Epidemiology Program. On behalf of Commissioner Frieden I would like to thank you for the opportunity to testify regarding Intro 589-A.

Phthalates are a diverse group of chemicals widely used because they impart flexibility and resilience when added to polyvinyl chloride plastics (PVC). Phthalates are found in a wide variety of consumer products including personal care products, such as soaps, shampoos and deodorants; vinyl products, such as floor tiles, shower curtains, upholstery, and waterproof clothing; children's toys and vinyl-covered books; care and feeding items; gel caps and coatings on some pharmaceuticals; and medical equipment such as serum bags and IV medical tubing. As a result, human exposure to phthalates is common. Several studies confirmed the presence of phthalates or their metabolites in persons of all age groups, including newborns exposed prenatally.

People are exposed to phthalates in the food they eat, the air they breathe and through direct contact with the many products that contain the chemicals, with ingestion the most common means of exposure. Children, toddlers in particular, have larger exposures than adults, primarily through food and contaminated dust. Young children may also be exposed by mouthing PVC products. Generally, phthalates are metabolized and excreted quickly and do not accumulate in the body.

All six phthalates identified in Intro 589-A have a potential for children's exposure, are present in a wide variety of products, and have been subject to at least some scientific investigation. DEHP and DINP, the most common plasticizers used in children's PVC products, have been studied more exhaustively. The main health concerns posed by phthalate exposure are their potential to interfere with male hormones and male reproductive organ development. There is also a possibility that the chemicals have an adverse effect on female reproductive organs as well.

It is important to note that the studies to date have primarily been conducted on animals and it is difficult to extrapolate animal test results to humans: doses administered to test animals are remarkably higher than those experienced by people in the normal course of development. Moreover, the processes of reproductive tract development are quite simply different for rodents than they are for humans. Thus, though animal studies raise important concerns about phthalate exposure, we cannot assume that people will experience the same health effects as test animals. For example, recent reviews by the National Toxicology Program found clear evidence that DEHP causes adverse developmental or reproductive effects in animals but limited evidence for similar effects in humans at the time.

Intro 589-A would ban the sale of toys, childcare and child feeding products containing phthalates. DOHMH supports the Council's intent to guard against potential adverse health effects from phthalates, however DOHMH opposes this legislation. The efficacy

of a ban on such products is dependent on reliably knowing which products contain the chemicals. However, this legislation covers broad categories of products for which the ingredients are unknown. No federal regulations exist requiring disclosure and labeling of ingredients in plastic products, therefore neither the Department nor the more than 15,000 distributors and retailers in New York City who may sell the targeted products can readily know which products contain phthalates.

Without federal labeling, the phthalate ban proposed in Intro 589-A puts an unfair burden on local businesses, as well as upon the Department. In order to comply with the proposed ban, either businesses or the Department would have to perform laboratory testing to identify phthalate content of every plastic product sold to determine whether it is covered by the bill. The children's plastic toy and care products industries are dynamic markets where new product lines are continually introduced and old lines modified. The potential number of products covered by Intro 589-A is difficult to estimate but is potentially in the thousands. We surveyed environmental laboratories nationwide and identified only a handful with capacity to test phthalates in plastics. In addition, a standardized laboratory method has not been developed and evaluated to accurately measure phthalates in plastic

In addition, testing a plastic product for the six chemicals referenced in Intro 589-A is costly, ranging from \$200 to \$700 per item. This would quickly become prohibitively expensive and infringe upon the ability of both wholesalers and retailers to conduct business in the City. Complying with the 'no sale' requirement would be prohibitively difficult, and businesses may either be compelled to leave the City or break the law, neither of which are satisfactory outcomes.

In summary, any ban of children's products containing phthalates should be considered first at the federal level where production and labeling standards can be implemented for manufacturers as has been done in the European Union. Banning phthalates from children's products at the point of production would eventually eliminate them from the consumer market. Without a supporting federal intervention to require labeling and disclosure of product ingredients, local efforts to identify and prohibit the sale of children's products that contain the six phthalates will likely prove ineffective and haphazard.

Thank you for your interest in this issue. I'm happy to answer your questions at this time.

# COUNTY OF SUFFOLK

LYNNE C. NOWICK  
SUFFOLK COUNTY LEGISLATOR



CHAIR:  
PARKS & RECREATION COMMITTEE  
MEMBER:  
PUBLIC SAFETY COMMITTEE  
HEALTH & HUMAN SERVICES COMMITTEE

## COUNTY LEGISLATURE

June 28, 2007

The Council of The City of New York  
Office of the Speaker  
City Hall  
New York, New York 10007

Dear Members of the City Council and the Committee on Health:

I am sorry that I am not able to attend the Committee on Health's hearing on Int. No. 592 in relation to restricting the sale of medication containing dextromethorphan (DXM) as I am at a scheduled committee meeting of the Suffolk County Legislature. As the sponsor of Suffolk County Resolution 1170, which prohibits the sale of cough/cold suppressants that contain DXM to anyone under the age of 19, I wholeheartedly support this measure. Once in effect, cashiers in Suffolk County will have to check proof of age for youth purchasing cold or cough medicine with DXM.

DXM is an ingredient found in many cough suppressants and when used improperly causes serious adverse effects such as seizures, hallucinations, irregular heartbeat, respiratory distress, brain damage, coma and even death. As a mother and a legislator, I am very concerned about the number of youngsters who abuse these medications by taking extremely large doses to get "high."

During Suffolk County's public hearings, we heard from a number of drug treatment counselors that young people were abusing cough suppressants because it was easily accessible and affordable. One counselor related a story about a young man who was temporarily blinded from abusing cough medicine and that when he recovered his sight he continued to take large doses of cough medications. I received a call from a mother who had no idea her son was abusing Coricidin until he suffered a seizure and he admitted what he was doing. Coricidin contains dextromethorphan, but no alcohol. He is now in a treatment program.

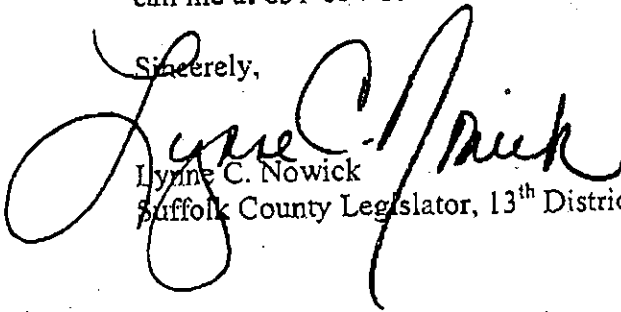
Last week my office received a phone call from Costco Wholesale to advise us that they were implementing the law immediately since they sell large packages of cough suppressants. In addition, CVS/Pharmacy has already instituted a chain-wide policy to restrict sales to minors because they were aware of this trend. They will adjust the age for the stores in Suffolk County.

In conjunction with this law, I believe it is imperative that we educate the public about the deleterious effects of DXM to prevent its abuse. I have sponsored a resolution to designate the month of August as National Medicine Abuse Awareness Month. The Community Anti-Drug Coalitions of America and I will be working together to organize community awareness programs geared to educate parents and teachers.

I believe it is incumbent upon government officials, such as us, to protect the well being of children and to preserve our youth. This legislation is a step in that direction and I applaud Council Member Maria Bacz for introducing this initiative.

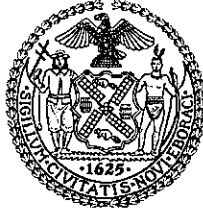
Thank you for this opportunity and if you have any questions, please do not hesitate to call me at 631-854-3900.

Sincerely,



Lynne C. Nowick  
Suffolk County Legislator, 13<sup>th</sup> District

LCN:see



**THE CITY OF NEW YORK**  
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg  
*Mayor*

Thomas R. Frieden, M.D., M.P.H.  
*Commissioner*

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nyc.gov/health

Testimony

of

**Jorge R. Petit, M.D.**  
**Associate Commissioner**  
**New York City Department of Health and Mental Hygiene**

before the

**New York City Council**  
**Committee on Health**

regarding

**Intro 592-A: A local law to amend the administrative code of the city of New York,  
in relation to restricting the sale of medication containing dextromethorphan.**

June 28, 2007

250 Broadway, New York City

Good afternoon Chairman Rivera and members of the New York City Council Health Committee. I am Jorge R. Petit, MD, Associate Commissioner for Mental Hygiene at the Department of Health and Mental Hygiene. I am joined today by Dr. Louis F. Cuoco, Acting Assistant Commissioner for Chemical Dependency. On behalf of Commissioner Frieden, thank you for the opportunity to testify on Intro 592-A.

Dextromethorphan, or DXM as it is often called, is a common ingredient in many over-the-counter cold and cough remedies. According to the federal Substance Abuse and Mental Health Services Administration, large doses of dextromethorphan can produce hallucinations and a "high" similar to psychotropic drugs. Large doses of DXM may also lead to unpleasant or dangerous side effects. However, these side effects are no worse, and far less common than those resulting from large doses of many other drugs that are considered safe.

Data on the extent of DXM abuse is scarce. Since 2003, of over 480,000 cases of toxic exposures reported to the NYC Poison Control Center, 112 cases – or 0.002 percent—were for dextromethorphan exposure. About half of these 112 DXM exposure cases involved suspected suicide attempts, and 44 percent, approximately 49 cases, were reported as DXM abuse or misuse. Of all intentional DXM misuse and abuse exposures reported during this six and a half year period, 64 percent – or 31 cases – were by teens 13 -19 years of age. To put this data into context, there were over 10,000 cases of intentional abuse and misuse reported to Poison Control during the same period, putting DXM abuse by teens at 0.3 percent of all abuse and misuse cases.

In a review of hospitalization data for the seven-year period 1997-2004, we found that, on average, 16 New York City residents per year were hospitalized for exposures to cough syrup. Of those hospitalized, approximately 40 percent were children under the age of 18, and nearly half of all hospitalizations involved suspected suicide attempts, rather than attempts to get high. Published news accounts about DXM abuse in suburban counties, and on Long Island in particular, suggest that the problem may be more prevalent there

Intro 592-A would limit the sale of medications containing dextromethorphan to individuals older than eighteen. A key Department of Health and Mental Hygiene priority is helping New Yorkers live free of dependence on alcohol and drugs, however the Department lacks any indication that this legislation will have a significant public health benefit. Dextromethorphan abuse is a complex problem, and Intro 592-A raises a number of concerns that prevent us from supporting this legislation.

The proposed legislation may have unintended consequences for consumers who require cold or cough remedies for legitimate, medicinal purposes. For example, under the proposed legislation, young mothers would not be able to purchase these medications for themselves or their children, and college freshmen may have to rely on older classmates to buy it for them.

Under this legislation, all consumers would experience difficulty making an informed choice about which product to buy. More than 100 over-the-counter medications contain dextromethorphan. Choosing among them can be a daunting task, particularly for those who have adverse reactions to other ingredients commonly found in cough medication, such as aspirin. This task would be made more complex by placing cough medications behind the counter, where consumers' access to ingredient information and contraindication labeling, as well as the time to read it in a busy pharmacy, is much more limited.

Furthermore, the danger of adolescents abusing DXM may not be ameliorated by restricting access to dextromethorphan to those eighteen and older. Restricting sales in New York City would not prevent youth who want dextromethorphan from purchasing cough medication online, where it is readily available, or in New Jersey, Nassau or Westchester County.

Enforcement of the proposed legislation poses other challenges. Pharmacies, bodegas and supermarkets would have to request consumer identification for purchases of over-the-counter cold remedies. The Department of Consumer Affairs would have to send inspectors out to monitor whether businesses are complying with the law and devise a system to address complaints about non-compliant businesses.

The Department is committed to improving the health and mental hygiene of New Yorkers, including addressing adolescent substance abuse. However, the Department cannot support this legislation without more information regarding the extent of dextromethorphan abuse in New York City; the effectiveness of restricting sales of products containing DXM; the unintended public health consequences of limiting minors' access to these medicines; and the logistical challenges and operational costs of compliance and enforcement.

We appreciate the Council's interest in this issue, and are pleased to answer any questions you may have at this time.

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**Comments on Int. No. 589 – In relation to the sale of toys, childcare and child feeding products that contain phthalates**

Good afternoon. My name is Rick Locker, General Counsel to the Juvenile Products Manufacturers Association (JPMA).

JPMA is a not-for-profit trade association composed of more than four hundred (400) members, whose aggregate sales at the retail level exceed \$5 billion annually. We are dedicated to child safety issues. We sponsor Baby Safety Month in September every year. We work with the KIDS (Kids in Distressed Situations), First Candle (formerly known as The SIDS Alliance), International Safe Kids, and the U.S. Consumer Product Safety Commission (in Bethesda, Md.) to promote child safety. We are actively involved in the development of more than 17 different ASTM safety standards for nursery products. Please check us out at [www.jpma.org](http://www.jpma.org). We are national in character but local in nature. More than half of our members are small businesses with sales under one million dollars a year. Many are located in New York City.

On behalf of JPMA and the Industry, I would like to address the subjects of BPA in polycarbonate and phthalates in vinyl child care items and toys, which the proposed legislation before you (**Int. No. 589**) needlessly proposes to ban.

We welcome any serious review of safety issues related to children. We are committed to their well being. The products our members make are dedicated to the care or enjoyment of children. However, a ban as is being proposed is simply not supported by the science. In addition, risk assessments performed by the federal agencies with authority and responsibility to regulate consumer products made with these plastics supports the safety of consumer products made with these plastics. Proponents of this bill base their support on an unsubstantiated hypothesized threat to child health. Banning reasonably produced and government established safe products could force consumers to use less tested, less safe, alternative materials. In the process, such a Ban actually deprives Consumers of the ability of consumers to choose which products they want to buy for the care and enjoyment of their children.

We are gravely concerned that laws not be passed based upon unverified reports or data that ignore or misinterpret the science. You've already heard from expert witnesses steeped in the sciences, that Di-isononyl phthalate (DINP), the phthalate most commonly used in toys (with a 50-year history of safe use) are safe as used in products. You've heard that there is record of considerable evidence on the safety of these plastics. For example:

- an exhaustive study done by an independent U.S. federal government agency, the U.S. Consumer Product Safety Commission (CPSC) specifically looked at the use of DINP in toys. The Agency relied on a Chronic Hazards Advisory Panel, derived from expert members of the National Academy of Sciences, review of data which determined that **children were not at risk from exposure in consumer products.**
- Following behavioral studies of what children actually do with toys, and using worst case scenarios and an exhaustive risk assessment, the CPSC study concluded that **"...consumers may have a high level of assurance that soft plastic products pose no risk to children."**
- The U.S. CPSC was not alone in its findings. Similarly, an independent assessment by the European Chemicals Bureau of the European Commission found that DINP is **"unlikely to pose a risk for consumers..."**

This independent extensively conducted government research confirms that children are not at risk when they play with or use vinyl toys and child care products softened with the phthalate DINP. This evidences the fact that there is no solid, scientific evidence that any person has faced a significant health risk because of the mere presence of phthalates in toys.

No other substance has the solid, safe track record in toys that DINP does, and please remember that the CPSC cautioned in their study, toys made with alternative substances could be "...weaker or more brittle [and] may break and result in a choking hazard."

**Our members' products are among the safest of all consumer products commonly found in the home.** Protective vinyl covering prevent bacteriological contamination of child care products; car seats prevent thousands of injuries and deaths. The plastic vinyl used adds to the safety benefits inherent in these products specifically designed for safe use with children.

In sum, there is simply no sound, scientific reason to ban the use of vinyl child care items and toys. Please don't act rashly. Thank you.

**TESTIMONY BEFORE THE COUNCIL OF THE CITY OF NEW YORK  
COMMITTEE ON HEALTH**

**MOUNT SINAI PEDIATRIC ENVIRONMENTAL HEALTH SPECIALTY UNIT  
CENTER FOR CHILDREN'S ENVIRONMENTAL HEALTH  
AND DISEASE PREVENTION RESEARCH**



**MOUNT SINAI  
SCHOOL OF  
MEDICINE**

**PHTHALATES AND CHILDREN'S HEALTH**

**June 28, 2007**

**MAIDA P. GALVEZ, MD, MPH**  
Assistant Professor

**JOEL A. FORMAN, MD**  
Associate Professor

**BARBARA BRENNER, DrPH**  
Associate Professor

**PHILIP J. LANDRIGAN, MD, MSc**  
Professor and Chair  
Department of Community and Preventive Medicine  
Mount Sinai School of Medicine

## **Phthalates**

Phthalates are a family of chemicals added to some plastics to make them softer and more flexible. Worldwide production has increased from very low levels in the mid 1940's to approximately 3.5 million metric tons/year (Bornehag et al. 2004; Cadogan and Howick 1996). Due to its widespread use, concerns have been raised that children, especially infants and toddlers, may be uniquely vulnerable and hence may suffer long term health effects from phthalate exposure at critically important stages of development.

## **Phthalates are Widely Prevalent**

Phthalates are found in many common consumer products such as food packaging, vinyl flooring and wall covering, medical supplies such as intravenous tubing, and personal care products including fragrances, cosmetics and nail polish.

## **Children are At Risk for Exposure to Phthalates**

Phthalates are widely used in products manufactured specifically for children including toys, infant bottles and pacifiers. Diethylhexylphthalate or DEHP, a common phthalate found in children's toys and products, is produced in volumes approaching 2 million tons per year. ***It is estimated that the total intake of DEHP is higher in all children younger than 19 years than in adults. Highest estimated phthalate intakes are in children under 4 years old.*** Since phthalates are not chemically bound to the plastics to which they are added, they can leach out of products causing exposure by ingestion of foods found in plastic packaging, children's mouthing of products with phthalates, breathing in dust generated from phthalates containing products, or through direct contact with skin.

## **Phthalate Exposure is Widespread**

The Centers for Disease Control and Prevention has published three national surveys assessing phthalate exposure by measuring levels in the urine of the US population ages 6 years and older. These surveys indicate that the US population is widely exposed to phthalates (Centers for Disease Control 2001-2003). ***Measurable concentrations of phthalates are present today in the bodies of nearly all Americans and children have disproportionately high levels..***

## **Children are Uniquely Vulnerable to Phthalate Exposure**

There is a growing concern that children may be uniquely vulnerable to phthalate exposures as they frequently place toys and other plastic products in their mouth, an age appropriate behavior. This is in part because children (1) consume more calories per kilogram of body weight, (2) breathe faster than adults, (3) consume more dairy products and other fatty foods which often have higher levels of phthalates and (4) mouth, suck and chew on plastic toys and products.

## **Health Effects in Children**

Animal studies demonstrate that phthalates can affect the liver, kidneys, thyroid, testes and reproductive system. Phthalates have also been shown to cause fetal death, malformations, infertility, and liver and kidney cancer in laboratory animals.

Pregnant laboratory animals exposed to DEHP have borne offspring with skeletal, cardiovascular and eye abnormalities, neural tube defects, increased rates of spontaneous abortions, increased infant mortality, and stunted growth both during and after pregnancy. Thus, exposures in pregnancy may be harmful to offspring even in the absence of clinical symptoms in the mother. This further demonstrates the unique vulnerability of children when exposed at critical stages of development.

Human studies are limited. A study by Bornehag et al (Environmental Health Perspectives 2005) demonstrated that phthalates, within the range of what is normally found in indoor environments, are associated with allergic symptoms in children. These symptoms included allergic rhinitis, eczema and asthma. A study by Colon et al (Environmental Health Perspectives 2000) raised the question of a

possible association between plasticizers and early breast development in young Puerto Rican girls.

Mount Sinai School of Medicine is one of three Breast Cancer and the Environment Research Centers (BCERC) in the country, a consortium established by the National Institute of Environmental Health Sciences and the National Cancer Institute to assess the role of environmental factors, including phthalate exposure, on early puberty in 1200 girls across the country.

The Mount Sinai Center for Children's Environmental Health and Disease Prevention Research is currently examining the role of phthalates and other plasticizers and their impact on children's growth and development, specifically with respect to children's risk for obesity. This community based project has enrolled 400 East Harlem children ages 6-8 years old. Included with this testimony are materials developed by our Center to educate New York City families about phthalates and potential health concerns.

### **Protecting the Health of New York City Children**

The full range of phthalate toxicity in humans is not yet known due to the lack of human studies. In July 2000, an expert panel convened by the Center for Evaluation of Reproductive Risks to Humans of the National Toxicology Program and funded by the National Institute of Health **expressed concern that infants and young toddlers because of their diets and mouthing behaviors, might have higher exposures to DEHP at a time when the male reproductive tract is still developing and potentially vulnerable** (Cortes et al. Int J Androl 1987). Studies have demonstrated that the system most sensitive to phthalate exposure is the reproductive tract of immature males. Changes are seen in the testes as well as decreased sperm numbers (Poon et al, Food Chem Toxicol. 1997 and Lamb et al, Toxicol Appl Pharmacol. 1987).

In response to the disturbing disorders seen in the experimental studies of phthalate toxicity that were noted above, the European Union and the City of San Francisco have taken action and reduced the burden of phthalate exposure in vulnerable populations. **In fact, due to the uncertainty in predicting total phthalate exposure of infants and very young children through ingestion, mouthing, and inhalation of phthalates, the United States and Canada have recommended removal of all phthalates from infant bottle nipples, pacifiers, teething, and infant toys intended for mouthing.**

In these instances, government has taken a precautionary approach, refusing to wait until human studies confirm the health effects already seen in animals. These measures have been enacted to protect our most vulnerable populations, infants and toddlers at critical stages of development, and hence at greatest risk for a wide range of potential health effects.


New York City has the opportunity to join the ranks of the European Union and San Francisco in clearly stating that children's environmental health is a top priority and New York City will not continue to allow products to be tested in the global market to see whether decades later there is the potential for harm. We have seen this cycle of public health tragedies time and again, with lead, asbestos, mercury and countless other environmental hazards.

We must ensure that toys and products used regularly by children are free from harmful chemicals such as phthalates. Council member Gioia's proposal propels New York City to the forefront of children's environmental health protection. Legislation banning the use of phthalates in children's toys and products will protect the health of generations of NYC children.

Reference: American Academy of Pediatrics Committee on Environmental Health. Pediatric Exposure and Potential Toxicity of Phthalate Plasticizers. Pediatrics 2003, Vol. 111, No 6.





# A Pocket Guide to Plastics For Easy Reference

## Front of card


Pocket Guide to Plastics  Guía del Buzillo a los Plásticos

Growing Up Healthy  
(212) 241-3181  
Creciendo Saludable

safer Plastics  
*Plásticos Más Seguros*




 PETE	 HDPE
 LDPE	 PP



## Back of card

Pocket Guide to Plastics  Guía del Buzillo a los Plásticos

Growing Up Healthy  
(212) 241-3181  
Creciendo Saludable

Plastics to Avoid  
*Plásticos Que Deben Evitar*

 V (Usually PVC or vinyl)	 PS (Usually Styrofoam)
 OTHER	

 Mount Sinai Community Health Bulletin 





### Quick Guide to Safe Plastics

Staying Healthy in a Changing Environment #3




All plastics are not the same. Some are safer than others. When plastics come in contact with food and water, they can leak certain chemicals. The Growing Up Healthy Pocket Guide to Plastics can be used while shopping to help you make the best choices for you and your family.

**Check the symbol on the bottom of plastic items before you buy:**

**The safer plastic choices for food and beverages**

 PETE	 HDPE	 LDPE	 PP
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**Plastics to try to avoid**

 V (Usually PVC or vinyl)	 PS (Usually Styrofoam)	 OTHER
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**Other tips for the safe use of plastics:**

1. Try not to use plastic containers in the microwave. If you can, it's safer to use glass or ceramic containers.
2. Beware of using plastic wraps in the microwave. A safer choice is waxed paper.
3. Try to reduce your use of products made of PVC, vinyl or Styrofoam.

For more information, contact: Dr. Luz Claudio or Peere Chace (212) 241-1222 [peere.chace@mssm.edu](mailto:peere.chace@mssm.edu)

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# Mount Sinai Community Health Bulletin



## PHTHALATES

Staying Healthy in a Changing Environment #2



**Q.** What do these everyday household items have in common?

**A.** These products sometimes contain chemicals called phthalates, which may be unhealthy.

### What are Phthalates?

Phthalates (pronounced THAL-ates) are a family of chemicals added to some plastics to make them softer and more flexible. Phthalates are often found in products made of vinyl, or PVC. Household items that may contain phthalates include:

- vinyl flooring
- raincoats
- shower curtains
- some children's toys

Phthalates can also be used to make fragrances last longer in products such as cosmetics and perfumes. Nail polish may contain phthalates, which are added to make the polish last longer.

### Are Phthalates Harmful?

Some laboratory studies have shown that phthalates can cause liver cancer and kidney damage in lab animals. Other studies have found that phthalates can cause problems with the reproductive system. Very few studies have examined the health effects of phthalates on humans. Even so, many companies have removed phthalates from their products due to the suspected health effects. However, many products on the market still contain phthalates.

### How Am I Exposed to Phthalates?

Phthalates can enter the body through direct contact with the skin. Phthalates can also enter the body through the mouth when babies or children bite or suck on vinyl toys. Phthalates have been removed from pacifiers, teething rings, and rattles, but other toys are not required by law to be phthalate-free. New research also suggests that phthalates might aggravate asthma and allergies.

### What Can I Do?

We don't yet know exactly how phthalates affect human health. Until more research is done, it makes sense to reduce our use of vinyl and PVC products as much as possible. Healthy alternatives to vinyl include products made of cloth, ceramic tile, metal, and glass.


### How Can I Tell if A Product Contains Phthalates?

There is no easy way to tell if a product contains phthalates. Sometimes you'll notice a distinct "plastic" odor. If you see a '3' or 'V' (or both) along with the recycling arrows stamped on an item, the plastic probably contains phthalates.



For more information, contact: Dr. Luz Claudio or Reeve Chace, (212) 241-1233, [reeve.chace@msm.edu](mailto:reeve.chace@msm.edu)

Mount Sinai Medical Center GOO#03-0389



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**Testimony of Jeffrey Holtzman  
President and CEO of The Goldberger Company  
before the New York City Health Committee  
June 28, 2007**

Good afternoon. My name is Jeff Holtzman and I am the president and CEO of the Goldberger Company, a New York City based corporation which has been manufacturing dolls for over 90 years. I was the president of The Metropolitan Association of Doll, Stuffed Toy and Plastic Manufactures Inc., an association of local manufacturers working with Local 223 of the AFLCIO, from 1996 – 2001.

I am attending the hearing at the invitation of Councilman Eric Gioia.

I believe that unless the City of New York is able to craft a bill which would be accurate in its assessments of health risks, fair to all sides and reasonable to implement and regulate, we may never reach legislation to protect our youngest members of society.

While all soft phthalate-free vinyls may contain trace amounts of phthalates, we consider “phthalate-free vinyl” as vinyl that meets or exceeds the limits of EN71, the European Standard and Ordinance 120, the ordinance of the city of San Francisco. The Goldberger Co. is one of the first doll manufacturers to reduce the use of phthalates in all of our baby dolls.

I am neither a scientist nor a government policy maker; I am a businessman and also a concerned parent and I feel it is necessary to take this pro-active approach.

I support Councilman Gioia’s position on limiting phthalates, however, I believe that the proposal, as it is currently written, will produce unintended consequences similar to those the city of San Francisco has experienced with Ordinance 120. Because their ban is so broad, the city is now in court defending what may be indefensible positions and threatening the life of a bill designed to protect children.

As Councilman Gioia’s legislation refers to questionable chemicals that may enter a child’s system orally, I believe it is not necessary for the proposed bill to include materials which would never come in contact with a child’s mouth. Inaccessible parts, such as the inside of a toy, be not subject to the same limitations as surface areas. For example, if a toy has a mechanism inside that contains phthalates, as many electronic mechanisms do, the child is, essentially, at no risk. The legislation, however, as written, would already ban this toy in the marketplace.

The City of New York has an opportunity here to set the standards for the entire nation. I would like to offer my help to Councilman Gioia to achieve the outcome of fair legislation.





Public Hearing  
Re: Int. No. 589  
New York, New York  
June 28, 2007  
Presented by: Marian K. Stanley  
American Chemistry Council

STATEMENT OF  
THE AMERICAN CHEMISTRY COUNCIL PHTHALATE ESTERS PANEL  
OPPOSING Int. No. 589

“A Local Law to amend the administrative code of the city of New York, in relation to the sale of toys, childcare and child feeding products that contain phthalates”

**SUMMARY OF THE PANEL’S POSITION**

Extensive science shows that the bans proposed in this Bill are unnecessary to protect human health. Government-sponsored risk assessments in both the U.S. and Europe have demonstrated that human exposures to phthalates in consumer products, including child care products and toys, are generally well below any level that has been shown to cause adverse health effects in laboratory animals and below government established safety levels. Importantly, an exhaustive scientific review of the safety of children’s vinyl toys containing phthalates conducted by the U.S. Consumer Product Safety Commission (CPSC) recently concluded, “there is no demonstrated health risk posed by PVC toys or other products intended for children 5 years of age and under.”

The effect of the bans on phthalates proposed in Int. No. 589 would be to place a significant burden on both manufacturers and retailers of phthalate-containing products, and on the consumers who rely on the performance and convenience of products made with phthalates, while providing no measurable benefits to human health. For these reasons, the Panel opposes Int. No. 589.

**THE PANEL IS COMMITTED TO THE SAFE USE OF PRODUCTS MADE WITH PHTHALATES**

The Panel is composed of all major manufacturers and some users of the primary phthalate esters in commerce in the United States. Since its inception in 1973, the Panel has demonstrated its commitment to the safe use of their products by sponsoring health, safety and environmental research on phthalate esters. Results of Panel-sponsored research are routinely shared with government agencies around the globe in order to support a comprehensive and thorough assessment of the safety of its members’ products. Panel research and conclusions are peer-reviewed and published in respected scientific journals. Phthalate esters produced by Panel

members have been subjected to extensive health and environmental scrutiny by both independent scientists and national and international government bodies. The Panel is committed to continued research and testing of phthalates and works closely with government agencies to help maintain the safe use of these materials in a wide array of products consumers find valuable in everyday life.

**SCIENTIFIC EVIDENCE SHOWS THAT THE BANS ON PHTHALATES PROPOSED IN INT. NO. 589 ARE UNNECESSARY TO PROTECT HUMAN HEALTH**

The Panel strongly supports regulation of chemicals based on sound science. Phthalates are among the most well toxicologically defined chemicals on earth, having been the subject of hundreds of studies in lab animals and numerous government-sponsored assessments of the risks to human health posed by exposure to phthalates. The Panel firmly believes the great weight of scientific evidence demonstrates that the bans on phthalates proposed in Int. No. 589 are unnecessary to protect human health.

Int. No. 589 proposes to ban di(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), and di-n-octyl phthalate (DnOP) in concentrations exceeding 0.1% in any toy, childcare product, or child feeding product. At the outset, the proposed ban of some of these six phthalates in children's toys would do little to protect children's health if for no other reason than these phthalates typically are not used in such children's products. BBP is most commonly used in flooring and insulating sealants, DBP is used primarily in adhesives, as a solvent for organic compounds and in cosmetics and personal care products, and DEHP is used primarily in medical devices and some soft plastic toys, but not those intended to be placed in the mouth by children. In addition, numerous government risk assessments of these phthalates, as well as a U.S. Consumer Product Safety Commission risk assessment of diisononyl phthalate (DINP), the phthalate most commonly used in toys, have demonstrated that exposure to phthalates in toys and children's products generally poses no significant risk to children.

Both the U.S. National Toxicology Program (NTP) and the EU have performed risk assessments on phthalates proposed to be banned by Int. No. 589, and have generally found no significant risk to children from exposure to these phthalates.<sup>1</sup> For example,

- For BBP, the NTP assessment found “*minimal concern for adverse developmental effects in fetuses and children*” and the EU assessment, which looked at all sources of exposure to children, including toys, found “*no concern for local exposure to BBP*” and “*no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.*”
- For DBP, the NTP assessment found “*minimal concern*” for fetal developmental effects for pregnant women with typical exposure, and “*some concern*” for male fetal development in women with high exposure, though this conclusion was based on exposure estimates that turned out to be significantly higher than actual

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exposures. The EU assessment, to be thorough, considered the “unintentional use” of BBP in toys. Even with such use, the EU found no “*no need for further information or testing or risk reduction measures*” to protect consumers, including children.

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As mentioned above, the most relevant government risk assessment with respect to phthalates in toys is the U.S. Consumer Product Safety Commission’s 2001 safety assessment of vinyl toys softened with phthalates, in particular the phthalate that is by far most commonly used in toys – DINP.<sup>2</sup> This extensive risk assessment found “*no demonstrated health risk*” to children from exposure to DINP from toys and child care articles. The CPSC declined to take action on a petition to ban the use of phthalates in children’s toys following its intensive review, which had included evaluation of children’s behavior in mouthing toys. Similarly, the NTP risk assessment of DINP found “*minimal concern*” for adverse effects on human reproduction or fetal development, and for developmental effects in children and the EU assessment of DINP concluded that exposure to DINP from toys and baby equipment is “unlikely to pose a risk” for infants and newborns, and that such exposure “is not considered of concern.”

Based on phthalate use patterns in toys, the weight of scientific evidence, Int. No. 589’s ban on phthalates in children’s articles is unnecessary to protect children’s health.

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## STOP COUGH MEDICINE ABUSE

CHPA's Efforts

The makers of over-the-counter medicines are in the business of improving people's health and quality of life. Educating parents about the potential abuse of our medicines is part of that mission.

**Fact:** The U.S. Food and Drug Administration recognizes OTC cough medicines containing dextromethorphan as safe and effective.

**Fact:** Millions of Americans rely on OTC cough medicines containing dextromethorphan for cough relief, with few side effects.

**Fact:** One in 10 teens reports having abused OTC cough medicines to get high.

The fact is, parents need to be aware that their teens may be abusing OTC cough medicines, as well as prescription drugs. That is why the makers of medicines have joined with the Partnership for a Drug-Free America to raise awareness about this new substance abuse problem: teens intentionally using medicine to get high.

### **Educate. Communicate. Safeguard.**

Research shows that parents have tremendous influence over their teens' decisions not to abuse drugs. To prevent medicine abuse, the best advice is to:

- Educate yourself about the medicines teens may be abusing,
- Communicate with your teens about the appropriate use of medicines and the dangers of abusing them, and
- Safeguard the medicines in your home.

### **Partnership for a Drug-Free America**

The CHPA/Partnership for a Drug-Free America Rx and OTC Medicine Abuse Awareness Campaign includes:

- Educational brochures for parents in English and Spanish
- A web site for parents and one especially for teens, offering peer-to-peer videos about the dangers of abusing cough medicine
- Television (Pharm Town and The Hood), radio, and print public service announcements
- Supporting federal legislation to keep raw, unfinished dextromethorphan out of teens' hands as well as an initiative designating August 2007 as "National Medicine Abuse Awareness Month."

### **Community Anti-Drug Coalitions of America**

CHPA also is pleased to join forces with the Community Anti-Drug Coalitions of America (CADCA) to develop a new educational community toolkit to help coalition and prevention leaders mobilize their communities and educate key stakeholders about the dangers of OTC cough medicine abuse. CADCA represents over 5,000 community coalitions nationwide. This toolkit, which is available at [www.doseofprevention.org](http://www.doseofprevention.org), was unveiled at CADCA's National Leadership Forum VII in February 2007.

## **STOP COUGH MEDICINE ABUSE | CHPA'S EFFORTS**

Additionally, on June 7, Senator Joseph R. Biden, Jr., (D-Del.) introduced a resolution designating August 2007 as "National Medicine Abuse Awareness Month." Supported by CHPA and CADCA, this initiative highlights August—when students nationwide will be preparing for the upcoming school year—as an opportunity for parents to educate themselves and to talk to their teens about the dangers associated with medicine abuse. Dovetailing this effort, CHPA and CADCA will host town hall meetings nationwide this summer with local CADCA affiliates. States interested in hosting their own town hall meeting in August will have access to all materials via [StopMedicineAbuse.org](http://StopMedicineAbuse.org).

### **Five Moms: Stopping Cough Medicine Abuse**

In May 2007, CHPA launched "Five Moms: Stopping Cough Medicine Abuse," an online grassroots campaign to help parents fight teen medicine abuse. At the heart of the Five Moms Campaign are five exceptional women, from different walks of life and from all across the country, who are all dedicated to spreading the word about the dangers of cough medicine abuse.

This campaign is designed to use the very same tactics medicine abusers are using: spreading and promoting information on the Internet. The Five Moms' goal is to get the word out to as many parents as possible that cough medicine abuse is happening in their homes, and that the Internet is a driving force. Through their website [www.FiveMoms.com](http://www.FiveMoms.com), the Five Moms offer information about cough medicine abuse. Additionally, these remarkable women hope to spread the word through a short "viral video" via e-mail to their friends and family, with the goal of the video reaching a million moms by the end of the year.

### **D.A.R.E. America**

CHPA is supporting D.A.R.E. America in the development and launch of new curricula on medicine abuse. D.A.R.E. America will be developing new programming on the subject for fifth-, seventh-, and ninth-graders. This program also will include a community outreach component.

For more information on these partnerships, contact Elizabeth Funderburk, 202.429.9260 or [efunderburk@chpa-info.org](mailto:efunderburk@chpa-info.org). For more information about dextromethorphan—the active ingredient in many over-the-counter cough medicines—and cough medicine abuse, visit [www.chpa-info.org](http://www.chpa-info.org) and read CHPA's Frequently Asked Questions.

**TESTIMONY OF LAWRENCE A. MANDELKER on behalf of  
THE NEW YORK METROPOLITAN RETAIL ASSOCIATION (NYMRA) before the  
COMMITTEE ON HEALTH**

**Chair: Joel Rivera**

**Thursday, June 28, 2007, 1:00 p.m.**

**250 Broadway, Floor 14**

**NYC COUNCIL PROPOSED INT. NO. 589-A  
SALE OF TOYS, CHILDCARE AND CHILD FEEDING PRODUCTS  
THAT CONTAIN PHTHALATES**

Chairman Rivera and members of the Committee: I am testifying today on behalf of NYMRA, the New York Metropolitan Retail Association. NYMRA is an organization consisting primarily of national chain retailers operating in the City of New York.

Frankly, we don't have enough expertise to do more than ask two questions.

(1) Is a ban necessary, or would appropriate labeling suffice?

(2) With respect to the products covered by the proposed ban on toy, child care or child feeding products containing phthalates, assuming that the banned products can be replaced with products that do not contain phthalates, will retailers be allowed to sell off their existing inventory?

## TESTIMONY

### Of Joan Lawrence to the New York City Council

#### Hearing of the Committee on Health

June 28, 2007

**RE: Int. No. 589 In relation to the sale of toys, childcare and feeding products that contain phthalates.**

I am Joan Lawrence, VP, Safety Standards and Regulatory Affairs for Toy Industry Association (TIA). TIA is a not-for-profit trade association composed of more than five hundred (500) members, both large and small in size.

Toy Safety is the number one priority for the Toy Industry Association and its members. We have always recognized the special relationship we have with children, who are our principal consumers; their safety and well-being is always our top priority. We have led in the area of toy safety for more than seven decades, including development of the first comprehensive toy safety standard in the 1970s, and today continue to ensure that U.S. standards serve as models for the worldwide industry. Our efforts have paid off as illustrated in annual reports of the CPSC, which regularly list toys as being among the safest of 15 consumer products commonly found in the home.

My primary roles with Toy Industry Association are to:

- develop safety standards for toys, working with industry, government, consumer organizations, and academics in this effort; the US's risk-based standards are widely used as models around the globe

- educate industry on these standards so that they comply and
- educate parents and caregivers on choosing appropriate toys and ensuring safe play.

In addition to 15 years with TIA, and my role as chair for toy safety standards development within ASTM International, I am a mother of three young children myself, including a five-year-old and three-year-old twins, so my role in toy safety is one I take very seriously. On behalf of Toy Industry Association and its members, I would like to address the Committee today on the subject of phthalates in soft vinyl toys, which Int. No. 589 proposes to ban, as we are concerned that it may *inadvertently jeopardize the safety of toys*.

TIA commends the bill sponsors for their keen interest in the safety of children. We share that interest; however, a ban on phthalates in toys is not supported by the science specific to these products and how they are used. Further, such a ban does a disservice by needlessly alerting parents and caregivers to a non-existent threat, at best, and could subject consumers to less tested, less safe, alternative materials.

Let me explain why we believe this to be true. First, as an industry focused on safety, we are quite concerned by reports that ignore or misinterpret the science -- particularly the science specific to toys and di-isononyl phthalate (DINP), the phthalate most commonly used in toys -- and ignore its nearly 50-year history of safe use. There is considerable evidence on the safety of DINP. For example:



- An exhaustive, peer-reviewed, multi-year risk assessment conducted by an independent U.S. federal regulatory agency, the U.S. Consumer Product Safety Commission (CPSC), that oversees the safety of toys, specifically looked at the use of DINP in toys.
- The CPSC study concluded that "...consumers may have a high level of assurance that soft plastic products pose no risk to children."
- CPSC Epidemiologist and lead researcher on this issue, in February 2007, reconfirmed the Consumer Product Safety Commission's position. Having reviewed recent studies regarding phthalates, the CPSC *reaffirmed* their earlier decision on the safety of these products.
- Similarly, an independent assessment by the European Chemicals Bureau, the scientific body of the European Commission found that DINP, is "unlikely to pose a risk for consumers..."

This independent government research confirms that children are not at risk when they play with toys softened with the phthalate DINP. In fact there is simply no solid, scientific evidence that any person has ever been harmed by the presence of phthalates in toys.

No other substance has the solid, safe track record in toys that DINP does, and as the U.S. Consumer Product Safety Commission (CPSC) cautioned in their study, toys made with alternative substances could be "...weaker or more brittle [and] may break and result in a choking hazard." We are very concerned that mandating the removal of DINP from

children's products will not improve their safety – and will, instead, have the opposite effect.

In sum, there is simply no sound, scientific reason to ban the use of phthalates in toys and, in our common mission to ensure the safety of children, we urge you not to do so.

Thank you.



Public Hearing  
Re: Int. No. 589  
Council of the City of New York  
Committee on Health  
New York, NY  
June 28, 2007  
Presented by: Raymond M. David, Ph.D., DABT  
American Chemistry Council

STATEMENT OF  
THE AMERICAN CHEMISTRY COUNCIL PHTHALATE ESTERS PANEL  
OPPOSING INT. NO. 589

Good morning, Chairman Rivera and Members of the Committee on Health. The American Chemistry Council Phthalate Esters Panel appreciates the opportunity to present testimony on Int. No. 589, a proposed local law to amend the administrative code of the City of New York, in relation to the sale of toys, childcare and child feeding products that contain phthalates. The Panel respectfully states its opposition to this measure.

The Panel joins with the Council in seeking to protect human health. In this specific instance, however, we are convinced that the extensive scientific research undertaken in the area of phthalates shows that a ban is unnecessary. Government-sponsored risk assessments in both the U.S. and Europe have demonstrated that human exposures to phthalates in consumer products, including child care products and toys, are generally well below any level that has been shown to cause adverse health effects in laboratory animals and below government established safety levels. Importantly, an exhaustive scientific review of the safety of children's vinyl toys containing phthalates conducted by the U.S. Consumer Product Safety Commission (CPSC) recently concluded, "there is no demonstrated health risk posed by PVC toys or other products intended for children 5 years of age and under."

My name is Dr. Raymond David. I am a board-certified toxicologist and have been working on phthalate esters for nearly 15 years. I presently serve as the chair of the toxicology research group of the Phthalate Esters Panel.

**REVIEW BY INDEPENDENT AND REGULATORY SCIENTISTS SHOWS THAT THE BANS ON  
PHTHALATES PROPOSED IN INT. NO 589 ARE UNNECESSARY**

The Panel strongly supports regulation of chemicals based on sound science. Phthalates are among the most well toxicologically defined chemicals on earth, having been the subject of hundreds of studies in lab animals and numerous government-sponsored assessments of the risks to human health posed by exposure to phthalates. The Panel firmly believes the great weight of scientific evidence demonstrates that the bans on phthalates proposed in Int. No. 589 are unnecessary to protect human health.

Int. No. 589 proposes to ban di(2-ethylhexyl)phthalate (DEHP), dibutyl phthalate (DBP), benzyl butyl phthalate (BBP) in concentrations exceeding 0.1% in toys and child care articles and diisononyl phthalate (DINP), diisodecyl phthalate, and di-n-octyl phthalate in concentrations exceeding 0.1% in toys and child care articles if that product can be placed in the mouth for use by children under three years of age. At the outset, the proposed ban of some of these three phthalates in children's toys would do little to protect children's health if for no other reason than these phthalates typically are not used in such children's products.

- BBP is most commonly used in flooring and insulating sealants.
- DBP is used primarily in adhesives, as a solvent for organic compounds and in cosmetics and personal care products.
- DEHP is used primarily in medical devices and some soft plastic toys, but not those intended to be placed in the mouth by children.

In addition, numerous government risk assessments of these phthalates, as well as a U.S. Consumer Product Safety Commission risk assessment of diisononyl phthalate (DINP), the phthalate most commonly used in toys, have demonstrated that exposure to phthalates in toys and children's products generally poses no significant risk to children.

Both the U.S. National Toxicology Program (NTP) and the EU have performed risk assessments on phthalates proposed to be banned by Int. No. 589, and have generally found no significant risk to children from exposure to these phthalates.<sup>1</sup> For example,

- For BBP, the NTP assessment found "***minimal concern for adverse developmental effects in fetuses and children***" and the EU assessment, which looked at all sources of exposure to children, including toys, found "***no concern for local exposure to BBP***" and "***no need for further information and/or testing and for risk reduction measures beyond those which are being applied already.***"

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- For DEHP, the only concerns noted by the NTP for children were from very high exposures of infants or mothers from intensive medical treatments, and “**some concern**” for children older than one year, based on very high assumed exposures from all sources. The EU assessment also expressed some concern for exposures to children. Again, however, DEHP is not used in the manufacture of children’s articles that are intended to be mouthed, and the actual risks from exposure to such products are very low.

As mentioned above, the most relevant government risk assessment with respect to phthalates in toys is the U.S. Consumer Product Safety Commission’s 2001 safety assessment of vinyl toys softened with phthalates, in particular the phthalate that is by far most commonly used in toys – DINP.<sup>2</sup> This extensive risk assessment found “**no demonstrated health risk**” to children from exposure to DINP from toys and child care articles. The CPSC declined to take action on a petition to ban the use of phthalates in children’s toys following its intensive review, which had included evaluation of children’s behavior in mouthing toys. Similarly, the NTP risk assessment of DINP found “**minimal concern**” for adverse effects on human reproduction or fetal development, and for developmental effects in children and the EU assessment of DINP concluded that exposure to DINP from toys and baby equipment is “unlikely to pose a risk” for infants and newborns, and that such exposure “is not considered of concern.”

### EXPOSURE LEVELS ARE FAR BELOW LEVELS OF CONCERN

In the face of uncertainties, the scientific community compares the exposure level that causes harm to surrogate species like laboratory animals to the exposure level for humans. If the difference is greater than 100 or 1000, we consider the exposures to be risk free because it is not IF people are exposed that is the question, but HOW MUCH they are exposed to --- it’s the **DOSE** that makes the poison. In the case of phthalates, the biomonitoring conducted by the CDC has demonstrated that exposure levels are 100-1000 below the levels that produce no effects in laboratory animals. Thus, we are NOT at risk for the effects seen in animals.

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## **ASSOCIATIONS OF EXPOSURE TO EFFECTS IN HUMANS IS NOT DEFINITIVE**

Some scientists have tried to associate exposure to phthalate esters with a variety of effects from obesity to infertility to outright malformations. Frequently, these studies have reported conflicting findings from each other and contrasting results from evidence in laboratory animals. Given the widespread use of phthalates in different products, such studies are not strong enough to provide convincing evidence of cause-and-effect – at least that is the opinion of independent scientists from EPA and NTP.

### **Conclusion**

Thank you, Mr. Chairman, for the opportunity to present testimony in opposition to Int. No. 589. Based on phthalate use patterns in toys and the weight of scientific evidence, we do not agree with the proposition that the ban on phthalates in children's articles is necessary to protect children's health.



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### **Conclusion**

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*celebrating 125 years*

**The Council of the City of New York**

**Committee on Health**

**Hearing on Int. No. 592 –**

**In relation to restricting the sale of medication containing dextromethorphan.**

June 28, 2007  
14<sup>th</sup> Floor Hearing Room  
250 Broadway  
New York, New York

**Testimony Submitted by the Consumer Healthcare Products Association**

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Good afternoon and thank you for the opportunity to present testimony on this important issue. The Consumer Healthcare Products Association (CHPA) is the national trade association representing the manufacturers of nonprescription or over-the-counter medicines. OTC medicines are approved by the U.S. Food and Drug Administration (FDA) as safe and effective when used according to label directions. OTC medicines have a wide margin of safety and can be found in virtually every medicine cabinet in America.

Dextromethorphan (DXM) is a safe and effective OTC ingredient found in well over 100 OTC cough and cold products. First approved by FDA in 1954, it is an effective, non-narcotic cough suppressant that works by raising the coughing threshold in the brain. It has no pain relieving properties and is not addictive. While DXM is used safely by millions of Americans each year to relieve coughs due to the common cold or flu, parents should be aware that some teenagers and young adults are intentionally abusing large amounts of medicines containing DXM in an effort to get high.

CHPA appreciates the opportunity to present testimony on Councilmember Baez's proposed ordinance to restrict sales of OTC medicines containing DXM to any person under the age of 18. CHPA supports age restrictions as a way to keep DXM out of the hands of teenagers and we applaud the actions of many New York retailers who have already imposed voluntary age restrictions in their stores.

Unfortunately, CHPA strongly opposes that part of the proposal that would require DXM products to be moved behind the counter in all retail outlets throughout the city. We believe that this step is unnecessary, unworkable, and not in the public interest.

Section 1 of the proposed ordinance states that there are approximately 120 OTC products that contain DXM. In most stores, these products occupy several feet of self-service shelf space from the floor to the top shelf and there is not enough room behind any counter in the store to accommodate the existing variety of medicines. Retailers would have to greatly reduce the number of products available, thus reducing access and consumer choice. The OTC marketplace is the most robust marketplace in the entire healthcare sector because consumers are empowered to make their own decisions in selecting the products that work best for themselves and their families. Moving DXM products behind the counter would greatly reduce the consumer's ability to self select and significantly diminish the value that OTC medicines provide the healthcare system.

More importantly, if products are moved behind the counter, consumers will not have the ability to read labels and compare ingredients when making purchasing decisions. Requiring a clerk or pharmacist to supervise this label comparison process is unnecessary and a significant waste of our precious healthcare resources.

There is no evidence to suggest that theft of DXM medicines is a significant problem. If it were, retailers would be able to handle the issue in the store by more closely monitoring the cough/cold aisles or limiting the number of products on the shelf.

CHPA and the companies who manufacture these products believe that education and prevention are the keys to stopping teenage cough medicine abuse. Our strategy is to increase awareness and give parents, teachers, and other key influencers the tools they need to reach teens about this problem.

In developing our education and prevention strategy, we reached out to the experts at the Partnership for a Drug-Free American (PDFA) for assistance. Together, CHPA and Partnership began an ongoing initiative in 2003 to ensure that adults with influence and oversight over young people are aware that teens may be considering abusing DXM. Aside from efforts to educate key audiences regarding the potential for abuse of medicines containing DXM, CHPA, in conjunction with the Partnership, launched the Rx and OTC Medicine Abuse Education Campaign in May 2006. This multi-year, communications campaign will help parents and families understand and prevent the abuse of medicines, including cough medicines containing DXM, by teenagers and young adults.

Specifically, CHPA and the Partnership are:

- Distributing television, radio, and print public service announcements to help raise parental awareness about this teen substance abuse problem;
- Disseminating an educational brochure for parents, *Preventing Teen Cough Medicine Abuse: A Parent's Guide*, in English and Spanish.
- Operating a parent-oriented web site with information on DXM abuse, as well as a teen-oriented site—[www.dxmstories.com](http://www.dxmstories.com)—to provide teens with accurate information about this substance abuse issue;
- Reaching out with information to a variety of organizations, including parent groups, educator associations, the poison control center network, health professional organizations, and law enforcement; and

- Supporting federal legislation to keep raw, unfinished dextromethorphan out of teens' hands as well as an initiative designating August 2007 as "National Medicine Abuse Awareness Month."

### **Community Anti-Drug Coalition of America**

CHPA also is pleased to join forces with the Community Anti-Drug Coalitions of America (CADCA) to develop a new educational community toolkit to help coalition and prevention leaders mobilize their communities and educate key stakeholders about the dangers of OTC cough medicine abuse. CADCA represents over 5,000 community coalitions nationwide. This toolkit, which is available at www.doseofprevention.org, was unveiled at CADCA's National Leadership Forum VII in February 2007.

Additionally, on June 7, Senator Joseph R. Biden, Jr., (D-Del.) introduced a resolution designating August 2007 as "National Medicine Abuse Awareness Month." Supported by CHPA and CADCA, this initiative highlights August—when students nationwide will be preparing for the upcoming school year—as an opportunity for parents to educate themselves and to talk to their teens about the dangers associated with medicine abuse. Dovetailing this effort, CHPA and CADCA will host town hall meetings nationwide this summer with local CADCA affiliates. States interested in hosting their own town hall meeting in August will have access to all materials via StopMedicineAbuse.org.

## **Five Moms: Stopping Cough Medicine Abuse**

In May 2007, CHPA launched "Five Moms: Stopping Cough Medicine Abuse," an online grassroots campaign to help parents fight teen medicine abuse. At the heart of the Five Moms Campaign are five exceptional women, from different walks of life and from all across the country, who are all dedicated to spreading the word about the dangers of cough medicine abuse.

This campaign is designed to use the very same tactics medicine abusers are using: spreading and promoting information on the Internet. The Five Moms' goal is to get the word out to as many parents as possible that cough medicine abuse is happening in their homes, and that the Internet is a driving force. Through their website [www.FiveMoms.com](http://www.FiveMoms.com), the Five Moms offer information about cough medicine abuse. Additionally, these remarkable women hope to spread the word through a short "viral video" via e-mail to their friends and family, with the goal of the video reaching a million moms by the end of the year.

## **D.A.R.E. America**

Additionally, CHPA is working with D.A.R.E. America to develop school based curricula on medicine abuse for 5th, 7th, and 9th graders. For more information on these partnerships, contact Elizabeth Funderburk, 202.429.9620 or [efunderburk@chpa-info.org](mailto:efunderburk@chpa-info.org).

Again, thank you very much for the opportunity to testify on this important proposal. I am happy to answer any questions that you might have and will provide copies of any and all of the materials that I have talked about.





NATIONAL ASSOCIATION OF  
CHAIN DRUG STORES

Testimony of the National Association of  
Chain Drug Stores (NACDS)  
Before the Committee on Health  
On Proposed New York City Resolution  
Number 592-A

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On behalf of the chain pharmacies operating in New York City, the National Association of Chain Drug Stores (NACDS) thanks the Committee for consideration of these comments on Resolution Number 592-A, a local law to amend the administrative code of the city of New York to restrict the sale of non-prescription medications containing dextromethorphan to minors. For the reasons discussed in this testimony, we ask that this legislation not be enacted.

Chain pharmacy shares the concerns about teenagers purchasing and abusing non-prescription medications containing dextromethorphan. Many of our members have already voluntarily implemented programs to prevent sales of dextromethorphan containing medications to persons under 18 years of age by checking identification. Because these over-the-counter medications are being abused by teenagers, this voluntary approach is reasonable and logical to prevent abuse by teenagers.

We believe that voluntary age restriction programs imposed by pharmacies and other retailers along with an educational outreach program for parents and schools on the dangers of abuse of household medications offers the best approach. We do not support placing these over-the-counter (OTC) medications where they are inaccessible to the public. Maintaining public access to these beneficial OTC cough and cold medicines is essential to allow legitimate customers the right to select the medication that they want to treat coughs and colds.

Restricting the access of legitimate consumers to these medications could force consumers to see prescribers for cough and cold medications and increase health care costs. Dextromethorphan is a safe and highly-effective cough suppressant. It is the most common ingredient in over-the-counter cough medicines in the United States. There is no available over-the-counter alternative to it. Dextromethorphan was approved by the FDA in 1954 as an option to codeine cough syrups to prevent abuse. When used in therapeutic doses, DXM produces very few side effects and has a decades-long history of safety and efficacy.

We do not support this legislation because we support the voluntary approach discussed above and because it would make it very difficult for legitimate consumers to obtain dextromethorphan to treat a cough or cold.

We believe that the issue of teen substance abuse must be the focus of educational outreach programs to address the causes of teenage abuse of DXM and other household medications. Parents must be involved in the actions of their children. We would like to work with you to educate parents, teachers, coaches, and teens about the dangers of drug abuse, including dextromethorphan. Teenagers likely to abuse dextromethorphan are also known to abuse other household products such as aerosols, cleaning fluids, glue, gasoline, and other products that produce a "high." Education on the broader teen substance abuse issue remains the key to addressing this problem.

Thank you for consideration of our comments.

**TESTIMONY OF LAWRENCE A. MANDELKER on behalf of  
THE NEW YORK METROPOLITAN RETAIL ASSOCIATION (NYMRA) before the  
COMMITTEE ON HEALTH  
Chair: Joel Rivera  
Thursday, June 28, 2007, 1:00 p.m.  
250 Broadway, Floor 14**

**NYC COUNCIL PROPOSED INT. NO. 592-A  
RESTRICTING THE SALE OF MEDICATION CONTAINING  
DEXTROMETHORPHAN**

Chairman Rivera and members of the Committee: I am testifying today on behalf of NYMRA, the New York Metropolitan Retail Association. NYMRA is an organization consisting primarily of national chain retailers operating in the City of New York.

Instead of mandating a public education campaign warning minors, their parents and their guardians of the danger when safe, highly effective over the counter products containing DXM are abused, Intro 592-A would solely burden retailers with the task of trying to prevent the abuse of these products by minors. Some of our members sell products containing DXM and some do not. But even those members that do not sell such products are troubled by the implications in the bill. NYMRA is therefore constrained to voice its opposition.

First a little background: DXM was approved by the FDA in 1958. It is a safe, non-addictive, highly effective cough suppressant. When used in therapeutic doses, it produces very few side effects. Even when massively abused, it is not physically addictive.

DXM is the most common ingredient in over-the-counter cough medicines in the U.S. It is found in over 120 different over-the-counter products in almost every dosage form: liquid, tablets, caplets, gel-caps, gel strips, etc.

This is not to say that products containing DXM cannot be abused. Ingestion of 25X the recommended adult dosage of products containing DXM can create a hallucinogenic effect. When, in order to produce a high, DXM is combined with alcohol, other medications from a parent's medicine cabinet, or with illegal drugs, DXM can even become unsafe.

Modern retailing has adapted to our faster on-the-go culture. Customers are looking for speed, ease and convenience. They want to be in and out of stores as soon as possible. They prefer self-service whenever practical, as well as fast moving check out lines. Intro 592-A would reverse that trend. It would require that all of the different over-the-counter products that contain "DXM" not be accessible to customers in open displays. As a practical matter, these products would have to be

stored and sold behind drug counters as if they were prescription drugs. Stores would have to create or enlarge drug counters, reduce their open shelf capacity and staff their drug counters with extra employees.

Products containing DXM are inherently different from cigarettes, alcohol and products containing pseudoephedrine (PSE). Society has decided that use of cigarettes and alcohol by minors is inherently unsafe. Even so, beer is available in open displays. In contrast, products containing DXM are highly beneficial and can safely be taken by minors.

PSE is the primary ingredient of methamphetamine, a highly addictive drug often associated with crime. In addition, meth's by-products are highly flammable and highly toxic. In contrast DXM abusers generally do not commit crimes, there are no by-products and abuse is not physically addictive.

Some of our members who sell these products already implement voluntary restrictions on under age buyers. When the customer checks out, the label prompts the cashier to ask for i.d. But should retailers be forced to put cashiers, some of whom are minors themselves, in the position of checking i.d.s for so many different products? Will customers abide the long lines?

Finally, one must always consider the long-term implications of governmental action, i.e., the proverbial slippery slope. Today, we are discussing whether the sale of products containing DXM should be restricted. Tomorrow it will be glue, paint or rubbing alcohol, all of which can be abused by minors, or screw drivers, steak knives, scissors, wrenches, or baseball bats, all of which can be used to create mayhem or commit crimes.

Minors and those who care for them must be warned of the dangers they face if they abuse products containing DXM. Parents, teachers, clergy, community leaders such as yourselves, PSA's and appropriate labeling are the way to address this problem. An education campaign should be mandated.