

**FORMALDEHYDE IN TEXTILES
AND CONSUMER PRODUCTS**

HEARING

BEFORE THE

SUBCOMMITTEE ON CONSUMER PROTECTION,
PRODUCT SAFETY, AND INSURANCE

OF THE

COMMITTEE ON COMMERCE,
SCIENCE, AND TRANSPORTATION

UNITED STATES SENATE

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

APRIL 28, 2009

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SENATE COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION

ONE HUNDRED ELEVENTH CONGRESS

FIRST SESSION

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FORMALDEHYDE IN TEXTILES AND CONSUMER PRODUCTS

TUESDAY, APRIL 28, 2009

U.S. SENATE,
SUBCOMMITTEE ON CONSUMER PROTECTION, PRODUCT
SAFETY, AND INSURANCE,
COMMITTEE ON COMMERCE, SCIENCE, AND TRANSPORTATION,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:33 a.m. in room SR-253, Russell Senate Office Building, Hon. Mark L. Pryor, Chairman of the Subcommittee, presiding.

OPENING STATEMENT OF HON. MARK L. PRYOR, U.S. SENATOR FROM ARKANSAS

Senator PRYOR. I'll call the meeting to order. Thank you for coming to the Consumer Protection, Product Safety, and Insurance Subcommittee hearing on formaldehyde in textiles and consumer products.

I want to thank everyone who's attending. I want to thank the panelists. And I certainly want to thank Senator Casey for his leadership.

We're here to discuss the health effects associated with formaldehyde exposure and the potential safety standards necessary to protect the public's health. I'd like to begin by thanking Senator Casey for his leadership on this issue and for attending today's hearing. We're also going to allow him to participate and ask questions as if he's on the Subcommittee today. The reason we're doing that is because he has been instrumental in pushing the Consumer Product Safety Commission to conduct a study on the uses and risks of formaldehyde. Because of his efforts, the Commission is now required to focus on public risks that had not received adequate government attention before.

Before we hear from Senator Casey, we will hear from Dr. Ruth Etzel. Dr. Etzel is an adjunct professor at George Washington University School of Public Health and Health Services. She's an epidemiologist, a doctor, a founding editor of the American Academy of Pediatrics book on Pediatric Environmental Health and is here today representing the American Academy of Pediatrics.

After Dr. Etzel, we'll hear from Dr. David Brookstein, who is dean at Philadelphia University's School of Engineering and Textiles. Dr. Brookstein's specialty is the dermatological effects of formaldehyde in textiles and apparel.

And finally, we'll hear from Dr. Phillip Wakelyn, a consultant at Wakelyn Associates, also speaking on behalf of the National Cotton Council. Dr. Wakelyn has over 30 years of experience in this area.

I'd like to thank all the witnesses for appearing before the Subcommittee today. Your insight will be extremely helpful to all of us as we consider our next step.

The Subcommittee has been at the forefront of exposing and regulating consumer product risks for years. In this Congress, we will redouble our efforts to improve product safety. The Consumer Product Safety Commission is implementing the biggest overhaul to its statutory mandates in a generation. This will require ongoing, careful Congressional oversight as the new requirements affect every child's product in the stream of commerce.

As we continue to strengthen consumer rights in this area and in others, we'll strengthen the safety net to provide strong protections for every American. In the end, we certainly hope that citizens will know that the products they buy and use each and every day will perform to the highest standards. That is one of the main purposes of the Subcommittee, and it's a responsibility that we take seriously and that we'll discuss today during our subcommittee hearing.

I'd like to now turn it over to my Ranking Member, Senator Wicker, and congratulate you on being the Ranking Member. I look forward to working with you this Congress.

**STATEMENT OF HON. ROGER F. WICKER,
U.S. SENATOR FROM MISSISSIPPI**

Senator WICKER. Well, thank you, Chairman Pryor. And, indeed, this is the first hearing of our subcommittee, and I appreciate your chairmanship and your leadership in this subcommittee, and I appreciate your words of welcome.

Thank you for holding this hearing today. This hearing is a part of the necessary debate on the issue of formaldehyde in textiles.

The people in my home State of Mississippi know a thing or two about textiles. Mississippi is the home to numerous furniture manufacturers, and northeast Mississippi is considered the upholstered furniture capital of the world, and we're proud of that.

Formaldehyde is a substance with a variety of uses. Our bodies naturally produce formaldehyde in small amounts. It is also present in our indoor and outdoor environments through natural and manmade means. Industry produces it for use in many beneficial products we use every day. It can be found in antiseptics, medicines, cosmetics, dishwashing liquids, fabric softeners, shoe-care agents, carpet cleaners, glues, adhesives, paper, plastic, and other products. And, as I read that list, Mr. Chairman, I think I see about ten items that I probably used yesterday and last night, because last night was laundry night at the Wicker condo.

Now, the textile industry uses formaldehyde mainly in the finishing process, to give natural textiles the quality and aesthetics that consumers want, including stain and wrinkle resistance.

The Federal Government has studied formaldehyde exposure for decades and has already regulated its use and presence in a number of different ways. Regulations limit the airborne concentration of formaldehyde in certain environments, emission rates from certain products, and concentration rates of consumer products. OSHA regulates formaldehyde exposure in the workplace. The Department of Housing and Urban Development regulates the presence of

formaldehyde in manufactured wood products. CPSC considers formaldehyde a “strong sensitizer” when found at levels above 1 percent in consumer products.

Because of health concerns raised over contaminated FEMA disaster housing used to house Hurricane Katrina victims, Mississippians and people across the Gulf Coast now have a better understanding of the use of formaldehyde in consumer products. FEMA now applies the HUD formaldehyde standards for manufactured wood products to the Agency’s procurement requirements for travel trailers.

Industries such as the textile industry are looking for ways of reducing the use of formaldehyde in the finishing process. While formaldehyde-free options already exist, research is ongoing to find ways to produce cost-effective alternatives. For example, the University of Southern Mississippi has created technology to use soy protein-based adhesives in place of formaldehyde-based adhesives in the manufactured wood process. Advances like these will help further limit excessive formaldehyde exposure in the home, workplace, and environment.

Senator Casey joins us this morning. He’s to be congratulated for fighting to include a study on formaldehyde in textiles during last year’s consumer product safety debate. As a result, the Consumer Product Safety Improvement Act of 2008 included language requiring the GAO to work with the CPSC to conduct a study on the use of formaldehyde in textiles and any associated risks to consumers.

It is my understanding that the study has not commenced, but that it will be completed by the statutory date of August 2010. I look forward to seeing that study. It should provide Congress, the CPSC, and consumers with information necessary and to evaluate steps forward on formaldehyde use in textiles. Any further restrictions on use or limits on the inclusion of formaldehyde in consumer products need to be based on sound science.

I look forward to working with you, Mr. Chairman, and with Senator Casey, on not only providing the best consumer protection that we can possibly have, but also the best protection for the consumer dollar that we can have at the same time.

Now, I would like to ask, as I conclude my opening remarks, for a unanimous-consent request. I received a letter yesterday, co-signed by the American Apparel and Footwear Association, the American Manufacturing Trade Action Coalition, the National Council of Textile Organizations, the National Cotton Council, and the Northern Textile Association. These organizations wrote on behalf of Dr. Wakelyn’s participation in today’s hearing and stated that his testimony reflects the views and concerns of these apparel and textile groups. So, at this point, Mr. Chairman, I ask unanimous consent that this letter be inserted into the record.

Senator PRYOR. Without objection.

Senator WICKER. Thank you very much.

Senator PRYOR. Thank you.

[The information referred to follows:]

April 27, 2009

Hon. MARK PRYOR,
Chairman,

Hon. ROGER WICKER,
Ranking Member,

Senate Subcommittee on Consumer Protection, Product Safety, and Insurance,
Committee on Commerce, Science, and Transportation,
Washington, DC.

Dear Senators Pryor and Wicker:

This is to advise that the testimony presented by Dr. Phil Wakelyn during the hearing scheduled for April 28 titled "Formaldehyde in textiles and Consumer Products" reflects the views and concerns of a broad coalition of textile and apparel interests, including the National Cotton Council, the National Council of Textile Organizations, the National Textile Association, the American Manufacturing Trade Action Coalition, and the American Apparel and Footwear Association. As you may know, these organizations joined together last year to express support for a review and update of previous studies on formaldehyde in textiles and apparel.

The following is an excerpt from that letter. "There have not been safety related problems raised in the U.S. concerning formaldehyde in textile and apparel. CPSC extensively studied formaldehyde and textiles in the 1980s . . . The listed Associations strongly recommend that in view of all the studies over the last 30 years and regulations already in place concerning formaldehyde and textiles, CPSC should only be required to do an updated review of the situation to determine if there are unreasonable risks to consumers caused by textiles and apparel due to the use of formaldehyde containing substances in their manufacturing. This study should be completed to determine if further action is necessary before requiring further actions by CPSC or other regulatory agencies."

We appreciate the opportunity for Dr. Wakelyn to participate in the hearing and to respond to questions.

Sincerely,

AMERICAN APPAREL AND FOOTWEAR
ASSOCIATION
AMERICAN MANUFACTURING TRADE
ACTION COALITION
NATIONAL COUNCIL OF TEXTILE
ORGANIZATIONS
NATIONAL COTTON COUNCIL
NORTHERN TEXTILE ASSOCIATION

Senator PRYOR. Senator Casey has earned a reputation of being a very reasonable and very hardworking Senator since he has been here representing Pennsylvania.

Senator Casey, it is an honor to have you with the Subcommittee today. Please open.

**STATEMENT OF HON. ROBERT P. CASEY, JR.,
U.S. SENATOR FROM PENNSYLVANIA**

Senator CASEY. Mr. Chairman, thank you very much. I hope this is on. We don't get a chance to be at the witness table very often, so I'm honored that you would allow me this privilege and also that you would convene this hearing. I'm grateful for that. And the same goes for Senator Wicker. Thank you very much. Thank both of you for your thoughtful statements on this issue.

I do want to thank you for conveying—or, convening, I should say, today's hearing, and for this opportunity to testify, about the dangers to consumers from formaldehyde use in textiles and other consumer goods. This important safety issue was first brought to my attention by Dr. David Brookstein of Philadelphia University. He will be testifying here today, and I want to thank him for his

efforts to bring attention to this issue. I look forward to hearing his testimony.

Formaldehyde has a number of commercial uses, including as an adhesive, a resin applied to paper goods, and as insulation. Formaldehyde has long been used in the textile industry to make clothing crease-resistant or wrinkle-free.

The Consumer Product Safety Commission has identified formaldehyde as a potential hazard. In 1997, the CPSC issued a report on the dangers of formaldehyde. The report, among other things, stated that, "Formaldehyde is a colorless, strong-smelling gas. When present in the air at levels above .1 ppm, or parts per million of air, it can cause watery eyes, burning sensations in the eyes, nose, and throat, nausea, coughing, chest tightness, wheezing, skin rashes, and allergic reactions. It has also been observed to cause cancer, in scientific studies using laboratory animals, and may cause cancer in humans." A long quotation from a 1997 Consumer Product Safety Commission report. Yet, despite these findings, the Commission has yet to take any action on testing textiles for dangerous levels of formaldehyde.

The United States currently trails other nations in responding to threats of formaldehyde. Australia, Germany, France, the Netherlands, Austria, Finland, Norway, China, Japan, Poland, Russia, Lithuania, and South Korea have all adopted standards for formaldehyde use, particularly in textiles in clothing. We need similar protections in the United States of America. The risk of not setting standards and waiting until after major problems surface are too great. American consumers deserve protection from dangerous goods, and they necessarily rely upon the government for this protection.

It's a simple fact that consumers can't test products on their own. We need to make sure that the products we bring to market are safe, particularly those used by children.

Some may argue that many domestic and international manufacturers already adhere to self-imposed standards on formaldehyde use in goods, ranging from apparel to particleboard. However, these voluntary standards do not carry the penalties for violators, and there is evidence that foreign manufacturers in China have ignored the standards. According to the Associated Press, the New Zealand government launched an investigation into Chinese garments imported to New Zealand after children's clothes from China were found to contain dangerous levels of formaldehyde. In 2007, according to the American Apparel and Footwear Association, more than 25 percent of clothes sold in the United States were imported from China.

As a first step to developing regulations, we need to better understand the dimensions of the problem. Currently, we do not even have a basic understanding of the scope of formaldehyde use in products. We need additional information about the prevalence of formaldehyde in goods, and, most importantly, the impact it is having on American consumers.

To assist in reaching that goal, I successfully sponsored an amendment to the Consumer Product Safety Improvement Act which calls for a study by the U.S. Government Accountability Office, what we know as GAO, on the use of formaldehyde in the

manufacture of textiles and apparel articles. The law gave the GAO, as Senator Wicker mentioned, until August 2010 to complete the study. Of course, they can move that date up if they want.

[Laughter.]

Senator CASEY. That's the deadline. And we hope they would.

I understand, from the GAO, that they have not yet begun work on the report, but we'd all like to take the opportunity today to encourage GAO to commence work on this important study.

I look forward to reviewing their findings once the study is completed, and it's my hope that today's hearing will provide an opportunity to learn more about the dangers of formaldehyde use in consumer products. And Congress's oversight responsibilities with respect to executive agencies, I believe, and I know my colleagues believe, are among its most important functions. As such, I'd like to commend Senator Pryor and Senator Wicker for your efforts at oversight and for bringing this issue to our attention at this time.

I want to thank both of you for the opportunity to share these comments. I look forward to joining the members of the Committee to listen to the expert testimony and ask questions of the witnesses; I would add, parenthetically, this is a rare privilege when you're not a member of the Committee, and I'm grateful for that opportunity. I'm serious about that. It's rare that we have the chance to do this.

The information added today to the public record, in addition to the report by the GAO, will lay the groundwork for necessary regulation of this harmful chemical. I will reiterate my assertion that we trail other countries in setting a safety standard on this issue, and I hope that our efforts today will change this fact and that, in the end, this hearing will result in stronger protections for children and families.

Mr. Chairman, thank you for this opportunity.

[The prepared statement of Senator Casey follows:]

PREPARED STATEMENT OF HON. ROBERT P. CASEY JR.,
U.S. SENATOR FROM PENNSYLVANIA

Thank you, Mr. Chairman, for convening today's hearing and for the opportunity to testify about the dangers to consumers from formaldehyde use in textiles and other consumer goods. This important safety issue was first brought to my attention by Dr. David Brookstein of Philadelphia University. I understand that that Dr. Brookstein is here to testify. I thank him for his efforts to bring attention to this issue and I look forward to hearing his testimony.

Formaldehyde has a number of commercial uses including as an adhesive, a resin applied to paper goods and as insulation. Formaldehyde has long been used in the textile industry to make clothing crease-resistant, or wrinkle-free.

The Consumer Product Safety Commission (CPSC) has identified formaldehyde as a potential hazard. In 1997, the CPSC issued a report on the dangers of formaldehyde. The report among other things stated that, "formaldehyde is a colorless, strong-smelling gas. When present in the air at levels above 0.1 ppm (parts in a million parts of air), it can cause watery eyes, burning sensations in the eyes, nose and throat, nausea, coughing, chest tightness, wheezing, skin rashes, and allergic reactions. It also has been observed to cause cancer in scientific studies using laboratory animals and may cause cancer in humans." Yet, despite these findings, the CPSC has yet to take any action on testing textiles for dangerous levels of formaldehyde.

The United States trails other nations in responding to the threats of formaldehyde. Australia, Germany, France, the Netherlands, Austria, Finland, Norway, China, Japan, Poland, Russia, Lithuania and South Korea have all adopted standards for formaldehyde use, particularly in textiles and clothing.

We need similar protections in the United States. The risks of not setting standards, and waiting until after major problems surface, are too great. American consumers deserve protection from dangerous goods and they necessarily rely on the government for this protection. It is a simple fact that consumers can't test products on their own. We need to make sure that the products we bring to market are safe, particularly those used by children.

Some may argue that many domestic and international manufacturers already adhere to self imposed standards on formaldehyde use in goods ranging from apparel to particle board. However, these voluntary standards do not carry penalties for violators and there is evidence that foreign manufacturers in China have ignored the standards. According to the Associated Press, the New Zealand government launched an investigation into Chinese garments imported to New Zealand after children's clothes from China were found to contain dangerous levels of formaldehyde. In 2007, according to the American Apparel and Footwear Association, more than 25 percent of clothes sold in the United States were imported from China.

As a first step to developing regulations, we need to better understand the dimension of the problem. Currently, we do not even have a basic understanding of the scope of formaldehyde use in products. We need additional information about the prevalence of formaldehyde in goods and, most importantly, the impact it is having on American consumers.

To assist in reaching that goal, I successfully sponsored an amendment to the Consumer Product Safety Improvement Act which calls for a study by the U.S. Government Accountability Office (GAO) on the use of formaldehyde in the manufacture of textile and apparel articles. The law gave the GAO until August 2010 to complete its study. I understand from the GAO that they have not yet begun work on the report. I would like to take the opportunity today to encourage GAO to commence work on this important study. I look forward to reviewing their findings once completed.

It is my hope that today's hearing will provide an opportunity to learn more about the dangers of formaldehyde use in consumer products. Congress' oversight responsibilities with respect to executive agencies are among its most important functions. As such, I would like to commend Senator Pryor for his efforts at oversight and for bringing attention to this issue.

Thank you for the opportunity to share these comments. I look forward to joining the members of the Committee to listen to the expert testimony and ask questions of the witnesses. The information added today to the public record, in addition to the report by GAO, will lay the groundwork for necessary regulation of this harmful chemical. I will reiterate my assertion that we trail other countries in setting a safety standard on this issue. I hope that our efforts today will change this fact and that in the end this hearing will result in stronger protections for children and families.

Senator PRYOR. Thank you, Senator Casey, and we look forward to your questions and participation in this hearing.

If I may, now, ask the panel to come up. I'd like you to go ahead and take your seats. I'd like to hear witnesses on the panel in this order: Dr. Ruth Etzel first, Dr. David Brookstein second, and Dr. Phillip Wakelyn third. I've already done a very brief introduction; I hope that'll suffice. So, I think what we're doing is 5 minutes for your statement. If you can keep it to 5 minutes, that would be great, it would help the Committee flow better and allow us to get to our questions.

Dr. Etzel, why don't you lead off, please. Thank you.

**STATEMENT OF RUTH A. ETZEL, M.D., PH.D., FAAP ON BEHALF
OF THE AMERICAN ACADEMY OF PEDIATRICS**

Dr. ETZEL. Good morning. Can you hear me?

Senator PRYOR. He's adjusting the volume there. Go ahead.

Dr. ETZEL. My name is Ruth Etzel, and I'm proud today to represent the American Academy of Pediatrics at this hearing.

Formaldehyde is a toxic, pungent, water-soluble gas used in the aqueous form as a disinfectant, fixative, tissue preservative, and

it's a very versatile product for a wide range of uses. Formaldehyde resins are used in wood products, such as particleboard, paper towels, plastics, paints, manmade fibers such as carpets and polyester, cosmetics, and other consumer products, including many with which children have regular contact. According to recent research and media reports, formaldehyde may be found in fabrics and children's clothing, children's furniture, baby bath products, and other products.

Formaldehyde gas is known to cause a wide range of health effects. A common air pollutant in the home, formaldehyde is an eye, skin, and respiratory tract irritant. In other words, it can cause burning or tingling sensations in the eyes, nose, and throat.

Children may be more susceptible than adults to the respiratory effects of formaldehyde. Even at fairly low concentrations, formaldehyde can produce rapid-onset nose and throat irritation, causing cough, chest pain, shortness of breath, and wheezing. At higher levels of exposure, it can cause significant inflammation of the lower respiratory tract. Children may be more vulnerable than adults to the effect of chemicals like formaldehyde because of the relatively smaller diameter of their airways. Children may also be more vulnerable because they breathe more rapidly than adults and they may be developmentally incapable of getting out of an area quickly when exposed.

Studies since 1990 have found higher rates of asthma, chronic bronchitis, and allergies in children exposed to elevated levels of formaldehyde. In 2004, the International Agency for Research on Cancer reclassified formaldehyde as a known human carcinogen.

Formaldehyde can cause contact dermatitis in susceptible people. Dr. Brookstein will discuss this matter in more detail, so I will only note that children are just as susceptible as adults to the effects of formaldehyde exposure on the skin.

Due to its toxicity, various nations have taken steps to limit the use of formaldehyde in some applications. Several nations, including Finland, Norway, the Netherlands, and Germany, have set standards for the presence of formaldehyde residues in fabrics. Other nations, including Japan, China, Russia, Lithuania, New Zealand, and South Korea, have set limits on formaldehyde in textiles and/or other wood products.

The American Academy of Pediatrics has made formaldehyde recommendations to Congress and the Administration in the past, and we would like to reiterate those and submit others for your consideration.

First, the Consumer Product Safety Commission should limit formaldehyde residues in children's clothing and other products. Given that at least a dozen other nations already restrict formaldehyde residues in children's clothing, the CPSC should collaborate with the EPA and other agencies with scientific and medical expertise to determine similar limits to be imposed in the United States. There is already a considerable body of evidence that is sufficient to allow CPSC to make a reasonable judgment in this area. The agencies should also require labels on children's clothing and other products used for babies and children that indicate the presence of formaldehyde residues.

Second, more research should be done on formaldehyde and children's health. In July 2007, the Academy suggested to the House of Representatives Committee on Energy and Commerce that FEMA and Federal health agencies undertake a rigorous study to determine children's exposure to formaldehyde in FEMA trailers and its correlation with reported symptoms, and determine steps that should be taken to safeguard their health. To my knowledge, no such study has been planned or implemented.

Children may be exposed from multiple sources, and it remains unclear what effect the multiple sources may have on their developing bodies. The Consumer Product Safety Improvement Act of 2008 requires the Comptroller General to conduct a study, within 2 years, of the "use of formaldehyde in the manufacture of textile and apparel articles to identify any risks to consumers caused by the use of formaldehyde in the manufacturing of such articles."

Third, EPA should adopt California's proposed restrictions on formaldehyde emissions from wood products. In January 2009, the American Academy of Pediatrics joined numerous other organizations in urging EPA Administrator Lisa Jackson to adopt, nationwide, the restrictions on formaldehyde emissions from hardwood plywood, particleboard, and medium-density fiberboard set under the California Air Resource Board Airborne Toxics Control Measure.

Finally, fourth, the CPSC should develop educational materials for consumers about formaldehyde and its presence and role in various products and its health risks. The CPSC could provide an important service by providing up-to-date educational materials about formaldehyde. A search of the agency's website reveals a number of documents about formaldehyde, but most of them are from the 1970s and 1980s. The last version of the comprehensive document, "Update on Formaldehyde," appears to be the 1997 version.

The American Academy of Pediatrics commends you, Mr. Chairman, for holding this hearing today to call attention to the hazards of formaldehyde exposure among children. We look forward to working with Congress to minimize the exposure of children and all Americans to all potentially toxic chemicals.

I appreciate this opportunity to testify, and I will be happy to answer any questions.

Thank you.

[The prepared statement of Dr. Etzel follows:]

PREPARED STATEMENT OF RUTH A. ETZEL, M.D., PH.D., FAAP ON BEHALF OF THE
AMERICAN ACADEMY OF PEDIATRICS

Good morning. I appreciate this opportunity to testify today before the Commerce, Science and Transportation Subcommittee on Consumer Protection, Product Safety and Insurance regarding formaldehyde in textiles and consumer products. My name is Ruth Etzel, MD, PhD, FAAP, and I am proud to represent the American Academy of Pediatrics (AAP), a non-profit professional organization of more than 60,000 primary care pediatricians, pediatric medical sub-specialists, and pediatric surgical specialists dedicated to the health, safety, and well-being of infants, children, adolescents, and young adults. I am the Founding Editor of the AAP's book on Pediatric Environmental Health, and I am currently editing a 3rd edition. I am also a former Chair of the AAP Committee on Environmental Health and the founding chair of the AAP Section on Epidemiology.

Formaldehyde is a toxic, pungent, water-soluble gas used in the aqueous form as a disinfectant, fixative, or tissue preservative, making it versatile for a wide range of uses. Formaldehyde resins are used in wood products (*e.g.*, particleboard, paper

towels), plastics, paints, manmade fibers (e.g., carpets, polyester), cosmetics, and other consumer products,¹ including many with which children have regular contact.² According to recent research and media reports, formaldehyde may be found in fabrics and children's clothing,³ children's furniture,⁴ baby bath products,⁵ and other products. Formaldehyde is also used in the resins used to bond laminated wood products and to bind wood chips in particleboard. Particleboard may be used in various types of furniture, including cribs and other items meant for use by or with children. The experience of Gulf Coast families living in mobile homes and travel trailers after Hurricane Katrina brought these hazards to the nation's attention; trailers, which have small, enclosed spaces, low air exchange rates, and many particleboard furnishings, may have much higher concentrations of formaldehyde than other types of homes.^{6,7}

Formaldehyde gas is known to cause a wide range of health effects. A common air pollutant in the home,⁸ formaldehyde is an eye, skin, and respiratory tract irritant. In other words, it can cause burning or tingling sensations in the eyes, nose and throat. Children may be more susceptible than adults to the respiratory effects of formaldehyde. Even at fairly low concentrations, formaldehyde can produce rapid onset of nose and throat irritation, causing cough, chest pain, shortness of breath, and wheezing. At higher levels of exposure, it can cause significant inflammation of the lower respiratory tract, which may result in swelling of the throat, inflammation of the windpipe and bronchi, narrowing of the bronchi, inflammation of the lungs, and accumulation of fluid in the lungs. Pulmonary injury may continue to worsen for 12 hours or more after exposure. Children may be more vulnerable than adults to the effects of chemicals like formaldehyde because of the relatively smaller diameter of their airways. Children may be more vulnerable because they breathe more rapidly than adults for their size, and they may be developmentally incapable of evacuating an area promptly when exposed.⁹

Formaldehyde may exacerbate asthma in some infants and children. Studies since 1990 have found higher rates of asthma, chronic bronchitis, and allergies in children exposed to elevated levels of formaldehyde.^{10,11,12,13}

In 2004, the International Agency for Research on Cancer (IARC) announced there was sufficient evidence that formaldehyde causes nasopharyngeal cancer in humans and reclassified it as a Group 1, known human carcinogen (previous classification: Group 2A). IARC also reported there was limited evidence that formaldehyde exposure causes nasal cavity and paranasal cavity cancer and "strong but not

¹ International Agency for Research on Cancer. IARC Monographs on the Evaluation of Carcinogenic Risks to Humans. Volume 88. Formaldehyde. Available online at <http://monographs.iarc.fr/ENG/Monographs/vol88/volume88.pdf>.

² Kelly T. J., Smith DL, Satola J. Emission Rates of Formaldehyde from Materials and Consumer Products Found in California Homes. *Environ Sci Technol*, 1999;33(1): 81–88.

³ "Poison found in kids' clothes from China." *New Zealand Sunday Star-Times*, August 19, 2007. Available online at <http://www.stuff.co.nz/sunday-star-times/497>.

⁴ Environment California Research & Policy Center. Toxic Baby Furniture: The Latest Case for Making Products Safe from the Start. May 2008. Available online <http://www.environmentamerica.org/reports/toxic-free-communities/stop-toxic-pollution/toxic-baby-furniture-the-latest-case-for-making-products-safe-from-the-start>.

⁵ Environmental Working Group. No More Toxic Tub: Getting Contaminants Out of Children's Bath and Personal Care Products. March 2009. Available online at <http://www.ewg.org/node/27698>.

⁶ American Academy of Pediatrics Committee on Environmental Health. Air Pollutants, Indoor. In: Etzel, R. A., ed. *Pediatric Environmental Health*, 2d Edition. Elk Grove Village: American Academy of Pediatrics, 2003.

⁷ Spengler JD. Sources and concentrations of indoor air pollution. In: Samet JM, Spengler JD, eds. *Indoor Air Pollution: A Health Perspective*. Baltimore, MD: Johns Hopkins University Press; 1991.

⁸ American Academy of Pediatrics Committee on Environmental Health. Air Pollutants, Indoor. In: Etzel, R. A., ed. *Pediatric Environmental Health*, 2d Edition. Elk Grove Village: American Academy of Pediatrics, 2003.

⁹ Agency for Toxic Substances & Disease Registry. Medical Management Guidelines for Formaldehyde. <http://www.atsdr.cdc.gov/MHMI/mmg111.html#bookmark02>

¹⁰ American Academy of Pediatrics Committee on Environmental Health. Air Pollutants, Indoor. In: Etzel, R. A., ed. *Pediatric Environmental Health*, 2d Edition. Elk Grove Village: American Academy of Pediatrics, 2003.

¹¹ Wantke F., Demmer C. M., Tappler P., Gotz M., Jarisch R. Exposure to gaseous formaldehyde induces IgE-mediated sensitization to formaldehyde in school-children. *Clin Exp Allergy*. 1996 Mar; 26(3):276–80.

¹² Garrett M. H., Hooper M. A., Hooper B. M., Rayment P. R., Abramson M. J. Increased risk of allergy in children due to formaldehyde exposure in homes. *Allergy*. 1999 Apr; 54(4):330–7.

¹³ Rumchev, K. B.; Spickett, J. T.; Bulsara, M. K.; Phillips, M. R.; Stick, S. M. Domestic exposure to formaldehyde significantly increases the risk of asthma in young children. *Eur Respir J*. 2002 Aug; 20(2):403–8.

sufficient” evidence linking formaldehyde exposure to leukemia.¹⁴ The U.S. National Toxicology Program classifies it as “reasonably anticipated to be a human carcinogen.”¹⁵

Formaldehyde can cause contact dermatitis in susceptible people. Dr. Brookstein will discuss this matter in more detail, so I will only note that children are as susceptible as adults to the dermal effects of formaldehyde exposure.

Due to its toxicity, various nations have taken steps to limit the use of formaldehyde in some applications. Several nations have set standards for the presence of formaldehyde residues in fabric, including Finland, Norway, the Netherlands, and Germany. The European Union limits formaldehyde in children’s clothing to 30 parts per million.¹⁶ Other nations, such as Japan, China, Russia, Lithuania, New Zealand, and South Korea have set limits on formaldehyde in textiles and/or wood products. Among these nations, the strongest restrictions are in place in Japan, which requires no detectable residue of formaldehyde in clothing for children birth to 3 years of age.¹⁷

Recommendations

The American Academy of Pediatrics has made formaldehyde recommendations to Congress and the Administration in the past, and would like to reiterate those and submit others for Congress’s consideration.

CPSC should limit formaldehyde residues in children’s clothing and other products. Given that at least a dozen other nations already restrict formaldehyde residues in children’s clothing, CPSC should collaborate with EPA and other agencies with scientific and medical expertise to determine similar limits to be imposed in the U.S. While more research is needed to refine our understanding of formaldehyde’s impact on child health, there is already a considerable body of evidence that may be sufficient to allow CPSC to make a reasonable judgment in this area. The agency should also require labels on children’s clothing and products that indicate the presence of formaldehyde residues.

More research is needed on formaldehyde and children’s health. In July 2007, the Academy suggested to the House of Representatives Committee on Energy and Commerce that the Federal Emergency Management Agency and Federal health agencies undertake a systematic, scientifically rigorous study of this issue to determine children’s exposure levels and correlation with reported symptoms, and steps that should be taken to safeguard their health. To our knowledge, no such study has been conceived or implemented. It also remains unclear to what extent children may be exposed to formaldehyde from multiple sources, and what effect this may have on their developing bodies. The Consumer Product Safety Improvement Act of 2008 requires the Consumer Product Safety Commission (CPSC) Comptroller General to conduct a study within 2 years of “the use of formaldehyde in the manufacture of textile and apparel articles . . . to identify any risks to consumers caused by the use of formaldehyde in the manufacturing of such articles . . .” This report is due in January 2011.

EPA should adopt nationwide California’s proposed restrictions on formaldehyde emissions from wood products. In January 2009, the AAP joined numerous other organizations in urging Environmental Protection Agency Administrator Lisa Jackson to adopt nationwide the restrictions on formaldehyde emissions from hardwood plywood, particleboard, and medium density fiberboard set under the California Air Resource Board Airborne Toxics Control Measure.

CPSC should develop educational materials for consumers about formaldehyde and its presence and role in various products, as well as potential health risks. The CPSC could provide an important service by providing up-to-date educational materials about formaldehyde. A search of the agency’s website reveals a number of documents about formaldehyde, but many of them are from the 1970s and 1980s. The

¹⁴International Agency for Research on Cancer, “IARC Classifies Formaldehyde As Carcinogenic to Humans,” Press Release No. 153, June 15, 2004, http://www.iarc.fr/ENG/Press_Releases/archives/pr153a.html.

¹⁵Krzyzanowski M., Quackenboss J. J., Lebowitz M. D. Chronic respiratory effects of indoor formaldehyde exposure. *Environ Res.* 1990 Aug;52(2):117–25.

¹⁶Information on European Union laws regarding limits on formaldehyde in textiles available online from the Centre for the Promotion of Imports from developing countries, <http://www.cbi.eu/>.

¹⁷American Apparel and Footwear Association. Restricted Substances List. February 2009. Available online at http://www.apparelandfootwear.org/UserFiles/File/Restricted%20substance%20List/AAFARSL_Release4Feb09.pdf.

last version of the most comprehensive document, "An Update on Formaldehyde," appears to be the 1997 revision.¹⁸

The American Academy of Pediatrics commends you, Mr. Chairman, for holding this hearing today to call attention to the potential hazards of formaldehyde exposure among children. We look forward to working with Congress to minimize the exposure of children and all Americans to all potentially toxic chemicals. I appreciate this opportunity to testify, and I will be pleased to answer any questions you may have.

Senator PRYOR. Thank you, Dr. Etzel.
 Now Dr.—is it "Brookstine" or "Brooksteen"?
 Dr. BROOKSTEIN. "Brookstine."
 Senator PRYOR. "Stine," OK. I'm sorry——
 Dr. BROOKSTEIN. Thank you.
 Senator PRYOR.—I fouled that up in your——
 Dr. BROOKSTEIN. It's all right.
 Senator PRYOR.—in the earlier introduction.
 Go ahead, Dr. Brookstein.

**STATEMENT OF DAVID BROOKSTEIN, Sc.D., DEAN AND
 PROFESSOR, SCHOOL OF ENGINEERING AND TEXTILES,
 PHILADELPHIA UNIVERSITY**

Dr. BROOKSTEIN. Thank you. Thank you, Chairman Pryor and members of the Committee, for this opportunity to testify on a matter of great concern to the American public.

I am Dr. David Brookstein, Dean and Professor of Engineering at Philadelphia University's School of Engineering and Textiles. My testimony is based on over 35 years of experience as a textile engineering professor and research, including co-founding the Institute for Textile and Apparel Product Safety at Philadelphia University.

I applaud the Committee today for holding this hearing, as the possible health effects of formaldehyde in textiles have not been fully examined, nor are the long-term health effects fully understood.

I'd also like to express my appreciation to Senator Casey for his interest and leadership on protecting our Nation's citizens from potentially toxic materials in consumer products.

I am here to discuss the toxicity of chemicals, such as formaldehyde, used to treat textile-based products. I will also speak to how other industrialized nations regulate this chemical, thus ensuring the health and welfare of their citizens. Finally, I will describe how at least one industry trade group has dealt with this issue.

Now, in the summer of 2007, reports began to surface about high levels of lead in children's toys. These reports, and subsequent inquiries into other product categories, led to hundreds of thousands of products being recalled. However, the potential harmful effects to consumers from textile-based products was one area that escaped the initial scrutiny. Recalling that many years ago the Federal Government recognized the lethal toxicity of asbestos fibers and TRIS flame-retardant children's sleepwear led me to question whether it was cause for concern with textile-based products currently available to consumers. So, I began looking to research on

¹⁸U.S. Consumer Product Safety Commission. An Update on Formaldehyde, 1997 Revision. Available online at <http://www.cpsc.gov/CPSCPUB/PUBS/725.pdf>.

potentially toxic chemicals, like formaldehyde, that are used to treat textiles and apparel. What I discovered is that, as with toys and other consumer products, most apparel items are no longer manufactured in the U.S. and, therefore, are not subject to our manufacture and environmental standards.

Now, why are formaldehyde-treated textiles a problem? Formaldehyde is a commonly used chemical in the treatment of apparel items for permanent press and has long been recognized as toxic. As early as the 1950s, physicians noted that patients were presenting with serious cases of contact dermatitis brought on by skin contact with textile items. The medical literature is replete with many studies showing the adverse dermatological effects of formaldehyde. At a recent workshop held at Philadelphia University and facilitated by Senator Casey and attended by personnel from the CPSC, Dr. Susan Nederost, a dermatologist, reported seeing numerous patients with contact dermatitis caused by allergic response to formaldehyde exposure from coming in direct contact with chemicals and apparel. There's particular danger to infants and small children from being dressed in articles of clothing that have been treated with toxic chemicals.

People are also exposed, and experience health problems, as a result of release of formaldehyde vapors from home furnishings, such as draperies. In recent testimony to the U.S. House of Representatives, relatively high levels of formaldehyde in home and office blackout shades and other drapery items was reported. However, as of yet, there are no formaldehyde restrictions or standards for clothing and other textile items that are distributed and sold in the U.S. This is largely because there's not been enough focus or research to truly understand and appreciate the seriousness of the problem.

Senators Casey, Brown, Clinton, and Landrieu offered an amendment in the recent CPSC Improvement Act to study the use of formaldehyde in textile and apparel articles. The amendment, agreed to unanimously, calls for a study by the GAO, in consultation with the Commission, on the use of formaldehyde in textile and apparel articles, and seeks to identify any risks to consumers caused by the use of formaldehyde. The law calls for the study to be completed and reported to the Congress by August 2010.

Industrialized countries deal with formaldehyde in clothing and textiles. And I have an exhibit over here, which is also in my written testimony, that I prepared that shows you the standards of many of these countries. While currently there are no U.S. standards or regulations associated with formaldehyde in clothing and textiles, the American Apparel and Footwear Association, has issued a restricted substance list and has requested that its members abide, voluntarily, to the standards listed, an obvious recognition of a potential problem. While this hearing is specifically focused on formaldehyde, my written testimony discusses other toxic chemicals that are sometimes used, but not regulated, in the U.S.

Now, in view of my testimony and the wide body of knowledge associated with the use of toxic chemicals in textiles and apparel, I believe that now is the time to look again at the issue of apparel—issue of formaldehyde and other potential toxic dyes and fin-

ishes in textile and apparel. I respectfully recommend the following:

One, that Congress make sure that its recent legislation calling for a formaldehyde study in textiles and apparel be conducted in a timely fashion.

Two, that consumer product safety standards be implemented based on the findings of these studies.

Three, that legislation similar to that for formaldehyde be enacted for other known toxic chemicals used in textiles and apparel.

And, four, that a reasonable and ongoing testing program be established at an independent laboratory similar to the Underwriters Lab, for textile and apparel items, including components of such articles in which formaldehyde and other known toxic chemicals were used in their manufacture.

The suggested study of the use of toxic chemicals in textiles and apparel products will provide Congress the needed information to consider whether new laws and/or regulations are necessary to protect the health and welfare of the American—of American citizens.

In conclusion, I would like to again express my appreciation to the Committee and to Senator Casey for this opportunity to provide testimony on this important issue that affects the health of our citizenry. I stand ready to serve the Committee in any way in the future.

Thank you.

[The prepared statement of Dr. Brookstein follows:]

PREPARED STATEMENT OF DAVID BROOKSTEIN, SC.D., DEAN AND PROFESSOR,
SCHOOL OF ENGINEERING AND TEXTILES, PHILADELPHIA UNIVERSITY

Thank you Chairman Pryor and members of the Committee for this opportunity to provide testimony to the Senate Subcommittee on Consumer Protection, Product Safety and Insurance. I would also like to express my appreciation to Senator Robert P. Casey, Jr. who is at the vanguard of protecting our Nation's citizens from potentially toxic materials in consumer products. My testimony is based on over 35 years of experience as a textile engineering professor and researcher including co-founding the Institute for Textile and Apparel Product Safety at Philadelphia University.

In the summer of 2007, reports surfaced about high levels of lead in toys and other consumer goods and there were hundreds of thousands of items recalled. One area that initially escaped scrutiny at that time was textile and apparel product safety. Years before, the Federal Government recognized the lethal toxicity of asbestos fibers and TRIS flame retardant in children's sleepwear and acted appropriately to ban their use in consumer products. Today, once again, the question of safety is front and center and researchers are looking for answers regarding the safety of textiles and apparel. By researching the prevalence of other potentially toxic chemicals, such as formaldehyde, dyes and finishes, used every day in clothing, we will be able to determine just what chemicals and at what levels could pose risks to all of us, especially our children—and possibly lead to medical conditions ranging from contact dermatitis to neurotoxicity, endocrine disruption and possibly cancer.

Many clothing items are in direct contact with the skin. During contact there can be perspiration which involves moisture transport between the skin and the dyed and chemically treated clothing items. Dyes are used to enhance the appearance of textiles and chemical treatments affect the performance of textile products. While modern dyes and chemical treatments are chemically bound to the fibers in the clothing, there is the possibility that residual dye (dye bleed) and finishes (treatment chemicals) are released in direct contact with the skin. Textile materials are a capillary and porous material with different pore sizes, and can be saturated with both liquid and gaseous water during wear. The transportation of perspiration through this material at different temperatures is a very complex process, which can involve convection, capillary flow, penetration, molecular diffusion, evaporation, and solidification.

On August 14, 2008 Public Law 110–314 (Consumer Product Safety Improvement Act) was enacted. The purpose of the law was to establish consumer product safety standards and other safety requirements for children’s products and to reauthorize and modernize the Consumer Product Safety Commission.

Formaldehyde is a commonly used chemical treatment for apparel items and has long been recognized as toxic. Accordingly, Senators Casey, Brown, Clinton and Landrieu offered an Amendment to study the use of formaldehyde in manufacturing textile and apparel articles. The Amendment, agreed to unanimously, calls for a study by the GAO in consultation with the Commission, on the use of formaldehyde in the manufacture of textile and apparel articles, or in any component of such articles, to identify any risks to consumers caused by the use of formaldehyde in the manufacturing of such articles, or components of such articles. The law calls for the study to be completed by August 2010 but, to our knowledge, the GAO has not yet begun the study.

Formaldehyde treatment of cellulosic fibers such as cotton was first taught in an invention by the British inventors Foulds, Marsh and Wood in U.S. Patent 1,734,516 in 1929. The inventors claimed that “one of the greatest defects of a fabric composed entirely of cotton has been the ease with which such fabric is creased or crumpled when crushed or folded under pressure in the hand.” The invention was to use a mixture of chemicals including formaldehyde to cause a chemical reaction with the cellulose that would cause cross-linking and thus render the fabric wrinkle free.

Substantial commercial interest developed as inherently wrinkle-free synthetic fibers were commercialized and by the 1950s family fabric caretakers (mostly women) were delighted by the potential of wrinkle-free fabrics that would add to other labor-saving chores that were being introduced to the public. As more and more women joined the workforce the entire family became interested in easy care clothing.

In 1985, The U.S. National Institute for Occupational Safety and Health (NIOSH) completed its first research study of formaldehyde. The study examined death certificates among 256 deceased workers from three plants which made shirts from formaldehyde treated cloth. Formaldehyde was used at these plants to help make shirts more crease resistant. The 1985 study found a significantly increased risk of cancer of the buccal cavity (cancer of the inside of the mouth) and for multiple myeloma (cancer of the bone marrow). In 1988, NIOSH completed its second study of formaldehyde exposure. This study looked at employment records from 11,030 workers who had been employed at any one of three plants. Two of the three plants were the same as in the previous study. As in the 1985 study, the 1988 study found a significantly increased risk for cancer of the buccal cavity. Excess risks were also seen for multiple myeloma and leukemia.

In 2004, NIOSH conducted a substantially large study of cause of death among clothing workers exposed to formaldehyde and found that:

1. The death rates from all causes combined and for all cancers combined among the 11,039 workers in the updated study were lower than expected, based on the U.S. population rates.
2. There were no deaths from cancers of the nasopharynx (nose). The death rate for cancer of the buccal cavity (inside of the mouth) was only slightly elevated.
3. The overall risk for myeloid leukemia was almost 1½ times what was expected.
4. For workers who were employed at the plants for 10 or more years and were first exposed 20 years earlier, the risk for myeloid leukemia was increased over 2 times what was expected.
5. The increase in myeloid leukemia was also seen among those workers who were first exposed prior to 1963, when formaldehyde exposures were likely higher.

NIOSH reported that the overall average concentration of formaldehyde measured by NIOSH at the three plants during the early 1980s was 0.15 parts per million (ppm). This was below the permissible level at that time, which was 3.0 ppm over an 8-hour work day. Exposures were similar across departments and plants. In 1987 the permissible level of formaldehyde exposure was reduced to 1.0 ppm and in 1992 was further reduced to 0.75 ppm. OSHA regulation 29 CFR 1910–1048 regulates the exposure limit for workers in the U.S. textile and apparel industry to 1 part formaldehyde per million parts of air as an 8-h time-weighted average. The NIOSH

study was based on a group of scientific research papers published from 1985–2004.^{1,2,3}

While the NIOSH studies and subsequent regulations were directed at American workers, the same concerns obtain for American consumers.

In 2004, the World Health Organization International Agency for Research on Cancer (IARC) categorized formaldehyde as a known cancer-causing agent in humans.

The United States apparel manufacturing industry has declined precipitously and today it has been estimated that approximately 90 percent of consumer apparel sold in the United States is not manufactured in the United States. Accordingly, today the safety hazards associated with formaldehyde to U.S. apparel workers is negligible, if any. Yet while there are essentially no occupational hazards associated with formaldehyde processing of apparel to U.S. workers there could be hazards to those overseas workers who produce clothing and textiles for the U.S. marketplace. Additionally, American workers can be exposed to potential toxic off-gassing from textile products when imported items are received in U.S. distribution centers.

However, humans can be exposed to formaldehyde associated with textiles and clothing in an additional manner than that from manufacturing. For instance, in the clothes treated with formaldehyde can come into direct contact with the skin. In 1959, Marcussen (Denmark) reported that during a period between 1934–1958 there were 26 cases (11 percent of studied cases) of garment formaldehyde dermatitis.⁴ Marcussen also reported results of a study conducted from 1934–1955 a study in which 1–3 percent of 36,000 eczematous patients showed formaldehyde sensitivity.⁵ In 1965, U.S. dermatology researchers O'Quinn and Kennedy reported contact dermatitis caused by formaldehyde in clothing.⁶ Hatch published a complete review of references to clothing based formaldehyde sensitivity in 1984.⁷ The medical literature is replete with many studies showing the adverse dermatological effects of formaldehyde. An excellent current review of this subject has been written by Fowler "Formaldehyde as a Textile Allergen" in 2003.⁸

Below is a table which shows common formaldehyde resins used in textiles and apparel.

Resin Type	Relative Formaldehyde Release*
Urea formaldehyde/DMU	High
Melamine formaldehyde	High
DMDHEU (Fixapret CPN)	Low
DMDHEU blended or reacted with glycols (modified) (Fixapret ECO)	Very low
Dimethoxymethyl dihydroxyethylene urea (methylated DMDHEU)	Very low
Dimethyl dihydroxyethylene urea (Fixapret NF)	None

* High signifies a formaldehyde release of > 1,000 ppm; low, a release of < 100 ppm; and very low, a release of < 30 ppm.⁹

At a recent workshop held at Philadelphia University attended by personnel from the Consumer Product Safety Commission, Dr. Susan Niderost of University Hospitals of Cleveland/Case Western Reserve University reported that patients with al-

¹ Stayner, L.; Smith, A. B.; Reeve, G.; *et al.*, Proportionate mortality study of workers in the garment industry exposed to formaldehyde. *Am J Ind Med* 1985;7:229–240.

² Stayner, L. T.; Elliott L.; Blade L.; *et al.* A retrospective cohort mortality study of workers exposed to formaldehyde in the garment industry. *Am J Ind Med* 1988;13:667–681.

³ Pinkerton, L. E.; Hein, M. J.; Stayner, L. T. Mortality among a cohort of garment workers exposed to formaldehyde: an update. *Occup Environ Med* 2004;61(3):193–200.

⁴ Marcussen, P. V., Contact Dermatitis Due to Formaldehyde in Textiles, 1934–1958, Preliminary Report, *Acta Derm. Venereol.* 39,348–356 (1959).

⁵ Marcussen, P. V., Dermatitis Caused by Formaldehyde Resins in Textile, *Dermatologica*, 125, 101–111 (1962)

⁶ O'Quinn, S. E., and Kennedy, C. B., Contact Dermatitis Due to Formaldehyde in Clothing Textiles, *J. Am. Med/ Soc.* 194, 593–596 (1965).

⁷ Hatch, K. L., Chemicals and Textiles, Part II: Dermatological Problems Related to Finishes, *Textile Research Journal*, Vol. 54, No. 11, 721–732 (1984).

⁸ Fowler, J. F., Formaldehyde as a Textile Allergen, Elsner, P.; Hatch, K.; Wigger-Alberti W. (eds): *Textiles and the Skin. Curr Probl Dermatol.* Basel, Karger, 2003, vol 31, pp 156–165.

⁹ Hatch, K. L, Maibach HI. Textile dermatitis: an update. (I). Resins, additives and fibers. *Contact Dermatitis* 1995;32:319–26.

¹⁰ Reid, J. D.; Arceneaux, R. L., *et al.*, Studies of wrinkle resistant finishes for cotton textiles (I): Release of formaldehyde vapors on storage of wrinkle resistant cotton fabrics. *Am Dyest Rep* 1960: 49, 490–531.

¹¹ Berman, M., Testimony to the Ways and Means Trade Subcommittee U.S. House of Rep-

lergic contact dermatitis, such as that caused by allergic response to formaldehyde exposure, results in substantial amount of days missed from employment.

Another exposure route is from off-gassing of stored or closeted clothing with relatively high levels of formaldehyde. As early as 1960 researchers reported on release of formaldehyde vapors on storage of wrinkle-resistant cotton fabrics.¹⁰ The exposure route from off-gassing of formaldehyde could soon be recognized as a significant health risk to United States consumers as a result of recent testimony to the U.S. House of Representatives which reports the relatively high levels of formaldehyde in house and office blackout shades and other drapery items.¹¹ Using the AATCC Test Method #112 free formaldehyde values of between 1000 ppm and 3000 ppm were found in a relatively large group of imported items available in the United States marketplace.

As of yet, there are no formaldehyde restrictions or standards for clothing and other textile items that are distributed and sold in the United States. However more and more nations are adopting standards for formaldehyde in clothing and textiles. In Japan, textile fabrics are required by law to contain less than 75 ppm free formaldehyde, as measured by the method described in Japan Law 112. And no formaldehyde is tolerated for infant clothing. The Hong Kong Standards and Testing Center produced the table below which shows the status of formaldehyde regulations in countries that are currently addressing this situation.¹² From the table, the Committee can easily see how other industrialized countries are dealing with this important issue that affects the health of their citizenry.

Country	Regulations / Requirements	Objection Limit / Limit
Germany	Gefahrstoffverordnung (Hazardous Substances Ordinance) Annex III, No. 9, 26.10.1993	Textiles that normally come into contact with the skin and release more than 1500 mg/kg formaldehyde must bear the label "Contains formaldehyde. Washing this garment is recommended prior to first time use in order to avoid irritation of the skin."
France	Official Gazette of the French Republic, Notification 97/0141/F	The regulations apply to products that are intended to come into contact with human skin, including textiles, leather, shoes, etc. Textiles for babies: 20 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 400 mg/kg
Netherlands	The Dutch (Commodities Act) Regulations on Formaldehyde in Textiles (July 2000)	Textiles in direct skin contact must be labeled "Wash before first use" if they contain more than 120 mg/kg formaldehyde and the product must not contain more than 120 mg/kg formaldehyde after wash.
Austria	Formaldehydverordnung, BGBl Nr. 194/1990	Textiles that contains 1500 mg/kg or above must be labeled.
Finland	Decree on Maximum Amounts of Formaldehyde in Certain Textiles Products (Decree 210/1988)	Textiles for babies under 2-year-old: 30 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 300 mg/kg
Norway	Regulations Governing the Use of a Number of Chemicals in Textiles (April 1999)	Textiles for babies under 2-year-old: 30 mg/kg Textiles in direct skin contact: 100 mg/kg Textiles not in direct skin contact: 300 mg/kg
China	Limits of Formaldehyde Content in Textiles GB18401-2001	Textiles for infants and babies: ≤20 mg/kg Textiles in direct skin contact: ≤75 mg/kg Textiles not in direct skin contact: ≤300 mg/kg
Japan	Japanese Law 112	Textiles for Infants: not detectable Textiles in direct skin contact: 75 ppm

In addition Poland, Russia, Lithuania and South Korea now regulate formaldehyde in textiles and apparel.

Formaldehyde is also found in glues and adhesive used to bond materials to each other such as in layers of shoes and fabrics to each other. In particular, para-ter-

⁷Hatch, K. L., Chemicals and Textiles, Part II: Dermatological Problems Related to Finishes, *Textile Research Journal*, Vol. 54, No. 11, 721-732 (1984).

⁸Fowler, J. F., Formaldehyde as a Textile Allergen, Elsner, P.; Hatch, K.; Wigger-Alberti W. (eds): *Textiles and the Skin. Curr Probl Dermatol*. Basel, Karger, 2003, vol 31, pp 156-165.

⁹Hatch, K. L., Maibach HI. Textile dermatitis: an update. (I). Resins, additives and fibers.

tiary butylphenol (PTBP) formaldehyde resin is sometimes used. This type of formaldehyde resin can also cause allergic reactions.¹³

Some have suggested that one way for the consumer to deal with residual formaldehyde on newly purchased clothing is to just wash it prior to wearing it. This is fundamentally problematic since many consumers will not heed this labeling “suggestion” and will just wear newly purchased clothing without taking the time to wash it. Additionally, further scientific evidence needs to be obtained that shows there is no residual formaldehyde on clothing even after its been washed. And finally, there are many items where formaldehyde is used and there is no opportunity for pre-washing. These items include baseball caps and footwear.

While currently there are no U.S. standards or regulations associated with formaldehyde in clothing and textiles the American Apparel and Footwear Association (AAFA) published a 2008 Restricted Substance List (RSL) which was refined in 2009. AAFA requested that its members abide voluntarily to the standards listed. For formaldehyde the RSL suggests no detectable formaldehyde for infant clothing (0–36 months), 75 ppm for clothing in direct contact with skin (>36 months) and 300 ppm for textiles with no direct skin contact (>36 months).

In addition to formaldehyde in textiles and apparel, there are other well documented toxic chemicals that are used in clothing, furniture and other textile-based consumer items. In particular, there are two classes of dyes that are commonly used in consumer textile-based products that are widely recognized as having the potential to cause allergic contact dermatitis and possibly to cause cancer. These two dye classes are azoic (azo) and disperse dyes. There is such a widespread concern associated with the use of azo dyes in textile-based products that many countries have enacted restrictive standards and stringent regulations that limit their use. In 2002 the European Union published a Directive (2002/61/EC) to restrict the marketing and use of certain dangerous substances and preparations (azo colorants) in textile and leather products. Thus, in the European Union their use is regulated by law; in the United States, at this time, there exist only voluntary standards by those companies that agree to regulate their use.

In 2006 a series of previously unreported cases of dermatitis appeared in Finland. Rantanen, a Finnish physician, reported that by 2007 “many cases from all over the country” were reported in the Internet discussion forum of the Finnish Dermatological Society. After an extensive investigation it was found that the cases were due to exposure to dimethylfumarate (DMF).¹⁴ It was reported by British newspaper accounts that sachets of DMF were put in thousands of Chinese manufactured furniture items to prevent mold while in storage or while being transported.¹⁵ Rantanen reported that the patients showed strong positive patch test reactions to upholstery fabric samples and to dimethylfumarate, down to a level of 1 ppm in the most severe case. It was concluded that the cause of the Chinese sofa/chair dermatitis epidemic was likely to be allergy to dimethylfumarate, a novel potent contact sensitizer. Thus, a serious health issue can occur, not from the furniture fabric but from the release of allergenic agents contained in the foam cushioning. As can be seen from the picture of a patient exposed to DMF the condition presents itself in a most devastating manner.

¹³Geldof, B.; Am Roesyanto, I. D.; Van Joost, T. H., Clinical aspects of para-tertiary-butylphenol formaldehyde resin (PTFR) allergy, *Contact Dermatitis*, 1989, 21, 312–315.

¹⁴The cause of the Chinese sofa/chair dermatitis epidemic is likely to be contact allergy to dimethylfumarate, a novel potent contact sensitizer T. Rantanen *British Journal of Dermatology* 2008 159, pp218–221.

¹⁵Brown, D.; Thousands injured by ‘toxic gas from Chinese sofas, *The Times*, July 21, 2008 UK.



Patient Exposed to Dimethylfumurate in Sofa

The European Union acknowledged the dangers of using dimethylfumurate in consumer products and issued European Directive (2009/251/EC) on March 17, 2009. The directive requires that products containing DMF are not to be placed on the market. The Directive also requires any product containing DMF that has already been placed on the market be withdrawn by May 1, 2009 and that consumers be made aware of the potential risks.

Brominated chemicals, used to make fabrics flame retardant, are another class of toxic substances that is of great concern to researchers. Of particular concern to child safety advocates are flame retardant fabrics used in children's car seats. While flame retardant fabrics play a beneficial role in preventing or minimizing serious injury, the long-term harmful effects to children exposed to this class of toxic chemicals is unknown and should be a matter for further research.

Unfortunately, a recent study conducted at Philadelphia University using an X-Ray Fluorescence analyzer showed a range of bromine readings from about 0.43 percent to 0.86 percent. It is widely recognized by the research community that levels in excess of 0.1 percent are considered toxic. Consequently, this standard has been adopted by the European Union in the Restriction of Hazardous Substances (RoHS) standards. The RoHS Directive is an EU Legal Directive for environmental regulations concerning the Restriction of Use of Hazardous Substances. The Directive requires the removal of five hazardous substances from electric and electronic equipment (Pb, Cd, Cr, Hg, Br compounds). While these toxic compounds are restricted in electric and electronic equipment, we were concerned that the same chemical compounds might be used in children's car seats. Accordingly, an extensive chemical analysis of the fabric was conducted to determine the bromine compounds that were present in car seat fabric with relatively high levels of bromine. Two specific brominated compounds were found: Hexabromocyclododecane (HBCD)—0.425 percent and Tetrabromobisphenol A (TBBPA)—1.185 percent.

HBCDs are included on the OSPAR¹⁶ list of chemicals for priority action. HBCDs have been identified by the U.K. Chemical Stakeholders Forum as persistent, bioaccumulative and toxic.¹⁷ While currently no specific regulatory actions are being taken in the United States, HBCDs have been identified for risk assessment in Canada, Australia and Japan. Further regulatory/assessment activities in these countries will take place over the next few years.¹⁸

Studies suggest that HBCD affects thyroid hormone levels, causes learning and memory defects in neonatal laboratory animals, and has been detected in breast milk.¹⁹ There are indications that oral exposure to HBCDs induces drug-metabolizing enzymes in rats, such as hepatic cytochrome P450 (CYP),²⁰ and that HBCDs may induce cancer by a nonmutagenic mechanism.^{21,22} There are reports that HBCDs can disrupt the thyroid hormone system²³ and affect the thyroid hormone receptor-mediated gene expression.²⁴ Following neonatal exposure experiments in rats, developmental neurotoxic effects can be induced, such as aberrations in spontaneous behavior, learning, and memory function.²⁵ HBCDs can also alter the normal uptake of neurotransmitters in rat brains.²⁶

TBBPAs are included on the OSPAR list of chemicals for priority action. TBBPA is known to off-gas to the environment, though the amount of off-gassing varies depending how the TBBPA was combined with other materials.²⁷ Lab tests have suggested that it may disrupt thyroid function.²⁸ Studies also suggest that it may adversely affect hormone levels and the immune system.²⁹ Histological findings showed that the slight enlargement of the hepatocytes, inflammatory cell infiltrations and focal necrosis of hepatocytes were more marked in liver of treated groups (from 350 mg/kg Body Weight) than in control group. The present data suggest the possibility of inducing hepatic lesions by TBBPA.³⁰

¹⁶The 1992 OSPAR Convention is the current instrument guiding international cooperation on the protection of the marine environment of the North-East Atlantic. It combined and updated the 1972 Oslo Convention on dumping waste at sea and the 1974 Paris Convention on land-based sources of marine pollution.

¹⁷Covaci, A.; Gereke, A.; Law, R.; Voorspoels, S.; Kohler, M.; Heeb, N.; Leslie, H.; Allchin, C.; Boer, J.; Hexabromocyclododecanes (HBCDs) in the Environment and Humans: A Review. *Environmental Science & Technology*, 2007, vol. 40, No. 12.

¹⁸National Chemicals Inspectorate (KEMI) *Draft of the EU Risk Assessment Report on Hexabromocyclododecane*, Sundryberg, Sweden, 2005.

¹⁹Birnbaum, L.; Staskal, D., 2004. "Brominated flame retardants: cause for concern?" *Environmental Health Perspectives* Vol. 112:1.

²⁰Germer, S.; Piersma, A. H.; van der Ven, L.; Kamyschnikow, A.; Fery, Y.; Schmitz, H. J.; Schrenk, D. Subacute effects of the brominated flame retardants hexabromocyclododecane and tetrabromobisphenol-A on hepatic cytochrome P450 levels in rats. *Toxicology* 2006, 218, 229–236.

²¹Helleday, T.; Tuominen, K. L.; Bergman, A.; Jenssen, D. Brominated flame retardants induce intragenic recombination in mammalian cells. *Mutat. Res.* 1999, 439, 137–147.

²²Ronisz, D.; Finne, E. F.; Karlsson, H.; Forlin, L. Effects of the brominated flame retardants hexabromocyclododecane (HBCDD) and tetrabromobisphenol-A (TBBP-A) on hepatic enzymes and other biomarkers in juvenile rainbow trout and feral eelpout. *Aquat. Toxicol.* 2004, 69, 229–245.

²³Eriksson, P.; Viberg, H.; Fischer, C.; Wallin, M.; Fredriksson, A. A comparison on developmental neurotoxic effects of hexabromocyclododecane, 2,2',4,4',5,5'-hexabromodiphenylether (PBDE 153) and 2,2',4,4',5,5'-hexachlorobiphenyl (PCB 153). *Organohalogen Compd.* 2002, 57, 389–392.

²⁴Yamada-Okabe, T.; Sakai, H.; Kashima, Y.; Yamada-Okabe, H. Modulation at a cellular level of the thyroid hormone receptor-mediated gene expression by 1,2,5,6,9,10-hexabromocyclododecane (HBCD), 4,4'-diiodobiphenyl (DIB), and nitrofen (NIF). *Toxicol. Lett.* 2005, 155, 127–133.

²⁵Eriksson, P.; Viberg, H.; Fischer, C.; Wallin, M.; Fredriksson, A. A comparison on developmental neurotoxic effects of hexabromocyclododecane, 2,2',4,4',5,5'-hexabromodiphenylether (PBDE 153) and 2,2',4,4',5,5'-hexachlorobiphenyl (PCB 153) *Organohalogen Compd.* 2002, 57, 389–392.

²⁶Mariussen, E.; Fonnum, F. The effect of brominated flame retardants on neurotransmitter uptake into rat brain synaptosomes and vesicles. *Neurochem. Int.* 2003, 43, 533–542.

²⁷Birnbaum, L.; Staskal, D., 2004. "Brominated flame retardants: cause for concern?" *Environmental Health Perspectives* Vol. 112:1.

²⁸Kitamura, S.; Kato, T.; Iida, M.; Jinno, N.; Suzuki, T.; Ohta, S.; Fujimoto, N.; Hanada, H.; Kashiwagi, K.; Kashiwagi, A. 2005. "Anti-thyroid hormonal activity of tetrabromobisphenol A, a flame retardant, and related compounds: Affinity to the mammalian thyroid hormone receptor, and effect on tadpole metamorphosis." *Life Sciences*. 2005 Feb 18; 76(14); 1589–601.

²⁹Birnbaum, L.; Staskal, D. 2004. "Brominated flame retardants: cause for concern?" *Environmental Health Perspectives*. Vol. 112:1.

³⁰Tada, Y.; Fujitani, T.; Ogata, A.; Kamimura, H. Flame retardant tetrabromobisphenol A induced hepatic changes in ICR male mice, *Environmental Toxicology and Pharmacology*. August 2007.

In view of my testimony and the wide body of knowledge associated with the use of toxic chemicals in textiles and apparel I believe that now is the time to look again at the issue of formaldehyde and other potential toxic dyes and finishes in textiles and apparel. It is recommended that future legislation dealing with consumer product safety should include a study on the use of formaldehyde and other known toxic dyes, finishes, and preservatives in the manufacture of textile and apparel articles, that consumer product safety standards be implemented based on the findings of these studies, and a reasonable testing program be established for textile and apparel items including components of such articles in which formaldehyde and other known toxic chemicals were used in their manufacture.

The suggested study of the use of toxic chemicals in textiles and apparel products will provide Congress the needed information to consider whether new laws and/or regulations are necessary to protect the health and welfare of American citizens.

In conclusion, I would like to again express my appreciation to the Committee and to Senator Casey for this opportunity to provide testimony on this important issue that affects the health of our citizenry. I stand ready to serve the Committee in any way in the future.

Senator PRYOR. Thank you.
Dr. Wakelyn?

**STATEMENT OF DR. PHILLIP J. WAKELYN, CONSULTANT,
WAKELYN ASSOCIATES, LLC**

Dr. WAKELYN. Yes, thank you—can you hear me? Thank you for inviting me to this hearing. I'm Dr. Phillip Wakelyn. I'm here to try and provide some technical information on formaldehyde in textiles.

I, too, have been involved in this for a short period of time, probably for the last 35, 40 years. I have a Ph.D. in textile chemistry. I was involved as a consultant and advisor to USDA since the early 1970s on all the fantastic research they've done on low-emitting resin technology, all the awards they have won for the outstanding work. So, when people stand up here and say that, "Oh, nothing's been done. We don't have any information," I think they've forgotten what has happened. This issue was extensively studied and looked at in the 1980s and early 1990s, and CPSC did conduct extensive research, look at extensive research, and do many things.

But, let me start by saying this, that my testimony this morning does reflect the views of a broad coalition of textile and apparel interests, which was mentioned earlier, and these same interests supported the GAO study in formaldehyde.

I also would like to say, today with me is—sitting behind me is Hardy Poole, formerly with ATMI. And he and I were party to all of these studies, extensive studies, that are referenced in my testimony, by the textile industry, by CPSC, at various places, like Research Triangle Institute, the Oak Ridge National Laboratories. And so, if there are additional questions that he might answer, he can assist in that.

Now, my understanding was that this hearing was to be, and is supposed to be, about formaldehyde in textiles, and I'll limit mine to that, even though much of the testimony and much of the things said so far would go beyond that.

I also would like to say—and you have my full testimony for the record, so these are a few things that I'd like to address that have been addressed by others, but, I think, incorrectly.

There are no valid safety-related problems raised in the U.S. concerning low levels of formaldehyde in clothing. The evidence is strong that formaldehyde in textiles does not pose an unreasonable

risk to injury of consumers. This is a finding that the Consumer Product Safety has already made, and I would be very sure that, when they review the data from the GAO study they will come to the same conclusion. There is no need for legislation or regulatory action, and we'll await the GAO study.

Now, allergic contact dermatitis in textiles is very rare. There are many causes for it other than chemical additives. And there are many claims, nonspecific claims of irritation and reaction, that are incorrectly blamed on formaldehyde and that are not part of formaldehyde, including several major cases that have been recently—where the garment was not treated with formaldehyde, the garment did not contain formaldehyde, and the person wasn't allergic to formaldehyde. But yet, that doesn't stop the press from implicating it.

The—there is a difference between airborne levels and fabric levels, and I've explained that in my testimony, and in cross-examination I would be happy to talk about that.

We talk about where formaldehyde is used in textiles. It's mainly used for easy-care, wrinkle-resistant for sheeting, shirting, dress goods. There's a tiny bit that's used for pigment dyeing and pigment printing. And there's a very little bit that can be used in fire retardants, but are not presently being used on children's sleepwear.

Formaldehyde-containing chemicals, by the way, are—formaldehyde *per se* itself is not used; it's chemicals that contain formaldehyde that, under certain conditions, can release trace amounts. As I say, it's mainly used on cotton and cotton blends.

Of all of the apparel offered for retail in the United States last year, 2 percent contained any wrinkle-resist, 13 percent of all the cotton sold last year contained some wrinkle-resist. There is no easy-care in children's products, and formaldehyde is essentially not used in children's products. Formaldehyde also is not used on synthetic textiles, such as fabric and apparel made from nylon and polyester.

Now, one thing that was mentioned earlier was the New Zealand situation. It would be—the correct story of the New Zealand situation is that the country of New Zealand tested—after that news program, tested 99 items, 84 of which were Chinese. They showed that 97 of those contained very low levels, if any, formaldehyde, or nondetect; 2 had slightly above their proposed standard of 100—that is by the international Japanese standard. And it's very important how you make this measurement. Those two, by simple washing, were acceptable levels. So, it's been known for a long time that Clorox 2 and simple laundering removes—lowers the level—either totally removes or lowers it to a nondetect or nonlevel of concern.

In the 1980s, as I mentioned, CPSC looked at the data, they banned or significantly reduced the urea-formaldehyde insulation under the Federal Hazardous Substances Act. They also looked at detailed studies—as I say, did all of these studies that are listed in my testimony—at Oak Ridge National Laboratories, Research Triangle Institute—they made a decision at that time that formaldehyde from textiles did not present an unreasonable risk of in-

jury. They found that urea-formaldehyde insulation needed to be regulated, not textiles.

Also, under Proposition 65, you can walk into a hotel, you can buy a new house, you can go into a restaurant, you see Proposition 65 signs. For textiles, we presented chamber data, they studied this, they looked at it. Textiles are below the 40-microgram-per-day safe-harbor level. And when people say we don't know what's coming off of fabrics—from these chamber studies, even if it's 500 micrograms per gram or parts per million on the fabric, they were below the safe-harbor limit in California.

So, there is a tremendous amount of information. And it was mentioned that California recently, in 2007, has regulated pressed-wood products—by the way, EPA had a Advance Notice of Proposed Rulemaking in the Federal Register in December to address formaldehyde from pressed-wood products. They have looked at textiles; they are not concerned with textiles in California, either, as litigious as they are.

So, there is not a problem. It's not in children's clothing at all in the United States. No new regulations or legislation are necessary concerning formaldehyde in textiles unless the required GAO study—clearly shows that there are areas of concern, and any of this should be based on sound science and not people's perception. Many times, formaldehyde is blamed for any product or any rash or anything that people get from textiles, and it's many—most of the time, it's shown that these people aren't even allergic to formaldehyde.

So, I will try to answer any questions, but my answers, I hope, will be based on published research and on science.

[The prepared statement of Dr. Wakelyn follows:]

PREPARED STATEMENT OF DR. PHILLIP J. WAKELYN, CONSULTANT,
WAKELYN ASSOCIATES, LLC

Summary

There have been no valid safety related problems raised in the U.S. concerning the low levels of formaldehyde on clothing and textiles. In view of all the studies over the last 30 years indicting that there is not a formaldehyde problem with U.S. textiles products and regulations already in place concerning formaldehyde and textiles, no new regulations are necessary. Because the evidence is so strong that formaldehyde in textiles does not pose a problem to consumers, there is no need for legislative or regulatory action concerning formaldehyde and textiles unless the results of the GAO study, required by Section 234 of the CPSIA which became law August 14, 2008, indicate that action is necessary.

1. Introduction

Allergic contact dermatitis caused by textiles is rare. There are many reasons other than chemical additives used in processing of textiles that can cause irritation/allergic contact dermatitis—the fabric itself, physical effects of the clothing rubbing the skin, heat retention from perspiration soaked clothes, poor hygiene, fasteners, and other devices attached to clothing, etc. For example, some people may find that fabrics such as wool irritate their skin but it is not an allergy and not chemically related. It is important to note that formaldehyde is ubiquitous and is a natural product present in the air from many sources—natural processes, in fruits, vegetables and blood, by combustion processes, including motor vehicles, cooking, household heating and brush fires and produced by cigarette smoking.

2. Fabric levels of formaldehyde should not be confused with airborne levels of formaldehyde gas

Fabric levels of formaldehyde are determined by two generally accepted methods (see Appendix 3). Typically, fabric levels are expressed as micrograms of formaldehyde per gram of fabric ($\mu\text{g/g}$ or ppm). Airborne levels are expressed as micrograms

or milligram of formaldehyde gas per cubic meter of air (μg or mg/m^3 ; ppb or ppm). There is not a clear correlation between fabric levels of formaldehyde and airborne levels of formaldehyde gas because release mechanisms are numerous and complex. Many factors affect releases and airborne levels, *e.g.*, material and treatment, temperature, humidity, room size, air exchanges in the room, etc. Chamber studies of textiles indicate that a 300–500 $\mu\text{g}/\text{g}$ fabric level would have air emissions less than the California Proposition “safe harbor” level of 40 $\mu\text{g}/\text{day}$ per textile.

The health risk of high fabric levels is dermatitis; high airborne levels can cause respiratory health problems. The CPSC in the 1980s considered urea formaldehyde foam insulation (UFFI) to be a hazardous product and took actions under the FHSA against its use. The CPSC Report, “An Update on Formaldehyde, 1997 Revision” indicates: p.3 “. . . Formaldehyde is one of several gases present indoors that may cause illnesses. Many of these gases, as well as colds and flu, cause similar symptoms.” To reduce levels of formaldehyde from pressed wood products, mandatory formaldehyde standards for emissions from pressed wood products have been promulgated and proposed [CA Air Resources Board an airborne toxic control measure (ATCM) to reduce formaldehyde emissions from composite wood products and from finished goods that contain composite wood products (17 CA Code of Regulations, sections 93120–93120.12) passed 4/07 effective 1/1/09; U.S. EPA, ANPR, “Formaldehyde Emissions from Pressed Wood Products”, 73 FR 73620, 12/3/08].

In the 1980s CPSC determined that no standard was needed for fabric levels or textile product emissions of formaldehyde for textiles and apparel. CPSC extensively studied formaldehyde and textiles in the 1980s at the Oak Ridge National Laboratory, Research Triangle Institute, and elsewhere (see data below). After numerous studies, it was concluded that formaldehyde levels in textiles and formaldehyde emissions from textiles were so low that they do not pose an acute or chronic health hazard for consumers, *i.e.*, that clothing/apparel does not present an unreasonable risk to consumers from formaldehyde.

According to chamber tests and other studies on a wide range of textiles/apparel products before and after washing that had been treated with formaldehyde containing chemicals/adducts, the air emissions levels of formaldehyde gas from textiles and apparel were below the level of concern. Further, it was concluded that formaldehyde emissions from textiles and apparel do not require a warning label under California Proposition 65 or by EPA, because test data have shown that their emissions are below the level of concern (<40 $\mu\text{g}/\text{day}$ per textile).

3. *Dyeing and Finishing of Textiles—where formaldehyde containing chemicals/adducts are used*

Textile fibers can be natural or manufactured. Natural fibers are cellulose vegetable fibers (bast, leaf, seed hairs) such as cotton or linen or protein animal fiber such as wool or silk. Manufactured fiber such as rayon and acetate are cellulose polymers; synthetic polymer fibers include nylon, polyester, polypropylene, and spandex.

Textiles go through many processes to produce a dyed and finished commercial textile. As many as twenty or more finishing treatment can be used (see WD Schindler and PJ Hauser, 2004. *Chemical finishing of textiles*, Woodhead Publishing, Ltd). Some textile finishing processes use formaldehyde containing chemicals/adducts—for easy-care/durable press/wrinkle resistance for sheeting, shirting, dress goods, knits, and slacks; for textile pigment dyeing for a small number of sheets and for pigment printing; and for flame retardance for very little if any children’s sleepwear and protective work clothing.

Formaldehyde containing chemicals/adducts are used mainly on cotton and cotton blends and other cellulosic fabrics/textiles (see Appendix 5). Easy care/wrinkle resist cotton apparel accounts for 2 percent of the total apparel offerings at retail and for 13 percent of total cotton apparel purchased in 2008. The majority easy care cotton apparel is men’s apparel. There is almost no easy care children’s apparel and almost no children’ wear is treated with formaldehyde containing chemicals/adducts of any kind.

Formaldehyde containing chemicals/adduct finishes are not used on synthetic textiles such as fabrics/apparel/clothing made from nylon and polyester.

4. *Formaldehyde and Textiles*

Formaldehyde-releasing finishes provide crease resistance, dimensional stability, and flame retardance for textiles and can serve as binders in textile pigment printing and dyeing (Priha, 1995). Easy-care/durable press/wrinkle resistance finishing is one of the many finishing operations used to give finished textiles the quality and aesthetics that consumers demand. These finishes are generally applied to cellulose and cellulose blend fabrics—fabrics used for sheeting, shirting, dress goods, knits,

and slacks. The primary effects of these finishes on cellulosic fibers are reduction in swelling and shrinkage, improved wet and dry wrinkle recovery, smoothness of appearance after drying and retention of intentional creases and pleats. Commercially available apparel is not treated with formaldehyde directly to produce easy-care/durable press/wrinkle resistant textiles. Formaldehyde has not been shown to be a useful reagent to produce wrinkle resistant cotton (Priha, 1995). Methylolamide agents (N-methylol compounds, formaldehyde adducts of amides or amide-like nitrogenous compounds), which introduce ether cross-links between cellulose molecules of the cotton fiber, are the most widely used to produce wrinkle resistant cotton [see P. J. Wakelyn, N. R. Bertoniere, A. D. French, *et al.*, 2007. *Cotton Fiber Chemistry and Technology*. Series: International Fiber Science and Technology, CRC Press (Taylor and Francis Group), pp. 75–76].

Durable-press/wrinkle resistant resins or permanent-press resins containing small amounts of formaldehyde have been used on cotton and cotton/polyester blend fabrics since the mid-1920s to impart wrinkle resistance during wear and laundering. Priha (1995) indicated that formaldehyde-based resins, such as urea-formaldehyde (UF) resin, were once more commonly used for crease resistance treatment. However, better finishing agents with lower formaldehyde release have been developed and are what is currently used. Totally formaldehyde-free crosslinking agents are now available but they are expensive and do not perform as well (*e.g.*, can affect some dye shades).

There are a small amount of sheets where acrylic and acrylic-based binders that can contain traces of formaldehyde are used for pigment printing and dyeing. Very little if any halogen phosphorus flame retardants that contain formaldehyde are used on children's sleepwear and protective work clothing.

Some apparel that is treated with formaldehyde containing chemicals/adducts can potentially release trace amounts of formaldehyde, even though they are bonded to the fiber. If apparel, cotton and cotton blends and other cellulosic fabrics/textiles, are treated with formaldehyde-derived chemicals (*i.e.*, formaldehyde adducts of amides or amide-like nitrogenous compounds, acrylic binders or halogen phosphorus flame retardant compounds), the potential trace amount of formaldehyde that could be released should be far below levels that would cause irritation or any health effects or affect the environment.

It has been reported that the average formaldehyde level contained by textiles made in the USA is approximately 100–200 µg free formaldehyde/g as measured by the AATCC Method 112 sealed jar test (results using AATCC Method 112 are about 4 times higher than that measured using ISO 14184–1/Japanese Law 112 Method) (Scheman *et al.*, 1998). Modern innovations through the use of derivatives and scavengers and other low-emitting resin technology (Wakelyn, *et al.* 2007 cited above) keep the levels below 100–200 ppm (as measured by AATCC 112 Method). The AATCC 112 method has been the most common way for determining formaldehyde levels in fabrics in the U.S. but since textiles are international products ISO 14184–1 and the Japanese Law 112 Method are now being used more often.

Tests in New Zealand on Chinese textiles (see Appendix 4), which were conducted after incorrect stories reported high fabric formaldehyde levels, showed that “97 of 99 items had no detectable or very low levels of formaldehyde.” “Two items had above the acceptable level of 100 parts per million, but simple washing reduced formaldehyde to well below acceptable levels.”

It is easy to neutralize the formaldehyde with Clorox 2. It has been known for a long time that simple laundering with normal commercial detergents greatly reduces any formaldehyde or lowers to non-detectable levels.

Published scientific studies indicate that it is very rare for even highly sensitized individuals to have a reaction to formaldehyde fabric concentrations as low as 300 ppm [by AATCC Method 112] (Hatch and Maibach, 1995). And patch testing with formaldehyde, textile resins that can release formaldehyde, and formaldehyde-releasing preservatives lend support to the idea that the causal agent of allergic contact dermatitis due to wearing durable press fabrics may be the resin rather than formaldehyde that may be released.

—Hatch, K. L.; Maibach, H. I. (1995) Textile dermatitis: an update (I). Resins, additives and fibers. *Contact dermatitis*, 32:319–326.

—Priha, E. (1995) Are textile formaldehyde regulations reasonable? Experiences from the Finnish textile and clothing industries. *Regulatory toxicology and pharmacology*, 22:243–249.

—Scheman, A. J.; Carrol, P. A., Brown, K. H.; Osburn, A. H. (1998) Formaldehyde-related textile allergy: an update. *Contact dermatitis*, 38:332–336.

—*Clothing Dermatitis and Clothing-Related Skin Conditions*, August 2001, (<http://www.lni.wa.gov/Safety/Research/Dermatitis/files/clothing.pdf>).

5. *U.S. Government studies regarding formaldehyde and textiles*

Both the U.S. Consumer Product Safety Commission (CPSC) and the U.S. Environmental Protection Agency (EPA) have determined that no standard for fabric levels or product emissions is necessary for textiles and apparel.

CPSC extensively studied formaldehyde and textiles in the 1980s at the Oak Ridge National Laboratory, Research Triangle Institute, and elsewhere. After these studies, it was determined that formaldehyde fabric levels and formaldehyde emissions from textiles do not pose an acute or chronic health problem to consumers.

—Robins, J. D. and Norred, W. P., Bioavailability in Rabbits of Formaldehyde from Durable Press Textiles, Final Report on CPSC IAG 80–1397, USDA Toxicology and Biological Constituents Research Unit, Athens, GA, 1984.

—ORNLT/M–9790 ‘Formaldehyde Release from Durable-Press Apparel Textiles’ Final Project Report to CPSC Oct 1985 [TG Mathews, CR Daffron, ER Merchant] <http://www.ornl.gov/info/reports/1985/3445600564985.pdf>

—RTI ‘Percutaneous Penetration of Formaldehyde’ (July 1981–83) submitted in Jan 1984 to ATMI and FI by A R Jeffcoat, RTI [rhesus monkey study] [Any formaldehyde that was release did not show up in any organs of the animal. Dr Peter Pruess previously with CPSC and now with EPA was involved these studies.]

—CPSC Briefing Package on formaldehyde and textiles “Status Report on the Formaldehyde in Textiles Portion of Dyes and Finishes Project” [Sandra Eberle (to Peter Pruess and others), 1/3/84] p.4 Conclusions: ‘current evidence, although not conclusive, does not indicate that formaldehyde exposure from resin-treated textiles is likely to present a carcinogenic hazard.’

Formaldehyde emissions from textiles do not require a warning label under CA Proposition 65.

Much work was done by the textile and cotton industries when Prop 65 was first implemented in 1986. The textile and cotton industries resolved this issue with the CA Health and Welfare Agency in 1987 to 1992. Chamber and other studies were done with various textile products before and after washing. The state of CA indicated in a letter to the textile industry in 1988 that the state has no information that suggests that textiles pose a risk (Letter to W. A. Shaw, Textile Industry Coalition from Dr. S. A. Book, Science Advisor to the Secretary, California Health and Welfare Agency, Mar 22, 1988). The regulation of Proposition 65 is now under Office of Environmental Health Hazard Assessment (OEHHA), CA EPA. The concern in CA lately has been with emissions from wood products not textiles. As far as I am aware there has not been a bounty hunter suit in CA against apparel. No product has a “general exemption” but a product is not required to have warning labels and has no requirements under Prop 65 unless that product causes potential exposure above the “safe harbor limit” to any substance that is on the Prop 65 list. The key point is that the trace emissions of formaldehyde from an individual textile does not exceed the “safe harbor level” of 40µg/day for formaldehyde (gas) [<http://oehha.ca.gov/prop65/pdf/2009FebruaryStat.pdf>].

6. *Conclusion*

In view of all the studies over the last 30 years indicting that there is not a problem with U.S. textiles and regulations already in place concerning formaldehyde and textiles, no new regulations are necessary. There should be no action concerning formaldehyde and textiles unless the results of the GAO study required by the CPSIA clearly show that areas of concern still exist.

APPENDIX 1

Formaldehyde containing chemicals used in textile and apparel dyeing and finishing are regulated by U.S. CPSC and other U.S. regulatory agencies.

- CPSC has the authority to regulate formaldehyde under the *Federal Hazardous Substances Act* (15 U.S. Code 1261–1278). CPSC already has authority to regulate substances/chemicals or mixtures of substances on textiles that may cause substantial personal injury or illness during any customary or reasonably foreseeable handling or use and has a regulation [under “strong sensitizer” in section 2(k) of the Act, 16 CFR 1500.13(d) (repeated in 1500.3(b)(9))]. CPSC has banned chemicals in the past under the FHSA and investigated formaldehyde, flame retardants, dyes, and other chemicals used in preparation, dyeing, and finishing of textiles.
- EPA under the *Toxic Substances Control Act* (TSCA) has authority over all chemicals in commerce and can set restrictions or ban chemicals. They currently have a significant new use rule that covers any flame retardants as well

as any textile chemicals. EPA also can regulate emission levels from products but is not concerned with formaldehyde emissions from textiles and apparel.

- OSHA has the authority to regulate exposures of formaldehyde within a workplace (29 CFR 1910.1048). The OSHA workplace level is 0.75 ppm (8 hr TWA). Also products containing > 0.1 percent formaldehyde and “materials capable of releasing formaldehyde into the air, under foreseeable conditions of use at concentrations reaching or exceeding 0.1 ppm are subject to regulation including labeling, worker training and MSDS’s.
- California Proposition 65 [the Safe Drinking Water and Toxic Enforcement Act of 1986] requires labeling for chemicals known to the state of California to be carcinogens or reproductive toxins that cause exposures of significant risk. Product emissions of formaldehyde gas from textiles and apparel do not require labeling under California Proposition 65, because tests have shown that their emissions are below the level of concern, *i.e.*, the “safe harbor level” for formaldehyde that does require labeling is <40 µg/day per textile. 40 µg/day per textile is negligible compared to natural background levels.
- There are also *national and international voluntary standards* (*e.g.*, American Association of Textile Chemists and Colorists [AATCC], the American Society for Testing and Materials [ASTM], and International Organization Standards [ISO]) that are used in the textile industry. In addition, the American Apparel & Footwear Association [AAFA] publishes a Restricted Substances List (RSL) that many companies are using in addition to their own RSLs.
- There are also *eco-labeling standards*, *e.g.*, the EU Ecolabel for Textiles, Öeko-Tex Standard 100 and sustainability standards (*e.g.*, NSF-336) for textiles are being developed by the American National Standards Institute (ANSI).

APPENDIX 2

International standards, company requirements, voluntary labels

There are governmental restrictions, company requirements (*e.g.*, Levi Strauss, Marks and Spencer) and several labels (*e.g.*, EU Ecolabel, Oeko-Tex Standard 100) that set limits for free or easily freed formaldehyde in textiles. The European ecolabel for textiles [EU (2002), Ecolabel for Textiles, <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:133:0029:0041:EN:PDF>] has a limit of 300 ppm formaldehyde (by ISO-14186-1/Japanese Law 112 Method). Finished fabrics for adult clothing and other skin contact textiles may be labeled and called low formaldehyde finished according to Oeko-Tex Standard 100 when their free formaldehyde content is lower than 75 ppm (Japan Law 112 Method).

Eight countries in the world have formaldehyde requirements for textiles ranging from 1500 ppm (in Germany) to 75 ppm (in Japan measured by the Japanese Law 112 Method) for textiles that contact the skin. The other countries are 100–120 ppm (measured by the Japanese Law 112 Method/ ISO 14184-1). Discussion in the “*Proposed Government Product Safety Policy Statement on Acceptable Limits of Formaldehyde in Clothing and other Textiles*” by the New Zealand government [<http://www.consumeraffairs.govt.nz/policyresearch/product-safety-law/proposed-statement/proposed-policy-statement.pdf>] gives a summary of International formaldehyde limits in clothing and other textiles (p. 3). International regulatory limits show a diverse spread. Japan has the most stringent limits for clothing in direct contact with the skin, 75 ppm. The section on Test Method on p. 5 first paragraph states: Below 20 ppm the result is reported as “not detectable”. This is for the proposed acceptable testing method, ISO 14184-1, which is essentially the same as Japan Law 112 Method. Oeko-Tex 100 defines measured values <20 ppm on the substrate according to Japan Law 112 Method as non detectable. In the AATCC Method 112 the margin of error or the “zero” level in low-level samples is 75 ppm.

APPENDIX 3

Measuring the amount of formaldehyde in textiles

There are currently two generally accepted methods of measuring formaldehyde in textiles. The method used needs to be specified. It is important an acceptable testing method be used. It is the only way that meaningful data can be obtained.

- AATCC Method 112 (“sealed jar test”)—Free and releasable/hydrolysable formaldehyde may be captured by this procedure. The test specimen is suspended over an aqueous solution in a sealed jar at a given temperature for a specific time. Formaldehyde gas given off is absorbed in to the aqueous solution; form-

aldehyde in the solution is derivatized and the color of the resulting complex is measured with a visible spectrophotometer. Formaldehyde amount is expressed as micrograms of formaldehyde per gram of fabric ($\mu\text{g/g}$ or ppm). The margin for error or the “zero” level in low-level samples is about 75 ppm. This has been the predominant method used by the U.S. Textile Industry.

—AATCC Technical Manual, Test Method 112

- ISO-14184-1 and Japanese Law 112 Method [The ISO and the Japanese methods are essentially the same and give the same results]—Free formaldehyde is measured and probably only a small amount of releasable/hydolizable formaldehyde is measured. The formaldehyde is extracted from the specimen into water, the formaldehyde is derivatized and measured with a visible spectrophotometer as above. The limit of detection for both methods or “zero” level is 20 $\mu\text{g/g}$ or ppm. The ISO Standards for testing formaldehyde provide internationally agreed methods of testing.

—ISO 14184-1:1998 Textiles—*Determination of formaldehyde—Part 1: Free and hydrolized formaldehyde (water extraction method)*

—ISO 14184-2:1998 Textiles—*Determination of formaldehyde—Part 2: Released formaldehyde (vapour absorption method)*

—*Law for the Control of Household Products Containing Harmful Substances (Japanese Law 112) and Japanese Industrial standard (JIS) L 1041*

- An AATCC Method 112 reading of 300 ppm (meeting most U.S. retailer requirements) may give a ISO-14184-1/Japanese Method 112 value of 75 ppm—an exact correlation between the two methods is not possible. Other methods for measuring formaldehyde on fabrics have described but how they correlate with the ISO-14184-1/Japanese Law 112 Method or the AATCC 112 Method is not published.

APPENDIX 4

New Zealand testing in 2007 on Chinese clothes

http://times.busytrade.com/489/1/Chinese_Clothes_Gain_Good_Comment_From_New_Zealand.html

Chinese Clothes Gain Good Comment From New Zealand

From.fibre2fashion—(October 23, 2007)

Chinese clothes gained good comment from New Zealand for its high safety index, which has much to do with the Chinese government’s Longtime effort on improving product quality. On October 17, the New Zealand Ministry of Consumer Affairs posted on its website the result of the formaldehyde test it conducted on 99 items of Chinese clothes.

According to the Ministry, among the 99 items, 97 did not contain or contained formaldehyde lower than the country’s standard, and the two items that contained formaldehyde higher than the standard could lower its formaldehyde content through simple cleaning. The test result of New Zealand authority showed that Chinese clothes were safe.

We noticed the wide publicity of high formaldehyde content in Chinese clothes on New Zealand media since August this year. The test that New Zealand government conducted and the result it released proved that Chinese products were safe. China appreciated the objective attitude of New Zealand in handling this issue.

Chinese government attached great importance to product quality and safety. A series of recent measures to tighten quality control and food safety control would significantly improve the quality and reputation of Chinese products.

According to the China Customs, China exported about 290 million U.S. dollars worth of clothes to New Zealand, accounting for 70.5 percent of its apparel market. In the formaldehyde test that New Zealand conducted this time, Chinese exports made up 84 percent of the tested clothes. Ministry of Commerce of the People’s Republic of China (MOFCOM) . . .

http://www.fibre2fashion.com/news/textile-news/newsdetails.aspx?news_id=42744

New Zealand: Formaldehyde tests show no health issue in clothes

October 18, 2007

Test results released show little cause for concern about levels of formaldehyde in clothing and textiles on sale in New Zealand.

“In response to concerns raised by television programme Target, the Ministry of Consumer Affairs tested 99 items of clothing and manchester,” says Consumer Affairs Minister Judith Tizard.

“97 of 99 items had no detectable or very low levels of formaldehyde.” “Two items had above the acceptable level of 100 parts per million, but simple washing reduced formaldehyde to well below acceptable levels.”

Twenty parts per million is accepted internationally as the zero mark under which formaldehyde in fabric is not detectable.

Ms Tizard says the Ministry used the correct method of testing and its results were robust and credible. “Target used the wrong testing method, which is why their results were so dramatically different.”

“In line with international best practice for testing clothing, the Ministry tested for free formaldehyde only. Target tested for combined free and bound formaldehyde. They then compared this with international standards for free formaldehyde.”

“It was like testing apples and oranges against a standard for apples only.”

The government is to issue a product safety policy statement setting acceptable levels of formaldehyde in clothing, a move that will provide greater certainty for New Zealand consumers.

“We are consulting on the appropriate levels, but expect they will be similar to those used as benchmarks in the Ministry’s testing, which were based on levels used by overseas regulators.”

Submissions on the proposed policy statement are due by 26 November.

The Ministry of Consumer Affairs have been working closely with the Australian Competition and Consumer Commission, who are today also announcing a consistent approach to acceptable levels of formaldehyde in clothing.

New Zealand Ministry of Consumer Affairs

APPENDIX 5

Easy care market information 1) what is offered at retail, 2) what the consumer is buying.

1. Retail Offerings

Apparel

- Easy care cotton apparel accounts for 2 percent of the total apparel offerings at retail.
- The majority (97 percent) of easy care cotton apparel is men’s apparel.

Easy Care Apparel Categories

Category	Share of Products with Easy Care
Total Men’s Apparel	4%
Men’s Dress Shirts	9%
Men’s Casual Pants	14%
Men’s Other Pants	15%

Home Textiles

- Easy care cotton apparel accounts for 1 percent of the total home textile offerings at retail.

Category	Share of Products with Easy Care
Bedding	1%
Sheeting	3%

Source: Cotton Incorporated’s Retail Monitor™ is a quarterly survey of apparel products at 26 major U.S. retailers. Information is collected in the store and online. In first quarter 2009, data were collected from 42,564 apparel products. The home textiles data is from the 2009 Home Textiles Audit. Data were collected from over 25,000 products from nine retailers from four different retail channels—mass, chain, specialty and department.

2. Consumer Purchases

- Easy care cotton apparel accounted for 13 percent of total cotton apparel purchased in 2008.

- The majority (66 percent) of easy care cotton apparel purchased was men's apparel.

Easy Care Apparel Categories

Category	Share of Purchases with Easy Care
Total Men's Apparel	20%
Men's Dress Shirts	39%
Men's Casual Pants	25%
Men's Other Pants	45%

Source: The consumer purchase data is from NPD Fashionworld's AccuPanel, a panel of 12,000 consumers who report their apparel purchases on a monthly basis; therefore, the data are based on purchases from all retail channels including mass merchants, national chains, department stores, specialty stores, off-price, factory outlets, warehouse, Internet, etc. . . . The figures are projected to be representative of the U.S. population for consumers ages 13 and older—so this does not include children's apparel.

Senator PRYOR. Thank you. Let me go ahead and jump in with a few questions. Dr. Wakelyn, and you gave us some percentages and what I would like to know is about what percentage of the textiles in apparel currently sold in the United States contain formaldehyde? About what percentage?

Dr. WAKELYN. Offered at retail—this is the latest data from Cotton Incorporated's lifestyle monitoring and studies, and they—because their major business is cotton, they do detailed studies every year on availability. What's offered at retail, only 2 percent of the products contain any wrinkle-resist finishes. Everything else is just trace amounts that are used.

Senator PRYOR. All right, let—

Dr. WAKELYN. Then it—then, also what was sold at the marketplace, the cotton that was sold, 13 percent of that contained wrinkle—but, most all of this is adult menswear. That is the major market. They've tried to get into womenswear to a larger extent, and haven't been as successful. It's really not used in children's products to speak of.

Senator PRYOR. OK. Well, let me ask this. You mentioned it's used for wrinkle resistance. Are there other chemicals available to do wrinkle-resistance fabrics?

Dr. WAKELYN. The science behind this—and this is something that I might mention, that I participated with, and was involved in, consulting and on task force at the U.S. Department of Agriculture and also with Cotton Incorporated, on all the work that they did in the 1970s, early 1980s, with formaldehyde in textiles that led to the low-emitting resin technology, and that's what is used. Dr. Brookstein mentioned several of these in his testimony—the low and very low that he mentioned are the only things that are used in the United States. As a result, I also wanted to mention that, in 2007, I was the lead author of a book, with researchers at U.S. Department of Agriculture, on cotton fiber chemistry and technology, and it contains a lot of the chemistry involved with this low-emitting resin technology—

Senator PRYOR. But—

Dr. WAKELYN.—the scavengers and the systems, to keep these very low levels.

Senator PRYOR. But, are there other chemicals available to do wrinkle-resistant—

Dr. WAKELYN. There are—

Senator PRYOR.—fabrics?

Dr. WAKELYN. They have done a good bit of research at USDA on formaldehyde-free finishes, and some of these are very good, but they are expensive, for one thing, and they can affect the dyeing. So, there are some limits in how you can use these particular products or textiles.

Senator PRYOR. OK.

Dr. WAKELYN. Again, remember, the textile situation, where you're talking about the amount of—small amount of formaldehyde that can be measured on the surface is different from formaldehyde gas in the environment.

Senator PRYOR. OK.

Dr. Wakelyn, let me ask this—you mentioned formaldehyde is not used in children's clothes. Is that—

Dr. WAKELYN. Formaldehyde-containing resins are essentially not used. The children's market in wrinkle-resist is almost zero. The children's market with regard to children's sleepwear, those types of products are not used. And the way it's used—only in a small amount of sheeting for dye printing and pigment dyeing, they use these materials.

Senator PRYOR. And—

Dr. WAKELYN. Those are the overwhelmingly vast majority—all—almost all the uses of formaldehyde in textiles in the United States currently.

Senator PRYOR. Now, when you say that, are you referring to just U.S. manufacturers or are you referring to everything in the U.S. marketplace?

Dr. WAKELYN. Things in the U.S. marketplace.

Senator PRYOR. OK. And have the domestically based textile companies—you know, the folks that actually make the domestically-produced textiles here—are they self-regulating in any way?

Dr. WAKELYN. Since the middle of 1980s, when Levi Strauss set levels for their customers, between the customer and the textile mill, all of the—several times in the 1980s and 1990s, a lot of work was done. There was a publication that I referenced from 1998 saying that the level in the United States is somewhere between 100 and 200 micrograms per gram. And that is on the AATCC test. That's the American Association of Textile Chemists and Colorists. That number is actually four times higher than the international standard of the ISO or the Japanese that all of these are based on. So, the real level in U.S. textiles as of 1998, which was the same as it was in the late 1980s, and with the modern technology they're using, is probably somewhere no more than about 50 to 75 micrograms per gram on the fabric.

Senator PRYOR. Dr. Etzel and Dr. Brookstein, let me ask, based on your experience and scientific research—give us a sense of about how many formaldehyde-related complaints there are per year? How many people come in and report symptoms, et cetera? Could you give us a sense of that?

Dr. BROOKSTEIN. The medical, you do it.

Dr. ETZEL. That's a very difficult question, Mr. Chairman, because the kinds of symptoms that we've described that occur from formaldehyde can also occur from many other chemical residues. And so, it's almost impossible for an individual pediatrician or

adult physician to identify the specific cause, unless someone comes in with a product that they think has injured them. And so, it's very difficult to actually get the kinds of numbers you're asking about.

Senator WICKER. Well, thank you very much. Well, Dr. Wakelyn—

Dr. BROOKSTEIN. Can I—

Senator WICKER. Oh, I'm sorry.

Dr. BROOKSTEIN. There was this question that—while I'm not talking about the medical, I will tell you this. We did some preliminary work at the University, where we looked at children's wear, we looked at children's khaki pants and we looked at children's dress shirts. These are not infants, but they were certainly children. And we found 3 out of 11 pairs—we found, in almost all of the clothing, there was formaldehyde, but there was only perceptible formaldehyde in 3 out of 11. And, to me, that's significant. In the shirts, it was 1 out of 10, we found. Now, this was a small random test. And one of the things that we propose that the GAO does is do a much more extensive test so we can actually have a body of knowledge that we can make determination on. But, we did find formaldehyde in children's clothing in our testing.

Dr. WAKELYN. I would like to respond to that question, also, and particularly respond to what Dr. Brookstein said. To be able to say that you detected—formaldehyde is a—in the atmosphere all the time. Textiles act as a sink. You mentioned that carpets contain it. No, they don't. They are not treated with it, but they can pick up as a sink.

OK. He said 3 out of 11, 1 out of 10. What he's—has he measured that using the standard methods? There are two standard methods that are recognized in the world on how you measure this. And if you don't use those particular measurements, the—your data has, really, no meaning, because the handheld instrument, some of these other things, have not been correlated with that.

And, oh, by the way, the zero level or nondetect level in the Japanese or the ISO's test is under 20 parts per million, micrograms per gram. That is because of the uncertainties in the test. In the U.S., it's 75 or 80 in the AATCC test. So, just because somebody says they detect it, that doesn't mean to say that it's there in any quantity or that it's not considered a zero level or that it's at a level that's going to cause any concern. It creates an improper perception if you say, "Oh, well, I've detected it there, so therefore it has to be a problem." Most of the time, when people are exposed to and get some type of textile irritation, a lot of times, the dermatologist will say, "Oh, it has to be formaldehyde." Many of these products don't even contain formaldehyde, were not treated with formaldehyde, and the person isn't even allergic to formaldehyde.

Senator WICKER. Thank you.

Dr. Wakelyn, is it likely that you or the other two panelists brought any formaldehyde into the room today? Are you wearing any formaldehyde?

Dr. WAKELYN. I would think most of the men in this room have easy-care, wrinkle-resist shirts on and have been wearing them for years. These have been in the marketplace, certainly the more

modern ones, for the last 25 years. Ask them if any of the people in the room have had any problems wearing those shirts.

Senator WICKER. Dr. Brookstein has raised his hand.

Dr. BROOKSTEIN. Yes. Mr. Wicker, I bought this new shirt yesterday for this hearing. It is permanent press, and I plan on testing it tomorrow in our laboratory. Unfortunately, I couldn't test it prior to today, but I will be testing it tomorrow.

Senator WICKER. OK.

Dr. BROOKSTEIN. Using Japanese 112, a standardly—a standard approved testing method, which we did all our testing with.

Senator WICKER. Dr. Wakelyn, is that a test—

Dr. WAKELYN. Yes, that—

Senator WICKER.—that you have confidence in?

Dr. WAKELYN. The Japanese test and the ISO 14184–1, are the standard testing that are used, and that's what these are based on.

Senator WICKER. OK. Well, Dr. Wakelyn, you mentioned the test in the 1980s at Oak Ridge, extensive studies of formaldehyde and textiles. Do you know if the tests brought us a unanimous result from those scientists? Was there a minority view offered? And what are the chances that under 2009 and 2010 standards or at the current level of knowledge, there might be a different result?

Dr. WAKELYN. Well, those—

Senator WICKER. There are two questions there.

Dr. WAKELYN. Those tests, both for primate tests—and with rabbits, were done on the skin. I doubt that there would be any difference in the results of those today. They were extremely extensive studies.

The Consumer Product Safety Commission has been a bit maligned by some of the testimony here today, too, as though they don't do anything and haven't done anything. They have been extremely well respected. Their health sciences department has done tremendous work in this area, and contributed in that area, and they continually look at some of these things, when things are raised. They were involved in these studies. And, in fact, the person that was at CPSC at that time that was done was in charge of many of these studies, or was certainly involved in them, is Peter Pruess, who's head of the formaldehyde work at EPA presently.

So, no, I think that they were—they used the technology that was available at that time, but I think that the results would be the same.

Senator WICKER. Well, do you know if there was a minority review—

Dr. WAKELYN. There wouldn't be.

Senator WICKER.—minority—

Dr. WAKELYN. I don't think there would be, no. These are published reports, and they're published in the refereed journal publications. I've listed four of them in here, and I'll be happy to provide them to the Committee—

Senator WICKER. Please—

Dr. WAKELYN.—if they so desire.

Senator WICKER. Please do that.

[The information referred to follows:]

1. Robins, J. D. And Norred, W. P., Bioavailability in Rabbits of Formaldehyde from Durable Press Textiles, Final Report on CPSC IAG 80-1397, USDA Toxicology and Biological Constituents Research Unit, Athens, GA, 1984.

2. ORNL/TM-9790 "Formaldehyde Release from Durable-Press Apparel Textiles" Final Project Report to CPSC Oct 1985.

[TG Mathews, CR Daffron, ER Merchant] <http://www.ornl.gov/info/reports/1985/3445600564985.pdf>.

3. RTI "Percutaneous Penetration of Formaldehyde" (July 1981-83) submitted in Jan 1984 to ATMI and FI by A. R. Jeffcoat, RTI [rhesus monkey study] [Any formaldehyde that was released did not show up in any organs of the animal. Dr. Peter Pruess previously with CPSC and now with EPA was involved these studies.]

4. CPSC Briefing Package on formaldehyde and textiles "Status Report on the Formaldehyde in Textiles Portion of Dyes and Finishes Project" [Sandra Eberle (to Peter Pruess and others), 1/3/84].

Studies 1, 3, and 4 are retained in Committee files. Study 2 can be found at the link mentioned above.

Senator WICKER. Now, I believe the chart belongs to Dr. Brookstein, is that correct?

Dr. BROOKSTEIN. Yes, sir.

Senator WICKER. Well, Dr. Wakelyn, let me ask you, then, about these other countries. Finland, Norway, the Netherlands, Germany, have set standards for fabric, beyond what we set in the United States. And then, with regard to wood and textiles, we can add Japan, China, Russia, Lithuania, New Zealand, and South Korea. Why do you think they did that? Do you think that was based on scientific overkill? Or you—have you looked at scientific results—

Dr. WAKELYN. Well—

Senator WICKER.—from any of those countries?

Dr. WAKELYN. Let me say this, to begin with. If you'll look at the numbers there, they range from 1,500 parts per million, which would be the—Austria and Germany, which are very severe litigious countries, down to much, much lower levels. One reason why the Japanese levels have been very low, and have been very low for years, is, people have looked at that as a nontariff trade barrier. They require people bringing things into Japan to have higher levels—I mean, to have lower levels than what they produce in their own country. They don't really test their own products. So, you see a great variation of what is in here; and particularly with regard to infants, they want a nondetectable level, and most, as I say, infant clothes in the United States are not treated with formaldehyde of any kind. And if you make a measurement, it does not exceed what's considered a zero or nondetect level.

No, these countries have decided that they need some kind of standard in place. We do have—under CPSC sensitization, we do have, under various agencies, wood products—pressed-wood products, that is—although there's very good technology out now to produce wood products that don't exceed the HUD level or the California level. There are all kinds of other products, besides textiles, but textiles have been thoroughly looked at, at CPSC in the late 1980s. Now, they can take a relook at all of that information and relook at what's in the published literature, but there has not been—there has not been a valid complaint against formaldehyde in textiles in the United States.

Senator WICKER. OK. Well, thank you very much. And one final question, the Chair has agreed to indulge me.

Dr. Brookstein, on page 8 of your testimony, there's a very troubling picture of a patient exposed by dimethylfumarate—

Dr. BROOKSTEIN. Fumarate.

Senator WICKER.—fumarate. I thought I did pretty well on that. [Laughter.]

Senator WICKER. Dimethylfumarate.

Dr. BROOKSTEIN. Got it close.

Senator WICKER. That's not formaldehyde, is it?

Dr. BROOKSTEIN. No. It's not formaldehyde. But, I took the privilege of putting this in there. This is a serious problem that's occurring in Europe right now. It's starting to break—it had broken out a little bit in—no pun intended—

Senator WICKER. Yes, right.

[Laughter.]

Dr. BROOKSTEIN.—in Canada. These were—this is an example of a patient that was exposed to something that was inserted—a preservative in foam for sofas, and it took a while for the dermatologists in Scandinavian countries to realize what was going on. And I've been working with a—the physician over there in Finland, and I wanted the Committee to see this, because this is an example of what happens when you don't do the science and don't check things out. Now, this is not formaldehyde. I make it very clear. But—in my written testimony—I wanted this picture for you all to see.

Senator WICKER. Right. And when—and I appreciate you doing that. It—you mentioned in the—on the first page of your testimony, TRIS—

Dr. BROOKSTEIN. Yes.

Senator WICKER.—which was an attempt by consumer advocates to help the situation by preventing fire-related deaths and fire-related injuries among infants. It turns out that, in fact, we were doing harm—we were doing more harm than good, and TRIS was summarily removed from the market.

I assume that dimethylfumarate was considered to be a beneficial product and make sofas better and perhaps—

Dr. BROOKSTEIN. To my—

Senator WICKER.—cut down on—

Dr. BROOKSTEIN.—to my understanding, it was to protect against mold. You mentioned, though—

Senator WICKER.—cut down on something you don't want. Mold. It turns out—

Dr. BROOKSTEIN. Well, in shipping, yes. In shipping.

Senator WICKER. Right.

Dr. BROOKSTEIN. You mentioned the TRIS. There's another concern I have about children's car seats, that they're putting brominated flame retardants on them that are clearly neurotoxins, things like that. There are no regulations associated with that. We—I've done some testing on this. We've done—we've put a lot of this material on children's car seats to make them flame retardant, and I don't see where that's necessary, and you're exposing children to really dangerous items.

Senator WICKER. Thank you. Well, let me just say that I share your concern, and I have a long history of trying to work with the CPSC on this issue. Let's protect consumers from a variety of hazards, including toxins, including fire injuries and fire death, but

let's don't, in the name of protecting against fire, cause another hazard that we have to deal with.

So, thank you very much for your testimony.

Dr. WAKELYN. I'd like to—

Senator WICKER. Thank you, Mr. Chairman, for your indulgence.

Dr. WAKELYN.—respond. Can I respond to that, please?

The TRIS situation was something that was only used on synthetic fibers to prevent melt drip, and it was removed from the test, so it's—it was banned and no longer used, but it was never used on cotton and cellulosic materials.

The fire retardants that he says there are no regulations, there are actually several States in the United States and also the penta and octa version of those are not manufactured anymore, and EPA has reviewed them. The deca version is not really used in the United States in these products, and some of these other brominated fire-retardants that are used in backcoatings probably will not be used in the United States. There are various States that have already banned them, and because they're banned in certain States, the manufacturers, at least in the United States, are not going to sell them here, and in Europe they're still under review, whether they really cause problems or not, and whether they break down. But, some of these things are not being used anywhere. So, to suggest that they're being used, and he finds bromine on a particular compound, doesn't mean anything.

Now, this hearing doesn't deal with flame retardants and flammability, but—and that should be part of another hearing—but, we need to have accurate information presented if we're going to talk about some of these issues.

Senator PRYOR. Senator Casey?

Senator CASEY. Mr. Chairman, thank you again for calling this hearing. And I want to thank each of the witnesses before us today.

I wanted to start with Dr. Etzel and to establish, for the record, just a little bit about your background. You're a board-certified pediatrician, is that correct?

Dr. ETZEL. I am board certified in two specialties, pediatrics as well as preventive medicine.

Senator CASEY. Both. And also, you have a Ph.D. in epidemiology, is that correct?

Dr. ETZEL. That's correct.

Senator CASEY. And I was struck by the beginning of your testimony in the middle of page 3, where you say, in part—and this is in the first full paragraph, and I'm quoting your testimony—"Children may be more susceptible than adults to the respiratory effects of formaldehyde. Even at fairly low concentrations, formaldehyde can produce a rapid onset of nose and throat irritation, causing cough, chest pain, shortness of breath, and wheezing." And then you say, in the next sentence, "At higher levels of exposure, can cause significant inflammation of the lower respiratory tract, and—which may result in swelling of the throat, inflammation of the windpipe, and bronchial" and it goes on from there.

I wanted to have you talk about that for a moment, because there's some conflict here in our testimony. We've heard Dr. Wakelyn. And I think we'd all agree on one thing, that we can set aside discussion about the effects on adults, for purposes of this

point I'm making, but I think we're most concerned about the impact this can have on children. And I'd ask you to talk about that.

Dr. ETZEL. Yes, thank you for that question. A lot of people, in the past, used to consider children as just miniature adults, but we pediatricians have tried to educate the public that, in fact, children are not miniature adults and that they breathe more, pound per pound, than an adult would. And their risks are higher, because of their developmental stage. We know that, at very low levels of exposure to formaldehyde in the air, levels of .016 parts per million, they can cough and have respiratory irritation, and as low as .05 parts per million they can develop asthma. And these are rates that actually are quite low, and rates that children could routinely be experiencing in the indoor environment.

Senator CASEY. And I know that also in your testimony, starting on page 5, you set forth a series of recommendations. The first recommendation is that the Consumer Product Safety Commission should limit formaldehyde residues in children's clothing and other products, which I think is important to repeat for the record, and that more research is needed on formaldehyde and children's health. And then you go on to set forth two other recommendations: that EPA should adopt California's proposed restrictions on formaldehyde emissions from wood products, and then, finally, the Consumer Product Safety Commission should develop educational materials for consumers about formaldehyde.

I wanted to ask you about some of the references in the Committee materials, where there are a series of references to both—let me just get this; I have it here. Oh, here it is. If you can speak to the National Cancer Institute reporting that several studies indicate that embalmers and anatomist professionals who are potentially exposed to formaldehyde have increased risk of developing leukemia and brain cancer, juxtaposed to the general public. And also, the reference in several studies to the fact that this is a known carcinogen, if you can speak to either of those.

Dr. ETZEL. The levels of exposure for embalmers, for example, are extremely high, and it's well known that this is an occupational risk of being employed in the embalming industry. Based on data from occupational cohorts like this, in many other occupations, as well, the International Agency for Research on Cancer looked at updated data, prior to the data that Dr. Wakelyn talked about, and found that there was lots of evidence that humans exposed to these occupational levels of formaldehyde were at risk of developing cancer.

And based on this, we also know that there's probably no safe level of exposure to this occupational carcinogen. And because of that, we set more restrictions now, since the IARC came out with that, than we did prior.

Senator CASEY. I know—I'll get to your colleagues, maybe in a second round, but I know Senator Klobuchar is—

Dr. WAKELYN. Can I respond to some of that? Basically—

Senator CASEY. Why don't we do this—why don't we do it in the next round so we don't—

Dr. WAKELYN. Well, no, but I wanted to put on the record—

Senator CASEY.—interfere on—

Dr. WAKELYN.—what you were asking her about, respiratory diseases. That's an airborne exposure, that's not a surface treatment—

Senator CASEY. Right.

Dr. WAKELYN.—from a textile. It's an entirely different situation. I mean, you were suggesting that I had testified to certain things that you possibly didn't agree with, and that—

Senator CASEY. I wasn't suggesting anything about what you testified to, I was making reference to the testimony.

Dr. WAKELYN. But, if we're going to talk about the toxicology, IARC report is out, they have done this. National Cancer is doing a report now. So, if you want to get into toxicology, you need to get toxicologists here, and we certainly can give you further details on the toxicology if you would like answers to those questions.

Senator CASEY. Well, we'll go back to that when our time is—
Senator PRYOR. Senator Klobuchar?

**STATEMENT OF HON. AMY KLOBUCHAR,
U.S. SENATOR FROM MINNESOTA**

Senator KLOBUCHAR. Thank you so much, Mr. Chairman. Thank you for holding this hearing.

Thank you, Senator Casey, for appearing before our committee and helping to raise awareness of this issue.

I was very involved in the Consumer Product Safety Act, as was Senator Pryor, and I know that an amendment to that Act was championed by Senator Casey and Senator Clinton—to make sure that more research needs to be done on the long-term effects of formaldehyde exposure. I also know that the GAO should release a study next year on this.

Could all three of you say what the status of the studies here is? It seems that there's some major disagreement. I would think it would be helpful to get this study, as the CPSC really hasn't looked at this, from what I understand, for many years.

Dr. Brookstein?

Dr. BROOKSTEIN. Senator Klobuchar, I'm under the understanding, too, the study hasn't been started at all yet. And, you know, my whole thesis is, every country's looking at this, we're not. A study has been legislated, and it's not being done. And that's the bottom line. Let's not be afraid of what the information's going to be; let's get information and then we can make decisions based on good, firm, up-to-date science.

Senator KLOBUCHAR. Dr. Wakelyn?

Dr. WAKELYN. I agree with that, that the GAO study has not started, and I've checked on it very recently, but it will be starting soon. And CPSC will be working with the Government Accountability Office in doing this particular study.

And yes, I agree with Dr. Brookstein, that, rather than already assuming that there is a major problem that needs a regulation, as some people have testified to here, we should wait—we should await this particular study with regard to formaldehyde in textiles, which is what the study is—it's not about airborne levels and other effects—it's about formaldehyde in textiles, and whether there is a problem that is an unreasonable risk that requires either a fabric-level or an airborne-level standard from this. And I think that both

the Consumer Product Safety Commission, with their excellent staff—people may not like some of their commissioners, but they have never been critical of the technical staff that they have there, both in health sciences, which are very good, and they have done outstanding work over the years.

Senator KLOBUCHAR. Thank you. And I think one of the issues is, they need more commissioners. So.

Dr. Etzel?

Dr. WAKELYN. Oh, I'll agree with you, they need a—

Senator KLOBUCHAR. I'm glad. We're in so much—

Dr. WAKELYN.—third commissioner—

Senator KLOBUCHAR.—agreement, here. This is great.

[Laughter.]

Senator KLOBUCHAR. Dr. Etzel?

Dr. ETZEL. The American Academy of Pediatrics touched base yesterday with the individual at GAO who will be responsible for conducting the study. He's well aware that he needs to begin it, and plans to begin it soon. And we look forward to the results.

Senator KLOBUCHAR. And do you think, Dr. Etzel, just your perspective on this, that most pediatricians are aware of what you see as a risk from formaldehyde?

Dr. ETZEL. Most pediatricians are well aware of the risks of formaldehyde. What they aren't aware of is the fact that formaldehyde is in far more products than most people realize. And if pediatricians were aware of all these products, they would probably begin to tell their patients about it. But, the fact is that that is not common knowledge.

Senator KLOBUCHAR. Dr. Wakelyn, I was just listening—

Dr. WAKELYN. Yes.

Senator KLOBUCHAR.—to your testimony, and, as we've discussed here, Japan, Germany, France, and a number of other countries have adopted some different standards for clothing and textiles. What has been the impact of those standards on the industry as a whole?

Dr. WAKELYN. Well, some of these, you see, are extremely high, and just about every standard that's there, U.S. textiles currently meet. So, what it is, is they're—because various retailers, various companies, have been requiring these things for years, they're essentially meeting these standards if they're importing into those countries, and they have been for years. And what's coming into the United States, my understanding is, from the testing I've seen now, they're—you're correct, I haven't seen any detailed testing, maybe for 10 years in this area, but, if anything, the technology is better now than it was 10 years ago, and, at that time, they were very, very low levels.

Senator KLOBUCHAR. OK. And do you agree that the products coming in would meet—or, the products that we produce in our country would meet some of these standards? Do you have any—

Dr. BROOKSTEIN. I would like to say—

Senator KLOBUCHAR.—information that they wouldn't?

Dr. BROOKSTEIN. I would like to answer that, and it's also related to this question about airborne. We have someone in the room here today—Mr. Mark Burman—who testified at the U.S. House of Representatives about very high levels of formaldehyde that he found

in imported draperies. Now, I don't know if that vaporizes or not, but—

Senator KLOBUCHAR. No, I—and I was just trying to get at this one point, and I—

Dr. BROOKSTEIN. Well—

Senator KLOBUCHAR.—would love, if I had more time—

Dr. BROOKSTEIN. OK, all right.

Senator KLOBUCHAR.—to get into it, but I—just this point that we're producing textiles—and Dr. Wakelyn was saying that these standards in other countries, which was my question—

Dr. BROOKSTEIN. Well—

Senator KLOBUCHAR. Do our textiles meet those standards?

Dr. BROOKSTEIN. Most of the textiles that we wear and use in the United States they are not produced in the United States—overwhelmingly, over 90 percent are imported.

Senator KLOBUCHAR. OK.

Dr. BROOKSTEIN. OK?

Senator KLOBUCHAR. But, the ones that we do produce, do they meet those standards?

Dr. BROOKSTEIN. I don't know. That's part of—

Senator KLOBUCHAR.—know? Maybe we don't—

Dr. BROOKSTEIN. That's part of what we would like to study as part of the—

Senator KLOBUCHAR. And so, then your other concern is the ones coming in from foreign countries, and that we would have a standard. Is that—

Dr. BROOKSTEIN. That is my concern.

Senator KLOBUCHAR. OK.

Dr. WAKELYN. Let me—

Senator KLOBUCHAR. Dr. Wakelyn?

Dr. WAKELYN.—respond further. One of the things that was raised earlier is products from China, and that's why the toys and food and various things were raised issues and, "Oh, why didn't we raise this with regard to Chinese textiles?" And then, it was mentioned about the New Zealand television program. And, by the way, after the New—the country of New Zealand did their tests on 99 fabrics, the television station had to pay a \$4,000 fine, and the Government of New Zealand apologized to China. But, 84 percent of those fabrics were Chinese, and they found no problems with the Chinese fabrics.

So—and China has one of the lowest levels, as you can see, on this. So, you may have problems with other things from China; I'm not going to discuss that now. But, with regard to the testing that was done in 2007 and 2008 on almost 100 Chinese fabrics, there was not a problem.

Senator KLOBUCHAR. Well, we're looking forward to the GAO study and trying to get to the bottom of this so we do everything we can to protect kids. And I thank you all for your testimony.

Senator PRYOR. Thank you, Senator Klobuchar.

We're going to have a second round, here. For everybody's notice, the Senate is scheduled to have a vote, about noon, which is 16 or 17 minutes from now, so I'll ask a few questions and then I'll turn it over to Senator Wicker.

Let me ask this, if I may, of you, Dr. Wakelyn. Did the majority of companies that manufacture textiles, apparel, baby furniture, et cetera acknowledge that formaldehyde is a health risk?

Dr. WAKELYN. Oh, certainly. That's one reason why the levels are so low, and the levels are below level—that are known to cause any skin irritation. In fact, they're published—Maibach & Hatch, since the early/middle 1980s, have done tremendous amount of research, they've written I don't know how many review articles. They've written a book in the—around 2005 on—talking about allergic contact dermatitis with regard to textiles and all of this. And they point out—they point out several things, that the level is where, even a sensitized person or a sensitive person, an allergic person, does not have a problem at 300 micrograms per gram of fabric level. And that's on the AATCC test, so that would be about 75 ppm on this particular test here. OK?

Senator PRYOR. Let me interrupt there, because our time is short. You've said, a few times in the hearing, that this hearing is limited. This hearing is really not limited. The Consumer Product Safety Commission has a broad range of product types that they oversee, about 15,000 total, and we're not trying to limit this hearing to one category.

Earlier today, I asked you about whether there are other things that can be added to cotton fabrics that will make them wrinkle-free, and you said that there are some, they're more expensive, they have an issue with color, the dyes in the fabric. But, what about for the other uses of formaldehyde or—in products like furniture and other textiles, generally—are there replacement chemicals that we know are safe in other areas besides just clothing?

Dr. WAKELYN. Well, in furniture, it's not the textiles that are of any concern, it's the pressed-wood products. And the—I can't speak for the wood products industry, but I have been involved with some of them over the years, and the formaldehyde issue, and they have done a tremendous amount of work. There are resins that they can use. Senator Wicker mentioned some of the work that they were doing with soy proteins and other adhesives. And some of these show great promise.

You have to remember that the reason why the formaldehyde-containing resins are used in wood products, and that is that they serve a function that is difficult to replace. But—so, I can't really talk for the wood products, other than that I know there's a lot of research and a lot of good products.

With regard to textiles, this research continues, but the biggest research that was done, along with looking at nonformaldehyde-containing finishes, which were certain types of acids that are used—I don't want to get arcane on getting into the chemistry—but, a lot of things dealing with scavengers and after-treatments that keep the level very, very low, either well below—either non-detectable or at very low levels. And then, after a garment is—if you use Clorox 2, it's known to neutralize it. If, after a simple commercial wash, as the New Zealanders found, you've lowered it to almost a nondetect or a very low level that's below the level that is published that these things would cause a problem.

I also might say that it's not even sure that, in formaldehyde-containing resin treatments of textiles, that it's even the formalde-

hyde that's causing the problem, with various studies. And I have a paper in my—referenced in my testimony that discusses that.

Senator PRYOR. Right.

Senator WICKER?

Senator WICKER. Two quick things, I hope. Mr. Chairman, I ask unanimous consent that Dr. Brookstein be allowed to enter into the record the result of the test that he's going to conduct on his shirt.

[Laughter.]

Senator PRYOR. Without objection.

Dr. BROOKSTEIN. OK, that means I have to do it now.

[Laughter.]

Dr. BROOKSTEIN. I will get that to you.

[The information referred to follows:]

SCHOOL OF ENGINEERING & TEXTILES—PHILADELPHIA UNIVERSITY
Philadelphia, PA, May 19, 2009

Hon. ROGER WICKER,
U.S. Senate,
Washington, DC.

RE: REQUEST TO TEST FORMALDEHYDE LEVEL IN SHIRT I WORE AT U.S. SENATE
SUBCOMMITTEE HEARING ON CONSUMER PROTECTION, PRODUCT SAFETY AND
INSURANCE HEARING ON APRIL 28, 2009

Dear Senator Wicker;

During the hearing of the U.S. Senate Subcommittee on Consumer Protection, Product Safety and Insurance, on April 28, 2009, you asked me if I had tested the newly purchased, unwashed shirt that I was wearing that day. I responded in the negative and you then asked me to test it for formaldehyde content.

Responsive to the subject request I tested an exemplar shirt identical to the one I wore at the Senate Subcommittee hearing. Using our standard and internationally recognized laboratory procedure (EN ISO 14184-1) I found a level of 32 ppm of free formaldehyde in the shirt. The shirt was made from 100 percent cotton and was produced in China.

While I testified that the U.S. does not currently have allowable formaldehyde level for clothing and textiles, this value of 32 ppm is above what is considered the "detectable levels" in other countries.

Please feel free to contact me if you require additional information.

Sincerely,

DAVID BROOKSTEIN, Sc.D.,
Dean and Professor.

Senator WICKER. Great, thank you.

And it seems that the essence of the disagreement among these three witnesses is that Dr. Brookstein and Dr. Etzel believe more research is necessary, and Dr. Wakelyn's view is that valid, conclusive tests have already been done that have provided us with the information we need. So, let me just—this is my one question, to Dr. Etzel and Dr. Brookstein. Are you familiar with the CPSC and EPA tests at Oak Ridge in the 1980s? And why do you feel they're not conclusive or adequate?

Dr. ETZEL. I would say one of the issues is that many of the products that infants and children are exposed to today didn't even exist in the 1980s, and therefore couldn't be tested. We're talking about an array of different things, from baby shampoos to things that get applied to babies' skin to the kinds of apparel that their parents might wear that the baby would be exposed to by being on the dad's lap or on the dad's shoulder. So, circumstances have changed considerably since the 1980s, and to use data that's so outdated to make a decision about products today seems ill-advised.

Senator WICKER. Is that your view, Dr. Brookstein?

Dr. BROOKSTEIN. Yes. And there's a major difference in the market. In the 1980s, the vast majority of the clothing and the textile products that we used as consumers were made in the United States, and there were very strict environmental rules that prohibited the use of these materials. Today, the vast majority of what we wear and use as draperies and furniture is imported, so it's a totally different situation now.

We don't—we can't be sure what's coming in meets any kind of considered standards such as that, so it's a—it's a totally different marketplace.

I'm not questioning if the scientific evidence in the 1980s was good or bad. I'm sure it was very good. The question is—it's a different marketplace today. We distribute differently today. We get materials differently today. We have to look at these. And then, of course, there are different items, as Dr. Etzel has talked about.

Senator WICKER. And, Dr. Wakelyn, would—

Dr. WAKELYN. Yes, I would like to clarify what you said in my remarks. My remarks are dealing with formaldehyde in textiles. I do not think formaldehyde in the textiles that are sold in the United States present any sort of problem and are below levels of any kind of concern. But, I did—am not testifying on, because I have not looked at every consumer product out there, that a child can be exposed to. But, with regard to textiles and the textiles that children wear, I think that there's adequate—more than adequate data to—and I'm sure GAO will find that in their particular study—to say that there is not a problem that needs a standard with formaldehyde in textiles in the United States. But, any other consumer products, that I can't testify to.

Senator WICKER. Thank you very much.

Senator PRYOR. Senator Casey?

Senator CASEY. Thank you very much.

Dr. Brookstein, I wanted to go back to your recommendations, which are set forth on page 4 of your written statement. One that we haven't talked about, and I think it bears some attention, is number 4, your recommendation that a testing program be set up by an independent lab. Can you talk about that for a moment?

Dr. BROOKSTEIN. Yes, I can. In any issue, there are going to be many different stakeholders that are going to want to advance their particular thinking. And that's understandable. I think it's important that we have an organization that can look at this from an unbiased academic viewpoint and do what we call, in academics, good science, where there's no one looking over us with any kind of vested interest. We're there as scientists, just trying to get the facts and know what the data is—are.

Senator CASEY. In terms of the GAO study, obviously we want to have that done as soon as possible, and—I don't know if you're about to say something—

Dr. BROOKSTEIN. You know, when I go to the Port of Newark and I see those containers of materials coming in, and I go to the Port of Los Angeles and I see those containers coming in, I would like to know what's in those containers with regard to textiles, as soon as possible.

Senator CASEY. And Dr. Wakelyn, I know that, in your testimony, in the first paragraph, you say, in part, "There's no need"—

I'm quoting here—"There's no need for legislative or regulatory action concerning formaldehyde in textiles, unless the results of the GAO study indicate such action is necessary." Now, a moment ago, you said—I want to make sure I understand what you said—that you're limiting what I'll call a "no action" recommendation or point of view to formaldehyde, textiles, and children, or is it more expansive than that?

Dr. WAKELYN. It's formaldehyde in textiles. I do not think—and I agree with you that we need the GAO study, and we need it done right away, because there seems to be, I think, misunderstanding and confusion about nothing being done or the Consumer Product Safety Commission hasn't done its due diligence. They have many things on their plate, they have done much work in this area, they—you would be very impressed with their health scientists that they have there and the things they've turned out. So, yes, I think the GAO study absolutely needs to be done, and needs to be done quickly. But, my statements deal with just formaldehyde in textiles.

Senator CASEY. OK. Well, I think we can all agree on the need for the GAO study. We may not agree on the following. I don't understand why it's apparently such a big problem to have the GAO—or, to have the Consumer Product Safety Commission do at least one or more of the following:

Number one, update any research they've done in this area from the 1980s. We're talking more than 20 years ago, now, or right around 20 years ago.

Number two, it wouldn't have to be the Consumer Product Safety Commission—there are others, as well but issue some kind of guidance standards, even something that falls short of regulations. Why, as important as the GAO study is—and I've fought hard for this, and I believe it's important—but, why should we say that all those other studies since the 1980s which might conflict with or might raise questions about the GAO—or, the CPSC findings in the 1980s—why should all those other studies and press reports be completely dismissed and say, "We don't need to update from the 1980s, and we're just going to wait for a GAO study"? I don't understand why they can't do more. We're not asking them to do something which is unreasonable, we're just saying to the Consumer Product Safety Commission, "Don't wait for GAO; update your research, give some guidance, set forth some basic standards that might even not rise to the level of regulation." What do you say to that?

Dr. WAKELYN. Oh, no, I—they have a—for strong sensitizers, they have a standard under Federal Hazardous Substances Act. But, no, they—

Senator CASEY. Say that again. I didn't understand—

Dr. WAKELYN.—update—under the Federal Hazardous Substances—

Senator CASEY. Right.

Dr. WAKELYN.—Act, they have, for strong sensitizers, and they—under the Federal Hazardous Substances Act, they did ban urea-formaldehyde insulation, because they thought that was a problem back in the 1980s.

Now, they could update these studies. These studies are rather expensive, and if the Senate or Congress, in their infinite wisdom, will provide the appropriate funds for CPSC to do this, I'm sure they would be very pleased to do these particular studies. At the same time, they sort of have their hands filled with meeting the requirements of the Consumer Product Safety Improvements Act, with the staff that they have presently. So, if you can increase their staff, increase their funds, and get them another commissioner, I think the Consumer Product Safety Commission would be happy to undertake some of these studies that you're talking about.

As far as issuing a guidance, sure, they could update that. The document you referred to from 1997 actually was referring to airborne levels and referring to an update of the urea-formaldehyde insulation standard, and was not referring to levels in textiles.

Senator CASEY. I'm glad to hear that, but I—

Dr. WAKELYN. And you also mentioned one other thing about the New Zealand study. You seemed to not have seen—I have two news articles attached to my statement that—where the New Zealand Government did testing after that, made the television station pay a fine and apologize to the public and apologize to the country of China, because the—what the television station had done is not used the proper testing methods, and put out scare tactics that were not accurate. And when they actually tested products, they didn't find it.

So, no, I'm not saying that testing isn't out there and it shouldn't be done; it should be done correctly if it's done—

Senator CASEY. We're not hanging our hat on one New Zealand study. OK? There are a lot of other studies and reports that we're pointing to here.

Let me say, in conclusion, two things—one is, this committee—I'm not a member, but I know something about what this committee's been doing—has been trying to give the Commission a lot more resources, a lot more help. I hope that argument for more resources or more staff is bipartisan because there has not been a lot of support in the last 8 years. OK, that's number one.

Number two is, I really believe that any Federal Government agency, like the Consumer Product Safety Commission, for example, should err on the side of caution when it comes to something which poses a danger, and, in particular, which poses a danger to children. There may not be a consensus, conclusive study, but when you have reports and when you have epidemiologists and others raising questions about this, I think they should err on the side of safety and issue some kind of guidance or standards, which may not rise to the level of new regulations, in addition to waiting for what the GAO concludes.

Dr. WAKELYN. I agree with that, but I would also mention—sure, they should put out guidance; they put out guidance on all sorts of things, and I would imagine they will be doing that, just like they're putting out one on lead in textiles and lead in consumer products. They're putting together these types of documents, and they are doing that.

Senator CASEY. Well, in my judgment, they're not doing enough. So, we'll keep after them.

Thanks very much.

Senator PRYOR. Thank you. We have only another minute or two before the vote starts, so, if I may, Dr. Etzel, let me ask you a couple of very brief questions.

One is about Japan. Are you familiar with what they're doing in Japan?

Dr. ETZEL. I have some very basic familiarity.

Senator PRYOR. OK. So, they have a national standard in Japan, and what I was going to ask you is, Do you know whether there is a study out there that would tell us whether the incidence of exposure and the health issues related to formaldehyde have gone down since Japan has done this? Do you have any idea?

Dr. ETZEL. It would be almost impossible to do such a study, and the reason is that no country has surveillance for the kinds of health effects that we would see. It isn't done in the U.S., it isn't done in Japan or even in any European country, and that's because these are nonspecific health effects that cannot be attributed by any clinician directly to a substance unless they do skin testing. Now, you could probably find a dermatologist in Japan who could systematically do skin testing and see if the skin tests are less likely to be positive now, but that would be about the only thing. I don't think you could get any evidence about the other respiratory effects.

Senator PRYOR. OK. And you are familiar with the California law?

Dr. ETZEL. Yes, sir.

Senator PRYOR. And is it your opinion that we should apply that California law as a national standard?

Dr. ETZEL. Yes. We suggest that the EPA Administrator consider applying it nationwide.

Dr. WAKELYN. Can I respond to that?

Senator PRYOR. No.

Dr. WAKELYN. EPA has—

Senator PRYOR. No. No.

Dr. WAKELYN. No, EPA has—

Senator PRYOR. No, no, no.

Dr. WAKELYN.—proposed some—

Senator PRYOR. No. You cannot respond to that, because you've had twice the air time these two guys put together have had. And I've tried to move you along, but—no, I'm talking to Dr. Etzel.

Dr. WAKELYN. Well, I was just wanting to tell you that EPA has already proposed something.

Senator PRYOR. Dr. Etzel, let me ask you. Your view is, and your association's view is, that we should apply the California standard nationally. And is that because your primary concern is exposure to children or to the general population?

Dr. ETZEL. The concern of the American Academy of Pediatrics is primarily for children, because of the reasons I mentioned earlier, that their exposure to these things because of their developmental stage is likely to be higher than that of adults.

Senator PRYOR. And is it across the board or is it just in the fabrics? In other words, is it in the baby cribs, whatever it may be, or is it just in the fabrics?

Dr. ETZEL. The concern of the Academy is that children have a cumulative exposure to many, many different products that they

encounter on perhaps a daily basis. It could be that they are encountering a small amount in their crib sheet, and a small amount in their shampoo, and a small amount from dad's permanent-press shirt, and another small amount from dad's permanent-press pants. And the cumulative effect of these and other exposures can put them at risk for health effects.

Senator PRYOR. OK. Do you have a concern that if, Japan already has a standard, and if Europe may be going down the track to having a standard, we don't know that for sure yet, but assuming they are—do you have a concern that those products that can't be sold in Japan, can't be sold in places where there are bans, may be, in effect, dumped into the U.S. market because we don't have a standard?

Dr. ETZEL. To be honest, sir, I hadn't thought about that. I suppose it's a possibility.

Senator PRYOR. Dr. Brookstein, do you have anything on that?

Dr. BROOKSTEIN. I can't opine on that.

Senator PRYOR. Well, I think that, at this point, we have a vote going on, on the floor, so what I will do here is, I will keep the record open for 2 weeks, for 14 days, and we would encourage our colleagues, including Senator Casey, who's not on the Subcommittee, but who has been a very important part of this—we would encourage them to get their questions in to us as quickly as possible so we can get them to our panel and let you answer those questions as quickly as you can.

This has been very helpful to us. We know that formaldehyde is a substance that exists in nature, and we also know that formaldehyde is a chemical that's added to many, many products, and I think it's important for the United States to have a good handle on what the exposure of formaldehyde does and what the levels would be under the proper circumstances. So, thank you all, all three of the panelists, for helping us today to take one step in this process, and we appreciate your testimony very much.

Thank you.

[Whereupon, at 12:04 p.m., the hearing was adjourned.]

A P P E N D I X

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. TOM UDALL TO DR. RUTH A. ETZEL

Question. I would appreciate hearing the panelists' views on warning labels.

The Australian Competition and Consumer Commission, which is similar to the U.S. CPSC, encourages textile and apparel makers to label articles of clothing with a "wash before first use" recommendation—since washing should significantly reduce the level of any residual formaldehyde. Is this a policy response that the forthcoming GAO study will consider? Based on what is already known today, do you recommend that textiles and apparel sold in the U.S. have a "wash before wearing" label?

Answer. At this time, the AAP has no knowledge of whether the Government Accountability Office will examine this issue as part of its forthcoming study on formaldehyde. We hope to be consulted during the development of the report and look forward to reviewing the final product.

The U.S. Federal Trade Commission (FTC) sets Federal guidelines about how and when clothing must be labeled with regard to fiber content, washing instructions, and the like. There are currently no specific guidelines about when or whether clothing should or must be labeled "wash before wearing." In my personal experience, however, many parents disregard the "wash before wearing" labels because they do not understand why they should do so. It would be useful for the FTC or CPSC to study whether such a label is warranted, and how it could be improved to ensure that parents follow its recommendation.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. TOM UDALL TO DR. DAVID BROOKSTEIN

Question 1. I would appreciate hearing the panelists' views on warning labels.

The Australian Competition and Consumer Commission, which is similar to the U.S. CPSC, encourages textile and apparel makers to label articles of clothing with a "wash before first use" recommendation—since washing should significantly reduce the level of any residual formaldehyde. Is this a policy response that the forthcoming GAO study will consider?

Answer. In my written testimony submitted to the Subcommittee I provided a chart showing formaldehyde regulations and standards for various other countries. In that chart I showed that both Germany and The Netherlands require warning labels for consumers that suggest washing of garments before first use if they contain formaldehyde.

It is my understanding that the forthcoming GAO study will not consider this as a policy response.

Question 1a. Based on what is already known today, do you recommend that textiles and apparel sold in the U.S. have a "wash before wearing" label?

Answer. Based on the practices of other countries and the potential health and safety risks associated with the use of formaldehyde in textiles and apparel that the U.S. should have "wash before wearing" or the like on apparel sold in the US. Unfortunately though, there are apparel and other consumer textile items that cannot be washed prior to first use.

RESPONSE TO WRITTEN QUESTIONS SUBMITTED BY HON. TOM UDALL TO DR. PHILLIP WAKELYN

Question 1. I would appreciate hearing the panelists' views on warning labels.

The Australian Competition and Consumer Commission, which is similar to the U.S. CPSC, encourages textile and apparel makers to label articles of clothing with a "wash before first use" recommendation—since washing should significantly re-

duce the level of any residual formaldehyde. Is this a policy response that the forthcoming GAO study will consider?

Answer. No, I do not view this as necessary. The incidence of the use of formaldehyde-containing resins in textiles is very low. The CPSC has not received valid complaints concerning formaldehyde in textiles in the U.S. Skin irritation reactions due to chemicals on or in commercial apparel are extremely rare and there have been no valid safety problems raised in the U.S. concerning the low levels of formaldehyde on clothing and textiles that have been treated with formaldehyde containing resins. And CPSC has already done extensive testing concerning formaldehyde and textiles.

The purpose of the GAO study mandated in the CPSIA is for GAO to do an independent, scientific review of the available data concerning the risk to the public of formaldehyde and textiles. The results of the GAO risk determination should dictate whether GAO needs to consider 'policy response' options. The inclusion of a "wash before first use" recommendation as an option for consideration before the GAO has evaluated risk to the public from formaldehyde and textiles would suggest a congressionally expected outcome to the GAO study.

Question 1a. Based on what is already known today, do you recommend that textiles and apparel sold in the U.S. have a "wash before wearing" label?

Answer. No, a "wash before wearing" label is not necessary for the following reasons:

1. Skin irritation reactions /contact dermatitis due to chemicals on or in commercial apparel are extremely rare.
2. There have been no valid safety problems raised in the U.S. concerning the low levels of formaldehyde on clothing and textiles that have been treated with formaldehyde containing resins.
3. There are many causes for skin irritation other than chemical additives to textiles.
4. There are claims of skin irritation that are incorrectly blamed on formaldehyde—where the textile was not treated with formaldehyde-containing chemicals, does not contain formaldehyde by valid testing, and the person alleging that formaldehyde caused their skin irritation problem is not allergic to formaldehyde.
5. Easy care/wrinkle resist cotton apparel accounts for only 2 percent of the total apparel offerings at retail and for only 13 percent of total cotton apparel purchased in 2008. And there is almost no easy care children's apparel and almost no children's wear is treated with formaldehyde containing chemicals of any kind.

The CPSC, which is data driven, has not received valid complaints concerning formaldehyde in textiles. There are no data that indicate that formaldehyde in textiles in the U.S. presents an "unreasonable risk of injury to the public". Labels already contain too much information and can be confusing to consumers. Many people routinely cut labels out of apparel.

The only two countries in the world that I am aware of that suggest "wash before wearing" labels for clothing are Germany and the Netherlands.

Question 2. Dr. Wakelyn, you argue that industry studies and voluntary standards ensure the consumer safety of clothing potentially containing formaldehyde.

Yet the specific Japanese and ISO standards mentioned in your remarks are test methods, not product specification standards which limit formaldehyde content levels.

Answer. My testimony, oral statement, and responses to questions did not say that these test methods (*i.e.*, ISO 14184-1 and the Japanese Law 112 Method) were 'product' standards. I clearly indicated that they were valid, acceptable test methods to determine formaldehyde levels in textiles. Fabric levels are not the same as airborne levels and should not be confused with airborne levels.

[Please see my written testimony.]

Question 2a. What is the current voluntary industry standard, if any, for formaldehyde content in textiles and apparel?

Answer. For years the voluntary level has been 300 µg formaldehyde/gram of fabric as measured by the AATCC Method 112 sealed jar test. Although correlation between the AATCC 112 test and the two international methods (*i.e.*, ISO 14184-1/ Japanese Law 112 Method are essentially the same) is not perfect, results using AATCC Method 112 are about 4 times higher than that measured using ISO 14184-1/Japanese Law 112 Method, *i.e.*, the level would be about 75 µg formaldehyde/grams of fabric using those international test methods and the same as the inter-

national voluntary standard Oeko-Tex 100. Testing has shown that the actual levels are less than half of that level. It was reported in the published, peer reviewed literature in 1998 that the average formaldehyde level contained by textiles made in the U.S. is approximately 100–200 µg free formaldehyde/gram of fabric as measured by the AATCC Method 112 sealed jar test (25–50 µg formaldehyde/g of fabric or ppm measured by the Japanese Law 112 Method/ ISO 14184–1) (Scheman *et al.*, 1998). Below the standards for the few countries that have standards are discussed (see below).

Question 2b. Is this standard developed and maintained by an ANSI-accredited organization?

No, there is not an ANSI-accredited or ISO-accredited standard for formaldehyde levels in textiles. However, there are valid, acceptable test methods to determine formaldehyde levels in textiles that should be used to determine fabric levels.

Question 2c. If compliance with this voluntary standard—or other individual company requirement—ensures consumer safety, why should such standards not be incorporated into a mandatory consumer rule for textiles and apparel?

Answer. It is not necessary to have a mandatory standard for formaldehyde in textiles in the U.S. Apparel products in the U.S. marketplace today are safe. It is extremely rare to hear of an irritation problem associated with fabric or clothing and the first time the item is washed, by normal, simple washing procedures used in the home, surface chemicals are eliminated, including formaldehyde-containing resin surface residues. There have been no valid safety related problems raised in the U.S. concerning the low levels of formaldehyde on clothing and textiles that have been treated with formaldehyde-containing resins. In addition, easy care/wrinkle resist cotton apparel accounts for only 2 percent of the total apparel offerings at retail. In addition, there is almost no easy care children's apparel and almost no children's wear is treated with formaldehyde containing chemicals of any kind.

To promulgate a mandatory standard, the Consumer Product Safety Commission, which is data driven, has to be able to show that formaldehyde in textiles in the U.S. presents an unreasonable risks of injury to the public [CPSA, Sec. 2 (15 U.S.C. 5051) (b)]. The CPSC has not received valid complaints concerning formaldehyde in textiles in the U.S. and the evidence is strong that formaldehyde in textiles does not pose an "unreasonable risk of injury to consumers." CPSC thoroughly studied this issue when there was concern about formaldehyde on or released from consumer products in the 1980s. In 1982, after thorough review, CPSC banned the sale of urea formaldehyde foam insulation (UFFI) for use in residences and schools based on unreasonable risk to consumers from the irritation and sensitized effects of formaldehyde emitted by UFFI. During this same period, CPSC studies the risk from formaldehyde and textiles. But after extensive research (see CPSC Briefing Package on formaldehyde and textiles, "Status Report on the Formaldehyde in Textiles Portion of Dyes and Finishes Project" [Sandra Eberle (to Peter Pruess and others), 1/3/84] p.4) determined that the evidence does not indicate that formaldehyde exposure from resin-treated textiles is likely to present an unreasonable risk to the public that requires any action.

A mandatory standard would require all textiles to be tested unnecessarily. A mandatory standard would clearly pose a costly, unnecessary burden on the textile and apparel industries through testing and record keeping plus all the requirements that would come in under the CPSIA (*e.g.*, certificate of conformity and tracking label requirements) as well as increasing the cost to the consumer.

Modern innovations through the use of derivates and scavengers and other low-emitting resin technology (Wakelyn, *et al.* 2007) keep the levels below 100–200 µg/g or ppm (as measured by AATCC 112 Method used in the U.S.; 25–50 ppm measured by the Japanese Law 112 Method/ ISO 14184–1). This technology includes proper choice of agent and using optimum preparation and curing conditions. Industry buys chemical formulations marketed as ultra-low formaldehyde resins (N-methylol agents plus alkyl compounds).

Only eight countries in the world have formaldehyde requirements for textiles ranging from 1500 ppm (in Germany, measured by the Japanese Law 112 Method/ ISO 14184–1; 6000 ppm by the AATCC 112 test used in the U.S.) to 75 ppm (in Japan measured by the Japanese Law 112 Method; 300 ppm by the AATCC 112 test used in the U.S.) for textiles that contact the skin. The other countries are 100–120 µg/g or ppm (measured by the Japanese Law 112 Method/ISO 14184–1; 400–480 ppm by the AATCC 112 test used in the U.S.). Discussion in the "Proposed Government Product Safety Policy Statement on Acceptable Limits of Formaldehyde in Clothing and other Textiles" (p. 3) by the New Zealand government [<http://www.consumeraffairs.govt.nz/policylawresearch/product-safety-law/proposed-statement/proposed-policy-statement.pdf>] gives a summary of International formalde-

hyde limits for clothing and other textiles. Requirements in some countries are essentially 'non-tariff trade barriers' since they are only enforced on imported textiles.

May 12, 2009

Hon. Mark L. Pryor,
Chairman,
Senate Subcommittee on Consumer Protection, Product Safety, and Insurance,
Committee on Commerce, Science, and Transportation,
Washington, DC.

Hon. Roger F. Wicker,
Ranking Member,
Senate Subcommittee on Consumer Protection, Product Safety, and Insurance,
Committee on Commerce, Science, and Transportation,
Washington, DC.

Dear Chairman Pryor and Ranking Member Wicker:

The Formaldehyde Council, Inc. (FCI) submits these comments in response to the April 28, 2009, "Formaldehyde in Textiles and Consumer Products" hearing before the Subcommittee on Consumer Protection, Product Safety, and Insurance of the Senate Commerce, Science, and Transportation Committee. FCI is a trade association of the leading producers and users of formaldehyde that is dedicated to promoting the responsible use and benefits of formaldehyde and ensuring its accurate scientific evaluation. We are writing to provide additional information not reflected in the Senate hearing testimony.

- FCI fully supports the testimony of Dr. Phillip J. Wakelyn of Wakelyn Associates, and we do not repeat his observations and conclusions here. Our comments therefore primarily address respiratory health factors associated with exposure to formaldehyde.
- The testimony presented to the Subcommittee regarding the effects of formaldehyde as a cause of asthma or an agent that exacerbates asthma was misleading. Frankly, the scientific literature on the issue provides answers contrary to those presented at the hearing.
- Dr. Ruth A. Etzel's testimony regarding the potential respiratory effects of formaldehyde on children was not based on a thorough review of the literature on formaldehyde. While her general observations on childhood exposure scenarios and physiology may be sound, these general observations were misapplied or misleading with regard to formaldehyde. Dr Etzel incorrectly summarized the scientific literature, as they did not find "higher rates of asthma, chronic bronchitis, and allergies in children exposed to elevated levels of formaldehyde" as Dr. Etzel proclaimed.¹
- Formaldehyde is a normal intermediary metabolite and a natural component of exhaled human breath.

Formaldehyde is a well-researched chemical, with a rich literature of human, animal and other studies. Some of these studies involved the intentional exposure of human volunteers in exposure chambers for relatively short periods of time to precisely measured amounts of formaldehyde in the air. This enabled researchers to assess the levels at which symptoms are produced or not produced. When discussing the potential irritant effects of formaldehyde, it is critical to remember that formaldehyde is naturally produced by all living organisms, including humans, with measurable levels always present in the blood. Because of its presence in the blood, known amounts of formaldehyde are also emitted in the breath quite independently of what might be in the external environment. Formaldehyde does not accumulate either in the environment or the human body since the body's ability to metabolize (*i.e.*, breakdown) formaldehyde is so efficient that when humans (or monkeys or rats) are exposed to formaldehyde no increase in normal blood levels of formaldehyde can be detected.

Formaldehyde and Asthma

Asthma, particularly in children, is often mentioned as an endpoint of concern with respect to either being caused by or exacerbated by the irritant properties of formaldehyde. With all due respect, however, the scientific literature and a number of expert reviews demonstrate that people with asthma are no more sensitive to

¹Dr. Etzel cited to Wantke, F. et al 1996; Garrett, M. H. et al 1999; and Rumchev, K. B., et al 2002.

formaldehyde than non-asthmatics. The weight of the scientific evidence supports a lack of association between formaldehyde exposure and asthma induction or exacerbation.²

Discussion of Specific Studies

The following studies were cited to the Subcommittee, and the FCI feels that the context of the studies and the findings need to be better described.

1. Wantke *et al.* (1996)

Wantke *et al.* (1996) studied 62 students in Austria and reported finding IgE specific to formaldehyde.³ However, among the 24 of the 62 children who had elevated IgE specific to formaldehyde, only 3 had RAST scores over 2.0.⁴ There was no dose-response relationship between formaldehyde levels and RAST scores. The three classrooms studied had 43, 69 and 75 ppb of formaldehyde measured, respectively. RAST scores were not elevated at 69 ppb compared to the 43 ppb classroom, as shown below.

	75 ppb (n=22)	69 ppb (n=22)	43 ppb (n=18)
RAST over 2.0	2	0	1
RAST 1.3–1.9	10	6	5
RAST 1.0–1.2	10	16	12

Thus, there does not appear to be dose-response relationship between formaldehyde and IgE. Moreover, the IgE levels in the study did not correlate with either number or severity of reported symptoms. The authors acknowledge that “IgE-mediated sensitization to formaldehyde is rare and a matter of controversy.” They further state: “Our data as well as the literature [ref. omitted] do not conclusively explain the clinical relevance of specific IgE against formaldehyde.” The Wantke *et al.* Study did not compare children and adults, and thus also does not speak to any differential sensitivity.

2. Garrett *et al.* (1999)

Contrary to what was presented to the Subcommittee, Garrett *et al.* (1999), found “no evidence of an association between asthma in the children and formaldehyde levels.” This conclusion was founded on a study of asthmatic and non-asthmatic children in two small towns in Victoria, Australia. The paper does not address differences in adult and children’s responses because relevant data for adults were not collected. It does characterize the Wantke *et al.* (1996) study relevance as “unclear” because the sensitization was not associated with symptoms.

In full candor, several factors compel caution in relying on this study:

- The paper likely was based on a graduate student thesis (the acknowledgments note a postgraduate publication award), and the paper presents extensive multi-variate analysis. Of all the analyses performed, the study notes:

a crude odds ratio for atopy of about 1.4 with an increase in bedroom levels of formaldehyde of 10 $\mu\text{g}/\text{m}^3$ (adjusted for parental asthma and sex); however, the confidence interval for this finding is 0.99–2.00; and an adjusted odds ratio of 1.42 for atopy with an increase in the highest recorded formaldehyde level by 20 $\mu\text{g}/\text{m}^3$ (confidence interval 0.99–2.04). (As the majority of scientists and researchers recognize, odds ratios of 1.4 are generally not considered to be strong evidence of a causal connection.)

- The study took place in two small towns “surrounded by open-cut brown coal mines and power stations, which provide considerable employment.” The authors had difficulty locating nonasthmatic children to participate in the study. Outdoor measurements were taken but not reported.
- The authors note there was no significant association between formaldehyde levels and house age. This is surprising, since any off gassing of formaldehyde from wood products or other formaldehyde-containing materials would be ex-

² See, *e.g.*, IOM (2000); Franklin, *et al.* (2000); and Garrett, *et al.* (1999).

³ IgE refers to Immunoglobulin E, a class of immunoglobulins that includes the antibodies elicited by an allergic substance (allergen). A person who has an allergy usually has elevated blood levels of IgE. The E in IgE stands for erythema (redness).

⁴ RAST stands for RadioAllergoSorbent Test. A sample of blood is mixed with substances known to trigger allergies. The test measures the level of allergy antibodies (specific IgE antibodies) in the blood which are present if there is an allergic reaction.

pected to decline over time. Thus, the accuracy of formaldehyde measurements could be open to question.

- In discussing the implications of their findings, Garrett *et al.* Note the increased prevalence of allergic diseases in many Western countries, and suggest that materials emitting formaldehyde have become increasingly popular at the same time. The authors apparently do not appreciate that formaldehyde resin technologies have been improved substantially over the last two decades, and that releases of formaldehyde have been greatly reduced.
- It is difficult to rule out systematic recall or selection bias in this case-control study. With respect to exposure issues, no personal monitors were used, and there were no associations or trends for levels reported for the bedrooms, which are the one place in the house where some form of continuous exposure is likely to occur.
- The distribution of results claimed by the investigators hardly seems to be persuasive evidence of a systematic health risk. There was no significant increase in the adjusted risk for either asthma or respiratory symptoms with increasing formaldehyde exposure.

3. Rumchev *et al.* (2002) and (2004)

In Rumchev, *et al.* (2002), household formaldehyde levels were determined by passive sampling in the homes of 88 children aged 6 months to 3 years who were diagnosed at a hospital with asthma, and compared with 104 community controls. Cases had a statistically significant higher mean formaldehyde exposure compared to controls, 32 ppb (38 $\mu\text{g}/\text{m}^3$) and 20 ppb (24 $\mu\text{g}/\text{m}^3$), respectively. After adjustment for confounding factors, such as indoor air pollutants, relative humidity, indoor temperature, atopy, family history of asthma, age, sex socioeconomic status, pets and environmental tobacco smoke, Rumchev *et al.* (2002) reported that children exposed to formaldehyde levels of 60 $\mu\text{g}/\text{m}^3$ had a 39 percent increase in odds of having asthma compared to children exposed to less than 10 $\mu\text{g}/\text{m}^3$ (or estimated to be approximately 1.4 95 percent CI 1.1–1.7 from data presented in a graph). However, considering the marginally increased risk observed, together with the number of potential sources of bias, such as selection bias and validity of diagnosis in the young, this study should not be considered sufficiently robust evidence of an association between formaldehyde exposure and increased risk of asthma in children or an appropriate basis for regulation or governmental guidance.

In addition, as noted previously, formaldehyde is exhaled in the breath, with studies suggesting that breath levels may range from 1.2–72.7 ppb to 300–1,200 ppb (Moser *et al.* 2005; Ebeler *et al.* 1997). Based on the existing literature, the exposure levels reported in Rumchev *et al.* (2002) are in the range of formaldehyde expected to be found in exhaled breath. This raises the questions of causation, association, and how one might reasonably differentiate self-exposure from an exogenous source of exposure at approximately the same concentration.

Those limitations and weaknesses are validated by a second report by Rumchev, *et al.* (2004), which raises questions regarding whether Rumchev (2002) is an adequate basis for the derivation of a reference concentration specifically for formaldehyde. Rumchev, *et al.* (2004) used the same cohort of children and evaluated the same asthma endpoint as Rumchev, *et al.* (2002), but focused on the association with the other chemicals and particulates rather than formaldehyde. As for formaldehyde, Rumchev, *et al.* (2004), found that asthmatic cases were exposed to higher levels of volatile organic compounds (VOCs).

An editorial was published concurrently (Brunekreef, B. 2004) with Rumchev *et al.* (2004), which focused on nitrogen dioxide (NO_2), VOCs, and particulates. The editorial indicates that (1) diagnosis of asthma in children is “notoriously difficult,” and (2) case-control studies, as used by Rumchev, inherently are rife with potential and actual sources of confounding and bias. An example given is that Rumchev *et al.* (2004) did not attempt to evaluate the impact of recent indoor painting. These issues raise serious questions regarding the adequacy of the study as a sole source for deriving a reference exposure.

As Brunekreef (2004) noted in his comments on Rumchev *et al.* (2004) and other studies:

The issue of whether indoor VOCs are a risk factor for asthma in children therefore seems still to be largely undecided. In view of the methodological difficulties outlined above, prospective studies are more likely to produce progress in deciding whether we need to worry about indoor VOCs as determinants of asthma at the relatively low concentrations typically encountered in the home environment.

In view of the issues raised by Rumchev (2004) showing that a number of VOCs were associated with asthma as well as the inherent and broader limitations associated with Rumchev, *et al.* (2002), Rumchev, *et al.* (2002) does not provide a reasonable basis for adopting a new level. A careful reading of the studies cited as the basis for concluding that children are differentially sensitive to formaldehyde shows essentially no support for that proposition.⁵

While there are isolated reports of an association between formaldehyde and asthma-like symptoms, these are generally small, poorly controlled studies that do not show dose-response relationships between formaldehyde and asthma [or surrogate measures such as atopy (*i.e.*, a personal or familial tendency to produce antibodies in response to low doses of allergens, and, as a consequence, to develop typical symptoms such as asthma or conjunctivitis) or report results at formaldehyde levels (*e.g.*, low ppb) that are implausible (*e.g.*, at levels now known to be normally emitted in the breath)]. Poorly conducted studies that do not control exposure to cold air, nuisance dust, molds, etc, all of which can contribute to asthma-like symptoms, should not be relied upon when there is ready data from controlled chamber studies. Controlled chamber studies surpass other types of studies because they eliminate uncontrolled variables. And, under these conditions, asthmatics exhibit no more sensitivity to formaldehyde than nonasthmatics.⁶

Based on the preceding discussion, it should be evident that there is no compelling or reliable evidence that children are more or less susceptible to the irritant effects of formaldehyde than adults. As ATSDR concluded, there is no appreciable difference between children and adults in the targets for irritation, *i.e.*, eyes, nose and throat, at formaldehyde exposure levels that have been reliably determined to affect adults. "Whereas there are numerous studies of adults occupationally exposed to formaldehyde and exposed under acute controlled conditions, data regarding the toxicological properties of formaldehyde in children are limited. Nevertheless, the same type of effects that occur in adults are expected to occur in children. . . . Symptoms expected to occur in children include eye, nose, and throat irritation from exposure to airborne concentrations between 0.4 and 3 ppm. . . ." ATSDR (1999).

Additionally, in an extensive review on upper respiratory tract and eye irritation effects of volatile chemicals by a group of experts, a higher susceptibility of children was not mentioned. (Doty *et al.* 2004). In a recent study by Meininghaus *et al.* (2003), the air levels of several respiratory irritants were measured (*e.g.*, SO₂, ammonia, acetic acid, formic acid, hexanal, butanal, acetaldehyde and formaldehyde) in school settings. For formaldehyde, the air concentrations were between 20–25 µg/m³ (17–21 ppb). Of interest was that reported symptoms (*i.e.*, dry sensation of the eyes, irritation of the upper respiratory tract, headache and a rough tongue) were initially reported by the adults (*i.e.*, some of the teachers), and it was only after this that several children complained about similar symptoms suggesting a higher sensitivity in adults than in children. The authors concluded that psychological factors (*e.g.*, increased attention from authorities, the presence of 'experts' and sampling equipment, and a strong group behavior) may have resulted in individuals paying more attention to health effects related to sensory irritation.

FCI trusts that you will find this information compelling and the Subcommittee on Consumer Protection, Product Safety, and Insurance will give it due consider-

⁵Sufficient evidence of a causal relationship or an association with asthma only exists for cats, cockroaches, house dust mites, ETS (preschoolers), dogs, fungi or molds (Rhinovirus) and high-level exposures to nitrogen oxides, not formaldehyde or other VOCs. For an elaboration, see the National Research Council (2004) *Emergency and Continuous Exposure Guidance Levels for Selected Submarine Contaminants*, p. 87.

⁶There also are studies indicating that asthmatic individuals are not more sensitive to the irritant effects of formaldehyde than healthy people (Sheppard *et al.* 1986, Sauder *et al.* 1987, Kulle *et al.* 1993, Green *et al.* 1987, Witek *et al.* 1987). In a recent study by Ezratty *et al.* (2007), 12 subjects with intermittent asthma and allergy to pollen were exposed, at rest, in a double-blind crossover study to either formaldehyde (0.4 ppm) or purified air for 60 minutes. The order of exposure to formaldehyde and air-only was randomized, and exposures were separated by 2 weeks. There was also an allergen inhalation challenge after each exposure. Airway responsiveness to methacholine (a test that involves the inhalation of increasing concentrations of methacholine, a potent bronchoconstrictor) and lower airway inflammation (*i.e.*, as measured by inflammatory cells in sputum) were also assessed 8 hr after allergen challenge. Formaldehyde exposure did not affect allergen-induced increase in responsiveness to methacholine, and there was no formaldehyde-associated effect on the airway inflammatory response. In this study, exposure to 400 ppb (0.4 ppm) formaldehyde had no significant deleterious effect on airway allergen responsiveness of patients with intermittent asthma; in fact the authors reported a trend toward a protective effect. Overall, the weight of evidence suggests that asthma is not caused by or exacerbated by low-level exposure to formaldehyde.

ation. Should you require any additional information, please do not hesitate to contact me.

Sincerely,

BETSY NATZ,
Executive Director
Formaldehyde Council

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