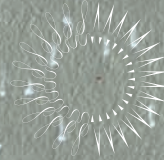




Woodrow Wilson
International
Center
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*Project on Emerging
Nanotechnologies*



THE
PEW
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the
CONSUMER PRODUCT SAFETY COMMISSION
and **NANOTECHNOLOGY**



PEN 14 AUGUST 2008

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CONTENTS

- 1 FOREWORD**
- 2 AUTHOR'S PREFACE**
- 3 EXECUTIVE SUMMARY**
- 5 ABOUT THE AUTHOR**
- 7 BACKGROUND**
 - 7 Nanotechnology and CPSC
 - 10 CPSC: History and Hope
 - 12 CPSC: The Reality
 - 13 Case Study: Stand 'n Seal
 - 14 Five Generic Weaknesses
in CPSC's Product Oversight Capacity
- 19 ANALYSIS OF CPSC'S TOOLS FOR REGULATING NANOPRODUCTS**
 - 19 Consumer Product Safety Act
 - 21 The Federal Hazardous Substances Act:
Labeling and Bans
 - 21 Poison Prevention Packaging Act
- 22 CONGRESS'S ROLE IN CONSUMER PRODUCT SAFETY**
- 23 RECOMMENDATIONS**
 - 23 What CPSC Should Do
 - 23 What Congress Should Do

- 25 APPENDIX 1: CONSUMER PRODUCTS
WITH VOLUNTARY STANDARDS
- 26 APPENDIX 2: A HISTORY OF THE
VOLUNTARY SAFETY STANDARD FOR
BABY BATH SEATS
- 27 APPENDIX 3: 1970 PROPOSED CONSUMER
PRODUCT SAFETY ACT

- 28 ENDNOTES

the
CONSUMER PRODUCT SAFETY COMMISSION
and **NANOTECHNOLOGY**

E. Marla Felcher

PEN 14 AUGUST 2008

The opinions expressed in this report are those of the author and do not necessarily reflect views of the Woodrow Wilson International Center for Scholars or The Pew Charitable Trusts.

FOREWORD

During the fall of 2007, many Americans faced a hazard in their products that had been banned for 30 years—lead. As millions of children’s toys were recalled, it became clear that government oversight had failed, and that the agency primarily responsible for the oversight of these toys—the U.S. Consumer Product Safety Commission (CPSC)—was stretched too thin from years of neglect, underfunding and the challenges posed by an increasingly global manufacturing system.

It is against this background that we need to ask the question: Is CPSC adequately prepared to deal with nanotechnology, which is now found in more than 600 manufacturer-identified consumer products ranging from infant pacifiers to paints to appliances, to clothing?¹ This report provides an assessment of CPSC’s “nano readiness” by examining the agency’s history, mandate, resources and tools. Though CPSC was once touted as “the most powerful federal regulatory agency ever created,” the findings of this analysis indicate that CPSC is poorly positioned to address the oversight challenges posed by nanotechnologies today—challenges that will expand in scope and complexity in the near future as nano-enabled consumer products enter the marketplace at an increasing rate.

Though CPSC’s oversight responsibilities extend to potentially half of all the nanotechnology products presently on the market, the agency has been starved of funds under the U.S. government’s National Nanotechnology Initiative (NNI). The NNI is tasked with coordinating the U.S. government’s investment in nanotechnology research and development within 25 different federal agencies.² Even under optimistic scenarios, CPSC may only receive \$1 million to begin to address nanotechnology in the future, a paltry sum given the government’s \$1.4 billion annual investment.³

This report lays out a clear set of steps that the federal government must take to make sure that the public is protected from any potential risks associated with nanotechnology in consumer products. CPSC can play a key role in ensuring that we reap the benefits of our investments in nanotechnology, but to do so, the agency will need significant and immediate repair.

—David Rejeski
Director, Project on Emerging Nanotechnologies

AUTHOR'S PREFACE

I would like to thank Pamela Gilbert, a partner at the law firm Cuneo Waldman & Gilbert, LLP, and Rachel Weintraub, director of product safety and senior counsel for Consumer Federation of America, who reviewed my report. For years, both attorneys have worked tirelessly on product safety issues. Ms. Gilbert served as the executive director of the Consumer Product Safety Commission during the Clinton administration and, before that, as legislative and executive director of Public Citizen's Congress Watch and program director at U.S. Public Interest Research Group. Ms. Weintraub currently serves on the board of directors of the International Consumer Product Health and Safety Organization and, before joining the Consumer Federation of America, worked as a consumer advocate with U.S. Public Interest Research Group. All Americans owe an enormous thank you to Ms. Gilbert and Ms. Weintraub for their commitment to product safety, particularly the safety of children's products and toys.

I would also like to thank Charlie Peters, founding editor of *Washington Monthly* magazine and president of Understanding Government, and Beth Peters for being among my most consistent and enthusiastic non-family cheerleaders.

Finally, I owe gratitude to David Rejeski and the Project on Emerging Nanotechnologies at the Woodrow Wilson International Center for Scholars for their encouragement and generous support.

EXECUTIVE SUMMARY

When it was created in 1972, the U.S. Consumer Product Safety Commission (CPSC) was hailed as “the most powerful federal regulatory agency ever created.”⁴ It has never lived up to these expectations, struggling since its inception to carry out its mandate: *to protect Americans from unreasonable risks associated with consumer products*. In the 1970s, CPSC strived to set priorities and to justify its existence; in the 1980s, it fought for its life against many in the U.S. House of Representatives, U.S. Senate and White House who wanted to abolish it. In the 1990s, CPSC staff and consumer advocates breathed a sigh of relief when a Democrat was elected to the White House, but by the end of the decade, there was little to celebrate. Congress, with the blessing of the White House, cut, then froze, CPSC’s budget. At the same time, retailers were building and filling mega-stores with inexpensive foreign-made goods, creating, by the 21st century, a vast resource imbalance between CPSC and the industries it regulates.

This imbalance goes far to explain why, during 2007 House and Senate hearings, the picture of CPSC that emerged was one of a crippled agency, failing to protect Americans from unsafe products. In the past five years alone, tens of millions of toys covered with lead paint (a substance that has been banned for decades) turned up in children’s playrooms, dozens of children required abdominal surgery after swallowing tiny magnets that had broken off of shoddily made and inadequately tested toys and dozens of do-it-yourselfers were rushed to hospitals with respiratory illness after inhaling the fumes of a spray-on grout made with a poisonous ingredient. CPSC regulators were slow to discover these problems, slow to notify consumers and even slower to take action against the manufacturers that profited from the sale of these hazardous products.

CPSC’s inability to carry out its mandate with respect to simple, low-tech products such as Thomas the Tank Engine toy trains, Barbie dolls and Easy-Bake Ovens bodes poorly for its ability to oversee the safety of complex, high-tech products made using nanotechnology. The agency lacks the budget, the statutory authority and the scientific expertise to ensure that the hundreds of nanoproducts now on the market, among them baby bottle nipples, infant teething rings, teddy bears, paints, waxes, kitchenware and appliances, are safe. This problem will only worsen as more sophisticated nanotechnology-based products begin to enter the consumer market.

PROBLEM SUMMARY

1. CPSC’s data collection system is not nano ready.
2. CPSC has limited ability to tell the public about health hazards associated with nanoproducts.
3. CPSC has limited ability to get recalled nanoproducts out of use.
4. CPSC lacks sufficient enforcement staff to identify manufacturers that fail to report nanoproduct hazards to the agency.
5. CPSC does not have sufficient authority to promulgate mandatory safety standards for nanoproducts.

RECOMMENDATIONS SUMMARY

1. Build CPSC's nanotechnology knowledge base and expertise.
2. Identify companies and industries that are currently manufacturing nanoproducts and request that they submit research studies, risk assessment data and any information they possess that will enable CPSC scientists to assess nanoproduct safety.
3. Coordinate with other health and safety agencies, and combine efforts to evaluate the risks associated with nanoproducts.
4. Convene a Chronic Hazard Advisory Panel (CHAP) to evaluate the health and safety risks associated with nanoproducts currently on the market that are intended for use by children.
5. Appeal to industry to begin work on voluntary safety standards for the most prevalent nanoproducts currently on the market and those that are intended for use by children.
6. Urge the U.S. Congress to amend the Consumer Product Safety Act to give CPSC the authority to require manufacturers to identify any nanomaterials in their products.
7. Encourage the Congress to adopt Section 11 of the Consumer Product Safety Act bill recommended by the National Commission on Product Safety in its 1970 Final Report, which would give CPSC the authority to promulgate safety standards for "new" consumer products based on new and emerging technologies, including nanotechnology.

ABOUT THE AUTHOR

E. Marla Felcher teaches at Harvard University's Kennedy School of Government and writes as a freelance journalist. She also serves as a director on the boards of several non-profit organizations.

In 2001, Dr. Felcher published *It's No Accident* (Common Courage Press), an account of the Consumer Product Safety Commission's inability to effectively regulate manufacturers of children's products. This book has been used as the basis for legislation at both the state and federal levels. Dr. Felcher has also written about consumer product regulation for multiple magazines, including *Mother Jones*, *The Atlantic Monthly* and *Slate*, as well as for The Century Foundation and Understanding Government.

After earning a B.A. in psychology from Carnegie Mellon University and an M.B.A. from the University of Texas, Dr. Felcher worked in marketing for Gillette and Talbots and as a consultant for clients that included Ben & Jerry's, J. Crew, Burlington Industries and Nabisco. In 1992, she earned a Ph.D. in marketing from the Kellogg School of Management at Northwestern University. She subsequently joined the faculty of Northwestern's Medill School of Journalism, where she taught advertising and marketing.

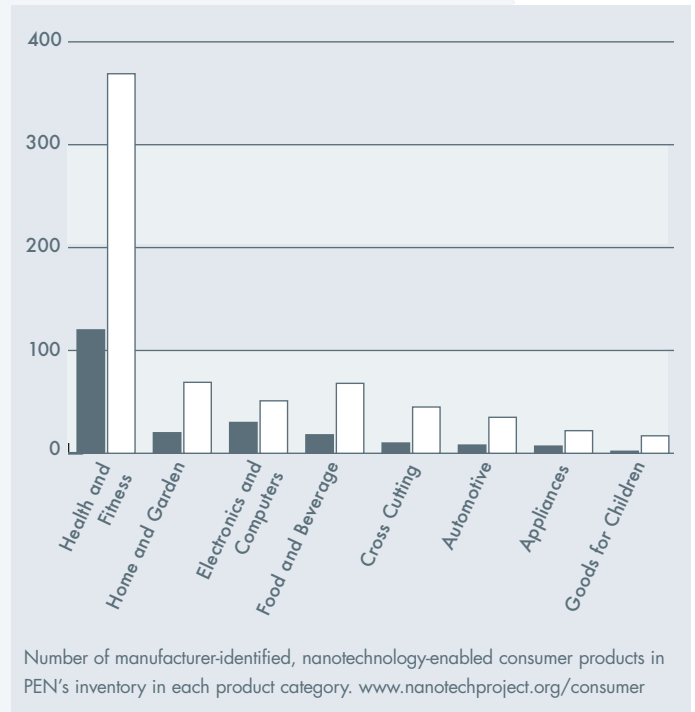
BACKGROUND

NANOTECHNOLOGY AND CPSC

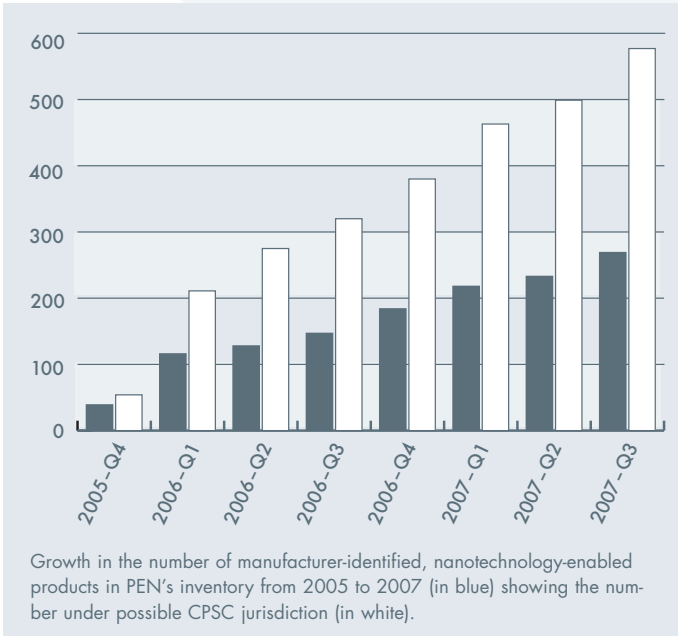
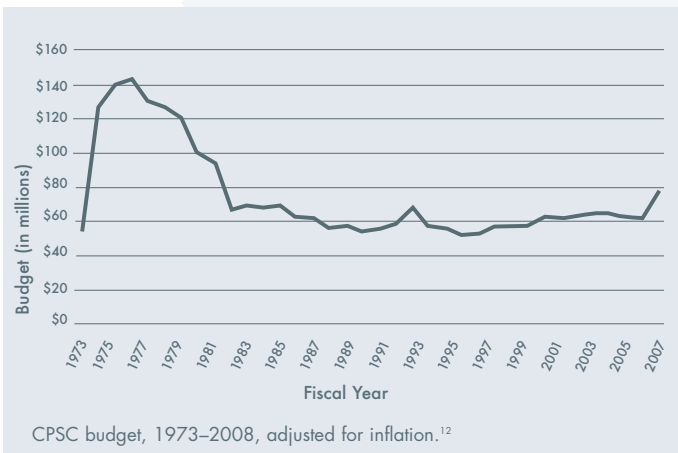
The U.S. Consumer Product Safety Commission (CPSC) is charged with protecting the public against unreasonable risks of injury or death associated with consumer products. More than 15,000 consumer goods fall under CPSC's jurisdiction, including toys and baby products, sports equipment, fitness equipment, home improvement and garden equipment, clothing, appliances, electronics and computers. An inventory of manufacturer-identified, nanotechnology-enabled consumer products maintained by the Project on Emerging Nanotechnologies (PEN) at the Woodrow Wilson International Center of Scholars indicates that nanotechnology has already found its way into every one of these product categories (Figure 1).

Nanotechnology involves the ability to measure, see, predict and make things at a scale of approximately 1 to 100 nanometers. (A nanometer is roughly the size of 1/100,000th the width of a human hair.) At this scale, properties of materials can change, giving one the ability to do new and unique things, such as create more effective, better targeted drugs; stronger, more flexible materials; and more nutritional, longer-lasting foods. Nanotechnology has the potential to affect every area of life, from consumer products to energy to medicine. But some of the properties that make nanotechnology so exciting also give rise to concern. Little research has been done on the potential risks of nanotechnology and nanomaterials, some of which could have serious impacts on the environment and on human health and safety.

FIGURE 1. Products in Each Category



Given the large global investment in nanotechnology research and development, now estimated at around \$12 billion annually, the number of goods and products that incorporate nanotechnology is likely to increase dramatically in the near future.⁶ Since PEN launched its inventory in March 2006, the number of products in its inventory has grown from 212 to 609.⁷ These products come from 321 companies in 20 countries, and all of them are available for purchase by consumers.⁸ A preliminary analysis indicates that approximately half of nanotechnology consumer products currently on the market would fall under CPSC's jurisdiction (Figure 2).

FIGURE 2. Products under CPSC Authority**FIGURE 3. CPSC Budget, 1973–2008**

According to an analysis by Lux Research, nanotechnology will represent an estimated \$3.1 trillion in manufactured goods by 2015, or about 15 percent of global manufactured goods.⁹ A rapid increase in both the number and complexity of these products places significant responsibility on CPSC to take the

lead in regulating this new technology, but the agency is not in a position to do so. Testifying before a U.S. Senate subcommittee in 2007, CPSC Commissioner Thomas H. Moore, who has served at the agency since 1995, summed up the situation: “I do not pretend to understand nanotechnology and our agency does not pretend to have a grasp on this complicated subject either. For fiscal year 2007, we were only able to devote \$20,000 in funds to do a literature review on nanotechnology.”¹⁰

As CPSC staff struggles to get up to speed by reading the literature, governments, industry and the financial community continue with their multibillion-dollar investments in the development and commercialization of new nanotechnology products. Every day, new nanoengineered products make their way onto stores' shelves, among them kids' pants, teddy bears, baby bottles, pacifiers, teething rings, plastic food-storage containers, socks, chopsticks, humidifiers, mobile phones, computer processors and tennis racquets. The benefits of nanotechnology to these products, often stated in manufacturers' claims, are straightforward and easily understood by consumers—pants are waterproofed, blouses become stain resistant, socks eliminate foot odor, baby bottles and pacifiers fight bacteria and computers are faster. But what about the unknown health risks associated with these products? Is it safe for an infant to spend hours each day sucking on a nano-enhanced pacifier? The dearth of information on the toxicity of nanomaterials and the inability to generalize findings from one product to the next have serious implications. Wide variation in the types of *nanoproducts* on the market (e.g., teddy bears and computers), in the types of *engineered nanomaterials* used to make these products (e.g., carbon, silver, titanium dioxide) and in the locations *where*

nanoproducts are manufactured (40 percent imported into the United States) creates a daunting regulatory task.

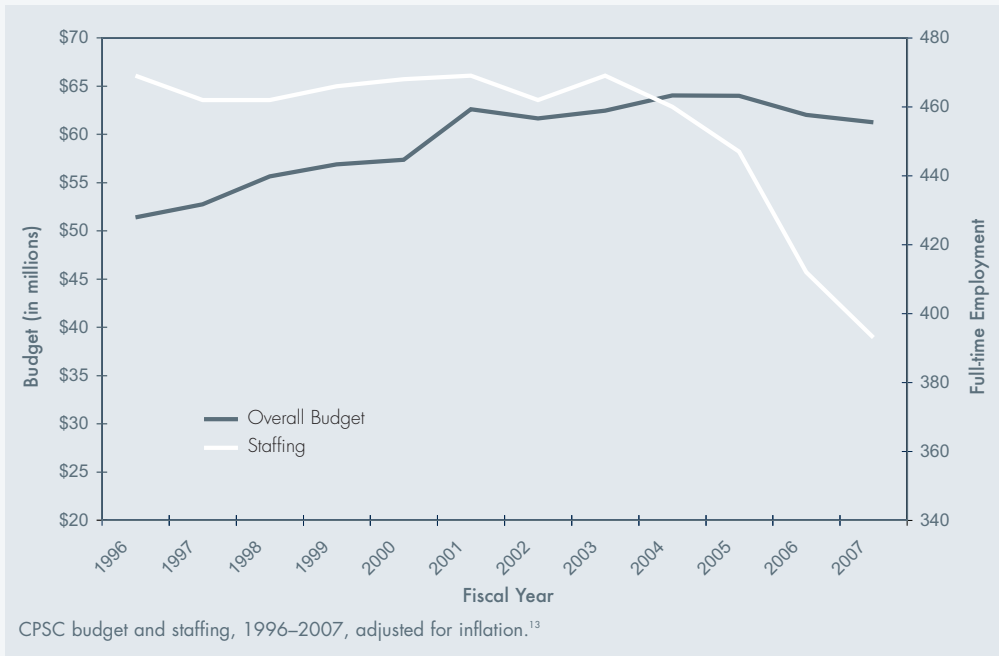
In 2007, when tens of millions of toys were recalled for being covered with a substance that CPSC had banned from children’s products 30 years earlier—lead paint—Congress turned its oversight attention to CPSC. What emerged from a series of U.S. House of Representatives and Senate hearings was a picture of an agency that had been crippled by deep budget cuts during President Ronald Reagan’s administration and subsequently neglected for the next 25 years. CPSC’s 2007 budget, \$63 million, was 40 percent less than what it had been in 1974, adjusting for inflation, and its staff, which had peaked in 1981 at 900 employees, was down to 393.¹¹

The U.S. Food and Drug Administration (FDA) has pre-market testing authority for drugs and medical devices; CPSC has no such authority. Manufacturers of CPSC-regulated

products are not required to safety test their products before they are sold in the United States; the agency’s method of regulation is largely post hoc. “We do not have the luxury of getting ahead of a problem,” CPSC Commissioner Thomas H. Moore told a Senate subcommittee in 2007. “We have to wait until one develops and then try to solve it, usually after it has killed or injured consumers.”¹⁴

Lacking the authority to safety test products before they reach the market, CPSC relies heavily on manufacturers to test their own products, and, if a problem surfaces after the goods are in stores, to obey the law that requires companies to self-report product hazards and defects within 24 hours. There is ample evidence that companies do not take either of these responsibilities seriously. A 2007 study by Canadian business school professors Hari Babuji and Paul W. Beamish found that close to 70 percent of the toy recalls in 2006 were due to design flaws as opposed to manu-

FIGURE 4. CPSC Budget and Staffing, 1996–2007



facturing mistakes (e.g. lead paint)—hazards that should have surfaced during pre-market safety testing.¹⁵ And a recent study by Public Citizen revealed that companies often wait *years* to report hazards to CPSC.¹⁶

The congressional hearings of 2007 also pointed out the importance of political will in carrying out CPSC's mandate. Twice in recent years, much of CPSC's work has come to a halt as a result of President George W. Bush letting the agency languish with only two commissioners (one short of the three needed for a quorum). When Bush appointed an interim acting chairman, she opposed legislation intended to strengthen the agency. "I'm not trying to fight with you," Senator Mark Pryor (D-Ark.) told the acting chairman during the Senate subcommittee hearings. "I'm trying to get you more money."¹⁷ ¹⁸

During this same time, CPSC career staff morale plummeted and many, including some of its most experienced scientists, left the agency. In December 2007, Robin Ingle, a well-respected statistician who had worked at CPSC for a dozen years, made the painful decision to leave her job after the agency's general counsel (a political appointee) pressured her to change language in a report she had written on all-terrain vehicles (ATVs), a product associated with the deaths of about 800 people each year—a quarter of them children. The general counsel, a former defense lawyer for the ATV industry, asked Ingle to write that ATV-related deaths were *decreasing*, even though her data showed that the number of deaths was not only higher than it had ever been in the 20 years CPSC had been keeping track of such events but also increasing at an alarmingly high rate. Rather than change her report, Ingle quit and wrote an

op-ed in the *Washington Post* detailing the many ways political appointees were muzzleing CPSC scientists. "The agency should listen to its own scientists" "and stop silencing the life-saving research happening in its buildings," Ingle wrote.¹⁹

Going forward, these constraints will severely limit CPSC's ability to effectively regulate products that incorporate nanotechnology or some future technology that scientists and engineers may develop in the coming decades.

What follows in this report is a brief history of CPSC, with a focus on the tools granted to the agency by Congress. Following this, challenges regulators have faced in implementing Congress' plan over the past 35 years will be identified and illustrated through a case study. These constraints have prevented the agency from carrying out its original congressional mandate—to *protect Americans from unreasonable risks associated with consumer products*.

CPSC: HISTORY AND HOPE

Before 1960, the U.S. government's response to regulating product safety was tragedy driven, product specific, and non-systematic. The Refrigerator Safety Act of 1956 and the Flammable Products Act of 1953, passed in response to widely publicized stories of flammable sweaters and children's cowboy chaps, are representative of legislation during this era. In the mid-1960s, Senate Commerce Committee staff began to push for broad-based legislation that would cover an extensive list of consumer products. In 1967, a joint resolution of Congress created the National Commission on Product Safety (NCPS), a bipartisan effort to assess the impact of product-related injuries in the United States.

In its 1970 Final Report, the NCPS concluded that American consumers were unnecessarily exposed to unacceptably high levels of risk associated with common household products like hair dryers (asbestos), toys (small parts), cribs (strangulation) and home appliances (fire).²⁰ The report prompted Congress to evaluate a number of solutions, among them an expansion of FDA's authority to regulate all household products and the creation of an omnibus agency that would subsume FDA and also oversee household products. In a joint conference, the House and Senate ultimately passed a bill in 1971 that left food and drugs largely under the jurisdiction of FDA and placed 15,000 other consumer products under the control of a new product safety agency.

In 1972, Congress passed, and President Richard Nixon signed, the Consumer Product Safety Act, creating CPSC.²¹ Congress also transferred the Federal Hazardous Substances Act and the Poison Prevention Packing Act to CPSC for enforcement, which gave the agency authority mainly in the ability to require child-proof packing and hazard warning labels. CPSC was to be headed by five commissioners appointed by the president of the United States. Each commissioner would serve a seven-year, staggered term. Three commissioners were required to form a quorum.²² The president would designate one commissioner to be chairperson. Of the five commissioners, no more than three were to be affiliated with the same political party.

CPSC's mandate was, and remains, far-reaching with respect to both the number of products under its jurisdiction and the regulatory tools granted to it by Congress. The agency was originally imbued with the power to:

- collect and maintain a national database of product-related injuries and deaths;
- disseminate product safety news to the public;
- recall dangerous products from the marketplace;
- levy civil penalties against companies that fail to report product defects and hazards to the agency; and
- create safety (performance) standards for products and ban any product that is too dangerous to be made safe by a standard.

While the Consumer Product Safety Act of 1972 was drawn largely from sample legislation drafted by the National Commission on Product Safety in its 1970 Final Report, legislators cut a key provision before signing off on the act. The provision in question was section 11, which would have given CPSC the authority to promulgate safety standards for "new" consumer products for which there is little or no research available regarding safety. In writing this provision, CPSC's architects were anticipating the day when CPSA statutes would fall short of giving the agency the authority to adequately oversee the safety of new, high-tech, scientifically complex products. Fearing the provision would give the agency too much authority, legislators did away with it.

CPSC opened its doors for business with an annual budget of \$34.7 million and a staff of 786.²³ By 1977, both its budget and staff had increased, but the agency was still, by far, the smallest federal health and safety agency in the nation (see Table 1).

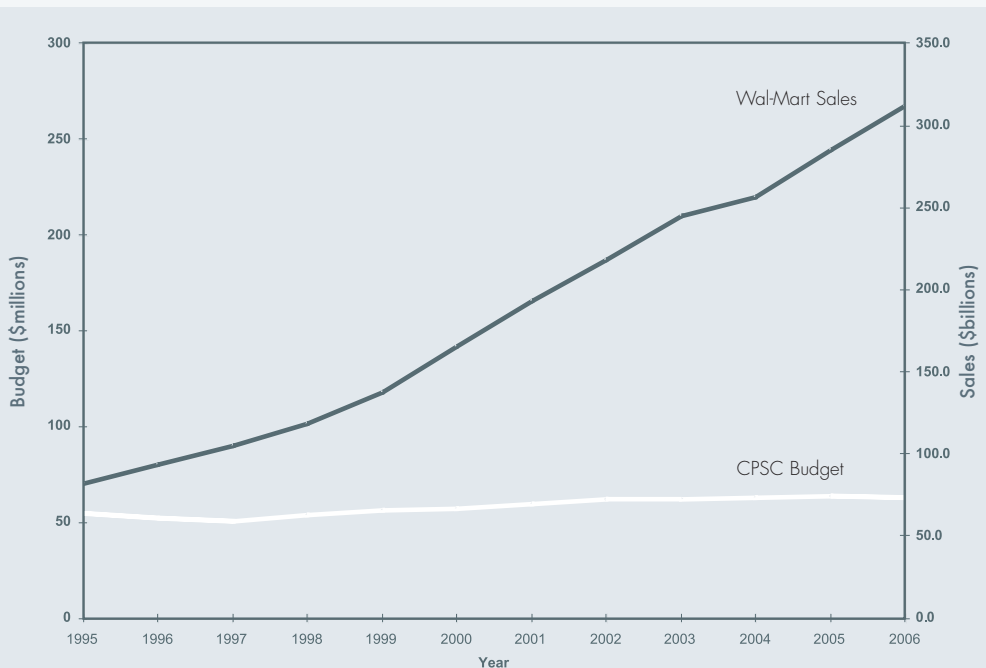
TABLE 1. 1977 Budget and Staff Figures for Various Government Agencies³⁴

AGENCY	1977 BUDGET	1977 STAFF
CPSC	\$39 million	900
FDA	\$276 million	7,500
Occupational Safety and Health Administration	\$130 million	2,700
Environmental Protection Agency	\$1 billion	10,200

CPSC: THE REALITY

Although initially hailed as “the most powerful federal regulatory agency ever created,” CPSC has never lived up to its expectations.²⁵ Early on, commissioners had tough choices to make with respect to how they would allocate agency resources—specifically, which product risks they would mitigate and how. Their choices were to utilize recalls, which affected a single product (e.g., Thomas the Tank Engine toy

trains), or safety standards, which affected many products within an industry (e.g., lead paint banned from all toys). The commissioners chose to focus on safety standards, which turned out to be a strategic mistake. Standards development usurped an inordinate amount of staff time and took years to complete, and CPSC consequently had too little to show for its efforts. During its first five years, the agency produced only three safety standards; moreover,

FIGURE 5. CPSC Budget and Wal-Mart Sales, 1995–2006.

CPSC Budget and Wal-Mart Sales, 1995–2006.²⁸

those standards covered products that CPSC critics complained presented trivial hazards: architectural glass, matchbook covers and swimming pool sliding boards. CPSC became an easy target for politicians eager to demonstrate their distaste for government waste, and the agency was nearly abolished by President Jimmy Carter and, a few years later, by President Ronald Reagan.

When Reagan left office in 1988, the agency's budget had decreased by \$7.4 million, back to its 1973 level, and staff had been reduced by 40 percent. The agency's authority to impose mandatory safety standards on products had been eroded, as had its ability to make public announcements about dangerous products.

Over the next 20 years, CPSC was largely ignored by both the White House and Congress. In 1994, President Clinton sent a mixed message to the agency when he appointed a highly respected consumer advocate as chairman and then signed off on a congressionally proposed budget cut.

During the first decade of the 21st century, structural changes in the marketplace have created an enormous resource imbalance between CPSC and the industries it regulates, making it more difficult than ever for the agency to keep up with consumer demand for goods. In 1999, the baby-equipment industry (high chairs, pacifiers, baby bottles, teething rings, etc.) reported sales of \$4 billion; in 2005, sales were up to \$7.3 billion.²⁶ Mega-retailers, where most CPSC-regulated products are sold, were pursuing aggressive growth strategies, insisting their suppliers cut costs and provide cheaper goods. In 1997, Wal-Mart had sales of about \$100 billion; by 2007, its sales exceeded \$340 billion.²⁷

As retailers expanded their reach, manufacturers deepened their supply chains. Mom-and-pop stores were becoming increasingly rare, as were small, privately owned, U.S.-based manufacturers who bought their raw materials from only a handful of local suppliers. In 2006, Chinese imports accounted for 86 percent of the toys sold in America. Mattel, the world's largest toy company, made its toys in four Chinese factories, which, in turn, were supplied by 3,000 subcontractors.²⁹

In short, the marketplace is considerably more crowded and complex today than it was in 1972 when Congress charged CPSC with the task of protecting Americans from dangerous products. To say that CPSC's budget and authority have not kept up with these changes is a gross understatement.

FIVE GENERIC WEAKNESSES IN CPSC'S PRODUCT OVERSIGHT CAPACITY

The weaknesses in CPSC's product oversight capacity are not unique to Stand 'n Seal and can be linked to the erosion of CPSC's budget and authority. The weaknesses have broad implications for the agency's ability to address any products using nanotechnologies.

1. CPSC'S DATA COLLECTION SYSTEM IS NOT NANO READY.

Congress imbued CPSC with one significant non-regulatory responsibility—the creation of a National Injury Information Clearinghouse to “collect, investigate, analyze, and disseminate product-related injuries.”³⁰ The agency's main source of information about product-related injuries is its hospital reporting system. At emergency rooms across the country, CPSC has trained hospital staff who collect data on emer-

CASE STUDY: STAND 'N SEAL'

by E. Marla Flecher

The following case study shows how CPSC's insufficient budget and authority prevent the agency from fully carrying out its mission. The subject of this case, an aerosol spray product called Stand 'n Seal, did not contain nanomaterials. Nonetheless, the Stand 'n Seal recall provides an apt test case to evaluate CPSC's readiness to regulate nanoproducts because, like nanoproducts, Stand 'n Seal contained a chemical ingredient that required sophisticated laboratory equipment and expertise to detect and evaluate for safety—equipment and expertise the agency lacks. In one important respect, however, overseeing the safety of Stand 'n Seal was an easier task for CPSC than overseeing the safety of nanoproducts because the hazards associated with Stand 'n Seal's ingredients are well documented and acute, while little is known about the acute or chronic health risks associated with nanoproducts.

Stand 'n Seal was a do-it-yourself aerosol spray used to seal grout around tiles in bathrooms and kitchens. It was sold only in Home Depot stores, beginning in late 2003.

In the spring of 2005, consumers started calling poison control centers, CPSC and the Stand 'n Seal 24-hour hotline to report that they had gotten sick after using the product. Many required hospitalization after experiencing dizziness, shortness of breath, vomiting and foaming at the mouth. Some suffered extensive lung damage and spent days in intensive care.

Neither CPSC nor Stand 'n Seal manufacturer, Roanoke Companies, followed up on the dozens of consumer complaints. Roanoke's chief executive officer instructed an employee staffing the company's hotline not to disclose to those calling that others had called with similar complaints because he did not want to "cause unnecessary public concern."

In mid-June 2005, a doctor from the Denver-based Rocky Mountain Poison and Drug Center, who had been fielding calls from emergency room doctors treating Stand 'n Seal-related injuries, called Roanoke to say that he planned to report the product's hazard to

CPSC regulators. The doctor's call prompted Roanoke to contact CPSC.

The Consumer Product Safety Act required Roanoke to notify regulators within 24 hours of discovering that its product may have presented a safety hazard. Roanoke had waited about three weeks.

Roanoke and CPSC jointly recalled Stand 'n Seal on August 31, 2005, nearly three months after the company first learned its product was making people sick. During this time, dozens of people became ill and two died. The recall notice reported that 88 consumers had experienced "adverse reactions" after using Stand 'n Seal, including 28 "confirmed reports of over-exposure." Consumers who had bought the \$10 product were instructed to return it to Home Depot for a refund.

As it turned out, one of Roanoke's suppliers had replaced a Stand 'n Seal ingredient, DuPont chemical Zonyl 225, with Flexipel S-22WS, which was made by a smaller manufacturer. Initially, Roanoke did not know about the switch. But when the company found out, it did not tell anyone that the safety sheet accompanying Flexipel S-22WS warned that the chemical should not be used in an aerosol can because it could cause serious respiratory illness, even if used in a well-ventilated room.

After the August recall, Roanoke assured CPSC that it had fixed the problem. The company shipped replacement batches of Stand 'n Seal to Home Depot stores. Regulators had to trust that the new Stand 'n Seal shipments were safe; the agency did not own laboratory equipment that could identify the chemicals in the product.

CPSC's trust was misplaced. Rather than remove the hazardous Flexipel S-22WS from the product, Roanoke simply added a substance that gave the aerosol spray a stronger odor, intended to signal to users that they should use it in a well-ventilated area.

The number of people sickened by Stand 'n Seal after the recall is unknown; Roanoke will not disclose this information, and CPSC is prohibited from disclosing it unless Roanoke gives regulators permission to do so.

* Sources:

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gency room visits for product-related injuries. The information is stored in CPSC's National Electronic Injury Surveillance System (NEISS) database. CPSC augments its emergency room data with coroners' reports, insurance investigations, reports of lawsuits, fire investigations and consumer calls to its own hotline.

In 1997, the Government Accounting Office (GAO) concluded that CPSC was doing a poor job of keeping track of product-related injuries. Specifically, the NEISS database "underestimate(d) the total number of deaths and injuries with any given consumer product. The extent of this undercounting is unknown."³¹ GAO investigators reached this conclusion after learning that the agency based its injury estimates on data reported from only 101 hospitals. Today, there are only 96 hospitals in CPSC's sample.³²

A small sample size is not necessarily a fatal shortcoming of the NEISS system, as its primary function is to help CPSC staff identify patterns of hazards as they emerge and before too many people are injured. But, as the Stand 'n Seal case demonstrated, the agency does not monitor the NEISS data closely and it does not always follow up calls and reports, even when multiple sources implicate the same product as being responsible for dozens of serious injuries.

Another shortcoming of CPSC's reporting system, the one that is perhaps most relevant to its oversight of nanoproducts, is that NEISS captures only injuries caused by acute hazards. Chronic hazards are not reported. If Flexipel S-22WS, the hazardous chemical in Stand 'n Seal, did not sicken users immediately and instead caused injuries in the long term (as lead does), CPSC would not have recalled it because the agency would likely have not known about it. CPSC does not have the staff or expertise to systematically track injuries caused by most chronic hazards.

During the summer of 2007, when CPSC recalled tens of millions of Thomas the Tank Engine trains, Sesame Street figures and other toys because they were covered with lead paint, each of the dozens of recall press releases stated that no injuries had been reported. Failing to collect data on a hazard, of course, does not eliminate the hazard.

Lesson 1: The current NEISS system significantly underestimates acute, product-related injuries and deaths and is ill-equipped to capture information on injuries and deaths caused by chronic hazards.

2. CPSC HAS LIMITED ABILITY TO TELL THE PUBLIC ABOUT HEALTH HAZARDS ASSOCIATED WITH NANOPRODUCTS.

While the Consumer Product Safety Act requires CPSC to collect and disseminate product-related safety information to the public, section 6(b) of the act, strengthened in a 1981 amendment, limits the agency's ability to carry out this responsibility.³³ Since 1981, CPSC has been prohibited from releasing to the public *any* information that identifies a brand or manufacturer by name, without first getting the company's permission to do so. In other words, before Stand 'n Seal was recalled, if a doctor calling CPSC to report an injury had asked if other injuries had been reported, regulators would not have been permitted to answer the question.

Similarly, the manufacturer must approve every word regulators use in any press release that announces a recall to the public. The recall notice for Stand 'n Seal, negotiated between Roanoke lawyers and CPSC, did not report that the product had sent multiple consumers to intensive care, nor did it disclose that two persons had died. It said only that

“overexposure” to the fumes could result in “respiratory-related illness.”³⁴

CPSC did not issue a second recall notice when it learned that the product shipped to Home Depot to replace the recalled cans also contained Flexipel S-22WS. Consumers who bought the product had no way of knowing that it was dangerous—unless they used it and got sick.

Lesson 2: Which product-hazard information CPSC discloses to the public, and when, is strongly influenced by the product’s manufacturer. Press releases announcing product recalls sometimes trivialize or fail to reveal the true extent of the danger.

3. CPSC HAS LIMITED ABILITY TO GET RECALLED NANOPRODUCTS OUT OF USE.

Recalls are voluntary agreements negotiated between CPSC and a manufacturer or distributor that require the company to take a hazardous product out of the stream of commerce and to notify consumers who already own the product to stop using it. When a company agrees to a recall, it first notifies retailers to take the product off their store shelves. With fewer than 100 field investigators to monitor hundreds of thousands of stores where products under CPSC’s jurisdiction are sold (e.g., there are more than 2,000 Home Depot stores and about 4,000 Wal-Marts in the United States), CPSC must take retailers’ word that they have removed a recalled product from their stores.³⁵

During 2007 congressional hearings, it was revealed that retailers sometimes continue to sell products long after they have been deemed dangerous.³⁶ For example, the Illinois Attorney General’s office found 15 stores selling a toy more than a year after CPSC had recalled it.³⁷

The toy had killed a child and sent dozens to the hospital for emergency surgery.

In addition, a number of tests indicated that children’s products with hazardous levels of lead were found in stores months after they had been recalled. In November 2007, California sued Wal-Mart and 19 other manufacturers and retailers for selling toys covered with lead paint.³⁸

Reaching consumers with recall news is more difficult than reaching retailers. CPSC notifies the public about recalls via press releases issued to the media. Whether or not a newspaper or television station reports a recall story is hit or miss; CPSC does not have the authority to require the media to report it. The agency does have the authority to require companies to use more effective notification techniques, such as direct mail notices and paid advertising, but it rarely uses this authority. As a result, injuries and deaths can, and do, occur *years* after a product has been recalled, as was the case with Stand ‘n Seal.

Lesson 3: If a nanoproduct is recalled because it presents an acute hazard, CPSC can ask the company to notify consumers in a number of ways. The notification technique most commonly used is a press release issued to the media, which may or may not result in the public learning about the hazard. If a nanoproduct presents a chronic hazard, CPSC is unlikely to detect a problem and therefore unlikely to recall it.

4. CPSC LACKS SUFFICIENT ENFORCEMENT STAFF TO IDENTIFY MANUFACTURERS THAT FAIL TO REPORT NANOPRODUCT HAZARDS.

Section 15(b) of the Consumer Product Safety Act requires a manufacturer to notify regulators immediately if it suspects a product “creates an

unreasonable risk of serious injury or death.”³⁹ The agency interprets “immediately” to mean within 24 hours. Congress enacted this statute with the aim of placing the burden of hazard identification on companies, rather than on regulators. Manufacturers, Congress reasoned, are likely to learn that one of their products is hazardous before CPSC is privy to this information. This was the case with Stand ‘n Seal.

In 1994, *Consumer Reports* magazine noted that the law is often ignored, and, when it is, “few scofflaws are ever punished” for hiding product hazards.⁴⁰

A 2008 study by the non-profit advocacy group Public Citizen found that between 2002 and 2007, companies took an average of 993 days—*almost three years*—to notify CPSC of a known product defect.⁴¹ Roanoke waited weeks to report the Stand ‘n Seal hazard.

CPSC has had the authority to levy a civil penalty of up to \$1.8 million on a company for failing to self-report a hazard. The Consumer Product Safety Improvement Act of 2008 (passed by the House and Senate and signed by President George W. Bush on August 14, 2008), raises the penalty to \$15 million, an amount most legislators believe is necessary to compel companies to obey the hazard self-report law.⁴²

As of August 2008, CPSC had not fined Roanoke for failing to report the Stand ‘n Seal hazard in 2005.

Lesson 4: CPSC does not have enough staff to discover nanoproduct hazards on its own or to identify companies that flout the hazard self-report law.

5. CPSC DOES NOT HAVE SUFFICIENT AUTHORITY TO PROMULGATE MANDATORY SAFETY STANDARDS FOR NANOPRODUCTS.

Congress originally imbued CPSC with the power to impose mandatory safety standards on products. Regulators would develop the standard, and manufacturers would be prohibited from selling products that did not comply with it. Attached to this authority, however, were onerous procedural requirements that made the mandatory standard-setting process cumbersome and resource consuming.

In 1982, Congress passed and President Ronald Reagan signed an amendment to the Consumer Product Safety Act that *prohibited* the agency from promulgating a mandatory standard if a voluntary safety standard would “eliminate or adequately reduce the risk of injury and it [was] likely there [would] be substantial compliance with the voluntary standard.”⁴³ Today, CPSC rarely promulgates mandatory safety standards; voluntary standards are the norm.

Voluntary safety standards differ from mandatory standards in two important respects. First, industry, not CPSC, decides which hazards will be addressed, which will be ignored and, ultimately, what it means for a product to be “safe enough.” Second, the individual manufacturer can decide whether or not to comply with a voluntary standard. Consumers often have no way of knowing whether or not a product they buy complies with a safety standard.

There are many advantages to voluntary standards: manufacturers have product-specific expertise that regulators rarely possess, the standards can be faster to implement than a government-initiated mandatory standard and, most important, industry, not the resource-stretched CPSC, does the bulk of the work. And yet, as early as 1970, the National Commission on Product Safety warned against CPSC relying too heavily on voluntary safety standards to

keep consumers safe, noting that such standards tended to be “chronically inadequate, both in scope and permissible levels of risk.”⁴⁴

Today, dozens of products are covered by voluntary standards, among them gas grills, baby walkers, high chairs, lawnmowers and smoke detectors (see Appendix 1 for a full list). Some products, like baby bath seats, a product used to bathe an infant in an adult-sized bathtub, can be on the market for years before industry develops a safety standard for them. During this time, consumers use the product, unaware of its hazards and, in the case of bath seats, unaware that dozens of infants have drowned while using it (see Appendix 2). Other products can be on the

market indefinitely without a safety standard. For example, there are no mandatory or voluntary safety standards for many nanoproducts on the market, including baby bottle brushes, infant teething rings and pacifiers. Nanoproducts such as appliances, for which voluntary standards do exist, address the safety of electrical components but not the nanomaterials used to make them.

Lesson 5: Given the variety of nanoproducts and the wide range of nanomaterials used to make them, it is likely that many nanoproducts will be on the market for years before industry even begins to develop safety standards that will address their safety.

ANALYSIS OF CPSC'S TOOLS FOR REGULATING NANOPRODUCTS

This section provides an analysis of CPSC's tools for regulating nanoproducts. It is organized around the three statutes that give the agency authority to regulate nanoproducts: the Consumer Product Safety Act, the Federal Hazardous Substances Act and the Poison Prevention Packaging Act. Each act gives CPSC limited authority to regulate specific aspects of nanoproducts.

CONSUMER PRODUCT SAFETY ACT

Because CPSC does not have pre-market testing authority, its efforts to protect consumers from unsafe products must be largely post hoc. If a nanoproduct is found to present an acute hazard after it is sold, the agency can recall it. In this respect, CPSC treats nanoproducts no differently than it treats other products under its jurisdiction.

CPSC does have two important pre-emptive regulatory tools that give it limited authority to influence the safety of products before they reach the market: (1) the power to promulgate mandatory safety standards; and (2) the authority to ban products that are too dangerous to be made safe by a standard.

Mandatory Safety Standards: Acute Hazards

A mandatory safety standard requires that a product conform to certain "performance" standards, but it may not stipulate how a manufacturer is to design that product. For example, a mandatory safety standard could require a manufacturer to ensure that nanomaterials do not leach out of a baby bottle nipple when an infant sucks on it, but the standard could not

dictate exactly how the manufacturer should achieve this.

Manufacturers, not regulators, are responsible for testing their products and for making sure they conform to any relevant mandatory standard. CPSC does not typically see the results of these tests unless the agency is considering a recall, in which case regulators request the information. If the company refuses to release it, CPSC can issue a subpoena to get it. Companies are also prohibited from selling products that do not comply with a mandatory standard, but it is only after the non-conforming product is sold and in use that CPSC can step in and recall it. Most mandatory standards address acute, rather than chronic, hazards.⁴⁵

CPSC regulators typically take a "carrot-and-stick" approach to mandatory-standard rule making. CPSC offers manufacturers the carrot of writing their own voluntary standard; if they come up with a standard the commission does not like, the agency can pull out the rule-making stick. However, for the stick to be effective, industry must genuinely believe that the CPSC commissioners will follow through and promulgate a final rule. During the administration of President George W. Bush, manufacturers have had little incentive to write stringent voluntary standards, knowing the agency has not been interested in promulgating mandatory standards.⁴⁶

Mandatory Standards and Product Bans: Chronic Hazards

The Consumer Product Safety Act prohibits CPSC from promulgating a product safety rule

(either a mandatory safety standard or an outright product ban) “relating to a risk of cancer, birth defects, or gene mutations from a consumer product,”⁴⁷ until a Chronic Hazard Advisory Panel (CHAP) determines the risk involved from exposure to the product. CPSC commissioners appoint seven people to serve on a CHAP; the participants are chosen from a list of experts nominated by the National Academy of Sciences.

CPSC has convened CHAPs only a handful of times; the process is cumbersome and expensive (CPSC is responsible for paying the scientists on the panel) and therefore usurps valuable staff time and money from the chronically resource-strapped agency. CPSC has used CHAPs to assess the chronic hazards associated with consumer products that contain formaldehyde, asbestos and phthalates, a class of chemicals used frequently in plastic children’s products.

CPSC’s interest in the toxicity of phthalates, beginning in the 1980s and continuing today, has much to teach us about the process the agency will undergo and the hurdles it will encounter if it chooses this route to regulate nanoproducts. There are a number of broad similarities between phthalates and nanomaterials:

- Many types of phthalates (DINP, DEHP, etc.) are used to make diverse types of products (baby bottle nipples, rubber ducks, Barbie dolls, etc.), just as many types of nanomaterials (nanosilver, nanocarbon, etc.) are used to make diverse types of nanoproducts (teddy bears, tennis racquets, etc.).
- The same products that contain phthalates are now being made with nanomaterials (e.g., infants’ pacifiers and teething rings).

- Both phthalates and nanomaterials can enter the human body through multiple pathways, such as the lungs or digestive tract.
- Jurisdiction over phthalates in the United States, like jurisdiction over nanomaterials, is spread over multiple agencies. The U.S. Environmental Protection Agency regulates phthalates that are released into the environment, the FDA is responsible for phthalates used in medical devices, the National Institute of Occupational Safety and Health is responsible for exposure to phthalates in the workplace and CPSC regulates consumer products that contain phthalates.

Despite these similarities, phthalates and nanomaterials differ in two important respects. First, phthalates have been the subject of thousands of scientific studies documenting their effect on the health of animals and humans—some demonstrating a link between the chemicals and decreased sperm count and sexual malformation in boys—while little is known about the chronic hazards associated with nanomaterials. Second, nanomaterials are scientifically far more diverse than phthalates, increasing the complexity involved in understanding their toxicology. The CPSC does not have the authority to require manufacturers to conduct scientific research to determine whether or not a specific nanomaterial is hazardous or safe.

Should researchers find a link between nanoproducts and adverse chronic health effects, CPSC may nonetheless disregard it. The thousands of studies conducted on phthalates, mostly by American scientists and funded largely by the U.S. government, led 11 consumer advocacy groups to petition

CPSC in 1998 to ban the chemical from children's products. Two years later, CPSC convened a CHAP to study the toxicity of one type of phthalate, DINP. In 2001, the CHAP concluded that "there may be a risk for any young children who routinely mouth DINP-plasticized toys for 75-minutes per day or more."⁴⁸ In 2002, CPSC concluded that the risk was not serious enough to deem DINP hazardous to children, and the petition for a phthalate ban was denied. The European Union banned phthalates in children's products in 1999. The Consumer Product Safety Improvement Act of 2008 bans children's products containing three types of phthalates, DEHP, DBP, and BBP, but not DINP.

Given the dearth of scientific evidence on the effects of nanomaterials on human health, it is unlikely that a CPSC-convened CHAP will have sufficient evidence to conclude, especially in the near future, that any nanomaterial presents a substantial risk to human health. Without such a finding, the agency is unable to promulgate a mandatory safety standard or a ban.

THE FEDERAL HAZARDOUS SUBSTANCES ACT: LABELING AND BANS

The 1960 Federal Hazardous Substances Act requires that "hazardous substances" be labeled if they are toxic and intended to be used in a household or by children. The act defines "toxic" as any substance (other than a radioactive substance) which has "the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface."⁴⁹ It covers both acute and chronic toxicants (e.g., carcinogens, neurotoxins).

Because CPSC does not have the authority to test products prior to marketing to determine whether or not they are toxic, it is the manufacturer's responsibility to make this determination for its own products. Although the agency does not stipulate the exact hazard label wording, the outer wrap of the product must contain information such as the name and address of the manufacturer; the chemical name of the hazardous ingredient; and the words "Danger," "Caution" or "Warning," depending on the level and type of toxin. Products that contain carbon tetrachloride, cyanide salts, vinyl chloride and lead paint are among those that have been banned.

If future research indicates that a nanoproduct under CPSC's jurisdiction is toxic, that product will be required to comply with Federal Hazardous Substances Act labeling requirements. If a label will not adequately protect consumers from the hazard, the nanoproduct can be banned.⁵⁰

POISON PREVENTION PACKAGING ACT

The Poison Prevention Packaging Act gives CPSC the authority to initiate rule making to require child-resistant packaging for hazardous household substances.⁵¹ Its goal is to protect children under five years old from being injured or killed when they open containers of hazardous products and then eat or drink the contents. Among the dozens of products for which CPSC currently requires child-resistant packing are furniture polish, lighter fluid, paint solvent, liquid glue remover, mouthwash, aspirin and prescription drugs.

A nanoproduct would have to be deemed hazardous to children before it would be subject to packaging rules under the Poison Prevention Packaging Act.

CONGRESS' ROLE IN CONSUMER PRODUCT SAFETY

If Congress determines that CPSC is not addressing a product hazard or is doing so too slowly, legislators can take the matter into their own hands. For example, in 1988, Congress voted to ban lawn darts, a toy that had seriously injured children when it punctured their skulls. Until that time, CPSC had required manufacturers to warn of lawn darts' dangers through a label, as specified by the Federal Hazardous Substances Act. When legislators learned that children continued to be seriously injured by the toy, they intervened and ordered CPSC to ban it.

More recently, Congress has attempted to strengthen CPSC legislatively with the Consumer Product Safety Improvement Act. Lawmakers were motivated to act after tens of millions of children's products were recalled during the summer of 2007 and media attention revealed an agency that was underfunded, understaffed and overwhelmed by its mandate. The legislation addresses nanotechnology directly, by allocating \$1 million to study the safety of nanoproducts. Other provisions of the bill, which was approved by a conference committee of House and Senate leaders on July 28, 2008 (and signed by President George W. Bush on August 14, 2008) will indirectly bolster the agency's ability to address nanoproduct safety:

Budget: Authorizes a budget of \$118 million for FY 2010, gradually increasing to \$136 million by 2014.⁵² Congress must approve these numbers via their appropriations process each year.

Testing: Requires third-party safety certification of children's products.⁵³

Recalls: Requires manufacturers to label children's products with tracking information so that they can be identified if recalled. Retailers will be prohibited from selling recalled products.

Subcontractors: Requires companies to identify all subcontractors in their supply chains.

Quorum: Restores CPSC to five commissioners to prevent future absences of quorum.

Public Information: Establishes a public database that includes reports of injuries, illness and death, complete with brand and product names.

Fines: Increases the upper limit of the penalty for failing to disclose a product hazard from \$1.8 million to \$15 million.

Attorneys General: Allows states greater leeway in enforcing federal product safety laws.

Rule Making: Simplifies rule making from its current three-step process to a two-step process.

Staffing: Increases CPSC staff to at least 500, with no less than 50 inspectors stationed at ports of entry.

RECOMMENDATIONS

WHAT CPSC SHOULD DO

Build the agency's nanotechnology knowledge base and expertise. There has been a brain drain of scientists from CPSC. First and foremost, the agency must hire scientists with the expertise to evaluate nanotechnology research and products.

Identify companies and industries that are currently manufacturing nanoproducts and request that they submit research studies, risk assessment data and any information they hold that will enable CPSC scientists to assess the safety of nanoproducts. The Consumer Product Safety Act gives CPSC general investigative authority, as well as the authority to issue subpoenas in order to compel uncooperative companies to submit relevant safety information.

Coordinate with other health and safety agencies, and combine efforts to evaluate the risks associated with nanoproducts. Most of the tools that give the agency the authority to regulate nanoproducts require documentation that the nanoproducts present a chronic risk. Given its budget constraints, CPSC will never have the resources or expertise to fully evaluate the chronic hazards associated with nanoproducts. This expertise exists at other agencies, most notably EPA and FDA.

Convene a CHAP to evaluate the health and safety risks associated with nanoproducts currently on the market that are intended for use by children. CPSC has a long history of putting the safety of children first, by allocating a disproportionate amount of its scant resources to regulating children's products (i.e., rule making and recalls). This

should be the case with nanoproducts, especially those already on the market, such as pacifiers and teething rings, that expose infants to untested nanomaterials directly and for hours each day.

Appeal to industry to begin work on voluntary safety standards for the most prevalent nanoproducts currently on the market and those that are intended for use by children. In 2004, the American National Standards Institute (ANSI), a standards-development organization, created an ANSI-Nanotechnology Standards Panel. The goal of this panel is to "provide a framework within which stakeholders can work cooperatively to promote, accelerate and coordinate the timely development of voluntary consensus standards..."⁵⁴ CPSC should set priorities with respect to which specific nanoproducts the panel should address.

WHAT CONGRESS SHOULD DO

Amend the Consumer Product Safety Act to give CPSC the authority to require manufacturers to identify the presence of nanomaterials in their products. CPSC has the authority, under the Federal Hazardous Substances Act, to require warning labels on products that contain hazardous substances. However, a product must be deemed toxic before such a label can be required. Given the dearth of data on the risks associated with nanomaterials, it is not likely that toxicity data will be forthcoming any time soon. In the meantime, consumers should have the right to know if the products they buy, particularly those used by their infants and children, contain untested nanomaterials.

Adopt Section 11 of the Consumer Product Safety Act bill recommended to Congress by the NCPS in its 1970 Final Report, which would give CPSC the authority to promulgate safety standards for any “new” consumer products based on new and emerging technologies, like nanotechnology—specifically products where “there exists a

lack of information adequate to determine the safety of such product in use by consumers”⁵⁵ (see Appendix 3). Empowering CPSC with this authority would give the agency the tools it needs to oversee the safety of products that use nanomaterials, as well as new technologies that scientists and engineers may develop in the future.

APPENDIX 1: CONSUMER PRODUCTS WITH VOLUNTARY STANDARDS

(Source: <http://www.cpsc.gov/volstd/standards.html>)

Carbon Monoxide

- CO Alarms
- Gas Appliances (CO Sensors)
- Generators, Portable

Chemical

- Air Cleaners
- Child-Resistant Packaging
- Gasoline Containers, Child-Resistant.
- Lead in Children's Vinyl Products

Children's Products (Other)

- Bassinets/Cradles
- Bed Rails
- Beds
 - Bunk
 - Toddler
- Blind Cords
- Booster Seats
- Changing Tables
- Cribs
 - Commercial
 - Full Size
 - Non-Full Size and Play Yards
- Chairs
 - High
 - Youth
- Infant Bedding and Accessories
- Infant Bouncers
- Infant Carriers
 - Frame

- Handheld
- Soft
- Infant Gates
- Infant Swings
- Infant Walkers
- Playground Equipment
 - Age < 2
 - Home
 - Public
- Playground Surfacing
- Stationary Activity Centers
- Strollers
- Toys

Child Drowning

- Bath Seats
- Infant Tubs
- Pools/Hot Tubs/Spas
 - Portable Pools
 - Pool Alarms
 - Pools and Spas
 - Suction Release Devices

Electrical/Fire

- Arc-Fault Circuit Interrupters
- Batteries
- Electric Lighting
- Extension Cords
- Electric Heaters
- National Electrical Code
- Smoke Alarms

Electrocution

- Fans, Portable
- Ground-Fault Circuit Interrupters

Fire

- Cabinet Heaters/Cylinders
- Candles
- Emergency Escape Masks
- Lighters
- Sprinklers
- Turkey Fryers

Household/Recreation (Mechanical)

- All-Terrain Vehicles
- Amusement Rides, Portable
- Bicycles
- Fuel Tanks
- Furniture
- Garage Doors/Gate
- Operators
- Helmets, Recreational
- Hot Tubs and Spas
- Inflatables (Constant-Air)
- Ladders
- Mowers
- Pressure Cookers
- Ranges
- Soccer Goals
- Scooters, Motorized
- Table Saws
- Tree Stands, Hunting
- Window Guards

APPENDIX 2: A HISTORY OF THE VOLUNTARY SAFETY STANDARD FOR BABY BATH SEATS⁵⁶

Bath seats are a product designed for bathing an infant in a regular bathtub; the baby sits on a plastic seat that is affixed to the bottom of a tub with plastic suction cups. The infant's legs straddle a plastic post attached to a chest-level plastic ring that surrounds him; the baby can hold on to the ring for support. The product retails for under \$20 and is frequently found in second-hand stores for less than \$10, making it affordable for most families.

Bath seats first appeared in stores in 1981. In 1993, CPSC asked manufacturers to begin work on a voluntary standard after 14 babies had drowned while using the product and dozens more had nearly drowned. A year later, when industry had not yet come up with a voluntary standard, CPSC staff recommended that the agency move forward on a mandatory safety standard. The agency's three commissioners disagreed with CPSC staff, opting to give the industry another chance to voluntarily improve the safety of the seats.

Five years later, in 1999, manufacturers completed their voluntary safety standard, but the committee of manufacturers who had written it ignored the request of CPSC staff engineers to address the two hazards that were

most likely to cause a child to drown: (1) the suction cups that affixed the seat to the bathtub were not strong enough and often allowed the seat to tip over; and (2) the leg openings were too big, allowing the baby to slide through a single opening and drown. The voluntary standard did not address either of these design features. It called for no significant changes to bath seats already on the market.

In 2000, after 66 children had died while using bath seats, nine consumer groups filed a formal petition with CPSC asking the agency to initiate rule making on a mandatory safety standard for the product. They considered the voluntary standard too lax.⁵⁷ This time, the commissioners voted yes. When manufacturers told the agency they would strengthen the voluntary standard, regulators agreed to halt their work on a mandatory standard.

Six years later, in 2006, industry's more stringent voluntary bath seat standard went into effect. Between 2001 and 2006, another 58 children had drowned while using the seats. Today, parents and caregivers continue to use bath seats made before the voluntary standard went into effect; since 2006, two dozen additional children have died while using the seats.⁵⁸

APPENDIX 3: 1970 PROPOSED CONSUMER PRODUCT SAFETY ACT

FROM THE FINAL REPORT OF THE NATIONAL COMMISSION ON PRODUCT SAFETY, 1970

PROPOSED CONSUMER PRODUCT SAFETY ACT

NEW PRODUCTS

Section 11(a). —The Commission shall have authority to promulgate standards and procedures for the purpose of insuring that new consumer products are adequately designed and tested to minimize unreasonable risk of death or personal injury to the public.

(b). —For purposes of this section a “new consumer product” is a consumer product which incorporates a design, material, or form of energy exchange which (1) has not previously been used substantially in consumer products and (2) as to which there exists a lack of information adequate to determine the safety of such product in use by consumers.

ENDNOTES

1. According to the Project on Emerging Nanotechnologies' Consumer Products Inventory, Consumer Products Inventory, Project on Emerging Nanotechnologies, <http://www.nanotechproject.org/inventories/consumer/>.
2. More information about the NNI can be found on its website. About the NNI, National Nanotechnology Initiative, http://www.nano.gov/html/about/home_about.html.
3. M.P. McQueen, "Senate Forges Consumer-Safety Bill," *Wall Street Journal*, February 16, 2008, A3.
4. Teresa M. Schwartz, "The Consumer Product Safety Act: A Flawed Product of the Consumer Decade," *The George Washington Law Review* 51.1 (1982): 43–44.
5. Consumer Products Inventory.
6. According to Lux Research, in 2006, "worldwide investment in nanotechnology research and development reached \$11.8 billion, up 13% from 2005." Lux Research, *The Nanotech Report: Investment Overview and Market Research for Nanotechnology, 5th Edition* (2007): iii.
7. Consumer Products Inventory.
8. *Ibid.*
9. Lux, iii.
10. Thomas H. Moore, Statement Submitted to Senate Committee on Commerce, Science, and Transportation's Subcommittee on Consumer Affairs, Insurance, and Automotive Safety, Washington, DC, March 21, 2007. See <http://www.cpsc.gov/pr/moore2007.pdf>.
11. "Product Safety Regulator Hobbled by Decades of Negligence," OMBWatch, <http://www.omb-watch.org/article/articleview/4154/1/527>.
12. *Ibid.*
13. *Ibid.*
14. Moore.
15. Hari Bapuji and Paul W. Beamish, "Toy Recalls—is China Really the Problem?" *Canada-Asia Commentary* 45 (2007): 1–8.
16. Public Citizen, "Hazardous Waits: CPSC Lets Crucial Time Pass Before Warning Public About Dangerous Products," Public Citizen's Congress Watch, <http://www.citizen.org/documents/HazardousWaits.pdf>.
17. David Lazarus, "Product Safety Under Fire," *San Francisco Chronicle*, April 1, 2007, B1.
18. The position of CPSC is interesting given the recent action by FDA, whose commissioner finally went to Congress in May 2008 and requested a budget increase of \$275 million. See "Tools for the FDA: The Food and Drug Administration Finally Asks Congress for More Money," *Washington Post*, May 19, 2008, A16.
19. Robin Ingle, "Which Toys Are Okay? Don't Ask the Safety Police," *Washington Post*, December 23, 2007, B3.
20. *Final Report*, National Commission on Product Safety, 1970.
21. Consumer Product Safety Act. Pub. L 92–573, 86 Stat. 1207. 27 October 1972.
22. Under President Ronald Reagan, funding was eliminated for two of the five commissioners. No more than three commissioners have served together since this time.
23. Schwartz, 44.
24. *Ibid.*
25. *Ibid.*
26. "Juvenile Products Industry Experiences Extraordinary Sales for 2006," Juvenile Products Manufacturers Association, <http://www.jpma.org/pdfs/06IndustrySalesrsls.pdf>.
27. Based on net sales as reported in Wal-Mart's 1997 and 2007 annual reports. Reports are available at <http://walmartstores.com/Investors/7666.aspx>.
28. *Ibid.* CPSC data available at <http://www.omb-watch.org/article/articleview/4154/1/527>.
29. When one of these subcontractors used banned lead paint on millions of toys, it was overlooked by the Chinese factories that had subcontracted out the painting work, by Mattel's inspectors and by CPSC. The paint was discovered in 2007 by a French importer.

30. Robert Adler, "From 'Model Agency' to Basket Case—Can the Consumer Product Safety Commission Be Redeemed?" *Administrative Law Review* (1989): 67.
31. "Consumer Product Safety Commission: Better Data Needed to Help Identify and Analyze Potential Hazards," General Accounting Office, 1997.
32. Vicky Leonard, CPSC Technical Information Specialist, National Injury Information Clearinghouse, personal e-mail correspondence, May 22, 2007.
33. U.S.C. Sect. 2056(b) (1982).
34. News.
35. Renae Merle, "Panel Urges More Scrutiny Over Imports, Report Criticized for Lack of Concrete Proposal," *Washington Post*, September 11, 2007, D1.
36. Two weeks after 1.5 million Thomas & Friends wooden railway toys were recalled because of lead paint, Illinois investigators found they were still being sold in some Target, Kohl's, Wal-Mart and Kmart stores, as well as in the Chicago Children's Museum gift shop. See Maurice Possley, "Recalled Thomas toys in stores: State finds more unsafe pieces," *Chicago Tribune*, June 28, 2007. Magnetix magnetic building block toys were recalled on March 31, 2006, and again on April 19, 2007, after children continued to be injured, in some cases fatally, after swallowing them. On May 7, 2007, the *Chicago Tribune* reported that it had bought the recalled toys from Toys "R" Us, Walgreens, Wal-Mart and Amazon.com. See Patricia Callahan, "Inside the Botched Recall of a Dangerous Toy," *Chicago Tribune*, May 7, 2007, A1.
37. Callahan.
38. Joseph Pereira and Steve Stecklow, "Wal-Mart Raises Bar on Toy Safety," *Wall Street Journal*, May 14, 2008, B1.
39. Consumer Product Safety Act. Pub. L 92-573, 86 Stat. 1207. 27 October 1972.
40. Consumer Reports, "Product Recalls: Less Than Meets the Eye," November 1994: 732-735.
41. The data used in the Public Citizen report represents companies that were caught and subsequently fined by CPSC for violating Section 15 of the Consumer Product Safety Act, which requires them to report product hazards to the agency immediately. See Public Citizen's Congress Watch, "Hazardous Waits: CPSC Lets Crucial Time Pass Before Warning Public About Dangerous Products," Public Citizen, http://www.citizen.org/documents/Hazardous_Waits.pdf.
42. Jim Tankersley and Patricia Callahan, "Bill Targets Toy Safety," <http://www.chicagotribune.com>, July 29, 2008.
43. Robert Adler, "From 'Model Agency' to Basket Case—Can the Product Safety Commission be Redeemed?," *Administrative Law Review* 61 (1989): 98.
44. *Final Report*, National Commission on Product Safety, 1970.
45. One notable exception is the mandatory standard that prohibits lead paint on products intended for children.
46. A mandatory standard addressing mattress flammability was finalized during the George W. Bush administration; however, a preamble shielding manufacturers from future product liability lawsuits slipped into the standard at the 12th hour. Thomas Moore, the sole Democrat on the commission, has noted that the exception undermines CPSC's ability to improve mattress safety in the long run.
47. Consumer Product Safety Act. Pub. L 92-573, 86 Stat. 1207. 27 October 1972. See Section 28 on Chronic Hazard Advisory Panels.
48. "Report to the U.S. Consumer Product Safety Commission by the Chronic Hazard Advisory Panel on Diisononyl Phthalate (DINP)," U.S. Consumer Product Safety Commission, <http://www.cpsc.gov/library/foia/foia01/os/dinp.pdf>.
49. Federal Hazardous Substances Act. 15 U.S.C. 1261 and 16 C.F.R. Part 1500. 12 July 1960.
50. The only action under Federal Hazardous Substances Act that requires CPSC to convene a CHAP is rule making to ban a specific substance.

51. Poison Prevention Packaging Act. Pub L 91-601, 84 Stat. 1670. 30 December 1970.
52. "Consumer Products Safety Reform Clears Congress," OMB Watch, <http://www.ombwatch.org/article/articleview/4316>.
53. Products will be safety tested only for hazards addressed by mandatory safety standards, such as those that prohibit lead paint, small parts and sharp edges. This provision will affect nanoproducts only if CPSC first promulgates mandatory standards that address their safety.
54. Jeffrey Bromme, "Nanotechnology and the Consumer Product Safety Commission," *Product Safety & Liability Reporter* 33.11 (2005).
55. *Final Report*, National Commission on Product Safety, 1970, 12.
56. For a more complete history of bath seat rule making, excerpted here, see E. Marla Felcher, *It's No Accident: How Corporations Sell Dangerous Baby Products* (Common Courage Press, 2001), 38–42.
57. "Baby Bath Seats-Deaths Only, January 1, 1983 to February 25, 2000," CPSC files.
58. U.S. Consumer Product Safety Commission, National Injury Information Clearinghouse Report, Baby Bathtub Seats or Rings, Calendar Year 2001 to January 18, 2008.

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