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Chemicals, Products and Regulatory Failure: A Prescription for Greener Chemistry and Better Public Health

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Chances are, a parent or patient has asked you recently about the health risks from lead paint on a toy train, or from flame retardants in sofa cushions.

How do you respond? Passing it off as a Chinese toy problem is too simple, and wrong. "The real problem," says Donald Kennedy, former commissioner of the U.S. Food and Drug Administration (FDA) and current editor of Science, "is that the U.S. regulatory system for toxic industrial chemicals is not effective and is a threat to public health."

Kennedy's dire assessment is not unique. Numerous analyses (National Academy of Sciences, 1984; the General Accounting Office, 1994, 2005, the University of California, 2006) have itemized the failures of the Toxic Substances Control Act (TSCA) of 1976, the law under which the Environmental Protection Agency (EPA) regulates metals and other chemicals used by industry, including those used in making toys and other everyday products. (Pesticides and cosmetics are regulated under separate laws.)

In November 2007, the American Public Health Association passed new policy recognizing that "TSCA has fallen short of its objectives and has not served as an effective vehicle for the public, industry, or government to assess the hazards of chemicals in commerce or control those of greatest concern, and that, as a consequence, the statute has not served to motivate industry investment in cleaner technologies…"

In decades past, regulatory failure led to tobacco companies marketing nicotine addiction to children, making that a mainstream medical issue. Similarly, our collective failure to effectively regulate heavy metals, phthalate plasticizers, and other industrial chemicals of concern in toys, baby bottles, and other consumer products puts

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children in harm's way.

The American Medical Association's mission statement includes the "betterment of public health." To this end, the following description of problems with TSCA and prescription for more effective chemicals policy are relevant to medical practice.

Knowledge and safety gaps

One of TSCA's chief failures is that it perpetuates longstanding scientific ignorance about the hazards of industrial chemicals—what University of California-Berkeley public health scientist Michael Wilson, PhD, MPH, has called "the knowledge gap."

Prior to passage of the TSCA, and mostly since World War II, manufacturers put some 62,000 industrial chemicals into commercial use. Especially after the war, the emergent chemical industry excelled at introducing new chemicals, mostly derived from fossil fuels, and new products made from them, to feed the eager demands of the American public.

Until quite recently, society's operating presumption has been that use of such chemicals, including in products, was medically harmless. Thus, little concerted effort was made to routinely monitor for them in human tissue or in the environment. Scientific scrutiny did not begin in earnest until the 1970s, after an increasing numbers of chemicals were detected as air and water pollutants.

Congressional passage of TSCA was the flawed reaction to these findings. Three decades later, the vast majority of TSCA chemicals still have undergone little or no testing to determine whether or not they represent a hazard to humans.

By design, TSCA perpetuates gaps in our medical knowledge because the 1976 law "grandfathered" in the 62,000 chemicals then in commercial use without any additional toxicological testing. Ninety-two percent of industrial chemicals produced today at more than a million pounds per year were grandfathered in by TSCA.

TSCA also carries no requirement that makers of new chemicals (an estimated 2,000 per year) generate or disclose, to the EPA or to end users, any toxicological data before these chemicals are sold on the market and used in creating new products. In this way, TSCA ensures that our knowledge gap will be recapitulated for every new generation of chemicals. The list of TSCA-registered chemicals now numbers 81,600.

TSCA puts the burden for proving hazard or risk squarely on government, yet fails to obligate chemical producers to provide the EPA with the product information necessary to do so in the first place. The result: regulatory paralysis, which Wilson refers to as the TSCA "safety gap." Fewer than 5 percent of all TSCA-registered chemicals have been reviewed for safety by government agencies.

Exacerbating the safety gap is the ever-widening scope of chemicals and products involved. The chemical industry designs, produces, and imports 42 billion pounds of industrial chemicals into the U.S. each day.

Evidence of chemical harm

The body of science around human health impacts from exposure to industrial chemicals has burgeoned in recent years—particularly since a landmark National Academy of Sciences study 15 years ago highlighted children's' vulnerability. There is clear evidence that exposure to environmental chemicals early in development can harm children and has increased the incidence of certain childhood diseases and disabilities. A wide range of chemicals are implicated, chiefly including heavy metals such as lead, mercury, and cadmium; certain compounds that bioaccumulate in human tissue or persist in the environment; pesticides; and air pollutants. (World Health Organization, 2006)

According to Wilson (2006), environmental chemical exposures cause 100 percent of cases of childhood lead poisoning, and contribute to an estimated 10 percent to 35 percent of asthma cases, 2 percent to 10 percent of certain cancers, and 5 percent to 20 percent of neurobehavioral disorders. Strong and growing evidence also implicates fetal and early childhood exposure to environmental chemicals in the rise of certain adult disease, such as cancer and heart disease.

Unfortunately, TSCA's gaps ensure a huge time lag between the widespread use of industrial chemicals in commerce and the medical and scientific community's recognition of the chemical hazards to humans. Any public health response necessarily will lag behind the new science further still.

What TSCA's gaps have meant for lead, mercury, PCBs, and a handful of other chemicals now recognized as toxic to the developing brain is that generations of children have been harmed before medical science has recognized the problems from their industrial use and environmental dispersal, and before there has been a public policy response.

These may just be the tip of a neurotoxic iceberg. Nearly 200 other industrial chemicals cause clinical neurotoxicity in adults; their developmental impacts are unknown. (Grandjean and Landrigan, 2006) Thousands of other potential neurotoxins have simply never been assessed. Biomonitoring data also have expanded in recent years. A recent study of American Red Cross samples of newborn cord blood (n=10) detected 287 total industrial chemicals, including 217 animal or human neurotoxicants. (Houlihan J et al. 2005. Environmental Working Group)

Environmental monitoring revealed that Minnesota's history of manufacturing perfluorocarbons, a class of synthetic compounds used to make non-stick coatings for cookware, clothing and upholstery, resulted in pollution—perhaps irreversible—of drinking water sources in the Twin Cities' eastern suburbs. Only after manufacture and widespread use of perfluorocarbons did manufacturers acknowledge that their "non-stick" properties also help make them among the most environmentally persistent chemicals ever discovered. As with many other TSCA chemicals, comprehensive toxicity testing of perfluorocarbons lagged behind their commercial use by decades.

Finally, recent data call into question some long-held assumptions about the safety of extremely low-level exposure to industrial chemicals. Basic to risk management has been the assumption of a threshold below which exposure to environmental chemicals could be deemed "safe." For an ever-increasing number of industrial chemicals, and especially for exposures among fetuses or young children, this assumption is no longer tenable. For environmental lead, PCBs, perhaps mercury and a growing list of hormone disrupting chemicals, no fetal exposure should be presumed "safe."

A healthier way forward

Our ineffective chemicals policy is costly. Last year, costs to Minnesota from chemical contributors to childhood asthma, learning and behavioral disorders, cancer, lead poisoning and birth defects were conservatively estimated at $1.5 billion — each year. (Schuler K., et al. 2005)

Beyond medical costs, to workers and the general public, are the other costs imposed on government, on ecosystems, and on the business community. Estimates are that hundreds of billions of dollars have been lost from the economic productivity of generations of children exposed early-in-life to lead and PCBs, and who had lower intelligence and lower lifetime earnings as a result.

Economic costs also include a projected $250 billion for cleaning up 77,000 existing hazardous waste sites, plus another 600 new U.S. sites anticipated each month over the next 25 years. These costs likely will deepen with expanding global chemical production. Experts expect that global chemical production will quadruple by 2050.

What can physicians do to meet the challenges posed by poorly regulated chemicals? Here are three places to start, in the clinic, in public policy, and with the business community.

Take a routine environmental environmental history that asks about chemical exposures at home, through the diet, via consumer product use and in the workplace. The Pediatric Environmental Health Toolkit, endorsed by the American Academy of Pediatrics, offers clinician guidance on taking an environmental history, a referenced guide for responding to patient questions, and anticipatory guidance for patients on how to avoid such exposures.

Support a "green chemistry" approach. The American Chemistry Society believes "it is better to prevent the entry of hazardous chemical substances into the environment than to address their known and unknown consequences at a later date." Green Chemistry is a validated approach that emphasizes 12 principles such as less energy use, less use of toxic chemicals, and less waste. Increasingly, American industry is embracing green chemistry as a way to meet global demands for cleaner and safer chemicals and products. Safer alternatives to many industrial chemicals of concern already are available and feasible to use.

A just-completed overhaul of industrial chemicals regulation in Europe, called REACH, is driving the changing marketplace. To sell in the EU, American companies will have to change their products and/or manufacturing practices to respond to REACH's stricter safety standards; the question is whether manufacturers will clean their entire production line or continue producing a separate product line for the less strict TSCA standards.

Some forward-thinking companies, such as Pfizer, Interface Fabrics, Dell and Faribault Mills in Minnesota, already invest in green chemistry and cleaner production. Public policies to support the more rapid adoption of cleaner technologies could benefit manufacturers and the public alike. Minnesota lags behind other states such as Massachusetts, Michigan, and New York in promoting green chemistry research and education, aiding industry in reducing the use of toxic chemicals, and spurring business investment and workforce development to position the state favorably for the coming changes to the chemicals industry.

Advocate for effective chemicals regulation. Though TSCA fails to provide an effective federal framework for helping manufacturers to adapt to global changes, some U.S. states are now doing so. In October, California effectively phased out the manufacture or sale of young children's products containing phthalate plasticizers by 2009, as Europe had done previously due to concerns around hormone disruption. But phthalates remain for sale elsewhere in the U.S., including Minnesota. Likewise, baby bottles of polycarbonate plastic, which leach another hormonally active plasticizer, bisphenol-A, are no longer sold in Japan, yet are widely available in the U.S.

Some health professionals in Minnesota already play an important role in fostering a change in perspective to that supports cleaner technologies and adoption of safer substitutes for toxic chemicals. They belong to Healthy Legacy, a statewide coalition that has that as one of its three policy platforms.

The good news is that we can easily make toys and household products that are both useful and safe. In fact, we should expect nothing less.

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Additional resources

- Collaborative on Health and the Environment: www.healthandenvironment.org/
  Note the "New Scientific Consensus Statement" on environmental agents associated with neurodevel opmental disorders
- Pediatric Environmental Health Toolkit: http://psr.igc.org/ped-toolkit-materials.htm
- American Chemistry Society, Green Chemistry Institute: www.acs.org (click on "Green Chemistry Insti tute" under "Emerging Science")
- University of California, Program in Green Chemistry and Chemicals Policy, http://coeh.berkeley.edu/ news/06_wilson_policy.htm
- Health Observatory, Institute for Agriculture and Trade Policy: www.healthobservatory.org
- Healthy Legacy: www.healthylegacy.org