

# Ten Reasons to Join Our Effort to Get The Chemical Industry to Come Clean



## Reason #1 to join Coming Clean: There are no mandatory health studies required to put a chemical into commerce.

As amazing as it may seem, there are no mandatory pre-market health testing or approval requirements under any federal law for chemicals in cosmetics, toys, clothing, carpets, or construction materials, to name just a few obvious sources of chemical exposure in everyday life.

The Environmental Protection Agency (EPA) does require some tests for a handful of new compounds (as opposed to heavily used older compounds) via the pre-manufacture notice (PMN) program. These tests provide little protection for the public, however, because they apply only to chemicals that are new and little used, and because studies for critical human-health effects such as cancer, birth defects, and nervous-system toxicity are rarely if ever required.

This explains in large part why products such as hair spray, hair dye, pacifiers, stain repellents, glues, construction materials and plastic wraps, to name just a few, are put into commerce for decades before their dangers are discovered and the products are removed or reformulated.

### How did this happen?

The chemical industry wanted it this way.

Since the 1950s the chemical industry has systematically blocked all efforts to require comprehensive health studies for the compounds it produces. Comprehensive testing for the health effects of chemicals is not required under the Occupational Safety and Health Act, the Toxic Substances Control Act, or the cosmetics provisions of the Food Drug and Cosmetics Act. (Testing is required for chemicals directly added to food).

### But what about industry's voluntary testing program?

It's a total bust.

In 1998, the EPA and the chemical industry launched their much-ballyhooed voluntary testing program for high production volume (HPV) chemicals. To date, the program has been little more than a PR exercise. As of February 2001, the EPA has received no new tests – zero – as a result of the HPV program.

### Voluntary testing means no testing.

In 1998, EPA reported that 43% of 2,800 chemicals produced in volumes of 1 million pounds per year or more, have no basic toxicity data, or screening level data, at all. Fifty percent have incomplete screening data, and only 7% of these so-called high production volume (HPV) chemicals have a complete set of screening level toxicity data. Screening level data, even if they indicate a problem, are not sufficient to restrict the use of a compound.

On October 9, 1998, EPA's administrator Carol Browner sent letters to the CEOs of more than 900 chemical companies that manufacture HPV chemicals, inviting them to participate in EPA's voluntary testing initiative, the "HPV Challenge Program." As of February 2001, 28 months after these invitations were mailed, not a single test has been started and just 17 testing work plans have been submitted to EPA. About half of the companies have not responded at all to the invitation, while 469 companies have indicated some level of commitment. Of the 2,863 chemicals initially identified, 25% (708 chemicals) remain entirely without a commitment for testing from the manufacturers.

For more information and a complete set of references, visit [www.comeclean.org](http://www.comeclean.org).

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## Reason #2 to join Coming Clean: People vary enormously in their reaction to toxic substances.

People are incredibly different in their reactions to chemicals, allergens, drugs, diseases and a host of external stimuli. That's why the government applies safety factors to the results of animal studies when they set safe exposure limits for pollutants or contaminants in food and water. Often, however, these safety factors are not enough to protect large numbers of sensitive people.

Many factors determine how a drug, allergen, or toxic substance will affect a person: genetics, metabolism, age, sex, size, disease, diet and environment. The result is vast variability in the human response to chemicals, viruses, drugs and a host of substances (up to 100,000-fold differences), most of which is influenced by factors that individuals cannot control.

Examples of the enormous differences between sensitive and "immune" populations include:

- A recent EPA sponsored review found that susceptible individuals are up to 450 times more sensitive to common allergens like ragweed and wheat flour.
  - About 30 percent of people carry a poor version of the enzyme paraoxonase, which makes them 11 times more vulnerable to certain neurotoxic insecticides.
  - People with a "natural" immunity to typhoid fever are 10,000 times more resistant to the disease than the least sensitive person.
  - While some people absorb 13% of the mercury from their stomach into their blood, others only absorb 1%.
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- About 2 million people in the United States are allergic to peanuts. At least three people have died from peanut allergy using a knife that has been "wiped" after making a peanut butter sandwich. But most other people can eat as much peanut butter as they can stand.

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## Reason # 3 to join Coming Clean: The Fetus, Infants, and Children are Usually More Vulnerable to Toxic Exposures.



Infants and children are not little adults, and they are often more vulnerable to the adverse effects of drugs, chemicals, radiation or disease. In spite of this fact, only one law, which covers pesticides, requires regulators to base safety judgments explicitly on risks faced by the fetus, infant and child (and even this law has not been rigorously enforced). For most toxic substances in commerce and consumer products, there are no health studies at all. Those that are done are typically done on adult test animals.

### **The fetus, infants and children are more vulnerable to toxic substances:**

**Nitrate** - Prolonged exposure to tap water with 20 parts per million (or 1 drop out of 50,000 drops) nitrate can kill an infant, but will have no observable effect on an adult.

**Mercury** - Exposure in the womb at 100 parts per billion will significantly increase the likelihood of learning deficits in childhood, while the same dose during adulthood has no measurable effect.

**Lead** - Doses at age 2 that cause IQ deficits throughout childhood produce no effect in adults.

Researchers at a 1997 EPA-sponsored national conference on children's environmental health summarize children's vulnerability in the context of chemical exposures:

Many organ systems in young children – the nervous system in particular, but also the lungs, the immune system, and the reproductive organs – undergo extensive growth and development throughout pregnancy and in the first months and years of extra-uterine life. During this period, structures are developed and vital connections established. These systems are not well adapted to repair any damage that may be caused by environmental toxicants. Thus, if cells in the developing brain, immune system, or reproductive organs are destroyed by neurotoxicants, or if development is diverted by endocrine disruptors, there is high risk

that the resulting dysfunction will be permanent and irreversible. Depending on the organ damaged, the consequences can include loss of intelligence, immune dysfunction, or reproductive impairment.

### **Four important factors make the young more vulnerable:**

1. The developing human body, particularly the fetus, has critical windows of vulnerability. Many studies have shown that the peak incidence of birth defects coincides with the timing of key developmental events. Maternal exposures on a particular day of pregnancy might cause devastating effects to a baby, while exposures on the very next day would cause no discernible effects whatsoever.
2. Children get higher doses of chemicals than adults because, pound for pound, children drink more water, eat more food, breath more air and have twice the body surface (skin) of adults.
3. Just doing what children normally do can increase doses of chemicals. Children put their hands in their mouths more often than adults, and play closer to the floor where some chemicals are more likely to be concentrated.
4. The developing brain is extremely sensitive. A host of factors make the brain a particularly vulnerable target of chemicals for early-life exposures. The blood-brain barrier, which protects the developing brain from some chemical exposures, is not fully developed at birth. Chemical substances have been shown to be three to 10 times as toxic to newborns as adults, or in some cases, to damage the newborn brain and not the adult brain, in part due to differences in the stages of development of the blood-brain barrier.

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## **Reason #4 to join Coming Clean: Cancer rates are increasing, particularly for cancers that affect the young.**

Cancer incidence increased steadily between 1973 and 1996, and probably for longer than that, although the government did not keep track of cancer rates before 1973. The increase was consistent across many types of cancer, from breast cancer, which increased steadily at 1.5% per year, to prostate cancer, which skyrocketed at 4.4% per year. Overall, cancer incidence in the U.S. rose by 1.1% per year during that time, or about 11,000 more cancers per million people each year. For some cancers the increase appears to have leveled off, but for many others cancers, rates continue to rise.

### **Isn't this just because people are living longer?**

No. All of the rates represent the increase after accounting for an aging population.

### **Isn't the increase just the result of better detection?**

For some portion of some cancers better detection explains the increase, but better detection does not account for the overall dramatic increases in cancer incidence that have occurred in the past 30 years.

### **Childhood cancers are on the rise.**

In the 20 years from 1975 to 1995, childhood cancer rates rose 15%, from 130 cases per million children in 1975 to 150 cases per million in 1995. Between 1992 and 1996, 20 of every 100,000 preschool-age children (ages 4 and younger) were diagnosed with cancer, or 200 times the one-in-a-million lifetime risk level at which the federal government attempts to set regulations controlling chemical exposures.

- Childhood leukemia, the most common childhood cancer, increased by about 17% between 1973 and 1996 – from 23 to 27 cases per million children. (EPA 2000)
- Childhood brain cancer's incidence and other central nervous system tumors in children rose by 26% between 1973 and 1996.

### **Reproductive cancers are on the rise.**

Since the chemical industrial revolution of the 1940s and 50s, the population has been deluged with chemicals that disrupt normal functioning of the endocrine (hormone) system. Today, the aver-

age person born in the United States has 50 or more industrial chemicals in his or her blood that have been shown to disrupt normal functioning of hormones in animal studies. The levels of some of these compounds are similar to the amounts linked to adverse effects in animal studies. Many of these compounds have also been shown to cause cancer of the testes, breast, prostate, and other reproductive organs in laboratory animals. These chemicals include DDT, PCBs, dioxin, bisphenol-A, and phthalates, to name just a few. It is widely suspected that these compounds are contributing to increases in cancers of the reproductive organs in the human population.

**Breast cancer.** Among girls born today, three of every 100 are expected to die of breast cancer. Invasive female breast cancer increased an average of 1.5% per year between 1973 and 1996, for a total increase of 25.3%. Among those 65 and younger, breast cancer incidence rose 1.2% per year, corresponding to a doubling every two generations (58 years). Currently, a woman's lifetime odds of developing breast cancer stands at 1 in 8. If trends continue, her granddaughter could face a 1 in 4 chance of developing breast cancer.

**Testicular cancer.** At its current pace, the incidence of testicular cancer is doubling about every one-and-a-half generations (39 years). In the U.S. the incidence of testicular cancer rose 41.5% between 1973 and 1996, an average of 1.8% per year. While rates of testicular cancer continue to drop among older men (65 and up), younger men are not so lucky. Testicular cancer is the most common cancer among young men, disproportionately striking men in their 30s, with the highest rate of diagnosis among those between the ages of 30 and 34.

**Prostate cancer.** Prostate cancer rates rose 4.4 percent a year between 1973 and 1992, or more than a doubling of risk in a generation. Since 1992, the incidence has declined, but it is still 2.5 times the rate in 1973. Part of this increase can be explained by better detection, but increased incidence has also been accompanied by an increase in mortality – which better detection cannot explain. Prostate cancer is now the most common cancer among U.S. men, and the second most lethal, killing an estimated 31,900 men in the year 2000 alone.

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## **Reason # 5 to join Coming Clean: Because it's bogus when the chemical industry says, "The doses of these toxins are so low that you'd have to drink 50,000 bathtubs to get a dose that caused any harm in animal studies."**



**There are a number of reasons why this statement is not true:**

- It's not just the dose, it's the timing. Low doses of certain chemicals at specific days of fetal development can cause permanent problems that often only manifest later in life. The same dose at a different time may have no measurable effect at all.
- Tiny doses are often toxic to some people. Recent EPA-funded research found that some people are 10,000 times more sensitive than the average (median) person to certain forms of air pollution.
- Sometimes low doses are more toxic than high doses. Industry almost never does tests to determine low-dose effects, so when they say low doses cause no effects in animals, it is almost always because they haven't looked. Low-dose toxicity appears especially true for chemicals that affect the endocrine (hormone) system. The reason appears to be that defense mechanisms kick in at higher doses.
- Low-dose effects can be easily missed by standard high-dose animal studies (assuming that the tests have been done at all). A low-dose effect that occurs in just one out of every 1,000 people could be missed completely by animal studies that use only 500 animals at relatively high doses. An effect that occurred in one in 1,000 people would injure 270,000 people in the U.S. population.
- People are often more sensitive to toxic substances than test animals. In a recent survey, humans were shown to be up to 200 times more sensitive than animals to 21 chemicals known to cause birth defects.

- We are all exposed to mixtures of hundreds of chemicals, and no one knows the dangers of these mixtures in our blood. Not only that, no one can ever know. To test just 100 chemicals in combinations of three would require 162,000 tests for just one effect, such as cancer. For nervous system toxicity, it would take another 162,000. And so on and so forth.

**Here are some examples of how people are harmed by low doses of chemicals:**

- PCBs at just five parts per billion in maternal blood during fetal development can cause adverse brain development, and attention and IQ deficits that appear to be permanent. Five parts per billion is equivalent to one drop of water in 118 bathtubs.
- Dioxin causes a significant change in the sex ratio of children born to men who have just 80 parts per trillion of the chemical in their blood. Men father nearly twice as many girls as boys when their blood levels of dioxin reach the equivalent of just one drop of dioxin in 7,400 bathtubs.
- Low doses of lead cause learning deficits in children, but the same dose has no effect on adults. Just 10 mg per deciliter, or 100 ppb (the equivalent of one drop in six bathtubs) in the blood of a 2 year old can cause a significant decrease in IQ in adolescence and adulthood. A 5/1,000ths-ounce chip of lead paint can put a child in the emergency room with lead poisoning.

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## **Reason #6 to join Coming Clean: Because it's bogus when the chemical industry claims, "There is no evidence of human harm from exposure to X."**

Industry routinely claims that chemicals are safe just because there are no reports or evidence of human harm. This claim is both wrong and misleading.

For the overwhelming majority of chemicals in commerce today, industry has no idea what the potential for human harm really is. Every day, hundreds of millions of people are exposed to a soup of chemicals through thousands of consumer products. None have been thoroughly studied individually, and none have been studied at all in combination.

Aside from chemicals directly added to food, there are no comprehensive health and safety studies required to put a chemical into commercial use in the United States. Companies usually perform crude toxicity screening tests to ensure that their products present no immediate hazard to users. They don't explode, they don't burn the users, and they don't cause acute illness. But standard animal tests for cancer, birth defects, reproductive toxicity, genetic toxicity, immune-system toxicity, endocrine toxicity and other long-term health problems are not required under law and are almost never performed.

With no pre-market chemical testing required in animals, it is little wonder that industry claims there is no evidence of harm in humans: there are basically no studies at all. Instead, the chemical industry is conducting one giant experiment on the human population, without consent, and with no apparent concern for the outcome.

Industry often knows from experience and worker injury (as opposed to safety testing) that specific chemicals cause major health problems for their workers. Yet the typical response is not to protect workers but to spend millions on public relations and lobbying campaigns to make sure that worker injury does not lead to restrictions on the commercial use of a chemical.

There is evidence of human harm from exposure to chemicals at even background levels. PCBs are the best example, where eating just two to three meals of Great Lakes fish per month during pregnancy causes a significant incidence of motor and behavioral deficits in the exposed children.

DDT is another example of human harm at background levels. This insecticide shuts down breast milk production in women with elevated, but "normal" levels of DDT an average of 6 ½ months before women with low levels of DDT.

While there may not be human studies for some chemicals, there are animal data showing serious adverse effects and animal studies are quite reliable predictors of human harm. The phthalate class of plasticizers is one good example in which scores of tests from government and independent (non-industry) researchers show birth defects in animals at relatively low doses.

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## **Reason #7 to join Coming Clean: Because it's bogus when the chemical industry claims, "That was the old chemical industry. We have changed our ways."**



The old industry was really bad. The new one is just as bad, but has better PR.

### **Dursban**

In 1996, Dow chemical was fined a paltry \$740,000 for withholding from federal officials information it had obtained via lawsuits filed against the company on behalf of 276 individuals poisoned with the insecticide Dursban. Concealing this information was a clear violation of the law, which requires manufacturers to submit any information they have on the adverse effects of their pesticides. Dow argued that it didn't consider these 276 poisonings adverse effects. By withholding these data from health authorities, Dow was able to perpetuate a false image of safety for the product for more than 10 years, during which time thousands of additional people were poisoned. Within six months of receipt of this information from Dow, the EPA canceled the two most hazardous Dursban products. Four years later, the EPA pressured Dow to phase-out all indoor uses of all Dursban products. Dow never conceded that Dursban represented any risks under normal use, and characterized the phase-out as a market decision.

### **Scotchgard**

For 23 years, from 1976 to 1998, 3M executives sat on information that the entire U.S. population is contaminated with the stain repellent Scotchgard. Animal studies done in the early 1980s showed serious liver toxicity and carcinogenic effects, but the company took no action to monitor or reduce human exposure. When animal studies showed disastrous results in reproduction studies – all the exposed test animals died four days after birth – 3M agreed to phase out Scotchgard over three years. For this behavior, 3M has been praised as a model corporate citizen.

### **Genetically Modified Food**

Many giant chemical companies are developing genetically modified foods and other products, commonly known as GMOs. The strategies employed in product development and market entry for GMOs are strikingly similar to those that gave birth to the chemical revolution. The initial market objective was to eliminate all health and safety testing requirements. This was achieved when the FDA granted industry's request that genetically modified food be treated as substantially equivalent to unmodified food, unless specifically identified as different by industry. A manufacturer's claim of substantial equivalence means that no safety testing is required before the food is marketed. As with chemicals, this wholesale absence of information has not stopped the industry from issuing broad assurances of safety.

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## **Reason #8 to join Coming Clean: Because it's bogus when the chemical industry claims, "These are the best-tested chemicals in the world."**

**Oh really?**

**Then how come they are:**

- Not tested for effects on fetus
- Not tested for effects on infants and children
- Not tested in mixtures
- Not studied in the human population
- Not monitored in soil, water, air, or food
- Not monitored in wildlife
- Not monitored in humans.

## **Reason #9 to join Coming Clean: Because it's bogus when the chemical industry claims, "Animal studies can't predict human harm – people are not just big rats."**

To the contrary, animal studies are quite reliable predictors of human harm. In fact:

- Every single chemical pollutant found to cause cancer in humans was accurately predicted by animal studies.
- Nearly every single chemical (98%) found to cause birth defects in humans, was accurately predicted by animal studies.
- Animal studies are a basic stepping stone of toxicology. Those who say otherwise typically don't like the results of the test in question. In fact, industry is effusively supportive of animal studies when they support a claim of safety for one of their products.

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## **Reason #10 to join Coming Clean: Because it's bogus when the chemical industry claims, "Exposures are well within safe limits."**



**This statement is both wrong and misleading.** For many pollutants present in human blood and tissue, safe levels are routinely exceeded, particularly for infants and young children. For most, however, safe limits have not even been established.

### **Dioxin**

An average person's daily exposure to dioxin far exceeds government safe limits. According to the U.S. EPA, every day Americans ingest from two to 100 times the safe daily amount of dioxin. Breast-feeding infants get the highest dose. Their average daily exposure exceeds the safe lifetime limit by a factor of 35 to 50.

### **PCBs**

Average blood levels of PCBs in the United States are at the low end of levels that increase the risk of neurological impairment in children. Levels in people who eat Great Lakes fish just once a month are three times that amount.

### **Phthalates**

A recent study by scientists at the Centers for Disease Control found phthalates, a family of plasticizers, in every one of 289 people tested. The highest levels were above the current EPA safe level, but the EPA has stated publicly that the level is based on poor science (a study from 1953) and will be low-

ered. When this will happen is not clear. The most pervasive phthalates cause serious birth defects in animal studies. Notably, levels of these phthalates were found at the highest levels in women of child-bearing age.

### **Pesticides**

Over the past two years the EPA banned all or most uses of four major neurotoxic (organophosphate) insecticides. Why? Because a new law forced the agency to look at pesticide risks to infants and children. When EPA looked, they found that normal use of the pesticides was not safe for infants and children. In some cases, safe exposure levels for children were exceeded by 1,000-fold. The pesticides banned or restricted over the past two years are methyl parathion, chlorpyrifos (Dursban), diazinon, and guthion, all of which had been in widespread use for at least 35 years.

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