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Weak Rules on Toxins and Safety

For 14 years until just last month, GlaxoSmithKline sold a denture cream called Super Poligrip that contained high levels of zinc.

The zinc helped with adhesion and was probably safe so long as people used moderate amounts of cream. Indeed, the human body needs small amounts of zinc to function. But some people ended up using much larger amounts, and they began to develop the kind of nerve damage associated with excess zinc.

Johnny Howell of Winston-Salem, N.C., who was using a tube of Poligrip a week, had to quit his job as a car mechanic and now needs a walker to get around his house. He is 53 years old. Rodney Urbanek, another Poligrip customer, began using a walker in 2007, at age 63. He died a year later, apparently a result of a copper deficiency from “zinc overload,” according to his autopsy.

Now, the science here still is not completely clear. One researcher I interviewed said he wanted to see more evidence before being confident that Poligrip was the problem. Other researchers said they thought the causal chain was clear. Poligrip has a lot of zinc. Too much zinc causes copper deficiency. A lack of copper causes nerve damage.

Either way, the evidence has become strong enough that last month GlaxoSmithKline — which also makes Tums, Nicorette and the country’s top-selling asthma drug — stopped making the version of Poligrip with zinc, after having previously resisted just such a move. In Japan, responding to regulators’ concerns, the company has also recalled from stores any remaining zinc-infused cream.

All of which makes you wonder: did it have to come this?

Every society needs to make a choice about how to prioritize consumer safety. If you try too hard to avoid problems, you can end up stifling daily life. Outlawing gasoline, for instance, would doubtless reduce pollution and respiratory disease, but no one is suggesting such a step. Europe, with its hostility to genetically modified foods, arguably errs on the side of being too cautious about chemicals and other such substances.

But the United States clearly seems to be on the other side of the line. We are not taking toxic risks seriously enough.

Several common diseases, like certain cancers and developmental disorders, have been rising in recent decades, and scientists are not sure why. In some cases, evidence suggests chemicals may be the reason.

Nobody can be sure, though. The science is not far enough along, partly because our regulation of toxins is so limp. Companies don’t have to release much of their internal safety data. And regulators face a terribly high burden of proof. They can often take action only after they have demonstrated that a substance is harmful — a task that corporate secrecy can make impossible.

“I can get information on only 20 percent of chemicals we interact with on a daily basis,” says Alan Goldberg, a toxicologist at Johns Hopkins. Erik Olson, a food and consumer product expert at the Pew Charitable Trusts, sums up the situation this way: “We’re a heck of a lot closer to the Wild West than the nanny state.”

The story of denture cream and zinc is a good example. A dentist in the Navy noticed the link between zinc and copper deficiency in the 1950s, according to Dr. Harold Sandstead of the University of Texas in Galveston. Studies in later years confirmed the relationship. Early last decade, researchers made the connection from excess zinc to copper deficiency to neurological problems. “It’s nothing new,” Peter Hedera, a Vanderbilt University neurologist, told me. “If you researched the field, you would find out.”

In 2008, Dr. Sharon Nations of Southwestern Medical Center in Dallas and other researchers published a study in the journal *Neurology* that took the research one step further. It specifically tied denture cream to severe

neuropathy. Dr. Hedera followed up that study with another one analyzing 11 patients with high, unexplained zinc levels. To his surprise, all 11 turned out to be heavy users of denture cream.

Yet even after those studies appeared, GlaxoSmithKline continued to sell Poligrip. The company simply inserted a small piece of paper into the product's box containing some mild statements that barely even seemed to be warnings. The headline on the insert was, "For Best Results Start With a Small Amount."

Perhaps even more questionable than GlaxoSmithKline's response has been that of Procter & Gamble, the giant consumer products company that also makes Crest, Tide, Pampers and Head & Shoulders. Procter is still selling a denture cream with zinc in it. Why? The cream, Fixodent, has only about half as much zinc as Poligrip did.

Even so, it may be enough to cause problems. Some of the 11 patients in the Hedera study were Fixodent users. "I would withdraw both" — not just Poligrip but also Fixodent, Dr. Hedera says.

The companies' argument all along has been that if people use moderate amounts of cream, they will be fine. "All Fixodent products are safe to be used when used as directed," Michelle Vaeth, a company spokeswoman, says. GlaxoSmithKline didn't take more aggressive action because it "did not want to cause alarm," said Nick Kronfeld, the company's medical director. "The product has been safe and effective when used according to the label's directions." GlaxoSmithKline halted manufacturing as soon as it considered the science to be persuasive, he added.

But given the vagueness of the instructions, the reality of how closely people read fine print and the levels of zinc involved — "really high," says Jane Flinn, a biopsychologist at George Mason University — the companies sure seemed to be taking a risk with their customers' health.

Mr. Howell, the former mechanic, who is suing GlaxoSmithKline, said he was careful to apply the cream how the instructions showed. He was less careful, however, about dosage. One of his lawyers, Stephen McCarthy, told me the packaging did not previously contain specific instructions about how much to apply. GlaxoSmithKline did not dispute this.

Today, Mr. Howell has to rely on friends to drive him to the grocery store. "Before all this started happening, I used to have a race car and I used to go fishing all the time," he said.

"Now, I can't drive. I wrecked my car because my legs wouldn't hit the brake. I tore the whole side of my car off."

It's too late to prevent much of whatever damage has been caused by denture cream. But it is not too late to prevent the next such problem, and there will be a next one. Companies are just not going to regulate themselves. Their mission is to make money, and they pursue it well. They have shown again and again — with lead in paint, mercury in canned tuna and zinc in denture cream — that they are less zealous about protecting consumer safety. Many executives choose to believe, and to publicize, the studies that make their products look good, while casting doubt on studies that don't.

Fortunately, there are some reasons for optimism. Lisa Jackson, the E.P.A. administrator, appears to take toxic risks more seriously than recent predecessors.

Congress also plans to take up a bill this year that would update toxic regulations. As my colleague Charles Duhigg has reported, recent court rulings have helped neuter the existing regulations. The chemical industry seems less opposed to a regulatory overhaul, in part because lax regulation may help low-cost Chinese chemical companies more than American firms.

Needless to say, new regulations have their drawbacks. They could deprive us of products that would have made life better or cheaper and that, despite some early indications to the contrary, turned out to be perfectly safe. Think for a minute about all the Poligrip users who liked the product, were using it without problems and can't do so anymore.

On the other hand, if you have a friend or family member with dentures, don't you wish GlaxoSmithKline and Procter & Gamble had been more up front about the apparent risks?