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## **A crawling issue: Head lice treatments worse than the pest itself?** <sup>[1]</sup>

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As children flock back to school, the annual plague of head lice lurks beyond the classroom doors.

The vile creatures don't spread disease but can be a severe nuisance for teachers and families. The vermin are estimated to afflict between 6 million and 12 million young children in the U.S. each year and parents generally turn to a variety of pesticide-based shampoos and treatments for relief.

Parents often aren't aware that some of the most prescribed and over-the-counter treatments can be harmful to children, an *iWatch News* investigation found. The Food and Drug Administration's adverse event reports – collected anonymously from doctors, hospitals and others – detail cases where the pesticides in lice treatments have been involved in conditions ranging from headaches to death. The reports were obtained under the Freedom of Information Act.

One of the biggest worries for some health experts is a prescription treatment for head lice and scabies called lindane. The pesticide has been targeted for worldwide phase-out since 2009 by the Stockholm Convention, a global treaty that targets some of the world's deadliest toxins. The U.S. has not ratified the treaty, and has no imminent plans to ban lindane for head lice.

Since 2006, lindane can no longer be used here on crops or cattle, or for any other purpose regulated by the Environmental Protection Agency. A so-called “second line” treatment – meaning it's only to be used if other methods fail – for head lice and scabies, lindane has been linked to <sup>[3]</sup> cancer, seizures and deaths, according to the FDA.

“It's not permitted to put lindane on your dog in the U.S.,” said Joe DiGangi, PhD, a senior science and technical advisor at the International POPs Elimination Network, an umbrella organization for groups that seek to eliminate some of the world's most toxic chemicals. “But they're still allowing it to be put on your child's head.”

Lindane accounted for \$10.5 million in U.S. sales in 2010 for head lice and scabies, according to IMS Health, a healthcare information company.

Pesticides called permethrin and malathion can also be problematic for lice treatment. Permethrin <sup>[4]</sup> is found in popular over-the-counter products, such as Nix. Malathion <sup>[5]</sup> and lindane <sup>[6]</sup> generally require a prescription for drugs that go by the names Ovide or Kwell, respectively.

Nix, along with other products, has been approved for use on children as young as two months old.

Jerry Jabbour, vice president and general counsel at Wockhardt USA, whose subsidiary manufactures lindane, said that the U.S. is not bound by the Stockholm Convention, and that many of the more problematic issues with lindane have been linked to agricultural uses and the pesticide's inability to be broken down naturally in the environment.

“Is it a powerful pesticide?” Jabbour asked. “Yes. But when used as directed...it’s a good alternative when first line therapies don’t work. Anything that you use on your body or in your body, it has the potential for adverse events to happen. We see there’s physician demand for the product...and we feel like we’re providing an alternative.”

Robyn Ungar, a spokeswoman for Insight Pharmaceuticals, which manufactures Nix, said the product hasn’t been directly linked to problems associated with the pesticide.

“Nix simply provides a solution for parents or guardians looking to treat and eliminate head lice and their eggs in a single and easy-to-use application,” Ungar said. “Furthermore, the pesticide ingredient in question, permethrin, is an effective alternative to harsher chemical treatments.”

But health experts are concerned about recent studies that show the shampoos are less effective than they used to be as lice become increasingly resistant. That can often mean parents are shampooing their children again and again – a dangerous practice, especially if parents ignore strict time limits between treatments. Even though many doctors consider the pesticides safe in low doses, advocates say that many pediatricians wouldn’t recognize the signs if something did go wrong.

“Doctors are so ignorant about the impact of these neurotoxins on people that you could have a significant number of responses among children but nobody really connects the dots,” said [Stuart Calwell](#) <sup>[7]</sup>, a West Virginia lawyer who has litigated cases against chemical and pesticide manufacturers. “If weeks and months go by and the child’s behavior begins to change...rarely there’s a connection.”

“It’s one thing to spray pesticides on broccoli to kill bugs, but when did it come about to put it on children to kill bugs?” Calwell asked.

Malathion has been linked to seizures and other health problems. A [2007 study](#) <sup>[8]</sup> said there is “some association” between pesticide exposure and childhood cancer, while other reports have shown children are more susceptible to problems with malathion than adults.

Permethrin, another pesticide often combined with other chemicals and contained in both over-the-counter and prescription shampoos and lotions, has similar neurotoxic properties that have some experts questioning whether it should be applied to a child’s head.

[Richard Clapp](#) <sup>[9]</sup>, an environmental health expert and professor emeritus at Boston University, said each compound can produce problems. Malathion, a neurotoxic chemical, can cause weakness and tingling in arms and legs, as well as seizures, Clapp said. Permethrin, especially when combined with other problematic chemicals, can cause seizures and, down the road, behavioral problems. In a 2009 memo, the EPA classified permethrin as “likely to be carcinogenic to humans” in some conditions.

“My kids are grown up now, but I would tell them not to put [pesticides] near their kids,” Clapp said.

Many pediatricians consider the compounds safe in low doses – problems generally arise when they are overused or directions aren’t followed. But some health experts argue putting a pesticide on a child’s head to treat pests that are relatively harmless is overkill in itself and could cause unattributed problems down the road.

## **Crawling critters**

School was about to start last August and a pregnant Monica Tienda was desperate to get rid of the crawling lice on her 7-year-old daughter Chelsea’s head.

Over several months, Tienda bought every over-the-counter product she could find, spending more than \$1,000. None worked.

After dozens of treatments, Chelsea's head was raw from scratching and the effect of chemicals in the shampoos, Tienda, of Dickinson, Texas, said in an interview. Chelsea screamed and cried every time she was shampooed, telling her mother that it burned terribly. "I keep telling her, 'Well, if you want to get rid of it...we have to do this,'" Tienda said. "We don't have a choice."

Tienda said she wasn't aware that any of the products she used were pesticides, or what chemicals were in them. She said none of the products worked and she eventually spent the time necessary to comb "thousands" of lice out of Chelsea's head.

"I don't know what's in the products," she said. "It doesn't make sense that they'd put them out [in the store] if they're harmful for you."

Tienda's obsession with ridding her child of head lice isn't unusual.

The market for head lice products and services is growing. Sales of the most popular over-the-counter shampoos and other treatments amounted to nearly \$75 million in 2010, according to data compiled by SymphonyIRI group, a Chicago-based marketing research firm. That's up from \$67 million in 2009. (The data exclude sales from Wal-Mart and other "club" stores, as well as gas stations and convenience stores.) Sales of prescription treatments, such as malathion and lindane, totaled nearly \$74 million in 2010, according to IMS Health.

With the exception of lindane-based prescriptions, there is little recognition of the concerns with the pesticides on the products' labels. Ovide, which contains malathion, has a product insert that includes warnings for pregnant or nursing mothers. But under "adverse reactions," it states: "Malathion has been shown to be irritating to the skin and scalp. Accidental contact with the eyes can result in mild conjunctivitis. It is not known if OVIDE Lotion has the potential to cause contact allergic sensitization." It also notes that malathion is highly flammable.

Stephen Manzano, associate general counsel with Taro Pharmaceuticals, which makes Ovide, said malathion has been proven safe in low doses. He said the product has fully complied with FDA regulations, is FDA approved, and the company has not received reports of serious problems with the product.

"I can understand the buzzwords, 'pesticides and kids,'" Manzano said. "But I draw you back to pharmaceutical-grade malathion, which is regulated and has...a very small amount [of malathion]. Combined with [our] safety record over many years, it speaks for itself."

Advocates have a different story. Deborah Altschuler, the president of the National Pediculosis Association, a nonprofit group that advocates on head lice issues, has long urged parents not to use pesticides on children. She said she has collected more than 1,000 reports dating from the 1980s from worried parents who ask about links to seizures, behavioral problems and leukemia, among other problems. She said the fact that parents are led to pesticides as a first line of defense against head lice "puts children and entire families in jeopardy."

## **FDA complaints**

Through its Adverse Event Reporting System, the FDA received about 200 complaints relating to lindane, malathion and permethrin from January 2005 through October 2010. Lindane-related products were allegedly involved in 10 deaths; permethrin was listed in six (including two suicides), malathion two. Other reports described conditions such as shortness of breath, hallucinations and nausea.

The FDA's system is far from comprehensive because reporting is voluntary. The agency has a disclaimer on its website: "[T]here is no certainty that the reported event was actually due to the product. FDA does not require that a causal relationship between a product and event be proven, and reports do not always contain enough detail to properly evaluate an event."

The FDA declined to make a scientist or an administrator available for an interview. In a written response to questions from *iWatch News*, spokeswoman Shelly L. Burgess said the agency monitors adverse reactions to products.

"All approved drugs are required to show safety, however, safety does not mean zero risk, because all drugs are associated with risks," Burgess wrote. "A safe drug is one that has reasonable risks, given the magnitude of the benefit expected and the alternatives available. A patient runs the risk of experiencing reactions resulting from the product's interaction with the body. These usually have been identified and are indicated as possible risks in a product's labeling."

Many of the FDA reports involve several different substances, along with the pesticides used for head lice and scabies. One death, reported in October 2006, lists lindane lotion as a possible contributing factor. Another, reported in August 2005, lists lindane lotion as the "PS" or "primary suspect."

In some cases, health problems have been immediate and stark. Tim Davis, an Alabama lawyer, sued a lindane manufacturer, pharmacist and doctor after a six-month-old child, Jared Gardner, died following application of a lindane cream to treat scabies. According to court documents, an autopsy cited lindane toxicity as the cause of Jared's death in October 2001.

"It was a horribly sad case," said Davis, who said the case settled confidentially out of court. The FDA has since ensured lindane products carry a "black box warning," the strongest warning the FDA imposes. "The warnings were not nearly as strong...when this happened."

## The Science

Dr. Barbara Frankowski, a Vermont pediatrician who co-wrote a review of head lice treatments for the American Academy of Pediatrics, said that there have been few documented cases of problems with head lice shampoos.

"When you think about it, you get more pesticides eating your salad than you bought at the grocery store if you don't wash everything well," she said. "Who knows what kind of pesticides we're [being exposed to] every day?" She added that many parents treat their children for head lice when they don't have an active case – unnecessarily exposing them to pesticides.

Others say head lice treatments pose a special kind of risk. Children are generally more susceptible than adults to chemicals, these experts say, and the application of a product directly to a child's head – where only a thin layer of skin protects the developing brain -- seems particularly foolish.

Lindane has a particularly troubling history.

According to the FDA, "lindane products can cause serious side effects for many reasons, even when used as directed."

Dr. Lynn R. Goldman, a former pediatrician and former assistant administrator of the EPA's Office of Prevention, Pesticides and Toxic Substances, said the most serious problems associated with lindane – seizures and deaths – likely result from incorrect use of products. "People do make mistakes," said Goldman, now dean of George Washington University's School of Public Health and Health Services. "And that a child would die for treating a minor condition like head lice is unconscionable."

"I believe that the FDA should [remove] the approval of this product (lindane) from the market. I know that there are clinicians who would come in and say it's necessary, and I just don't agree with that."

However, Goldman said she believes permethrin and malathion are relatively safe.

Still, FDA spokeswoman Burgess wrote that, "No new evidence regarding safety or efficacy has been presented to cause the Division [of Dermatology and Dental Products] to amend its conclusion that the use of lindane as a second line treatment in pediculosis [head lice] and scabies, when used as labeled, is safe and effective."

## The Solution

Head lice experts say one of the hardest things about the bug is that many children are treated for head lice when they don't actually have any. Further, "natural" solutions such as mayonnaise or tea tree oil can be ineffective.

Tea tree oil, for example, can be used in excess and cause illness, Frankowski said.

"From the pediatricians' point of view ... we make sure 'Does your child really have an active case of head lice?' Frankowski asked. "If not, they really shouldn't be using the [pesticide-based] products." She also reminds parents not to reuse them outside of the time limits the American Academy of Pediatrics recommends.

But many "natural" advocates say the best approach is to pick the lice and their eggs out, one by one. Many schools have a "no-nit" policy so kids can't go back to school with a single nit (egg) in their hair, an often harrowing proposition for parents.

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