

Legislative Analysis



RESTRICT LINDANE LICE OR SCABIES TREATMENTS TO DOCTORS' OFFICES

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House Bill 4402 without amendment

Sponsor: Rep. Dan Scripps

Committee: Great Lakes and Environment

First Analysis (3-17-09)

BRIEF SUMMARY: The bill would require prescription lice or scabies treatments containing the pesticide chemical lindane to be applied under a doctor's supervision in the doctor's office.

FISCAL IMPACT: The bill has fiscal implications for state and local government in the case of violations of the provisions of the new Part 140 which could affect law enforcement, judicial, and corrections systems. Michigan's Medicaid program of medical services to low income children and families has had a restrictive policy on use of lindane since 2004, so any state Medicaid savings from avoidance of adverse human effects is already established. It is possible there could be some impact on state employee health costs with reduced use.

THE APPARENT PROBLEM:

Lindane is a persistent, bioaccumulative organochlorine pesticide chemical currently available in Michigan and most of the United States (except for California which has banned it altogether) only as a second-line treatment for lice or scabies to be used if safer alternatives have failed or cannot be tolerated. It is considered especially risky when used by persons weighing less than 110 pounds, infants (especially premature infants), children, the elderly, persons with a history of seizure disorders, those with open sores, and persons with compromised immune systems. Even when used as directed, it is possible for lindane to cause seizures or death. Such serious effects are more likely when the product is misused or used incorrectly (such with repeated or prolonged treatments, or accidental ingestion).

Because of neurotoxicity, lindane shampoos and lotions to treat lice and scabies require a doctor's prescription and are not available over the counter. Further, in 2003, the FDA issued a public health advisory, a medication guide, and a black box warning, and also limited package sizes to one and two ounces. The Department of Community Health does not allow lindane to be used to treat head lice and scabies for Michigan children covered by the Medicaid program except with prior authorization, which has reduced the number of lindane prescriptions being written for Medicaid patients in Michigan.

Although now allowed only as a pharmaceutical treatment for lice or scabies in humans, lindane was once manufactured and widely used in the United States and other countries as a pesticide to treat seeds, crops, lumber/timber, cattle, and other farm animals.

However, most agricultural uses of lindane were banned in this country in the 1980s due to concerns about its toxicity, the fact that it breaks down very slowly, and because it accumulates in the environment and in the bodies of humans and animals. Lindane's last remaining registered agricultural use in the U.S. — the pre-treatment of certain types of seeds — was cancelled by the EPA, effective July 2007 (with existing stocks allowed to be used 2009).

California was the first state to adopt an outright ban on the use of lindane for any purpose, but other states besides Michigan, including New York and Minnesota, have also considered bans or restrictions. According to the EPA, lindane is banned for use in 52 countries, restricted or severely restricted in 33 countries, not registered in 10 countries, and registered in 17 countries. The United States, Canada, and Mexico, through the efforts of the Commission for Environmental Cooperation of North America (CEC), have been attempting to phase out or limit lindane's use. To this end, Mexico has decided to discontinue all uses — pharmaceutical or agricultural — of lindane. Canada, like the U.S., currently allows only the pharmaceutical use of lindane.

Proponents say that even with lindane being recommended only as a second-line treatment with a black box warning, poison control centers in Michigan continue to receive many calls relating to lindane. With in-office doctor-supervised use, supporters expect that fewer persons for whom the drugs are contraindicated will receive them, and opportunities for accidental ingestion will be greatly reduced. In addition, persons would not be able to share their medications with others, as they sometimes do now, and persons unable to read warnings written in English would be at less risk for misusing the products. Some say that these restrictions, along with existing FDA warnings, will further steer patients who truly do not need lindane or in whom its use is ill advised toward other safer and effective alternatives, yet still allow its use as a supervised, second-line treatment when truly needed. Although proponents say that there have been no problems in California or countries with outright bans, the bill only restricts lindane to doctors' offices, allowing it to remain available if truly necessary.

In addition to the direct health risks posed by lindane, particularly for children, supporters of the bill point to environmental issues associated with the use of lindane. For each ton of lindane (gamma-hexachlorocyclohexane (HCH) isomer) that is manufactured, many other tons of even more toxic byproducts (alpha and beta hexachlorocyclohexane isomers) are produced. Although no longer manufactured anywhere in Michigan¹ or elsewhere in the United States, HCH isomers are persistent and capable of long-distance atmospheric travel, so lindane's manufacture anywhere in the world is of concern. Carried over long distances through the atmospheric and ocean currents, HCH isomers vaporize and condense, touching down on oceans and lakes. Like other persistent organic pollutants, HCH isomers accumulate in colder climates such as the Arctic, placing indigenous peoples with diets heavy on animal fats at greater risk for negative

¹ Lindane used to be produced in Michigan. For instance, a site at which agricultural lindane and other pesticides were once produced and packaged in Michigan from 1945 through 1979 — the Parsons Chemical/ETM Enterprises site in Grand Ledge, Michigan — was subsequently designated a contaminated Superfund site requiring expensive cleanup activities.

health effects. According to "Lindane and other HCH Isomers: An EPA Risk Assessment Fact Sheet," dated February 8, 2006), the highest known concentrations are in the Beaufort Sea (located off the coast of Alaska), and the Canadian Archipelago; marine mammals in those regions have elevated residues of HCH isomers. See: (www.epa.gov/oppsrrd1/REDs/factsheets/lindane_isomers_fs.htm)

In addition, when lindane is rinsed off a person's head or body, it washes down the drain, and enters into municipal wastewater treatment systems or septic tanks. Proponents of the legislation say that for each lindane shampoo treatment that goes down the drain, up to six million gallons of municipal wastewater may be contaminated with the pesticide. Concerns about both health effects and water contamination led the state of California to ban pharmaceutical lindane in 2002. See Humphries, et al., *Environmental Health Perspectives*, Vol 116, no. 3, March 2008, "Outcomes of the California Ban on Pharmaceutical Lindane: Clinical and Ecological Impact," December 11, 2007, available online at www.ehponline.org/members/2007/10668/10668.pdf.

It has been suggested that to reduce the risk of adverse health effects of lindane (while still allowing it to be used when truly necessary) and to minimize the environmental contamination in Michigan and elsewhere, Michigan should only allow pharmaceutical lindane to be used under direct medical supervision.

THE CONTENT OF THE BILL:

The bill would amend the Public Health Code to make it unlawful to sell, give away, use, or prescribe any product used for the treatment of lice or scabies in human beings that contains the pesticide chemical lindane. If, however, a person's doctor considered it necessary, a lindane product could be lawfully obtained by the physician and a treatment given to a patient in the physician's office under the doctor's supervision.

Penalty. A violation of the ban on the sale or use of a product containing lindane to treat lice or scabies except in doctors' offices would constitute a misdemeanor punishable by a fine up to \$5,000. A person violating the lindane ban could also be charged with any other violation of law committed while selling or using the lindane product.

MCL 333.14001

BACKGROUND INFORMATION:

North American Regional Action Plan concerning lindane. Lindane (the gamma isomer of hexachlorocyclohexane or HCH), and related isomers (e.g. alpha and beta HCH isomers) are in the organochlorine group of pesticides known to be neurotoxic, environmentally persistent, and bioaccumulative. For this reason, many of the pesticides in this class, such as DDT, have been banned in much of the world. The United States is currently cooperating with Canada and Mexico under the auspices of the North American Commission for Environmental Cooperation (CEC) to implement an action plan developed in 2006 to reduce the risks from exposure to the various isomers of HCH, and

as warranted, eliminate or ban uses of lindane. See *The North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers*, www.cec.org/files/PDF/POLLUTANTS/LindaneNARAP-Nov06_en.pdf.

Morton Grove Pharmaceuticals, Inc. Lindane is no longer manufactured in the United States and only one company, Morton Grove Pharmaceuticals, Inc. of Morton Grove, Illinois, produces pharmaceutical products containing lindane in the United States. Morton Grove was acquired by Wockhardt Limited, an international company headquartered in Mumbai, India, in October, 2007. In December 2007, the FDA sent a warning letter to Morton Grove about misleading advertising information it had distributed about its lindane products, including some literature aimed at school nurses. Among other things, the company was warned that some of its communications overstated the efficacy of its products, minimized the more serious risks associated with them, particularly in children, and included misleading dosing information.

See www.fda.gov/cder/warn/2007/Lindane-wl.pdf

Morton Grove's correction of this information can be read here:

See www.lindane4lice.com/LindaneShampoo_consumers.html

ARGUMENTS:

For:

Proponents say that requiring the direct medical supervision of lindane lice and scabies treatments will reduce the risk of adverse effects, including serious neurological effects, associated with lindane products, particularly in children whose bodies absorb more lindane. They expect medical supervision to reduce the number of cases where lindane is accidentally ingested, misused (such as by leaving it on for too long or using it more than once), shared with someone for whom it was not prescribed, or used by persons who should generally not use it, including infants, children, the elderly, and persons weighing under 110 pounds. But because the bill would not impose a complete ban, lindane would remain available as a second-line, in-office treatment for patients whose doctors believe that they truly need it. Supporters expect that few patients will truly need in-office lindane treatments as Californians and people in over 50 countries get by without it. Since the Medicaid program began requiring pre-authorization a few years ago, most patients are prescribed other treatments.

In addition, the bill would likely reduce the possibility of lindane possibly finding its way to Michigan's water and other natural resources. Michigan's water and soils (and people) may have already accumulated a certain amount of lindane from past agricultural and pharmaceutical use of lindane. Why should we add to this toxic legacy, when we know that safer and less persistent chemical alternatives are available (and even safer non-chemical alternatives are available) for treating head lice?

Finally, to the extent that demand for lindane is reduced in Michigan and elsewhere, presumably less of it will eventually be manufactured in the developing countries where its manufacture is still allowed, decreasing pollution not only in those countries but around the world. It is well recognized that persistent organochlorine pesticides such as lindane travel by air or water over wide areas and accumulate northern climates, in particular, Arctic regions, posing a special risk to native people who eat a traditional diet.

This bill has broad support among Michigan's medical and environmental communities.

There is no Michigan manufacturer of lindane or lindane products, so this bill's restrictions will not harm Michigan's economy in any way but will protect some of our most vulnerable citizens and our valuable natural resources.

Against:

Opponents say that lindane is a useful and effective second-line treatment for head lice and scabies, and that requiring doctors to supervise applications, particular scabies treatments, would be impractical and expensive. Lindane lotions for scabies must be left on for eight hours.

An environmental consultant employed by ChemRisk testified that lindane is virtually undetectable in Michigan's environment and that, therefore, the bill is unnecessary. He also pointed out that any substance, even water, can be dangerous if consumed in large quantities and that detection of a substance in the environment is not tantamount to a problem.

The consultant's February 21, 2008 opinion letter to the Great Lakes and Environment Committee, written at the request of Morton Grove Pharmaceuticals, about an identical bill that passed the House last session, is available online on a Morton Grove Pharmaceutical website:

http://lindane.com/pdf/Dr_Len_Sweet_Expert_Statement.pdf

An attorney for Morton Grove testified that his company receives very few adverse event reports each year and has only received one such report from Michigan.

Opponents say that the negative environmental effects of lindane going "down the drain" in a doctor's office are no different than those of lindane that goes "down the drain" at a person's home.

Finally, opponents say that federal regulators, not state legislatures, should adopt rules for the pharmaceutical use of lindane. They say that the legislature is overstepping its jurisdiction by placing limits on products regulated by the FDA. The FDA has thoroughly reviewed the pros and cons of products containing lindane and has concluded that they should remain on the market, albeit as second-line treatments with black box warnings.

POSITIONS:

The Department of Community Health indicated support for the bill. (3-12-09)

American Academy of Pediatrics, Michigan Chapter, testified in support of the bill. (3-5-09)

Clean Water Action testified in support of the bill. (3-5-09)

The Michigan Council for Maternal and Child Health indicated support of the bill. (3-12-09)

The Michigan League of Conservation Voters testified in support of the bill. (3-5-09)

The Michigan Nurses Association testified in support of the bill. (3-5-09)

The Michigan Environmental Council indicated support of the bill. (3-12-09)

Pediatric Pharmacy, Children's Hospital of Michigan indicated support of the bill. (3-5-09)

Sierra Club indicated support of the bill. (3-5-09)

ChemRisk testified in opposition to the bill. (3-5-09)

The Michigan State Medical Society indicated opposition to the bill. (3-5-09)

Morton Grove Pharmaceuticals, Inc. testified in opposition to the bill. (3-5-09)

A group of four doctors or scientists (Dr. Shayne C. Gad, Dr. M. Joycelyn Elders, Dr. Adelaide H. Hebert, and Dr. Len Sweet) sent a joint memorandum in opposition to the bill. (3-12-09)

Legislative Analyst: Shannan Kane
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■ This analysis was prepared by nonpartisan House staff for use by House members in their deliberations, and does not constitute an official statement of legislative intent.