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Committee on Great Lakes and Environment
P.O. Box 30014
Lansing, MI 48909-7514

Re: Hearing on Michigan House Bill 4402 -- Lindane

Good morning Representative Warren and Members of this Committee, my name is Leonard Sweet, I am a scientist with a PhD in toxicology and environmental science, and I appreciate this opportunity to offer my expert opinion in opposition to HB 4402.

By way of background, I am an alum of three University of Michigan graduate programs (in toxicology, environmental science, and public health). I have researched and published on the toxicity potential and risk profile of lindane. I am currently employed as a Senior Health Scientist at ChemRisk, which is a consulting firm providing state of the art toxicology, industrial hygiene, epidemiology, and risk assessment services.

Lice and scabies are a significant and ubiquitous global public health issue. I am aware of the controversy and concern around lindane, scabies, and lice. As a father of twin boys in the K12 school system in Michigan, I am very aware of the notes that come home warning of lice, for which there are very limited treatment options. I recognize that people are passionate about this issue, and about treating people afflicted with these conditions, and about being concerned for our state's environmental health. I am not advocating complacency about a chemical, but I am advocating the truth.

Lindane medications are one of the few treatment options for these medical conditions. In light of the serious restriction this Committee is considering on the use of the lindane medications, I have objectively reviewed the state of the science on lindane, in particular with regard to its environmental risk profile in our state.

As decision makers who use science as one factor in your overall policymaking, you need to have scientifically honest, transparent, and verifiable information presented to you by reliable experts such as myself, and not over hyped, skewed, and misinterpreted information by those who call themselves experts but lack knowledge, skill, experience, training, and education in environmental science.

I understand that other scientific information has recently been presented to this committee that appeared to be in support of restricting lindane (as well as many other chemicals). There are various reasons why I disagree with some of the claims you have heard. In general, I disagree with the "hazard du jour" approach and believe that scientific testimony should not be overblown or hyped, but should rather clarify with facts in hand what is known on a given question and should where appropriate allay unfounded fears. For example, to imply that lindane presents a risk comparable to lead and mercury in the environment is incorrect. Further, it was pointed out that lindane was detected at a very low level in Detroit wastewater sludge in 2002 and 2004, yet no citation or study reference was provided to verify this statement, and it is unclear to me as a

scientist why this is presented as a negative and how HB 4402 would lead to a different detection if it was due to past pharmaceutical use. Detection in sludge, also termed “biosolids”, is a sign of proper and effective wastewater treatment. It means any lindane entering the treatment plant (whether from past agricultural use or pharmaceutical use) will not end up in the treated water coming out of the treatment plant, because it has been either degraded by the bacteria or is bound to the solids/sludge. Also, there are many chemicals that can be detected in sludge at far greater levels than lindane, including birth control chemicals, pain killers, caffeine, etc. So detection at very low levels does not equal exposure and risk. We can detect dioxin in paper towels, we can detect mercury in this room, it doesn't mean there is a risk. Furthermore, actual data from the treated water (not sludge) coming out of Michigan's WWTP (see Appendix) shows no detection of lindane, which is where any potential environmental exposure and risk could arise.

I understand that prior testimony also asserted that a “black box” warning for lindane is “highly unusual” and it was implied that this label is very negative for lindane. In fact, this is neither unusual nor negative because there are almost 400 well known and beneficial chemicals with “black box” warnings (See Slides in Appendix), including Ibuprofen and Naproxen anti-inflammatory, antidepressants like celexa, ritalin for ADHD, beta blockers for blood pressure, iron containing vitamins, and interferon immune system boosters. Black box warnings that include medication guides are designed to ensure safe and effective use, and they are a sign that the chemical has been very well studied. Finally, prior testimony has asserted that lindane is “completely banned in over 50 countries”. This statement does not present a balanced and accurate view of how in numerous countries around the world it is not banned (e.g., Canada can get online and over the counter, see Appendix) and is in fact a treatment of choice because of its favorable efficacy, cost, safety record, and use in cases of resistance to other treatments.

Before I present the three reasons why there is no compelling rationale to supplant more than 50 years of FDA guidance with HB4402, let me illustrate why it is dangerous to hype substances as “bad” actors. I recognize that there may be a difference between how you and I perceive environmental risks.

You see this bottle before you containing water, dihydrogen oxide. Is it good or bad? Well we know that water makes up much of our bodies and that if we were to abstain for more than a few days we can become ill and die. So it's Good? However, we also know from many reports in news and scientific literature about people who have died from hyponatremia (water intoxication, low salt levels)/cerebral edema because they have drunk too much water too quickly. Bad?. Further, If I heat up this water, and empty it on my skin, I can get badly scalded and possibly die. Bad. Further, if I tip the contents of this bottle out over the walkway in front of this building and the temperature is below 32, then the water will freeze and people can slip, fall, injure themselves or at least their dignity slipping. I tell you this because that is why it matters not whether a chemical is used, but how it is used, and it matters where and at what level we find that chemical. And this also illustrates the importance of margins of safety and therapeutic index. There can be too much of a good thing.

In the next few minutes, I would like to address why I believe there is no compelling reason nor benefit in proceeding with the recommendation of House Bill 4402:

1. Lindane is virtually undetectable in the environment of the State of Michigan. No exposure, no risk.
See Slides in Appendix

Lindane was not detected in Michigan's fish, drinking, surface water, wastewater, soil, sediment, or air. This is staggering considering how sensitive the analytical levels of detection are. To put it in perspective, if there were the equivalent of a grain of sand of lindane in a swimming pool in any of these samples, it would have been detected, yet it was not detected. Yes there are some past studies that have detected very low levels of lindane in North America, and the investigators have attributed the vast majority of those detections to past agricultural uses. What is important is the weight of all the evidence, not just one or two studies suggesting detection. There is no compelling evidence that lindane medications are entering the Michigan environment in a quantity or concentration that will have any immediate or long term harmful impact. Finally, HB 4402's proposal to use lindane medications at a physician's office will have no measurable environmental benefit vs. using in one's own home. In both scenarios some lindane is washed down the drain, and is treated by the WWTP if not degraded en route. Even if every Michigan resident poured a bottle of lindane shampoo down the sink every day, EPA worst case models predict that lindane levels in surface water would be far too low to cause adverse effects.

2. The state of the science does not demonstrate that the use of lindane products presents an unacceptable risk to environmental health and safety.

See Slides in Appendix

Lindane is not listed by the US EPA as a High Priority PBT (persistent bioaccumulative toxicant) in the environment. In fact when considering the environmental toxicity of lindane to organisms in surface water, the levels required to pose any sort of health threat to organisms are hundreds and thousands of times higher than the limit of detection. Also, the US EPA conducted a study in 2002 that looked at down the drain use of lindane medications and potential environmental risk and they concluded that "The Agency does not have risk concerns for concentrations of lindane in surface water and as a source of drinking water from consumer use for both lice and scabies treatments."

The environmental impact of pharmaceutical uses of lindane has frequently been mischaracterized. For example, one claim is that a single treatment for head lice or scabies would result in 6 million gallons of water above the California standard. Viewed in the absence of treatment and material mass balances, a variety of commonplace substances would be considered toxic. Of course, wastewater treatment collection systems are dynamic systems with active treatment processes and flows at large systems exceeding 100 billion gallons a year. As evidenced by the down-the-drain screening model utilized by the Environmental Protection Agency, a credible assessment of environmentally relevant levels is based on system flow rates, worst case receiving water dilution rates and reasonable estimates of wastewater treatment removal efficiencies.

3. Restricting use of lindane will effectively lead to increased use of substitutes. What is the environmental risk of increased use of malathion and permethrin? We know that the CDC detected these chemicals in the blood and urine of children in the US, but lindane was not detected. We know that there was a huge controversy in California when it sprayed malathion to treat fruit flies, there were a lot of activities alleging environmental impacts from malathion. Replacing any chemical without an in depth analysis of the risks and benefits of propose substitutes and their increased use is not sound public policy and may create a significant and unintended environmental risk for the future.

In closing, I urge the Committee members to review and carefully consider these comments confirming that there is no credible science supporting the restriction of use of lindane medications based on environmental concerns in Michigan. The benefits of lindane medications are real and significant, while the so-called environmental risks exist are merely theoretical. Restricting lindane medications will have no positive effect on the environmental health of Michigan. In fact, restricting lindane medications and replacing them with lesser studied products containing malathion and permethrin may adversely impact Michigan's environment and result in increased chemical resistance to the treatments.

Our state should rely on sound science as presented by experts in the field when making policy decisions that impact the welfare of our citizens and entire industries.

Thank you for giving me the opportunity to speak to you today about this important matter. That concludes my prepared testimony. If you have any questions, I would be happy to address them.

APPENDIX

Human Exposures

Lindane was not detected in over 10,000 human biomonitoring samples from all ages by the Centers for Disease Control (source: <http://www.cdc.gov/exposurereport/>)

Table 231. gamma Hexachlorocyclohexane (whole weight)

Geometric mean and selected percentiles of serum concentrations (in ng/g of serum or parts per billion) for the U.S. population aged 12 years and older, National Health and Nutrition Examination Survey, 1999-2002.

	Survey years	Geometric mean (95% conf. interval)	Selected percentiles (95% confidence interval)				Sample size
			50th	75th	90th	95th	
Total, age 12 and older	99-00	*	< LOD	< LOD	< LOD	< LOD	1759
	01-02	*	< LOD	< LOD	< LOD	< LOD	2280
Age group							
12-19 years	99-00	*	< LOD	< LOD	< LOD	< LOD	660
	01-02	*	< LOD	< LOD	< LOD	< LOD	756
20 years and older	99-00	*	< LOD	< LOD	< LOD	< LOD	1139
	01-02	*	< LOD	< LOD	< LOD	< LOD	1522
Gender							
Males	99-00	*	< LOD	< LOD	< LOD	< LOD	863
	01-02	*	< LOD	< LOD	< LOD	< LOD	1060
Females	99-00	*	< LOD	< LOD	< LOD	< LOD	936
	01-02	*	< LOD	< LOD	< LOD	< LOD	1220
Race/ethnicity							
Mexican Americans	99-00	*	< LOD	< LOD	< LOD	< LOD	631
	01-02	*	< LOD	< LOD	< LOD	< LOD	563
Non-Hispanic blacks	99-00	*	< LOD	< LOD	< LOD	< LOD	380
	01-02	*	< LOD	< LOD	< LOD	< LOD	509
Non-Hispanic whites	99-00	*	< LOD	< LOD	< LOD	< LOD	646
	01-02	*	< LOD	< LOD	< LOD	< LOD	1045

< LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample. See Appendix A for LODs.

* Not calculated. Proportion of results below limit of detection was too high to provide a valid result.

Michigan Surface Water

US. Geological Survey and Michigan Department of Environmental Quality STORET database. Lindane was virtually undetected in over 100 surface water samples in Michigan (source: <http://www.epa.gov/storet/dbtop.html>)

Org Name	Station ID	State	County	Activity ID	Activity Start	Characteristic Name	Result Value as Text
Michigan Department of Environmental Quality	190134	MICHIGAN	CLINTON	WATERQUALITY	6/20/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	470494	MICHIGAN	LIVINGSTON	WATERQUALITY	9/5/2000 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	130359	MICHIGAN	CALHOUN	WATERQUALITY	5/28/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290001	MICHIGAN	GRATIOT	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560064	MICHIGAN	MIDLAND	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560064	MICHIGAN	MIDLAND	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	800490	MICHIGAN	VAN BUREN	WATERQUALITY	7/17/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	800493	MICHIGAN	VAN BUREN	WATERQUALITY	7/17/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	140134	MICHIGAN	CASS	WATERQUALITY	8/15/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	130360	MICHIGAN	CALHOUN	WATERQUALITY	5/28/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	470196	MICHIGAN	LIVINGSTON	WATERQUALITY	9/5/2000 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	130358	MICHIGAN	CALHOUN	WATERQUALITY	5/28/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	110644	MICHIGAN	BERRIEN	WATERQUALITY	7/5/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290016	MICHIGAN	GRATIOT	WATERQUALITY	9/19/2000 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290016	MICHIGAN	GRATIOT	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	800491	MICHIGAN	VAN BUREN	WATERQUALITY	7/17/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	110637	MICHIGAN	BERRIEN	WATERQUALITY	7/5/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290016	MICHIGAN	GRATIOT	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	130364	MICHIGAN	CALHOUN	WATERQUALITY	5/28/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	110644	MICHIGAN	BERRIEN	WATERQUALITY	9/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560063	MICHIGAN	MIDLAND	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	130362	MICHIGAN	CALHOUN	WATERQUALITY	5/28/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290016	MICHIGAN	GRATIOT	WATERQUALITY	9/19/2000 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	140133	MICHIGAN	CASS	WATERQUALITY	8/15/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560064	MICHIGAN	MIDLAND	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	190133	MICHIGAN	CLINTON	WATERQUALITY	6/20/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290001	MICHIGAN	GRATIOT	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	130363	MICHIGAN	CALHOUN	WATERQUALITY	5/28/2002 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290001	MICHIGAN	GRATIOT	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560063	MICHIGAN	MIDLAND	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	800499	MICHIGAN	VAN BUREN	WATERQUALITY	7/18/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560063	MICHIGAN	MIDLAND	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560064	MICHIGAN	MIDLAND	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290001	MICHIGAN	GRATIOT	WATERQUALITY	9/19/2000 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	560063	MICHIGAN	MIDLAND	WATERQUALITY	7/10/2001 0:00	BHC-gamma (Lindane)	*Non-detect
Michigan Department of Environmental Quality	290001	MICHIGAN	GRATIOT	WATERQUALITY	10/1/2001 0:00	BHC-gamma (Lindane)	*Non-detect

Michigan Wastewater

Lindane was not detected in any effluent (treated wastewater) samples for wastewater treatment plants (WWTPs) reported in EPA's Permit Compliance System for Michigan

e.g., Adrian, Michigan

FACILITY NAME (1): ADRIAN WWTP **NPDES :** MI0022152
FACILITY NAME (2): **LIMIT TYPE :** 5 = FINAL
PIPE NUMBER : 001 **SEASON NUM :** 1
REPORT DESIGNATOR : A **PARAMETER CODE:** 39782 = LINDANE
PIPE SET QUALIFIER : 9 **MONITORING LOCATION :** 1 = EFFLUENT GROSS VALUE
MODIFICATION NUM : 0

MONITORING PERIOD END DATE	DISCHARGE IND	QTY MAXIMUM	QTY AVERAGE	CONC MAXIMUM	CONC AVERAGE	CONC MINIMUM	RNC DETECTION CODE	RNC DETECTION DATE
31-OCT-2007		0		0.00				
30-APR-2007			0.00000	0.00				

http://oaspub.epa.gov/enviro/pcs_det_reports.pcs_tst?npdesid=MI0022152&npvalue=1&n

PCS Detailed Reports

31-OCT-2006		0	0	0.00			N = RPT-NONRECEIPT OF DMR/CS RPT
30-APR-2006		0.000000	0.000000	0.00			N = RPT-NONRECEIPT OF DMR/CS RPT

FACILITY NAME (1): ADRIAN WWTP **NPDES :** MI0022152
FACILITY NAME (2): **LIMIT TYPE :** 5 = FINAL
PIPE NUMBER : 001 **SEASON NUM :** 2
REPORT DESIGNATOR : A **PARAMETER CODE:** 39782 = LINDANE
PIPE SET QUALIFIER : 9 **MONITORING LOCATION :** 1 = EFFLUENT GROSS VALUE
MODIFICATION NUM : 0

MONITORING PERIOD END DATE	DISCHARGE IND	QTY MAXIMUM	QTY AVERAGE	CONC MAXIMUM	CONC AVERAGE	CONC MINIMUM	RNC DETECTION CODE
31-JAN-2007		0	0	0.00			N = RPT-NONRECEIPT OF DMR/CS RPT
31-JUL-2006		0	0	0.00			N = RPT-NONRECEIPT OF DMR/CS RPT
31-JAN-2006		0	0	0.00			N = RPT-NONRECEIPT OF DMR/CS RPT

Michigan Fish

Lindane was “not quantified in any of the fish samples” in the Michigan Fish Contaminant Monitoring Reports from 2006, 2005, and 2003, MI DEQ (source: http://www.michigan.gov/documents/deq/wb-swas-fcmp-2006report_198916_7.pdf)

e.g., 2006 Annual Report

SECTION 3.0

RESULTS AND DISCUSSION

3.1 EDIBLE PORTION MONITORING

The 2006 Annual Report includes the analytical results available by January 15, 2007, for edible portion fish samples collected in 2004 and 2005. A total of 510 edible portion fish tissue samples are summarized in this report. This includes samples from 15 species and 33 locations (Figure 1).

3.1.1 General Highlights

- Several chemicals analyzed were not quantified in any of the fish samples, including aldrin, heptachlorostyrene, lindane, pentachlorostyrene, terphenyl, and toxaphene. However, the breakdown product of aldrin (i.e., dieldrin) was quantified in fish tissue samples from 15 of 18 locations in which they were analyzed (Table 9).

Michigan Waste

The US EPA's Toxics Release Inventory reports no releases of lindane from 1998 to 2006 in Michigan (source: <http://www.epa.gov/triexplorer/trends.htm>)



TRI Explorer
m=62&fid=m63&fid=m66&fid=m67&fid=m73&fid=m79&fid=m90&fid=m94&fid=m99&fid=RELLBY&_service=ox&_type=pl&_op=T&_display=st&_tr=tr&_d=2006

You are here: [EPA Home](#) | [TRI](#) | [TRI Explorer\(ver 4.7\)](#) | Reports

Releases: Trends Report

Data source: 2006 Data Update as of June 11, 2008

[Instructions for use](#)

No data for TRI On-site and Off-site Reported Disposed of or Otherwise Released for LINDANE, in Michigan by All Industries during 1998-2006. (STYR)
Please make another report selection.

Release:
Trends Report

March 3, 2008

Go to [TRI Explorer Home](#) |

[TOP OF SCREEN](#)

.....
This request took 4.04 seconds of real time (v9.1 build 1461).

Drinking Water

U.S. EPA Estimated that in 16 states it surveyed as well as nationally, and based on tens of thousands of water samples Zero public water systems exceeded the MCL for Lindane (US EPA 2003 "Six Year Review of Drinking Water Regulations"; source: http://www.epa.gov/ogwdw000/standard/review/pdfs/support_6yr_occurrencemethods_final.pdf)

Contaminant	MCL (in mg/L)	Best Estimate of Systems Estimated to Exceed the MCL		Range Estimate of Systems Estimated to Exceed the MCL	
		16 States	National	16 States	National
Endothall	0.1	0	0	0 - 0	0 - 0
Endrin	0.002	0	0	0 - 0	0 - 0
Ethylene Dibromide	0.00005	18	76	7 - 32	28 - 133
Glyphosate	0.7	0	0	0 - 0	0 - 0
Heptachlor	0.0004	0	0	0 - 0	0 - 0
Heptachlor Epoxide	0.0002	0	0	0 - 0	0 - 0
Hexachlorobenzene	0.001	0	0	0 - 0	0 - 0
Hexachlorocyclopentadiene	0.05	0	0	0 - 0	0 - 0
Lindane	0.0002	0	0	0 - 0	0 - 0

**Approved Use in other Countries
e.g., in Canada, available online and over the counter**

The screenshot shows a web browser window with the URL <http://www.onlinecanada.com/ms/customer/search.php?substring=undine&source=google&id=C0265f7f15ACF08D00606amp>. The page header includes the "Online Canada EN" logo, a "Click Here to Login" link, and navigation icons for "Login", "Cart", "Live Help", and "Mail". A banner for "FREE SHIPPING ON ALL ORDERS" is displayed, along with a "Search Drugs" search bar and contact information: "Tel: 1-866-799-3784" and "Fax: 1-866-799-3784".

Drug Search Results

Below are your search results. You may view more information about a product by clicking on the corresponding image or product name. Please note that some medications may have a different name or they may not be available in Canada. If you cannot find a particular medication online, please contact us and we will be glad to assist you.



Undine (Solution)

NO prescription required

Manufactured by: Not available

Select a Size:

Buy Now

(Please select a product from the drop-down menu and click on "Buy Now")



Undine (Shampoo)

NO prescription required

Manufactured by: Not available

Select a Size:

The browser status bar at the bottom shows "Internet" and "75%" zoom level.

