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Congress of the United States
House of Representatives
Washington, DC 20515–2107

May 31, 2012

The Honorable Margaret Hamburg
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg:

I write to urge the Food and Drug Administration (FDA) to take immediate steps to halt the use of lindane, a toxic and environmentally persistent insecticide, as a pharmaceutical treatment for head lice in children. Lindane is classified as an organochlorine insecticide that has been used both in prescription shampoos to treat head lice and scabies, under the jurisdiction of the FDA, as well as in agriculture as a common pesticide to treat crops, forestry products and livestock under the jurisdiction of the Environmental Protection Agency (EPA). Out of recognition of its toxicity to humans and its environmental persistence, in 2006 the EPA cancelled all pesticide registrations for agricultural uses of lindane. In addition, in 2009 more than 160 nations agreed to ban the agricultural use of lindane under the Stockholm Convention on Persistent Organic Pollutants. Despite these actions and the known danger that lindane poses to human health, the FDA continues to allow the use of this insecticide as a treatment for head lice in children. Lindane's continued use in prescription shampoos and lotion have also been associated with increased resistance and reduced efficiency in the treatment of head lice as well as with contamination of waterways.

A variety of adverse reactions to lindane pharmaceuticals have been reported, ranging from skin irritation to seizures, and, in rare instances, even death.[1] Based largely on animal studies, the International Agency for Research on Cancer (IARC) classified lindane as a possible human carcinogen, and in 2005 the U.S. Department of Health and Human Services (HHS) determined that lindane may be reasonably expected to cause cancer in humans.[2] In addition to carcinogenic effects, lindane exposure can harm the

[1] Thomson Micromedex. Lindane topical. In: Volume 1: Drug Information for the Healthcare Professional. 2. Greenwood Village, CO: Thomson Micromedex; 2006. pp. 1940–1943.
[2] Agency for Toxic Substances and Disease Registry, U.S. Department of Health and Human Services. Toxicologic profile for alpha-, beta, gamma- and delta-hexachlorocyclohenxane. August 2005 and International Agency for Research on Cancer (IARC). Summaries & Evaluations: Hexachlorocyclohexanes (Group 2B). Updated March 2, 1998.

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nervous system. When the EPA evaluated the health and environmental costs associated with lindane use in agricultural settings it noted that "lindane primarily affects the nervous system causing neurotoxic effects...when people are exposed to lindane through food, water or the atmosphere, they will accumulate lindane residues in their fatty tissues, and these lindane residues will remain there for an undetermined amount of time."[3]

Since infestations of lice and scabies are most often found in large institutions such as schools, it is reasonable to assume that a large portion of the U.S. population of patients treated with lindane is comprised of children. In fact according to the Centers for Disease Control and Prevention (CDC), in the United States, infestation with head lice is most common among children 3 to 11 years of age, with an estimated 6 to 10 million infestations that occur each year.[4] As the EPA has noted, infants and children are especially sensitive to the health risks posed by pesticides because of their developing organs and immature excretory system.[5] Furthermore, recent evidence suggests that because of the widespread use of this chemical treatment, lice and scabies have become increasingly resistant to lindane, reducing its efficacy as a treatment. In fact, studies of lindane have found that it only kills 50-70 percent of lice eggs.[6] As FDA has previously acknowledged,[7] parents may be inclined to overuse lindane in their zeal to treat their children as quickly as possible, which increases the amount of lindane children are exposed to, consequently increasing the likelihood of adverse impacts. Additionally, head lice and scabies can be effectively treated without the use of lindane. A 2002 study that compared efficacy of five available products on resistant head lice found that lindane was the least effective of all the products.[8] With other alternatives that are more effective, non-toxic, and less expensive, the continued approval of lindane as a treatment for head lice and scabies is unnecessarily dangerous.

In addition to lindane's toxicity and ineffectiveness, it also has been found to contaminate waterways. This occurs when lindane-containing shampoos and lotions are rinsed down the drain after use. According to the EPA the "pharmaceutical use of lindane for treatment of lice and scabies results in exposure to the treated individual, as well as exposure to the general population as a result of 'down the drain' release into drinking water."[9] This contamination of water supplies and the expense associated with wastewater treatment was part of the reason why California took action in 2002 to ban the pharmaceutical use of lindane. Wastewater treatment engineers in Los Angeles calculated that a single treatment for head lice or scabies contains enough lindane to bring

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[3] U.S. EPA, Lindane Voluntary Cancellation and RED Addendum Fact Sheet, available at http://www.epa.gov/opp00001/reregistration/REDs/factsheets/lindane_fs_addendum.htm

[4] http://www.cdc.gov/parasites/lice/head/gen_info/faqs.html

[5] See: http://www.epa.gov/pesticides/food/pest.htm

[6] Barbara L. Frankowski, MD, MPH, et al., *Head Lice*, 3 Pediatrics 110, 638-643 (2002).

[7] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm110845.htm

[8] Terri L. Meinking, et al., *Comparative in vitro Pediculicidal Efficacy of Treatments in a Resistant Head Lice Population in the United States,* 2 Arch. Dermatol. 138, 220-224 (2002)

[9] U.S. EPA, *Lindane Voluntary Cancellation and RED Addendum Fact Sheet, available at* http://www.epa.gov/opp00001/reregistration/REDs/factsheets/lindane_fs_addendum.htm (last visited May 5, 2010).

six million gallons of water above this California water quality standard.[10] Although lindane does have a drinking water standard set by the Safe Drinking Water Act, it is not required to be removed completely. Since lindane is highly stable for long periods of time, it has the potential to accumulate in the bodies of in organisms, including humans, at levels that could pose health concerns.

Given the scientific evidence on the toxicity of lindane, its ineffectiveness as a lice and scabies treatment and the ability of this chemical to enter into U.S. drinking water supplies despite its removal as a viable pesticide by the EPA, there is simply no basis for FDA's decision to continue to allow the use of this substance for head lice and scabies treatment. In order to better understand FDA's plans and progress on this issue, I ask for your prompt response to the following questions.

1. The pesticide registration that allowed lindane to be used on seeds, lumber and cattle was withdrawn by the EPA, with last uses of this chemical cancelled in 2007. Why is this compound still allowed for use on children even after the FDA noted that lindane is especially harmful to this segment of the population?

2. What has FDA learned from adverse event reports and other information collectively gathered by the federal government, including information gathered by the Agency for Toxic Substances and Disease Registry (ATSDR), with regards to lindane's impacts on children? Please provide copies of any adverse event reports that inform your response.

3. Has the FDA taken into consideration the long-term chronic impacts that lindane exposure may have on children? If so, what has FDA concluded? If not, why not?

4. In 1995, the FDA labeled lindane as a "second-line therapy" meaning that it should be used in patients who did not respond to other FDA approved therapies, such as the pesticides malathion, pyrethrin and permethrin. Much like lindane, all of these pesticide treatments have also been associated with toxic impacts on the nervous system. As a result, children may often be exposed to multiple similarly-acting chemical lice treatments in a short-period of time. Has FDA evaluated the cumulative short and long term health impacts associated with exposure to multiple pesticide treatments in children? If so, what did FDA find? If not, why not? Has FDA considered these cumulative impacts in context of whether lindane should remain as an approved therapy for lice and scabies?

5. Has the FDA evaluated the increased resistance that head lice and scabies have developed to lindane treatment? If so, does FDA continue to believe that

[10] CSDLAC. Lindane Usage Reduction Pilot Project, 1998 Pollution Prevention Leadership Grant Program, Final Report. Los Angeles: County Sanitation Districts of Los Angeles County; 2001.

lindane is an effective treatment for head lice and scabies in children? Please explain. If not, why not?

6. The National Environmental Policy Act (NEPA) requires all federal agencies, including FDA, to include any "new and significant" information regarding the environmental consequences of their proposed activity. Does the FDA believe that EPA's withdrawal of lindane's registration as a pesticide is "new and significant" information that would trigger a new NEPA analysis? If not, why not? If yes, please provide information regarding the new NEPA analysis and what the FDA concluded.

7. Does the information regarding lindane's transmission down household drains and into waterways and drinking water supplies factor into the decisions the FDA makes regarding lindane's continued approval for use in lotions and shampoos? If so, how? If this was not considered, why not?

8. If FDA determined that approval of lindane as a treatment for head lice and scabies was no longer warranted because of safety and efficacy concerns, what immediate actions could FDA take to halt the use of lindane and to ensure the public is protected from this dangerous chemical?

Thank you for your assistance and cooperation in this matter. I request that you provide a full and complete response within 15 working days or no later than June 21, 2012. Should you have any questions about this request, please have your staff contact Dr. Avenel Joseph of my staff at (202) 225-2836.

Sincerely,

Edward J. Markey

Edward J. Markey