

MEDICAL SOCIETY
of the
STATE OF NEW YORK

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Director

Division of Governmental Affairs

MEMORANDUM IN OPPOSITION

**IN SENATE HEALTH
COMMITTEE**

S.3938-A (FLANAGAN)

**IN ASSEMBLY HEALTH
COMMITTEE**

A.6802-A (WEISENBERG)

AN ACT to amend the public health law, in relation to banning the sale, use, and prescription of any product containing the substance commonly known as Lindane to certain individuals

This measure would take away the ability of physicians to use their medical judgment in the use of any product containing hexachlorocyclohexane, or Gamma benzene hexachloride, and its salts and isomers. The bill prohibits the sale, use or prescription of this product to pregnant women and to anyone under the age of sixteen, and allows its use only for the treatment of scabies. If this bill passes, the State Legislature would be enacting more stringent restrictions on a drug than the Federal Food and Drug Administration, which is the body designated to be the watchdog in these matters. Passage of this bill would mark the first time the legislature would ban the use of a drug approved by the FDA for a specific use. Many other drugs could potentially meet a similar fate. The Medical Society believes that this is a bad precedent to set.

The bill allows gamma benzene hexachloride or hexachlorocyclohexane to be used only in the treatment of scabies provided that it is ordered and commenced under the supervision of a health care provider licensed under title eight of the education law, acting within his or her scope of practice, but does not allow its use for lice. The health care provider must appropriately instruct the patient, parent or guardian concerning proper procedures prior to and following the commencement of administering these medications, including removal and washing. **The Medical Society of the State of New York opposes this bill.**

While our physicians agree that Hexachlorocyclohexane or Gamma benzene hexachloride, commonly known as Lindane, should be available only pursuant to a prescription from a physician, they strongly feel that physicians have the right, as well as the education and training, to use any medication in any way that they deem appropriate. This is evidenced by the off label use of many drugs. If you limit the use of Lindane to scabies, and another condition or disease arises for which it is the medicine of choice, a physician would not be able to prescribe it for that use. This could potentially close the door to the off label use of the most effective drug available.

The FDA Medication Guide says:

- Do not use Lindane Lotion unless you have scabies and were treated with another medicine that did not work for you or you cannot use other, safer medicines to treat your scabies.
- Do not use Lindane Shampoo unless you have head lice and another medication did not work for you or you cannot use other, safer medicines to treat your lice.
- Lindane Lotion and Shampoo is mainly for adults and children who weigh at least 110 pounds. If you weigh less than 110 pounds use Lindane only if your doctor thinks it is medically appropriate.
- Do not use Lindane if you need to treat a premature or young baby.
- Do not use Lindane if you are breastfeeding as it can get in your milk and may be fed to your baby.
- If you are pregnant, do not use Lindane unless you have talked to your doctor about using it. Ask your doctor for a safer medicine. Use Lindane only if needed.

Although there are alternatives available to Lindane in the treatment of head or body lice, or scabies, they are not always effective on everyone. The egg sacs, or nits, can burrow under the skin and are difficult to destroy. Lindane has been shown to effectively treat both the lice and the nits. However, this measure would prohibit the use of Lindane for lice and restrict its use for scabies.

The position of the FDA is that Lindane should remain available, as a second-line treatment of scabies and lice, for patients for whom first-line therapies have failed or cannot be tolerated. The Medical Society agrees that Lindane should be available as an alternative treatment if the physician so decides.

Since 1951, when Lindane was first introduced into the U.S. healthcare market, it has undergone repeated and comprehensive reviews by medical and scientific subject matter experts working with the FDA and the EPA. In every instance, expert reviewers have concluded that carefully defined uses of Lindane do not pose a significant risk to public health or public safety. Consistently, the FDA has maintained its position that the benefits of Lindane outweigh the potential risks when used appropriately, pointing out that all medications have risks. Similarly, the EPA has consistently concluded that the medical use of Lindane poses no significant threat to public health or the environment when used as currently directed. Both the FDA and the EPA agree that Lindane medications are safe when used properly, and that the majority of serious adverse events have resulted from product misuse. To minimize the risk of misuse and enhance product safety, the FDA has taken the following actions:

- Single-use packaging – 16 oz. bottles are no longer allowed; dosages are limited to single-use 2 oz. bottles
- Boxed warnings – Updated prescription labeling for healthcare professionals, highlighting serious risks and essential information on patient selection
- Patient-friendly medication guide – Attached to each package and required by law to be dispensed with each Lindane prescription by pharmacists to educate patients and caregivers on potential risks, proper use, and contraindications (i.e., use in small children – a bolded statement that Lindane is mainly for adults and children who weigh at least 110 pounds and that if you weigh less than 110 pounds you should use it only if your doctor thinks it is really needed. It also states that people who weigh less than 110

pounds and the elderly have higher chances for side effects because more Lindane may go through their skin.)

- Ongoing research – Manufacturer-sponsored studies requested by the FDA are currently underway to further improve the safety profile and effectiveness of Lindane medications

The Medical Society believes that enhanced patient education by the physician at the time a prescription is given, as to the proper use of Lindane, coupled with the medication guide that is dispensed with the 2 ounce unit dose that is allowed by the FDA, would be appropriate.

Restricting Lindane medications in the U.S. healthcare market will force many patients with scabies and lice to purchase less-regulated Lindane products from Canadian suppliers through websites or other channels. In Canada, Lindane is available without a prescription and is easily purchased by patients who are not required to see a healthcare provider for proper diagnosis and counseling. Moreover, it is supplied in bottles containing as much as 17 oz. of Lindane that come with minimal information on proper use and safety warnings. In this situation, the risk for misuse and serious side effects is dramatically increased. Keeping Lindane on the market in the U.S. as a prescription therapy regulated by the FDA protects the American public from this danger.

Because of the above, the Medical Society of the State of New York opposes this bill and urges that it be defeated.

Respectfully submitted,

5/9/07 – Oppose
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