

Public Citizen

NEWS RELEASE

LINDANE

HOLD FOR RELEASE:
Thursday, June 15, 1995, 10 a.m. EDT

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DEEMED TOO TOXIC FOR MOST INDOOR USE, PESTICIDE LINDANE STILL PRESCRIBED FOR HUMAN APPLICATION

2 Million Prescriptions a Year Despite Reports of Convulsions and Deaths

The EPA requires anyone using lindane as a pesticide to wear protective clothing and waterproof gloves and severely limits its application in areas of human habitation; 20 states have banned its use indoors. Nevertheless, as Public Citizen's Health Research Group points out today in its petition to Dr. David Kessler of the U.S. Food and Drug Administration, the toxin is still widely prescribed for use as a remedy for scabies and pediculosis (lice).

"The EPA restricts how and where exterminators spray lindane, but the FDA still allows millions of American consumers to rub this toxin into their scalps where it can be readily absorbed into the body," commented Sidney M. Wolfe, MD, of Public Citizen. People most at risk are children, elderly persons and immunocompromised patients (such as persons with AIDS).

Public Citizen is calling upon the FDA to ban all prescription drugs containing lindane in view of 162 reports between 1972 and July 1994 of adverse reactions ranging from convulsions in 50 people to blood disorders. Six persons, including two children 1 and 9 years old, have died after applications of lindane.

Two leading manufacturers stopped making their lindane products in recent years, but generic equivalents have captured much of that market share. Creams, lotions and shampoos containing lindane are 1% Bio-Well, GBH, G-well, Hexit, Kildane, Kwellada, Kwildane, PMS Lindane, Thionex and generic versions. Over two million prescriptions for lindane were filled in retail pharmacies in 1992.

"There are much safer alternative treatments for scabies and lice infestation, notably over-the-counter medications like Nix that contains permethrin, which is more effective than highly toxic lindane," said Dr. Wolfe.

To obtain a copy of Public Citizen's petition to the FDA, call the number listed above.end/



Buyers Up • Congress Watch • Critical Mass • Health Research Group • Litigation Group

Joan Claybrook, President

June 15, 1995

David A. Kessler, MD, JD
Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Citizen's Petition to Immediately Ban Lindane

Dear Dr. Kessler,

Public Citizen, a nationwide consumer organization with nearly 110,000 members hereby petitions the Food and Drug Administration (FDA), pursuant to the Federal Food, Drug and Cosmetic Act 21 U.S.C. Section 355(e), and 21 C.F.R. 10.30, to remove the prescription drug lindane (gamma isomer of benzene hexachloride or hexachlorocyclohexane) -- indicated for the treatment of scabies and pediculosis (lice) from the market due to the high degree of neurotoxicity (88 reported cases of neurotoxicity including 50 people with convulsions and two deaths in children aged one and nine years), the fact that it is a carcinogen, and the availability of safer and equally effective alternatives. Since at least 1992, the World Health Organization has recommended that lindane not be used for scabies or lice.

A. ACTION REQUESTED

We hereby request that the widely sold scabicide and pediculicide lindane (cream, lotion, and shampoo: 1% Bio-Well; GBH; G-well; Hexit; Kildane; Kwell; Kwellada; Kwildane; PMS Lindane; Scabene; Thionex;¹ and generic versions) be removed immediately from the market. In 1992, according to data from IMS, 2.3 million prescriptions for lindane were filled in the U.S. retail pharmacies.

B. STATEMENT OF GROUNDS

Lindane has been available for treatment of scabies and pediculosis since 1948. In 1981, the FDA examined the safety of lindane in response to a Consumers Union (CU) petition for a ban on the use of lindane as a pediculicide and for stronger warnings to be added for its use as a scabicide. In 1983, Public Citizen's Health Research Group (PCHRG) submitted comments on the petition filed by CU and urged an outright ban on all medical uses of this dangerous pesticide. In spite of evidence presented as to the hazards of lindane, the drug was allowed to remain on the market, in part due to the lack of proven alternative methods of treatment. Since then, several more effective treatment methods have become available. Since these alternative treatments are safer and more effective, it is necessary that the more dangerous product, lindane, be removed from the market.

Background

Scabies is an ectoparasitic infestation in which mites (*Sarcoptes scabiei*) make burrows in the skin and lay eggs. The primary symptom is itching, although crusting (Norwegian scabies) may occur. Symptoms may be more severe in immunocompromised patients, such as those with Acquired Immunodeficiency Syndrome (AIDS).² In these patients a higher number of mites may infest the body, leading to the possibility of opportunistic bacterial infection through the damaged skin. Scabies is primarily associated with groups in close personal contact. The primary groups at risk of contracting scabies are children, nursing home residents, and AIDS patients.^{3,4} These populations are particularly sensitive to the potential toxic effects of lindane.

Pediculosis results from blood-sucking ectoparasitic infestation by three different species of lice. Head lice (*Pediculus humanus capitis*) primarily affects the scalp; body lice (*Pediculus humanus corporis*) which inhabits clothing and infests the trunk and limb to feed; and pubic lice (*Phthirus pubis*) which infests pubic hair and skin. They thrive in overcrowded, unhygienic and substandard living conditions but are also commonly seen in people of higher socio-economic status. The most serious cases often involve elderly, infirm, or mentally retarded individuals. Head louse infestations are more common in children than in adults, and girls or young women are infested more often than boys or young men.⁵

Lindane

Lindane is a moderately toxic organochlorine insecticide approved for topical use in scabies and pediculosis. Although it is not meant to be taken internally, it is readily absorbed through the skin.⁶ Studies involving a single topical application of lindane to the forearm, indicate that at least 9 percent of the applied dose was absorbed through the skin.⁷

There is inadequate information on the exact incidence of adverse experiences

following lindane treatment. No large scale systemic examination of the incidence of adverse experiences following use of lindane in the treatment of scabies or pediculosis was identified. An examination of the adverse drug experience reports from the FDA's spontaneous reporting system database demonstrates the hazardous nature of lindane. A total of 162 adverse events were reported to the FDA from October 1972 through July 1994; six of the reactions were fatal. Neurotoxicity was the primary adverse experience reported. A total of 88 cases (54 percent of all case reports) reported neurotoxic effects, with convulsions being the most common neurotoxic adverse experience noted, occurring in 50 (31 percent) cases. In addition, rashes were reported in 13 cases (8 percent) and adverse reactions of the blood system were reported in three cases (2 percent). Thirty-four percent of the adverse experiences were reported in children aged 10 years or younger; half of the adverse experiences were reported in those aged 19 or younger.

Because of the limitations of the FDA's spontaneous reporting system database, under-reporting of adverse experiences is very substantial and the actual number of serious adverse events and deaths associated with lindane use is likely to be ten times higher. This extent of under-reporting is often cited by the FDA itself. In addition, only the more severe instances of toxicity are likely to be reported, and mild adverse effects would be under-reported.

Lindane-associated Deaths

The FDA adverse drug experience database includes six reports of deaths associated with lindane use as a prescription drug. Three of these deaths occurred in children: two were associated with acute neurotoxicity in children aged one and nine years old, and the third child aged two years old suffered fatal aplastic anemia.

Lindane Neurotoxicity

The exact mechanism of lindane's action on the central nervous system is not understood, but it may involve inhibition of GABA (Gamma Aminobutyric Acid) receptors.⁸

Lindane neurotoxicity has often been associated with inappropriate use. In some of these cases, patients were often given lindane on consecutive days and the drug was not washed off in between. In one case, an 18 month old child was given 1 % lindane on two consecutive nights. After the first application, lindane was washed off in the morning; after the second application, however, lindane was not washed off. The child subsequently suffered a seizure which lasted for 30 minutes. The child recovered following intravenous diazepam treatment.⁹ In another case, a two month old infant was found dead in his crib following whole-body application of 1% lindane lotion after a hot bath. Lindane had been washed off 18 hours after application.¹⁰

In another report, three elderly patients in a chronic care ward had seizures after

application of 1% lindane lotion for treatment of scabies. In this case, lindane had been applied after a hot bath which is not recommended since it is thought to increase percutaneous absorption. None of the patients had any past history of seizures. No other cause for the seizures could be identified and the serum lindane concentrations were higher than expected. The authors concluded that elderly patients, like children, may be at risk for lindane-induced seizures.¹¹ In another case, a three year old boy with congenital ichthyosiform erythroderma developed convulsions within 15 minutes of a single application of 1% lindane cream. The child suffered another seizure 24 hours later. The child subsequently recovered, and the seizure was in part attributed to decreased skin barrier function.¹²

Lindane and Bone Marrow Toxicity

At FDA hearings in the past, concerns have been expressed regarding lindane's potential to cause hematological side effects. More cases of bone marrow toxicity associated with lindane exposure have now been reported. In one case, a patient applied 1% lindane lotion from his neck to his knees twice daily for three weeks. Three weeks following cessation of exposure, he was admitted to the hospital with bleeding gums, weakness and shortness of breath. He was suffering from severe pancytopenia (decrease in all blood cells). Bone marrow aspirates revealed hypocellularity and confirmed the diagnosis of aplastic anemia (anemia resulting from failure of cell production in the bone marrow).¹³ In another report, three cases of organochlorine pesticide-associated aplastic anemia have been described.¹⁴ The first patient was a 12 year old who was exposed to lindane for two to three months after his room was treated for woodworm. He displayed pancytopenia and marked hypocellularity in the bone marrow. Eighteen months later, he was still neutropenic (low white blood cells) and thrombocytopenic (low platelets). The second case was a 28 year old computer operator who was actively involved in the renovating of an old building for several months and had applied pentachlorophenol (a major metabolite of lindane, used as a wood preservative) to timber work. His bone marrow picture was consistent with severe aplastic anemia. In the third case, a 26 year old laborer was exposed to lindane while cleaning pipes at a pesticide factory. He was admitted to the hospital with severe pancytopenia. Bone marrow aspirates confirmed severe hypocellularity. Over a period of months, aided by antithymocyte globulin therapy, his peripheral blood counts returned to normal. In yet another report, a 14 year old boy self-administered lindane on eight occasions over a six week period. He developed anemia and his bone marrow was characterized by decreased megaloblastoid erythroid series reflective of bone marrow toxicity. Over a period of two months, his blood values returned to normal.¹⁵ Finally, the FDA adverse drug experience database contains three cases of anemia associated with the use of lindane.

Recent laboratory studies also indicate that lindane has significant toxicity to the bone marrow. In one study, mice given lindane daily at doses of 20 and 40 mg/kg body weight had suppressed cellularity in the bone marrow, and a decreased number of colony forming units, suggesting a decreased capacity for producing blood cells.¹⁶ In another

study, human and rat bone marrow cells were treated with lindane. The results showed that human cells were more sensitive than rat cells to lindane. For an equivalent level of cell toxicity, the lindane concentration used for human cells was 1,000 times lower than the concentration used for rat cells.¹⁷ These reports provide additional evidence of the toxicity of lindane to the bone marrow and suggest that humans are more susceptible to the hematotoxic effects of lindane than rats.

This evidence of the hematotoxicity of lindane is particularly troublesome since one of the groups identified as being particularly at risk of scabies infestations are immunocompromised patients such as those with AIDS. The hematotoxic effects of lindane could be expected to aggravate the immunocompromised state of AIDS patients, many of whom also have bone marrow toxicity from the other drugs -- such as AZT -- they are taking.

Citizen Petition By Cancer Prevention Coalition

PCHRG supports the January 17, 1995 petition to the FDA by the Chicago-based Cancer Prevention Coalition, to ban the use of lindane as a treatment for lice and scabies because of animal evidence of the carcinogenicity of lindane and a recent study suggesting increased rates of brain cancer in children treated with lindane shampoos.

Effective Alternatives To Lindane Are Available

Since the early 1980s, more effective and safer treatment regimens for scabies have been developed. In particular, treatments based on permethrin (products such as Elimite and Nix) and the combination of natural pyrethrins with piperonyl butoxide (A-200 Pediculicide Shampoo; RID Lice Killing Shampoo; R&C) have proven to be as effective as lindane, and do not cause serious adverse experience. These treatments may use up to five percent permethrin, but due to the lower absorption of permethrin through the skin (on the order of one percent), there is a lower effective dose absorbed than in the case of lindane. In addition, permethrin is more rapidly detoxified in the body.

According to the editors of the *Medical Letter* "Permethrin 5% cream appears to be as effective as 1% lindane and more effective than crotamiton [Eurax] for treatment of scabies. Since the new drug appears to be safer than lindane, *Medical Letter* consultants consider it the drug of choice for this indication."¹⁸

Treatments based on permethrin have been demonstrated to be at least as effective as lindane. In one study, the cure rate in patients with scabies was 98 percent with 5% permethrin, 84 percent with 1% lindane and 88 percent with 10% crotamiton.¹⁹ In addition, these alternative treatment regimens have been effective in cases in which the parasite was resistant to lindane.^{20,21,22} Due to the emergence of lindane resistant strains of scabies, the California Department of Health is recommending alternative therapies to treat scabies.²³

Studies have also demonstrated the increased effectiveness of alternatives to lindane for the treatment of pediculosis. In one study, 74 percent of all patients were louse-free after two weeks of therapy with 1% lindane shampoo, compared to 98 percent who were treated with 1% permethrin cream rinse.²⁴ In another study, treatments based on permethrin or pyrethroids had lower rates of reinfestations compared to lindane.²⁵ In one *in vitro* study ovicidal activity and killing times were evaluated for six pediculicides, using viable eggs and recently fed head lice from infested children. In this study 0.5% malathion (this product is no longer available in the U.S.) demonstrated the quickest knock down and kill time. The pyrethrin products were the next quickest killers while 1% lindane shampoo was the slowest-killing product.²⁶

These alternatives to lindane have a higher therapeutic index (ratio of the dose that cause toxicity to the clinically effective dose) which makes them a markedly superior choice for the treatment of scabies. Permethrin is estimated to be less toxic than lindane by a factor of 36.²⁷ Many commentators have suggested that the lower toxicity of the permethrin and the pyrethroids make them superior choices for the treatment of scabies.^{28,29,30,31,32}

Lindane and the World Health Organization

Lindane is not recommended by the World Health Organization (WHO) for the treatment of scabies or lice. "Because of its persistence in the environment and its toxic degradation, lindane -- which was formerly widely used to treat head lice -- is no longer recommended for use."³³ The WHO's Model List of Essential Drugs (revised in November 1993) includes only benzyl benzoate and permethrin under the heading scabicides and pediculicides.³⁴

Leading Lindane Products Discontinued

Since our 1983 submission to the FDA to ban lindane, Reed & Carnrick, the major manufacturer of lindane in the U.S. has discontinued their products (Kwell Cream; Kwell Lotion; Kwell Shampoo) because of 'commercial reasons'. In a July 26, 1993 notice Reed & Carnrick announced "This is to confirm that the manufacture of Kwell products has been discontinued and all remaining inventory has been depleted."³⁵ However, the 1995 edition of the *Physicians' Desk Reference* still carries a two page entry for Kwell products.³⁶ Interestingly Stiefel another manufacturer of lindane products (Scabene Lotion; Scabene Shampoo) has also discontinued its products because of 'commercial reasons'. Incidentally both Kwell and Scabene products are still listed in the 1995 edition of the FDA's *Orange Book*.³⁷ Unfortunately, generic versions of lindane have captured a significant share of the market previously dominated by Kwell and Scabene.

Lindane's Status at the Federal Level

Because of lindane's potential to cause acute toxicity, and concerns about its

oncogenicity, teratogenicity, reproductive effects, and other chronic effects, the federal Environmental Protection Agency (EPA) has canceled lindane products for use as vaporizers; and for direct application to aquatic environments. Lindane is a restricted use pesticide registered for use on the following outdoor sites: fruit trees, ornamental trees/plants, golf courses, residential turf areas, seed treatments, vegetable crops, livestock, and dogs, etc. The applicators are required to observe certain precautions: wear protective clothing, apron, water-proof gloves, water-resistant hat, etc.

There are two EPA approved lindane-containing products for indoor residential use, i.e. structural pest control. These products are not to be applied to currently occupied (living or working) areas. Such living areas include finished basements and finished attics, and workplaces.

Lindane's Status at the State Level

We conducted a survey of the pesticide agency in all 50 states and the District of Columbia and found that at least 20 states, namely Alaska, Arizona, California, Connecticut, Hawaii, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Montana, Nebraska, New Mexico, New York, North Carolina, Oregon, Rhode Island, South Dakota, Vermont, and Washington do not allow household (indoor) use of lindane to treat pests because of its toxicity. With reckless disregard to the lives and health of children, elderly and the immunocompromised, the FDA is continuing to allow the use (with direct application to the skin when it is readily absorbed) of a dangerous product whose indoor use in households against pests is not permitted in 20 states (See Table below).

State	Regulatory Status of Lindane
Alabama	Same as EPA. ¹
Alaska ²	"To our knowledge, the pesticide lindane is not used for household use by any commercial applicator."
Arizona	There are three products "that can be used by exterminating companies treating homes for outdoor lawn and tree damaging pests."
Arkansas	Same as EPA. ¹
California	"There are no lindane products registered for use on household or domestic dwellings".
Colorado	Same as EPA. ¹
Connecticut	No lindane product registered for indoor use for many years.
Delaware	Same as EPA. ¹ Lindane not commonly used by pest control companies.
District of Columbia	Same as EPA. ¹
Florida	Same as EPA. ¹

State	Regulatory Status of Lindane
Georgia	No additional state restrictions over and above those imposed by EPA. ¹
Hawaii	"I am not aware of any household uses currently registered in Hawaii."
Idaho	Same as EPA. ¹
Illinois	Same as EPA. ¹
Indiana	Same as EPA. ¹
Iowa	Same as EPA. ¹
Kansas	Same as EPA. ¹
Kentucky	Same as EPA. ¹
Louisiana	Same as EPA. ¹
Maine	"Household use of lindane by exterminating companies is not a permitted use."
Maryland	Same as EPA. ¹
Massachusetts	No additional restrictions. Exterminating companies generally apply pesticides "indoors" which is NOT an allowed label use and consequently not to be used.
Michigan	"[T]here are no products registered in this state which allow the use of lindane by exterminating companies in the household."
Minnesota	"I don't think it is used indoors."
Mississippi	"[Use] to treat support structures for wood destroying pests (not inside home use)."
Missouri	Same as EPA. ¹
Montana	Majority of lindane products are for seed treatment. No products registered by commercial pest control companies.
Nebraska	"[N]o registered uses for interior treatments."
Nevada	No additional restrictions other than placed by EPA.
New Hampshire	Same as EPA. ¹
New Jersey	Same as EPA. ¹
New Mexico	"No lindane product is currently registered for general structural uses; therefore the use of a lindane product in or on a human-occupied structure by an exterminating company or anyone else would be considered a violation of State or Federal law."
New York	There are no registered lindane products approved for household (indoor) use in the state of New York.
North Carolina	"There are no products registered for household use by exterminating companies in North Carolina."
North Dakota	Same as EPA. ¹

State	Regulatory Status of Lindane
Ohio	Same as EPA. ¹ "[O]nly indoor use now allowed for lindane is application to wood for control of boring and other related insects. Exterminators might use the products in this manner."
Oklahoma	Same as EPA. ¹
Oregon	"Although there are some products that could be used around the outside of a house there are no indoor household uses."
Pennsylvania	Same as EPA. ¹
Rhode Island	"All products are registered for outdoor use.....there are no products registered for use within the home."
South Carolina	Same as EPA. ¹
South Dakota	"[H]ousehold uses are not registered in South Dakota."
Tennessee	Same as EPA. ¹
Texas	Same as EPA. ¹
Utah	Used "only in garden-household products. There are no products registered for exterminating companies."
Vermont	"There are no products registered for use by exterminating companies for household use."
Virginia	Same as EPA. ¹
Washington	There are no products that would allow a household use of lindane for extermination purposes.
West Virginia	Same as EPA. ¹ "I do not believe there are any existing agricultural or exterminating company uses for this product."
Wisconsin	"Although household uses are permitted.....the majority of lindane used by homeowners is probably for control of insects on ornamental plants."
Wyoming	Same as EPA. ¹

1= Application allowed only in areas not currently occupied such as unfinished basements and attics.

2= Alaska is the only state which does not have its own registration system. Any pesticide registered with the EPA may be used there.

Conclusion

In conclusion, effective alternatives exist for lindane for the treatment of ectoparasitic infestations such as lice or scabies. Due to the lower toxicity of alternative treatments, there is no reason to keep lindane on the market because of its greater potential for causing adverse reactions.

Lindane Should be Banned

Over the years lindane's label has been strengthened to warn physicians of its hazards, particularly in infants, pregnant women and nursing mothers. However, the FDA continues to receive reports of serious neurotoxicity (including 5 reports of convulsions in 1993) associated with lindane use.

The argument has been made that lindane is safe when used according to the labeling recommendations. Since this product is generally used in a home setting without physician supervision, there is a real danger of misuse of the substance or even some uses as directed. The narrow therapeutic index for lindane implies that any misuse, either through accidental ingestion or inappropriate administration, can result in potentially serious health effects. Given the existence of effective treatments with lower potential for serious health effects, lindane should not be permitted to remain on the market.

We call on you to withdraw approval for the use of lindane for the treatment of scabies and pediculosis before any more Americans are exposed to this needless risk. There can be no excuse for allowing a drug to remain on the market for which considerably safer and effective alternatives exist.

C. ENVIRONMENTAL IMPACT STATEMENT

The Environmental Protection Agency has classified lindane as a hazardous waste that must meet certain disposal requirements. The EPA has recommended guidelines on how much lindane can be present in drinking water for specific periods without health effects. The Occupational Safety and Health Administration (OSHA) regulates levels of lindane in the workplace.

D. ECONOMIC IMPACT STATEMENT

The requested action will eliminate manufacturers' revenues from the sale of lindane products but will increase the sale of relatively safer and effective alternatives.

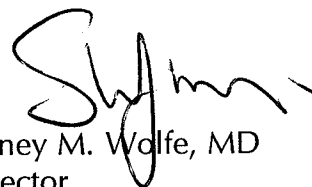
E. CERTIFICATION

We certify that, to our best knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioners which are unfavorable to the petition.

Sincerely,



Syed Rizwanuddin Ahmad, MD, MPH
Researcher



Sidney M. Wolfe, MD
Director

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