HEXACHLOROPHENE AND NEWBORNS

A number of recent studies have raised serious questions concerning the toxicity of hexachlorophene preparations used for total body bathing of newborn infants. A summary of three such studies follows:

1. Fifty newborn infants, bathed daily with a 3% hexachlorophene product, showed hexachlorophene blood levels of .009 to .646 micrograms/ml. on the day of hospital discharge. No obvious toxic symptoms were noted in the newborns. (Curley, A., et al. Lancet, Aug. 7, 1971.)
2. Rats fed hexachlorophene to achieve mean hexachlorophene blood levels of 1.21 micrograms/ml. showed brain changes characterized by cerebral edema limited to the white matter, and cystic spaces of the brain believed produced by fluid accumulation. (Gaines, T.B., Kimbrough, R.D. Paper read at the 10th annual meeting of the Society of Toxicology, Washington, D. C., March 7-11, 1971. See also Kimbrough & Gaines, Arch. Environ. Health 23:114-118, Aug. 1971.)
3. Newborn monkeys washed daily with 3% hexachlorophene for 90 days showed mean hexachlorophene plasma levels of 2.3 micrograms/ml. When they were sacrificed, the white matter of the brain, particularly the cerebellum, brain stem and all parts of the cord, showed lesions consisting of cystic spaces like those described above. (Studies submitted by Winthrop Laboratories to FDA on November 18, 1971.)

These studies challenge the safety of hexachlorophene bathing of infants, a practice which has been widely advocated as effective prophylaxis against nursery epidemics of staphylococcal skin infections. A critical review of the studies on which this claim is based indicates that whereas there is no doubt that hexachlorophene bathing decreases skin colonization of gram-positive organisms, there is a lack of substantial evidence that hexachlorophene washings by themselves prevent staphylococcal disease or show antibacterial activity against gram-negative organisms. Hospitals are known to operate nurseries safely without the use of this product.

The FDA has been in close contact with the Committee on Fetus and Newborn of the American Academy of Pediatrics regarding these findings. In light of these findings and since other methods of control of infection are available, we have jointly concluded that the use of hexachlorophene for total body bathing of infants in hospital nurseries or at home is not recommended. In its place the committee recommends the following procedures:

> "At present we recommend dry skin care, washing with plain soap and water or tap water alone for skin care of the newborn infants. It should be emphasized that the most important factor in the transmission of infection from infant to infant is hand contact. This can be minimized by scrupulous hand washing before entering the nursery as well as just before and just after handling each infant. Either an iodophor preparation or 3% hexachlorophene emulsion is recommended."

The labeling of 3% hexachlorophene products is being amended to advise against their use for total body bathing.

The effectiveness of 3% hexachlorophene for other uses has been studied by the Food and Drug Administration and the National Academy of Sciences. On December 8, 1971, FDA published NAS Drug Efficacy Study evaluations rating such products effective for use as bacteriostatic skin cleanser (including surgical scrub). They are rated possibly effective* for use in the treatment of impetigo in newborns and of other staphylococcal skin infections, and in the treatment of cradle cap and in helping to clear acne. They are found to be lacking in substantial evidence of effectiveness for use in the relief of pruritus ani, for the broad claim as a vaginal douche, in the treatment of chronic eczema, in irrigating or cleansing wounds and burns, and as an "aid to personal hygiene".

Further studies will be necessary to determine the ultimate usefulness of hexachlorophene preparations.

*A rating of possibly effective means that there is little evidence of effectiveness for the given indication. Substantial evidence of the effectiveness of drugs is required by law. The responsibility for substantial evidence of effectiveness of a drug rests with the manufacturer.