Reviewer's report

Title: Effectiveness of Isopropyl Myristate/Cyclomethicone Solution of Removing Cuticular Hydrocarbons from Human Head Lice (Pediculus humanus capitis)

Version: 1 Date: 8 May 2012

Reviewer: Jacob Levitt

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The paper can be more succinct. It should be organized into the following sections:

Abstract: Why was the Methods Section not included here? Delete the first two sentences of Background portion of the abstract. References do not belong in the abstract.

Background: The background as it stands functions more as a discussion of competing anti-lice products and focuses mainly on their negative aspects rather than providing a fair-balanced discussion. For example, to state that permethrin and malathion are neurotoxic (as if to imply neurotoxic to humans rather than selectively to susceptible lice?) chemicals found in lawn and garden pest control preparations is irrelevant and alarmist and are cited to enhance the marketing position of the current IPM product. This is overtly unethical. Indeed, it appears to be written as a marketing piece for the Piedmont (or allied company) sales force. As such, the majority of background is irrelevant to the subject at hand – specifically, an examination of the solubility characteristics of lice exoskeletons in various test media. A more in-depth discussion of exoskeleton make up, nit shell make up, and general mechanism of action of an agent that dissolves the lice exoskeleton would make this paper much stronger. A discussion of the safety of IPM at concentrations of 50% (without trying to intimate that the safety of the 50% concentration products are equivalent to that of products containing GRAS levels of IPM) might be helpful. References to cure rates of the IPM/cyclomethicone product at specific dosing regimens/intervals are appropriate here. In this context, would your cure rate increase if you applied the product three times daily or at Days 0 and 9 as suggested by Lebwohl et al (Lebwohl M, Clark L, Levitt J. Therapy for Head Lice Based upon Life Cycle, Resistance, and Safety Considerations. Pediatrics. 2007 May;119(5):965-74.)? Could you explain the effects of the IPM product on nits?

Objective/Hypothesis: Clearly state this upfront.

Methods: Why weren’t cyclomethicone and IPM tested independently as solvents to determine if one or another accounted for the solubility or if there is synergy between the two ingredients? Can this work be done and the paper resubmitted? Interesting (nice to have, not need to have) would be to examine dimethicone alone as well. Where did the lice come from? Were they reared? Were they
collected from infested patients?

Results: Does the chromatogram quantify levels of CHC or merely demonstrate qualitative dissolution of the cuticle? If the former, what percentage of the cuticle, by weight, is dissolved?

Discussion/Conclusions: The subject of this research was not on the efficacy of IPM/cyclomethicone but rather on its mechanism of action. Assertions of appropriateness for its place in the therapeutic ladder of lice infestation do not belong in such a paper. Were the subject of the research a head-to-head trial versus existing first line agents or even versus placebo, the discussion would warrant such conclusions. In this particular study, the discussion should remain limited to the findings at hand – proving solubility of lice hydrocarbons in IPM/cyclomethicone. You do not even prove that the result of dissolving the exoskeleton indeed causes fatal dehydration of the lice. As such, you can only state that you hypothesize that lice die by dehydration. You should state explicitly that to prove this hypothesis, lice weights before and after application of the test substance should be measured, if possible controlling for humidity and if possible measuring water loss by measuring the increased ambient humidity in a closed system. Finally, please discuss how dimethicone differs from cyclomethicone insofar as you assert that the current IPM/cyclomethicone product purportedly does not coat/suffocate the louse but the dimethicone/cyclomethicone product does. Do you have evidence that proves the lack of activity (or perhaps that shows activity) of cyclomethicone?

1. Is the question posed by the authors well defined? Not as stated.
2. Are the methods appropriate and well described? They could be more detailed, perhaps doing a better job of summarizing the unpublished paper they reference that details the methods.
3. Are the data sound? Ostensibly.
4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes.
5. Are the discussion and conclusions well balanced and adequately supported by the data? No.
6. Are limitations of the work clearly stated? None are cited.
7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? Yes.
8. Do the title and abstract accurately convey what has been found? Title, yes. Abstract, no.
9. Is the writing acceptable? Yes.

**Level of interest:** An article whose findings are important to those with closely related research interests

**Quality of written English:** Acceptable
Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

Prior to September 2010, my family owned a controlling interest in Taro Pharmaceuticals, USA, which manufactured Ovide, a competing head lice product. Currently, my family owns negligible amounts of stock in Taro and has had nothing to do with the company since the hostile take over that ousted them.