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Simon Parenti
MATTIOLI ENGINEERING CORPORATION
7918 Jones Branch Drive, Suite 600
McLean, VA 22102

Dear Mr. Parenti:

The following is a report on the project for Transdermal Introduction of Topical Medication to Dermatologic Skin Problems.

Initially, using the equipment that you provided, we selected 12 patients for the study.

Patients had chronic skin disorders, namely psoriasis or lichen planus, which were minimally responsive to topical medications.

We selected a medium potency corticosteroid medication, available in liquid form for injection, to use for transdermal introduction into the rash areas. The medication was Kenalog 2.5mg per cc.

This medication, in liquid form, has a powder sub-strait and did not produce adequate results.

We then switched, approximately three weeks ago, to a high potency corticosteroid medication, without any powder sub-strait. This medicine was Clobetasol, liquid, in solution.

The Clobetasol produced prompt and dramatic improvement in the psoriasis and lichen planus lesions.

The test areas were only a fraction of the lesion size. For example, an area of lichen planus or psoriasis may measure 10cm in length by 5 or 6cm in width. Our test area was only approximately 2.0 x 2.0cm or 4sq cm.

The fact that prompt resolution of these lesions occurred, within two weeks, is very encouraging. The fact that the transdermaly treated part of the larger lesion, responded promptly and favorably, provides a realistic test.

We plan to treat approximately 20 patients, using wider areas of treatment, including the entire lesion as described above. Most of these patients had multiple lesions on various parts of the extremities and trunk areas.

Therefore, once satisfied that the transdermal introduction of the corticosteroid medication is effective, there are two things that must necessarily follow.

First, how long the impact of a transdermaly introduced medication will last, and whether or not there will be a direct or indirect or latent response to other lesions on other parts of the body.

Obviously, if there are only single or limited numbers of lesions, and small sizes, an effective treatment method, particularly if the results are long lasting, would be a significant improvement in the existing treatment modalities for these two diseases.

Therefore, we plan to select an additional group of patients with smaller lesions, and to observe those already treated to see if there are any improvements in untreated sites, consequent to the interruption of the disease process with a focal area treatment site.

For your information, psoriasis and lichen planus, both, are two diseases, for which the cause is unknown. There are multiple types of treatments, some with significant risks, for those patients with extensive involvement of body areas. There are probably more than 5 million patients in the United States alone, with either or both of these diseases. Therefore, any improvement in the treatment approach to these patients should be well received by both the patient community and the medical community.

There is another implication that would be extremely important, if the patients already treated, continue to have clearing in the areas treated, even though it was only a portion of their disease process. That implication would be that other types of medications, could be transdermaly introduced to patients with other diseases for which the cause is known, for which the lesions are smaller, and for which a continued benefit would ensue.

For example, there are medications evolving at the present time, of which I have mentioned a particular one to you, Imaquod, which is undergoing extensive testing in the United States today, the treatment of pre-malignant lesions and even for early malignant lesions. The philosophy of the Imaquod medication, is that it is an immune modulator, which causes an indirect effect of stimulating the natural body anti-body system, the immune system, to better combat these pre-

malignant and malignant lesions, to prevent additional lesions from occurring, and to treat existing lesions.

The Imaquod medication is also in a cream form, and may be available in solution or liquid form. We have already established that if the solution is not a clear solution, and is without powder or sub-strait base, then the transdermal approach works much more efficiently.

We will now proceed to enlist additional patients, for spot testing, photograph them before and after the result, and provide you with those photographs.

We will provide you a follow-up report in approximately one month.

Very sincerely yours,

George A. Farber, Sr., M.D.
Medical Director

GAF/pmc