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February 6, 2013

To: Dr. Aubrey Woodroof

Re: Technical review

Thank you for the opportunity to review your newest advancements in wound healing. Your contributions to burn care with your interactive wound healing dressings have been extraordinary and your most recent ideas offer a further advancement in the care of both acute and chronic wounds. The newest product design addresses the prevention of the pigmentation irregularities resulting from wound desiccation while still promoting the critical need for wound drainage. This design should support a strong patent position as well as significant patient benefits. In addition, with the exodus of TransCyte from the market there is a product void for the treatment of both partial and full thickness burns. In addition, the attributes of your new invention lend it for use in chronic wounds as well. There are currently two cell-based products on the market, Apligraft and Dermagraft, which are approved for venous and diabetic ulcers but not for pressure sores. I strongly believe that your product concept would offer a cost effective solution to all but the most severe full thickness ulcers and a completely new solution for the treatment of pressure sores. The pressures of health care reimbursement are driving product cost reductions, as well as reduction in care giver time per patient. In addition, there is a penalty in reimbursement for recurrent infections in health care facilities. This positions your invention well for the use in pressure sores where healing does not need to be the end point and where adherence of a dressing to the wound bed and long term prevention of infection is paramount. Your product should support the infiltration of the patient's into the scaffold which would permanently anchor the dressing in place which providing drainage.

From a regulatory standpoint, I believe that the existing predicate devices would support your new product getting 510K approval in all burn applications. The approval of the product for the pressure sore indication would most likely require a full thickness wound model in rodents and a small clinical trial, with ultimate approval as a special 510K. Of course a meeting with your colleagues at CDER in the FDA will help to solidify the approval path.

The need for a product advance like the one that you created is huge. Research firm Kilogram Information projects the global market for wound care will rise to nearly $21.0 billion in 2015. The wound care industry is a highly diverse and competitive arena - including everything from standard products such as dry bandages to sophisticated hydrogels and alginate dressings, and encompassing artificial skin and anti-infectives used in wound care. The aging population and more prevalent conditions such as diabetes are driving wound care, and these trends are influenced by future demographic trends, economic uncertainty, the impact of health care reform, uninsured patient levels, reimbursement pressures from third party payers, the continuing shortage of nurses and physicians, and increasing technology and supply costs. Emerging wound care products and technologies are well-positioned to capitalize on the growth in patient numbers and the demand from healthcare systems to reduce hospital stays.

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Market data estimates that more than 89 million patients are treated annually for all wound conditions. Of these wounds, more than six million are chronic wounds involving various types of skin ulcers that are often difficult and expensive to treat. In the U.S. there are approximately 3 million cases of pressure ulcers, 1 million cases of venous stasis ulcers, and 2 million cases of diabetic foot ulcers reported annually. The easiest classification of the different areas of wound care, treatment options include traditional, advanced, and active products. I have been in discussion with several high level scientists at 3M and they have reinforced their interest in evaluating/licensing new wound care products that offer a biologic component and can interact with the patient's own cells to optimize healing.

In addition to the wound care area your new invention offers promise in the treatment of hernias as well as pelvic floor repair. As a member of the Board of Directors of CR Board since 2005, I have become intimately familiar with the need for advanced products in these areas that combine biological activity to induce tissue infiltration along with materials that prevent local inflammation and adhesions. I believe that your design can easily be adapted to offer a solution in these rapidly growing and critically important surgical areas.

In summary, I believe that your latest invention has tremendous potential in acute and chronic wounds and additional surgical repair areas. I would be delighted to continue to be involved with its development as an advisor or member of your Board of Directors.

Sincerely,

Gail K. Naughton

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