MassBio
MASSACHUSETTS BIOTECHNOLOGY COUNCIL

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Massachusetts Biotechnology Council
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January 30, 2014

The Honorable Margaret A. Hamburg, M.D.
Commissioner
U.S. Food & Drug Administration
White Oak Office Building 1
10903 New Hampshire Avenue
Silver Spring, MD 20993

RE: Urgent Need for Clarification of FDA Regulatory Policy on Wound Care Products

Dear Commissioner Hamburg:

I am writing on behalf of the Massachusetts Biotechnology Council ("MassBio"), a non-profit organization made up of over 620 member companies and organizations that are committed to developing innovative, effective treatments to some of humanity's most devastating illnesses. The purpose of my letter is to respectfully request that the Food and Drug Administration (FDA) take proactive steps to provide regulatory clarity for wound care products because we believe the current lack of clarity poses significant threats to both the patient population and the ability of some of our member companies to bring new, innovative therapies to market.

Specifically, we believe it is critical that the FDA take prompt action to clarify that allografts marketed under Section 361 of the Public Health Service Act (361 HCT/Ps) and wound management devices marketed pursuant to premarket notifications (510(k)) may not be promoted as chronic wound healing therapies. The absence of guidance from FDA in this regard has resulted in direct competition between these products and those chronic wound healing products that have been approved through Premarket Approval (PMA), which in our view poses two serious problems.

First, if 361 HCT/Ps and 510(k)-cleared devices are permitted to be promoted with the same wound healing claims as PMA-approved or BLA-approved products that require enormous resources to develop, the incentive to invest in innovative chronic wound healing products that require FDA approval will be undermined. When we consider the compelling societal need for the development of innovative wound care products, this is an outcome we all certainly want to prevent.

The second problem is that in the absence of clarity from the FDA, unsubstantiated claims by the distributors of such products can mislead clinicians into selecting unproven products over Apligraf and Dermagraft – the only products approved by FDA to heal chronic wounds. This can prevent patients from receiving the appropriate chronic would therapy they require.

We're also concerned that the absence of a definitive policy statement from the FDA on the marketing of wound care products empowers the distributors of 361 HCT/Ps and 510(k) cleared products to conclude erroneously that their products are clinically interchangeable with PMA-approved products. In addition, we fear that the absence of such a definitive policy statement from FDA may have also played a role in the recently implemented Centers for Medicare and Medicaid Services (CMS) payment policy for this category of products. This policy has had devastating consequences for two of our members, Organogenesis and Shire PLC, two of the pioneering and leading companies in the development and commercialization of cell-based regenerative medicine products.

Because of our concern that patients have access to appropriate care and that federal policies encourage, and not stifle, the development of innovative new therapies, we respectfully request that FDA take action to clarify its regulatory policy with respect to chronic wound care products. If you or your staff should have any questions about MassBio's position in this matter, please do not hesitate to contact me.

Many thanks for your consideration.

Sincerely,

Robert K. Coughlin
President & CEO