ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

June 29, 2012

Elise Berliner Ph.D.
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

Dear Elise;

On behalf of the Alliance of Wound Care Stakeholders, I wanted to thank you and your staff for taking the time out of your busy schedules to meet with us regarding our concerns with the draft AHRQ technology assessment (TA) on skin substitutes.

We appreciate your complements and enthusiasm for our recently published paper, "Consensus Principles for Wound Care Research Obtained Using a Delphi Process" especially in reference to the importance of observational studies. We recognize that from our discussion it may not be possible to redo the TA to include observational studies, but in the future we think these types of studies should be included by predefining in a written protocol the eligibility of such studies in any TA.

While we understand that AHRQ cannot serve in a policy-making or advisor role to the Centers for Medicare and Medicaid Services (CMS), we believe that the Agency could serve in a position of influence by objectively noting stakeholders' concerns and comments. In that regard, we urge AHRQ to acknowledge the following in its final report:

- The level of evidence was good for many of the studies. This was a statement that you had made in the meeting but the draft report did not reflect this. We recommend that in the final report an inclusion of studies (including RCTs and others which were omitted in the draft) and a statement that the level of evidence for RCTs is good.
- There is difficulty in using the term "skin substitutes" to refer to these products since they do not replace or "substitute" for skin. We recommend instead that updated nomenclature be utilized which more accurately reflects the products in the marketplace. As was stated both in our meeting and our comments, the term "skin substitutes" is not used by FDA in its classification and CMS abandoned this nomenclature in 2010 in its coding descriptors. The Alliance proposed the term "cellular and engineered tissue alternatives" as a viable alternative, although we recognize that this term is still "a work in progress."
- Emphasis on "bias" both in blinding and funding of clinical trials should not be an automatic cause of concern for the integrity of data generated thus eliminating good evidence. As stated at our meeting, blinding should not matter if the outcome measures are objective. Moreover, adequate "blinding" is a well known problem in the area of medical device and product research which is not unique to "cellular and engineered tissue alternatives." In addition, due to limited funding by the state and federal governments and academic institutions for clinical studies,

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manufacturers remain the only funding source for efficacy studies performed specifically to meet the strenuous standards of CMS and the FDA.

We believe that this technology assessment was performed to the best ability of the contractor. However, we feel that the contractor's lack of experience in this unique field affected the quality of the final product and did not meet the same standard as, for example, the TA involving venous ulcer care. In the future, we hope that the AHRQ will seek contractors with wound care expertise when initiating a TA involving this subject, in order to ensure the highest quality and most consistent work product.

As discussed in our meeting, funding of studies is a critical issue. As far back as 2005, the need for more funding for wound care research was raised by the Medicare Coverage Advisory Committee. We appreciate your innovative suggestions regarding a public/private partnership with AHRQ and our contacting the Center on Medicare and Medicaid Innovation as alternatives given the limited funding of AHRQ. We would be interested in exploring your vision on the operations of this private/public partnership and its goals, objectives and study outcomes. In addition, we would be grateful if you could facilitate a meeting between the Alliance and Dr. Clancy to discuss these ideas. We will do some homework on our end, and would appreciate a follow up meeting with you as well regarding your thoughtful suggestions.

Again, thank you for a most productive and timely meeting. It is so beneficial to meet with you so that all parties can obtain a better understanding of the issues and next steps in working together.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director