Hon. Joe Barton, Chairman
The Committee on Energy and Commerce
U.S. House of Representatives
Fax: (202-225-3025)

February 16, 2006

Dear Congressman Barton:

I am President of BlueSky Medical Group, Inc. ("BlueSky"). We produce products used in negative pressure wound therapy. For more information about our company, we respectfully refer you to our web site, http://www.blueskymedical.com.

BlueSky is currently in contentious litigation with Kinetic Concepts, Inc. ("KCI"). The suit, which is pending in United States District Court in San Antonio, Texas, alleges patent infringement and other claims. BlueSky has counter sued asserting antitrust and other business disparagement claims. Trial is set for May 31, 2006.

We recently learned of your letter dated January 10, 2006 to Hon. Mark B. McClellan, M.D., PhD., Administrator for the Centers for Medicare and Medicaid Services. The letter may be found at http://energycommerce.house.gov/108/Letters/01102006_1773.htm. Your letter concerns the classification of a device and accessories manufactured by BlueSky into an existing negative pressure wound therapy (NPWT) HCPCS code, which would allow Medicare coverage of this product.

Your letter states that "concerns have been expressed, however, about the strength of the clinical data to support the BlueSky product's coverage." Naturally, BlueSky shares your desire to "ensure that, in this case, CMS thoroughly examined all aspects of this new product, including clinical effectiveness, patient safety in the home setting, and the appropriateness of its use by Medicare beneficiaries." Similarly, BlueSky needs to determine the extent to which KCI is attempting to influence these important issues, given the status of the litigation and KCI's dominance of the market for these products.

Toward that end, BlueSky respectfully requests from your office and the committee any correspondence, notes or other materials received or prepared concerning this matter. We would also appreciate any information you or the committee might have regarding the financial, political or business connections the authors of such materials have with KCI.

As your letter addressed safety, we also share concerns about patient safety in the area of Negative Pressure Wound Therapy ("NPWT"). Several reviews on this subject may be found at www.npwt.com. We respectfully request that the committee and its staff review the different approaches and adverse events contained on the FDA database and referenced on

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www.nwpt.com. A recent FDA Safety Alert is also attached. Information about our products, journal articles, and illustrations of good patient results are available at www.blueskymedical.com.

Additionally, we respectfully seek your support of the CMS coding decision as we feel that the government and your constituents will benefit from increased competition. A public hearing was held by CMS on the BlueSky coding request in June of 2005, and we are not aware that Kinetic Concepts, Inc. or other professionals participated or filed any information with CMS at this previous public hearing to discuss any concerns regarding the request.

The Food and Drug Administration has cleared our product for marketing. CMS has recognized The Versatile One Wound Vacuum System as Negative Pressure Wound Therapy. Many medical facilities are using the product as it produces good patient outcomes and is reasonably priced so as to make this important therapy available to patients in a cost-effective manner. BlueSky believes that fair competition in the medical device industry will create and support lower expenditures of scarce Medicare and Medicaid dollars and will benefit patients.

BlueSky also respectfully requests the opportunity to be notified about, and the opportunity to participate in any hearings discussing, the coding decision by CMS, and that this letter, the attached press release, and information contained on the website NPWT.com and BlueSkyMedical.com website be made part of any future record by this committee. We look forward to hearing your thoughts on this important issue. Thank you for your attention in this matter.

Sincerely yours,

Richard Weston

Richard Weston, President
BlueSky Medical Group, Inc.

Attachments: (2)

1. Jan. 10, 2006 letter
2. FDA Safety Alert

Cc: Senator Dianne Feinstein (415-393-0710)
Senator Barbara Boxer (619-239-5719)
Hon. John D. Dingell (202-225-4071)
Hon. Henry A. Waxman (202-225-4099)
Hon. Edolphus Towns (202-225-1018)
Hon. Frank Pallone, Jr. (202-225-9665)
Hon. Nathan Deal (202-225-8272)
Hon. Ralph M. Hall (202-225-3332)
Hon. Michael Bilirakis (202-225-4085)
Hon. Fred Upton (202-225-4986)
Hon. Paul E. Gillmor (202-225-1985)
Hon. Charlie Norwood (202-226-0776)

Hon. Sherrod Brown (202-225-2266)
Hon. Bart Gordon (202-225-4231)
Hon. Bobby L. Rush (202-226-0333)
Hon. Anna G. Eshoo (202-225-8104)
Hon. Gene Green (202-225-9903)
Hon. Ted Strickland(202-225-5907)
Hon. Diana DeGette (202-225-5657)
Hon. Lois Capps (202-225-5632)
Hon. Tom Allen (202-225-5590)
Hon. Jim Davis (202-225-5652)
Hon. Tammy Baldwin (202-225-6942)
Hon. Barbara Cubin (202-225-3057)
Hon. John Shimkus (202-225-5880)
Hon. John B. Shadegg (202-225-3462)
Hon. Charles W. Pickering (202-225-5797)
Hon. Steve Buyer (202-225-2267)
Hon. Joseph R. Pitts (202-225-2013)
Hon. Mary Bono (202-225-2961)
Hon. Mike Rogers (202-226-5820)
Hon. Sue Wilkins Myrick (202-225-3389)
Hon. Michael C. Burgess (202-225-2919)
Hon. Michael A. Ferguson (202-225-9460)

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The Committee on Energy and Commerce

Joe Barton, Chairman

U.S. House of Representatives

Letter to CMS requesting a report regarding their assessment and decision to classify a device manufactured by BlueSky Medical used for negative pressure wound therapy, allowing for Medicare coverage of this product.

January 10, 2006

The Honorable Mark B. McClellan, M.D., PhD.
Administrator
Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Dr. McClellan:

We appreciate the Centers for Medicare and Medicaid Services (CMS) important responsibility with respect to coding, coverage, and payment of healthcare technologies for Medicare beneficiaries. We write today about concerns regarding a set of recent 2006 coding decisions of the CMS Healthcare Common Procedure Coding System (HCPCS) Workgroup. In particular, we understand the HCPCS Workgroup has decided to classify a device and accessories manufactured by BlueSky Medical Group into an existing negative pressure wound therapy (NPWT) HCPCS code, which would also allow Medicare coverage of this product.

The medical community seems very enthusiastic about NPWT using the Vacuum Assisted Closure system because it has revolutionized the treatment of chronic and difficult to treat wounds. Concerns have been expressed, however, about the strength of the clinical data to support the BlueSky product's coverage. Given

our understanding of the medical community's views, we want to ensure that, in this case, CMS thoroughly examined all aspects of this new product, including clinical effectiveness, patient safety in the home setting, and the appropriateness of its use by Medicare beneficiaries.

Please provide a written report to us setting forth the data and reasons supporting the CMS assessment of these issues and the appropriateness of its use by Medicare beneficiaries with respect to covering the BlueSky product under the NPWT HCPCS code. We would appreciate your written response by Friday, February 10, 2006.

Thank you for your attention to this important matter.

Sincerely,

Joe Barton
Chairman

John D. Dingell
Ranking Member

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The Committee on Energy and Commerce
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Contact Us

DEVICE SAFETY

Keep a close eye on vacuum-assisted wound closure

BY SUZANNE MALLI, RN, BSN

AFTER BEING SERIOUSLY injured in a fall, a patient had his leg amputated. During his recovery, he was prescribed anticoagulants to prevent venous thromboembolism. Two weeks after the amputation, he began treatment with negative-pressure wound therapy (NPWT) to promote healing. During a dressing change while undergoing NPWT, he experienced serious bleeding from several areas in the wound. He later died, reportedly from severe hemorrhage and possible acute myocardial infarction. Further follow-up revealed that complications associated with bleeding initially started at surgery, before the NPWT was used.

What went wrong?

A noninvasive mechanical wound care therapy, NPWT assists in wound healing by applying controlled localized negative pressure to a wound's surface and margins. As specified in the device labeling, NPWT is applied to a special foam dressing packed in the wound cavity or over a flap or graft. Vacuum pressure helps remove fluids and infectious material from the wound, which encourages healing.

If a patient is undergoing NPWT, closely monitor him for signs and symptoms of overt and occult bleeding if he meets any of these criteria:

- He's actively bleeding.
- He's receiving anticoagulant therapy.
- He has weakened, irradiated, or sutured blood vessels or organs in proximity to the wound.

The patient in this case was especially vulnerable to hemorrhage during NPWT because he was actively bleeding from the surgical site and he was undergoing anticoagulant therapy.

What precautions can you take?

If NPWT is prescribed for your patient, take these steps to protect him from bleeding.

- Assess him for preexisting bleeding disorders or use of anticoagulants or other medications or herbs that prolong bleeding times, such as nonsteroidal anti-inflammatory drugs, aspirin, or gingko biloba.
- Carefully observe him for unusual or excessive bleeding after surgery.
- Make sure you know the contraindications and precautions for NPWT, including difficult wound hemostasis.
- Use protective barriers (such as gauze impregnated with petrolatum) to protect weakened, irradiated, or sutured blood vessels or organs that are close to areas being treated with NPWT.
- Know and follow your facility's policy and procedure for using NPWT.
- Review and follow the device manufacturer's instructions for use, including the appropriate negative-pressure setting recommended for the type of wound.
- Monitor patient for complications while device is in use. ◆

SELECTED REFERENCE

Mendez-Eastman S. Using negative-pressure wound therapy for positive results. *Nursing2005* 35(5):48-50, May 2005

Although you need to support the adverse event-reporting policy of your health care facility, you may voluntarily report a medical device that doesn't perform as intended by calling MedWatch at 1-800-FDA-1088 (fax: 1-800-FDA-0178). The opinions and statements in this report are those of the author and may not reflect the views of the Department of Health and Human Services.

Beverly Albrecht Gallisurasi, RN, BS, MPH, is a nurse-consultant at the Center for Devices and Radiological Health at the Food and Drug Administration in Rockville, Md., and coordinates Device Safety.

Suzanne Malli is a nurse-consultant at the Center for Devices and Radiological Health.