ALAN G. HEVESI
COMPTROLLER

JOAN M. SULLIVAN
ASSISTANT COMPTROLLER
Tel. (518) 402-4103
Fax (518) 474-2870

STATE OF NEW YORK
OFFICE OF THE STATE COMPTROLLER
110 STATE STREET
ALBANY, NEW YORK 12236

September 8, 2006

Mr. Jerry Korten, CEO
VersaMed
Two Blue Hill Plaza
PO Box 1512
Pearl River, NY 10965

Dear Mr. Korten:

Re: DOH Ventilator Purchase –
VersaMed Protest SF-20060231

This is in response to your correspondence dated June 28, 2006, and July 11, 2006, protesting the contract award by the New York State Department of Health ("DOH") to Viasys Pulmonetics, Inc. ("Viasys") for Portable Ventilators, in preparation for a potential pandemic influenza event.

The issues you raised in your protest related primarily to the alleged unfairness of the evaluation process and the ultimate medical judgments made with respect to the ventilator DOH selected for purchase. Specifically, you asserted that:

1 The procurement was flawed, in that the testing of the ventilators and the determination of award should have been made by qualified physicians, and not by a single respiratory therapist with the appearance of a conflict of interest;

2. No scientific testing criteria was established, no technical evaluation protocol was disclosed, and no documented test results were submitted;

3. Viasys products have been the subject of numerous safety recalls; and

4. Viasys promoted a product not yet approved by the Federal Drug Administration ("FDA").

Preliminarily, we note that the award to Viasys was not made on a best value basis following a formal competitive procurement pursuant to section 163 of the State Finance Law, but rather was made, in light of the exigency of a potential pandemic flu epidemic, on a single

source basis following a comparison of available ventilators. In light of the potential of a pandemic influenza outbreak, and the need to obtain ventilators on an expedited basis, we are satisfied that DOH was justified in awarding this procurement on a single source basis, as long as DOH could justify that it had made a reasonable medical judgment as to which ventilator would best meet the public health needs of the State.

Nonetheless, as outlined in our letter dated July 18, 2006, to Dennis Whalen, Executive Deputy Commissioner of DOH, this Office had concerns with the selection process utilized by DOH. Specifically, we were concerned that the "selection of the [ventilator supplied by Viasys] appears to have been made, primarily or exclusively based on the judgment of a single respiratory therapist who is an instructor at a local community college." We were further concerned that there was no evidence in the procurement record that the ultimate choice was made by or after consultation with qualified physicians who were satisfied that the selected ventilator would best meet the medical needs of the State in the event of a pandemic flu outbreak.

On August 10, 2006, we received a response from DOH, which provided further detail with respect to its selection process (a copy of which was provided to you). As set forth in the DOH response, the selection process started with the Department's review and assessment of previous work done in this area. Thereafter, the Department's Office of Science and Public Health and the Office of Health Systems Management convened a group of clinicians to: (i) identify the characteristics of the ventilator that would best serve the needs of the public and (ii) identify a process to evaluate ventilators and gather information necessary to make a selection.

The group recommended that advice and input come from a qualified respiratory therapist because such therapists are more highly trained in the actual operation and maintenance of the ventilator equipment, particularly in field and emergency situations. Therefore, the Department requested that the faculty of a local certified respiratory therapy school (Hudson Valley Community College) evaluate four different ventilators. Each ventilator was studied by the faculty and a preliminary report, including test results and a survey of physicians and respiratory therapists who had experience with one or more of the ventilators, was provided to DOH. The Department's clinical review group and its Executive staff reviewed the report and concurred with its findings. Therefore, we are satisfied that the choice of the ventilator, which would best meet the public health needs of the State, was made by DOH on the basis of medical judgments of qualified physicians in the employ of DOH, and have not been provided with sufficient evidence to overturn such determination.[1]

Therefore, since your first three assertions, as enumerated above, ultimately relate to these medical judgments made by DOH, as part of its single source determination, we will not further address such points.

[1] We note that we could find no evidence that Ms. Hyland had a conflict of interest or was biased towards a particular ventilator.

With respect to your assertion that the FDA has not approved certain features of the LTV-1000, DOH has affirmatively stated that the ventilator being purchased is the ventilator that was tested, which has FDA approval.

In light of the foregoing, we are denying your protest and, today, we will be approving the contract between DOH and Viasys.

Sincerely,

Charlotte E Breyer

For Joan M. Sullivan
Assistant Comptroller

c: Norman J. Levy, Esq.
Marybeth Hefner, DOH