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March 20, 2012

Mike McCafferty
Chief Executive Officer
Sheridan Memorial Hospital
1401 West 5th Street
Sheridan, WY 82801

Ron Mischke
Chairman, Board of Trustees
Sheridan Memorial Hospital
1401 West 5th Street
Sheridan, WY 82801

Dear Mr. McCafferty and Mr. Mischke:

Patients who receive medical care at Sheridan Memorial Hospital (SMH) would be appalled were they aware of the inaccurate and misleading public statements issued by the hospital following the public disclosure of SMH's failure to properly sterilize or disinfect reusable laryngeal mask airways (LMAs) between uses in patients undergoing surgery between May and November 2011. This SMH failure was characterized by the Wyoming Department of Health (WDOH) as "an immediate jeopardy situation."

The most disturbing of statements made by SMH were those suggesting that the procedures used by the hospital to wash the LMAs between May and November 2011resulted in sterilization or adequate disinfection of the devices. For example, we note the following:

- In its March 13 press release (copy enclosed), SMH stated that, during the period prior to the November 2011 inspection by the WDOH when SMH was not autoclaving the LMAs, the LMAs were "being scrubbed and processed through a washer **sterilizer**" and were "cleaned with soap, enzymatic chemicals and heated to **sterilization levels**" [emphasis added].

- In a March 14 article in *The Sheridan Press* entitled "Hospital addresses sterilization inquiry," Les Gross, the chief human resources officer at SMH, was quoted as saying, "[W]e were using a scrubber/washer/**sterilizer**" [emphasis added].

- In a March 16 article in the *Casper Star-Tribune* entitled "Sheridan hospital: No reason to change sterilization methods," the following statement was attributed to hospital officials: "They said [the LMAs cleaned between May and November 2011 were] just not **sterilized using the exact method** outlined by the mask's manufacturer" [emphasis added].

> In the same article, SMH spokesperson Danae Brandjord also was quoted as saying, "That alternative process still included a thorough scrubbing with a brush, followed by a disinfecting process in a washer **sterilizer** unit with enzymatic chemicals in **sterilization** level temperatures. The department of health required the addition of one step — the autoclave steam pressure step. The difference between the two methods was that one included autoclaving and was the manufacturer's recommended method" [emphasis added].

Likewise, in a February 21 internal memo to surgical staff and physicians (copy enclosed), the manager of SMH's Surgical Services had downplayed the significance of the hospital's failure to properly sterilize or disinfect the LMAs by referring to this serious failure as simply a "discrepancy."

However, it is our understanding that the washing procedures used by SMH between May and November 2011 involved use of an automated spray washer with sequential washings with an enzymatic cleaner and a neutral detergent, followed by rinsing with water and drying with forced air heat. Such cleaning procedures clearly would not have resulted in adequate sterilization of the LMAs and fall well short of the ***high-level disinfection*** required under the federal Centers for Disease Control and Prevention guidelines for such semicritical devices, which were referenced in our March 13 letter to the WDOH (copied to you both).

Moreover, if the procedures used by SMH to wash the LMAs between May and November 2011 had resulted in sterilization of the devices, there would have been no need for the WDOH to characterize the failure of the hospital to steam-autoclave the LMAs as "an immediate jeopardy situation" — as reported in the previously referenced March 14 article in *The Sheridan Press*.

Also of great concern is the claim by SMH in its March 13 press release that "[t]here have been no infections or complications that have been reported in relation to this situation, and none are anticipated." This statement is ludicrous for two reasons. First, because the hospital has not proactively notified affected surgical patients of their exposure to inadequately sterilized devices, patients experiencing any infections or complications would not have attributed such events to the exposure since they were unaware that inadequately sterilized LMAs had been used. Second, certain infections may be asymptomatic and, without appropriate screening, may have gone undetected so far.

In addition to the sterilization issue, the manufacturer's website states that the LMAs should not be used **more than 40 times**.[1] However, the March 14 article in *The Sheridan Press,* referenced above, attributes Charlotte Mather, chief nursing officer at SMH, as having said that the LMAs can be used "40-to-60 times." This statement suggests that SMH remains ignorant of critically important information regarding the safe use of the reusable LMAs.

[1] LMA North America, Inc. 40 use tracking program. Available at http://www.lmana.com/pwpcontrol.php?pwpID=6405. Accessed March 19, 2012.

Finally, SMH's press release, which states that "any patients who may have had surgery between May and November of 2011 and might have questions or concerns can contact the hospital," falls far short of what is needed with respect to notification of affected surgical patients. It is highly unlikely that such patients will see this press release, and if they did, they would still be unaware that their own surgeries involved the use of inadequately sterilized LMAs.

Therefore, as we stated in our letter to the WDOH, we urge SMH, without further delay, to implement a plan to (a) notify each patient who was exposed to the inadequately sterilized LMAs between May and November 2011 about the risks of this exposure, (b) offer them screening for any potential infections that may have resulted from such exposure, and (c) treat any patients found to have been infected. Fear of litigation, loss of business and damage to the hospital's reputation should not deter SMH from taking appropriate, responsible action and notifying all affected patients exposed to the inadequately sterilized or disinfected LMAs.

Thank you for your attention to this urgent matter.

Sincerely,

Michael A. Carome, M.D.
Deputy Director
Public Citizen's Health Research Group

Sidney M. Wolfe, M.D.
Director
Public Citizen's Health Research Group

Enclosures

cc: Mr. Thomas O. Forslund, Director, Wyoming Department of Health
Dr. Wendy Braund, State Health Officer, Wyoming Department of Health