



DUKE UNIVERSITY HEALTH SYSTEM

To: Duke University Health System physicians and hospital staff

From: Victor J. Dzau, M.D., President/CEO of Duke University Health System,
Chancellor for Health Affairs

Date: June 15, 2005

Re: Update on Hydraulic Fluid Issue

You have no doubt seen the recent news reports of patients who have indicated post-operative problems they believe are related to exposure to instruments accidentally cleaned with hydraulic fluid (mistakenly delivered to the hospitals by our supplier, Cardinal Health) prior to sterilization at Durham Regional Hospital and Duke Health Raleigh Hospital last November and December. While we understand that some patients have experienced symptoms following their surgeries, everything we know would suggest that no causal connection has been established between any of these patients' outcomes and instruments exposed to the fluid in the presterilization process.

I understand that you and your patients may be concerned about these media reports, and especially the suggestion that Duke has been unresponsive to patients. I feel badly that any patient suffers post-operative complications, but I know that there is always some risk of a poor outcome in any surgery, wherever a procedure is performed, even under the best of circumstances. I want to assure you that the health and welfare of our patients will always be our top priority, and we have given the patients who have contacted us the best information we have had at the time. We expect to have updated information from outside experts in the next few weeks, and when we get it, we will immediately share it with our physicians and their patients.

To understand our communications with patients thus far, it is important to understand the nature of the sterilization process. The best way to explain it, perhaps, is to imagine a powerful dishwasher in your home. You likely rinse off the dishes before you put them in the dishwasher, but the real cleaning takes place in the dishwasher itself. In this case, there is a manual cleaning followed by the automated process by which the instruments are initially rinsed with the fluid, a small amount of which is diluted into several gallons of hot water, and washed before the sterilization process occurs. The sterilization process itself involves very high temperature rinsing and then the equivalent of pressure-cooking in a 270-degree (Centigrade) oven, which is designed to destroy any possible organisms. As part of that process, a lubricant is applied to the clean instruments to be sure that they

do not lock up during surgery and rust is avoided. It is not uncommon that following the sterilization process, the instruments may feel a bit oily. Thus, when they did in November and December, it took us a while to figure out that this was beyond the normal level of oiliness. As soon as we did, we notified our patients and urged them to contact their doctors if they had any concerns. Each and every one of the more than 100 patient calls made to our two hospitals was answered, and patients were provided with the information we had at the time.

Although the Center for Medicare and Medicaid Services, which reviewed the situation, required prompt corrective action by both hospitals, CMS subsequently certified that both Durham Regional and Duke Health Raleigh Hospitals are in full compliance with CMS standards.

Our infection control experts have been monitoring the infection rates at the hospitals, before, during the period when the fluid was used, and since then. They have found no notable evidence of increased infection rates or that the sterilization was not fully effective. An outside expert has corroborated that the sterilization process was not compromised. In addition, Duke has obtained the expertise of outside scientists to conduct a trace chemical analysis of the surgical instruments that had been processed with the fluid, in order to thoroughly examine any potential exposures to patients. Given the unusual nature of this situation, the scientists literally had to create a methodology by which they could conduct such an analysis, which has taken more time than we had hoped. Nonetheless, their preliminary results, when combined with our monitoring of infection rates, reassures us that our patients have not been put at risk. As soon as we have their final report, which we expect in the next few weeks, we will share the results with our patients and our physicians.

In the last 24 hours, I have met with physician leaders across the Duke Health System. I was encouraged, but not surprised by the absolute commitment to patient safety and their support for the excellent work of our Chief Patient Safety Officer, Dr. Karen Frush. At each of these meetings, we discussed this situation and the importance of providing transparent information, both to members of our health system community and to our patients. We are committed to do so. I hope you find this information to be helpful.