

June 27, 2005

Dear,

We are writing to share with you additional information we have just received about the incident last winter, in which surgical instruments were accidentally exposed to hydraulic fluid before being sterilized at Duke Health Raleigh Hospital.

Last week we wrote to share with you the findings of an extensive, five-month study by outside scientists that investigated whether hydraulic fluid compromised the sterilization of the surgical instruments. This independent study, conducted by Professor William A. Rutala, Ph.D., M.P.H., director of the Statewide Program in Infection Control and Epidemiology at the UNC School of Medicine, confirmed our initial assessment that the sterilization of the surgical instruments was fully effective. We hope this independent, outside verification was reassuring to you.

Today we are writing to inform you of the findings of a second external study done by scientists at RTI International in Research Triangle Park. In January we asked RTI to conduct an analysis to determine how much hydraulic fluid remained on surgical instruments after they had been rinsed in very hot water and then sterilized, as was the case in the incident at Duke Health Raleigh Hospital.

We received the final results of the RTI study on June 24. Their report concluded that the residual amount of fluid on the instruments tested was very small, approximately 0.08 milligrams per instrument, on average. This is the equivalent of 0.002 of a drop.

To address the concern that heavy metals might have been introduced into the used hydraulic fluid as it circulated in the elevator mechanisms, the researchers also tested for the presence of contamination by 11 metals. With the exception of zinc, which is in one of the additives in the original fluid and present at the expected low level, the majority of the metals were not detectable and a few were barely detectable using sophisticated testing equipment.

The amount of zinc in one milligram of used hydraulic fluid was approximately 0.0004 milligrams. This amount is extremely small. For the sake of comparison, the amount of zinc in a Centrum adult multi-vitamin is 15 milligrams. This means someone would have to ingest 10 gallons of the used hydraulic fluid to ingest the amount of zinc found in one Centrum adult multi-vitamin.

Based on this new information, along with a full list of the chemical ingredients in the fluid provided by the manufacturer, Exxon-Mobil, we can now tell you with even greater certainty that this very low exposure, on the broad surface of an instrument or device, was not harmful to patients.

Woodhall Stopford, M.D., a toxicologist in the Duke University School of Medicine, reviewed RTI's analysis of the fluid, along with chemical safety information provided by Exxon-Mobil. Based on this information, Dr. Stopford performed an initial risk assessment and concluded that *none of the chemicals was likely to be harmful in the extremely small amounts to which patients were exposed*. Because these findings are so important, we wanted to share Dr. Stopford's comments with you:

“The original hydraulic fluid is greater than 99% solvent-refined mineral oil that has been extensively tested for acute and chronic toxicity. It has been shown to be non-toxic in various animal species tested and does not cause chronic health effects. The additives in the oil are present in extremely small amounts. Based on our initial analysis, they would not be expected to represent a risk to exposed patients.”

The findings to date are very good news, yet we realize that many patients have been frustrated because this information has been slow in coming. There have been two main reasons for this. First, the independent studies we commissioned were very extensive. It took the researchers months to design and conduct them, and additional time to verify the accuracy of their findings. In the case of the RTI study, the detailed questions we asked required the researchers to adapt complex methods of testing for this specific analysis. We could have done less sophisticated studies – and produced results faster – but that information would not have been as reliable.

We were also hampered by delays in obtaining information about the hydraulic fluid from the manufacturer, Exxon-Mobil. In February we requested from Exxon-Mobil a detailed list of the chemical ingredients present in the fluid at the time it was manufactured. This information was not provided to Duke until June 7, because the company considers it proprietary – in layman’s terms, a trade secret. Exxon-Mobil provided the information under the condition that it would be made available only to the scientists conducting the analyses. Once the chemical formula was received, the scientists were able to complete their work.

We recognize that despite these authoritative findings by two outside groups of scientific experts, you may continue to be concerned that this incident may have affected your health. If you have such concerns, we recommend that you contact one of the physicians that Duke has made available. Dennis Darcey, M.D. and Carol Epling, M.D., who are experts in environmental medicine, are available at no cost to you to consult with you and your physician on this matter. To make an appointment with either Dr. Darcey or Dr. Epling or to learn more about this service, please call 919-286-3232, ext. 223. Ms. Ellen O’Briant at the Duke Occupational Health Research Triangle Clinic will assist you. The clinic is located in Research Triangle Park at 1005 Slater Road, Suite 101, Durham NC 27705. So far, 17 patients have called to discuss consultations with these physicians.

This phone number for the clinic also serves as an information hotline where you can call with any questions about the incident. We welcome your call and look forward to assisting you. Next week we will announce the appointment of a patient liaison who will be available to assist patients with questions or concerns related to this incident.

The trust that you have placed in Duke Health Raleigh Hospital is one that we do not take for granted. The entire staff at Duke Health Raleigh Hospital sincerely regrets any concerns you may have experienced following your care with us.

In addition to the above, we are now considering a method to provide long-term follow-up for these patients.

We will continue to communicate with you as new information becomes available. In the meantime, if you have any questions or concerns, please call our information hotline at 919-286-3232, ext. 223.

Sincerely,

James P. Knight
Chief Executive Officer
Duke Health Raleigh Hospital

Victor J. Dzau
President, CEO
Duke University Health System