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The Honorable Leon Panetta
Secretary, Department of Defense
1400 Defense Pentagon
Washington, DC 20301-1400

October 25, 2011

The Honorable Kathleen Sebelius, Secretary, Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

Dear Secretaries Panetta and Sebelius,

The purpose of this letter is to urge an immediate external investigation by your departments in order to stop unequivocally dangerous procedures at the Bethesda National Naval Medical Center (NNMC), now the Walter Reed National Military Medical Center, and possible problems at the National Institutes of Health (NIH) that have resulted in the recent deaths (in August and September) of two NIH patients because they were given transfusions of blood platelets (blood cells that help to stop bleeding) previously determined and labeled by the NNMC blood bank to be infected with bacteria.[1] Internal investigations by the NIH and the NMC, although under way, are not adequate to remedy this serious problem.

All of the information in this letter was provided to me by an NIH physician, Dr. X,[2] who had been involved in the care of one of the two patients (Patient P) and was unaware — until his patient went into (infected platelet-induced) septic shock on July 25, 2011, shortly after the platelet transfusion — that the platelets were infected.[3] Patient P never recovered from this severe septic shock and died on September 7, 2011, of sepsis resulting in multiple organ failure. On the same day this patient received the infected transfusion, July 25 almost simultaneously, a second NIH patient under the care of a different physician was given the other half of the contaminated blood platelets that had been obtained from the NMC. This second patient also developed septic shock and died in August.

According to Dr. X, immediately after the first patient developed septic shock, Dr. X sent the container in which the platelets had been provided to the Pathology Department for investigation. The report came back later that day that the platelets were grossly contaminated with *Morganella*, an especially dangerous bacterium that can injure or kill patients with compromised immune systems. Both patients had compromised immune systems, as is common during chemotherapy treatment. Blood cultures of both patients confirmed that they had been infected with the same bacterium, an extremely unusual cause of hospital infections.

On the same day that Patient P developed septic shock, Dr. X told Patient P's partner about the contamination. According to Dr. X, when NIH officials found out about this disclosure, Dr. X was asked exactly what he had told the family. Subsequently, Dr. X was summoned to a root cause investigation meeting called by Dr. David Henderson (NIH Deputy Director of Clinical Care) and attended by Laura Lee (Dr. Henderson's assistant and the NIH Quality Control staffer); one of the nurses who cared for Patient P; staffers from the NNMC, the Walter Reed Army Medical Center, and the NIH blood banks; Dr. X and one of his residents; and an NIH lawyer who participated by telephone. While Dr. X was still at the meeting, the NNMC blood bank staffer confirmed that the unit of platelets sent to NIH was contaminated. The

[1] Because the NIH blood bank had no platelets for transfusion, platelets were supplied to the NIH by the NMC blood bank and were administered to the two patients on July 25, 2011.

[2] All the information in this letter concerning the nature and cause of the patient deaths was stated by Dr. X to be in the NIH medical records.

[3] Doctor X is not being identified because he has chosen not to be. Patient P is not identified because I do not know the identity because of patient confidentiality.

NIH lawyer told those present that they should feel free to speak about these patients, because “all is protected” and “will remain within the room.” Dr. X told them that he could not comply with that condition, as he would not hide the truth from the patient (still alive then) or his family, and he thus left the meeting.

Several weeks after NIH learned that Dr. X had told Patient P’s partner about the circumstances surrounding the platelet-induced infection, according to information he provided to me, Dr. X was specifically prohibited from seeing Patient P and has not been informed about the results of investigations as to why these deaths occurred.

1. If the NNMC had discovered that the platelets were infected, then (a) why were they not destroyed upon finding this out, and (b) why and when were they sent to the NIH?

2. When the platelets were sent from the NNMC to the NIH, how were they labeled? As contaminated or unlabeled? If they were unlabeled as contaminated, this may explain why they were used by NIH to transfuse the two patients on July 25.

3. When the contaminated platelets reached the NIH, were they labeled or unlabeled as contaminated? If labeled as contaminated, why were they transfused into the two patients?

4. Presumably the platelets were sent from the NMC blood bank to the NIH blood bank. If they arrived at NIH labeled as contaminated, did the NIH blood bank fail to label as contaminated the two portions into which they divided the platelets?

5. Why was the NIH hierarchy so concerned about Dr. X having told the partner about the circumstances of Patient P’s septic shock that they subsequently have prevented Dr. X from still taking care of Patient P and have kept Dr. X in the dark about their investigation (or that of the NNMC) into the matter?

My conclusion, based on the information provided by Dr. X, is that the deaths from overwhelming sepsis from infected platelets were entirely preventable had proper blood bank procedures been followed at the NMC. The platelets should have been destroyed. However, if the platelets were labeled by the NNMC as contaminate but still sent to the NIH blood bank, why did this occur and, if so, what happened at the NIH to allow these deadly platelets to be transfused into two patients, leading to their deaths?

In the absence of an immediate external investigation into this--- not simply those initiated by NNMC and the NIH--- with ironclad remedies that will prevent such infections and deaths subsequently implemented, patients at the MNMC, the NIH, and possibly military personnel in the field, may be exposed to these entirely preventable risks.

In addition to an immediate external investigation into what went so terribly wrong, long-term investigations by the Department of the Defense and the Department of Health and Human Services inspector general offices are necessary.

Sincerely,

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