

July 3, 1997



MASE-8 April).

Myles P. Cunningham, M.D., President American Cancer Society 1599 Clifton Road North East Atlanta, GA 30329

Dear Dr. Cunningham:

In your letter of April 27, 1997 to Secretary Shalala in support of CellPro's "march-in" request, you stated that, "We believe that an injunction in the absence of a comparable FDA-approved alternative could have a devastating impact on thousands of patients whose therapy could depend on [the CellPro] system."

Contrary to anything Baxter International (or others with a financial interest in removing the CEPRATE® SC System from the marketplace) may have represented to you, nothing has changed since you wrote those words. The CEPRATE® SC System is still the only FDA approved product on the market and the only device available to doctors for any and all cancer patients who need it. These facts cannot be contested.

That's why more than thirty cancer specialists from leading research institutions have submitted declarations to the Department of Health and Human Services in support of keeping the CEPRATE® SC System on the market and fully available for patient care. Among them, Dr. Richard Burt, Director of the Allogeneic Bone Marrow Transplant center at Northwestern Memorial Hospital, said: "I strongly believe that if the CellPro device were for any reason to become unavailable for my use ... the interests of my patients would be compromised — fatally, in some cases." Similar statements were made by other physicians as set out in the attached declaration summaries.

We believe that as a direct result of the entreaties from these doctors, as well as twelve United States Senators, twenty-five United States Congressmen and leading cancer organizations, (including the American Cancer Society), Baxter International was forced, on two separate occasions, to change the terms of the injunction they proposed to the court to limit the distribution of CellPro technology. However, Baxter is still seeking an injunction that will force CellPro to severely restrict if not cease its operations.

By its own admission, Baxter has made several serious "mistakes": in its injunction request that would have seriously impacted patient care. Its original request, in fact would have effectively stopped CellPro from providing treatment to more than 500 cancer patients already scheduled to participate in clinical trials as well as to shut down

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six (6) clinical trial sites treating children with leukemia for whom, according to their doctors, no alternative was available. The only way to ensure there are no further "mistakes" of such serious, indeed deadly, consequences is through the grant of a license to the antibody in dispute. That is what we have asked Secretary Shalala to do, and that is why patients still need your support on this issue.

Your June 26 letter refers to "ongoing negotiations between CellPro and Baxter Healthcare" and says that "agreements have been reached which will ensure that CellPro technology will continue to be available until Baxter's Isolex system receives final approval from the Food and Drug Administration." There have been no ongoing negotiations between CellPro and Baxter, and no such agreement has been reached.

In fact, NIH requested that both parties put forward offers and try to reach some sort of equitable settlement. CellPro complied immediately with this request. Baxter, however, both dismissed CellPro's offer and failed to present one of its own.

If Baxter is successful, CellPro will be unable to provide products for patient care, thus denying victims of breast cancer, leukemia, lymphoma, multiple myeloma and other dreaded diseases the benefits of the only FDA approved product. It also means the end of all clinical trials which we support. Already over 5,000 cancer victims have been treated with the CEPRATE® SC System and that is but the beginning of what this Company can do if given the chance.

With no approved FDA alternative, even if Baxter wants to put one of its machines in every hospital in America, few patients could actually use them. As you know, it takes months to obtain an IDE and get clinical trials started. Even then, not all patients can qualify and there are significant reimbursement problems. As Northwestern's Dr. Burt said: "Substituting ... the Baxter device would not be a practical option."

By contrast, any doctor in America now can order and use the CEPRATE® SC System. Any patient who needs it can have access to its life saving capabilities, right now. No other product can make that claim.

Dr. Cunningham, given the facts outlined above, we are confused about the reasoning behind your organization's reversal. I would very much like to personally discuss this issue with you, and am prepared to meet with you at your earliest convenience.

In the interest of public heath, the NIH asked that this matter be settled. We have put forward a good faith offer that would guarantee patient access. Perhaps you and your organization could play a role in facilitating that process.

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Thank you in advance for your time and consideration of this matter, I will call you next week to arrange a meeting.

Sincerely,

Richard D. Murdock

President and Chief Executive Officer

Rich Murdoch

cc: HHS Secretary Donna Shalala
NIH Director Harold Varmus