Cesar O. Freytes, M.D.
Director,
Bone Marrow Transplant Program
Associate Professor of Medicine/Hematology
University of Texas Health Science Center
San Antonio, Texas

- "It is my strong opinion that compelling public interests demand the continued, and legally unfettered, availability of the Cell Pro device for both experimental and fully-approved therapeutic applications."

- "From the standpoint of an investigator designing and planning a clinical study, the fact that CellPro's CEPRATE SC stem cell concentrator is the only FDA-approved device is a matter of considerable significance."

- "Even an ill-founded belief that the CellPro device might be enjoined has, in my opinion, a chilling effect on important medical research."

- "Any real (or imagined) doubt that a device will continue to be available will tend to discourage patients from willingness to submit to experimental therapies involving that device, and no investigator wants to spend time, effort and money to develop a therapy using a device that is at risk of disappearing from the market."

- "The CEPRATE SC stem cell concentrator represents a great improvement over prior technology for preparing stem-cell enriched suspensions for transplantation."

- "It is the only FDA-approved device which reliably prepares clinically useful volumes of concentrated stem cells."

- "For some categories of patients, there were no practical therapeutic options available before the advent of the CEPRATE SC concentrator and it still affords the only practical treatment option."

- "The FDA-approved status of the device not only reassures patients faced with the decision whether to participate in experimental studies but also streamlines the process of obtaining the necessary protocol approvals from the FDA and from protocol-approval bodies within hospitals and universities."

William Burns, M.D.
Professor of Medicine and Microbiology
Director of the Bone Marrow Transplant Program
Medical College of Wisconsin
Milwaukee, Wisconsin

- "I believe that the public interest would be seriously harmed if the CellPro CEPRATE SC stem cell separator were for any reason removed from the United States market."

- "My pilot study results to date suggest that the device affords a new, potentially lifesaving treatment option for multiple sclerosis patients for whom all conventional therapies have failed."

- "I believe that any threat that the CellPro device will become unavailable through injunction has an inhibitory effect on the willingness of patients to submit to experimental therapies using that device, and on the willingness of medical researchers to employ it in their efforts to expand the therapeutic usefulness of stem cell transplantation techniques."

- "Given a choice, I believe that any researcher whose goal is to see new therapeutic options become generally available would prefer to employ a device that is, or promises to be, FDA-approved and generally available."

- "The fact that the CellPro device appeared to be close to FDA approval was a fact that I judged to bode favorably for the general availability of the device and, therefore, the general availability of any useful therapy I might develop through the use of this device."

Stanley Calderwood, M.D.
Director of the Autologous Transplant Program
Principal Investigator in the Haploidentical Transplant Program
Hospital for Sick Children
Toronto, Ontario

- "Thanks to the CellPro device, the percentage of transplant candidates who can feasibly be transplanted has risen from 2/3 to nearly 100%."

- "I believe that compelling public health interests would be disserved if the CellPro CEPRATE SC and/or TCD device were to become unavailable in Canada."

- "Approximately one third of our patients who were otherwise candidates for allogenic bone marrow transplantation could not, before the advent of the CellPro device, be transplanted because no suitably matched donor could be found."

- "If the CellPro CEPRATE SC column were for any reason to become unavailable in Canada, clinicians at The Hospital would encounter hardship and patient care would be compromised."

- "If the CellPro device could not be used, some of our patients, notably those who are candidates for our haploidentical allogeneic transplant program, would be unable to survive the delay in treatment."

- "Based on our very limited experience, yields and purities with the Baxter device were not as good as those achieved with the CEPRATE SC device."

- "Compared to prior technology for autologous transplantation, use of the CellPro device affords several immediate advantages to both the clinician and the patient."

Kent Holland, M.D.
Professor of Medicine
Emory University Medical School
Atlanta, Georgia

- "It is my belief that there is a vital public interest in preserving the availability of the CellPro CEPRATE SC stem cell concentrator for therapeutic uses and related research uses in the United States."

- "It's removal from the U.S. market would effectively remove potentially life-saving therapy from patients who cannot afford to travel abroad for treatment."

- "The fact that the device is 'under a legal cloud' has, in my view, had a chilling effect on medical research."

- "For some categories of patients with terminal hematopoietic malignancies (e.g. leukemia). there never was any transplant option at all until the advent of the CellPro CEPRATE SC device."

- "CellPro's CEPRATE SC stem cell concentrator is markedly superior to the prior technology for preparing a stem cell transplant suspension."

Andrew M. Yeager, M.D.
Professor and Director,
Bone Marrow Transplant/Leukemia Program
Department of Medicine
Emory School of Medicine,
Atlanta, Georgia

- "It is my belief that if the CellPro immunoseparation columns involved in our trails and studies were to become unavailable, patients would die."

- "To change over to a different immunoselection device (assuming that there is a practical alternative) would entail not only delay but also waste of effort and research funds."

- "Before the availability of the CellPro device, there simply was no clinically practical technology that would have enabled us to cross the HLA (histocompatibility) barrier; haploidentical transplant would not have been an option; and all of these children would have died of leukemia within a few months after diagnosis of recurrence."

- "If for any reason the CellPro TCD device were to become unavailable, this study would need to be shut down. If that were to happen, children would die."

- "I regard the CellPro device as a very well engineered device which is manufactured to high quality-control standards which performs well in terms of yield, purity, reproducibility of results, and reliability of operation."

- "I would rate the quality of technical support from CellPro as superb."

Kenneth Anderson, M.D.
Department of Medicine
Division of Oncology
The Dana Farber Cancer Institute
Boston, Massachusetts

- "There is a compelling public interest in maintaining the availability of the CEPRATE devices, especially since the CEPRATE SC device is the only such device approved by the FDA."

- "Removal of the CEPRATE SC device would severely limit the treatment of cancer patients using high dose chemotherapy."

- "If the CEPRATE SC device were not available, it would severely limit physicians' ability to treat patients with high dose chemotherapy followed be reinfusion of purified progenitor cells, since there are no other FDA approved technologies for doing this."

- "Having and FDA approved product available (such as the CEPRATE SC device) makes it easier to obtain approval for investigational and experimental protocols incorporating that device."

- "The availability of the CEPRATE LC device was important to my efforts to develop protocols for patient treatment."

Anthony Elias, M.D.
Assistant Professor of Medicine
Clinical Director STAMP
The Dana Farber Cancer Institute
Boston, Massachusetts

- "If the CEPRATE SC device were not available, the current trials regarding small cell lung cancer, as well as the future tumor purging studies, would be significantly disrupted, delaying what appear to be significant advances in the treatment of certain types of cancer."

- "We are currently looking at undertaking additional trail involving the CEPRATE SC device. These trials would include CD34+ selection using the CEPRATE SC device. followed by negative selection of tumor cells for additional purging. Such protocols hold the possibility of significant reduction, if not elimination, of tumor reinfusion, with the resulting reduction in reoccurrence of the cancer."

- "Processing of the peripheral blood with the CEPRATE SC device results in substantial reduction in tumor contamination. In one patient tumor contamination was reduced from 170 cells per million to zero."

- "Having a commercially available and FDA approved product for CD34+ selection, such as the CEPRATE SC device, makes it much easier to pursue these important investigational treatment options. It is extremely difficult to combine more than one investigational agent/device."

Oscar Ballester, M.D.
Assistant Professor of Medicine
Division of Bone Marrow Transplantation
University of South Florida, Florida
Tampa, Florida

- "It is my view that there is a compelling public interest in keeping the CellPro CEPRATE SC device available inasmuch as it has a potential for improving the outcome for transplant patients."

- "I consider the availability of , and access to, the CellPro device as important to the development of other novel treatment procedures such as gene therapy."

- "If the CellPro device were to become unavailable, outpatients would not have any alternative choice other than the traditional Progenitor Cell Transplant technique."

- "I consider the availability of the CellPro CEPRATE SC device as important to separating contaminating tumors cells before an autologous transplant can be performed in a patient."

- "I chose the CellPro device because, in my view, it provides the transplant patient with the best option versus chemotherapy."

Helen Heslop, M.D.
Associate, Division of Bone Marrow Transplantation,
St. Jude's Children's Research Hospital
Associate Professor, Department of Pediatrics, University of Tennessee
Memphis, Tennessee

- "I believe there is a compelling public interest in keeping the CellPro CEPRATE SC and LC products availability because access to these devices is important for novel applications such as gene therapy, and more importantly, for patients who are not eligible for experimental clinical protocols."

- "If the CellPro CEPRATE SC and LC devices were to become unavailable, it would adversely impact my practice and research endeavors as I would have to reapply for FDA and institutional clearances of the clinical protocols that I have planned and for which I have obtained an NIH grant."

- "I chose the CellPro CEPRATE SC LC devices for my work because in addition the CellPro devices are reliable and have a good reputation."

Gordon L. Phillips, M.D.
Director, Blood and Bone Marrow Transplant Program,
Markey Cancer Center
Professor of Medicine, University of Kentucky
Lexington, Kentucky

- "There is a compelling public interest in maintaining the availability of the CEPRATE SC device in view of the emerging consensus that the transplant of inadequately purified stem cell suspensions are a cause of post-transplant failure."

- "The CEPRATE SC device significantly reduces the tumor volume reinfused into the patient. Moreover, the CEPRATE SC device is the only readily available product or method for achieving this goal."

- "Compared to conventional protocols, use of the CEPRATE SC device has the advantages of proven efficacy, reproducibility, and ease of use."

- "The availability of an FDA approved product, such as the CEPRATE SC device, makes it much easier to get experimental treatment protocols approved, as well as to recruit patients to undergo those treatments."

Albert Deisseroth, M.D., Ph.D.
Chief, Section of Medical Oncology
Department of Internal Medicine
Yale University School Of Medicine
New Haven, Connecticut

- "Over the past 5 years, the availability of the CellPro technology was instrumental in the implementation of many of our programs."

- "Let there be no doubt in anyone's mind that Cell Pro is the leader in reduction of cell separation technology to practice."

- "We support their efforts and hope that the courts will recognize the fact that they have opened the market in cell separation technologies on a clinical level and that they are continuing to provide leadership in the important area of medical technology, science and therapy."

- "It is a pleasure to write a letter in support of CellPro, Inc. in the strongest possible terms."

Oliver W. Press, M.D., Ph.D.
Professor, Medicine & Biological Structure
Acting Program Director, High-Dose Chemotherapy Service
University of Washington Medical Center
Seattle, Washington

- "If the CEPRATE SC stem cell concentrator were for any reason to become unavailable in the U.S. market, I believe that this would have a serious adverse impact on those patients for whom the device affords a potentially beneficial treatment option."

- "I have found CellPro's CEPRATE SC stem cell concentrator to be superior to heretofore conventional treatment options for many autologous transplant candidates."

- "Simply substituting another stem- and progenitor-cell immunoselection device for the CellPro device would not, in my estimation, eliminate the adverse impact on these patients."

- "I believe that for so long as the CellPro device remains the only FDA-approved device of its kind, unavailability of that device on the U.S. market would mean, as a practical matter, that there would be patients for whom the device might afford the best treatment for a life-threatening device."

Mary Horowitz, M.D.
Scientific Director,
International Bone Marrow Transplant Registry
Professor,
Medical College of Wisconsin
Milwaukee, Wisconsin

- "Although CellPro's Phase II clinical trial is still ongoing and the data are too rec ent to yield conclusions about long-term survival, a successful outcome would represent an important advance in cancer treatment."

- "If the CellPro TCD column were to become unavailable, our study of the device would obviously have to cease. "

- "Not only our research interests but also the welfare of our patients would suffer if we were deprived of access to the device."

- "If the CellPro device were to become unavailable, these very promising autoimmune studies would come to a halt."

- "Because the patients involved and to be involved in our autoimmune pilot studies are, by definition, persons with poor short-term prognoses, some of these patients would die, and others might become ineligible for the studies due to further deterioration in their conditions, during the period of delay that would be occasioned by a changeover (assuming that a changeover were otherwise possible) from the CellPro device to another stem-cell immunoseparation device.

- "I believe that if the Cell Pro CEPRATE SC Stem sell concentrator, and/or the CEPRATE TCD column, were to become unavailable in the United States for patient-related reasons, this would have severe negative impacts on the progress of important clinical research, as well as on the welfare of patients for whom the CellPro devices might hold the key to a superior treatment option, or even the only treatment option, against a fatal disease."

Claudio Anasetti, M.D.
Associate Professor of Medicine,
University of Washington (Seattle)
Associate Member, Division of Clinical Research,
Fred Hutchinson Cancer Research Center
Seattle, Washington

- "In my view, there is compelling public interest in maintaining the availability of, and access to, the CEPRATE SC device, because patients with advanced diseases would die without the benefit of the device which makes allogeneic transplantation feasible from HLA mismatched donor."

- "...its removal would set back the development of new transplant technologies and treatment options."

- "The ten (10) mismatched-donor transplant patients that we treated at the FHCRC could not have been treated without the use of CellPro CEPRATE SC column. If not treated, these patients would have died as they were afflicted by advanced leukemias."

- "I also believe that there is compelling public interest in keeping available the CEPRATE LC device (laboratory column), as the use of the laboratory column may further our confidence that a contemplated novel human study is promising and worth doing."

Gary Schiller
Assistant Professor of Medicine,
Division of Hematology & Oncology,
Department of Medicine
University of California, Los Angeles
Los Angeles, California

- "In my opinion, the availability of the CellPro device has opened up new fields of investigation such as transplant of mismatched related bone marrow."

- "I believe that the fact that a particular course of therapy is built on an FDA-approved device (such as CellPro's device) improves the odds that the new therapy will be widely practiced."

- "In addition, as a practical matter, the fact that a device is approved by the FDA is reassuring to the patient who may be considering to undergo a particular investigation procedure with that device, and helps the patient make an informed decision to undergo an experimental treatment."

- "I consider the availability of, and access to, the CellPro's CEPRATE SC device a compelling public interest. In fact, for patients afflicted with lymphoma, multiple myeloma, low grade lymphoma or breast cancer (where the purging of tumor cells is potentially valuable), who are otherwise ineligible for treatment with an investigational device, the CellPro device offers only available processing system."

Richard Burt, M.D.
Director,
Allogeneic Bone Marrow Transplant
Northwestern Memorial Hospital
Chicago, Illinois

- "I strongly believe that if the CellPro device were for any reason to become unavailable for my use, my research pursuits would suffer a serious setback and the interests of my patients would be compromised -- fatally, in some cases.

- "Substituting another immunoselectio n device, such as the Baxter device, would not be a practical option."

- "Use of the CellPro device has been made a phenomenal difference compared to our former practice in fully-matched allogeneic transplant cases, which was to use unprocessed donor bone marrow."

- "...the availability of the device has made it possible to transplant patients who need transplants to survive but have no fully-matched, or better-than-half-matched, donor available."

- "Prior to the advent of the CellPro device, these patients ha d no transplant option because no adequate and willing donor was known, and therefore no potentially curative therapy was available to them."

- "To those who would discount the miseries that patients suffer when deprived of treatment options they want, I would say that I wish they could experience what I have had to experience when explaining to a desperately sick patient why he does not meet the eligibility criteria for limited-enrollment study which he believes might hold his best hope of a life-saving cure."

- "To deprive investigators like myself, and their patients, of the right to carry out potentially life-saving therapies using the FDA-approved medical technology of their choice would be a devastating blow not only to the hopes of patients searching for potentially life-prolonging or curative treatments of fatal diseases, but also to investigators who have dedicated years of their lives planning out and conducting experimental treatments in pursuit of cures for the diseases from which those patients suffer."

Edward Ball, M.D.
Professor of Medicine
University of Pittsburgh Medical Center
Pittsburgh, Pennsylvania

- "There is compelling public interest in maintaining the availability of both the CEPRATE SC and CEPRATE LC devices, not only for the investigational work that I have described above, but also for protocols being developed by others for gene therapy and cancer treatment."

- "If the CEPRATE SC device were not available, it would have a significantly negative effect on my ability to carry out the current and planned investigational protocols that I have described."

- "With regard to FDA approved, non-experimental protocols using the CEPRATE SC device, that device provides reduced toxicity compared to conventional procedures."

John A. Zaia, M.D.
Director of Virology and Infectious Diseases
Chairman of the Advisory Committee for Gene Therapy
City of Hope National Medical Center

- "If I were unable for any reason to obtain or keep using CellPro's CEPRATE SC stem cell concentrator, my gene-therapy-for-AIDS research would be disrupted in profoundly serious ways. At the very least, the studies, as presently constituted, would have to be closed down."

- "If I were to attempt to change over to another stem cell immunoseparation device, such as the Baxter Isolex device, it is not clear that the FDA would permit me to proceed with further studies without the preclinical trials that established the safety of the GCSF stem cell mobilization in HIV positive patients."

- "Were the FDA to require me to repeat the preclinical trials with a different immunoselection device, I estimate that re-doing those trials would consume approximately six to nine months of time."

- "It would be unfortunate, and might even be considered unethical, to ask additional persons to volunteer for repeat studies to evaluate another system and again have to be at physical risk without the possibility of benefit."

- "I wished to employ a stem-cell selection device whose wide distribution would help assure the new therapies, if successful, would come into widespread use with minimum delay. If the availability for research and therapeutic use of the CellPro CEPRATE SC stem cell concentrator were curtailed for patient-related reasons, that goal would be jeopardized to the detriment, I believe, of patients who might potentially benefit from the therapies we are attempting to develop."

A. Keith Stewart, MB CHB
Medical Director of Oncology Gene Therapy
Toronto Hospital
Toronto, Ontario

- "If the CellPro CEPRATE SC stem cell concentrator were to become unavailable for my research and clinical use, such would be the source of considerable inconvenience for my patients and myself."

- "Replacing the CellPro devices would entail obtaining all governmental and institutional approvals necessary to purchase and use the devices, as well as retraining of our personnel (who by now have extensive experience and high competence in using the CellPro device) to achieve equivalent proficiency in operating the substituted device."

- "I would estimate that a changeover would require several months, with no assurance that the substituted device would work as efficiently for our applications as does the CellPro device."

- "An additional drawback, from the standpoint of the cost and availability of health care, is if there were only a single source for a stem cell immunoselection device, there would be no price competition and, therefore, little ability on the part of purchasing institutions to exercise cost control."

- "Since some of our patients have no treatment option other than immunoselected stem-cell transplant and have very short life expectancies if untreated, any withdrawal of the CellPro device from us would mean there would be no timely therapy that we could offer these patients."

John DiPersio, M.D.
Associate Professor of Medicine, Pathology and Pediatrics
Chief of Bone Marrow Transplantation and Stem Cell Biology
Washington University
St. Louis, Missouri

- "I believe there is a compelling public interest in the availability of, and access to, the CellPro device. Owning to the medical and research community's several years of experience with the CEPRATE SC device, we can now embark on new innovative transplantation patient care."

- "In my opinion, if the CellPro device is made unavailable it would particularly adversely impact patients who undergo mismatched-related allogeneic transplants."

- "Without the use of the CellPro device, these mismatched-related allogeneic transplant patients would otherwise die."

- "The use of the CellPro device as a superior T-cel l depletion mechanism is particularly important for minority recipients because for such recipients their unrelated donor pool is very small."

- "Transplant patients with heart or kidney problems cannot tolerate large volume of infusions, and accordingly, the CellPro device offers a very good way of concentrating the stem cell product for such patients."

- "From a clinical standpoint, the CellPro device provides us with many benefits including the potential for eliminating T-cells and tumor cells from stem cell products; the potential for eliminating T-cells and tumor cells from stem cell products; the potential for studying the defects of stem cells; and the potential for reducing toxicity of the infusion. If the CellPro device were to be made unavailable, these potentials would become unrealized."

Charles Hesdorffer, M.D.
Director, Bone Marrow Transplant Program
College of Physicians and Surgeons of Columbia University
New York, New York

- I believe that there is an unquestionable benefit to be derived from keeping the CellPro device (as the only FDA-approved device) on the market as its availability would spur new and novel treatment procedures.

- The continued availability of the CellPro device is important to our ongoing clinical protocols. I estimate that our efforts would be set back up to two years. Further, even if an alternative device were available, I would not be sure that it would work just as well for our purposes.

- If the CellPro device were to become unavailable, our clinical research and studies would be set back significantly. We would more than likely have to discard our already accumulated data, retrain staff with another device, and reapply for FDA and institutional clearances anew.

- The fact that CellPro's device is FDA-approved facilitates patient recruitment and consent to undergo an experimental procedure where the CellPro device is used in one of the steps of that experimental procedure.

- If the CellPro CEPRATE SC device were to become unavailable, patients who are not eligible for a clinical study (and for whom one must then use an FDA-approved device) would be left with only the traditional treatments such as PCT transplants which may involve undue risks of toxicity and other drawbacks.

- I also believe that there is a compelling public interest in keeping available the CEPRATE SC device as none of the other companies have a comparable device.

- I believe there is a compelling public interest in the continued availability, and access to, the CellPro CEPRATE SC device.

Jed B. Gorlin, M.D.
Director, Clinical Cryobiology Laboratory,
Division of Hematology,
Children's Hospital,
Boston, Massachusetts

- I understand that our supply of the CellPro device may be limited to the volume we were using as of March, 1997. Such a restriction would adversely impact our ability to advance our pilot study in neuroblastoma to the randomized trial, thereby limiting the availability of this potentially life-sustaining technology to these desperately ill children.

- I am a principal investigator of a clinical protocol that includes the use of the CellPro CEPRATE system. We are investigating the use of stem cell selection in double autologous peripheral blood stem cell selection in children with high-risk neuroblastoma and sarcomas.

- Currently, children with these conditions have less than 20% chance of long-term survival when treated with conventional chemotherapy.

- Others have demonstrated that relapse following autologous transplants can be contributed to by tumor contamination of the reinfused hematopietic stem cell product.

- We are hoping that by use of the positive selection column that we can achieve some degree of tumor purging, a concept supported by in vitro analyses.

- We are concerned that the current patient dispute might adversely affect our ability to continue this important clinical study.