SPEAKER 1: In order for a patient to be able to respond immunotherapeutically to ECP with an enhanced anti-CTCL immunity that's therapeutically relevant, that patient needs to be immunocompotent. So we can't use a cellular vaccine effectively in patients whose immune system has itself been paralyzed by the disease. And so an important bit of information in patient selection is this. 3/4 of patients with advanced cutaneous T-cell lymphoma, particularly in a leukemic phase, have a substantially suppressed CD8 T-cell population, CD8 T-cells being the cells that largely we want to stimulate to attack the CD4 malignant CTCL cells.

So 3/4 of the patients will have, on presentation, very low absolute CD8 counts. If that count is less than 1/4 of the normal absolute level, those patients almost never-- physicians like politicians should never say never, but the truth is that it's very, very rare, exceedingly rare, for patients with CTCL and major deficits in their CD8 population to respond. So in all probability, it is better for those patients to not get ECP at this point.

However, in those CTCL patients who have advanced disease and also have near normal or normal CD8 levels, it appears that 80%, according to published studies from us and elsewhere, of those patients will give a meaningful response. So the first screen that should be done are absolute CD8 counts. The second thing is that in order to immunize a patient against their CTCL antigens, you have to have access to the malignant cells in the apparatus.

If you don't injure those cells with photoactivated 8-MOP on passage through the cell through the apparatus, the new dendritic cells will not have access to the malignant cells' source of antigens. So a second important feature is the presence of at least a small population of circulating malignant cells in the blood so that they can be processed by the apparatus.

Those are the two main limiting decisions in which patients to treat. In addition, our long term recommendation has been that if a patient, if a CTCL patient, has progressive disease or is not responding in any identifiable, even laboratory fashion, as measured by the number of circulating malignant cells by cytophotographic examination of the malignant population of monoclonal antibody markers, or the intensity of tissue infiltration, if there is no response after three months, we recommend consideration of moving, again, onto a different kind of therapy. Those are our recommendations in CTCL.