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Good morning. I am Marc Stewart, a hematologist/oncologist and Medical Director of the Seattle Cancer Care Alliance at the Fred Hutchinson Cancer Research Center and University of Washington. I also Chair the Scientific Board of Directors of National Patient Advocate Foundation. I and the physicians I represent in academic cancer centers are dedicated to provide the best care possible and, with that, access to the drugs they need to survive or be cured of cancer and in all cases to have the best quality of life. Our scientific board members include physicians from the University of Washington, Fred Hutchinson Cancer Research Center, Northwestern University, Mayo Clinic, Johns Hopkins University and others.

Our physicians are struggling to provide care to cancer patients with many different diagnoses. At my institution over the past six months we have experienced shortages in at least 15 drugs used to treat patients with cancer. Many of these are key drugs for which substitutions may lead to diminished survival or increased toxicity. Furthermore, since most of the centers I represent are academic centers, the impact on research trials and translational research has been substantial. About 5-10 percent of our trials are affected directly with the potential for 20-30 percent if shortages continue.

I can give you a few examples about how this affects our patients' care and also how it impacts on our clinical research efforts:

I have received numerous calls from other centers asking our hospital to supply these drugs. Some of the most frequent calls come from the Alaska Native American Hospital in Anchorage where an outstanding solo oncologist who is struggling to provide native Americans at his center with the best care possible. Unfortunately, we have not been able to help him based on our own shortages. Recently, he treated a young Native American woman with lymphoma. When told that the treatment she would receive in Alaska was a substitute treatment due to the shortage, she asked two questions: "Why am I receiving medicines that we not cure my cancer as well as if I received the standard medicines? How can I possibly pay for bringing three kids to Seattle and live there for four months while I take treatment there?"

Also, our upfront clinical research study for treatment of multiple myeloma is a four drug regimen that includes liposomal pegylated doxorubicin, or Doxil. A gentleman in his 40s started treatment on this regimen. Abruptly, it became apparent that we did not have enough drug for the four intended cycles in our hospital. We made arrangements for the patient to follow up at an affiliated hospital that still had enough drug for the completion of the study. Our affiliate was approved to carry out the research; otherwise, the patient could not have continued. Our upfront clinical trial has enrolled 31 patients

out of 45, and further study has been halted. Our research studies have been halted. This man had two questions: “Why do I have to transfer to a new facility and give up my physician, nurses and staff? Why would I ever want to participate in clinical research again?”

We applaud the accomplishments of the FDA to prevent some of the drug shortages to date but also ask the FDA to continue to lift impediments to production of these drugs if regulatory impediments exist. It is important to note that most of the drugs associated with shortages are generic compared to Brand name drugs. This suggests that reimbursement issues and incentives may play a role in drug shortages and we need to understand these dynamics. To make progress in eliminating complex causes of drug shortages we need a comprehensive approach with involvement from many organizations and groups of healthcare services.

Clearly, as we search for solutions, it is important to keep in mind that our patients deserve access to the best and most established drugs available to continue to live as long as possible and with the best quality of life.