March 14, 2013

Margaret A. Hamburg, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: FDA Drug Shortage Task Force and Strategic Plan
Docket No. FDA-2013-N-0124

We are pleased to submit these comments on the Food and Drug Administration's (FDA's) drug shortages task force. The Alliance advocates for policies, programs, and investments to support the development of an early detection test; improved health care practices; access to life-saving therapies; and improved awareness among health professionals and the public of the risks and symptoms of ovarian cancer. Too many women are unaware of their risk of developing ovarian cancer; tens of thousands each year are diagnosed too late and, therefore, lose their lives unnecessarily. It is our mission to improve these outcomes.

Ovarian cancer is the deadliest gynecological cancer. According to estimates from the American Cancer Society, in 2013 approximately 22,240 new cases of ovarian cancer will be diagnosed and 15,500 women in the U.S. will die from ovarian cancer. Ovarian cancer mortality rates have remained virtually unchanged for nearly 40 years, while we have seen improvements in many other cancer types.

Ovarian cancer patients have been, and continue to be, affected by drug shortages, especially sterile injectible drugs used to treat cancer. Due to shortages, many of the inexpensive standard treatments for ovarian cancer are not available; if women can get drugs, they may not be the standard of care, they may not get drugs at the right time, or they may resort to more expensive or less effective drugs.

Quality

The FDA is known as the gold standard for high quality drugs. The Alliance recommends that the Agency consider remedial methods for meeting quality standards only when necessary, as it has done in the past. The quality of drugs available to patients must remain a priority.

Drugs sold in the United States must be of high-quality. Currently, this means complying with cGMP as well as FDA inspections. With additional resources, the FDA should monitor manufacturing facilities more often.

It is discouraging that patients and providers could have a drug that later goes in shortage, when treatments decisions have been made in reliance upon an assumption of continued supply. Patients and providers should be able to make treatment decisions based on medical evidence, not availability of drug.

We appreciate the flexibility with which FDA has deployed resources or used discretion to ensure that shortages are mitigated or resolved.

Communications

We appreciate the FDA's regular updates on drugs in shortage. It would be helpful to indicate what the drug is indicated for - one option would be list drugs in shortage with a link to the existing FDA web page for that drug. Additionally, information regarding the duration and severity of the shortage are useful for providers and patients to make good treatment decisions.

We encourage the FDA to coordinate with other agencies, including payers, to determine if the reimbursement structure for these drugs contributes to shortages. If it is found that the financial model needs to be altered, the Alliance stands ready to work with payers and regulators to ensure that patients continue to have access to evidence based medications.

Impact on R&D

We know that drug shortages have affected clinical trials. We already have too few therapies for ovarian cancer; delays in completing clinical trials further harm patients who have this deadly disease.

Thank you again for the opportunity to submit comments on the FDA's drug shortages task force. If you have any questions, please do not hesitate to contact us.