



**FDA Public Workshop on Approach to Drug Shortage  
Prepared Testimony of Dr. Len Lichtenfeld  
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I am Dr. Len Lichtenfeld, deputy chief medical officer of the American Cancer Society. Thank you for providing the Society the opportunity to participate in this important discussion on the U.S. drug shortage crisis.

The American Cancer Society is a nationwide, community-based voluntary health organization dedicated to eliminating cancer as a major health problem by preventing cancer, saving lives, and diminishing suffering from cancer through research, education, advocacy, and service. The Society, operating through its national office and 12 geographic divisions throughout the United States, is the largest voluntary health organization in the United States.

As a cancer patient advocacy group, the Society is deeply concerned about the impact of cancer drug shortages on cancer patients. Cancer treatments are based on evidence of effectiveness, frequently developed over the course of years. Those regimens are specifically designed around drugs and doses of drugs that must be followed for the maximum treatment benefit. Notwithstanding issues related to the side effects of these drugs as they affect dosing, the lack of availability of generally accepted and necessary cancer drugs as part of a particular patient's treatment can limit the benefit of that treatment with potentially disastrous consequences.

To a cancer patient, the unavailability of these essential drugs is truly a matter of life or death. It has been reported recently that of the 34 generic cancer drugs on the market, 14 are in

short supply.<sup>1</sup> The cancer drugs that are in short supply tend to be older and thus made by generic manufacturers. Despite the fact that these drugs may have been developed years ago, they remain mainstays of many currently available and effective cancer treatment programs. They may be inexpensive, but that doesn't make them less useful or necessary for a cancer patient's treatment.

The cancer drug shortage problem is worse at smaller hospitals, which may not have the buying power of larger hospitals and treatment centers.<sup>2</sup> That means patients in small towns may end up having to drive significant distances to get the drugs they need. Many patients have worked together with their oncologists to come up with "work-arounds" that may represent an alternative approach to treating their illness. This may include using a different drug or a different combination of drugs, waiting until the desired drug is available, or traveling to an alternate treatment center. However, the onus of cancer drug shortages should not be on the cancer patient, or their physicians. Patients should not have the added burden of worrying whether or not their treatment will be available, or whether another substitute treatment might be less effective.

For cancer patients and their families, the drug shortage has become a daily nightmare. In recent months, patients have been contacting the American Cancer Society through our call center, through our local chapter offices and through our volunteers nationwide to inform us of their desperate struggles to locate cancer drugs for their individual cancer treatments. These stories are compelling. Most importantly, these cancer patients want solutions. No cancer

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<sup>1</sup> Ezekiel Emanuel, "Shortchanging Cancer Patients," New York Times, August 6 2011, <http://www.nytimes.com/2011/08/07/opinion/sunday/ezekiel-emanuel-cancer-patients.html>

<sup>2</sup> Stacy Simon, "Cancer Drug Shortages Concern Doctors and Patients," American Cancer Society News and Features, September 7, 2011, <http://www.cancer.org/Cancer/news/News/chemotherapy-drug-shortages-concern-doctors-and-patients>

patient should have to face the extraordinary anxiety of a potential drug shortage in addition to the physical and emotional toll that the disease can inflict.

The American Cancer Society wants to address this crisis in a solutions-oriented manner. There is great urgency to find viable solutions to drug shortages. Due to the complexity of the drug shortage crisis, multiple solutions may be needed to address the multiple factors contributing to the problem. There appear to be numerous contributing factors to the shortages, and these factors may contribute differently to the shortages of particular drugs. The market system for pharmaceuticals has served patients well for many years, but we have to ask why is it failing now. We strongly support the efforts of the FDA and other agencies to develop a better understanding of the root causes of the current crisis. We also call on the pharmaceutical industry act expeditiously to provide the public with a full understanding of why and how this crisis has arisen. However, until the causes of the shortages are better understood, interim steps should be taken by the government to minimize adverse effects for patients to the maximum degree possible.

Through administrative action, the federal government should:

- Immediately expand its collection of information on the underlying causes of the current drug shortages. Clinicians and patients need better information about shortages and better options for purchasing the drugs they need for their treatments.
- Compile available inventories of drugs that are in short supply, including where shortages exist.
- Work with interested parties as information becomes available about the causes of specific drug shortages to resolve those shortages. For example, adequate production to meet demand in the near term could be leveraged by the National Cancer Institute's

infrastructure for drug development to provide short-term supplies for individual cancer drugs<sup>3</sup>.

Finally, the American Cancer Society strongly encourages manufacturers, distributors and other stakeholders in the drug manufacture and supply process to voluntarily step forward to help work expeditiously to find short- and long-term solutions to this critical problem. Media reports suggest that a grey market now exists for some of these drugs, which should be of great concern to all of us who care about patients and quality care. Such markets arise when there are misallocations and underproduction of crucial drugs, and it raises the possibility of price gouging or hoarding, which would further exacerbate the seriousness of the problem. There is an extraordinary need to find the root causes and take quicker actions to stem the drug shortage crisis. We ask that drug manufacturers, distributors, and other participants in the drug manufacture process develop immediate and long-term solutions to address this horrible crisis facing cancer patients. Every day that passes without available cancer drugs means fewer lives may be saved.

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<sup>3</sup> James Doroshow, “Cancer Drug Shortages: A Critical Problem”, NCI presentation, June 20, 2011, <http://deainfo.nci.nih.gov/advisory/bsa/bsa0611/presentations/Doroshow.pdf>