



ROBERT WOOD JOHNSON
MEDICAL SCHOOL
University of Medicine & Dentistry of New Jersey



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Robert S. DiPaola, MD
Director, The Cancer Institute of New Jersey

Good morning Mr. Chairman and Members of the Subcommittee. My name is Dr. Robert DiPaola, and I am the Director of The Cancer Institute of New Jersey (CINJ), the State of New Jersey's only National Cancer Institute (NCI)-designated Comprehensive Cancer Center. I am also a member of the American Association for Cancer Research (AACR) and its Science Policy and Legislative Affairs Committee. Thank you for convening this hearing and recognizing the impact that the current drug shortage problem is having on our patients, and on our ability to advance cancer research and improve patient outcomes.

You have heard about the effects of drug shortages on treating patients. As the director of an NCI-designated Comprehensive Cancer Center, I have the same frustrations regarding the care to our patients and the negative impact of drug shortages. Unfortunately, this impact is not only immediate for the patients in our clinics today, but also affects the future care of cancer patients. The next generation of cancer therapy is driven by today's clinical trials that are critical to meeting the national goal of improving the outcomes for cancer patients. Shortages of existing drugs is a complex problem. There are a number of ideas regarding what is causing them, and how they can be remedied; I am here today to discuss how this growing problem of shortages of already approved drugs, which in some cases have been used and made for decades, is affecting our best cancer care, our clinical trials, and is threatening our ability to continue on our trajectory of steadily improving cancer patient outcomes.

FDA statistics show that the number of drug shortages has more than tripled over the past six years, with a marked increase in drugs involving sterile injectables, which negatively impacts the treatment of cancer patients, as most shortages in oncology are sterile injectables. The medications in short supply include cancer treatment drugs, anesthetics, antimicrobials and pain medications. A list maintained by the American Society of Health-System Pharmacists recently identified 193 shortages in 2011, of which 22

are cancer drugs, and the shortage is predicted to worsen. These include drugs that are the standard treatment regimens used to treat patients with many different cancers in adults and children.

These shortages are now affecting clinical trial options for patients with cancer. Due to the uncertainty of being able to obtain many of these drugs, enrollment of patients on clinical trials has been delayed or stopped in several of our trials. Many of these drugs that are in short supply are a part of the standard regimens in which new treatments are added or compared within the clinical trial. Many of the drugs on the shortage list are also used in our large national cooperative group trials. The Coalition of Cancer Cooperative Groups reports that approximately 50% of active cooperative group cancer clinical trials involve drugs subject to shortages. Many reports contain examples in which sites are unable to enroll patients on approved clinical trials due to a lack of drug supply. Investigators in these clinical studies are unable to enroll new patients when the drug supply is not available; patients on-study are sometimes receiving alternate drugs when supply is not available, and there is concern about interpretation of results when drug substitutions occur.

It is important to remember that the impact from the drug shortage on clinical trials today will also have long-term effects on cancer research and future treatment options for cancer patients. Clinical trials represent the final step of a long process of developing new therapies that improve the outcome of patients, and add treatments for patients in which there were no effective prior options. When, after years of effort, a researcher discovers a potential new drug or treatment, that new drug is often best added to an existing treatment in combination and/or tested in comparison to the best current treatment in a clinical trial. If that trial yields positive results, patients can ultimately have access to a new and improved drug or treatment combination. Currently, however, we are running out of many of the existing drugs. When a clinical trial runs out of a drug, even temporarily, the trial results may be compromised, and an enormous amount of work and expense is wasted. This means that during a clinical trial, a shortage of only a few weeks in an existing drug might mean delays of years for the development of a new drug. **In other words, the drug shortages of today can have a ripple effect on the availability of new drugs and treatment combinations tomorrow.**

Today, we estimate that one in two men and one in three women will develop cancer in their lifetimes. This year, over 1.5 million Americans are estimated to be diagnosed with cancer and more than half a million Americans are expected to die of the disease - that's more than 1,500 people a day or more than 1 per minute. While these numbers seem staggering, we have made great strides in our ability to diagnose,

treat and prevent cancer and are at a most promising time in cancer research. Earlier this week the American Association for Cancer Research issued a progress report marking 40 years of progress in fighting cancer. In fact, thanks to advances made in cancer research, today more than 68% of adults are living five or more years, which increased from 50% in 1975. It was also reported that in the period from 1990 to 2007, death rates for cancer in the U.S. decreased by 22% for men and 14% for women.

The challenge we now face is to continue to turn groundbreaking science into lifesaving care, at an even greater speed. By facilitating clinical trials, we lay the groundwork for discoveries in basic cancer research to be translated into cutting-edge treatments for cancer patients. The current drug shortage is hindering our ability to treat cancer patients. We are entering a new era of cancer treatment and prevention; however, an inability to conduct clinical trials is a serious impediment to our goal and will hamper our ability to reduce the toll of cancer on the people and economy of our nation.

Thank you.