

TESTIMONY
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“Harnessing Science: Advancing Care by Accelerating the Rate of Cancer Clinical Trial Participation”
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First and foremost thank you to Chairman Davis and distinguished Committee members for providing me the opportunity to participate in this important hearing that hopefully will result in actions leading to improved outcomes for people afflicted with cancer. I have been active in the “war” on cancer for over 20 years participating in basic science, clinical trials and cancer care administration. I welcome the opportunity to share my ideas on why and how increasing participation in clinical trials, regardless of the status of innovation, will improve outcomes for people suffering with cancer. Over the past 35 years, government, industry and the public have spent billions of dollars to create and operate the agencies that oversee and fund efforts in basic and clinical discovery aimed to improve outcomes for people battling cancer. As a result, substantial advances have been made in the understanding of the biology of cancer and as a consequence new and more effective treatments have emerged.

Unfortunately, even with this focused and extensively funded effort, cancer remains a serious problem. This year in the United States alone, cancer is expected to claim more than 500,000 lives. Thus, criticism of our current system exists. In a recent article (FORTUNE, March 22, 2004) authored by Clifton Leaf, significant criticism is levied at the cancer research community claiming the culture is “dysfunctional” and that the search for knowledge has supplanted the search for cures, leading to discoveries of marginal benefit regardless of a great expense of time and money. I believe, however, that these claims are only partially correct and that as a consequence of our national effort, it is now within our reach to turn cancer in most cases, into a chronic disease, much like diabetes, while searches for prevention and cures continue. As Mr. Leaf eloquently points out in his article, we must make the entire system of discovery and application of new agents more efficient. Clearly, continued improvements in our understanding of the underlying route causes of cancer and methods of detection of efficacy and safety are essential. Of equal importance, however, is active and robust participation by people with cancer in clinical trials.

No matter how promising a therapy appears in laboratory testing, it is only through a clinical trial that safety and effectiveness can be established in people. Simply stated, no person or computer program is capable of predicting whether a new treatment will work or be safe in people. In my current experience, it is not the lack of good ideas that is slowing progress in our quest to cure cancer, but it is much more a result of the slow pace of completing active clinical trials. In 2003 there were approximately 1700 ongoing clinical trials of which the NCI sponsored 1200. Despite this large number of trials, only 3% of adult patients participated while 20% were eligible. Low participation in clinical trials slows the continuum of drug development from initial concept to FDA-approved products and as a consequence,

impedes improvements of outcomes for people with cancer. In addition, poor participation in clinical trials lengthens the new drug approval process (estimated at 10-12 years) and has the cascade effect of increasing new drug development costs (estimated at \$800 million), inflating the cost of the drug to consumers once approved, and worst of all, limiting the number of new agents that make it through the discovery pipeline. Advances in knowledge, which will lead to better questions, should continue to be supported but at the same time we need to improve participation in clinical trials.

Lack of participation is due to several factors that can and should be addressed. A lack of public knowledge of availability of clinical trials and a growing public bias against participation due to poor outcome high profile cases is a key factor. Government should do everything it can to educate the public on the value and importance of participating in clinical trials. In an era of shrinking reimbursement for clinical care, funding needs to be established for clinical programs (hospital and office-based) to support the required infrastructure (both research staff and informatics) to participate in clinical trials. Reductions in the growing regulatory burden including centralizing Institutional Review Boards (IRBs), streamlining adverse event reporting, and minimizing regulation resulting in increased cost and complexity, without compromising patient safety or privacy, must also be accomplished. Finally, insurance reimbursement for clinical trial cost needs to be addressed nationally. In my home state of New Jersey, I was a member of the N.J. working group to improve outcomes in cancer patients. Our group was successful in convincing the insurance companies covering N.J. residents to voluntarily reimburse for approved clinical trial related expenses. This could serve as a model for a national effort.

Another important aspect to improve outcomes for people with cancer is to have more clinical trials available. This can be accomplished by increasing the efficiency of moving clinical trial concepts through the approval process before they become available to the public. The current system should be more efficient and held to more business-like timelines for results. Specifically, the cooperative groups and the NCI review process take too long (at times years), and should have efficiencies mandated by government since it is government that supports their efforts. Moreover, encouraging and rewarding the national cooperative groups to work together on questions that require large numbers of patients to answer is essential. Finally, the issue of creating an environment (intellectual property protection, FDA approval support etc) for multiple agents to be tested together for effectiveness prior to FDA approval needs to be addressed.

In summary, I believe that it is an exciting time for those engaged in the battle against cancer. The fruits of our efforts over the past 35 years are just beginning to be realized. It is clearly no time to retreat or claim defeat but instead refocus our energies to make the entire system more efficient, less expensive and more user friendly. Our family and friends afflicted with cancer deserve our collective best effort. In doing so, participation in clinical trials should increase, resulting in meaningful answers and better outcomes sooner for those battling this dread disease. Thank you and I am happy to answer your questions.