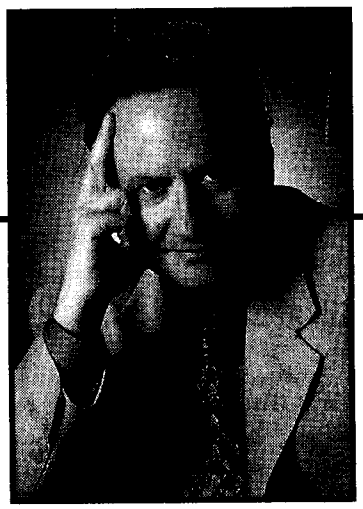

The War on Cancer

by Ralph W. Moss, PhD, Director, The Moss Reports

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In God We Trust, All Others Show Data: A Reply to the NCI Director's "Challenge Vision"

In a 2004 article, Andrew C. von Eschenbach, MD, the director of the National Cancer Institute (NCI), elaborated on his "challenge vision" for the National Cancer Program of the United States (Eschenbach 2004). Since the NCI has put forward a proposed budget of more than $6.2 billion dollars for the financial year 2005, Dr. von Eschenbach's article can also be read as a justification for this mammoth request.

Despite widespread concern that the 33-year-old war on cancer has not resulted in significant improvements in treating the dread disease, Dr. von Eschenbach continues to define the problem in essentially military terms. Like many a military commander, he assures us that victory is within our grasp, and that winning is just a matter of mustering enough resources and manpower. But he is obliged to admit, "The hoped-for 'cure' for this complex set of diseases has proven far more elusive than anticipated." He even makes reference to a cover story in *Fortune* magazine (March 22, 2004) that concluded that we are in fact, losing that war.

Yet Dr. von Eschenbach continues to believe that his organization is making rapid progress. He even puts forward the astonishing claim that it is possible for NCI, by pursuing its current research initiatives, to achieve "the elimination of the suffering and death due to cancer by 2015."

I had to read this statement over several times to make sure that my eyes were not deceiving me. Cancer annually kills 6.2 million people around the globe, and causes intense suffering to many millions more. The World Health Organization (WHO) predicts that by the year 2020 cancer rates will further increase by 50% to 15 million new cases per year (WHO 2003). In the US alone, in 2004 cancer afflicted nearly 1.4 million and killed 563,700. To eliminate that degree of suffering in just 11 years would be the greatest medical achievement in world history.

This is not the first time that we have heard breathtakingly over-optimistic projections about the imminent defeat of cancer. The Nixon White House promised a cure for cancer in time for the American bicentennial in 1976. That anniversary produced a spectacular OpSail display in New York Harbor, but, alas, no cure for cancer.

Over the last several decades we have gotten used to periodic predictions of the coming demise of cancer. "Decades of breakthroughs have raised hopes again and again for people with cancer," wrote *Fortune* editor Clifton Leaf in his article on losing the war on cancer, "but have failed to deliver on expectations" (Leaf 2004). Interferon, interleukin-2, endostatin, high-dose chemotherapy for breast cancer – most of the claims have turned out to be highly exaggerated. For the last ten years we have been hearing about the wonders of 'targeted' therapies and how they too are going to revolutionize oncology. But despite Dr. von Eschenbach's enthusiastic endorsement, the actual track record of these treatments has been disappointing. The orthodox medical community is by no means alone in making extravagant claims of this sort. On the alternative side, there have been books with titles such as *World Without Cancer*, *The Death of Cancer*, and *The Cure for All Cancers*. All of them have proven to be equally illusory. A cynic would say we've heard it all before. I myself favor the unofficial motto of the NIH: "In God We Trust. All Others Show Data."

Extraordinary claims demand rigorous documentation. For Dr. von Eschenbach to come forward with such a provocative assertion one would expect him to present an ironclad case. Yet some of his arguments are astonishingly weak.

For example, the philosophical foundation of Dr. von Eschenbach's case is that the impending conquest of cancer is an extension of the extraordinary progress that has been made in the last 100 years. "At the turn of the 20th century," he writes, "the likelihood of an individual surviving cancer was zero. Today, two out of three people diagnosed with cancer will be alive 5 years after diagnosis."

This statement is misleading on two counts. First, it is far from true that a century ago one's chance of surviving cancer was zero. Effective cancer treatment relies still, just as it has for the past 100 years, on one basic principle: the removal or ablation of the entire tumor wherever possible. Perhaps the best-known example of an effective form of treatment that has been around for over 100 years is the Halsted radical mastectomy for breast cancer. William Halsted, MD, a famous Johns Hopkins surgeon, published his classic paper on the subject in 1894. Halsted's paper was based on his experience with the surgical treatment of 50 cases, dating back to 1889. The recurrence rate among Halsted's patients was not 100%, as von Eschenbach tacitly suggests with his claim of 'zero survival.' In fact, the recurrence rate recorded by Halsted was a mere 6%! That's right. More than 100 years ago, 47 out of 50 (94%) of breast cancer patients treated at a major university hospital survived their cancer, even though many of these patients were already in the grip of locally advanced disease at the time of diagnosis. In fact, the "Halsted radical" remained the standard treatment for 75 years and only fell out of favor in the 1970s, when it was realized that less radical procedures were equally effective. (It is still sometimes used today.)

But a more pivotal issue is Dr. von Eschenbach's reliance on the statistical construct of improved five-year survival as an accurate yardstick of progress in cancer therapeutics. Change in five-year survival is actually an unreliable way of judging progress in the treatment of cancer, since it is susceptible to a statistical artifact called 'lead-time bias.' The

misleading nature of the five-year survival yardstick was exposed more than 35 years ago in a landmark article in the *Journal of the National Cancer Institute* (Hutchison 1968). It has been estimated that about half of the perceived benefit of treatment is actually due to lead-time bias (Shwartz 1980).

Lead-time bias is essentially the interval between the time that a cancer is detected using modern diagnostic techniques and the point at which doctors would have clinically detected it in the past. This statistical artifact came to the scientific community's attention when mammography (diagnostic X-rays for breast cancer) became common. As a result of mammography, breast cancer was being detected earlier, and more frequently, resulting in statistics that suggested that breast cancer patients were living longer. This was at first enthusiastically chalked up to the benefits of aggressive treatment, but upon closer examination, the presumed life-extension turned out to be illusory. In reality, women were simply being diagnosed sooner than they would have been before the advent of mammography. They were not actually living longer; they merely received an earlier diagnosis.

Yet, although universally acknowledged by medical statisticians, lead-time bias was – and continues to be – conveniently ignored and overlooked in study after study. It has led to the entrenched misconception that we really are winning the war on cancer because more people are living five years after their initial diagnosis. Lead-time bias, as I wrote in *Questioning Chemotherapy,* "accounts for much of the illusory 'improvements' seen over the last few decades in treating breast and other kinds of cancer. Patients are actually dying with the same regularity. But the statistics look a whole lot better" (Moss 1995).

"Even if therapy is ineffectual," wrote Yale University statistics professor Alvan R. Feinstein, PhD, "the period of survival will be increased" because of the "added time that is provided by the early, pre-symptomatic detection of the disease." These remarks of Prof. Feinstein's were published in the *New England Journal of Medicine,* the most widely cited medical publication in the US (Feinstein 1985). Yet, as I pointed out in *Questioning Chemotherapy,* these startling conclusions "are almost never taken into consideration by those who make public pronouncements concerning the alleged benefits of modern treatment" (Moss 1995).

Early diagnosis, in addition to creating the illusion of longer survival, has also resulted in a surge in the number of people being labeled cancer patients. Although it has undeniably saved many lives, screening has also resulted in the detection of very early stage cancers whose malignancy is questionable, such as ductal carcinoma in situ (DCIS) of the breast or very early, still-encapsulated prostate cancers, many of which would never have progressed to frank, clinically invasive cancer before the person died of other causes. Since these patients generally survive five years and more even without treatment, it is no wonder that the number of "survivors," especially of breast and prostate cancer, has increased in recent decades. In fact, today, breast cancer survivors make up 22% of the total and prostate cancer survivors make up another 17% (NCI 2004).

PSA Screening

Several years ago, Canadian oncologist Prof. Ian Tannock gently mocked the US tendency to multiply the number of prostate cancer cases through the over-zealous use of the Prostate Specific Antigen (PSA) test as a screening device. He referred to this, satirically, as the "eradication of a disease: how we cured asymptomatic prostate cancer." Dr. Tannock stressed that through aggressive treatment, the quality of life for a great many men could be seriously impaired, firstly by the knowledge that they had "cancer," and then by the morbidity caused by radical treatment (Tannock 2002). PSA-based prostate cancer screening has now been called into question and is no longer generally regarded as either sensitive or specific enough on its own for the accurate detection of prostate cancer.

My point is that this overly aggressive screening of the US population has greatly increased the number of people who have been shifted into the 'cancer patient' category. These newly minted cancer patients are then treated for a "disease" that in all likelihood would never have troubled them, much less killed them.

The combined impact of lead-time bias and over-zealous screening is profound. It has enabled politicians to claim triumphantly that there are now 9.8 million cancer survivors in the US – as if that alone were a sign of great progress in treating a fatal disease. This sort of statistical sleight-of-hand is the unsound foundation on which the concept of five-year survival is built.

Besides, curing early-stage cancer is relatively straightforward: surgery alone is often all that is needed. But curing disseminated cancer is a much more difficult challenge. It would be instructive if Dr. von Eschenbach would talk about the five-year survival statistics for patients with metastatic disease. That would give us a better measure of just how successful conventional (or 'targeted') treatments are in treating the hundreds of thousands of people for whom surgery, radiation and chemotherapy have failed to stop the progress of the disease. I would have liked to see von Eschenbach acknowledge and discuss the fact that for the statistically major kinds of advanced cancer there has been no significant improvement in survival between the 1970s and today (Leaf 2004). These are precisely the tough issues that will have to be tackled if NCI is going to eliminate the massive suffering and death caused by cancer – by 2015, or any year thereafter.

Manageable and Chronic

Dr. von Eschenbach also asserts that NCI is redefining cancer from the rapidly progressive disease of today to what he calls a "manageable, chronic" disease. I welcome the shift towards regarding cancer as a controllable disease, but the NCI is by no means the first to embrace that goal. In 1972, in an era when conventional medicine decreed that cancer had to be quickly treated in radical fashion, a layperson named Betty Lee Morales founded the CAM-oriented Cancer Control Society. The key concept was to seek out less toxic treatments that could be utilized over the long haul to keep cancer at bay. That in fact was the central concept of holistic or "metabolic" therapy. The CCS still exists and promotes this core philosophy. Other CAM pioneers (too many to mention here) developed this same philosophy. In the late 1990s, urologist William Fair III, MD, then of Memorial Sloan-Kettering Cancer Center, introduced this concept into many conventional medical circles, before his own death from cancer in 2002. Of course it is gratifying to hear this CAM philosophy espoused by the director of the NCI, but it would have been even more gratifying if he had expressed some belated appreciation of the unsung heroes of complementary medicine for their three decades of effort to reshape the goals and practice of oncology.

To be Concluded with References Next Month

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