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## EARLY DETECTION: THE NEW CANCER PARADIGM

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A seemingly healthy patient walks into the doctor's office for a routine checkup. The doctor says, "I have good news and bad news. The bad news is that based upon the latest statistics from the American Cancer Society, one out of two men and one out of three women will get some type of cancer during their lifetimes. If we wait until you have symptoms of cancer and the cancer is likely advanced, you will have a 25% chance of survival. The good news is that if we detect the cancer early, you would have a 95% chance of surviving and we now have a simple blood test for the early detection of the most common types of cancers. Do you want me to order the test?"

This is a conversation that a small company called Anixa Diagnostics hopes will soon take place in doctors' offices throughout the world. Anixa is part of a new wave of cancer diagnostic companies that are developing cutting edge technologies, based on new discoveries, which represent a significant change in the way that we think about and treat cancers.

For nearly 45 years, the national dialogue when it comes to cancers has remained essentially the same. We have been racing for the cure, praying for the cure, searching for the cure, researching for the cure, raising money for the cure, funding the cure, and developing treatments for the cure. Curing cancer has become the "national cancer objective". In the recent State of the Union address, President Obama announced a renewed national effort towards finding "a cure" for cancer. Each year, there are approximately 1.7 million new cancer diagnoses in the U.S. [\[1\]](#) so finding a cure for cancer certainly sounds like a noble objective.

However, with all of the time, money, and effort that has been spent in search of a cure, the number of overall cancer deaths has continued to increase. This year, 8 million people [\[2\]](#) worldwide will die from cancer related illnesses, including 600,000 people [\[3\]](#) in the United States. Some would argue that our national cancer objective, has become our national cancer obsession, diverting resources away from the development of alternative technologies that may be more effective in reducing cancer related deaths. In essence, that we may have been blinded by our own ambition of curing advanced cancers. New

technological advances are on the way that will result in a paradigm shift in how we think about and approach cancers. The time has come to take the blinders off and to change the national cancer dialogue.

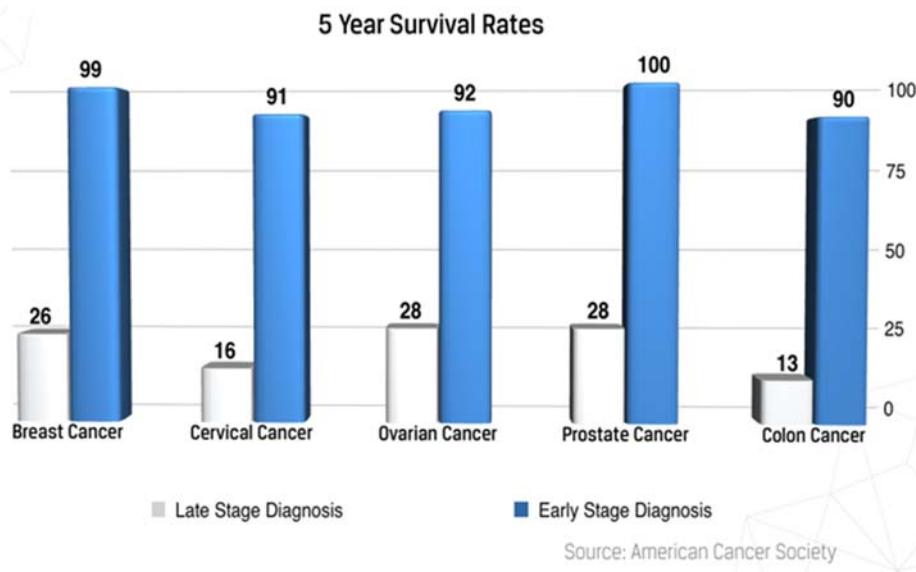
To fully understand how our obsession with curing advanced cancers got started, we need to go back to 1971 and the signing of the National Cancer Act. That bill officially started what is commonly referred to as the “war against cancer”. Two and one half billion dollars was allocated towards what President Nixon described as “a total national commitment towards the conquest of cancer” with a stated goal of “finding a cure”[\[4\]](#). Somewhat ironically, the President marked the occasion by predicting that the signing of the National Cancer Act may be remembered in history as the most significant action taken by his administration. Regardless, the national cancer objective was born. Forty-five years later, the U. S. government alone has spent more than \$100 billion funding cancer research in both the public and private sectors. Though we are nowhere close to a comprehensive understanding of cancers, such government spending has been tremendously beneficial, providing funding for basic cancer research which is the foundation for new cancer treatments.

To say that the war on cancer has been a failure is a bit disingenuous. While often thought of as a single disease, researchers and doctors know that cancer is over 120 different diseases, each with its own subtypes[\[5\]](#). So the concept of “curing cancer” as if it is a single disease, was flawed from the start. We have made significant progress in many cancer areas, and certain cancers such as childhood leukemia, are almost completely curable. However, for much of the past 100 years we have relied upon the same 3 treatment options in our approaches to cancer: surgery, chemotherapy and radiation. Over the years, surgeries have become more refined and less invasive and disfiguring, drugs have been developed to make chemotherapy more tolerable, and radiation has become more precise. We have developed better ways to use and combine the three basic treatments, but all too often, the side effects from the treatments continue to be as bad or worse than the disease itself.

Over the last four decades, with the emergence of the biotechnology industry, drugs such as antibodies and related antibody-drug conjugates have been developed for many cancers. However, these biological drugs are enormously expensive and are effective only for a small number of patients. New immunotherapy approaches, which focus on boosting the body’s immune system to fight cancer, have started to be approved in the last couple of years. Early results look promising, but overall effectiveness is yet to be determined, and again, affordability remains an issue.

Nearly a trillion dollars (in 2016 dollars) has been spent by the private sector in attempts to develop cancer therapeutics over the last 45 years[\[6\]](#). Drug companies are often the darlings of Wall Street, with the lure of the “next big cancer drug” fueling stock prices and enormous valuations. We continually read about new cancer drug “breakthroughs” that took billions of dollars to develop and that “dramatically” increase life expectancies for patients with a particular type or subtype of cancer. Associated with all of these stories are anecdotes of one or a small number of individuals that have beaten their once, terminal disease. While all of these drug therapies are beneficial, increases in average life expectancies from many

of these drugs are measured in weeks or months, as opposed to years. Such drug therapies can hardly be considered successful. Although new classes of drug therapies such as those noted above show promise, and are reasons for guarded optimism, the results from cancer drug therapies as a whole, in terms of significantly increasing life expectancies and reducing cancer related deaths, are disappointing at best.



One indisputable fact that our experience with cancers has taught us is that the earlier that cancers are detected, the higher the chances of survival. The five-year survival rates for patients diagnosed with stage 3 or stage 4 breast cancers, cervical cancers, ovarian cancers, prostate cancers, and colon cancers are 28%, 16%, 28%, 28%, and 13% respectively[7]. The five

year survival rates for patients diagnosed at stage 1 or stage 2 of the same five cancers are 99%, 91%, 92%, 100%, and 90%, respectively[8].

It may now seem obvious for us to have adjusted our cancer focus towards early cancer detection, but no such adjustment has occurred. Our obsession with the national cancer objective of curing advanced cancers seems to have clouded our judgment. The truth of the matter is that almost all cancers are curable if they are detected early enough. Unfortunately, for many cancers, it is technically challenging to detect them in the early stages of their growth. Additionally, relative to what has been spent on drug development, little time, effort and resources have been allocated to early cancer detection technologies. Based upon our objective of curing advanced cancers, our approach to cancer has been almost entirely reactive in nature. We wait until cancer symptoms appear, which in many cases is after the cancer has become advanced, and then attempt a cure. It is not that the war against cancer has been lost, it is that we have been fighting the wrong war.

To understand the positive impact that early intervention and detection can have in fighting a major disease, we should look at heart disease. For many years, the standard treatment modality for heart disease was to wait until the patient exhibited signs of the disease, much like our current approach to cancers. Only after a patient experienced shortness of breath, chest pain, or an actual heart attack, did we seek to intervene. Over the past many years, our approach to heart disease dramatically changed to one of prevention and early detection. Millions of people now take statins to reduce cholesterol, angioplasties are routinely performed to clear clogged arteries, stents are inserted to keep arteries clear, and heart healthy

diets and exercise are part of the routine. The result has been a 60% decrease in heart disease related deaths since 1971[9]. We believe that emphasis on early cancer detection will have similar results.

Our existing cancer screening technologies have become outdated and suffer from one or more deficiencies. To be useful, a cancer screening test needs to have four key characteristics: accuracy, reliability, ease of use, and cost effectiveness. Many of our existing screening tests, such as the prostate specific antigen (“PSA”) test, colonoscopy, and other tests, lack one or more of these key characteristics. Even the mammogram, held by some as the “gold standard” of current cancer screening, has a high rate of unreliability. For every patient that undergoes invasive and expensive follow-on testing based upon the initial results of a mammogram, only about 1 in 5 patients are ultimately diagnosed as having breast cancer[10]. That means that 80% of the mammography patients had follow-on medical procedures that were unnecessary, not to mention the negative psychological impacts. A screening test that has a combination of accuracy, reliability, ease of use, and cost effectiveness would be the “Holy Grail” of early cancer detection. Despite the lack of national resources that have been allocated to early cancer detection, many feel that the Holy Grail is within our grasp.

We are now at the forefront of a new wave of early cancer detection technologies that has been fueled by innovative start-up companies in the private sector. Bodily fluids such as blood, plasma, urine, saliva, and even breath are currently being studied for early indicators of cancers called biomarkers. Biomarkers include things like cells, proteins, DNA mutations, and biological reactions that are indicative of cancers. This relatively new field of identifying biomarkers for purposes of early cancer detection is sometimes referred to as “Liquid Biopsies.”

The concept of screening asymptomatic patients for early signs of cancer is as much of a departure for the patient as it is for the existing cancer establishment. No presumably healthy patient wants to think about the possibility of getting cancer or the concept of regular cancer screening. That is why the national dialogue about cancer needs to change. Sometime in the near future, we expect that doctors will order cancer screening tests during routine physical exams, much like screening tests for cholesterol to evaluate cardiac health are ordered today. Perhaps when we have the ability to use new approaches, such as the immunotherapies described above, on early stage cancer patients identified through screening, as opposed to on late stage cancer patients where they are currently being tested, the effectiveness of such approaches will be high enough to replace existing treatments like chemotherapy and radiation.

We need to be realistic about the probabilities of curing all advanced cancers in the foreseeable future and the consequences of pursuing that single minded purpose. If the American Cancer Society is correct and 1 out of 2 men, and 1 out of 3 women will get some type of cancer[11], approximately 120 million people in the U.S. will become cancer patients. We need to better prepare ourselves for what lies ahead. Although efforts have been made to publicize the benefits of certain types of cancer screening, such as self-examinations for breast cancer and skin cancer, we need to increase our efforts to publicize the virtues of early cancer detection for all types of cancers and the potential benefits of new cancer screening

technologies. We are at an inflection point in the fight against cancers with potential changes on the way from what some might consider to be disruptive technologies. Change is long overdue. The sooner that we begin to chip away at the monolithic thinking of the past 45 years, and open our minds to new approaches to how we think about and fight cancer, such as early cancer detection, the faster changes will happen and the better our chances of success.

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[1] <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/>

[2] <http://www.who.int/mediacentre/factsheets/fs297/en/>

[3] <http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2015/>

[4] <https://www.youtube.com/watch?v=qX8d1vOI8l8>

[5] <http://www.cancer.net/cancer-types>

[6] <http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/#62ea8de16bfcc>

[7] <http://seer.cancer.gov/statfacts/>

[8] <http://seer.cancer.gov/statfacts/>

[9] <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm4830a1.htm>

[10] <http://www.cancer.org/acs/groups/content/@research/documents/webcontent/acspc-045101.pdf>

[11] <http://www.cancer.org/cancer/cancerbasics/lifetime-probability-of-developing-or-dying-from-cancer>