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An Analysis of the Verisante Aura in the United States

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Introduction:

My passion for melanoma detection stems from my own diagnosis with a malignant melanoma five years ago. It took me years, from when I first noticed the unusual mole, to actually schedule an appointment with a dermatologist to get it examined. And when I finally entered a dermatologists' office, I could not even get it removed because they would not accept my insurance and I figured it was just a harmless mole anyway. Months later, when I eventually got around to scheduling an appointment with a reputable dermatologist, who accepted my insurance, it was black in the center, had irregular edges, and was twice the size from when I first started noticing it. It would have saved time, money, and significant worry from family and friends to diagnose the mole as melanoma in my primary care doctors' office years before it became so severe.

According to the *American Melanoma Foundation,* melanoma cases have been increasing the past thirty years, and over a million cases are diagnosed in the Untied States alone every year. Malignant melanoma is the most fatal of all skin cancers, as it causes three quarters of all deaths to skin cancer (Tfayli, 2009). Currently, diagnosis of melanoma is determined through physical exam by a dermatologist, where a suspicious lesion is biopsied and then sent to a pathologist. This process can be invasive, expensive, and time-consuming. Additionally, one study revealed that the accuracy of diagnosis through dermatologist varies between 49 and 81%, where one third of melanomas are misdiagnosed as benign lesions (Lui, 2012). However, a new technology developed by Verisante Inc. could revolutionize this diagnostic process.

The Verisante Aura is a technology produced by Verisante Inc, a Canadian company that uses Raman spectroscopy to detect skin cancer. In addition to my own

diagnosis with melanoma, I am particularly interested in the Aura because of its application of Raman spectroscopy. Two summers ago, I conducted preliminary research on the use of Raman spectroscopy to diagnose breast cancer at the Dannenberg lab at Weill Cornell Medical School. This research focused on preliminary data collection, and while it did reveal extremely promising results, the Raman machine I used required extensive training and was much too large and clunky to be practical in a doctor's office. Thus, it is extremely exciting to see the results of Raman spectroscopy experiments transformed into a polished, easy-to-use, and convenient technology to be utilized in physicians' offices on a regular basis.

The Aura itself is a compact, hand-held probe with a simple design that trained personnel can easily use to scan lesions or moles. Its function is to aid medical professionals in diagnosing skin cancer by instantaneously identifying spectral changes that are characteristic of the biochemistry of skin cancer cells. With the Aura, scans can be done quickly and accurately to avoid unnecessary biopsies. Not only does the Aura have the ability to dramatically speed up the diagnostic process, but also it has the capability to greatly enhance accuracy of diagnosis.

The basis of my thesis is to offer a cost-benefit analysis of the use of the Verisante Aura in the United States. This is not a traditional cost-benefit analysis, but addresses larger issues than just the financial costs and benefits. I will start my analysis by giving a background of the Aura scientifically and theoretically, then transition to more specific aspects of the use of the Verisante Aura. First, I will provide an overview of the technology, beginning with a description of the science behind Raman spectroscopy. Then, I will use relevant studies to reveal the extreme accuracy and success of Raman

spectroscopy. Next, I will address some inherent assumptions that influence how we think about the Verisate Aura, namely the assumed objectivity of science and technology, our definition of health, and the cultural significance of cancer. I will use this foundation developed in chapter two, to analyze case studies similar to the Aura that reveal how society is a reflection of the technology we use, and how in return technology shapes our society. I will use the example of the stethoscope as one of the most fundamental medical technologies to consider how technology changes the patient-doctor relationship. I will also examine the case study of the mammogram, as it is especially applicable to the Verisante Aura, since it faced similar issues in its acceptance. With this theoretical foundation in mind, I will focus more specifically on the Aura in chapter four, by studying the use of the Verisante Aura in Canada, Australia, and much of Europe, compared the United States. Followed by a discussion of relevant aspects of the United States healthcare system that affect the acceptance of the Aura. I will look at the various actors and stakeholders in the approval process and the power dynamics at play. Next, I will analyze the possibility for more screening technologies due to stipulations in the Affordable Care Act. Lastly, I will provide an unconventional, cost-benefit analysis of the Verisante Aura's use in the United States. This will not be a traditional cost-benefit analysis, but I will use the term cost-benefit widely and consider social, political, economic, and emotional changes that may emerge from the Aura. The bulk of my analysis will consider three main factors: the benefits of improved accuracy from the Aura, the problem of unequal access to this technology, and the possibility of losing an irreplaceable human aspect of medicine through the adoption of the Verisante Aura. I will

then conclude my thesis with my opinion on the use of the Verisante Aura in the United States.

Chapter One: Overview of Technology

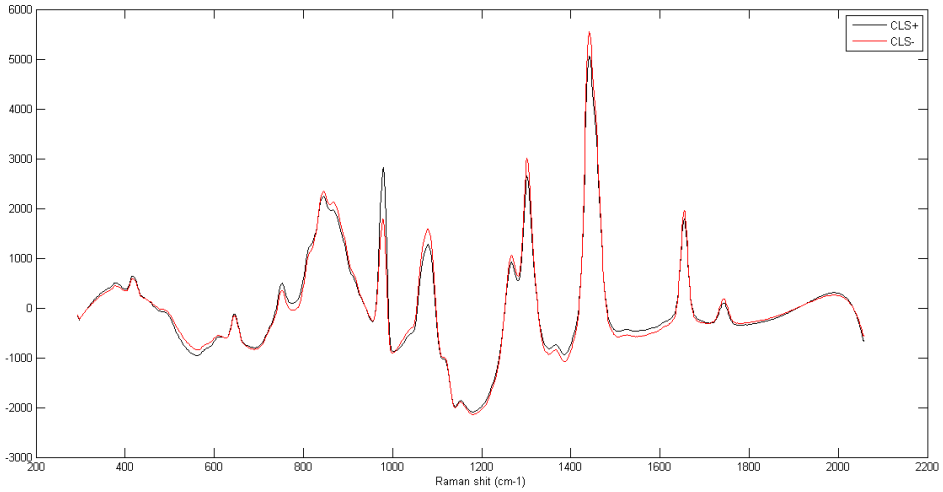
Optical Techniques Overall:

There have been recent advancements in optical techniques to diagnose melanoma. Optical techniques describe a category of diagnostic tools to non-invasively diagnose disease by studying how light interacts with human tissue. Some examples include optical coherence tomography, fluorescence spectrometry, reflectance spectrometry, confocal microscopy, and Raman spectroscopy. However, according to a recent study comparing the five techniques studied, Raman spectroscopy was the most successful at diagnosing melanoma proven with sensitivities and specificities above 90% (Calin, 2013).

About Raman Spectroscopy:

Raman spectroscopy is a non-invasive, screening technology that gives detailed biochemical information about tissues that can be used as a fingerprint of a cell's molecular and morphological reality (Brachule, 2014). The Aura uses Raman spectroscopy, which is an inelastic scattering process where a molecule absorbs a photon of light and emits a secondary photon of a different energy level. The molecule undergoes a transition from one energy to another after it is excited from the absorption of the incident photon and then as it de-excites to a lower energy level it emits a secondary photon that reveals unique characteristics about the molecule known as the Raman shift. Figure 1 is an example of a Raman spectra collected during my research in the Dannenberg lab during the summer of 2013. Each peak represents a characteristic molecular transition and as a whole the spectra can be used to identify a particular molecule. The frequency shift between the absorbed and emitted photon is specific to

each molecule and is called the Raman shift (Raman et al, 1928). The Raman shift can be used to distinguish cancerous cells from non-cancerous. In addition, Raman spectra are extremely useful for in vivo measurement as the laser fluencies and excitation wavelengths are non-harmful to tissue and can penetrate the skin far enough to reveal very specific information (Feld, 2000).

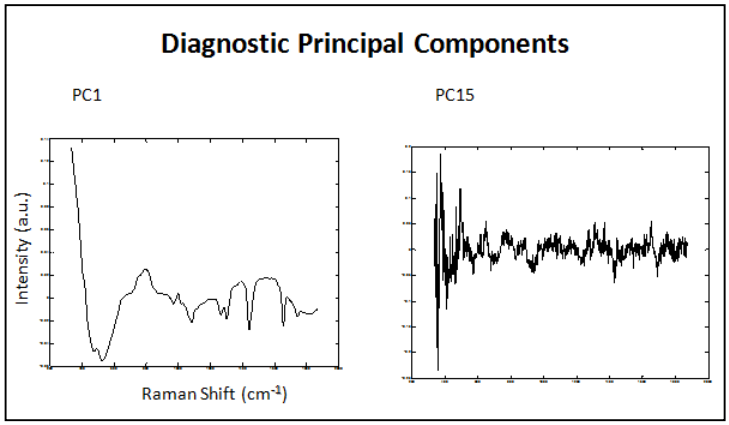


(Figure 1: Carpenter, Cassidy. *Example of Raman Spectra*. 2013. New York City, New York.)

In order to acquire the biochemical information about cancer using Raman spectroscopy, a laser is directed into a confocal microscope and focused onto an area of skin of approximately 2 μm in diameter. The device focuses the laser and collects the Raman backscattered light. Then, another device on top of the microscope collects the information. Following the collection process, the raw data is analyzed using principal component analysis (PCA). PCA is a multivariable method of analysis used to distinguish 'melanoma' from 'non melanoma,' that is used to develop the diagnostic algorithm. As described by Abigail Haka in *Identifying Microcalcifications in Benign and Malignant Breast Lesions by Probing Differences in Their Chemical Composition Using Raman*

Spectroscopy, "It is a chemometric technique that resolves the spectra of an entire data set into a few orthogonal PC spectra. PCA uses the entire Raman spectrum and does not assume any knowledge about the chemical composition of the tissue (Haka, 2002)."

PCA operates where principal components, or trends, that are assumed to be representative of the key differences between melanoma and non-melanoma are multiplied by weighing coefficients or scores (Figure 2). As Haka describes, "PCA can recognize small spectral variations and distinguish them based on biochemical similarities and differences. PCA isolates spectral trends that correlate with physical information and thereby provides a basis for development of a diagnostic algorithm (Haka, 2002)."



(Figure 2: Haka, Abigail. *Example of Principal Components*. 2006. Cambridge, Massachusetts.)

After the representative PC's are obtained, these PC's, or spectra, are normalized and mean centered to remove possible biases. Next, logistic regression is performed that connects the PC scores, representative of chemical differences, to actual diagnostic categories. Logistic regression is performed to differentiate 'melanoma' from 'non-melanoma.' Each skin sample is given a probability between zero and one of having

melanoma. If the probability is less than 0.50, it is considered ‘non-melanoma,’ and if it is greater than 0.50, it is considered as ‘ yes melanoma.’

Diagnosing Melanoma:

Raman spectroscopy greatly improves the rate of correct diagnosis over current clinical diagnosis of melanoma through dermatologist-pathologist teams, which is between 49 and 81%. One experiment revealed the power of Raman spectroscopy to differentiate between melanoma, pigmented nevi, basal cell carcinoma, seborrheric keratosis and normal skin. In this experiment of n=22, the sensitivities and specificities were 85% and 99% respectively (Gniadecka, 2003). An additional experiment used thirty-nine skin tissue samples encompassing normal, basal cell carcinoma, and squamous cell carcinoma and revealed a specificity and sensitivity of 100% (Lieber, 2008). The last study, used micro-Raman spectroscopy on HaCaT cells, melanocytes (MM), squamous cell carcinoma (SCC), and melanoma cells (MC). A great amount of variety was observed between all the different cell types. This study is extremely valuable as it shows the success of Raman spectroscopy at distinguishing between different cell lines (Wang, 2012). Another study was done to differentiate normal skin from pigmented nevi (or moles) based on different Raman shifts, which reveals that Raman spectroscopy is identifying chemical differences based on cancer, and not just pigmented skin from non-pigmented (Cartaxo, 2010). These studies indicate the ability of Raman spectroscopy to replace the current method of diagnosing melanoma through biopsies. Clearly there is great potential of Raman spectroscopy for skin cancer detection.

Clinical Uses:

While these experimental results are promising, the Aura is supposed to be used in a clinical setting, yet this has also been proved possible with the Aura. The Aura is an ideal technology for a clinical setting, because of the low measurement time for Raman spectra, since the Raman spectrometer system has an acquisition time of less than 1 second (Zhao, 2008). One study investigated the use of Raman spectroscopy to differentiate malignant tissue from benign in a clinical setting with accuracy that matched clinical examinations. In this study, benign and malignant skin lesions (n=518) were measured for 1 second each followed by lesion classification using a principal component with general discriminate analysis and partial least squares. The results were sensitivities and specificities between 95% and 99% (Lui, 2012). These studies reveal that not only is Raman spectroscopy highly accurate in the diagnosis of melanoma, but also it is extremely practical in a clinical setting proven by the fact that it is easy to operate, provides quick diagnostic results, and has the potential to increase access to skin cancer screenings.

Verisante Inc. has successfully transferred the results of many of the preliminary scientific studies on Raman spectroscopy into an easy-to-use, commercially available product that has the promise to be a standard technology in most dermatologists', or even primary care doctors', offices. In a joint study over six years, by the British Columbia Cancer Agency and the University of British Columbia Faculty of Medicine, the Aura was used in a human clinical study on one thousand lesions. According to a study at the Vancouver General Hospital Skin Care Centre, the Aura revealed a 99% sensitivity for differentiating malignant and premalignant skin lesions from benign ones and reduced unnecessary biopsies by 50-100%. However, there must be some degree of caution in

giving the Verisante Aura too much power over cancer diagnosis. Although there are major insights that can be gained from Raman spectroscopy, there is a risk that we will loose the human empathy, ingenuity and instinct for medical treatment acquired from experience alone. It is through the partnership of new, innovative, technology and human experience that medicine can utilize its full potential as a powerful healing force.

Chapter Two: Inherent Assumptions

Inevitability of Bias:

The Aura represents a fundamental change in modality in the diagnostic procedure for detection of melanoma. With such a revolutionary change, there are inherent assumptions that come with this technology and alter the way medicine and diagnosis are experienced. The first assumption concerning the Verisante Aura is that it is more objective than humans. While physicians do have unavoidable individual biases, this should not be used as an argument for the use of technology over humans, since technology, contrary to popular belief, also comes with unavoidable bias. Many of the arguments in favor of technology, over human expertise, are based on the assumption that technology is far more objective than humans. Yet, humans have constructed technology and a part of this construction imparts human subjectivity upon technology as well. Technology has just as much potential for bias as humans. This does not mean that technology is entirely unhelpful and wrong, only that when evaluating humans versus technology we cannot assume that technology is far superior in terms of objectivity. If we are going to critique humans for their subjective biases, we must do the same for technology.

Technological bias can be exemplified when distinguishing 'signal versus noise.' Much of experimental data is discarded and thrown out as 'noise' or experimental error. However, this process of discarding some data, and not all, presents bias by only publishing, or focusing, on data to prove a specific hypothesis and throwing out data that challenges it. In *Technological Medicine,* author, Dr. Stanley Reiser, brings up an example of this as he states,

> "systematic reviews of Randomly Controlled Trials (RCTs) are considered the best evidence of a therapy's effectiveness, superior to any single RCT. But in 2003 the movement drew attention to the absence of a system for registering all RCTs and disseminating their results, a problem since many of those conducted are never published and thus lost to scientific use. Research into the reasons for not publishing RCTs found that investigators are influenced by favorable study results and lose interest in studies that produce negative findings (Reiser, 121)."

This example raises the question of who decides what is signal or noise? Most of the time, the researcher making these decisions has an intrinsic motivation to support a hypothesis and get published in order to gain recognition and to further a career. Raman spectroscopy is no exception, as a critical step in the generation of the diagnostic algorithm is the 'normalization of data.' Normalization of the data raises the issue of how and who determines what is signal versus noise. There is significant opportunity for bias in filtering out much of the 'noise' collected in data. Science is not inherently objective, but is laden with social and personal motivations and is intrinsically tied to political and social factors at play. Therefore, contrary to the prevalent assumption, when evaluating the success of technology, including the Aura, it is critical to keep in mind that science and technology are rooted in human subjectivity.

Often times it is humans, who are innately biased, that process the data used to develop technology. The same applies to the Aura, as humans decide what PCs to include and what PCs to discard from the Raman spectroscopy data. Thus revealing that while technology is sometimes perceived as separate from human bias, it too is developed by humans and thus contains human bias. When the experimenter knows what PCs to look for to confirm their result, it is easy to identify the pattern. In order to get a few PCs representative of all the Raman spectroscopy data, you must remove certain PCs. This introduces another opportunity for bias based on who, or what, is making the decision of what goes into the few PC spectra representative of the entire Raman spectra. However,

this process can be extraordinary subjective because when you are looking for something, you perceive that you can see signal when often times it is just noise.

Another assumption concerning medical technology is that it is able to exactly capture and realistically observe what is occurring in the human body. However, with most technologies, even if the data does suggest there is a correlation in many experiments, most times the observer is not directly seeing anything, but rather observing a secondary effect of a precisely orchestrated experiment. Raman spectroscopy cannot observe cancer directly, but rather it has the ability to indirectly detect tissue changes that are a result of cancer. Therefore, when discussing Raman spectroscopy it is important to acknowledge the complex scientific reality surrounding diagnostic technology. Contrary to the prevalent rhetoric concerning diagnostic technologies, they are not directly observing cancer. Instead, they are finely tuned instruments designed to detect the smallest of changes related to cancer, and because of this specific goal in mind they come with an inherent bias.

There is a large degree of translation from melanoma to the biological changes associated with melanoma to the reflection of backscattered light back into the camera. Thus, it is possible that much of the original information about melanoma is lost through these multiple translations. There are limitations associated with simplifying something inherently complex and physically inaccessible to humans, such as cancer, into just a few trends. Inevitably, there are going to be some important aspects left out that cannot be entirely communicated through this algorithm. And since we cannot observe cancer directly, it is entirely possible that this simplification is a construction and not an accurate representation of melanoma. This is not to say that Raman spectroscopy is biased to the

point of wrong, in fact it is extremely accurate, but the rhetoric used to describe its success must also give equal accounts of its limitations and potential for bias.

Reiser describes the workings of diagnostic technologies as he writes, "new technologies permitted doctors to capture the sounds of the body doing its work, to probe the composition of its fluids, to fathom the state of its biological systems, and most dramatically, to visually display its intricate landscape-a process that located hidden diseases and defined them with a new scientific precision. Gradually, organ after organ gave up secrets of hidden workings to new technological probes, such as the stethoscope, ophthalmoscope, and X-ray (Reiser, 138)." Thus, diagnostic technologies are powerful and impressive tools that generate a great deal of information about the human body. Yet, it is critical to remember they are not as objective and clear-cut as often marketed, but are finely tuned instruments designed to pick up the smallest and often indirect effects of what is specifically being examined. Diagnostic technologies, including the Aura, are very accurate at observing a narrow context, but are incapable of providing a complete picture of the biological reality beneath the skin. Thus, the information they can reveal is limited to the specific and often ignores the broader picture. This is not to say that they are subjective to the point of being incorrect, but rather the rhetoric about such technologies must not be so overwhelmingly certain considering there is still a great deal of uncertainty regarding cancer and consequently a great deal of uncertainty regarding the changes Raman spectroscopy is detecting.

The rhetoric used to describe technology does not reflect this subjective nature, but is overwhelmingly objective. The dialogue surrounding scientific data and technology is often clouded with language that does not reflect the subjective and uncertain data

collection process. An example of misleading rhetoric used to describe scientific advances is in *The three worlds of health information,* by David Bawden when he states, "World 3 contains the integers, and the axioms which relate to them, it must necessarily contain all the theorems of number theory, whether or not these have yet been discovered. (It seems to the author, incidentally, that this goes an attractive answer to the perennial question of whether mathematical results are discovered or invented) (Bawden, 2001)." Bawden raises an important point concerning the language we use to describe technologies, is it discovered or invented? Often times we describe scientific results with more certainty than exists. While, the Aura has proven to be extremely accurate, we must be careful not to confuse accuracy with certainty.

All data is embedded in previous notions, and the Aura is no exception. The Aura is not objective in nature, since it is engineered toward a specific goal, to detect melanoma. Yet, the rhetoric used to describe results imply that the data is more certain and clear-cut than the often subjective and cloudy reality of experimental data. On the Verisante Inc. website that describes the Aura they use language such as, identify, detect, found, and reveal. However, the Aura is not directly identifying, finding, detecting, or revealing melanoma, but rather sensing precise, indirect signs of melanoma. This is not to say that the Aura is flawed, only that scientific rhetoric rests on certain incorrect assumptions of objectivity that obscures the reality of the scientific process to the general public. There is a critical hybrid between reliable data and fudging to accurately reproduce the scientific reality. The issue is that it is not always clear what that reality is and who decides what is signal versus noise, or what PCs to keep and what ones the throw out.

By simplifying the process, we do not acknowledge the complicated reality behind these discoveries. Words like observe, discover, and detect imply the process is more clear-cut than it is. We need more accurate rhetoric to describe the actual process of invention and observation. In *The Importance of the Human Element in Medicine* published in The American Journal of Surgery, author Burns Chaffee also reflects on this overwhelmingly optimistic and progressive way society embraces technology as he states, "Secure in the knowledge that we are following the higher standards which have come down to us through the ages, we make no reply to this barrage of pseudo-medical shrapnel, but its effect upon the mind of the general public is far reaching and detrimental. It has tended to shake the faith of the afflicted of the civilized world in all branches of the medical profession (Chaffee, 1931)." Chaffee states that we cannot blindly embrace technology without the least bit of skepticism or caution, and argues against the prevalent ideology of an overwhelming trust for technology that does not see both the positives and negatives associated with it.

The Verisante Aura comes with its own subjectivity through PCA analysis and the process of removing 'noise.' There is no unmediated reality, since all tools of measurement leave an imprint on the subject in order to obtain the measurement. Even the most seemingly pure and objective science and technology of our time, such as the Aura, has its own limitations. Yet, the prevailing ideology in science and technology does not acknowledge the inherent bias in all technology that there is no unmediated measurement or reality. The scientific community dismisses humans as inherently biased and subjective, yet what makes human subjectivity worse than technology? In *The Grammar of Science*, author Karl Pearson defines the scientific frame of mind as the

ability of a person to eliminate the self from judgments and thus make objective statements about the world. However, this constantly objective portrait of scientists is impossible, as people will always be influenced by social and political factors. While complete objectivity is something to be strived for in science, it is largely impossible and we must acknowledge the limitations in our objectivity to obtain a more thorough picture of science and technology. The technology we use has inherent subjectivity and by not acknowledging these limitations we are introducing more inaccuracy than the bias itself.

This is not to say that technology is worthless and all of science is wrong. In fact, the rational and critical approach that is the foundation of medicine is extraordinarily valuable and useful. However, as users of technology we must understand and accept their limitations alongside their benefits. Bawden describes this critical hybrid between accepting the changes of technology and being critical of its negatives as he states,

> "a rational and critical analysis of available information-which is what the evidence-based approach amounts to-enables us to articulate and explain the basis for the current state of knowledge; some of which is very firmly based indeed, and unlikely in practice to be overturned. However, this is a very different thing from stating *ex cathedra* that some point has been proven beyond further argument. We should always be open to new evidence and new interpretation; history shows many examples where this has not been the case in the health care domain (Bawden, 2001)."

I fundamentally believe that the science behind the Verisante Aura is extraordinarily valuable. However, I think the language prescribed to science in general simplifies the scientific process overall in a way that does not accurately reflect the complexity of the scientific process occurring.

Definition of Health:

Another assumption to consider is our definition of health, or conversely disease. In western medicine, there is an inherent assumption of disease as a material being and

something to be removed, attacked, and conquered. Yet, disease is also reflective of a larger issue concerning the environment of the person. The linkage of the external environment to health and illness is described in the Hippocratic work *Airs, Waters, and Places,* which provided the first theoretical and practical perspective on why understanding illness and prescribing actions to secure and enhance health in individuals required an awareness of how the person lived as well. It describes two basic environments within and through which humans functioned. The first is the internal biological sphere and the second an external worldly sphere influenced by nutrition, exercise, rest, mental health, culture, social customs, climate, and other external stimuli. Reiser summarizes the interplay of these two environments from *Airs, Waters, and Places* as he writes,

> "Stimuli from this external sphere influenced internal humoral function and relationships, disruptively to cause illness or accommodatively to maintain humoral balance and health. The linkage of the external environment to health and illness is innovatively, wisely, and elegantly portrayed in the Hippocratic work *Airs, Waters, and Places.* It advises physicians entering a new city to 'consider its situation, how it lies as to the winds and the rising of the sun…whether it be naked and deficient in water, or wooded and well watered, whether it lies in a hallow, confined situation, or is elevated and cold; and the mode in which the inhabitants live…what are their pursuits, whether they are fond of drinking and eating to excess, and given to indolence, or are fond of excursive and labour, and not given to excess in eating and drinking.' If the doctor worked hard to acquire these facts and from them discerned the illnesses peculiar to and common in these places, he would not make mistakes in his treatments and would be able to predict… (Reiser, 131)."

This account reflects a more holistic view of health as a product of a larger environment, while western medicine looks at disease as a more isolated, disconnected entity. Thus, these inherent assumptions about what defines disease are critical in how we look at cancer as a distinct object or just as a reflection of a larger issue. Do we look at disease from the point of view of what is causing the disease or what affect the disease is having

on the overall person? Or are both necessary to fully understand a person's health? Our perception of disease is critical to consider in light of the Aura, since a human physician can diagnose the environmental factors leading to cancer, whereas a machine cannot.

The rhetoric we use when discussing disease is influential in our perceptions of health. Reiser describes how our current way of discussing disease reflects a 'western' view point on health as he states,

> "The vocabulary employed to describe and discuss genes, using concepts like maps and bins that direct us to the location of things in places, reveals the influence of structuralist thinking in genetics. However the authors of 'The Genomic Gold Rush' article suggest, exploring the complex environments with which genes interact is needed to explain their role in disease. Thus, the focus of anatomic study has shifted over the past three centuries to increasingly smaller units of analysis-from the organ to the cell to the gene-but this work has continued to center medicine on the same fundamental question…Where is the disease? These developments make it essential for medicine and public health to place health and illness within a conceptual framework, in which understanding the conditions creating health for individuals and populations receive coequal study and status with those producing illness, and in which a broadened array of factors explaining and producing these basic states of being undergird analysis and practice in the health professions (Reiser, 155)."

Modern medical technology is reflective of a framework that practices the separation of the whole into parts by focusing on attacking specific physical manifestations of illness. Yet, it is necessary to connect the person to the larger context of their environment in order to completely understand the disease they are experiencing.

Cultural Perception of Cancer:

The way we discuss cancer is especially rooted in cultural assumptions. The rhetoric surrounding cancer care and treatment is based on war-like metaphors and violence. The origins of this dialogue may be traced to Nixon's 'War on Cancer' as Dr. Handel Reynolds discusses in *The Big Squeeze: A Social and Political History of the Controversial Mammogram*, "Not only would he be commander in chief of a military

battling an enemy in Southeast Asia but also he would be personally leading the charge against an enemy much closer to home. It is in this regard that Nixon is commonly considered to have launched the nation's 'War on Cancer' (Reynolds, 8)." This aggressive language particular to cancer has influenced our ideas and preconceptions concerning cancer treatment. Cancer has been vilified as something that must be viciously attacked and removed. As Reynolds states, "The idea that there are some cancers that don't need to be sought out and eliminated is difficult for lay people, and even some professionals, to grasp. It is, however, a phenomenon that has been repeatedly observed throughout the history of cancer screening (Reynolds)."

Cancer is infamous among diseases as being one of the most feared. We tend to avoid discussing cancer, and the word itself has become synonymous with evil and poison. This may be because we have not found a cure, or possibly we have a primal fear of cancer. Regardless, the world 'cancer' has transcended the confines of a medical diagnosis to hold a culturally significant connotation of fear and evil. This cultural significance greatly influences our medical perception of this disease as we distinctly think of cancer as something to be immediately removed as opposed to approaching cancer as the more biologically accurate reality, as a dysfunction of normal cell growth in our body. Most cancers are not caused by a bacteria, parasite, or virus that must be irradiated, but caused by internal mutations within our own DNA. Therefore, it is ironic that cancer especially has acquired this notable metaphor as needing to be violently eradicated since it is mostly a result of genetic, or environmental causes that lead to a dysfunction of our own cell-regulation machinery.

An excellent example of the extreme meaning prescribed to cancer is in a new documentary on *Public Broadcasting Service "*Cancer: The Emperor of All Maladies," which is a three-part, six-hour major television show presented by documentary filmmaker Ken Burns. This documentary is based off a book by Dr. Siddhartha Mukherjee called *The Emperor of All Maladies*, and describes the battle against cancer as a war occurring for centuries. Yet, author Dr. Siddhartha Mukherjee brings up the important point that despite his own rhetoric of assigning violent-war like metaphors to cancer it is a disease that comes from within us as he states, "The closer researchers looked, the more baffling the cancer cell became, especially once they realized that the disease wasn't something imposed from outside. The vulnerability is already within us. The very genes that make you grow, the very genes that keep you alive, will under different circumstances kill you (*Cancer: The Emperor of All Maladies*, 2015)."

The cultural significance of cancer is critically important in the development of the Verisante Aura, since we must consider why there are more diagnostic technologies and efforts to prevent and cure cancer than other leading killers. While this disease is a leading cause of death, we have a distinct preoccupation with cancer diagnostic technologies and finding a cure compared to other fatal diseases. This preoccupation may be the critical factor that helps the Aura through the FDA approval process. As Reynolds writes, "This widespread belief in the benefits of screening comes from our collective acceptance of the early detection message that has been widely promoted over the past several decades, direct-to-consumer marketing of screening tests by commercial enterprise, and our persistent primal fear of cancer (Reynolds, 76)."

Our obsession and concern over cancer is exemplified in the consumer market that has heavily promoted cancer prevention through BPA free water bottles, high-end moisturizes that advertise SPF-15, and the media exploding with news of Angelina Jolie and the BRCA1 gene. Not to say that these endeavors are not worthwhile, but just to point out the singularity with cancer among other medical issues in the consumer market. Another reason cancer is distinct, is because of the heavy government research money allocated to cancer every year, as the NCI receives annually 4.9 billion dollars for research funds (National Cancer Institute website). These factors must be considered not only for why the Verisante Aura is accepted, but also why it was invented in the first place.

Chapter Three: Case Studies: the Stethoscope and Mammogram

Technology is inherently a reflection of the culture of its time, while also re-shaping the lifestyle, ideology, and values of the same culture in return. There is a dynamic equilibrium between technology and society in how we influence technology and technology influences us. Thus, the context of technological innovation provides just as much critical information about a technology, as technologies themselves reflect about the culture of a given time period. Reiser describes this phenomena when he writes, "In general technologies are created by the existence of possibilities that the prevailing ideas, culture, and social climate of an era suggest to an innovator could be useful, interesting, or profitable. Thus, technologies are absorptive and reflective: they soak up and mirror back aspects of the environment in which they are created (Reiser, 187)."

Science and technology are entrenched in the society from which they emerge. The social environment provides a powerful influence on the process behind scientific and technological innovation. Technologies are simultaneously a product of the dominant paradigm, but are also developed in order to reinforce the dominant paradigm. Therefore, technologies carry and reinforce significant cultural and social messages, and can act as agents of change, but also agents of reinforcement. All technologies are a product of the context from which they emerge; however, I will focus on the stethoscope and the mammogram. I will use the example of the stethoscope since it is one of the most fundamental medical technologies and highlights some critical changes that emerge when a human skill is replaced by a technology, as Dr. Ariel Roguin states in *Rene Theophile Hyacinthe Laënnec (1781–1826): The Man Behind the Stethoscope,* an article published in The Journal of Clinical Medicine and Research, "the stethoscope may be the one

instrument common to all doctors…this instrument may even supersede the caduceus as the symbol of medicine-no other symbols so strongly identifies a doctor than a stethoscope dangling around the neck like a talisman (Roguin, 2006)." Next, I will present the case of the mammogram as it is faces many of the same issues as the Verisante Aura as a cancer diagnostic tool. There is a great deal of information that can be gleaned about the possible effects of the Verisante Aura by exploring case studies of introductions of current technologies concerning the context and the resulting positive and negative effects on society.

Stethoscope:

The first example is the discovery of the stethoscope by René Laennec in 1816. Roguin describes how Laennec's initial inspiration for the stethoscope was observing two children sending signals to each other using a long piece of solid wood and a pin. Later in the same year, Laennec was called to a young women with heart problems and, "was reluctant to start *immediate auscultation* (placing the doctor's ear on the patient's chest) because of the age, sex, and plumpness of the patient. In this moment of embarrassment, Laennec recalled his observation of the children's wood borne signaling. It was this observation that inspired Laennec's invention of the stethoscope (Roguin, 2006)." Laennec discovered that heart sounds could be heard more clearly using mediate auscultation, he then spent three more years testing different materials to make tubes and perfect his design listening to patients with pneumonia (Roguin, 2006). Laennec's invention of the stethoscope offered more accuracy than often subjective, patient descriptions. The technology allowed doctors to independently access pathology in the body by placing a tool on it, and the body revealed what was wrong by the sounds it

made. There was no concern about forgetfulness, fabrication, or motives. Thus, diagnosis was transformed into a purely physical diagnosis based on sounds that reached the ears of doctors, who alone analyzed their significance isolated from the subjectivity of patients. Reiser describes this transformation when he writes, "the stethoscope liberated doctors from patients and, by doing so, paradoxically enabled doctors to think they helped them better. This was the logic of the physical examination. Listening to the body seemed to get one further diagnostically than did listening to the patient (Reiser, 26)." This revolutionized the relationship between patient and doctor, by transferring the power from the verbal and emotional trust to placing it more in the hands of technology. The stethoscope reformulated the relationship between doctors and patients through the use of an instrument that took the mantle of illness out of the hands of patients and placed it into the doctor's orbit. The Verisante Aura also has the ability to alter the power dynamics between patient and doctor, by taking away decision making power and legitimacy from the doctor and giving it to a technology. The Aura, just like the stethoscope, has the capacity to transform the doctor-patient relationship where technology is trusted more than patient accounts or doctor intuition. Additionally, both technologies funnel a whole being with emotional, psychological, and physical realities into narrow, scientific results. Both cases, the Aura and stethoscope, reveal the tension between science and technology and a more personal and individualized approach to medicine.

The transformative power of the stethoscope had as much to do with its effects on the relationship between doctor and patient as it did with the evidence of illness it uncovered. As Reiser states, "In medicine, relationships and evidence are linked. How the facts about an illness are gathered and the nature of those facts critically effect how

doctor and patient regard each other (Reiser, 1).” Both the Verisante Aura and the stethoscope represent more than just physical entities, but also a fundamental change in diagnostic procedure that impacts power dynamics, the patient-doctor relationship, and how society views medicine altogether. In the case of the stethoscope, it established illnesses as entities with specific melioration remedies. This revolutionized medicine by turning the doctor’s role from focusing on the individual, to focusing on prognosis and the disease. As Reiser states, “For having named the entity making the patient sick made it possible to seek a standard therapy that worked and could be applied to all patients in this category (Reiser, 136).” While the stethoscope improved certain aspects of diagnosis, it was one of the factors that detracted from the individualized, patient-centered treatment. The stethoscope exemplifies the critical balance between embracing technology and science with caution rather than a zealous approach that does not acknowledge any limitations.

Mammography:

Mammography is a perfect example of how social and political factors can take pivotal roles in the acceptance of technologies. In the case of the mammogram there were external events that shaped the widespread pro-mammography climate. These included the growing women’s healthcare activism, politically important figures being diagnosed with breast cancer, the Vietnam War, and the AIDS epidemic.

Screening mammography came onto the scene in 1973 and encountered an audience ready to accept it. Political, social, and health movements had been occurring in the larger American society and underwent convergence later in the 1960s and mid 1970s, right at the time when the results of the early medical research on mammography

was becoming widely circulated. As Reynolds states, "though it is likely that this new screening test would have been successful on its own, this fortuitous alignment of external forces helped ensure that public acceptance would be rapid and durable (Reynolds, 5)." Additionally, results on mammography were being discussed immediately following studies of the Memphis Project that showed the Pap smear could be used on large populations and that early detection of cervical cancer was possible. Reynolds describes this event as she writes, "The pap smear represents the most dramatic validation of early detection in the history of medicine. These efforts were viewed as unmitigated triumphs of the principles long espoused by the ACS [American Cancer Society]. The elixir of success strengthened its resolve and bolstered its confidence. Thus, by the time screening mammography was introduced to the public in the early 1970s, the notion of early detection for effective cancer control had been successfully inculcated in the American psyche…and the growing women's health care activism, and the stage was set for screening mammography to have a successful opening act (Reynolds, 15)." Therefore, while mammography would have most likely been successful on its own, its quick acceptance was greatly aided by the success of the Pap smear immediately before.

In addition to the recent gains in other women's health medical devices, at this time three politically important figures were diagnosed with breast cancer, Betty Ford, Happy Rockefeller, and Nancy Reagan. All of these cases received significant media attention and caused a surge in interest in mammography. As Reynolds writes, "This mammographic 'save' involving the first lady predictably received widespread attention in the press and among the public at large. Its impact was swiftly felt at mammography centers across the country (Reynolds, 42)."

Major political events were occurring that also catalyzed the adoption of mammography. The public was becoming increasingly frustrated with the Vietnam War and Richard Nixon was eager to change the subject of the national conversation. Thus, in his state of the Union on January 22, 1971 he called for, "an extra $100 million appropriation to 'launch an intensive campaign to find a cure for cancer.' At no previous time in American history had cancer received this level of presidential attention (Reynolds, 7)." The effects of this political move are still evident in the cultural importance we place on cancer. There is a large amount of research money invested in cancer, which contributes to the cultural significance of this disease. Thus, the framing of cancer operates in a feedback loop where money is invested in cancer research because of the cultural attention placed on this disease; however, this cultural importance is largely because of the money invested in cancer research.

While the AIDS epidemic had a huge cultural effect, it has not maintained the same notoriety as cancer for such a continuation of decades, which is largely because it has not received as much research money. Where as the NCI receives annually 4.9 billion dollars for research funds (National Cancer Institute website), the federal funding for HIV/AIDS for domestic research was 2.8 billion dollars in 2015 (Kaiser Family Foundation website). Thus, the significance we ascribe to certain diseases is largely dictated by political actions such as research grants and external forces as much as the biological reality of diseases themselves.

That being said, the militant AIDS activism in the late 1980s was instrumental in giving rise to breast cancer activism in the early 1990s and pivotal in the establishment of screening mammography in American culture. As Reynolds writes, "Breast cancer

survivors took note of the success of militant AIDS activism and started forming their own organizations. Whereas the women's health movement of the later 1960s and 1970s was characterized by self-help and support, the modern breast cancer activist movement adopted the direct political action model of AIDS activists (Reynolds, 43)." The epidemic narrative that developed around breast cancer in the late 1980s was derived largely from the AIDS epidemic immediately before. Yet, this epidemic was extremely successful as a focusing event for large numbers of healthy women to feel the urgency of the breast cancer problem and the need for regular screening. Eventually, this anxiety derived from the epidemic narrative would force lawmakers to enact legislation promoting mammography and breast cancer research. Reynolds describe the benefits from mammography on breast cancer cause-related marketing as she writes, "it was the mammography-induced breast cancer 'epidemic' of 1987-1991 that led to the emergence of a new wave of activism, which drew the attention of the nation and its political leaders to this disease. One wonders whether the numerous major accomplishments of this period would have been possible without the focusing effect of this milieu for the concept of cause marketing to a population anxious about breast cancer to take hold (Reynolds, 82)."

Verisante Aura:

These case studies reveal the power of technology to change society, but more significantly how technology often emerges as a product of a prevalent ideology or culture. These examples can be used to evaluate the Verisante Aura and ask questions such as what about our current society is reflected in the Aura, and what potential effects could it have on us? Currently, there is an influx of non-invasive cancer diagnostic tools. One example is recently FDA approved *Colorguard*, a non-invasive colon cancer test that

can be used in the privacy of your own home. There have been numerous occasions of simultaneous discoveries in the history of science, where an idea spreads and leads a number of individuals toward a particular finding, or invention, within the same period.

One recent event that could heavily influence the approval of the Verisante Aura is the new emphasis on screening technologies in the Affordable Care Act. The stipulations in Obamacare are potentially incentivizing medical technology companies to invest more in screening technologies. It is also possible that the current emphasis on early detection of cancer is a response to the failure to discover a cure, despite the billions of dollars invested in cancer research that started with Richard Nixon and the "War on Cancer" in the 1970s. This campaign has increased cancer awareness, improved treatment options, and has made strides in improving life expectancies, but it has been largely disappointing through the years in terms of discovering a *cure* for cancer. Thus, the influx of cancer screening tools is largely a response to the fact that a cure for cancer has not been discovered. As a response to the failure to find one solution, it is possible that scientists have diverted their attention to improve screening tools.

The consumer market is currently expanding with new wireless technologies such as bluetooth, wifi, and technologies that are in some way 'non-invasive.' The new trend in consumer technologies is to be sleek, slim, and unseen with examples such as google-glass, the iPhone getting continually thinner, MacBook Airs, and countless wireless devices. The most noteworthy example is a new product from Apple called the "Apple Watch." In *Time Magazine,* authors Lev Grossman and Matt Vella discuss the Apple Watch in an article titled, "iNeed?" Grossman and Vella describe how the watch has the potential to change human interactions with a never before seen level of connection to

technology. Additionally they state how, "the Apple Watch represents a redrawing of the map that locates technology in one place and our bodies in another (Grossman and Vella, 47)." This consumer culture is critical in light of the Aura, as it has emerged with a technological revolution in our instrumentation and precision. The Verisante Aura is just one example of the many noninvasive detective devices on the market right now such as, non-invasive glucose monitors for diabetes, coronary heart disease, and even brain-to-brain communication technologies. The influx of these non-invasive diagnostic tools comes from a culture of increased sensitivity and precision from our digital devices. It is now an expectation to have tools that allow tasks to be completed with minimal interference.

There is now even an app called 'First Derm' that can 'spot cancer.' This app, developed by Dr. Alexander Borve, lets people submit anonymous images to board-certified dermatologists, where the faster the opinion, the higher the cost ranging from $25 to $100. Author Lorraine Sanders interviewed Dr. Borve in an article titled *Can An App Spot Your Cancer* published on ozy.com where he states, " 'There's not enough dermatologists,' says the 39-year-old. 'Let's filter away the ones that don't have to go to a dermatologist and get them to go to Walgreens, and the ones that really have to see a dermatologist, they can go in and get treated.' Börve and his team encountered 2,000 people that weekend and found four suspected melanomas. Few of those people may have realized they were chatting about moles and sketchy skin growths with one of the world's foremost experts on telemedicine (Sanders, 2015)." In some ways this app is remarkably similar to the Verisante Aura, since the fundamental objective is to decrease the time of diagnosis and improve access. However, this app still requires the knowledge

of a physician to diagnose melanoma, just through the additional lens an iPhone camera, whereas, the Aura uses an entirely unique diagnostic algorithm to diagnose melanoma. Therefore, the two diagnostic processes are not comparable. Yet, this app does reveal our consumer culture demanding more instantaneous results through easy wireless means.

Chapter Four: Actors in the Approval Process

With these theoretical considerations in mind we can now look more specifically at the Aura in the United States Food and Drug Administration (FDA) approval process. There are a multitude of actors surrounding this new technology including, but not limited to, the United States health care system, insurance companies, and the FDA itself. In addition to these more institutional actors, there are individual actors that must be considered such as the scientists, dermatologists, and especially the patients who this technology will be used on. These actors have the potential to impact the approval process as well. However, this type of holistic thorough analysis is outside the parameters of this thesis, but cannot be forgotten as they do add a more nuanced and complex dimension to the approval process than is discussed here.

The United States Healthcare System:

We cannot evaluate the Aura without considering the context of the United States healthcare system under which it will be operating. In the US healthcare system, the uninsured must pay fees for diagnostic technologies, such as the Aura. While the Aura does not in any way prevent melanoma, it does improve early detection, which promotes less intensive treatments for early stage cancers, as opposed to expensive, invasive, and more time-consuming procedures for late-stage, progressive cancers. Thus, the population health improvements from the Aura can only be actualized if individuals have access to this screening technology *and* access to treatment. Therefore, it is critical to consider the benefits of the Aura in context of the environment in which it is placed. Its success in Europe and Canada may be in part because of the universal healthcare systems in place that provide access to the Aura for all segments of the population. However, the

current United States healthcare system excludes a huge percentage of the population from access to the Aura, namely the uninsured, which according to *The Gallup Pole,* was still thirteen percent of Americans at the end of 2014 (note, this does not include non-US citizens living in the United States).

In the United States healthcare system fees discourage people from seeking treatment until their problems become critical and they go to the emergency room where costs are drastically higher than the original costs would be to address the problem. In *Health Care Reform and Politics: What Everyone Needs to Know,* by Lawrence Jacobs and Theda Skocpol, they discuss how the uninsured will often wait until their health problems are severe before going to the emergency room and as a result, end up paying a premium for this sporadic more expensive care delivered to the uninsured. They summarize this phenomena as, "emergency rooms cannot provide routine preventative care or deal with ongoing conditions…emergency care as substitute for affordable normal access is often neither cost-effective; and of course it is not truly 'free.' Hospital bill collectors may hound nonpaying patients for years thereafter, and if bills cannot be collected, costs are shifted onto everyone else (Jacobs and Skocpol, 22)." Not only does this lead to increased healthcare costs, but also it results in worse prognosis. In *Universal Healthcare: What the United States Can Learn From the Canadian Experience,* Armstrong, Armstrong, and Fegan discuss a study comparing survival rates for breast cancer between poor women in Toronto and Detroit, "poor women in Toronto have a survival rate for breast cancer that is 30 percent higher, for ovarian cancer that is 38 percent higher, and for cervical cancer that is 48 percent higher…the research suggests that Canadian Medicare, with no user charges at the point of service, encourages

appropriate and timely use, while user charges and other provisions that limit choice make the US health care system less effective (Armstrong, 132)." The United States spends far more than other industrialized countries on healthcare, yet has worse results. The increased healthcare spending of the United States is discussed by Jacobs and Skocpol, when they state that, "the United States spends about twice as much per person as other industrial countries do on average, and more than 50 percent more than the next-biggest spender, eating up a huge and growing chunk of what our national economy produces (Jacobs and Skocpol, 21)." The private insurance companies that support the United States healthcare system sponsor this inefficient allocation of medical funds because of profit-centered policies. Private insurance companies prioritize profits over the actual health outcomes of the population. This profit-seeking-coverage system practices "over-care" for the wealthy individuals who can afford health care, while not delivering any preventative care to a significant portion of the population. Compared to other countries, the United States has less of a market for the Verisante Aura, since there are fewer people that have the insurance coverage to maintain periodic skin checks. Armstrong and Armstrong make this point when they say, "care is not only more costly but also more poorly distributed. Services are concentrated where the returns are highest, among the wealthy and in high-density urban areas. Meanwhile, 'those hospitals that care for the poor are suffering significant financial losses and closing…Public administration in Canada, by contrast, makes it possible to produce more equitable distribution while reducing unnecessary duplication (Armstrong, 120)." This creates a system that can only treat illness once it has already progressed because individuals without health insurance cannot go to primary care doctors for earlier detection of disease. Thus, our current

system is not an ideal climate for the Aura as it faces barriers to entry including fees that disincentivize early detection of disease, which improves prognosis, decreases the costs of prognosis, and saves lives.

In the film *Escape Fire*, directed by Matthew Heineman and Susan Fromke, they accurately describe the United States healthcare system as a "disease care system." The root of this problem is the presence of private, profit-seeking companies controlling the health of the population. According to Arnold Relman in the article *The Health Reform We Need and Are Not Getting*, the reason for greater health expenditures in the US is that, the system is owned by investors and behaves like a profit driven industry as he states,

> "The commercialization of our health system dates back only a few decades, but its consequences are profound. Investors now own about 20 percent of nonpublic general hospitals, almost all specialty hospitals, and most freestanding facilities for ambulatory patients, such as walk-in clinics, imaging centers, and ambulatory surgical centers. These medical care businesses, like other businesses, need profits to satisfy their investors, and for this purpose they use marketing and advertising, directed at physicians and the general public."

No other health care system is as focused on generating income, shown solely in the amount of aggressive advertising that treats health care like another commodity. As Relman states this advertising, "increases health costs, while hospitals concentrate on the delivery of profitable, rather than effective, services. It also favors those who can pay over those who need medical care but can't afford it." Thus, one of the main issues with diagnostic technologies in the United States is the lack of universal access. A major roadblock for the Verisante Aura's success will be the fact that it assumes that most people can receive access to the Aura, and more significantly if someone does get a positive result from the Aura they have the resources to get treated. However, with the large population of uninsured in this country this is not a guarantee.

Mammography:

Many of the same concerns of access with respect to the Aura, were faced by mammography. In fact, the socio-political events surrounding the acceptance of mammography were instrumental in shaping more preventative measures in U.S. healthcare. Breast cancer screenings increased not because women began to listen to the advice of the American Cancer Society, but because there were political actions taken to require regular mammograms to be paid for by third-party insurance companies. As Reynolds discusses, "This issue was attacked on two fronts: at state capitols and in Washington, D.C. Local ACS chapters and other breast cancer activist groups pressured state legislatures all across the country to enact legislation requiring insurance companies to cover screening mammography or to provide such coverage as an optional benefit. It should be noted that up until this time, it was virtually unheard of for third-party payers to cover preventive service…By 1992, forty-two states and the District of Columbia had enacted laws promoting insurance coverage for screening mammography (Reynolds, 45)." Thus, mammography was influential in changing U.S. healthcare legislation to reflect more preventative measures that included diagnostic technologies. Therefore, the case of the mammogram reveals that the United States healthcare system is changing both practically and ideologically to reflect more emphasis on diagnostic and preventative measures to disease. Thus, while the Aura is facing barriers in the FDA approval process, it has a higher chance of being approved now because of political changes in the past twenty-five years that prioritize preventative care.

While legislation was enacted that required insurance companies to pay for regular mammograms, this still left out the uninsured segment of the population that does

not have access to regular mammograms to this day. Universal access remains to be the biggest obstacle to the success of the mammogram as Reynolds writes,

> "The fight over screening women under fifty has always been about *access*. Lack of insurance coverage for screening mammography is a known barrier that keeps women from being tested. It is clear that, at both the federal and state levels, political leaders have made the decision that American women have a right to screening mammography starting at age forty. Given the fact that the science is now mature and unlikely to change, one is hard-pressed to envision a scenario in which political leaders would ever consider rolling back insurance coverage mandates. Without a threat to access, another major fracas is unlikely to arise (Reynolds, 71)."

By understanding the case of mammography we can attempt to foresee the potential roadblocks in store for the Verisante Aura, namely the issue of access. However, the development of the Affordable Care Act has the possibility of decreasing the number of uninsured, and thus increasing access to both the mammogram and the Verisante Aura. In October 2010, during Breast Cancer Awareness Month, President Obama stated in his proclamation, " 'The Affordable Care Act, which I was proud to sign into law earlier this year, requires all new health insurance policies to cover recommended preventive service, without any additional cost, including annual mammogram screenings for women over 40.' (Reynolds, 70)." Thus, there is hope that the Verisante Aura will follow a similar path as the mammogram and become a basic screening technology that health insurance companies are required to provide.

The Affordable Care Act:

The Affordable Care Act has the potential to create ideological, as well as practical changes to the United States healthcare system by prioritizing preventative care. According to *The Gallup Pole* during the fourth quarter of 2014, the uninsured rate has dropped 4.2 percentage points since the Affordable Care Act's requirement for Americans to have health insurance one year ago. Most health plans under Obamacare,

including marketplace private insurance plans, are required to cover a set of preventative services and diagnostic tests at no extra cost. The list includes fifteen services for all adults including, but not limited to, type II diabetes screening, immunization vaccines, colorectal cancer screening, and even depression screening. Therefore, despite having a history of a reactive healthcare infrastructure, with the Affordable Care Act, the United States has the prospect of building a healthcare system that is more focused on preventative care and screening technologies. The Affordable Care Act could be influential in the approval and use of the Aura in the United States. The Aura is an example of how the adoption of technology is a result of social and political factors as much as the science itself, since its acceptance in the United States may have been far more difficult even five years ago before Obamacare. Yet, it is still important to place the potential success rates of diagnosing melanoma in context of the forty million United States citizens that despite the Affordable Care Act (Gallup, 2015) still do not have health insurance and will still not have access to the Aura.

The Food and Drug Administration:

Another actor in the advancement of the Verisante Aura in the United States is the FDA itself. According to the FDA website, medical devices are classified into Class I, II, or III, where regulatory control increases from Class I to Class III. The regulatory control level is based on assessed risk value. Device classification depends on the intended use and the indications for use. The basic regulatory requirements that manufactures of medical devices must comply with are establishment registration, medical device listing, premarket notification 510(k), investigation device exemption for clinical studies, quality system regulation, labeling requirements, and medical device reporting. In order to be

placed in class 1, the least stringent of the three device classes, "the FDA must first determine if there is sufficient information to support a classification decision. Second, the FDA must decide that the General Controls [General Controls are the basic authorities of the Medical Device Amendments that provide the FDA with the means of regulating devices to ensure their safety and effectiveness] are sufficient to provide reasonable assurance of the device's safety and effectiveness." Additionally, medical device companies must comply with the FDA Safety and Innovation Act, which includes performance goals and user fees paid to the FDA by medical device companies when they register and list with the FDA and when they submit an application to market a medical device in the U.S. According to the FDA website, this act is in order to provide, "a steady and reliable funding to maintain and support a staff of trained reviewers who must determine whether a proposed new product is safe and effective for patients within a certain time period (FDA.gov)."

Private stakeholders are major actors in the political game of FDA approval and have the money and lobbying power in Congress to get what they want. As Jacobs and Skocpol state, "teams of well-connected lobbyists are squaring off against officials in the Obama administration and the state capitals. The lobbyists represent stakeholders determined to win lenient rules, even to the point of quietly recessing decisions they apparently lost when the Affordable Care Act made it through Congress (Jacobs and Skocpol, 156)." The FDA is strongly influenced by special interest groups that lobby the government, and thus is severely influenced by private companies, who do not want to pay for proactive care measures, such as the Aura. Insurance companies will fight back through money, legions of lobbyists, and media campaigns. An example of private

companies influencing FDA decisions is in an article titled *The Revolving Door: FDA and the Monsanto Company,* author Edward Bonnette discusses how, "most high-level FDA employees have a background in either medicine or law, but one of the largest private-sector sources is the Monsanto Company. Over the past decades, at least seven high-ranking employees in the FDA have an employment history with the Monsanto Company. Connections have led many to speculate whether any conflicts of interest exist within this revolving door between the big food companies and the department charged with regulating them (Bonnette, 2013)." It is not just insurance companies with stakes in the FDA approval process, but private food companies, pharmaceutical companies, and many other industry lobbyists that influence the approval process more than our narrow image of objective science and facts allows.

According to a recent investigation by NYU journalism professor Charles Seife published in The Journal of the American Medical Association, the FDA never told the public, doctors, or scientists about fraud that the agency uncovered. The FDA inspects several hundred clinical sites, however, "the FDA has no systematic method of communicating these findings to the scientific community, leaving open the possibility that research misconduct detected by a government agency goes unremarked in the peer-reviewed literature (Seife, 2015)." The findings presented in this study reveal the FDA needs to be more transparent concerning their proceedings and findings. The same can be said with respect to the Verisante Aura and its approval process in the FDA. Information regarding where the Verisante Aura is in the approval process, what factors are being considered, and who is making this decision is largely unavailable. The overriding problem both with the Verisante Aura and the more recent study on the FDA hiding fraud

is that the FDA should be more accessible to the public. The reasons for the Aura not being approved by the FDA are still unknown, yet it is clear that they are not primarily technical in nature. The Aura is a perfect example of how technologies are embedded with social and political dynamics, and any discussion about a technology must consider their contextual nature.

Chapter Five: Cost-Benefit Analysis of the Verisante Aura

In this final chapter I will discuss what I consider to be the main costs and benefits of the Verisante Aura. In light of the issue of over diagnosis with mammography, I consider a primary benefit of the Aura its ability to decrease the number of false positives by dermatologists, eliminate unnecessary biopsies, and decrease needless skin cancer treatments. However, a major issue I foresee with the Aura is the matter of unequal access to this technology for all people living in the United States. Finally, a major concern of mine is the loss of the human element in the patient-doctor relationship.

Over Diagnosis:

Currently, there is a great deal of controversy in the United States healthcare system for over prescribing drugs, surgeries, and even diagnostic tests. In an article published on *National Public Radio* titled 'Doctors Urge Their Colleagues To Quit Doing Worthless Tests,' author Richard Knox discusses the issues associated with too much medical technology as he writes,

> "The effort represents a growing sense that there's a lot of waste in U.S. health care, and that many tests and treatments are not only unnecessary but harmful. Harvard economist David Cutler estimates that a third of what this country spends on health care could safely be dispensed with. 'That's certainly the number we use,' Dr. Steven Weinberger, CEO of the American College of Physicians, tells *Shots*. 'Most of us feel something like $750 billion or so could be eliminated from the system out of the $2.5 trillion or so that we spend on health care.' Weinberger says unneeded diagnostic tests probably account for $250 billion (Knox, 2012)."

Therefore, increased use of medical technology has some benefits, but it is incorrect to assume that they are always positive. Before the Verisante Aura is introduced into the medical community, there must be restrictions on its operations in order to ensure there are not unnecessary uses or procedures based on diagnosis that could cause more harm than good. That being said, if used correctly the Verisante Aura has the ability to

decrease unnecessary procedures and expenditures since currently accuracy of clinical diagnosis of melanoma by a dermatologist varies between 49% and 81% (Lui, 2012), while Raman Spectroscopy has sensitivities and specificities above 95% (Haka, 2015).

Mammography can be used as an important case study of the issues with diagnosis of false positives. Over diagnosis refers to the identification of indolent or low potential cancer that, absent screening, would not have become evident during the individuals lifetime. H. Gilbert Welch and William C. Black describe over diagnosis of cancer as when either the cancer does not progress, or possibly even regresses, or progresses so slowly that the individual dies of some other cause before developing symptoms (Reynolds, 85). A basic assumption concerning diagnostic technologies is that identifying and treating more early stage cancers decreases the number of late stage cancers and an overall population health improvement. In other words, for every early stage cancer diagnosed there should a corresponding decrease in late stage cancers. However, this is not always the case. Reynolds describes this phenomenon in the case of mammography as she writes,

> "Population –based screening had resulted in a huge increase in the incidence of early stage disease with only a very slight decrease in late stage disease…suggesting that screening may detect many non-aggressive cancers that would have progressed if undetected and would have had no impact on the individuals life. The practical result of this has been a dramatic increase in the number of individuals treated for cancer without necessarily improving the health of the population, phenomena known as *overdiagnosis* and *overtreatment* (Reynolds, 63)."

In the case of breast cancer the most common over diagnosed breast cancer is ductal carcinoma in situ (DCIS). With DCIS, one third to one half of abnormalities would never progress to lethal invasive breast cancer if left alone (Reynolds, 80). However, because of our inability to distinguish good actors from bad actors, all patients with DCIS receive

treatment for breast cancer. In the late 1980s and 1990s, it was DCIS that was partly responsible for the epidemic narrative just as screening mammography was being widely practiced. The explosion in the number of DCIS cases increased the number of women diagnosed with breast cancer and escalated the disease to an epidemic where mammography was incorrectly presented as the cure. However, DCIS is poorly understood and up to half of the cases detected would not progress to more dangerous, lethal cancers. Thus, many DCIS cases represent a perfect example of over diagnosis. However, as Reynolds writes, "The difficulty is that there is currently no method to predict accurately which DCIS cases will progress and which ones will not. For that reason, essentially all women diagnosed with DCIS, approximately 53,000 in 2009, undergo treatment, typically lumpectomy and radiation therapy, but also mastectomy in many cases (Reynolds, 31)." Thus, because there is no way to distinguish the harmless DCIS cases from the dangerous ones a significant amount of unnecessary is spent trying to do so, "For every $100 spent on screening, an additional $30 to $33 is spent to evaluate false positive findings. In the Medicare population, it is estimated that the workup of false positive mammogram results is $250 million annual expense. (Reynolds, 76)."

Not only are there economic ramifications associated with over diagnosis, but also there are physical and emotional harms as well. In the case of breast cancer, there is the possibility of radiation-induced breast cancer in addition to the emotional stress as, "perfectly rational, healthy women began to view their breasts as ticking time bombs. This relentless messaging has resulted in a pervasive tendency for healthy women to overestimate both their own personal risk of breast cancer and the potential benefits of

mammography (Reynolds, 49).” Thus, mammography changed the message of early detection from one of ‘if you notice something get it checked out’ to ‘always be wary.’ This is similar to the Verisante Aura, as currently most patients seek the expertise of a dermatologist if they notice unusual changes with a mole, however, the Verisante Aura has the potential to turn skin checks into a more routine aspect of medical care. This is largely positive, however, like mammography patients who go in for screenings must be accurately informed on their risks of dying of skin cancer in order to not cause unnecessary emotional stress with routine checks. Reynolds describes this need for accurate information as she writes, “Women referred for mammography need to know not only that mammography may reduce their risk of dying of breast cancer but also that some mammography-detected cancers would never have caused symptoms in their lifetime. Women diagnosed with DCIS need to be better informed about what is known and what is not known about the natural course of this disease (Reynolds, 93).” With breast, and skin cancer, we need more accurate and explicit information about the actual risks to avoid over diagnosis, but also to promote early detection for applicable cases as well.

The case of mammography reveals the potential dangers of over diagnosis of false positives. However, in the case of the Verisante Aura far from adding to the number of false positives, the Aura has the potential to decrease the number of unnecessary biopsies and surgeries for skin cancer, since it greatly improves accuracy over the dermatologist-pathologist team. Thus, the issue of over diagnosis of false positives with mammography reveals the significant benefit of the Verisante Aura over the dermatologist-pathologist combination as a way to diminish the costs and dangers associated with over diagnosis of

melanoma. Therefore, the case study of mammography reveals the importance of eliminating false positives, which is possible with the Aura.

Access:

The Verisante Aura has the primary benefit of increasing accuracy of melanoma diagnosis and saving time, money, and lives. The advantages of early detection are significant and the Aura is small and easy-to-use so that it can be at health fairs and other community venues across the country. It can increase access to skin checks by bringing screening technology to areas typically underserved without dermatologists. Easy access to screening technologies has delivered huge benefits starting in the 1950s as campaigns were developed for multi-phasic population screening that,

> "bundled tests together in a technological recreation of the periodic examination but without the need for a doctor visit. Adopting the strategy of the mobile X-ray unit, these tests were brought to the people. Screening booths were set up at neighborhood and county fairs, in local schools and in health departments, places where people went for enjoyment or were heavy and convenient to reach. These bundled screening tests also consumed less time and expense than did periodic examinations (Reiser, 146)."

However, one issue with increased screening is that it is no objective in itself, since just finding cases of melanoma and not treating them has no value. There has been an exponential growth in new screening tests and efforts to apply them based on the assumption that early detection of disease is beneficial. The current paradigm based on early detection, which is what the Aura is a product of, is largely positive, and yet often neglects to address a solution if a disease is actually detected. Early detection in the United States is problematic, since many screening fairs still do not address the larger problem that there needs to be access to *treatment*, in addition to screening. Therefore, it is largely an assumption that increased access to screening helps undeserved populations

get treated for skin cancer, because the Aura can only diagnosis melanoma and does nothing to treat the condition itself.

Human Element:

Another consideration with the Aura is that it is a fundamental change in diagnostic procedure from human to technology and this context comes with unforeseen negative consequences as well. Screening is a limited technological intervention that requires follow-up, if there is a positive result, consisting of further testing and examination by doctors. Screening for a disease must be distinguished by the level of certitude attached to the diagnosis. While the same technology can be used for screening and diagnosis, there must be a human present for the aspect of diagnosis. There are negative consequences associated with not having a human attached to a technological screening, since if there is a positive result the machine does not understand the emotional, psychological, or health differences between the two results, while a human does and would know how to comfort, direct, and support the patient.

The example of the app 'First Derm' has an unintended consequence of diminishing the significance of cancer. Imagine if an individual sent a picture of mole to this app and received a message back that they did have melanoma and they happened to receive the message alone, or in an environment with no support to receive such life-changing news. Even if the diagnosis is negative, when someone seeks a diagnostic test for melanoma, they are seeking that test because of the *possibility* that it might be cancer. That possibility is a concern that must be addressed with the insight and empathy of a physician that can comfort the patient regardless if the test reveals positive or negative results. Thus, when discussing cancer diagnostic technologies it is important to consider

the cultural significance we prescribe to cancer, and the anxiety that brings when going for a screening.

For this same reason, the Verisante Aura is not a technology that can be used in a Walgreens, like blood pressure or diabetes tests, or operated by a technician. We must consider that we are discussing the possibility of *cancer* and the biological, and more significantly cultural meaning we prescribe to it. We uniquely label cancer with a special notoriety among diseases, and this must be considered when discussing the context, or environment, of cancer diagnostic technologies. Thus, a physician who thoroughly understands the biological, as well as emotional and psychological realities that accompany a cancer diagnosis must operate the Verisante Aura.

In addition, while diagnostic technologies may be more precise, they have the inescapable tendency to focus on the particular and ignore the bigger picture. As Reiser states, "diagnostic technologies focus users on particular aspects of reality. The more compelling and authentic this reality seems, the greater the users' belief that is says enough. In this way a partial perspective of a complex reality becomes an acceptable substitute for the whole. Thus, if the sound tells all, why bother with what the person think or feels (Reiser, 13)." There is a danger with technologies that only focus on one aspect of a person's health, since not only do they not account for the interplay of biological and molecular factors, but also environmental and psychological factors. We do not live in bubbles and neither do our illnesses. Diseases are a product of how we interact with the environment. Technology can offer some insights on the effects of the environment, but it is through an understanding of the complex relationship of the

molecules and pathogens in our body, in addition to the factors in our environment that we can fully understand disease.

The Aura is representative of a binary that heavily relies on technology and an approach to diagnosis and health in terms of sick or not sick, cancer or not cancer, positive or negative. But this framework often misses many critical elements of human health that are left between the binary. Logistic regression, which is used to establish the diagnostic algorithm for the Verisante Aura, sets up a binary framework based on 'cancer' or 'no cancer', yet there is a lot of information present between the binary that is ignored based on this diagnostic algorithm. The simplification of probabilities into strict 'yes' or 'no' categories reflects more certainty than actually exists. But this framework often misses a lot of critical elements of human health that are left between the binary. Additionally, this framework cannot account for the larger picture of human health such as, environmental, psychological, genetic, or social factors that play critical roles in disease. Therefore, we cannot replace the dermatologist-pathologist combination with the Verisante Aura entirely since doctors must explain the causative reasons a patient may have developed melanoma. It is not enough to identify a melanoma and remove it with surgery, but doctors must relay, with human emotion, the lifestyle elements that caused a disease and instill a sense of life and death if those are not changed. This treatment of care, compassion, and urgency cannot be relayed through technology, but only through humanity.

In addition, the Aura is incapable of recognizing individual patterns for certain patients. Say for instance a patient comes in with a mole that seems like it's growing a little, but nothing alarming, and the next time the patient comes in it has grown

significantly, but still not cancerous, the dermatologist will most likely remove it, since based on this pattern it has the potential to become cancerous. Yet, if the Aura were used to diagnosis the mole both times the diagnosis would be negative. Thus, the Aura has no way to account for cases that are in-between non-cancerous and cancerous. Diagnostic technologies cannot account for changes from month to month, or year to year, that are incredibly important in medical diagnosis as Reiser states, "Prognostic medicine practiced at its best demands rapt attention to changes in character and course of a patient's symptoms, thus making a doctor's ability to observe them and glean their present and future meaning the mark of medical excellence (Reiser, 133)." In other words, diagnostic technologies cannot account for long-term changes in the patient, or cases with a personal, or family history that would turn ambiguous cases to more serious concerns.

There is a critical human element that is lost when you replace a human task with a machine. Not only with pattern recognition, but humans have a problem-solving creative ingenuity that is irreplaceable. An example of this is provided in Bawden's article as he cites studies where by analyzing sets of literature on Medline databases for commonly occurring themes new information and new hypotheses were inferred. He describes this discovery as he states, "new knowledge, insights and hypotheses were discovered by putting together parts of knowledge-base which had hitherto been separated (Bawden, 2001)." New discoveries, hypotheses, and knowledge can be gathered simply through pattern recognition and human creativity of connecting seemingly unrelated evidence and facts. This human skill is vitally important in medicine as diseases are often times diagnosed based on patterns in patient history. By replacing

diagnosis with a machine, it is possible that much of the insight and pattern recognition will be lost. The Aura has an un-debatable advantage to act with such focused intensity at one task, which is proven by the superior sensitivities and specificities. Yet, this benefit is often purchased at the price of diminishing other aspects of the patient that are important to healthcare. Technologies often detract from the personal, cultural, and social expressions of illness by their design to explore only the immediate physical aspects of illness. While this fractionation of wholes has powerful benefits, it has extreme disadvantages since fundamentally the subject of care is the person who cannot be fully understood if divided into parts by different medical technologies.

If used as a substitute, technology has a tendency to diminish the strong relationship between patient and doctor that is vital in order to understand the external factors causing illness. Yet, if used as an additional resource to provide more detailed information on the biological functioning, technology can enhance the patient-doctor relationship. Technology must be used an additional tool, not as a substitute for a human doctor. A common assumption about technology is that it fundamentally decreases some unquantifiable human aspect between people. A lot of technology is used in a way that reflects that assumption. Yet, there is a way to use technology in a way that enhances and deepens human interactions.

Bawden uses Karl Popper's idea of three interacting worlds to discuss the well-rounded approach of obtaining a patient's health information from a variety of sources. Karl Popper is a philosopher of science and is most well known for his theory of the growth of scientific knowledge based on the falsification of hypothesis and theories. Popper's three worlds are defined where world one is the world of physical objects, such

as the biological concepts written in books and computers. World two is the mental world of thinking humans, such as the subjective thoughts, emotions, and individual thoughts. Lastly, world three is the objective, communicable knowledge, consisting of the content rather than physical objects such as books and databases. Bawden extends these worlds to health information as he states,

> "World 1, so far as health information is conceded, is a burgeoning reality, although it need not be so named. World 2 is seen to exist in the subjective, tacit knowledge, widely recognized as important for all health-care practice. This leaves World 3, the most contentious aspect of Popper's ontology. We have seen that the ideas of evidence-based practice point to an objective body of knowledge, which may be regarded distinctly from any physical manifestation. The imperfection and incompleteness of medical knowledge support Popper's view of knowledge as being unjustifiable but criticizable, and hence improvable. The highly structured nature of explicit medical knowledge, and its many inter-convertible semantic representations, make the same point. Abstract objects, concepts, plainly exist in the health-care domain, reinforcing the validity of the idea of World 3…The interactions between the Worlds, although they remain a difficulty, are seen to occur in the handling and accessing of health-care knowledge (Bawden, 2001)."

Often people think of health information as mostly just world one, yet Bawden draws attention to the fact that science and medicine consist of the interactions between all three worlds. One world alone is not wrong, but it is wrong not to acknowledge the interplay and dependency it has on the other two worlds. Tacit and procedural knowledge are generally accepted as important aspects of healthcare, encompassing the observational, experiential, verbal, and motor skills of the physician, even though they might be difficult to explain and not mentioned in textbooks. These skills play a critical role in medicine as Bawden states, "most clinical information is in doctors' heads, 'a constantly expanding and reinterpreted database' (Bawden, 2001)." This experienced-based knowledge is necessary to deal with complexities in real world medical practice that is distinct from the clear-cut scientific concepts in medical education. Yet, there is a danger of being

dependent solely on experience-based learning as Bawden warns, "reliance on experience-based knowledge alone may lead to 'poor practice, based on fashion and anecdote; hence the need, in Popperian terms, for World 2 to be challenged by interaction with World 3 (Bawden, 2001)."

Bawden also describes this difference as 'high-level' versus 'low-level' medical knowledge. High-level knowledge consists of details or facts, such as the structure of the human body and causes of disease that is learned in formal medical education. Low-level medical knowledge describes the complex issues of decision making for diagnosis and treatment and is a result of clinical experience. Bawden also describes how in healthcare there is a blurring between these two types of knowledge as he writes,

> "Patel et al speak of the tension between the 'art and science of medicine,' in which the 'art' involves 'the use of intuition, experience, and holistic perceptions in making clinical judgment and in the delivery of humane care'. The scientific dimension involves the application of explicit knowledge and the more intuitive artistic side draws on tacit knowledge; the 'inarticulate aspects that cannot be taught explicitly and are therefore only acquired by direct experience'. Similarly, Wyatt refers to tacit knowledge or intuition, defying recording, underlying personal skills, and transferred by face-to-face contact of apprenticeship. (While it is generally agreed that tacit knowledge is largely acquired by experience or personal interaction, there are other ways; Cimino, for example, refers to the role of anecdote in continuing education as a complement experience.) It is inarticulate in the sense that a physician may, for example, be able to correctly diagnose a case, but may not be able to provide an explanation to support the diagnosis. However, there is considerable blurring between the two forms of medical knowledge, since the seemingly intuitive judgments on a practitioner may be based on 'internalized' scientific knowledge, while considerable tacit knowledge...underlies scientific reasoning in medicine. Florance also demonstrates from an analysis of information search requests that clinical problem solving requires a blend of declarative (explicit) and procedural (tacit) information, and that the latter is difficult to obtain from formal sources (Bawden, 2001)."

Therefore, the best type of healthcare encompasses a combination between specific and accurate information and experience-based, intuitive knowledge. The same blurring would be an ideal climate for the Verisante Aura. The accurate and specific diagnostic

ability of world one would be enhanced by the Aura, however, it is also important to maintain the human element of world two that enhances the clinical intuition and individualized treatment option. The practice of medicine means integrating individual, clinical expertise with the most accurate, external clinical evidence from research.

The potential issue of this interaction between worlds one and two is that the explicit knowledge may be accepted with difficulty by practitioners because of the difference in structuring this material, compared with the structure of personal knowledge and the way tacit knowledge is acquired. For this reason, world three plays a critical role in the interaction between world one and world two as Bawden describes, "some tacit knowledge may be analyzed, recorded and thereby made explicit, and that 'much of the medical progress in modern times has been attributable to an evolution from tacit to explicit knowledge'. This seems an excellent illustration of Popper's evolutionary epistemology, and the consequent growth of World 3 (Bawden, 2001)." Thus, world three connects world one and world two by focusing on the conversion between different types of knowledge and pointing to the same knowledge base that is reflective of an underlying complex body of objective knowledge, consisting of the abstract concepts that are largely unknown until the translation between worlds one and two occurs. In other words, world three deals with undiscovered information that is revealed when tacit knowledge is translated to world one. Bawden describes world three in detail as he states,

> "Since one source of doubt about World 3 has always been the status of abstract concepts, it is worth nothing that these play a part in health-care, on a par with the physically real entities with which health-care deals…They may also be equated to a large extent, with the 'high level' medical knowledge noted earlier. The clearest statement of their existence is given by Moehr: 'in healthcare we are, of course, dealing with purely mental concepts, which have no material analog whatsoever. Typical examples are our disease notations. Most of these are purely mental artifacts'. Moehr suggest that it is the wealth of abstract World 3 objects,

> with their inherent ‘fuzziness,’ which necessitates the variety of nomenclatures and classifications noted above (Bawden, 2001).”

Thus, world three describes the fundamental ideas behind our definitions of disease and the actual meaning of medical concepts behind the language and definitions we prescribe to them. In this way, world three connects world one and world two by noting their common underlying knowledge that is simply accessed in different languages, yet both provide valuable aspects to medical care. What is difficult to understand about world three is that it has no material reality until there is a connection between the two worlds that attempts to connect them and then reveals information that was unavailable to us before. When worlds one and two are used simultaneously they have ability to offer more information and insight than either alone.

The interplay between all three worlds is an interesting and valuable exercise to apply when looking at the Verisante Aura, since the Aura itself compromises the factual, accurate, and evidence based information of world one. And the doctor giving treatment, advice, and relaying the information is critical in the analysis of the individual case with respect to experience and human ingenuity. Yet, world three is also vital to explore in this situation, as it offers a new dimension of unforeseen information that may be discovered through the evolution from tacit to explicit knowledge. Therefore, far from detracting aspects from medical care, the Verisante Aura has the capability to enhance the available knowledge, if used in the correct way. Through the connection of the Aura with a human possessing the knowledge of world two, we can connect these two information worlds and enter world three and enhance our understanding of medicine and enter a new, superior, untouched body of knowledge in world three that is only possible through the partnership of human and machine, or tacit and explicit knowledge.

Throughout the history of science, there has always been a backlash to new discoveries that question the dominant paradigm. A prevailing view is that there is too much specialization and technology that destroys the human element in medicine. However, in an address given by the retiring president of *The Los Angeles Surgical Society*, Burns Chaffee, he discusses these exact same issues, but he gave this address in 1931. Chaffee warns of the dangers of becoming 'medical Robots' that are 'coldly, scientific, highly skilled, but without hearts.' He also warns of the widening gap between doctor and patient as he states, "In spite of the vast strides that have been made in medicine and surgery, it seems to me that there is a gradually widening breach between physicians and their patients, which makes some of us yearn for the reciprocal feeling which existed in other days. When the general practitioner held sway, there was a feeling of perfect understanding between physician and patient. The physician was not only a healer of bodily ills, but was father confessor, advisor, a close friend and ally in times of stress (Chaffee, 1931)." It is essential to note that Chaffee was writing in 1931, a time that we would now consider as exemplifying a close patient-doctor relationship in comparison to now. Yet, Chaffee was also longing for a past time when he believed there was a closer relationship between patient and doctor. Therefore, it is possible that it is a continual worry throughout the history of medicine that technology and specialization will create a widening gap between patient and physician, when in reality it is a natural progression.

While Chaffee was writing almost a century ago, his advice is still incredibly applicable today as he discusses the irreplaceable power that sympathy, hope, and courage can play in medicine. These aspects of medical care are unquantifiable, but have

been necessary since the dawn of medicine to which no amount of specialized training or innovative technology can replace. Chaffee describes these aspects as he states, "hope and courage, which played a large part in his healing ability. It is this glorious combination of superlative skill and gentle tenderness, which should be the aim of every surgeon. Flawless technique cannot take the place of sympathy (Chaffee, 1931)." Thus, Chaffee attempts to describe the unquantifiable healing power physicians have that cannot be replaced. Throughout the history of medicine, there has been a fear of losing this human element and with every new technology the same worry will emerge again. This is not to say that we should not be wary, but merely proceed with caution. Chaffee is correct in that there is an irreplaceable human aspect in medicine as he states,

> "While it is necessary for the physician and surgeon today to exert himself for the best in science, it also is vital that he shall not lose the human touch which gave the old country doctor his priceless worth. We surgeons should not allow our patients to become merely cases. Ministering to the physician needs of humanity demands more than wielding of the scalpel and the prescribing of drugs. There should be a bond between the physician and the sufferer that cannot be diagrammed. His heart must reach out with pity and understanding to the afflicted. Unless this is so, the faith, hope and trust which are necessary to the successful practice of medicine and surgery will be lacking (Chaffee, 1931)."

Yet, he is also quick to add that this does not mean that we should not embrace new science and technology, as there is a critically important balance that compromises the best medical care between innovative technology and human compassion. Chaffee raises some excellent points that seem just as applicable now as in 1931. But this in itself might reveal that while technology and science are always changing, one thing that has stayed the same is our reaction to it. Chaffee was discussing how we should proceed with caution into new medical technology in case we lose the human element, yet his version of medicine without the human element is our version now. Thus, we live in a continual cycle of hesitation with accepting scientific change. While we must consider the negative

consequences of new technologies, such as the Verisante Aura, their existence is a natural progression and one that we must embrace.

Conclusion:

In conclusion, the Verisante Aura has proven to be highly accurate in numerous experiments with sensitivities and specificities regularly over 90%. However, prior to this technology being introduced to the United States there are some key assumptions that influence how we think about this technology. Namely, the assumed objectivity of science and technology, our definition of health, and cultural significance we prescribe to cancer. These assumptions are critically important to consider as they influence how we think about this technology. In addition, the stethoscope and mammogram reveal important points on how technology is a reflection of society, but also influences society in return. These case studies reveal how important the political and social context is in the acceptance of any technology, and the Aura is no exception. The Aura plays a unique role in the United States healthcare system, and cannot be treated the same way as it is in Canada, Australia, and Europe because of contextual differences. Thus, the approval process is far more complicated and political as a result of differences in the United States healthcare system, even with changes from the Affordable Care Act.

Overall, I consider the Verisante Aura to be a highly beneficial medical technology. It offers increased accuracy, decreased costs, improves prognosis, and most importantly it saves lives. However, there are two main issues that must be addressed concerning the adoption of this technology in the United States. The first is the contextual differences between much of Europe and Canada and the United States, namely the lack of universal healthcare system. Thus, the Verisante Aura must be implemented in the United States slightly differently than it has ever before by considering the fact that universal access to this technology is largely impossible, although the possibility is

improving with the Affordable Care Act. Secondly, a physician, and not just any personal, must operate the Verisante Aura. This is to ensure that diagnosis is not treated in a routine, checklist manner and that, if there is a positive result, the doctor will be able to interact with the patient in a way that can instill urgency, compassion, and empathy. The most powerful healing force is through the partnership of science and technology with human expertise, and neither one can stand alone without the other. If used correctly, the Verisante Aura can add, not detract, information from the patient-doctor relationship and the process of melanoma diagnosis. If the human-machine interface can be constructed in a way that preserves the human element of the patient-doctor relationship I believe the Verisante Aura to be a huge success for melanoma diagnosis in the United States.

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