Undertaking a graduate level degree program on a part time basis while working full time supporting a family and raising a teenage son is not necessarily a unique challenge as I have met others following this same path having far heavier burdens of time and budget management than I have faced. This graduate degree work has spanned four years since I joined the inaugural class in the Bioethics Department of Wake Forest University. Most of my fellow students that blazed this path have already graduated and moved on to begin or continue their professional careers. This program has exposed my mind to a wide range of issues and problems that affect those working in healthcare services, medical research and bio-manufacturing as well as the public each serves. I am grateful to the esteemed faculty of the bioethics department in their facilitation of my learning process in an arena of emotionally and politically charged ideas that affect each and every one of us. My highest complement to them is that I have yet to clearly identify exactly what each of their own personal views are on many issues…each taught their courses with the goal not of creating “like thinking students” but rather “independent thinking minds” able to examine and participate in wide ranging dialogues examining all aspects involving the ethics of life.
DEDICATION

First to the Scottish philosopher David Hume (1711-76) who in my interpretation articulated a distinction between rationally derived descriptive statements (what is) from normative prescriptive statements (what ought to be) and his belief that moral properties can be linked to the inherent nature of humankind.

Secondly to the philosopher and neuroscientist Patricia S. Churchill who articulates how the basis of our humanity appears to have linkage to biological mechanisms (in part via oxytocin receptors in the brain) and many of our most relished properties of humanity (nurturing etc.) are shared via common biology within the animal kingdom. Perhaps modern science is serving to retract the guillotine’s blade that dismissed Hume’s ideas prematurely.

Thirdly to John Gault who articulated his author’s philosophy on the creative value and socially beneficial merits contributed by those allowed freedom to satisfy the inherent drive from within (the unique self that “is” in their nature) apart from those driven to provide an illusion of comfort through homogeneity (commonness fed by what “ought” to be).
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<tr>
<td>CID</td>
<td>Chronic Inflammatory Disease</td>
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<td>NHIS</td>
<td>National Health Interview Survey</td>
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<td>AA</td>
<td>Arachidonic Acid</td>
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<td>IM</td>
<td>Inflammatory Messenger</td>
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<tr>
<td>NSAIDS</td>
<td>Non-steroidal Anti-inflammatory drugs</td>
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<tr>
<td>GLA</td>
<td>Gammalinolenic acid</td>
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ABSTRACT

James Hugh Crawford

LOST IN TRANSLATION: USING AN ETHICS BASED MODEL TO BRIDGE SCIENCE TO PUBLIC HEALTH POLICY

Dissertation under the direction of

Mark Hall, J.D.

The premise of this thesis is that success in reversing the growing epidemic of diseases related to chronic inflammation in the body will not be realized unless those designing and implementing interventions to benefit public health ensure ethics based guidelines become integrated as an analytical foundation to both support and justify action fighting chronic inflammatory disease. One such ethics based model proposed by Nancy E. Kass, ScD is examined throughout this thesis to illustrate how applying ethics based analytical tools can successfully translate cures to chronic inflammatory disease and stop its upward trend in the US. Scientific research has provided significant insight into how to reverse the trend of this disease but scientific research can become lost in translation to public understanding, resulting in public health policy that fails to achieve its stated goals. The modern diseases of inflammation are unlike diseases of the
past where an outside infectious agent was identified and cured by medicine.

This disease process is fueled by overindulgence of food, excessive eating and poor diet selection (made plentiful by modern technology) and lifestyles of low physical activity. This disease environment, pervasive in affluent countries, is exacerbated through mistranslation of science, allowing poor choices to be made on the individual level and enabling poor choices at the most complex system level. This mistranslation along with failure to utilize knowledge of process improvement often generates public health policy that is paternalistic and restrictive in selective areas, while permitting other processes to feed the problem. A leading example of the latter category is the dietary supplement industry, which uses techniques of marketing and advertising enabled by regulatory agencies that can cloud individual choices for products by implying cure and relief from disease without being held accountable to prove safety or efficacy. This thesis explains that, by distinguishing between common versus special causes (a concept initially developed for improving manufacturing processes) in addition to applying an ethics based methodology can generate public health policy that increases the individual’s ability to protect his or her own health while systematically improving the processes that currently feed the upward trend of chronic inflammatory disease in the US.
CHAPTER I

INTRODUCTION

The latter half of this century has witnessed an exponential rate of growth of knowledge and accumulation of scientific data, which is conservatively estimated to be doubling every five years\(^1\). The ever burgeoning bank of information about medicine and health is, for the most part, being filled by investigators applying the scientific method\(^2\). Researchers begin with a hypothesis and carefully design experiments using advanced instrumentation to observe and collect data that hopefully supports a stated hypothesis. Observations are repeated to gain confidence in the data from which to draw conclusions in hopes of gaining new knowledge. I know from my own experience working in a regenerative medicine research laboratory that many experiments can fall short of expectations to the point where the road to success is often paved with many failures in the process of proving a researcher’s hypothesis. It is slow and tedious work over time to collect enough data to provide insight and explain the nature of the phenomena being studied. After experiments are completed and results analyzed the hypothesis must then withstand a gauntlet of peer review and close examination of the conclusions drawn from the data obtained. All aspects of the process are challenged from experimental design,
methods of collecting data and the conclusions derived from the experiment.

Other independent researchers must then be able to duplicate the experiment and obtain the same results to further assure the results are not a fluke, or that bias has not entered into the design of the experiment or interpretation of results in to confirm the validity and reliability of the research claims. Almost all investigators in this scientific research process use strict care not to draw premature conclusions from early scientific findings until their experiment is fully concluded. This can be a challenge as funding and sponsorship critical to complete the work coaxes early disclosure of “research findings” before data is thoroughly analyzed and peer review has formally confirmed the accuracy of research findings.

Examples are examined in this thesis demonstrating how the non-scientific community can mistranslate research findings that may be prematurely released or flawed in presentation. These errors can have serious consequences in areas affecting public health policy. Such mistranslation of science can occur in varying degrees that include elevating premature findings as fact or creating misleading implications that cause others to arrive at mistaken conclusions either unsupported by the data or outside the limits and intent of the experimental design. The general public is not aware of the rigorous standards imposed by the scientific method and when early reporting occurs of research findings it
circumvents the important process of duplication of experimental results and peer review so critical in the scientific field. The nearly instantaneous widespread release of uncorroborated research findings through the Internet for public consumption allows for mistranslation further undermining the goals of the scientific method. On the other hand, an example is presented whereby seemingly solid scientific data and conclusions are examined by a member of the non-scientific community containing legitimate questions about the conclusions drawn by the scientists themselves. It is not uncommon that once all the puzzle pieces of scientific data are fully assembled investigators can be guided to entirely different conclusions than first hypothesized in the early experimental stages.

This thesis also examines how improper or incomplete interpretation of scientific findings using statistics can mislead the public perception in both the gravity and priority of a reported public health problem to support efforts to lobby public resources. I call these examples a loss in translation from science into public health policy. This thesis discusses examples demonstrating the ease with which one can draw seemingly logical, rational conclusions and provide subsequent arguments for action or change that are seemingly supported by solid scientific findings. Upon closer examination that supporting evidence may be fragile, misleading or completely false. What is often overlooked in stating a
case is a generalized reference to scientific research as justification for specific argument for policy or action. Discussion in this thesis will demonstrate the importance of understanding and examining the supporting science at least at a basic level before a subsequent argument or point is qualified for consideration.

If science is used as the basis of an argument then it must pass reasonable scrutiny or the conclusion is simply an unsubstantiated opinion not based in scientific fact. It is reasonable to ask where the data come from, what was the experimental design, has the experiment been repeated and data fully vetted, and if the findings (data) has been interpolated by statistics. This thesis will discuss the importance of using statistical tools but also point out examples of the ease in which statistics can allow conclusions to be drawn outside the original experimental design. Another example is to improperly correlate data or select portions of the data to falsely equate causation. These are just a few of the pitfalls in improperly translating scientific findings.

These errors in translating scientific discovery are more than just flaws in arguments as they can pose potential harm to society in terms of costs, wasted time, potentially making unhealthy decision and violation of ethical principles. Such errors in translation may be passed on to the public and result in action or policy regarding public health that simply cannot be justified by “scientific findings” as claimed or implied. The general population may understandably lack
even a basic understanding of modern science and technology but this thesis
contends there exists a basic ability to challenge and review scientific sources
along with the conclusions that is within the grasp of the general public and those
affecting the debate. This thesis will examine some basic questions a layperson
should ask in order to examine and challenge proposals and actions associated
with public health policy that are being justified by scientific findings. Public
health professionals such as bioethicists should be held accountable and willing
to do the work required to understand the science at a basic level and apply even
greater scrutiny to the data, its interpolation and advocated application to public
health policy.

A case in point is chronic inflammatory disease. A rush to fix a problem as
serious as chronic inflammatory disease is understandable when the health of a
population is declining as a result of this disease of modern humankind. But
eagerness to solve such a serious and growing problem with only best of
intentions for the public’s welfare should never be an allowable excuse for failure
to use rational thinking to examine solutions based in science. Too often,
eagerness and good intentions are substituted for action that results is based
upon mistranslating scientific knowledge into public health policy that has little or
even damaging effects to the very public they are intending to help. The epidemic
rise of chronic inflammatory disease provides a wealth of examples of
mistranslation of science by those advocating changes in our system of public health.

It was pointed out earlier that the scientific community is not immune from making these same types of errors in its own process of discovery. Experimental design can easily bias results along with premature interpretation of incomplete scientific data. Even when scientific data is recognized as accurate there can be great debate over what the data means between the scientists themselves. This is often evidenced with two or more conclusions and competing theories to fit the same data. It is for this reason that the scientific community maintains a rigorous process of cross-examination by peers to challenge conclusions drawn from data. The data itself must then be independently examined and reproducible by others. Patience and time is required before enough data is presented and cross-examined by peers to validate the knowledge to be gained. Public health officials, elected representatives or the general public that attempt to discredit or silence persons performing their due diligence to examine the data and conclusions used to advocate public health policy and action are violating the very foundation of how scientific knowledge can benefit society.

The ongoing scientific research into the causes of the growing and deadly health threat to society by chronic inflammatory disease has sufficiently revealed enough knowledge as to the causes of this epidemic as well as ways to begin
reversing the trend of this type of disease. This is a class of diseases that has exploded against modern humanity with symptoms once mistakenly considered by sufferers as a just part of growing old. Inflammatory disease is chronic in nature, attacking all ages and both genders throughout the body and in different manners and locations over a lifetime. It is often difficult to detect or diagnose before causing irreparable damage to tissue and organs. Those suffering have symptoms that range from simple discomfort and debilitating pain to premature death. As a result there is understandably heavy pressure on research and medical institutions to find cures, drug companies to produce therapeutics, and expectations from sufferers for remediation by health care professionals. Even elected representatives are assuming accountability and responsibility by suggesting, creating and implementing public health policy with goals of slowing growth of the disease with isolated and uncoordinated actions that fall short in follow up on efficacy and results. Even as the knowledge of the disease mechanisms have been revealed by research the remedies attempted have had little effect in reducing the incidence or slowing the rise of these diseases. It appears that implementing the cures for chronic inflammatory disease may be a greater challenge to society than the harm posed by the disease itself. Part of the cure is dependent on changing behavior in a society that has grown accustomed to cheap foods that delight taste with a vast choice and unlimited amount to
satisfy food craving. Beyond consideration of the ethical and legal considerations to curtail rights of an individual to choose their diet is the greater need effect change in the complex multilayered economic environment that encourages consuming the foods that provide an environment of constant inflammation in the body allowing the disease to feed and grow.

This thesis examines many of the components in the aforementioned environment caused by unhealthy and begins to examine what should be a systemic approach to curing these diseases. Ethical considerations must factor into any meaningful solution if it is to be accepted by a public that values individual choice. Knowledgeable public and private discussion is a very integral part of changing the current disease friendly environment. For this reason I believe it is necessary to include a basic discussion about our knowledge of inflammatory disease causes and cures. This basic insight into the inflammatory response of the body provides insight into translation of the science and some degree of recognizing policy and action that contribute to lowering the state of inflammation inside each person’s body. The foods we eat can serve to raise or reduce this constant state of alarm. The public expects relief and cure to their afflictions demanding answers and assistance from their elected officials. There is no absence of promises and announcements to provide relief to win elections, but the diseases related to inflammation inside the body continue to increase and
worsen. Those officials in turn look to the scientific community to provide them quick answers, but a rush to action can exacerbate or multiply the problems if one does not recognize the critical role of ethics in administering actions to benefit public health. The system that feeds chronic inflammatory disease is complex and will require an equally complex system to cure that will require ethically guided actions in order to be acceptable to the public. Curing flawed translation of science is part of the cure but even armed with the correct solutions those advocating action for public health welfare must be cognizant of using ethical tools in their methods while implementing public health policy.

Throughout the discussion of mistranslation of science in this thesis I will reference ethics based guidelines that contain questions that must be satisfied if one is to successfully deliver a cure to this modern foe of disease. Mistakes are being made by those advocating cures that have both wasted public resources and raised skeptical resistance from a public already suspicious of the motives and agenda of government representatives. There is always an ever present specter that any proposed action to benefit the public (or sector of the public) can have hidden agendas that do not necessarily contribute to fighting the disease. This thesis will also examine those influences and forces that may resist changing the system even if the results may be favorable to improving the public’s health.
It is a premise of this thesis that an ethical model can be considered part of an analytical process for improvement. Such a tool should be imbedded into any action requiring change of behavior in individuals, making public policy or making changes to the economic system. This ethics based model should respect personal freedom and choice and require a less intrusive regulation will not achieve similar results. Guidelines need to require goals are stated clearly are results proven in understandable terms to the general public. Part of the cure is making better choices in diet and practicing healthier lifestyles. But making the correct choice depends in part on improving the public’s recognition and understanding of what comprises healthy choices in diet and that practicing moderation in the diet allows for a wide selection and enjoyment of foods. Part of this ability by the public to discriminate between healthy and unhealthy choices is the awareness in detecting mistranslation of science. That detection may be as simple as knowing the right questions to ask in true Socratic methodology\(^3\). Lifting the fog of advertising and marketing can sharpen recognition of carefully parsed language designed to raise expectation for curative effects while purveyors escape accountability to prove implied claims and benefits specific to their product. We have an enormous market of dietary supplements in this country that closely follows regulation for truth in advertising but nevertheless allows if not invites mistaken perception of the product’s effectiveness.
Changes are needed to the current systems of both food production as well as marketing of dietary supplements on a global scale in order to reverse the rise of chronic inflammatory disease. In my opinion those markets and food production interests are not motivated by greed or evil intention, rather they are operating within the guidelines and rules established by regulatory agencies. The food production industry has enormous pressure to meet a growing demand for food while conserving land use, lowering pesticide application and keeping selection, quantity and costs within the reach of the entire population. The success of these health and diet stakeholders is illustrated in the most developed nations such as the United States, where stores are flooded with low cost enticing food along with a vast market of pharmaceuticals, mineral and vitamin supplements, exercise equipment, medical facilities and trained healthcare professionals all meeting society’s cravings, yet yielding the highest rate of chronic inflammatory disease in the world.

Tactics and strategy to reverse the trend

An army needs to know its enemy and have a strategy along with tactics to win battles and ultimately the war. This same is true in our fight against chronic inflammatory disease. Science has revealed the enemy and even identified the weapons to defeat the disease. But entering this field of battle against this modern disease without correct strategy and tactics has proven less than
successful by the simple fact that the disease and associated costs to society continues to trend upwards. The examination in this thesis applies an ethical based theory to fight chronic inflammatory disease and suggests tactics that have proven successful in historical settings that are similar to those found in our modern society. It is hoped that those affecting public debate including bioethicists will discuss and consider using the strategy and tactics suggested against the current pandemic of disease.

I have found both tactics (theory) and strategy (method) that is relevant to fighting chronic inflammatory disease present in an article titled “An Ethics Framework for Public Health” written by Nancy E. Kass ScD. She offers a six step framework derived in part from an earlier published piece and a similar framework proposed for public health and human rights by Gostin and Lazzarini for deciding when coercive public health interventions are ethical. Kass reviews the positive societal role public health action has played with interventions such as the laws passed in Massachusetts in 1701 to isolate smallpox patients from the general population and to quarantine ships to protect the public from infection. By the beginning of the 20th century the evidence was recognized that prudent actions taken by institutions serving public health were both cost effective and beneficial for all. The maintenance of a safe drinking water supply, proper sewage disposal and treatment, immunization against disease are leading
examples based on epidemiological research providing insight into causes, distribution, and control of disease. Kass correctly points out that these population driven goals can infringe on individual liberties in ethically troubling ways. The birth of bioethics was preceded by a troubling gestation period where scientific experimentation was performed on humans in the name of benefiting public health and gaining knowledge. Guidance was offered in 1979 by the Belmont Report\textsuperscript{7} outlining basic ethical principles in research involving human subjects. The Federal Policy for the protection of Human Subjects or the “Common Rule” appeared in 1991\textsuperscript{8} which was further codified in regulations including 45 CFR part 46. These guidelines provide the guidance to research to ethically pursue scientific research. I have used the guidelines offered by Kass as the theory in which to apply the strategic tools discussed in this thesis. The six guidelines are as follows:

1. What are the public health goals?
2. How effective is the program in achieving its goals?
3. What are the burdens are known or potentially exist?
4. Are there alternative approaches that minimize burdens?
5. Is implementation done with fairness?
6. How can benefits and burdens be fairly balanced?
These guidelines have been incorporated into this thesis to offer ethically based solutions to reverse the trend of chronic inflammatory disease. The first guideline is to clearly define what are the public health goals. At first glance this may appear fairly simple such as stating a goal to reverse the trend of a particular disease. Too often a noteworthy goal is offered and justified with scientific grounds but the method of action may be ill conceived or original justification based upon improperly translated scientific research. There is a deeper challenge in establishing a goal that is inclusive to all stakeholders using science translated and applying an ethical implementation to improve public health.

This ethical implementation includes the important second guidance step by placing a burden of proof on the policy, program or intervention regarding its effectiveness in meeting the stated goal. Those working to effect improvement in public health policy must focus on the metrics of their action as much as they focus on the goal itself. The public should be aware of how effective the program is in achieving its stated goal. Kass points out that this measurement requirement is what distinguishes this stepwise process of implementation as an analytical tool, much like the tools of statistical process control used to analyze data. In my own opinion statistical process control provides reliable tools by which to apply these ethics based guidelines. Kass states, “…While a rather
narrow evaluation may demonstrate success (in terms of participants’ understanding the message), a program ultimately cannot claim success if behavior is unaffected and the key measures of morbidity and mortality remain unchanged."4,pg 1778 The guidelines discussed by Kass do not require that each program or intervention reduce these key measures by themselves alone; rather they suggest adopting a multidimensional campaign along different fronts to evoke measurable improvement.

These suggested guidelines do carry a high degree of evidentiary ethics and methodology in results rather than sole focus on a well-intended goal. Results alone cannot justify the means if there are serious ethical violations to any major stakeholders. Kass states “The question for policy and ethics analysis, then, is what quantity of data is enough to justify a program’s implementation?”4,pg 1778 She offers the rule of thumb that the greater the burden posed by the program in terms of cost, constraints on liberty, or targeting vulnerable segments of the population, the stronger the evidence must be to demonstrate the program will meet its goals. These guidelines provide a stepwise analytical theory to correctly implement public health policy to reduce morbidity and mortality.

To lay the groundwork for applying Kass’s framework, Chapter II begins by describing the nature and extent of chronic inflammatory disease in order to
provide the basic understanding needed to discuss issues, policy, and actions. Chapter III then discusses the crux of this thesis with examples and discussion of how easily science can be mistranslated. Two key points to understanding are that correlation does not equal causation, and the inherent limitations of the mind to comprehend large numbers and statistics in order to identify and prioritize problems.

Chapter IV views the fight against chronic inflammatory disease in terms of a complex system with many stakeholders. Here is where step #2 in the Kass guidelines requires that proposed interventions or public health programs provide proof they achieve stated goals. Because the problems and elements feeding chronic inflammatory disease are integrated within the entire system that comprises unhealthy behaviors, foods and unproven over the counter remedies it will take a steady improvement in each of these processes that can be reliably measured over time. This thesis uses an historical example of how economic successful change was applied to the feudal based post WWII economy of Japan. I offer the possibility that we can draw general comparisons from the once entrenched feudal economic system of post war Japan to the equally well-entrenched systems within the US that feed the growth of chronic inflammatory disease. The remaining ethical guidelines offered by Kass are overlaid and discussed in terms of translating science accurately and developing strategies
that maintain an ethical basis while fighting the rise of chronic inflammatory disease in the US.
“Let food be the medicine and medicine be food” is very often attributed to Hippocrates and appears loosely derived from translated ancient Greek text. A reference to nutrition appears in the classic version of the Hippocratic Oath “I will apply dietetic measures for the benefit of the sick according to my ability and judgment…” but few, if any schools of medicine still use this phrase in the oath administered for graduating students, with the dietetic reference being dropped from the modern variants of the administered oath. This neglect of dietary focus in the oath administered for medical profession is shortsighted, not so much in terms of the positive medicinal value of food, but for the growing research data linking modern disease to the foods we consume. This first chapter presents the evidence and data describing the perplexing problem of diseases trending upwards in developed countries, specifically in the United States. The research into the causes and cures for this epidemic in the United States provides a leading example of the potential rewards obtained through scientific research. Breakthroughs in understanding the mechanisms of the disease have led to the development of drugs to mitigate effects and discover cures to these diseases that are progressing at a rapid pace. As this progress moves forward the complexity of the disease and interaction with so many variables including diet
and behavior is becoming apparent by the continued upward trend of disease related to chronic inflammation in the body. There has been a stunning trend reversal in mortality caused by disease occurring in the US after great strides were made in the past century to lower the incidence of premature deaths caused by disease. Evidence is growing, if not already overwhelmingly accepted, that nutrition, more specifically the food consumed in developed countries, is likely a causative or contributory factor in disease. Our horn of plenty is no longer a health panacea; rather research data indicates that the lack of prudence in what foods we eat, the ratios of food groups, along with the excessive quantity of food consumed indicates that our diet of modern foods is creating harm over our lives.

This chapter delves into how the types of diseases causing significant American mortality today are different than the major disease culprits of the past century. The foremost difference to recognize is that the diseases of the past had identifiable infectious agents such as a bacterium or virus. Infectious disease has drastically declined, as shown in the following chart (see exception note below graph).
Figure 1

NOTE: Downward trend in infectious disease mortality in the United States from 1900 to 1996.

With the exception of the influenza pandemic of 1918, death rates due to infectious diseases decreased until around 1980, at which time several factors (including HIV-related mortality and antibiotic resistance) have caused a slight rise.

The previous chart illustrates the unprecedented triumph over disease through improving medical knowledge, the introduction of antibiotics, minimizing infectious agents (carriers such as mosquitoes) and the significant improvements in public sanitation and potable drinking water during the last century. All of these elements working together and orchestrated through scientific research and public health policy served to identify and all but eliminate a wide array of infectious diseases. Tuberculosis (bacterium) and Polio (viral) are just two
examples of infectious disease that once plagued the US population and no longer pose the pandemic threat to our general population.

Following this victory over infectious disease is a disturbing rise in the incidence of disease different from the past, having stealthy properties with a cause difficult to diagnose. The nature of these diseases is complex due to the progression over time before symptoms are recognized. Another troubling characteristic is that these inflammation-related diseases are affecting the most affluent and industrialized countries that often have the most advanced medical care available. This disease when compared to the infectious diseases of the past is not easy to diagnose, especially in early stages. It is a disease process rather than an attack by a single destructive agent of infection. This process of disease of the inflammatory system growing over time makes the agent(s) creating disease difficult to trace and cure. Very often the harm from these diseases is recognized only after a period of years. Treatment of these chronic diseases is often focused on mitigating symptoms and slowing progression of the disease process.

Only recently have research scientists begun to understand the processes that trigger development of chronic inflammatory disease with insight into our metabolism. The over activation of the body’s own immune system can cause it to fight against its own tissues and organs. This stealth like manner with minor or
annoying symptoms over time makes the disease difficult to diagnose before the
disease can be recognized.

![Prevalence of Chronic Disease in the US](source)

**Figure 2**

One specific form of chronic disease is diabetes. According to a 2010 study
released by the U.S. Centers for Diseases Control and Prevention, diagnosed
cases of diabetes grew by 50 percent or more from 1995 to 2010 in 42 U.S.
States, and 100 percent or more in 18 States. Almost twenty million Americans
have been diagnosed with diabetes and even more disturbing is the lack of
awareness. It is estimated that 7 million persons have undetected diabetes
according to the CDC. Regionally the largest increases in diagnosed diabetes
are in the Southern States of the U.S. followed by the West, Midwest and
Northeast. The following two charts show a map plotting diagnosed diabetes
cases in 2004, then in 2007.

Figure 3

Figure 4
Persons that are classified as pre-diabetics are those already demonstrating impaired glucose tolerance or impaired fasting glucose levels. According to the Center for Disease Control (CDC) “in the United States, approximately 41 million people, amounting to almost one-fifth of the population in the United States, were estimated to be pre-diabetic in the year 2000.”

Due to this slow progression it has been difficult to understand the nature and cause of this disease trend, although growing research now points to a common denominator. The processed foods consumed by developed countries appear to be a primary culprit. For the purposes of this thesis the term affluent refers to the lifestyle and foods consumed in developed countries generally rather than the particular subpopulations most affected. In fact, it will be discussed later that the poor may be the most adversely affected by the affluent diet. This diet of affluence has unlimited quantity, with food choices geared to gratify taste rather than meet nutritional needs. Diet is not the sole culprit in these diseases since lower physical activity in the affluent countries (daily exercise) fails to burn up excess calories in the body which are then stored in fat cells. All of these factors, common to the affluent diet, combine to trigger an overactive or dysfunctional inflammatory system leading to disease. This awakening is further exacerbated by genetic disposition to specific autoimmune (inflammatory related) disease. This increase in disease is above the level
predicted with increased life expectancy. These statistics will be discussed later in this chapter when competing theories explaining this rise in inflammatory disease are examined.

These modern ailments are chronic in nature, very different from acute disease caused by infectious pathogens. These diseases are classified as chronic inflammatory disease (CID) and represent the cause for reversal in the trend for disease mortality in the affluent countries. The loss associated with these chronic diseases extends far beyond mortality, with treatments that mitigate symptoms creating a multibillion-dollar pharmaceutical industry, which, for the most part, controls symptoms but fails to cure the disease. As shown in the following figure, the individuals affected add monumental costs to the public health system and negatively impact the economic output of the country.
What is more unsettling in this chart is that, as the incidence of chronic disease continues to rise within the population, the subsequent cost associated with care continues to increase. A leading example is diabetes, which is currently the sixth largest cause of mortality, with approximately 21 million people (almost 7 per cent of the total population) suffering from the disease. The number is projected to more than double to almost 50 million by the year 2050. Even more disturbing is the lack of awareness of those afflicted: 30 per cent of these estimated cases involve people who do not as yet recognize that the disease is present. This is the stealth-like nature of CID[s common to many of the chronic
diseases, developing slowly over time with those afflicted not taking prophylactic measures to prevent or slow growth.

Asthma, which is depicted on the chronic disease chart as a pulmonary condition, is another chronic inflammatory disease on the rise. Most people with asthma can control their symptoms to prevent asthma attacks by avoiding asthma triggers and using prescribed medicines such as inhaled corticosteroids. Even when symptoms are under control the economic impact of a chronic disease is nevertheless huge and growing\textsuperscript{12}.

Arthritis is another example of chronic disease on the rise affecting a growing portion of our population. This inflammatory affliction costs $128 billion annually, and continues to be the most common cause of disability for Americans. The CDC analyzed National Health Interview Survey (NHIS) data from 2007–2009 and reported that “22.2% (49.9 million) of adults aged ≥18 years had self-reported doctor-diagnosed arthritis, and 9.4% (21.1 million or 42.4% of those with arthritis) had AAAL. \textsuperscript{13}.

All of these non-infectious diseases share something in common: none are caused by a contagious pathogen. The medicines, therapies and public health policies used successfully to fight against infectious disease are ineffectual against chronic inflammatory disease. All of these diseases are linked to dysfunction or over-activation of our own internal immune response systems.
Equally disturbing is the fact that the number of persons in the United States being diagnosed with chronic disease is growing and these same persons are more inclined to develop multiple co-occurring chronic conditions. In 2005, 21% or roughly 63 million Americans suffered more than 1 chronic condition. A person’s risk of having more than 1 chronic condition increases with age: 62% of Americans over 65 have multiple chronic conditions. With the aging of the US population, this number of Americans is projected to be 81 million by 2020”. This all adds up to escalating costs in the public health system as referenced by The Institute of Medicine’s seminal report “Crossing the Quality Chasm,” which noted that 23% of Medicare beneficiaries have 5 or more chronic conditions. It is our body’s highly evolved self-defense mechanisms designed to fight off infection and heal injury that appear to be the cause of inflammatory diseases. Our own body’s defense system becomes out of control and misdirected against itself.

**Basic Immunology 101**

In order to discuss inflammatory disease as it relates to public health policy, and to differentiate between infectious disease and inflammatory disease, there must be a basic understanding of the immune system, A basic awareness of this highly evolved system in humans allows an appreciation of the currently understood complexity, interaction and efficiency of our ability to fight off infection and disease when the immune system is functioning as it was designed. The
immune response system in humans is a very complex biological system with many elements, components, and interactions. Having a basic insight of the interactive nature of metabolic and immune systems will allow one to better recognize the problem and offer solutions in the forum of public health policy to fight inflammatory disease.

When these biological systems are functioning properly, the body recognizes a pathogen as a foreign body through a wide range of inflammatory messenger molecules that activate various components of the immune response depending on the type and degree of threat. These protective elements possess both selectivity and specificity in order to identify and attack a specific intrusion such as a germ. These messengers, once triggered, raise a general alarm within the body to fight infection. Just as there are activating messengers there are also mitigating agents that serve to calm the system’s response after the threat is gone. Initial activation can be triggered by a trauma injury to tissue, or by the immune system’s ability to recognize unique proteins called antigens. Such triggers can either be proteins from inside the body (foods), or oils on the skin (poison ivy) or attached on the outer surface of cells, germs, and viruses. Non-disease causing antigens on cells of our body allow the immune system to recognize itself, thus not triggering attack. In this way, the immune system tolerates the “self” but is triggered when an unknown antigen, “non-self”, is
introduced. As such, the immune system as a whole is comprised of multiple tiers of defense to recognize friend and foe when working in harmony to repel infection and promote healing.

**Innate immunity** is non-specific and considered part of the body’s natural barriers. Examples include the cough reflex to clear the lungs, the antibiotic nature of tears, skin oils, mucus and stomach acid, and the physical barrier of skin. It is also the first responder, being activated within hours after exposure. Also included as part of this innate system of protection is fever, since raising the body’s temperature will often destroy microbes unable to tolerate just a couple of degrees above normal body temperature. These components of the innate system provide a generalized response to fight a wide range of infections.

If the non-self antigen is able to overpower or elude these innate protections then there are additional lines of defense that, if triggered, activate with very specific attacks using an arsenal of biological weapons that are both selective and specific to the invading antigen. **Acquired immunity** is developed after exposure to an antigen, with a specific set of weapons (antibodies) ready to activate, multiply and deploy if the intruding antigen is detected in the future. **Passive immunity** denotes antibodies produced in another body.

The immune system most often relies on messenger molecules flowing in the blood stream to martial the necessary immune response. Also flowing in the
blood is a vast array of bioactive chemicals and proteins such as antibodies
created to fight specific antigens or complement proteins, and interferon that
battles viral intruders. Some of these elements directly attack foreign substances
in the body while others work together to assist the immune system cells.” 16

It is the bio activating chemicals and proteins present in the foods we eat and
created within the body itself that can trigger metabolic imbalances causing
disease. A basic appreciation of this wide array and interaction of biological
alarms that activate the immune system, primarily the inflammatory response,
should cause one to moderate quick judgment as to cause and corrective action
in terms of public health policy.

In his book Inflammation Nation 15 Dr. Floyd (Ski) Chilton aptly frames the
issue being discussed in this thesis: “Since inflammation is at the root of a whole
host of diseases plaguing our country, it is tempting to see the body’s
inflammatory response as the enemy, but this would be a terrible mistake.
Indeed, this is part of the paradox behind inflammatory disease: there’s nothing
inherently wrong with inflammation; in fact, just the opposite is true. The immune
system’s impressive show of inflammatory firepower is not only appropriate, but
also absolutely vital to sustaining life. It’s not overstating the case to say that
inflammation is a keystone of your own health, and of our very survival as a
species 17”. If one simply suppresses the immune system to lower the
inflammation level, then the body is less able to fight off an invading virus or bacteria. An infection such as the common cold can be fatal for someone with AIDS or having their immune system deliberately and severely suppressed to minimize the body’s rejection of an organ transplant.

**Theories about the Cause in the Rise of Inflammatory Disease**

Scientific research such as reported by Dr. Chilton at Wake Forest continues to point to a common denominator linking inflammatory diseases such as lupus, Crohn’s disease, and psoriasis to the self-defense system of inflammation. These and many others are being classified as inflammatory diseases, conditions where the body’s own defense system turns against itself. Dr. Chilton’s dietary research further concludes “…that our diet is a major—if not the most important—external factor behind the inflammation epidemic.” There are competing ideas about the causes of this dramatic increase in inflammatory disease, which are summarize as follows along with comments from Dr. Chilton’s book, Inflammation Nation:

**The Gene Theory** explains the spike in inflammatory disease as a genetic susceptibility, concluding that people living in affluent countries share genes that predispose them to diseases like arthritis, asthma, heart disease, and diabetes. Certain people are more genetically susceptible to certain diseases than others, as evidenced by so many of these ailments running in families. Genes are not the only factor determining whether you have, or will get, one of these
inflammatory conditions. Epidemiologists who study the factors affecting the
distribution of diseases tell us that even genetically similar people can have
dramatically different levels of inflammation depending on where they live. Dr.
Chilton cites the epidemiological statistics from Germany shortly after the
unification of the eastern and western sections. These two populations had
practically identical genetic characteristics but very different level life styles (in
terms of diet). The poorer, less developed population of children from East
Germany had fewer cases of asthma, allergy and hay fever (all inflammation
related diseases) than children living in the more affluent West German section\textsuperscript{15}.

The Pollution Theory is an argument often brandished by those with agendas
who associate data such as the skyrocketing increase in asthma sufferers with
industrial pollution. But this claimed correlation to respiratory disease begins to
break down with the dramatic increase in other non-respiratory inflammatory
diseases like Crohn’s disease and eczema. Another weakness in direct
correlation is that the affluent countries where the incidence of asthma has
doubled in the last 2 decades have had their air pollution significantly improve
during that same period. The worst cities in the United States for asthma start
with Knoxville, Tennessee, followed by Little Rock, Arkansas, and St. Louis,
Missouri, while cities notoriously known for their poor air quality such as Atlanta,
Chicago, and Los Angeles are far down this same list. The example of post
unification Germany again serves to dispel a direct connection to pollution. Children living in East Germany who had heavy levels of toxins in their water and unrestricted air pollution actually suffered less from asthma than children living in neighboring, far less polluted environments. There are many solid reasons to reduce pollution in the environment, but inflammatory disease is not one of them.

Diseases of Old Age Theory is an explanation that the rise in inflammatory diseases can be dismissed as a normal aging process claiming that the increase is simply due to longer life expectancy. Chilton’s book discusses that in the last century, before medical advances and the advent of antibiotics, diseases like tuberculosis and pneumonia often didn’t allow people to live long enough to develop diseases of old age such as arthritis. There are changes in our bodies as we age that do place us at higher risk of developing certain inflammatory diseases. But the epidemiological evidence weakens this theory of causation due to living longer. “Nearly 65 percent of people with arthritis are under sixty-five. We’re twice as likely to develop this disease as our parents were, and at much younger ages. Most of the increase in inflammatory diseases has occurred at a time (from 1970 to the present) during which life spans have not significantly increased”. 18

The Hygiene Hypothesis has been described by Chilton as a pollution theory in reverse “It’s not because we’re dirty that we’re getting sick, it’s because we’re
too clean”. It is suggested that the children in an affluent society who frequently use antibiotics, pristine water and waste disposal are less exposed to disease-causing agents, thus failing to develop a robust immune system to fight disease. The studies that have examined this theory in children who live on farms find that they have a significantly lower prevalence of allergies than children from the same areas not living on farms. “Complex statistical analysis identified these children’s exposure to livestock and poultry as the feature of farm life that most protected them against asthma and hay fever”. Dr. Chilton agrees there is substantial data to support this theory, although he points out significant weaknesses, such as that one would expect that a variety of infections would bolster people against allergic diseases such as asthma, “but, in fact, many infectious agents actually trigger allergic reactions and asthma symptoms”. He concludes that although the hygiene hypothesis is a very promising theory, it warrants further development since it doesn’t fully apply to the whole scope of inflammatory diseases, including arthritis and diabetes.

The Dietary Nexus to Inflammatory Disease and Obesity

The abundance of food available to the populations in developed nations is a fairly recent luxury of the past century. The linkage between what we eat to our health has ancient roots in cultural remedies and herbal medicine. There have been cause and effect studies done since the 1900’s suggesting links between
diet and food supplements to claims of cures, health improvement, prevention or treatment of disease. Some of these early studies, although not meeting today’s research standards, still carry great influence in dietary discussions and claims. Early studies are referenced (or misrepresented) in order to advocate special diets or supplements to claim health benefit or fight specific diseases. This early research (dating back 60 years) will be examined more closely in a later chapter describing how research statistics can be selected and manipulated to advocate a predisposed conclusion or agenda. Well-designed scientific research today is providing evidence that does provide linkage to the foods we eat and our health. This thesis examines on segment of this research, how the foods we eat affect the inflammatory system and overall health and well being of the body.

**Inflammation Messengers**

Dietary research into metabolic mechanisms in the body has revealed Arachidonic Acid (AA) as a key player in the inflammatory response system beneficial to good health\(^{19}\). AA and other biologically active components serve to mediate the inflammatory system in the body so response is adequate, measured, and quelled\(^{20}\). When this and other components fall out of homeostasis metabolic imbalance or excesses occur an environment within the body promotes inflammatory disease. AA is a key player as it is part of a metabolic pathway producing two very powerful inflammatory messengers (IM’s).
The first IM is Leukotriene, which directs white blood cells (such as killer cells) to the site of infection and influences the scale of attack. A second messenger that is part of this pathway is prostaglandin which is responsible for directing a cascade of inflammatory responses to an injury site including redness, swelling, increased blood flow, as well as signaling the pain sensation in the nervous system. Dr. Chilton refers to this as the billion dollar pathway since a major part of the pharmaceutical industry has been built upon drugs to treat symptoms of many inflammatory diseases such as pain, swelling, constriction of airways, and inflammation of joints. Their mechanism works by blocking the AA inflammatory pathway. Common drugs such as Celebrex and Singulair are part of a family of non-steroidal anti-inflammatory drugs (NSAIDS) a long used ancient remedy to treat pain and inflammation originally derived from the bark of birch trees commonly called aspirin21. These drugs all fight the symptoms of the disease rather than the cause.

A Major Culprit in Inflammatory disease

Researchers have mapped how the body produces inflammation messengers (IM) produced through metabolic processes in our body. This process has been termed the AA pathway by Dr. Chilton and can be activated to produce an overabundance of molecular triggers that in turn unnecessarily activate IM's
raising a constant false alarm state within the body. The foods we eat to nourish our bodies in many cases provides the raw materials for metabolic processes including the AA pathway. It is also the case that the foods we eat may not nourish our bodies but can still affect our metabolic processes. Dr. Childers provides great detail written in layman’s terms about how this AA pathway functions in the inflammatory response cascade. His book describes how a properly balanced diet of foods and nutrients designed to provide the fuel to drive this AA pathway is necessarily inefficient in producing AA. The author uses the illustration of a series of stacked buckets, each one filled with water that drains down to another like a waterfall. Each bucket has a certain size hole that controls the water flowing into the next bucket below. This picture of a controlled rate of water flow illustrates the biochemical production of Arachidonic Acid and subsequent inflammation messenger molecules all playing a part in the body to both trigger inflammation response, control production, and limit this response to return the body to a “non-alarm” state. The amount of AA produced by eating the proper foods in moderate proportion allows more than enough AA to maintain sufficient inflammatory messengers to operate when the immune system is triggered into high gear. An over stimulation of production of AA, or worse, if AA is supplied directly by an imbalance or overabundance of food in the diet disrupts the natural checks and balances of a body in natural homeostasis, resulting in an
overproduction of IMs and subsequent over activation of the immune response system. This constant state of alarm is unnatural and is being linked to inflammatory types of disease. The body is never allowed to rest and just as running a machine at full speed overheats without a proper balance of oil to reduce friction, a raised inflammatory state in the body triggers many metabolic cascades that move out of natural balance into an unhealthy state of continuous inflammation more prone to disease and system failures.

Arachidonic acid is metabolized from Omega-6 fat, a family of unsaturated fatty acids. It is present in large amounts of processed foods and characteristic of diets of an industrialized nation such as the U.S. and those living in developed nations. What dietary researchers like Dr. Chilton and nutritionists are pointing out is that we are taking in high levels of food molecules that are foreign to what our metabolic system is designed to utilize in feeding and growing our bodies. The healthy body requires a variety and quantity of food to sustain activity, and the body requires activity that either burns the available energy immediately or stores it during a sedentary state for later activity. There is a balance for each individual and when any of these factors are out of balance our metabolism and health are affected over time. A prehistoric perspective must be first applied in terms of how our mechanisms of food metabolism evolved and are designed to function. Dr. Chilton provides this with the following quote: “It’s certainly no secret
that the way we eat is out of sync with our body’s needs. Most of the evolutionary forces that shaped our genetic development were exerted over ten thousand years ago when we were hunter-gatherers. Nothing in that programming could have prepared us for the Big Mac. Our bodies, and more specifically our genetics, simply aren’t designed to eat the ‘foods of affluence’ available to a twentieth-century urban dweller. It is this disconnect that I blame for many of our current medical ills”.

Not all polyunsaturated fats are the same, some variants of these molecules being healthy and useful in normal metabolism while others are useless in human metabolism or even harmful when out of proportion to what a natural diet would supply. There are Omega-3’s found in many fish and Omega-6’s found in soybeans. It is a mistake by nutritionists to classify either as a “good fat” or a “bad fat” since both of these fatty acids are considered essential nutrients and required foods. There are foods inherently high in Arachidonic acid such as red meats, poultry, and egg yolks that introduce of AA directly into our bodies circumventing the naturally constrained production within our body. That dripping bucket illustration used by Dr. Chilton described how one bucket, Omega-6, also called Linolenic acid (LA) that is very plentiful in our diet is inefficiently converted (slowly dripped) into a bucket of GLA (gammalimolenic acid) and then dripping into another bucket to become DGLA (dihomogammalinolenic acid) and finally
producing AA. Even with a heavy diet of Omega-6 there is a natural limiting process and our bodies are not flooded with AA. An overabundance on the other hand triggers the inflammatory messengers and raises the overall inflammatory state of the body. The types of foods associated with developed nations such as the United States are loaded with ready-made AA that bypassed the inherent metabolic process of limiting AA production, thus creating a constant state of inflammation. Add an excessive volume of food consumed along with very little exercise and you see why inflammatory disease finds the bodies in our population ready and willing to nurture their destructive processes of disease.

The Obesity Connection to Inflammatory Disease and Diabetes

It is simple math to understand how an unlimited supply of food measured in calories along with little physical activity to burn off those calories would lead to weight gain. But research into obesity is finding causes beyond and far more complicated than simple over consumption and lack of exercise. The AA pathway, if constantly elevated, places the body into a state of chronic inflammation, which in turn exacerbates fat cell expansion creating an unhealthy state within the cell itself. These fat cells (adipose cells) serve many functions beyond simple storage such as production of a key enzyme called adiponectin. It
is this enzyme produced by a healthy adipose cell that serves a role in mitigating inflammatory response. Inflammatory disease and obesity are not simply maladies running on parallel tracks, but are responses and triggers raising a state of alarm in the body (inflammation) and at the same time losing ability to quell the alarm state. There are a number of straightforward connections between those excess pounds to the epidemic rise of inflammatory related disease.

Research at the University of California, San Diego by principal investigators Dr. Michael Karin and Dr. Jerrold Olefsky and associates addresses the cause of type II diabetes. This and related research data is providing clues to unravel the questions of why and how this epidemic is rising at such a fast pace in developed countries. The puzzle can be framed within the age-old question of “which comes first, the chicken or the egg”…is it obesity that triggers diabetes since so many overweight persons develop this disease? Or is there a triggering mechanism for this disease as well as obesity related to a state of chronic inflammation? Dr. Chilton’s book reports that research data strongly suggests that the insulin resistance that characterizes Type 2 Diabetes is not directly linked to the increase in body fat associated with obesity. Rather research connects insulin resistance to a chronic state of inflammation maintained in the body over time that over activates killer immune cells (macrophages). These
killer cells enter the fat tissue (adipose cells) or liver tissue, releasing cytokines (chemical messenger molecules) causing neighboring liver, muscle or fat cells to become insulin resistant, which can eventually lead to Type 2 diabetes.23

What the data in the past 30 years is showing is a continuing rise in inflammatory related disease paralleled by obesity in this country. There is no single cause to be isolated and treated by a “magic bullet” such as the case in infectious diseases. Complex inflammation disorders appear to be triggered or exacerbated by an overabundance of “inflammation messenger molecules” causing the immune system to run in overdrive continuously. This chronic state of inflammation increasingly fed by food and obesity, provides a fertile ground for inflammation diseases to arise. Symptoms accumulate over time until finally they corrupt and disrupt complex metabolic mechanisms evidenced by inflammatory disease.
Too Much of a Good Thing

The biological system in the human body uses a wide array of signaling molecules to turn on and turn off processes, including immune response to fight disease or its agents. The following list is a description of typical mechanisms and signs of inflammatory response.

A. Smooth muscles contract around large blood vessels to slow blood flow.

B. This slower flow allows specialized white blood cells to enter the site of injury.

C. The cells that comprise the walls of the smaller blood vessels shrink to create spaces that allow transport of killer white cells, tissue repair cells, and other materials to pass into and out of the site of injury.

D. This increased permeability in vessel walls actually increases the diameter of vessels causing swelling and redness.

E. Adhesion molecules become activated on the inner walls of vessels and capillaries further making surfaces sponge-like and sticky.

F. Other molecules activate coagulation pathways to create clotting that contain the infectious agent (microbes etc.) and triggers blood clotting to keep out further intrusion and loss of blood.
It is uncanny and revealing that these same basic signs of normal and helpful inflammatory response are characteristic of the disease but being over stimulated to the point where these protective mechanisms become enemies to otherwise healthy tissues and cells.

1. Asthma has a known connection to inflammatory response whereby the airways inside the lungs become inflamed and in classic inflammatory response the breathing passages swell making breathing difficult. This is an overreaction of the body’s disease fighting systems triggered by relatively harmless agents such as pollen that unleash the overabundance of inflammatory messengers and over response to the trigger.

2. Hay fever has been described by Chilton as “asthma of the nose” very often triggered by pollen, with similar symptoms of swelling, redness, mucous production and sneezing.

3. Rheumatoid Arthritis is classified as an inflammatory disease but rather than external agents triggering the symptoms, there are internal triggers that cause the immune system of the body to attack its own tissues such as joints and organs. The immune attack (autoimmune disease) then triggers other components of the inflammatory arsenal all directed to once healthy tissue.
4. Atopic Dermatitis is another disease known to be caused by an overactive inflammatory response with skin rash and subsequent open sores.

5. Lupus is a chronic autoimmune disease where the body attacks its own cells.

6. Inflammatory bowel disease is another chronic inflammatory related disease with many forms (such as Crohn’s disease) developing in the small intestine, with ulcerative colitis usually appearing in the upper bowel. Celiac Disease is yet another example where persons affected cannot eat foods containing gluten or risk raising an immune response that inhibits absorption of nutrients causing malnutrition.

Too much of a good thing becomes damaging to the body. Inflammatory disease develops slowly over time as a chronic disease that damages organs and tissues of the body and provides an environment that enables if not triggers other disease to occur. The following chart depicts the number of Americans with more than one chronic disease condition.
This same study by Johns Hopkins University reported that a person’s risk of having more than 1 chronic condition increases with age that projected 62% of American over the age of 65 have multiple chronic conditions (MCC). As the US population ages, and the incidence of chronic inflammatory disease continues to rise, the number of Americans with MCC is projected to reach 81 million by 2020\textsuperscript{24}.

Chronic disease is a real problem in our country, a pandemic of disease that continues to rise. The dietary connection is clear so why are we not reversing this upward trend? It is no wonder that those concerned with public health are raising the alarm to cure the disease rather than simply fight the symptoms. But now that the basic science has been presented this thesis will
examine cases where the first failure has been made: to advocate a cure before the science or data is fully understood.

It is at this point where the 6-step ethics framework proposed by Nancy E. Kass, ScD begins to integrate with an approach to fighting CID. Just as the disease itself is different from those faced by humankind in the past, so must the cure. The 6-step ethics framework proposed by Nancy E. Kass, ScD offers an analytical method to effect change over time while maintaining an awareness of the ethical implications in proposed interventions, policy recommendations and programs for the benefit of public health. It represents a theory of how to implement change and begins with identification of the goals. I feel these first two guidelines represent the most crucial ethical requirements.

What are the public health goals?

Clearly define the proposed program with goals clearly defined and having measurable improvement in public health. This chapter has illustrated one of the mechanisms of chronic inflammatory disease and related the types of food we eat, the quantity of food, and the lifestyle of low exercise all combing to provide a favorable environment in the body for the onset of CID. The goal is to reduce the trend of CID in the population and education of the public is certainly one tool available in order to allow the public to make better choices. One example offered by the Kass is a cardiac risk reduction health education program. Such a
program should have an ultimate goal (or be part of a larger goal) of lowering heart attacks. The goal is not that individuals become better educated that changing their behavior will reduce heart attacks; rather the resources invested in a program must yield improvement in terms of actually lowering heart attack risk. For example those participating should agree to be tested to measure the effectiveness in changing behavior since this evaluation provides crucial feedback in whether the program achieves health improvement. The author offers a caveat that every program must achieve an end goal; epidemiological studies may provide data that may later provide scientists insight on developing intervention resulting in reduction of morbidity or mortality. The point being made in this first step is that health programs including education, intervention or epidemiological studies must be designed with awareness of resources being spent to achieve the ultimate goal, with measureable results. The author also states that an intervention with a goal of improving access to health care by hard to reach populations or those being discriminated against due to obesity would offer relevant improvement in public health. The issue of interventions seeking to reduce social inequalities is addressed as a separate step number 3.

Other types of social benefits can be gained from public health programs. Reduction in sick days or increased employment can become measures of program success and leads to step #2;
How effective is the program in achieving its goals?

This second step places a burden of proof on the program or intervention regarding its effectiveness in meeting the stated goal. In my opinion it is this measurement requirement that distinguishes this stepwise process of implementation as an analytical tool, much like the tools of statistical process control used to analyze raw data. The design of any program to effect improvement must first examine what data exists in order to substantiate the achievement of goals. For example, a cardiac risk reduction education program has the reduction of cardiac events (both fatal and nonfatal) as its goal. Improving awareness of how personal behavior affects cardiac events may be part of a larger program with goals to stop smoking, change diet, or increase exercise. Many health education programs are very effective at raising awareness and communicating information but less successful at inducing permanent change in behavior. 25-27 Thus the author Kass states, “…While a rather narrow evaluation may demonstrate success (in terms of participants’ understanding the message), a program ultimately cannot claim success if behavior is unaffected and the key measures of morbidity and mortality remain unchanged.”

Kass does not require that each program or intervention reduce these key measures by themselves. Health education for the individual or a health
screening programs might provide additional parts of a behavior changing process that does effect positive change in morbidity and mortality. This analytical approach suggests a multidimensional campaign in different formats is appropriate and useful if data show that the combination evokes measurable improvement. However the author is quick to remind that multiple approaches that are hypothesized or assumed to improve key measures must be required to have further research to support such goals before being justified. While all programs must have some level of evidentiary basis rather than simply informed speculation, Kass points out that the quality and availability of existing data will vary. Kass continues, “The question for policy and ethics analysis, then, is what quantity of data is enough to justify a program’s implementation?” The rule of thumb offered is “the greater the burden posed by the program—for example, in terms of cost, constraints on liberty, or targeting particular, already vulnerable segments of the population—the stronger the evidence must be to demonstrate the program will meet its goals.”

Many public health programs are imposed on people by government and not necessarily requested by citizens. There is an ethical responsibility to demonstrate the validity of a program’s assumptions and ability to meet the goals claimed. This second step requires substantiated examination of existing data and proof of efficacy and raises the bar above assumption and bias. This
particular guideline requires proof be given by both those that challenge a program or intervention as well as those responsible for implementation. Those who initiate policies or programs in the name of public interest very often neglect this step. Communication to all stakeholders is a challenge in and by itself, but in a sense, public health policy that infringes on individual rights seems to call for informed “public” consent similar to that established for individuals in the Common Rule. It is my opinion that circumventing this burden of evidence for efficacy in any behavior modification, intervention, public policy or law will create greater problems than it solves. This is even more relevant for a country whose population values individual rights and noninterference from government.
CHAPTER III

ERRORS IN TRANSLATION

The first error in translating science into ethical public health policy is implementing or suggesting intervention on behalf of public health before establishing a basic understanding of the science and failure to examine the experimental design and interpretation of data. A disciplined rational analysis free of bias and personal agenda along with using basic analytical tools should become the standard for improving public welfare. This is a methodology of translating science that allows one to validate conclusions derived from the data. Failures in translation should be discovered in the early stage of translating raw data. It is a reasonable expectation from the public for those converting knowledge gained from science into public health policy. It is a process of due diligence to challenge the foundation of any professional dialogue or opinion that suggests intervention or policy be taken on behalf of public interest. Bioethics was born from mistakes and abuses harmful to the public that at the time were believed justified in the name of public welfare. Those who carry out public health policy are trusted by the public to be their watchdogs by maintaining a professional skepticism and by following a protocol that examines the underlying science, if their opinions and recommendations are to be accepted by those unable for whatever reason to perform their own thoughtful translation of science.
In order to illustrate how this failure in translation commonly occurs I will use a 2011 documentary movie that at first glance appears to have a solid foundation in facts to support conclusions about how to improve public health. The failures were not deliberate attempts to deceive but rather illustrate the ease with which scientific research can be translated into conclusions and suggested actions that the raw data does not support. The movie, “Forks over Knives”\textsuperscript{28} presents a compelling narrative with dietary research data that is very dramatic at times in making the argument that meat is the primary culprit of causing circulatory disease, and that a vegetarian diet will reverse the trends of the diseases afflicting our modern society. The movie proceeds in a logical fashion with scientific data to show that a diet of meat is responsible for the rise in chronic disease. Based on the science already presented in this thesis linking food (AA pathway) to inflammatory disease this conclusion by the Forks and Knives documentary does appear to have a reasoned foundation. But a close examination (due diligence of the science) by an Internet blogger uncovered a number of flaws in how the data was presented. Denise Minger is does not have the credentials of a research scientist, statistician, nor epidemiologist but has applied rational analysis in translating the science. This thesis contends that those that debate, influence or effect implementing of public health policy may lack formal scientific credentials but are nevertheless qualified by using analytical
methodology to uncover the mistranslation of science and challenge the basis of arguments that purport irrefutable evidence. Ms. Minger’s academic credential is that of an English major with a Bachelor of Arts degree and having a deep interest and passion for nutrition and healthy living. But she also understands how to examine the raw data as well as how it is presented when used to justify a conclusion. Her analysis of conclusions the evidence and conclusions advocated in the movie Forks and Knives illustrates that lack of expertise and academic credentials in a field of study does not preclude one’s ability to detect false or misleading conclusions drawn from scientific data. A rational examination of the experimental design, the raw data and the final translation and conclusions presented can be performed by anyone willing to understand the basic science and use relatively simple analytical tools and methods.

I am using the documentary movie of Forks and Knives as an example because it represents a powerful tool for public health education. This documentary is directed to the layperson and is designed to influence opinion and garner support from conclusions drawn from “irrefutable scientific data” to justify changing diet and eating behavior to improve public health. It is an illustration of how a basic rational-based analysis can identify mistranslation of the science and even support development of conclusions and actions opposite to what the producers of this movie present. The movie presents a chart based
upon scientific data collected during World War II. The charting of the data is dramatic evidence supporting the producer’s conclusion, but Ms. Minger applied a rational objective review of the raw data and how it was charted to uncover the mistranslation of science and false conclusion derived from the data.

Early in the movie a colorful graphic representation is shown that was derived from this original chart published in the medical journal The Lancet:

![Chart from The Lancet](image)

Figure 7

The chart is explained as a unique and rare example of a natural experiment that drastically changed the diet for an entire population due to the restrictions of movement and freedom imposed by warfare. During the documentary film the line moves upward as mortality from circulatory disease increases. Then a Nazi swastika is superimposed when drastic change in diet occurs to the entire
population. The narrator Dr. Esselstyn then continues his commentary and interpretation of what the data shows, he narration includes “look at the data for heart attack and stroke, have we ever seen a population have their cardiovascular disease plummet like this? from statins?, bypass surgery? or surgical stints?...no!”. Dr. Esselstyn continues…”but look what happened with the cessation of hostility in 1945, back comes the meat, back comes the dairy, back comes the strokes and heart attacks…such an absolutely powerful lesson”. Dr. Esselstyn is basing a conclusion that consuming meat and dairy products are harmful to public health causing an increase in strokes and heart attacks. Given these facts the viewer would be hard pressed to arrive at any other conclusion that what is presented, but herein lies the powerful lesson that skeptical challenge is required of both the raw data and how it is presented before acceptance of a conclusion should be allowed. If you are to advocate a conclusion related to public health action then you must first examine the data from which it was derived.

There is other evidence presented throughout the film to support and build upon the case that most, if not all of the chronic disease afflicting the U.S. could be controlled, or trends reversed by rejecting the present menu of animal-based and processed foods. But when Denise Minger applies her examination to both the experimental design and the data used to generate the table and graph, she
arrives at a very different and defensible conclusion than what the narration depicted. Her insight is gained by looking at the raw data table as to what foods decreased and what foods increased during the span of time depicted in the graph.

Table 1

Meat and dairy went down, but not to zero. Sugar reduced in half, and vegetables intake up 100%. But fish consumption rose a whopping 200%. This was a bigger change than any other dietary item, and was conveniently not mentioned by the narrator. Also total energy intake (calories) dropped 20%. Further investigation of the raw data uncovers that the first year (1940) of imposed rationing affected imported foods: breads, fats, sugar, coffee, and cocoa. It was during the second year (1941) that meat, pork, eggs, and dairy
products were rationed. But the drop in cardiovascular caused deaths was already beginning. Graphs and interpretive statistics often depict far more dramatic change than the actual numbers; the change in mortality dropped from 30 deaths per 10,000 to 24 deaths/10,000. This accounts for six more people per 10,000 dying from heart attack and cardiovascular disease, still a significant change but to the viewer of the movie such a drastic drop in a graph of the population might appear to represent much larger numbers. One could also reasonably ask if the ravages of World War II and occupation by the Nazis could have contributed to higher stress that played an active role in increased cardiovascular deaths. The experimental design did not identify all the factors or limit the effect of outside variables to the data.

The statement “Correlation does not Equal Causation” sums up this first example of how the translation of science is misrepresented. The data was not presented in total; rather segments of the data were picked that supported an agenda. This is the bias that can mislead from what the science is truly revealing, by presenting data in a manner that sways opinion or gains support for an agenda. As stated at the beginning of this thesis, this is a misuse and abuse of science. I believe it is a serious ethical failure, no matter how well intentioned is part of the accountability and responsibility of due diligence by bioethicists and those working for the public welfare.
The third step that Kass discusses in her ethical model concerns what burdens of the public health program are known or potentially exist? The author presents three broad categories of burdens or harms: risks to the individual’s expectations for privacy and confidentiality most commonly related to security of their personal data; risk to self-evident individual liberty and self-determination; and the risk related to justice issues such as public health agents administering public health interventions preferentially to certain groups. Again different types and levels of burden identification will be required depending on the scope, benefit and cost for the public health activity.

In the case of monitoring vital statistics and disease surveillance for a population, there are privacy concerns since data collection is mandatory and data may be identifiable to individuals or, worse, publically accessible. It is a personal matter as to what data is sensitive or perhaps embarrassing since individuals have their own preferences as to what violates privacy. The author provides examples of where vital statistics such as paternity or cause of death could be viewed as an invasion of privacy and breach of confidence in their records. In another example the vital statistics and publically collected data about ethnicity or neighborhoods could be potentially stigmatizing or harmful in some other way. Certainly there are even greater privacy concerns when data reports communicable disease since names are revealed of those with reportable
conditions, which can be socially stigmatizing. For some a breach of privacy is viewed as wrong regardless of any tangible harm done.

Health education seems like the ideal tool for intervention to use in a society that holds individual liberty and protection of privacy in such high esteem as the United States. Learning is voluntary with the goal of empowering the individual with the information to make informed decisions regarding their health. In terms of protecting individual liberty and imposition of burdens it is the most ethical intervention and is probably present in most if not all public health intervention strategies in varying degrees. How large a role education can play should be determined by applying the analysis from the first two steps; what are the public health goals and how effective is the program in achieving those goals? Education may not work in all settings, or the intervention may have a speed of delivery goal that requires a more coercive strategy if the intervention is to be successful in protecting public health or isolation and removal of the harm. A second point made by Kass examines the questionable ethics of an education campaign that is not focused on presenting the facts to allow an informed decision but relies on some form of manipulation or imagery to influence thinking or even coercion. The example given is smoking cessation campaigns trying to manipulate attitudes by suggesting people that smoke are unpopular by providing information that is partial, misleading, or even false in order to achieve its ends.29
The unique protection of liberty and individual rights granted to US citizens raises the bar of justification for proof of benefits and close scrutiny of burdens for public health intervention and actions professed to protect or improve the public health. Kass states “In some contexts, public health programs are designed primarily to protect individuals from themselves, revealing that much of public health is inherently and unabashedly paternalistic.” Step 3 of the ethics framework offered by Kass requires that known and potential burdens must be examined in a program health program. She recognizes the categories of “risks to privacy and confidentiality, especially in data collection activities; risks to liberty and self determination, given the power accorded public health to enact almost any measure necessary to contain disease; and risks to justice, if public health practitioners propose targeting public health interventions only to certain groups.”

Biomedical ethics in recent time has steered the medical profession away from paternalism exemplified by growing trends in patients having access to their personal health and medical information to participate in evaluating benefits and harms of intervention.

A fourth risk in health education is found when targeting messages to a specific demographic group even when justified on grounds of protecting public health. Promotions on billboards, radio and TV stations may stigmatize members of the targeted group creating negative perceptions in the public eye. Finally
incentives in a health education program may be offered as a preferred alternative to more forceful coercion but can still contain ethical questions such as providing a cellular phone to one group in order to assure access to emergency response yet deny this incentive to another group. The burdens imposed by regulations and legislation are self-evident as they are coercive in nature imposing penalties for noncompliance. Examples of speed limits and childproof bottles have demonstrated benefit to society. This approach must be used prudently with the burdens closely examined “Involuntary and coercive measures must be undertaken with a clear perception of the dangers they pose to a democratic society: loss of personal freedom to choose a lifestyle, dependence upon governments to define values and concepts of the good life, and the imposition of cultural homogeneity. Involuntary measures also assume a benign, wise, and responsive government—something history finds singularly rare.”

Non-coercive measures also can stigmatize or devalue people. The example given is smoking cessation campaigns trying to manipulate attitudes by suggesting people that smokers are unpopular, using information that is partial, misleading, or even false in order to achieve its ends.

I will illustrate Kass’s step number three with the example of removing the consumer’s choice to purchase a large fountain filled drink. The assumption is eliminating a large sized sugared drink will reduce the public’s sugar intake thus
reducing obesity. The introductory chapter of this thesis suggests that an analytical process be followed when any public health policy or intervention is considered. The first step is to consider whether the action considered meets its intended goal. The second step is to have the metrics in place to prove the action is effective. And the third step introduces a burden that the action is based in scientific fact and is open to reasonable challenge. Perhaps the large sized drink filled with ice does not have a proportional increase in sugar compared to smaller sized drinks that are not filled with ice. Perhaps one could argue the delivery of sugar into the body over time, such as by the use of the large ice filled fountain drink might inherently lessen sugar concentration and the effect of a “sugar high” and “insulin shock” simply by the action of ice melting and diluting the sugar as the drink is consumed. It is possible that extending the consumption time while at the same time lessening the sugar concentration could allow a more gradual release of insulin from the body. By the time the consumer finishes the larger size drink the larger less concentrated volume could serve to both quench thirst and reduce the amount of sugar and corresponding insulin released. One could further argue that drinking two of the smaller sized “healthy” drinks could be more harmful than drinking one super sized drink. This conjecture about drink size and insulin effects would require scientific investigation to prove but simply represents the ethical burden that public policy and intervention must meet in much the
same way the scientific method is challenged and debated. The desired ban by New York City and other health officials on the supersized sugared drinks may in fact to some degree create the opposite effect of what is intended.

The errors in translation discussed in this chapter were affected by a failure to understand the science, or were created by selective editing of the scientific data. Arguments were created that were unsound and/or invalid based on inconclusive data, flawed scientific method (poorly designed experiments), or simply faulty logic. The examples illustrate how those arguing for intervention or action to influence public opinion on health policy must first acquire basic understanding of the science, and then follow a process to examine the scientific data and the validity of their proposed actions to achieve the stated goals. Failure to perform this due diligence before properly translating science into opinion or intervention in the name of public welfare is unethical, as is “cherry picking data” or “accepting flawed data” by those considered professional experts in order to advocate and promote an agenda. Public health advocates and officials, if their opinion and arguments are to be taken seriously, must acquire a basic literacy of the science and become professionally satisfied the data is complete and collected in an unbiased fashion, before offering expert interpretation, opinion and suggested public health reform, intervention and policy.

The Second Error in Translation: Misrepresentation by Statistics
Statistics has the dubious honor of being the most quoted branch of mathematics especially by those seeking to qualify their public health care positions as irrefutable truth that supports what they advocate as the problem or the solution. The earlier example of the Norwegian cardiovascular mortality data demonstrated how correlating a partial set of data (reduced meat consumption) to an outcome (deaths per 10,000) supported the documentary’s argument that it was reduced meat consumption alone that improved the cardiovascular health of Norwegians in WWII. This was an example of isolating and correlating a partial set of data to the cause of the problem. Simply examining the data with a layperson’s level of scrutiny revealed many causes that may have been involved in what amounted to an interesting historical study, but far from a well-designed scientific study with all variables impacting diet examined. The argument, using data from this study, was clearly refutable. This next chapter is about the second ethical failure in translation moves beyond the basic science or how data is collected and correlated to cause. Many of the points I am using are examples and analysis from a book written by Joel Best, Damned Lies and Statistics\textsuperscript{32}. Too often a statistical number becomes the fulcrum supporting ancillary arguments to convince or quell an opposing view when in fact the statistic may be the fallacy that has been prematurely accepted. This second failure relates to
ongoing bioethical debates dealing with public health issues that use numbers and statistics to bolster arguments for public health policy intervention and policy.

The issue of diet being a cause (either direct or indirect) for inflammatory disease necessarily uses population statistics, most often furnished by government agencies, to predict the size of the problem, trends, and efficacy of corrective action. These numbers can be used to correlate how the population is being affected as well as to predict how the population will be affected in the future. It is through statistics that we accumulate the evidence and feedback to measure and improve. Merriam-Webster defines statistics as “a branch of mathematics dealing with the collection, analysis, interpretation, and presentation of masses of numerical data”. There is no knowledge in raw data scientific data; it simply represents a recording of an observable phenomenon. Public health advocates must be aware that statistical analysis involves a series of steps each moving further away from the raw data. It begins with a mathematical model comprised of the data, an abstract. This becomes information, and from that information knowledge can be derived through rational interpretation. Given the growing influence of diet on health, it is an ethical responsibility for advocates to understand statistics enough to judge whether the data is being presented accurately and used reasonably.
This second type of failure in translating science has a different nature from the previously discussed examples that identified how easily data could be misinterpreted by simply selecting only numbers that support a desired result, or by over simplification of the science in not considering all the variables or factors involved. This second loss in translation is rooted in the inherent limits of the human brain to relate the significance of very large numbers in terms of the big picture. In the book, Too Big to Know\textsuperscript{33} author David Weinberger describes how large numbers accumulated in population statistics can provide insight into the problems and solutions for society’s complex problems (such as trends and linkage of dietary causes triggering chronic inflammatory disease). But the amount of data is often so enormous that they exceed the brain’s ability to grasp and place them into a recognizable frame of reference. Weinberger references a letter printed in 1963 in the journal Science\textsuperscript{34} by Bernard K. Forscher, Chaos in the Brickyard. It advocates that scientists were generating too much data that Forscher called “bricks”, facts without regard how they fit together. The author argued that brickmaking had become an end to itself; “we are flooded with bricks, to the point of impossibility of locating the proper bricks for the task. We are being flooded with bricks, and spend more time hunting for bricks to complete a useful edifice because as soon as the foundations were discernible, they were buried under an avalanche of random bricks.” Using Forscher’s allegory I would
suggest that an astute person must examine the individual nature of the bricks (data and statistics) along with the mortar that binds them together (arguments and rational) before accepting conclusions no matter how personally appealing they may be.

**Innumeracy: an often-unrecognized handicap of the literate**

John Allen Paulos wrote a book called “Innumeracy; Mathematical Illiteracy and its Consequences”. Just as illiteracy defines a lack of reading or speaking ability, the author coins the term innumeracy to define a lack of understanding mathematics, specifically statistics. It was the goal of this book “to appeal to the educated but innumerate”. I believe this description of an innumerate but literate population aptly describes a substantial portion of the US population, not because of a decline in mathematical competency, but rather due to the use of large numbers and statistics representing numbers so large they are beyond comprehension.

This becomes a serious ethical issue when campaigns create social problems inserting a false sense of urgency by utilizing large numbers or statistics that do not properly convey the true relationship of the problem in terms of priority among public health issues. Large numbers can focus attention to or away from problems simply because they garner attention and make interesting news. The press is hungry to report large numbers and statistics that interest
readers, but the press seldom corroborates or places the numbers into perspective so that the readers can relate the impact to themselves or to their community. The use of a statistical press release has become the ammunition and justification by activists and agenda driven groups seeking to raise the public’s attention in hopes of persuading opinion and affecting policy and intervention for public health welfare. The significance (or insignificance) of such reported numbers can be overwhelming (and misleading) to the general public as well as those that consider themselves “literate” in science and managing public health policy. The sheer immensity of numbers used to establish an argument can carry the appearance of being based in fact and having irrefutable evidence. Yet upon closer examination that places the numbers into understandable perspective, the argument may be found to be misleading at best or inflated beyond actual relevance to greater, more pressing public health issues. The proviso that correlation does not imply causation (cum hoc non propter hoc, “with this, not because of this”) is as relevant to statistics as it is to scientific investigation. In the scope of this thesis I make the assertion that failure of an educated person, such as a bioethicist, to apply a reasoned, critical review of the statistical claims used to advocate or promote changes in public health policy is an ethical failure to perform due diligence that is expected by the general public.

Correct Translation of the Science Does not Solve the Problem
This thesis described one metabolic pathway that plays a key role in the inflammatory response within the body. Further evidence was provided on how the AA pathway can be over activated by the choice and portion of foods we consume thus creating an elevated state of inflammation in the body. The linkage of diet triggering disease driven by overactive inflammatory response is further evidenced by the incidence of CID within the US when compared to countries with differing diets consisting of non-inflammatory causing foods.

It is so easy for those that manage public health policy to summon the medical alchemy of past, recalling the success witnessed by public health policy that introduced a miracle vaccine, or a science that created magic antibiotic bullets to kill the infectious agent and cure the disease. Those advocating public health intervention or policy hear about the science that links sugary foods to obesity but fail to do the work of due diligence to understand the knowledge. They then attempt to ban the largest containers of sugared drinks in the name of reversing the trend of obesity. This is precipitated by their ignorance born in a failure to take time to understand and translate the science, and a rush for a quick fix that fails to recognize the difference between a disease caused by an infectious agent versus a disease state created over time by diet, sedentary lifestyle and our food-supply system. It often appears that today’s public leaders have changed little from those 200 years ago who lead witch-hunts that falsely
identified the cause and deadly solution to social problems. Similar examples of well-intended but misguided efforts to reverse the trend of chronic inflammatory disease will continue to occur in the future.

Statistical interpretation adds a layer of failed translation commonly unchallenged in the opening arguments about public health issues. The limits of the human mind to fully comprehend and relate enormous numbers to distinguish problems that have the greatest impact on the public’s health further clouds priorities and understanding. The previous chapters describe the need to remove a veil of basic ignorance of science and be wary of pitfalls in translation. It seems we are fighting a losing battle to rely on medical science to provide cures that basically focus on mitigating symptoms of a mature disease hatched over time in an inflamed state of the body created in major part by our behavior and foods we produce.

This brings up Kass’s step number four: are there alternative approaches that minimize burdens? After the burdens have been identified from step three it is my opinion that the honest translation of fair representation of the scientific data supporting public policy action is part of the ethical guideline in minimizing the burden. Over-statement and misrepresentation using statistics by special interests or agenda driven action represents the antithesis of step four’s requirement to minimizing burdens by creating an overinflated burden This is
beyond Kass’s original scope to minimize burdens or search for alternative methods of intervention or policy to achieve efficacy. Kass’s example was if there are options to address a public health problem, each avenue must be evaluated in terms of burdens and compared to risks of other moral infringements upon liberty, privacy, right to self-determination and justice, assuming benefits meet goals and required resources are available.

Step five becomes relevant at this point as well: Is the implementation done with fairness? The author Kass references the ethics principle of distributive justice, requiring fair distribution of benefits and burdens. The example is given of clean water supply, which cannot be limited to one community. As compelling as this example might be, we must recognize that radically different theories of justice prevail in society and this can be a source of justification in using statistics to influence public perception. Kass references the notions of justice, based on John Rawls in which unequal allocation of benefits is allowable to correct existing inequities. Similarly, Norman Daniels calls for all members of society to be brought to a level of “species–typical normal functioning.” Both of these philosophies can create a heavy burden in a society that advocates equal opportunity but not necessarily equal distribution. In my interpretation there is an ethical duty to clearly identify the burdens imposed in the name of fairness so as not to sacrifice undue loss of personal freedom or create a dependency upon
governments to define values, concepts or imposed minimums beyond that which affords choice and opportunity to individuals to improve their station in life. Redistribution via involuntary forfeiture imposes a burden of justice difficult to accomplish in a large population where one must examine individual rights versus the public welfare. Nevertheless there are justifications for public need outweighing individual rights especially when public health is at risk. When coercive restrictions and legislative methods are utilized there is a heavy burden to overcome when considering the negative rights granted to the citizens in the US.

There are further considerations within these last two ethical guidelines to consider. Progress is being made in developing cures to CID that halt the progress of the disease or in rare cases hope to reverse some of the damage. These drugs are enormously expensive to discover and in our world of dwindling public funds the ethical issue is properly raised as to whether these expensive therapies will be affordable to those affected, yet least able to pay? The cost of CID on the individual and their family is great, but an even greater, ever increasing cost burden is being placed on a society determined to care for this growing pool of CID afflicted, many with more than one chronic inflammatory disease. Current approaches are not defeating the disease; they only provide a fighting retreat in hopes of slowing or stopping the disease progression. Often the
disease progresses over a lifetime and manifests its intolerable effects after
damage is irreversible. The sufferer may simply accept the disease as part of life
with hope of only slowing progression while obtaining some level of comfort and
relief from pain. In some cases surgical replacement and repair of body parts and
organs offer relief, but as previously discussed at a heavy cost to society. These
maintenance drugs modify and change processes within the body and even
relatively short-term usage can create interactions and unintended
consequences. Some people believe that pharmaceutical companies have
deliberately focused on creating maintenance drugs in order to prolong profits.
This is unfair and fails to recognize that we have a very different disease from
what we have faced in the past. Chronic inflammatory disease is enabled if not
directly triggered by a body whose system is already imbalanced by an inflamed
state. Contrast this to fighting an infectious agent introduced into a once healthy
body (not in a state of constant inflammatory alarm) and you can appreciate we
have created a battlefield that favors disease.

What we have created by diet and lifestyle in the developed nations is a
system that creates normality of chronic disease. The system is supported by
many inputs; the population is one input into this system and has become a focus
by many in public health in part because people are direct users of health
services. The evidence presented clearly shows the costs of healthcare have
already reached unsustainable levels to treat these diseases. Another input into this modern system is the food supply. Food is plentiful with unlimited choices and those choices often favor the less healthy foods due to taste preference or processing with preservatives that allows distribution food. Overconsumption of food and a low exercise lifestyle are indicators of success of a society that can feed its population. But the system we have created as a result of such affluence is allowing us to eat ourselves into disease and premature death. Eating and exercising behavior alone is not the sole cause of the deterioration of health. It is a complex and interactive system that is too often being oversimplified by those influencing public health hoping for quick solutions using coercive.

Beginning at childhood we develop this constant alarm state of inflammation state that provides an environment to culture and grow complex metabolic and immune related disease over time. Contrast this to the recent past when the body was in a relative healthy state when attacked by an infectious agent awakening the inflammatory response and immune system that returned to rest after defeating the foreign agent (germ). If our body’s natural defenses were overwhelmed we relied on modern medicine to identify the culprit and create a drug to cure the disease (remove the infectious agent). This allowed the body to recover to a healthy state (no longer in a state of inflammatory response). There are many people that recognize that reliance on pharmaceuticals is not the way
to cure CID. Many now understand that reversing the rise of inflammatory disease will not be accomplished by a magic bullet; rather it will be a slow process of improving the system, or more correctly changing the inputs to produce desired results. There is no lack of solutions being debated or implemented to try and fight this epidemic. If you live in the United States the trends illustrated in this thesis show that if you do not already suffer from a CID you would likely suffer from a CID in the future. One of the failures in translating science to public health is to allow the perception that science will cure CID as it vanquished infectious disease. We continue to feed the public promises of scientific discovery around the corner to produce a miracle drug to cure their disease. Or in the near future the promise of regenerative medicine to replace those organs and tissues ravaged by age and disease will be realized. But the cost for such technology is enormous and it’s likely no society can afford or distribute such a solution on an equal basis. Reality demands that we identify what parts of the system we can economically change.

There are some simple ways to aid the individual in recognizing mistranslation of science that will be discussed in this thesis. There is also a need to educate consumers in recognizing carefully parsed language in advertising by companies selling and marketing dietary supplements, vitamins, herbs and botanicals, amino acids, metabolites, extracts, or combinations of
those ingredients. This is a giant industry using language that implies claims of relief and cure without providing evidence. Recognizing the limits of such claims is well within the grasp of an educated consumer. This recognition may be applied to advertisement for an over the counter supplements to cure an ailment but also to a public official justifying a policy or regulation claiming benefit to the public welfare. It will be pointed out that the floodgates of over-expectation of benefit through misleading advertisement by the vitamin and food supplement industry were opened by well intentioned lawmakers whose action created a shield from the standard of accountability that is adhered to by the pharmaceutical industry and regulated in the United States by the Food and Drug Administration (FDA). Misuse of statistics overburdens the human brain with the mind’s inherent limitations to relate large numbers in terms of relevancy and priority of problems, often deliberately to advocate political agendas or obtain public funds.

These problems and issues to be discussed in this thesis are only a few of those we face, and raising personal awareness and knowledge about the causes in order to make better choices is only part of the task. As mentioned earlier chronic inflammatory disease is thriving from the very foods we are producing to feed the growing multitudes of people. Our application of technology for food production has accomplished higher yields of foods that gratify taste and satisfy
appetite but it seems these same foods that meet the growing demand of our expanding population also produces an environment inside the body that is friendly to chronic inflammatory disease. Although the United States boasts of having a free market system there are necessary controls such as those for the banking industry to basically insure deposits. But at times oversight can become tampering with detrimental effects.

At first glance the complexity and enormity of all that needs to be addressed in the fight against chronic inflammatory disease is overwhelming. But the insight that research science is providing has identified many if not most of the causes of CID and has provided insight into treatment and cures. In the past, fighting infectious disease, knowing the cause and understanding the cure would certainly allow actions to reverse the rising occurrence of the disease but with CID this is not the case. It is evident that knowing the causes and cures for chronic inflammatory disease is the easy part of our fight against rising CID in the US. The obstacle is in proper implementation of the cures, changing a complex system containing many stakeholders.
CHAPTER IV

IMPROVING NOT TAMPERING

Discussion in this thesis has been divided into four chapters, the first establishing the gravity of the problem that inflammatory disease poses to our society followed by an examination of the mechanisms triggering this class of disease. The reader should now understand how CID is a “disease process” developing over a lifetime fed by our diet, lifestyle, food processing and ultimately the choices made by each individual. The third chapter compared how the successful methods of the past, led by improvements in sanitation and breakthroughs in developing medicines to treat and remove the infectious agents (germs) have failed to stem the progression of chronic inflammatory disease. It is worth repeating the fact that the same developed nations that defeated infectious diseases of the past seem to be hardest hit by growing chronic inflammatory disease. The third chapter examined how our population can be misled by innumeracy and flawed logic in the interpretation of research data and improper, even deceptive use of statistics. But this chapter discusses how statistical methods, when applied correctly, can offer a tool to reverse the trend of CID.

It has been made clear this disease of inflammation within the body is a destructive process working over time so it seems fair to suggest that actions to reverse the trend of CID must be framed as continuous improvements over time.
to remove the many factors that create the environment inside the body to trigger CID. I will suggest that improvements be targeted on two fronts: the system controlled by the individual such as lifestyle, and diet, and the system of food production and dietary supplements and self administered therapy for CID.

Thinking of CID as a process that creates disease over time is paramount to recognizing that the cure lies within changes in that process with improvements and benefits accruing over time. The foundation of a tool to make continuous improvements over time is found within the analytical tools of statistical process control (SPC). This thesis has pointed out how easily it is to disguise and misrepresent the data using derivative and inferential statistics. The tools of SPC are very direct and reasonably easy to understand and track improvement. Properly applied statistics can provide a method to understand, interpret and track success in reversing the trend of inflammatory disease.

This chapter reinforces what I believe is the single most important insight for those wishing to measure positive improvements in public health intervention. That insight is to identify the difference between natural occurring variation within a system (or process) and variation that is not normal and can be removed. Both types may have undesirable outcomes but the later allows adjustment to an existing process, while the former carries the more difficult task of changing the process by those that create the process (or system). This thesis examines CID
as a system and discusses the analytical tools and theories that are part of the method of improvement in addition to the ethical guidelines that moderate change. Public health must rely on population statistics to provide analysis of what is occurring to our population in terms of health and assure changes made are having positive effects and reducing costs. What we have is a system that has expanded over time with many inputs that contribute to both very desirable and very undesirable outputs. There is expected variation within any system often identified as undesirable defects or leading to an undesirable final product. When efforts are made to change any system including the inputs, one can worsen the system without a basic understanding about the nature of the defects and how a change can be made without worsening the product of the system.

Some defects may be inherent to the system and represent normal, random variation found everywhere in life. In those cases where the variation is part of the system itself, we would need to change the whole system in order to eliminate the targeted variation. Analytical tools also can be used to determine if a system is stable (controllable) or in a state of chaos (uncontrollable). When one considers all the varied components that comprise the system that feeds the growth of CID including laws and regulations, mistranslation of science, and misinformation on dietary supplements, I would venture a guess that there are few, if any processes associated with CID that could be classified as stable and
in control. But even in chaotic systems a rational objective method following ethical guidelines for implementation can be applied in order to identify the types of defects causing the undesired outcome. Change without this knowledge of variation and methodology is simply tampering and in almost all cases will result in creating more variation and undesirable outcomes. Examples will be provided in this chapter of how well intentioned changes are made in health care that are clearly actions of tampering with the system, increasing variation and worsening the desired product making it more expensive or containing greater defects.

In order to improve a system methods are needed to monitor and track changes to improve the system. A simple process chart can record temperature inside your home at fixed intervals throughout the day. As the temperature rises and falls the points on the graph reflect this change with an upward trend during the heat of the day, and a downward trend with the cooling night. Your desired outcome of the climate inside your home is a comfort zone which we can call the “upper limit,” which establishes the warmest comfortable temperature, and the lower limit, which reflects the coldest comfortable temperature. As the temperatures are recorded every 24 hours the chart of this “system” reflects the normal variation as the sun heats your home and it cools during the night. The temperatures inside your home may be outside your desired limits, but the system is stable with normal variation, simply having undesired product. You can
remove heavy clothing during the day and add back clothing at night to try and stay comfortable but such actions have no effect on the system of climate in your home; the cycle of temperature will vary but it is normal variation. If the output of a system in control is unacceptable then you must change the system to produce desired results.

Suppose we change the system in your home by adding a heat pump that cools during the day and warms during the night and you add a control to turn the system on and off. In the evening you feel a chill so turn on the heat, but it gets too warm so you turn on the cooling. You repeat this constant chase adjusting the heat pump and begin to see your control chart reflecting a lot of erratic jumps up and down and often outside the desired maximum and minimum temperatures. So you change the system again by adding a thermostat that is preset and automatically controls the heating and cooling. Your control chart now reflects your change with temperatures fluctuating but within those limits you deem comfortable. But perhaps those limits are too narrow, causing the heating and cooling to cycle on and off resulting in a very high electric bill. So you widen those limits to establish a comfort zone that you can afford and the chart reflects an occasional point or two above the max and min, but this is normal variation within the limits of your thermostatically controlled system. The next month you notice your electric bill is higher than expected and review your charts to discover
there is an occasional point or two above and below the limits, and a few points
way above those limits you set, and even a series of consecutive points just
barely running above or below your limits. What you are now viewing is two types
of variation occurring in your system. Recognizing the difference in this variation
is the basis of analytical tools used to improve a system generally termed SPC.

Just as the simple process of controlling temperature in your home was
depicted above, any information (data) from a process or large system, no matter
how complex, can be collected and plotted on a chart. The “comfortable
temperature limits” used in the previous example are most often derived from the
actual measurements using statistical formulas to establish upper and lower
limits for reasonably expected variation. If the measurement breaches the upper
or lower limits then one can predict when action can or should be taken. Reaction
is determined by rules such as how many data points were above a limit line, or
how far the data exceeded the established limit. Again in the simplified example I
offered of controlling temperature in a home, the points that occasionally went
above or below the limit lines represented normal variation in the process.
Perhaps a door opening allowed a pocket of warm air to influence and trigger the
thermostat to slightly over heat or cool. But the extreme points above or below, or
a series of outlier points, indicate a cause that is not statistically normal. Perhaps
your grandmother was feeling a chill or sweats and turned the thermostat up and
down throughout the day trying to keep it within her ideal comfort zone. This could represent over control or “tampering” in an otherwise stable system. Upon investigation you would discover an assignable cause for that variation.

Using these statistical rules to identify and understand the nature of the process was what a statistician named W. Edwards Deming (1900-1993) focused on for the majority of his life. His ideas began to formulate when he was employed at the Western Electric Hawthorne Illinois manufacturing plant during 1925 and 1926. This plant was a parts supplier to monopoly company Bell Labs and represented the early beginnings of mass production of a new communication technology called the telephone. The demand was overwhelming as the company needed to produce thousands upon thousands of relatively simple electronic components that comprised the telephone. The parts needed to be identical and defects had to be minimized to lower the costs of repair and replacement out in the field. It was here where another famous statistician name Walter Shewhart became Deming’s mentor, leading to his own development of statistical tools that could measure, control and improve any process including services, manufacturing, or a system design to fight disease.

Deming’s philosophy and statistical methods to improve quality in any process went unrecognized and largely ignored throughout the period preceding and following the end of WWII. At the onset of WWII quality and standardization
became critical issues for production of arms and ammunition. The statistical
tools developed by Shewhart continued to be applied to reveal unacceptable
levels of defects in a batch of mass produced weaponry. Many countries
including U.S. manufacturers adopted quality control systems that minimized the
presence of defects through inspection. Acceptable levels of defects were
established in a shipment (lot) through a random inspection method with
frequency and sampling quantity pre-established by statistical tables. These
tables predicted how many defects were present, often measured in parts per
thousand or parts per million. When a particular lot failed inspection, it was
manually re-inspected to see if the discovered defects were a random fluke. If
upon the second inspection a lower acceptable level of defects were found then
the whole lot was passed. If on the other hand, after a second or even third
random inspection failed, the lot was finally rejected or was simply 100%
inspected to cull out as many defects as possible through very inefficient and
costly human inspection.

**Changing the Paradigm with Statistical Process Control (SPC)**

The statistical tools developed by Shewhart represented a philosophy of
quality that presumed a certain defect level would be considered acceptable. The
method by which the acceptable level is determined is to randomly sample a
quantity from the batch, inspect the samples and log defects in order to predict
how many total defects were in the batch. This quality paradigm was impossible for Deming to change and he found few audiences willing to adopt his somewhat radical philosophy that no "controllable" defects were acceptable in any process, manufacturing or service. Customers accepted the paradigm that some level of defects was inevitable, and inescapable. Customers were also accustomed to having their items in the repair shop, whether it was a kitchen toaster or a car, even if purchased brand new. Simply delivering the quantity of manufactured goods, even though defects were known, was sufficient for the only nation with the capacity to produce the goods from the likes of Westinghouse for home appliances or Ford and General Motors for automobiles. When a quality issue arose from an inspection, the lot was inspected until enough defective parts were culled in order to pass and ship the lot. The customer had no other standard of quality to compare and paid for the defects.

Deming continued to preach his philosophy of quality improvement after the end of WWII but his words continued to fall upon deaf ears as U.S. manufacturers were locked in their mass production and quality through inspection paradigms. Japan, much like Europe, had its manufacturing industry totally devastated by the war but a unique opportunity to change paradigms was presented to two men, General Douglass MacArthur and Dr. Edwards Deming. MacArthur's task was to replace the de facto dictatorship cast-like society with a
free market system based on representative government and a free market
system. Powerful family-controlled financial and industrial conglomerates had
dominated Japan’s economy since the 19th century holding great influence over
Japanese national and foreign policy. These market cartels were called zaibatsu
and represented partnerships of vertical monopolies. It is not difficult to draw
general similarities between the post war zaibatsu and the current market system
within the United States having financial, economic and political cartels lobbying
and supporting one another through complex economic and market controls. It
was this corporate culture in Japanese society that General MacArthur
recognized as unacceptable, preventing the free market reforms he wanted to
establish. Being the victor in war afforded him the power to eliminate control by
those traditional industrial/governmental zaibatsus. At this same time General
MacArthur recognized the need to establish metrics to measure the changes he
was making and ordered a team of statisticians to begin taking a census to
quantify what he was changing. Dr. Edwards Deming was one of those
statisticians and would make a positive impact on the Japanese economic
philosophy that would arise from the disbanded system of zaibatsu.

Deming began to preach his quality philosophy to any that would listen.
Although the zaibatsu economic system was gone the families had survived and
were adapting to this drastic change in their culture no longer controlled by
concentrated economic stakeholders they entered a new competitive environment. The once favorable economic playing field established by those families no longer existed. Family names such as Toyota, Honda, Mitsuiu and Sumitomo along with Panasonic were now leading fledgling manufacturing companies on a leveled playing field while trying to compete against the US industrial might untouched by the ravages of war. Japanese products in the early 1950’s were not known for their high quality or technological advancement. As factories were rebuilt and the free market economic infrastructure matured the “Made in Japan” label carried this early connotation of poor quality and low technology products. This stigma hindered the introduction of early Japanese automobiles into the US market. Such early manufactured automobiles rivaled the level of quality of their US counterparts but the US auto industry was firmly entrenched in the culture and those first imports from Japan struggled even though priced below their competition. Those same Japanese manufacturing leaders and engineers such as Toyota and Honda recalled Dr. Deming’s efforts to teach his philosophy of quality improvement using statistical measures. He spoke to small groups and meetings of Japanese engineers of how such a system could be incorporated into the manufacturing process to continuously improve quality and in so doing would lower manufacturing costs. This was a radical philosophy countering the traditional belief that increased quality control
was accomplished by tighter inspection to cull out defects slowing production lines and adding costs. The dominant US auto industry played little heed to Deming’s quality philosophy using statistical process control.

In 1950 Dr. Edwards Deming, then a professor at New York University, was invited to present a series of seminars to the leading Japanese business leaders and engineers. The Japanese leaders embraced the Deming theory on quality improvement using statistical methods for process improvement. They committed to this change in manufacturing philosophy and instituted Deming’s ideas throughout their factories by identifying defects that could be eliminated in a statistically monitored system. This focus on in-process defect identification and elimination by those operating the machinery was radical in transferring the decision-making responsibility from traditional management to the worker. As Deming predicted this approach resulted in a constant improvement culture that was driven not by the managers that built the system but rather by the worker operating the process. This meant training the common laborer in both the philosophy of constant improvement as well as understanding the data they were using in making decisions. This control of knowledge and process granted to operators who were part of the system was heretofore unheard of in factory hierarchy where decisions traditionally came from managers, to supervisors, to operators. This reliance on empowerment to make decisions based on workers’
analytical tools was a revolutionary idea, breaking with traditional paradigms. It is important to note that without removing the central control and interference from company owners and managers through General MacArthur’s disbanding of the concentrated economic power of Japanese zaibatsus, this empowerment of the factory worker would likely never occurred.

Deming called it a cultural transformation of the workplace that started when teaching the same philosophy to management was taught to those operating the machinery. Sharing the goals allowed both to feel ownership in the process. And finally, they make the investment to provide training in using these analytical tools to measure and control their own processes, taking responsibility to make decisions to stop or start a machine that was traditionally never allowed at the operator level. The results of this shift in manufacturing paradigms were soon evident; the American buyer of automobiles began to notice these lower cost Japanese imports seemed to never be in the shop for repairs compared to their more expensive American counterparts. As the Japanese manufacturers continued on their continuous improvement march, defects were identified and eliminated from the process improving quality; production speeds picked up and costs were lowered. The traditional manufacturing view in the United States was that quality was expensive, involved loss of product through rejection, slowed production speed and simply added cost to the finished product. Soon it was no
longer just the reliability and lower cost of the Japanese automobile that sold
cars; they began to innovate, adding style and options to offer overall greater
value. This Deming system quickly acquired legendary status as the Japanese
recognize him for igniting the Japanese manufacturing and technological
revolution in the 1960’s and beyond. It was a cultural shift started by an
occupying army removing the zaibatsu economic system and having it replaced
by a system that empowered the common worker with knowledge and decision
making authority previously reserved to the managers. One of the most
prestigious business awards presented by the emperor of Japan is The Deming
Medal, awarded annually to a leading company demonstrating excellence in
quality and production.

Deming’s theory of continuous improvement, along with the analytical
tools of SPC can also be used to begin a process of reversing trends of CID in
this country. The correct application of statistical tools as outlined by Deming and
others meets the critically important second guideline presented by Kass “How
effective is the program in achieving its goals”. I believe that using the tools of
statistical process control also begins to satisfy Kass’s step #5, “Is the
implementation done with fairness,” and #6 “Can benefits and burdens be fairly
balanced,” by requiring a burden of statistical proof that actions taken are indeed
reversing the trends of CID for the population as a whole, rather than splintering
benefits to individual stakeholders. I am suggesting that part of meeting Kass’ fourth guideline of “alternative approaches that minimize burdens” is in part met by empowerment of those members that do not create or control the system that feeds growth in CID. Education of the population seems best suited to a citizenry granted unique negative rights against policy and intervention no matter how well intended. Coercive intervention is justified when an immediate threat to public safety is identified such as unsanitary conditions leading to infectious disease. By using the ethical guidelines established by Kass, the success of implementing actions and policies to reverse the upward trend of CID through a process of continuous improvement will focus attention on whether there are measureable results in an economic system that in many ways resembles the zaibatsus of post war Japan. The application of Deming’s theory of system improvement fits well with the ethical guidelines of Kass and the absence of the authoritarian control that General MacArthur had at his disposal in post war Japan.

Deming stressed the need to think in terms of processes whether it be manufacturing or providing service. There can be multiple and interacting processes running inside a large system that produces a desired output. Even within a complex and interactive system one can define the processes that produce the desired outcome, and identify key measurements or goals to track. A chart is created of those metrics and serves to alert if undesirable events occur.
or the quality of the product is unacceptable. Those key elements that define the product being produced are considered part of the process but some are labeled as common cause variation whose random occurrence is expected and normal. The other form of this variation is assignable cause and represents variation outside the predicted norm. This assignable cause variation can be identified and removed to improve stability. It is important to distinguish these two sources of variation because chasing common cause in a system is fruitless as it is natural to the system created. But special cause when identified can be removed with immediate improvement to the system. A stable system contains only common cause variation and produces an outcome that may or may not be acceptable. In this case the system must be changed in order to obtain desired results. The complex system that enables the growth of CID in this country is not stable as it is riddled with assignable cause and common cause. It is a complex system that is considered in chaos making it very difficult to properly identify the nature of causes producing unacceptable results. This chaotic system includes the low activity lifestyle of behavior, choices in diet, quantity of food consumed, dietary and health related supplements and the market system that produces and processes the available foods. All of these elements can be considered as processes within a complex interactive system each capable of creating and sustaining state of inflammation within the body. What is evident is that this
system is producing unacceptable results evidenced by the rising incidence of CID in the US.

**Special Cause and Common Cause**

This historical review of Deming’s philosophy and suggestion it be used as a method for correcting unacceptable results is far from unfamiliar to those working to improve healthcare systems today. This theory of improvement using analytical tools of statistical process control has been successfully applied in many areas for decades with varying results in improving quality, enhancing competitiveness and lowering costs within the healthcare industry. It is standard operating procedure in production of pharmaceuticals, laboratory equipment and medical devices, and has been used to improve the quality of service that medical institutions deliver to the patient.

Understanding and recognizing the occurrence of these two types of causal variation is important. The following is a list of some examples of common cause and assignable cause variation:

**Common Cause variation**

- Improper, inadequate instructions or procedures given to the operator
- Poor working conditions, e.g. climate extremes, poor lighting, dust
- Raw material defects unable to meet processing requirements
Response of process controls to maintain temperature or pressure

Normal machine wear and tear

A genetic predisposition to store fat resulting in being overweight

Healthcare waiting time

**Assignable Cause variation**

Operator falls asleep, or otherwise occupied (texting)

Operator does not follow instructions or procedures.

Operator adjustment of process controls chasing common cause variation

Equipment failure

New personnel

What should be recognizable to the reader is that the above examples could switch their category of variation depending on the process they occur within and what is presented as cause in the process could well be a sub-process in itself. The previously used term of tampering was defined as making a change to a process under the assumption it is addressing an assignable cause, when in fact, the change being made is to a common cause that is both expected and random occurrence natural to the system. Chasing common cause is a
waste of resources. The healthcare system is neither stable nor containing only common cause variation, and the categories of variation may change and become worsened by tampering.

The analytical tools of SPC are ideal to monitor and continuously improve a process if the system is stable -- containing almost entirely common cause variation with the unexpected assignable causes quickly identified. If in this case the results produced are unacceptable then the system must be changed to achieve different results. In the case of a system in statistical chaos such as the current state of chronic inflammatory disease, it is difficult to identify variation types; thus, making changes to the system or attempting to adjust or eliminate common causes only serves to add cost and increase variation yielding no consistent improvement in the desired result. One asks the question of “where to start?”

I believe it is not so much the identification of root causes of problems represents our current position in fighting CID, as it is “identification of root solutions” by a public that must make decisions in lifestyle and dietary choices. Unfortunately as has been pointed out in this thesis in the rush to solve problems those influencing and managing public health are doing a poor job of understanding root cause and providing the public with the knowledge to make healthy decisions. Even when a complex system such as public health is in a
state of statistical chaos, improvements can be accomplished through proper root cause analysis, which this thesis has defined as performing the ethical duty of due diligence to translate science into actions that benefit public welfare. The basic tools of analytical measurement advocated by Deming and others can be applied to track improvement in key measurements such as providing knowledge about choice of healthier diet. What Deming stressed as the first step was that top management must adopt the new philosophy of constant improvement and empowering those that operate the system.

A research paper presented in 1996 by James C. Benneyan at the Quest for Quality and Productivity in Health Services Conference discusses and provides examples using statistical process control to measure and improve health care quality\textsuperscript{40}. The author expands upon how the Deming theory stresses the need to break traditional paradigms of management by stating how roles between management and worker need to change. Benneyan states “a common theme emerges that management’s job is to study process performance and remove barriers which inhibit its performance – rather than evaluate, reward, and/or penalize individuals for system problems often beyond their control. Deming, in fact, was quite clear that a fundamental purpose of collecting and analyzing data is to understand and improve the process and \textit{neither for scrutinizing nor grading} the individual performance and value of the individual".
In the context of this thesis, both the public suffering from CID and suppliers of the foods are inputs into the system, while those public servants that have authority to manage and influence public health policy represent the management of the system.

A hypothetical example of a control chart applying some of the most basic analytical tools of SPC is shown below. A weekly measurement of inflammatory markers in a patient’s body is depicted. The vertical “y” axis represents the degree of inflammation detected and the horizontal “x” axis plots the frequency that the measurement was taken. The mean was calculated from the data and used to draw the center line (9.9) and 24 points are plotted in this chart. The first “unexpected event” is in having a run of seven points below the control line (CL), which is not likely to happen in a stable system. This would represent an assignable cause to investigate since the data is not acting in a random fashion. There is also a point above the upper control limit (UCL) that would also require attention as it is statistically predicted to be an assignable cause. The last 3 points shown are high but fall within the control chart limits; thus, they are likely to be common cause variation and so investing time and resources to find their cause will probably not improve the output of the system.
In the hypothetical example above the assignable cause for the "statistical run" could perhaps be because the patient followed a different diet low in arachidonic acid after reviewing this next table published by the National Cancer Institute\textsuperscript{41}.

**Table 2**

<table>
<thead>
<tr>
<th>Rank</th>
<th>Food Item</th>
<th>Contribution to intake (%)</th>
<th>Cumulative contribution (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Chicken and chicken mixed dishes</td>
<td>22.6</td>
<td>22.6</td>
</tr>
<tr>
<td>2</td>
<td>Eggs and egg mixed dishes</td>
<td>17.8</td>
<td>40.4</td>
</tr>
<tr>
<td>3</td>
<td>Beef and beef mixed dishes</td>
<td>7.3</td>
<td>47.7</td>
</tr>
<tr>
<td>4</td>
<td>Sausage, franks, bacon, and ribs</td>
<td>6.7</td>
<td>54.4</td>
</tr>
<tr>
<td>5</td>
<td>Other fish and fish mixed dishes</td>
<td>5.8</td>
<td>60.2</td>
</tr>
<tr>
<td>6</td>
<td>Burgers</td>
<td>4.6</td>
<td>64.8</td>
</tr>
<tr>
<td>7</td>
<td>Cold cuts</td>
<td>3.3</td>
<td>68.1</td>
</tr>
<tr>
<td>8</td>
<td>Pork and pork mixed dishes</td>
<td>3.1</td>
<td>71.2</td>
</tr>
<tr>
<td>9</td>
<td>Mexican mixed dishes</td>
<td>2.7</td>
<td>73.9</td>
</tr>
<tr>
<td>10</td>
<td>Pizza</td>
<td>2.6</td>
<td>76.5</td>
</tr>
<tr>
<td>11</td>
<td>Turkey and turkey mixed dishes</td>
<td>2.7</td>
<td>79.2</td>
</tr>
<tr>
<td>12</td>
<td>Pasta and pasta dishes</td>
<td>2.3</td>
<td>81.5</td>
</tr>
<tr>
<td>13</td>
<td>Grain-based desserts</td>
<td>2.0</td>
<td>83.5</td>
</tr>
</tbody>
</table>

Specific foods contributing at least 1% of eicosatetraenoic acid in descending order: shrimp and shrimp mixed dishes, soups, regular cheese.

Last Modified: 22 Sep 2013

Figure 8
Diet could also be attributed to the data point that is above the upper control limit (UCL) if, for instance, the patient had a large meal of chicken the night before. Assignable cause variation is what can be controlled, or repaired in a system. Chasing after common cause simply wastes resources.

SPC, even when applied in very basic formats such as the above hypothetical chart, can be used in early root cause identification of undesirable defects (such as raised inflammatory levels in the body) within a system that is statistically unstable. The upper and lower control limits may begin very wide and gradually be narrowed as improvements are made. The upper and lower limits can be arbitrarily established but normally set using standard deviation calculations of the actual data (known as sigma). In the early stages of process improvement these limits can be set at 1, 2 or 3 sigma, which predicts that 68%, 95%, or 98.7% of the common variation, respectively, will fall within these limits. Points outside these limits are suspect as being assignable cause and not inherent random variation. In a “stable process,” limits may be tightened to further increase sensitivity to detect the most minute assignable cause variation. Setting limits too narrowly when beginning the improvement process would make it an even greater challenge to identify variation, let alone determine if it is common to the system or a special, assignable cause.
A systematic review of examples of how the analytical tools of statistical process control can be applied in health care is presented in a paper that appeared in the journal Quality & Safety in Health Care. The authors begin by explaining, “Statistical process control (SPC) is a philosophy, a strategy, and a set of methods for ongoing improvement of systems, processes and outcomes.” They emphasize that improving healthcare performance requires us to change our way of working and note that change does not always mean improvement. They also state “the techniques of statistical process control, which have proved invaluable in other settings, appear not to have realized their potential in health care”. In actuality their research uncovered a wealth of applications in health care, citing 57 articles. Only 22 studies included in the review actually tested the utility of SPC; of the four controlled studies, only one included a control chart in the intervention and it was used as a minor component, which did not fully exploit the capabilities of SPC.

Nevertheless, this review thoroughly documents the utility of SPC as applied to a very wide range of medical conditions. Several tables appear in this review that I have chosen not to include in this thesis; instead, I simply summarize that the article listed nearly 100 variables that various SPC processes in medicine have measured, including; blood glucose, fasting blood sugar, asthmatic patients, patient pain scale, blood pressure, heart rate, days between asthma
attacks, average lengths of stay, times to administer treatments, total hospital length of stay, patient complaints, medication errors, acute bronchitis treatment, number of diabetes patients, average cost of hip replacement, patient satisfaction, and employee training. This list of variables contains a high percentage of indicators related to chronic inflammatory disease. The interested reader is strongly encouraged to read this review in its entirety, for the wealth of detail it provides.

The results and examples of the application of SPC listed in this referenced work lay a framework for how the analytical tools of SPC are presently being used to enhance treatment of patients suffering from chronic inflammatory disease. Going beyond treatment of individual patients, this thesis examines how SPC might be used to reverse the trend of CID across the population at large.

Deming discussed two roles within a system: management and the worker (or operator). The management is responsible for setting the goals, designing the system and providing the raw materials, the tools and the method of operation to name a few. Deming also believed management was responsible for unsatisfactory results 92% of the time. In this discussion I would categorize management to include those making public policy and regulation, furnishing information used to make healthcare decisions, providing dietary and health food
supplements, and the industry that provides and processes food. The worker role is the general public. Deming used a number of teaching tools in his classes to demonstrate that if the system was poorly designed the overall quality being produced would not improve regardless of how hard the worker tried to prevent defects.

This thesis contends that the rise in chronic inflammatory disease in the US represents management failure in many areas including mistranslating science, providing unsuitable material (food), promoting health food and dietary supplements with misleading and/or unproven claims of benefit. When one compares Deming’s definition of management responsibility to all six of Kass’s guidelines it becomes evident that improvement in quality defined as reversing the upward trend of CID in the US will not come from the worker (public) but rather require changes from the stakeholders that have created and maintained the system that is producing undesirable results. All six guidelines are the responsibility of management applying Deming’s responsibility assignment.

1. Establish programs with clearly defined public health goals

2. Provide metrics to determine how effective the programs are achieving goals.

3. Identify known and potential burdens
4. Investigate alternative approaches to minimize burdens

5. Assure implementation is done with fairness

6. Fairly balance benefits and burdens.

**History Repeats Itself**

Individuals can change their eating and lifestyle choices to improve their health but I do not believe that the public alone can accomplish the reversal of CID in this country. I have used Deming’s model of the factory worker to represent the public and Deming stated that the managers of the system were over 90% responsible for undesirable results. Those that govern, those that grow and distribute the food supply, and those that advocate and produce the dietary health supplements represent the managers in the U.S. today. In many ways the US system mirrors the cultural and economic environment that Japan exhibited at the end of WWII with the powerful families controlling the economy and culture. Part of that collection of interest groups in the US is found in the government regulations and laws that have tampered with the systems without being held accountable for results in terms of reversing the trend of CID. Positive similarities include a culture that values hard work and craftsmanship. The United States is unique with a fierce attachment to personal freedom and individual choice, but this country’s economy is unhealthy and being challenged, not from a
post war reconstruction, but in major part by an overwhelming and unsustainable cost for public health care with an aging population afflicted by epidemic proportions of chronic inflammatory disease. Many public health solutions, programs and suggested actions mimic the soft tyranny imposed by the victor of war to reorder both the infrastructure and societal behavior that General MacArthur undertook to transform post war Japan. In this scenario there was little requirement that the General in charge weigh the benefits against the potential harms before initiating changes. It is a mistake to apply this previously successful paradigm of coercive action in the United States unless a governing authority gains absolute power unrestricted by laws or negative rights afforded to its citizens. It is doubtful such power could be wrested without creating far greater harm than benefit, regardless of the public health improvement. Current attempts at coercive intervention by the government to improve fair distribution of healthcare through the population are neither universally popular nor appear successful in meeting stated goals. This is why I feel that successful actions to reverse the upward trend of CID in the US must incorporate some form of the ethical guidelines proposed by Kass.

When the oligopolies in Japan were disbanded along with the artificial controls and rules they were eventually replaced by smaller independents in a market “with less tampering”. Using Deming philosophy along with a cultural
tradition based on valuing hard work and quality craftsmanship a rational system of continuous improvement with measurable results was applied with resounding success. These same virtues are present in a major segment of the United States market-based system of health care.

Certainly an aging population will continue to add strain on the health care system within the United States and many other countries. The process of reversing CID growth will resemble the squealing sound of brakes slowing of a giant freight train before it finally comes to a halt and very slowly gains momentum in the opposite direction. For some removing the constant state of inflammation in the body may prevent or deter the onset of CID, while others may already be suffering and not yet realize it. The majority of medicines are at best only mitigating symptoms of these diseases, and cures may be far too expensive to afford at a time when medical costs are racing past dropping revenues and a slow growth in gross national product. Science may develop treatments but they will simply be unaffordable to all but a few. This creates an ethical dilemma of choosing the persons that will be offered the cure and what attributes this selection will be based upon. This ethical dilemma is confronted by Kass’s guideline #6 “how can the benefits and burdens be fairly balanced?” One part of the answer to this question may involve consideration of persons that take personal responsibility in making correct choices in diet and lifestyle. But not all
persons are educated to recognize healthy choices or readily obtain or afford these foods. This is part of the system that is management responsibility.

One of those “managers” of the system is the massive “grey market” of self-medication using over the counter drugs and herbal remedies. There is a tremendous volume of misinformation that oversimplifies causes and cures to CID. Perhaps our public health improvement efforts would be better served by restoring accountability of manufacturers to clearly state claims for their health supplements and provide clinical proof. The goal of advertising is to sell the product and clever statements are often misleading. This grey market of health foods and dietary supplements contains the potential infrastructure for making a very positive impact in reversing CID trends but not within the current unregulated system. Today’s market of self-medication represents every worst-case scenario described in this thesis and more. Mistranslation of scientific findings that are further misrepresented to the public is carefully worded advertising that promises potential cure that is never held accountable. Innumeracy in statistics allows deception, and misleading elevation of problems that syphon off resources to special interests while having little or no effect in reversing CID in the population.

In 1994, the US congress enacted the Dietary Supplement Health and Education Act (DSHEA), which amended the Federal Food, Drug and Cosmetic
Act to establish standards with respect to dietary supplements and other purposes. Congress cited a number of justifications to support their legislation that included: the importance of nutrition and the benefits of dietary supplements to health promotion and disease prevention documented in scientific studies; the link between the ingestion of certain nutrients or dietary supplements and the prevention of chronic diseases such as cancer, heart disease, and osteoporosis; and clinical research showing several chronic diseases can be prevented simply with a healthy diet, such as a diet that is low in fat, saturated fat, cholesterol, and sodium, with a high proportion of plant-based foods. It is also noteworthy that Congress further added that: preventive health measures, including education, good nutrition, and appropriate use of safe nutritional supplements will limit the incidence of chronic diseases, and reduce long-term health care expenditure; and consumers should be empowered to make choices about preventative health care programs based on data from scientific studies of health benefits related to particular dietary supplements.

This abbreviated list of citations was used as justification for the enactment of the DSHEA. They represent public health goals that Kass outlines as her first guideline. But what are lacking are goals that are clearly defined and associated with measurable results. The goals appear consistent with argument presented in this thesis as to reasons to reverse the upward trends of CID in the
US but there is an obvious lack of metrics to measure the success in achieving the goals. Another citation in the DSHEA states: studies indicate that almost 50 percent of the 260,000,000 American regularly consume dietary supplements of vitamins, minerals, or herbs as a means of improving their nutrition, and the nutritional supplement industry is an integral part of the economy of the United States and consumers are placing increased reliance on the use of nontraditional health care providers to avoid excessive costs of traditional medical services. In order to enable greater access to dietary supplements the DSHEA restricted the Food and Drug administration from their regulatory responsibilities and authority over supplements as long as manufacturers made no claims about preventing or treating disease with their product. Many would object that the advertising language and references to efficacy claimed by dietary supplements violate the intent of this law using skillful language that references cures and prevention in scientific research to disease without using words that make a direct claim for their specific drug in preventing or treating disease.

The first guideline outlined by Kass states that proposed programs have goals clearly defined and require proof of measurable improvement in public health. I would suggest that dietary supplements represent a program having intended benefit to public health and the DSHEA should be augmented to require proof beyond the general references since consumers are purchasing these
supplements with the intention of promoting better health while reducing health care expenditures. One example offered by Kass is a cardiac risk reduction health education program. Such a program should have an ultimate goal (or be part of a larger goal) of lowering heart attacks. The goal is not that individuals become aware that changing their behavior will reduce heart attacks. Rather the investment in this program should yield improvement in terms of actually lowering heart attack risk. For example those participating should agree to be tested to measure the effectiveness in changing behavior since this evaluation provides crucial feedback in whether the program achieves health improvement. Kass offers a caveat that every program must achieve an end goal; epidemiological studies may provide data that may later provide scientists insight on developing intervention resulting in reduction of morbidity or mortality. The point being made is that health programs including education, intervention or epidemiological studies be designed with awareness of resources being spent to the ultimate goal but not necessarily limited only to reduction of morbidity or morality. Other types of social benefits can be gained from public health programs. Reduction in sick days or increased employment can become measures of program success as well as less tangible benefits such as strengthening communities. The author also states that an intervention with a goal of improving access to health care by hard to reach populations would offer relevant improvement in public health. The
dietary supplement industry may not be required to meet the stringent standards imposed by the FDA on the food and drug industries, but there should be an obligation by those advocating and selling dietary supplements to prove health benefits beyond generalized correlation to scientific studies that were not designed for the supplement being marketed. The mere disclaimer that such a statement “has not been evaluated by the Food and Drug Administration” and that “this product is not intended to diagnose, treat, cure or prevent any disease” should not suffice. If this statement were truly made clear to the consumer then the product has no benefit to public health and no worth being ingested.

Kass’s second step places a burden of proof on the program or intervention regarding its effectiveness in meeting the stated goal. In my opinion it is this measurement requirement that distinguishes this stepwise process of implementation as an analytical tool, much like the tools of statistical process control used to analyze raw data. The design of any program to effect improvement must first examine what data exists in order to substantiate the achievement of goals. For example, a cardiac risk reduction education program has the reduction of cardiac events (both fatal and nonfatal) as its goal. Improving awareness of how personal behavior affects cardiac events may be part of a larger program with goals to stop smoking, change diet, or increase exercise. Many health education programs are very effective at raising
awareness and communicating information but less successful at inducing permanent change in behavior. Thus the author Kass states, “…While a rather narrow evaluation may demonstrate success (in terms of participants’ understanding the message), a program ultimately cannot claim success if behavior is unaffected and the key measures of morbidity and mortality remain unchanged.”

Kass does not require that each program or intervention reduce these key measures by themselves. Health education might provide an additional part of a behavior changing process that does effect positive change in morbidity and mortality. This analytical approach suggests a multidimensional campaign in different formats is appropriate and useful if data show that the combination evokes measureable improvement. However the author is quick to remind that multiple approaches that are hypothesized or assumed to improve key measures must be required to have further research to support such goals before being justified. While all programs must have some level of evidentiary basis rather than simply informed speculation, Kass points out that the quality and availability of existing data will vary.

Stemming the tide of inflammatory disease that has developed over decades from harmful foods in our diet, overconsumption, and an affluent lifestyle will require many changes to a complex system. In the United States this
poses a conundrum because our society values personal liberty along with a free market system. This struggle is apparent as well-intended public health policies and systems meet stiff opposition and become quickly burdened by the shortcomings of a state applying centralized controls to a complex system, moving at a pace that no bureaucracy can match. The struggles bog down with political division, competing agendas, and seemingly overwhelming logistical obstacles.

But just as there are proven tools to improve a process, there are stepwise methods for those that manage public health to use in forming consensus about solutions to reverse the trend of chronic disease. The changes are necessarily gradual and need to follow an ethical management formula rather than relying on the state’s coercive power and authority to pass laws for public health improvement. “The need for a code of ethics for public health then, might be viewed as a code of restraint, a code to preserve fairly and appropriately the negative rights of citizens to noninterference”. Taking coercive actions such as private property seizure, closure of businesses, destroying animals, or treating individuals against their will are certainly instruments available to use in protecting the public’s health, but such actions may mimic the same failed approach we are taking in fighting CID, using the methods that were used against infectious disease. Our approach to fighting CID must be different just as
the methods used to fight the causes of chronic disease are different than those used to kill agents of infectious disease.

Kass states, “The question for policy and ethics analysis, then, is what quantity of data is enough to justify a program’s implementation?” The rule of thumb offered is “the greater the burden posed by the program—for example, in terms of cost, constraints on liberty, or targeting particular, already vulnerable segments of the population—the stronger the evidence must be to demonstrate the program will meet its goals.”

Many public health programs are imposed on people by government and not necessarily requested by citizens. There is an ethical responsibility to demonstrate the validity of a program’s assumptions and ability to meet the goals claimed. This second step requires substantiated examination of existing data and proof of efficacy and raises the bar above assumption and bias. This particular guideline requires proof be given by both those that challenge a program or intervention as well as those responsible for implementation. Those who initiate policies or programs in the name of public interest very often neglect this step. Communication to all stakeholders is a challenge in and by itself, but in a sense, public health policy that infringes on individual rights seems to call for informed “public” consent similar to that established for individuals in the Common Rule. It is my opinion that circumventing this burden of evidence for
efficacy in any behavior modification, intervention, public policy or law will create
greater problems than it solves. This is even more relevant for a country whose
population values individual rights and noninterference from government.

The author Kass references the ethics principle of distributive justice,
requiring fair distribution of benefits and burdens. The example is given of clean
water supply, which cannot be limited to one community. As compelling as this
example might be, we must recognize that radically different theories of justice
prevail in society. The author references the notions of justice, based on John
Rawls in which unequal allocation of benefits is allowable to correct existing
inequities.36 Similarly, Norman Daniels calls for all members of society to be
brought to a level of “species–typical normal functioning,”37 which advocates
unequal distribution of resources. Both of these philosophies create a heavy
burden in a society. In my own opinion there is an ethical duty to closely examine
the burdens imposed in the name of fairness so as not to sacrifice undue loss of
personal freedom or create a dependency upon governments to define values,
concepts or imposed minimums beyond that which affords choice and
opportunity to individuals to improve their station in life. Redistribution via the
involuntary forfeiture imposes a burden of justice difficult if not impossible to
accomplish in a large population when one must examine each individual need
versus each individual capacity to provide, along with factors of personal choice
and personal effort. When coercive restrictions and legislative methods are utilized in this manner I believe it is an insurmountable burden to justify at least within the rules of this government of negative rights granted to the citizens.

**How can benefits and burdens be fairly balanced in fighting CID?**

In segment 6 of her ethical framework of analytical tools for public health, Kass asks the reader an all inclusive question: “if it is determined that a proposed public health intervention, policy, or program is likely to achieve its stated goals, if its potential burdens are recognized and minimized and if the program is expected to be implemented in a nondiscriminatory way, a decision must be reached about whether the expected benefits justify the identified burdens.” I believe many of the well intentioned efforts to date have failed either in a mistranslation of the cause, an unsound or invalid analysis of how to correct the problem, or a misguided and poorly executed public health response.

This thesis has focused on chronic inflammation disease, which is out of control in pandemic proportion with public health declining at an ever-increasing rate. The cost of this disease to society both in terms of individual suffering and unaffordable expense has created public health responses that often fail to translate research science to properly identify cause, let alone create a public health plan that can reverse the trend of this disease.
Based on the Kass framework, I would propose a public health improvement system that requires a verifiable education for the public about the same basic awareness presented in this thesis. Health education seems like a promising intervention to use in a society that holds individual liberty and protection of privacy in such high esteem as the United States. Learning is voluntary with the goal of empowering the individual with the information to make informed decisions regarding their health. In terms of protecting individual liberty and imposition of burdens, education is easier to justify than most interventions and is probably present in most if not all public health intervention strategies in varying degrees.

How large a role education can play should be determined by applying the analysis from the first two steps above: what are the public health goals and how effective is the program in achieving those goals? Education may not work in all settings, or the intervention may aim for a speed of results that requires a more coercive strategy if the intervention is to be successful in protecting public health. A concern is the questionable ethics of an education campaign that is not focused on presenting the facts to allow an informed decision but relies on some form of manipulation or imagery to influence thinking or even coercion. Another concern in health education is found when targeting messages to a specific demographic group even when justified on grounds of protecting public health.
Promotions on billboards, radio and TV stations may stigmatize members of the targeted group creating negative perceptions in the public eye.

Reversing the trend of CID in the US population poses a unique circumstance for improving public health; the cure for the population is rooted in changing lifestyle choices and dietary habits of each individual. Educating the public has been an obvious theme throughout this thesis with illustrations of how the results from scientific research can be mistranslated and misinterpreted, but I believe there is a significant segment of our population that will remain very vulnerable to the marketing and advertising techniques and practices to selling dietary supplements that may not deliver on customer expectations. I am not about to suggest that the DSHEA act be repealed, but I will suggest that the reasons and safeguards cited to enact this legislation have been allowed to fall by the wayside while the dietary supplement industry has continued to grow and prosper while very little progress is being made in reversing the trend of CID. The DSHEA removed the oversight of the FDA that is present in the pharmaceutical industry and I doubt the limited resources of this watchdog agency will allow them to evaluate the advertising statements made by the industry. But perhaps a strongly worded warning label similar to what was added to tobacco products could be useful in causing consumers to stop and evaluate spending money on products that can make no claim of treating, diagnosing, or curing disease. I
believe this important distinction is being lost in the fine print and artful use of advertising language. I would also suggest that a greater burden be placed on companies supplying health related products to the public by legally empowering individuals to bring suit against products that have not clearly stated they have no proof that their product can diagnose, cure or treat CID.

Any public health intervention or program including those addressing the over the counter market of self medication and dietary supplements should pass through an ethics framework similar to those discussed in this thesis. Perhaps a consumer ombudsman organization could be formed along the lines of the institutional review boards used by research institutions to monitor research involving human subjects. Such a review board could be comprised of members of the community, physicians and representatives from the companies manufacturing dietary supplements to approve the advertising claims. The methods, statistical tools and moral guidelines discussed in this thesis lead me to believe this country can create public health policy that will reverse the increasing trend of chronic inflammatory disease with a balance of benefit and burden to the entire population while preserving freedom of choice, tolerance for individual lifestyle, pursuit of happiness, and protection of individual privacy.
REFERENCES


2. Scientific method is a systematic pursuit of knowledge involving the recognition and formulation of a problem, the collection of data through observation following an experimental method, and the formulation and testing of hypothesis - Merriam-Webster online

3. The Socratic Method is named after the classical Greek philosopher Socrates and lightly defined in this thesis as a form of debate or inquiry very familiar to the legal profession (but defined in greater detail) in which the questions asked stimulate critical thinking. A negative method of hypothesis elimination used by mathematicians stating statistical problems versus the positive support of a hypothesis used in most scientific investigation.


9. Hippocrates c. 460 - c.370 BC was an ancient Greek physician during the age of Pericles during the Classic period of Greece. He is considered a primary figure in the history of medicine and is often referred to as the “father of western medicine. Founder of the Hippocrates School of Medicine he established it as a distinct and separate intellectual field of study and revolutionized the study of medicine in ancient Greece.
10. Source: "Content Analysis of Oaths Administered in U.S. Medical Schools in 2000, Academic Medicine, September 2004


13. Center for Disease Control and Prevention. MMWR weekly, vol. 59 / No. 39 October 8, 2010


21. The mechanism of aspirin used for thousands of years to relieve pain was originally derived from the bark of the Willow tree. How it worked remained a mystery until in 1971 British researcher Sir John Vane and associates discovered how this widely used pain and inflammation reducing drug (salicylic acid) worked by blocking the production of prostaglandins.

22. Essential nutrients cannot be synthesized by the body or produced in sufficient quantity to maintain a healthy body although the body can then convert these nutrients into other molecules needed in our metabolism.


30. Hippocrates (see reference 9.)


33. Weinberger D. Too big to know: rethinking knowledge now that the facts aren't the facts, experts are everywhere, and the smartest person in the room is the room. New York: Basic Books; 2011.


38. I have summarized the original notions of Total Quality Management and continuous improvement trace back to a former Bell Telephone employee named Walter Shewhart. One of W. Edwards Deming's teachers, he preached the importance of adapting management processes to create profitable situations for both businesses and consumers, promoting the utilization of his own creation -- the SPC control chart.

Dr. Shewhart believed that lack of information greatly hampered the efforts of control and management processes in a production environment. In order to aid a manager in making scientific, efficient, economical decisions, he developed Statistical Process Control methods. Many of the modern ideas regarding quality owe their inspiration to Dr. Shewhart.

He also developed the Shewhart Cycle Learning and Improvement cycle, combining both creative management thinking with statistical analysis. This cycle contains four continuous steps: Plan, Do, Study and Act. These steps (commonly referred to as the PDSA cycle), Shewhart believed, ultimately lead to total quality improvement. The cycle draws its structure from the notion that constant evaluation of management practices -- as well as the willingness of management
to adopt and disregard unsupported ideas --are keys to the evolution of a successful enterprise.

39. Definition of PROCESS

I have summarized three definitions of this term as follows,
a : progress, advance <in the process of time>
b : something going on : proceeding

2
a (1) : a natural phenomenon marked by gradual changes that lead toward a particular result <the process of growth> (2) : a continuing natural or biological activity or function <such life processes as breathing>
b : a series of actions or operations conducing to an end; especially : a continuous operation or treatment especially in manufacture

3
a : the whole course of proceedings in a legal action
b : the summons, mandate, or writ used by a court to compel the appearance of the defendant in a legal action or compliance with its orders

40. Benneyan, James. Using Statistical Process Control to Measure and Improve Health Care Quality, Mechanical and Industrial Engineering-University of Massachusetts Amherst, MA

41. [link]


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47. Chilton FH. Potential phospholipid source(s) of arachidonate used for the synthesis of leukotrienes by the human neutrophil. The Biochemical journal. [Research Support, Non-U.S. Gov't Research Support, U.S. Gov't, P.H.S.]. 1989 Mar 1;258(2):327-33.


63. Chilton FH, Murphy RC. Stimulated production and natural occurrence of 1,2-diarachidonoylglycerophosphocholine in human neutrophils. Biochemical and


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Education
May 2014  Wake Forest University, Winston-Salem  
Degree awarded, Master of Arts - Bioethics

August 2004 – June 2006  Forsyth Technical Community College  
Degree awarded, Associate of Applied Science Biotechnology

May 1973 New Mexico State University  
Degree awarded, Bachelor of Science - Biology

Chronological Work

2009 – Present  
KERANETICS LLC, Winston-Salem, NC  
Director GLP Laboratory Operations for an advanced bioscience company  
focused on creating keratin protein based applications for therapeutic,  
regenerative medicine and cosmetic science products. Administrative and  
management duties include supporting quality assurance with vendor  
qualification, authoring manufacturing procedures for contract  
manufacturing organization (CMO), purchasing and material/equipment  
research with strong vendor negotiation skills, inventory control, and  
document control. I am the environmental site coordinator for hazardous  
waste disposal, employee training and facility compliance. I have a wide  
range of laboratory bench skills for performing research experiments and  
product development. Skills in all aspects of mammalian cell culture,  
cryopreservation and working with BSL-2 viral pathogens in a GMP  
environment. Experience and training in quality theory, statistical methods  
and facilitating teams for process improvement translate into the research  
and bio-manufacturing environment. Information technology strengths  
include maintenance/support of cloud based Exchange Server and support  
for users in a MAC/PC based environment. I established a file sharing system  
via Mac OS server developing a MAC OSX based LIMS solution for data  
access/sharing between researchers and instrumentation.
Work History

Biotechnology

2006 – 2009

Wake Forest Institute for Regenerative Medicine, Winston-Salem

Laboratory Technician level III GMP Facility (2009)

GMP Core Technician III, promoted as construction of clinical translation GMP laboratory was started. Trained for working in a Class 100 facility (gowned cGMP) and experience writing SOP’s.

Laboratory Technician II WFIRM (2006 – 2009)

Responsible for total management and training for this labs cell culture facilities, four fully equipped cell culture rooms with 32 incubators and 16 biological safety cabinets. I created an inventory system for tracking and reordering supplies and created custom reports using Crystal Reports X providing faculty a tool to monitor and better manage costs.

2004 – 2006 obtained associate degree in biotechnology

Forsyth Technical Community College

Updated credentials to enter the growing bioscience industry.

Completed internship at Wake Forest Institute for Regenerative Medicine, after completing internship was hired full time as core manager.

2001 – 2004

PMI Inc., Lexington, NC

Quality Assurance and Technology Manager

Metal furnishings manufacturer. Installed ERP data collection system and trained employees. Accepted position to manage QA/QC 3 shift department and administer database/ERP system. Created custom reports using Crystal Reports to provide process improvement tracking reports to accurately calculate total costs for producing products.

1999 – 2001

INFORMATION SYSTEMS SERVICES, Lexington, NC

Enterprise Resource Planning Consultant

Installed and trained users of an ERP relational database product. This included design of network architecture and installation, updating existing software and assisting users in creating a database for cost estimating, job production, real-time data collection, inventory control, purchasing, accounts receivable, accounts payable, and payroll systems.

1998 Part Time

FORSYTH TECHNICAL COMMUNITY COLLEGE, Winston-Salem, NC

Instructor CIS 111

Taught Microsoft Word, Excel, Power Point, and Access Database
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Work History

Manufacturing

1985 – 1997 SARA LEE CORPORATION Winston-Salem, NC
(1995-1997) QPI (Quality Productivity Improvement) Manager
Managed three-shift operation for Quality Control and CAD/Pre-production and plate making departments with nine direct reports. Facilitator for self-managed teams providing performance measurement and goal achievement.

(1990-1995) Manager, Quality Control/Productivity Improvement
Managed department operations, customer contact and response for quality related issues and provided employee training in quality improvement philosophy, methods and develop self-managing teams.

Managed document printing with full profit center responsibility.

(1987-1988) Manager, Shop Floor Data Collection/Reporting System
Installed and maintained system for automated data collection.

(1985-1987) Supervisor, Quality Control
Supervised three shift operation for packaging fulfillment, package inspection and manual assembly.

Professional Certifications And Training

✓ Part time community college instructor for Estimating and Job Costing for small business owners.
✓ Past President of Hagen Users Group for member companies using automated data collection.
✓ Created and illustrated innovative biology charts for use in teaching basic biological principles.
✓ Developed innovative, self-contained teaching kits for high school and junior college biology principles.
✓ Co-owned medium sized advertising and printing company.

References Available on Request