Spring 2017

Direct-to-Consumer Drug Advertisements and Their Effects on Doctor-Patient Relationships

Alicia DeLeon-Dowd

DIRECT-TO-CONSUMER DRUG ADVERTISEMENTS AND THEIR EFFECTS ON DOCTOR-PATIENT RELATIONSHIPS

A thesis submitted to
Regis College
The Honors Program
in partial fulfillment of the requirements
for Graduation with Honors

by

Alicia DeLeon-Dowd

May 2017

Thesis written by

Alicia DeLeon-Dowd

Approved by

Thesis Advisor

Thesis Reader

Accepted by

Director, University Honors Program

TABLE OF CONTENTS

LIST OF FIGURES

ACKNOWLEDGEMENTS

I would first like to acknowledge my thesis advisor, Dr. Franco. It has been through her dedication and commitment to this project that has allowed for its successful completion. She has worked diligently with me, making sure everything is the best it can be. In addition, I would also like to thank my reader, Dr. DiSanto. He has provided me with insightful feedback, and he has made sure that all of my arguments are coherent. I would also like to thank my family and friends. Without their support and constant encouragement, I would have not been able to complete this project. They always believe that I can achieve anything my mind to, and this thesis is evident of that. Lastly, I would like to thank the Regis University Honors Program, Dr. Howe and Dr. Kleier. The Honors program challenges it students to think on a deeper level and to always be passionate in everything that they do. I am honored to have been a part of this program and believe that it has laid a foundation for my success in the future.

I. Introduction

Medicine has had a very significant impact on my life. When I just 5 years old, my mom was diagnosed with breast cancer. Having beaten the disease, we felt that we, as a family, were in the clear. Fast-forward to the beginning of high school, and my world was changed. My dad had three surgeries, one hip replacement and two to replace femoral hairline fractures, in three months. Our lives never really went back to "normal", and I have not seen my dad walk without some sort of assistance since. So my relationship with medicine and with doctors has been somewhat complicated. I have seen the wonders they can do, which I will discuss more later in this chapter. I have also seen how it can fail and change lives not necessarily for the better. There are many factors that determine the outcomes of certain diseases, but I believe that one of the most important is the doctor-patient relationship. There are also many factors that can affect that relationship, one of them being direct-to-consumer (DTC) drug advertisements. However, before explicitly discussing how DTC advertisements affect doctor-patient relationships, it is important to give some context as to how the medical field has evolved to what we know it to be today. In doing so, we will have the necessary foundation to understand how and why DTC advertisements affect doctor-patient relationships.

To begin, medicine, or rather the study and practice of medicine, has existed in every period of history where people have had to deal with disease and illness and had to find a way of resolving those ailments. How each period coped with its circumstances is a reflection of the time and the culture. Although some historians include ancient Egypt in

their discussions on the history of medicine, I will omit that period and begin with ancient Greece as it is more associated with the Western medical tradition. The most prominent figure to come out of ancient Greece was Hippocrates, who is widely known as the "Father of Medicine." He wrote a collection of texts and essays that have led to the tradition of Hippocratic medicine, which is largely the foundation of Western medicine. This tradition greatly emphasizes the patient rather than the disease itself, and it established the well known motto "At least do no harm" (Magner, 1992). This motto is still recited by today's physicians showing the lasting influence Hippocrates had. Along with explaining the role of the physician, Hippocrates was one of the first people to not blame the gods for the occurrence of the diseases because he believed that these diseases were a part of a natural process. Recognizing that there was not a causal relationship between the gods and disease is what Hippocrates believed made one a true physician (Magner, 1992). That is not to say Hippocrates did not believe in the gods, but he understood that nature played a pivotal role in medicine (Magner, 1992). With the insight of Hippocrates, the practice of medicine transitioned to a more rational way of thinking about disease. However, as time progressed into the Middle Ages, the Hippocratic tradition fell somewhat out of favor.

Medicine in the Middle Ages can be characterized by a complex interplay between medicine and religion, more specifically Christianity. Because Christianity was so prevalent through society, there was a shift in how people viewed the body and how it should be treated. The Greeks desired a healthy human body while Christians maintained a somewhat repugnant view of the body. That is, Christians could not view the body as

something to be desired, especially in a sexual context. However, they did believe that it deserved some care and respect because the body houses the soul, which is given by God. These beliefs led to a different way of healing illnesses. It involved prayers, exorcisms, etc. while Hippocratic medicine utilized empirical practices such as drugs, diet, and simple surgeries. Thus, there was clear difference between religious medicine and human medicine. Religious medicine relied on prayers, exorcisms, etc. while human medicine valued the use of drugs and simple surgical operations (Magner, 1992). Although practicing human medicine was not looked down upon, it had an unstable relationship with the Church, and that relationship had to be acknowledged. As time continued on, medieval scholars determined medical studies to be "an integral part of Christian wisdom" (Magner, 1992). That is, if all knowledge came from God, that included medical knowledge, and it began to be seen as a more serious subject to be studied. Thus, medical education was formally established in universities, but very few practitioners actually had university training. Despite this, in the Middle Ages, began the process of establishing medicine as a formal profession that included an education, standardized curriculum, licensing, and legal regulation. It was also during this time that the first "hospitals" were established. This term is used loosely because our current organization of hospitals is vastly different than the one used in the Middle Ages (Magner, 1992). Medieval hospitals were established for largely religious reasons and not scientific ones (Figure 1).

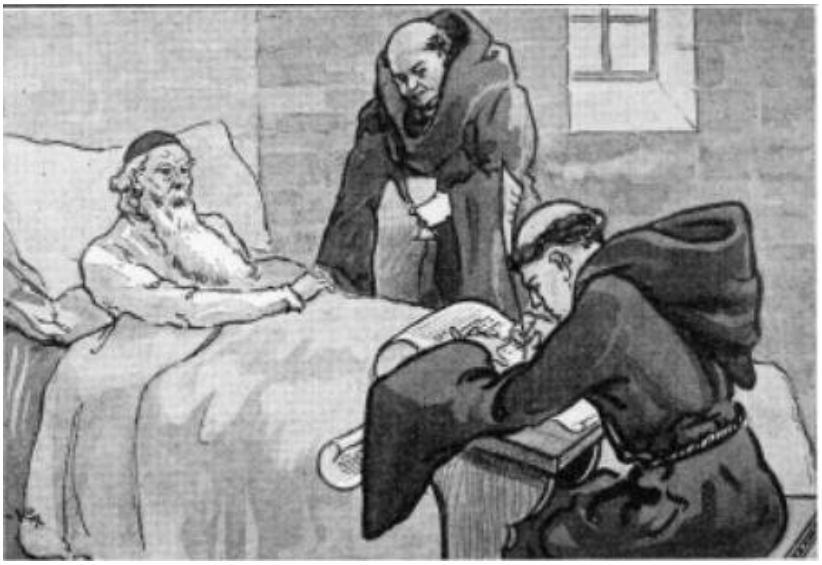


Figure 1. Image showing the role Christianity played in medicine during the middle ages (Medieval Life, 2013).

Medicine during ancient Greece utilized the practices established by Hippocrates while medicine during the Middle Ages was largely influenced by Christian tradition, but for both time periods, the treatments involved were not based on scientific reason. The Scientific Revolution was the beginning of the integration of medicine and science. Perhaps the most well known figure to come out of the Scientific Revolution, with regards to medicine, is William Harvey. Harvey discovered the circulation of the blood and changed the way people thought about the heart and the movement of blood (Magner, 1992). The Scientific Revolution also saw the use of phlebotomy and blood transfusions; although, neither of those practices would be perfected until an understanding of the immune system emerged (Figure 2). Nevertheless, the Scientific Revolution saw an increase in experimentation and began the process of using science to develop medical techniques. Although some of the techniques used were crude and

ineffective, it showed the interest physicians had in learning more about the body and finding ways to treat its illnesses using more effective means. These practices lay the foundation for more scientific research and developing improved techniques to treat different illnesses.

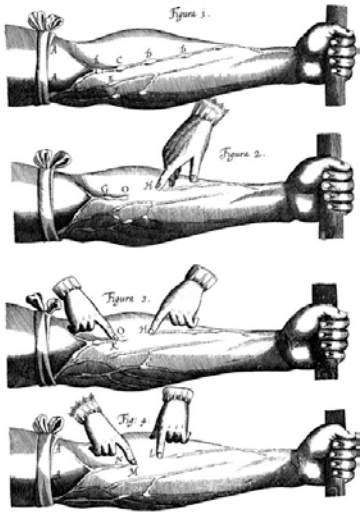


Figure 2. William Harvey discovered the circulation of during the Scientific Revolution (Schultz, 2002).

We can now enter into the modern era of medicine with scientists Louis Pasteur and Robert Koch leading the way. It was not until our understanding of microorganisms that scientists were able to develop treatments we are more familiar with today, and both Pasteur and Koch were instrumental in that understanding. Pasteur integrated several fields of science and is credited for identifying the role that microbes play in the fermentation process. Through these experiments, Pasteur became interested in disproving the spontaneous generation theory (Berche, 2012). In trying to show that microbes do not spontaneously generate in sterile medium, Pasteur developed the sterile techniques that gave way to modern microbiology and surgery (Magner, 1992). Pasteur was also a pioneer in the development of vaccines. Before developing a vaccine, he

became interested in infectious diseases during an epidemic of silkworms in southern France between 1865 and 1870 (Berche, 2012). Shortly thereafter, in 1878, Pasteur discovered a vaccine against fowl cholera. Like Pasteur, Koch, too, became interested in scientific research and began his work with *Bacillus anthracis*, more commonly known as anthrax. He discovered that bacteria could be cultured outside of the organism it was discovered in (Magner, 1992). He also discovered the bacteria that cause tuberculosis. Pasteur confirmed the causative role of *B. anthracis* (Berche, 2012). While Pasteur would go on to searching for a rabies vaccine, Koch began to research wound infection, and soon tuberculosis. The discoveries made by Pasteur and Koch, in conjunction with the germ theory, highlighted the idea that diseases could be controlled, and perhaps even stopped. It had implications for public health and triggered government-paid investigators to determine the sources of infection. It created a government-regulated medical profession, and "hospitals became one of the chief sites for scientific medicine in the nineteenth and twentieth centuries" (Jackson, 2011). In Western Europe, between 1883 and 1911, countries also passed national health insurance legislation, and shortly thereafter, there were regulations for food and drugs in the medical market (Jackson, 2011). As time has continued into the present age, a medical field with more government regulations was more commonplace. In regards to the United States, Jackson (2011) writes that the U.S. has become dependent on "big science" to solve its health issues, possibly because the U.S. does not have a national health care system, and thus, health insurance companies have become a defining characteristic of American medicine.

The history of medicine is long and complex, and a few traditions of medicine have been left out to provide clarity and to provide a more relevant history of the Western tradition of medicine that is the backbone of the today's tradition. Not every event in the history of medicine is still relevant today, but many themes are still relevant and have evolved into the practices that we are familiar with. These practices include treatments, scientific research, and patient-care. Thus, it is the medical practices of today that have sparked my interest in the field and that made me want to become a physician.

Looking back, I cannot pinpoint the exact moment that I wanted to become a physician. Rather, it was a succession of events that ultimately led me to the path that I am on today. One of those major events was the day my nephew, Ethan, was born. Ethan was born with a rare genetic disorder known as urea cycle disorder; he was diagnosed within 48 hours of being born. Only 15 at the time, I could have never predicted the impact that Ethan would ultimately have on my life. At 3 months old, he received a liver transplant from UCLA Ronald Regan Medical Center. Although there were other health complications along the way, today, he is healthy and as rambunctious as any 5 year old can get.

He is ultimately my inspiration for becoming a physician. I aspire to be like one of the physicians on the amazing team of physicians that provided Ethan with the best possible care as they were able to perform under dire circumstances. At all times, they remained calm and composed and were able to provide the best possible care for Ethan. Ultimately, that is what physicians should aim to do. Physicians should provide the best possible care even under unforeseen circumstances. This belief has been furthered

solidified by my time spent volunteering in an Emergency Department (ED) in Denver, Colorado. I saw the physicians providing care in a stressful environment to the best of their abilities. Often times, the patients are difficult and can be stubborn, which is expected. Patients are scared coming into the ED. Often, they do not want to be there and the long waiting time just adds to the anxiety they may already be feeling. Regardless, the doctors are expected to provide their patients with exceptional care.

Reflecting on these experiences, I began to consider what goes into "exceptional care." Does providing the best care only encompass achieving desirable results like a successful liver transplant? Or is writing a prescription a sufficient requirement for exceptional care? How much time does a physician need to evaluate, diagnose, and then treat a patient? It may seem obvious that this would require time; time that develops into a relationship with the patient, but is it even necessary for doctors to develop relationships with their patients? These thoughts led me into contemplating what it even means to be a physician and what his/her roles and duties are to his/her patients.

It became clear to me that the physicians who treated my nephew and those who work in my ED are practicing care that is ideal, and that care may not the standard but rather the exception. Doctor-patient relationships are becoming compromised in today's society, and I will be examining one particular issue that is compromising that relationship. Dr. Abramson, a retired family physician sheds light on this issue:

> The pressure from my patients to prescribe Celebrex and Vioxx did not let up, intruding into alliances that had been built up over many years. I tried to explain that these drugs offered no better relief than the older, less expensive anti-inflammatory drugs. I actually started to enjoy the challenge of trying to refocus my patients' attention back onto their underlying issues…I did my best to help them understand that their beliefs about these drugs were being masterfully

> manipulated by the companies' multipronged marketing efforts, and that these efforts were being driven far more by the goal of improving the drug companies' sales than improving patients' health or comfort. (Abramson, 2004)

Dr. Abramson was a physician for 28 years before he left his practice to write his book, *Overdo$ed America.* It tells of the new reality in American medicine; a reality in which television, magazine, and print advertisements of prescription drugs permeate our everyday lives. Those advertisements are known as direct-to-consumer drug advertisements, or DTC advertisements. The Federal Drug Administration (FDA) defines direct-to-consumer advertisements as "ads [that] are published in magazines and newspapers that are distributed to a general audience rather than to healthcare providers such as doctors, nurses, and pharmacists. DTC ads can also be broadcast through television or radio" (Drug Advertising: A Glossary of Terms, 2016), and huge amounts of money are being spent on DTC advertisements. Drug companies spent $4.5 billion on prescription drug TV advertisements (Millman, 2015). With that much money being poured into these advertisements, one has to wonder if the pharmaceutical companies have the patients' best interest at heart. The patients may not realize that their care can be compromised when there is an overload of drug advertisements giving them insight as to how physicians should provide care. They may not realize that the drugs being advertised are being advertised not in the best interest of the patients but in the best interest of the drug companies.

In today's world, it is nearly impossible to go anywhere or do anything without seeing an advertisement. Whether it is for clothes, makeup, or even drugs, they are everywhere, and it is very difficult to deny the influence that these advertisements have in

our everyday lives. Patients consume the information from the advertisements, and then go to their doctor with the information they received. However, not every advertisement applies to every patient. Doctors have to be able to communicate that not every drug-related treatment their patients see is going to be effective for whatever problem is being addressed. Thus, the doctor-patient relationship can be strained if the patient insists on having that particular drug. It then becomes essential for physicians to evaluate how to maintain their relationships with patients with the influence of drug advertisements, and in those situations, it becomes crucial for them to remember what it means to be a physician.

In my attempt to determine how drug advertisements are affecting doctor-patient relationships specifically, I will be analyzing, first, what it means to be a physician providing the best possible care. I will discuss physicians' roles and duties to their patients. To aid in this discussion, I will analyze the modern Hippocratic oath that many physicians recite today after completing their medical education. The oath provides an ethical outline as to how physicians should care for their patients and gives a more concrete understanding of the doctor-patient relationship. Once the role of the physician is fully understood, I can discuss how DTC advertisements are affecting doctor-patient relationships. After analyzing drug advertisements in today's society, I will then discuss what direct-to-consumer drug advertising might look like as medicine begins to evolve towards personalized medicine and determine how doctor-patient relationships might also evolve with personalized medicine. Although the overwhelming amount of drug advertisements in today's society leads some patients to better communicate with their

physicians, that communication does not lead to an improvement of the care the patient receives. Furthermore, those advertisements are resulting in skyrocketing drug prices and the inability for physicians to provide adequate care to their patients. Therefore, it is imperative that prescription drug advertisements be removed altogether or have limited availability to the general public. It is in the best interest of pharmaceutical companies and physicians to continue to put patient care and overall public health as priority.

II. Role of the Physician

The issue of drug advertisements brings up fundamental questions on what it means to be a doctor. Before I begin a discussion on how drug advertisements influence the care that doctors administer, it is important to begin with what physicians' roles are in the first place. There are different components to being a physician, and years of training are required. However, I will focus specifically on the role of the physician as it is related to diagnoses and treatments. It is ultimately how physicians develop relationships with their patients that will influence the diagnoses and treatments of those patients. Doctors must be compassionate, caring, understanding, and listen openly to their patients. Although developing these qualities and acting on them is at the discretion of the individual physician, there is an oath, or a variation of, that all doctors take at the end of their medical education that can serve as a guideline. The most widely used and well-known oath is the Hippocratic oath.

The original Hippocratic oath written by Hippocrates himself, is rarely used today. Instead, the modern oath was written by Louis Lasagna, the then academic dean at Johns Hopkins University, in 1964 (Eva, 2014). The modern Hippocratic Oath is as follows:

> I swear to fulfill, to the best of my ability and judgment, this covenant:
> I will respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow.
> I will apply, for the benefit of the sick, all measures which are required, avoiding those twin traps of overtreatment and therapeutic nihilism.

> I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon's knife or the chemist's drug.
> I will not be ashamed to say "I know not," nor will I fail to call in my colleagues when the skills of another are needed for a patient's recovery.
> I will respect the privacy of my patients, for their problems are not disclosed to me that the world may know. Most especially must I tread with care in matters of life and death. Above all, I must not play at God.
> I will remember that I do not treat a fever chart, a cancerous growth, but a sick human being, whose illness may affect the person's family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.
> I will prevent disease whenever I can, for prevention is preferable to cure.
> I will remember that I remain a member of society, with special obligations to all my fellow human beings, those sound of mind and body as well as the infirm.
> If I do not violate this oath, may I enjoy life and art, respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help. (“Hippocratic Oath”, 2004)

The oath touches on many prevalent aspects of today’s healthcare, but I will only analyze those lines in which patient care is applicable. The first line I wish to look at states, “I will apply, for the benefit of the sick, all measures which are required, avoiding those twin traps of overtreatment and therapeutic nihilism.” Overtreatment is the overuse of therapy, drugs, and psychotherapy. Therapeutic nihilism is exactly the opposite. It refers to undertreatment (Mamede & Schmidt, 2014). That is, the body should be able to heal on its own. Essentially, the oath is stating that there has to be proper balance of how a

patient is cared for. Letting the body heal on its own is not always the best or the most responsible mode of action, but overtreatment is just as harmful to the patient.

In regards to the relationship with the patient, the oath states, “I will remember that there is art to medicine as well as science, and that warmth, sympathy, and understanding may outweigh the surgeon’s knife or the chemist’s drug.” This line implies that there is a humanistic approach to medicine. Moving beyond science, “warmth, sympathy, and understanding” are necessary qualities for a doctor to have. Thus, it is emphasizing that caring for patients and treating them in a humanistic way is more important than the science of medicine. Patients are more than just bodies to practice surgeries on or to supply with drugs; they are people who should be treated as such. Treating people with warmth and understanding goes beyond solely trying to treat them. In fact, if treating a patient is actually degrading to who he/she is as person, then treatment should be avoided altogether.

The aforementioned line plays directly into the lines, “I will remember that I do not treat a fever chart, or a cancerous growth, but a sick human being, whose illness may affect the person’s family and economic stability. My responsibility includes these related problems, if I am to care adequately for the sick.” Caring for a patient extends beyond the illness itself. Physicians are treating “a sick human being” which implies that there is a certain standard to how they should be treated. Stating that humans are more than their illnesses shows a certain respect for not only their bodies but also their humanities. Furthermore, by stating that the patient’s illness could affect not only his/her family but its economy as well, implies that the physician is involved in something larger. Anything

the physician does has implications for the wider community. Therefore, it is necessary for physicians to think carefully about how they treat their patients and the larger impact on the patients, their families, and the greater society. If doctors can remember to do this, then they will be able to treat their patients not only with the appropriate treatments but also with a respect and dignity that all persons deserve. Doctors go into their profession with the intentions of healing, but they must remember that it is not just what they are healing but whom they are healing, the latter superseding the former.

The oath provides an ethical outline as to how physicians should provide care for their patients. It becomes evident that being a physician extends beyond the scope of scientific knowledge; it also involves a deep understanding of human nature (Hellín, 2002). Being a doctor extends beyond just knowing the science behind the medicine; it is also about realizing that the medicine is being applied to real people and should be held to a higher standard. Doctors must possess a wide array of knowledge and be able to retain information correctly so as to be of the most use to their patients. It is the best doctors that can use the knowledge they possess to effectively care for their patients. However, they must also possess qualities that show that they are understanding of people and the situations that they are in. There will often be times when patients and physicians live drastically different lifestyles, but they have to be committed to patient care regardless of the patients' lifestyle and value system (Hellín, 2002). Even if doctors themselves cannot relate to the situation their patients are in, they have to still show that they care and are willing to do what is necessary to improve the situation. Thus, doctors also have to be flexible, understanding, and fully committed to their patients. A physician

must provide care at all costs if it is in the best interest of the patient. Ultimately, the goal of the physician is to heal the patient with the understanding that the healing process encompasses being caring towards and having compassion for the patient.

Establishing a foundation for how patient care should be administered is essential to providing quality diagnoses and treatment. The first of the two, diagnoses, begins the process of effective treatment (Taylor, 2015). Diagnosis is defined as "the elucidation of the cause of heretofore unexplained symptoms, signs, and laboratory/imaging findings" (Taylor, 2015). Learning to diagnose is a skill that requires a significant amount of medical knowledge and learning how to apply that medical knowledge on a case-by-case basis. In order to be successful at that skill, a physician must also have a good memory, excel at physical examinations, and be an empathetic listener (Taylor, 2015). Of these skills, being an empathetic listener is perhaps one of the most important qualities. Patients are often more willing to disclose information to physicians they feel more comfortable with. It is through listening that a patient's current problem is discovered. Combined with the patient's medical history, an accurate diagnosis is dependent on there being an intimate relationship between the physician and the patient because the doctors must know a great deal of information about their patients and about their values (Hellín, 2002). That relationship develops as patients begin to feel more comfortable with their doctors, and they can begin to feel more comfortable with their doctor if they exhibit the aforementioned qualities. Furthermore, if there is an increased capacity for communication between the doctor and the patient, the strength of the doctor-patient relationship increases as well as the strength of the diagnosis.

Therefore, communication is essential to the development of doctor-patient relationship and leads to the most accurate diagnosis. Moreover, utilizing effective communication skills is becoming increasingly important when delivering the diagnosis itself. More than ever, there is an emphasis on full disclosure and communication skills in the medical field (Sisk et al., 2015). The American Hospital Association created "A Patient's Bill of Rights" in 1973, and from then on, patients have the right to know every aspect of their health and medical care regardless of severity (Sisk et al., 2015). Thus, knowing how to properly communicate about a diagnosis to a patient is becoming increasingly important. Of course, this is a challenging skill to learn and one that often improves over time, but it is essential to the discovery and the communicating of a diagnosis and then ultimately how a physician will treat said diagnosis.

Once a proper diagnosis is given, the physician can provide the best treatment. There are a myriad of treatments available, but the appropriate treatment must be administered for the given diagnosis. Many treatments today are administered according to science-based medicine and clinical guidelines (Taylor, 2015). However, it is possible that clinical guidelines can disagree, and while remaining aware of clinical guidelines is important, it is important to treat patients based on "evidence, experience, and clinical context" (Taylor, 2015). This means that the physician has to be knowledgeable about the current treatments available and consider any alternatives that might serve the patient better. When new treatments become available, physicians must also be knowledgeable about those as well. The physicians have to understand how the drugs work and their implications for patients. Each patient could potentially respond differently to different

drugs, and therefore, each patient might need a different treatment even if he/she have the same disease. The physician's full understanding of the drugs will help eliminate any unwanted side effects and mitigate any risks (Taylor, 2015). Thus, there are several important components that go into administering effective treatments.

Diagnosis and treatment are two crucial components of a physician's duties. The oath sets a standard for the practice of medicine that can be utilized when giving diagnoses and treatments. However, utilizing this oath in everyday situations becomes more complicated as the medical field itself gets more complicated. In theory, doctors should consider the Hippocratic oath everyday in their communication with and treatment of patients, but it will become clear in the next chapters that the principles of the oath can be forgotten in certain situations. It will become evident that the oath and the development of the doctor-patient relationships can shift when new complications, such as DTC advertisements, come into play.

III. A Brief History of Drug Marketing

Now that the role of the physician has been established, I can analyze how DTC advertisements can complicate that role. However, before discussing the drug advertisements of today, it is necessary to give a brief history on how they came to be in the first place. Much of the history of drug advertisements is connected with the FDA because it has largely controlled the regulation of drug advertisements. The FDA is responsible for many aspects regulating public health in the United States, including the safety of food, cosmetics, and medications among others. With regards to medications, the FDA is "responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health" (Federal Drug Administration, 2016). Because the FDA is responsible for regulating prescription drugs, it soon became responsible for regulating the advertisements of prescription drugs.

The regulation of prescription drugs began in 1906 with the Federal Food, Drug, and Cosmetic Act. The goal of the act was to provide consumers with the information about the effectiveness of certain medicines. The act was expanded in 1938 and again in 1962. It was in 1938 that proving the safety and effectiveness of drugs before they could be put on the market began. Prior to the provisions of this act and not until after World War II in 1945, self-medication, that did not have any scientific backing, was a popular practice. It was popular even more so than today because people were not seeking

pharmacological treatment as prevalently. Instead, prior to World War II, people were likely to self-medicate based off of unsubstantiated claims frequently found in newspaper advertisements. An example can be seen in an advertisement for cocaine toothache drops (Figure 3). The advertisement claims that the drops are an instantaneous cure, and people could obtain them without knowing if they actually worked and without recommendations from a physician. Shortly thereafter, drugs could only be obtained after a physician wrote a prescription. As a result, pharmaceutical companies began to advertise their products directly to physicians (Donohue, 2006). Prescription drug advertising was largely under the control of the Federal Trade Commission (FTC) prior to 1962, but in 1962, the FDA was granted jurisdiction over DTC advertisements (Donohue, 2006; Frosch et al., 2010).

Figure 3. Example of a drug advertisement prior to the enactment of the Federal Food, Drug, and Cosmetic Act in 1906 (Say Yes to Drugs?, 2014).

Final guidelines for drug advertising were issued in 1969. The advertisements: 1.) could not contain any information that was considered false or misleading, 2.) could contain a "fair balance" of the risks and of the benefits of using the drug, 3.) could present facts that are essential to the advertised uses of the drug, and 4.) must contain a summary of the risks involved with taking the drug (Boden & Diamond, 2008). The provisions, however, made no mention of advertising to the public (Donohue, 2006). The FDA does, in fact, provide an explanation as to why.

According to the FDA, there had been no necessary federal ban on DTC advertising because drug companies provided information about their products directly to doctors and pharmacists. They did this through medical journals, continuing medical education, sales calls, etc. (Abramson, 2004). It was not until the 1980s that some drug companies began providing more information about drugs to the general public, rather than to physicians, through advertisements (Background on Drug Advertising, 2015). In 1981, drug companies began advertising directly to the public and bypassing physicians. The first print drug advertisement was published in *Reader's Digest* by the company, Merck, that was advertising a new antipneumococcal vaccine (Ventola, 2011). Not long after, the first broadcast advertisement and print advertisements were put out by Boots pharmaceuticals to promote a prescription pain reliever, Rufen (Donohue, 2006). Boots was promoting a lower price of their version of ibuprofen as compared to Motrin, which was produced by McNeil Consumer (Figure 4) (Ventola, 2011).

Figure 4. Screen grabs from the first broadcasted drug advertisement by Boots pharmaceuticals promoting their product, Rufen, a pain relieve (Scott, 2015).

As a result of these advertisements, the FDA was forced to review its policies. In 1985, the FDA came to the conclusion that the these new drug advertisements would have to follow the same stipulations, such as the fair balance of both risks and benefits and the brief summary of potential side effects, which are outlined in the 1969 addendum to the Federal Food, Drug, and Cosmetic Act. Because of these stipulations, drug advertisements in the 1980s were largely print advertisements as the airtime was not long enough to include all of the necessary information as required by the FDA (Ventola, 2011). Drug companies, clearly not satisfied with these restrictions, applied pressure on the FDA to loose some of the restrictions (Abramson, 2004).

In order to address the dissatisfaction expressed by the pharmaceutical companies, the FDA held hearings in 1995 to discuss the regulations and potentially loosen its restrictions (Ventola, 2011). Pressure from the pharmaceutical companies forced the FDA to introduce new provisions for broadcasted advertisements in 1997 (Donohue, 2006). The advertisements no longer had to include a brief summary of the side effects; they only needed to include "major risks" and directives, such as a toll-free number, a print ad, a website, or a physician, for consumers to access the entire summary of potential side effects (Donohue, 2006; Ventola, 2011). Pharmaceutical companies quickly responded to these new policy changes, nearly doubling their spending on television advertisements. The amount of money invested into television drug advertisements climbed from $310 to $664 million between 1997 and 1998. By 1998, the total amount of money spent on all drug advertisements reached $1.3 billion. A majority of all spending for DTC advertisements transitioned to television advertising after the policy changes, and the 1990s saw nearly 80 percent of prescription drug advertisements focus on the drug itself rather than the medical condition (Donohue, 2006). The changes that took place resulted in a shift where pharmaceutical companies took the place of the physicians' diagnoses and treatment choices.

From the aforementioned statement, it could be argued that patients are consumers, and in fact, they are. However, should prescription drugs that treat serious illnesses be advertised in the same light as groceries? As was discussed earlier, "A Patients' Bill of Rights' was created in 1979. Patients have the right to full disclosure in regards to their healthcare, but it begins to get complicated when the patient becomes the

consumer. Where is the distinction made and what implications does it have in regards to drug advertisements? As was mentioned earlier, the 1990s saw a dramatic increase in the amount of information made available to patients. Not only was this information made available through televised advertisements, but also through the increase in technology, such as the use of personal computers and increased access to the Internet. Those gave patients access to a lot more information in regards to their healthcare and consequentially medical decision-making. It was also shown that in 1990, only about one-quarter of Americans felt confident with medical leaders as opposed to three-quarters in 1966 (Donohue, 2006). With this decline in trust and the increasing availability of information, it was inevitable that patients would begin to become more involved with their healthcare. It must be made clear that patients being involved in their healthcare are not the issue. The issue stems from DTC advertisements exploiting the changes that were occurring during this time, and any criticism of the advertisements was being ignored. It is evident that the amount of information made available to the patients along with expanding trend of patients becoming more involved in their care was responsible for the increasing amount of drug advertisements. The industry now invests billions of dollars into drug advertisements, and the criticisms of those advertisements are no longer being ignored. Critics of DTC advertisements come from physicians, consumers, and even some in the pharmaceutical industry (Donohue, 2006). There are concerns with whether or not the facts presented in the advertisements are actually beneficial to the patient and whether or not they are misleading patients. The advertisements have the potential to discredit physicians if physicians choose to not prescribe the advertised drugs. This could

be detrimental to physician-patient relationships and to the medical field as whole. Therefore, it is necessary to analyze how DTC advertisements have changed the healthcare industry, in what ways, and if there are any necessary changes that need to be made.

IV. Drug Advertisements Today

It seems as if everywhere we look, there is a new drug that is being advertised. What are doctors' moral obligations in providing the patient the best care they can while also dealing with outside sources essentially telling them how to treat their patients? How are doctors to respond to patients who insist on being prescribed a certain drug even if it is not in their best interest? Furthermore, if doctors do prescribe those medications, do they have some ethical obligation to ensure that their patients receive those medications despite their increasing costs?

Before addressing the physician's responsibility and DTC advertisements, the current FDA regulations on prescription drug advertisements need to be discussed. The regulations that were established in 1997 were not revisited until 2004 when the drug Vioxx, nonsteroidal anti-inflammatory drug (NSAID) used to treat arthritis, acute pain, and painful menstrual cycles was voluntary removed from the market (Frosch et al., 2010; Federal Drug Administration, 2004). Vioxx was one of the most advertised drugs in the United States from 1999 to 2004. The company that promoted the drug, Merck, spent nearly $100 billion promoting it, with nearly $1 billion in revenue (Ventola, 2011). In fact, Vioxx received Brand of the Year in 2001 as a result of the success of its advertising (Jaramillo, 2006). However, it was later found that Vioxx was linked to an increased risk of developing cardiovascular disease, and as a result, the drug was pulled from the market in 2004. Despite this, in 2004, the FDA again loosened regulations on DTC advertisements allowing print advertisements to only include a brief summary of the

product rather than the complete prescribing information (Ventola, 2011). This led the U.S. Senate leader in 2005, physician William Frist, to call for a two-year voluntary moratorium on DTC advertisements for newly approved drugs (Donohue, 2006). The purpose of the moratorium was to delay the time newly approved drugs were advertised directly to consumers to allow physicians time to understand the purpose of the drugs before they begin prescribing them to patients (Saul, 2005). In response to the proposed moratorium, some pharmaceutical companies announced a voluntary moratorium, and Pharmaceutical Research and Manufacturers of America (PhRMA), the pharmaceutical manufacturers trade group, proposed suggested guidelines that companies could adhere to with DTC advertisements. However, those guidelines were strictly voluntary, and it is not obvious whether or not the companies have adhered to the moratorium. Ultimately, no government regulations were put in place in regards to the moratorium (Ventola, 2011). Perhaps, this is why there was not a decrease in the amount of money being spent on drug advertisements after 2005 (Figure 5). In fact, as the amount of spending on DTC advertisements increased, FDA enforcement of regulations regarding DTC advertisements decreased (Figure 5). Several reasons are cited for this decrease, but the two main reasons are the same amount of staff remain to review the drug advertisements, despite the increase in number, and the FDA is underfunded (Ventola, 2011).

However, there was a decrease in spending of DTC advertisements from 2007 to 2008 because of the financial crisis that caused the economy to slow down, causing the first significant decrease in spending since 1998 (Figure 5) (Ventola, 2011). There was renewed interest on the issue in 2007 and again in 2009, but legislators failed to reach a

consensus on DTC advertisements, and thus, it remains a polarized issue (Frosch et al., 2010). The FDA plays a critical role in the regulation of DTC advertisements, but if it is failing to enforce regulations, patients are at risk of receiving misleading information. Legislators cannot adequately address the issue because it is such a divisive debate.

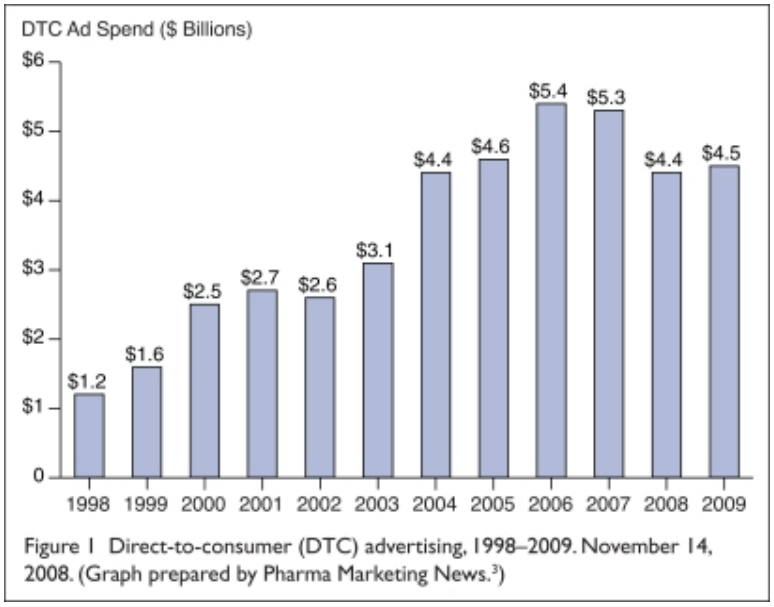


Figure 1 Direct-to-consumer (DTC) advertising, 1998–2009. November 14, 2008. (Graph prepared by Pharma Marketing News.[3])

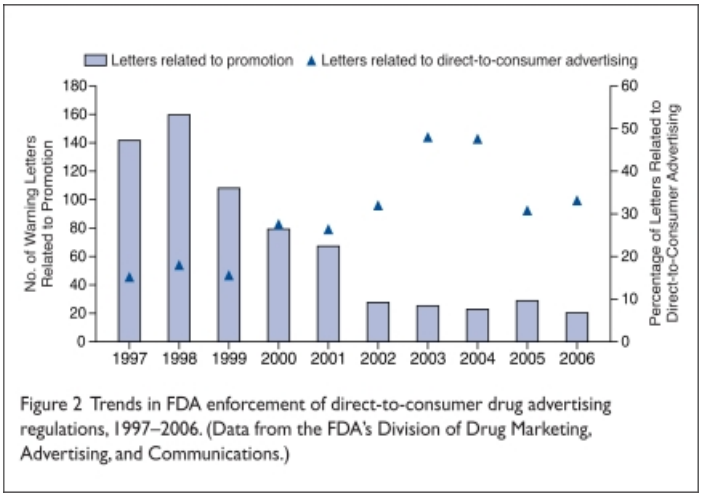
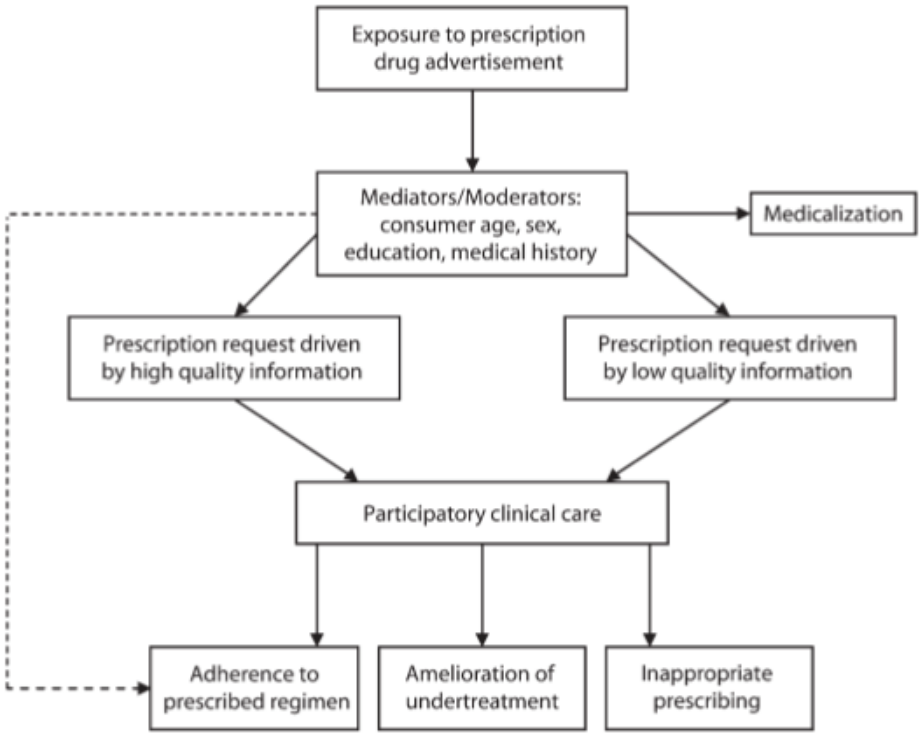


Figure 2 Trends in FDA enforcement of direct-to-consumer drug advertising regulations, 1997–2006. (Data from the FDA's Division of Drug Marketing, Advertising, and Communications.)

Figure 5. Top figure shows the amount of spending in billions on drug advertisements from 1998 to 2009. Bottom shows FDA enforcement of regulations regarding DTC advertisments. As spending on drug advertisements increase, FDA enforcement decreases (Ventola, 2011).

To provide clarity as to why DTC advertisements are so divisive, the positive and negative components of DTC advertisements needs to be discussed. As can be seen in Figure 6, Frosch et al. (2010) suggests that there is a conceptual framework that exposure to DTC advertisements follows. When people are exposed to DTC advertisements, that leads to prescription requests based off a variety of factors, including the age of the consumer, gender, education, and medical history. However, the information in the advertisements can be of either high or low quality, but regardless of the quality of information, it results in clinical care.



Note. Contextual factors to consider for this model include medical visit type and physician specialty (e.g., primary care, specialty care), physician marketing exposure, physician's previous patient communication training, system of care (e.g., health maintenance organization, fee-for-service), and quality-of-care indicators.

Figure 6. A model showing the effects of DTC advertisements (Frosch et al., 2010).

This is considered a positive effect, but one of the results is inappropriate prescribing i.e. prescribing medications when it is unnecssary (Figure 6) (Frosch et al., 2010). The other two outcomes: adherence to prescribed regimen and amelioration of undertreatment can be seen as positive outcomes, but those outcomes are very dependent of the quality of information presented in the advertisements, and the quality of the information presented is part of the controversy. Thus, the end result of that exposure can vary depending on the type of information patients receive.

First, I will discuss the arguments that supporters of DTC advertisements pose. Some of those arguments include, but are not limited to, informs the patient, encourages the patient to contact their physician, promotes patient-physician communication, strengthens the patient-physician relationship, increases treatment for under-diagnosed conditions, and reduces stigma associated with certain diseases (Ventola, 2011). Perhaps, the most widespread argument for the use of DTC advertisements is that they inform and educate the patients. According to Frosch et al. (2010), surveys have been administered to patients and physicians, and more than half of physicians claim that DTC advertisements have the potential to educate patients about various health conditions and treatments. In regards to the public, 75% of respondents claimed they had an improved understanding of various diseases and treatments, and 40% reported that they used the DTC advertisements to guide their decisions regarding treatment regimens (Frosch et al., 2010). Furthermore, proponents of DTC advertisements claim that the advertisements encourage patients to visit their physician thereby increasing physician-patient communication and strengthening the physician-patient relationship (Ross & Kravitz, 2013).

Along with increased communication between physicians and their patients, proponents of DTC advertisements claim that patients are more likely to follow their prescription regime (Figure 6). The likelihood they will follow their prescription regime is because the drug advertisements for the drugs they are taking will serve as reminders (Ross & Kravitz, 2013). However, data for this is scarce or has mixed outcomes. For example, Frosch et al. (2010) discuss a survey, nationally representative of the public, in which 82% of respondents believed that the drug advertisements could help them follow the physicians' guidelines for the prescriptions, but only 23% of patients recruited in waiting rooms said the advertisements would increase the likelihood of them taking the drugs. Proponents also argue that drug advertisements are making patients more aware of illnesses that could have gone unidentified and untreated (Royne & Myers, 2008). Thus, it can be said that proponents of DTC advertisements believe the educational value of the advertisements far outweighs any potential risks associated with the advertisements. However, the opponents of DTC advertisements have various reasons as to why the risks associated with DTC advertisements far outweigh any potential educational value.

The arguments against DTC advertisements directly counteract the arguments made in support of them. Opponents of DTC advertisements believe that they interfere with physician-patient relationships, increase the cost of medications, oversimplify complex medical issues, and promotes the use of newer products over older, safer, and cheaper alternatives (Kaphingst & Dejong, 2004). In regards to the physician-patient relationship, there are physicians who feel that the advertisements lead to patients making unnecessary, and even unwarranted, requests (Frosch et al., 2010). However, the

evidence on the effects of DTC advertisements on physician-patient relationships is conflicted. Frosch et al. (2010), report that 39% of physicians and 30% of patients believed the advertisements had a negative effect on the physician-patient relationship while an industry-funded survey found that 82% of physicians did not associate physician-patient problems with DTC advertisement. However, in yet another survey, 89% of family physicians did not believe that DTC advertisements benefitted their relationships with their patients. In fact, physicians are more likely to report negative aspects of DTC advertisements than patients are because the advertisements promote unnecessary medical visits and prescription requests. Despite this, one survey found that up to 78% of prescription requests were filled thus leading to inappropriate prescribing acts (Frosch et al., 2010). Not only is there inappropriate prescribing acts, but there is also an increase in prescribing acts altogether (Ross & Kravitz, 2013). This cause an overall increase in healthcare costs for the patient (Direct-to-consumer advertising under fire, 2009). Thus, there is the question of whether or not the DTC advertisements are actually benefitting the patients.

There are inherent risks involved when taking any medication, but if patients are being prescribed drugs that are medically unnecessary, are they fully aware of the risks involved? The answer to that question appears to be mixed. O'Donoghue et al. (2013) state that the advertisements themselves do not have or have very little information in regards to drug efficacy, and even if they do, patients have a difficult time understanding that information or overestimate the efficacy of the drug. Kaphingst & Dejong (2004) conducted a study in which participants were asked to answer true/false questions

regarding the drug advertisements they had been shown. The authors found that the chances of the participants answering correctly was lower when the questions involved risk information as opposed to other information presented in the advertisement. Furthermore, there was a lower chance of answering correctly if the information was given in text, both with and without audio, as opposed to just audio. Therefore, it seems that patients have the most difficulty comprehending the risks associated with advertised drugs.

Lastly, another argument against DTC advertisements is that they result in medicalization. Frosch et al. (2010) define medicalization as "the process by which nonmedical problems come to be defined as treatable illnesses, thereby potentially increasing unwarranted diagnoses." Scholars argue that medicalization has resulted from mass marketing and that the pharmaceutical industry has been the major driving force behind medicalization. There is an argument that medicalization is actually beneficial in that it reduces stigma around certain illnesses, but critics maintain that the boundaries around illnesses are only widened to expand the drug market rather than improving health (Frosch et al., 2010; Payton & Thoits, 2011). The process of medicalization may have been an unforeseen consequence of DTC advertisements, but evidence regarding the potential social benefits of the process is scarce.

The benefits and risks of DTC advertisements can be made more evident by using drugs that are currently on the market as examples. It can help to begin with Humira. Humira is a medicine that affects the immune system. It is a Tumor Necrosis Factor (TNF) blocker that can be used to treat a variety of autoimmune conditions, including but

not limited to rheumatoid arthritis, plaque psoriasis, and Crohn's disease (Medication Guide HUMIRA®, n.d.). Because of its capability to treat a variety of diseases, AbbVie Inc., the company that makes Humira, spent nearly $357 million on advertising for this product in 2015, which was the largest amount spent that year, and this made Humira one of the most advertised drugs in the United States (Robbins, 2016a). The timing of the large amount of spending on advertising is not surprising because the patent on Humira will expire on December 31, 2016. When patents are set to expire, pharmaceutical companies will raise the prices of the drugs in order to gain as much revenue as they can before the patent expires. With the patent expiring, generic drugs can now be produced and would often cost less than the brand name drug. However, the new generic drugs that are produced in place of Humira will likely cost just as much as Humira did before the costs of the drug began increasing because the companies that produce the generic drugs will price the drugs just below the name-brand drug (which has been increased) (Rockoff, 2016).

The advertisement itself may seem harmless to those who view it. One current advertisement shows a middle-aged woman packing and traveling to visit her family. The voiceover claims, "This is Humira helping me go further" (Figure 7). What viewers do not know is that this particular advertisement, known as "Go Further", generated an estimated $9.4 million in revenue for AbbVie (Bulik, 2016). This advertisement is only one of 9 advertisements for the drug, but the other advertisements are targeted for a variety of other diseases. This particular advertisement includes everything that is

required by the FDA. It includes major side effects and a directive to visit another source: a website and instructions to discuss Humira with a physician.

Figure 7. Advertisement for Humira (Bulik, 2016).

The website is displayed in white writing on a purple block across the bottom of the advertisement throughout the duration of the advertisement; though, the size of the website pales in comparison to the figures in the advertisement themselves. The major side effects are spoken rather than listed like the website, but the side effects are not displayed in the advertisement. This practice is not optimal as it is not always the easiest way for people to retain information. For Humira, those side effects are lengthy and can be very serious. They can include allergic reactions, blood and liver problems, and even psoriasis (Medication Guide HUMIRA®, n.d.). Yes, the drug that advertises its effectiveness in treating psoriasis can result in psoriasis for patients who have never had it or worsen the condition for those who were previously diagnosed with the condition.

The advertisement also briefly displays that financial help can be given to those who may not be able to afford the medication, but there is never any mention about how much it costs, without or without insurance. If Humira is such an essential drug for many Americans, why is there a need to advertise in it the first place? Would doctors not want to prescribe the drug in the first place?

Although makers of Humira spend the most amount of money advertising the drug, Humira is not a drug that most Americans need. Perhaps that is why more money is spent advertising it. Another health issue that affects many Americans is high cholesterol levels and the various diseases associated with it. A study conducted by Niederdeppe et al. (2013) found that DTC advertisements resulted in over-diagnosis of high cholesterol and consequentially over-treatment of high cholesterol. The study collected data using a nationally representative survey between 2001 and 2007. Questions from the survey included TV viewing habits, cholesterol diagnosis, statin (HMG-CoA reductase inhibitors) use, and other risk factors for coronary heart disease. Statins can block the build up of cholesterol in the liver, reduce LDL cholesterol (a main cause of coronary heart disease (CHD)), and reduce the risk of CHD. The authors also collected data on the advertisements themselves.

The results from the study showed a positive association between DTC advertisements, high cholesterol diagnoses, and statin use. The results were consistent for both men and women. The authors make it clear that individuals who were at a relatively low risk for future cardiac events primarily drove the results, and there were very little positive associations between the DTC advertisements and those individuals at a

moderate or high risk for future cardiac events (Niederdeppe et al., 2013). Furthermore, there were negative associations between the advertisements and women diagnosed with coronary heart disease. Of course, there are limitations to the study, which the authors address, but overall, the results imply exposure to DTC advertisements results in a diagnosis from physicians of high cholesterol in individuals who are at a relatively low risk for future cardiac events. This, in turn, results in individuals taking statin drugs that are unnecessary.

In 2011, Lipitor, a statin drug aimed at lowering cholesterol, became the highest selling drug in the world generating over $125 billion in sales over 14.5 years (Ennis, 2011). That same year, the patent on Lipitor expired, which meant that generic versions of the medication could now be prescribed (Roan, 2011). Regardless of the brand name, statins are still being prescribed, despite some controversy. There is now evidence that statin use increases the risk of developing type-2 diabetes. In 2012, the FDA warned about these side effects and required the maker of Lipitor to include warnings about the diabetes risk. However, the warning labels were implemented too late for some people, and there is now a pending lawsuit against the maker of Lipitor (Lipitor Lawsuit: Litigation for Statin Drug Linked to Diabetes, n.d.). Despite the evidence of serious side effects and a lawsuit, there are doctors who are still prescribing statins and are receiving money to do so. A study conducted by Dejong et al. (2016) found that 279,699 physicians received 63, 524 payments, mainly in the form of meals, from the pharmaceutical drugs. Rosuvastatin, common brand for Crestor® (a statin), represented 8.8% of statin prescriptions, and the authors found that those physicians who received one single meal

from the company promoting Rosuvastatin, prescribed Rosuvastatin more frequently than other statin drugs. Thus, there is another issue with doctors promoting certain drugs as well. If there is a shift from advertising more to the physician than to the patient, how should physicians respond accordingly?

Although Lipitor is controversial, perhaps the most controversial drug currently on the market is the EpiPen. The EpiPen came to be in the 1970s by a request from the Pentagon because the Pentagon needed a way to deliver a nerve gas antidote. This drug could alleviate the allergic reaction caused by exposure to nerve gas. Thus, it would be an immediate defense for soldiers who were exposed to nerve gas (Reimann, 2016). The EpiPen was officially introduced in 1980 and is used in the general public to treat life-threatening allergic reactions with epinephrine (Rubin, 2016). The drug company Mylan acquired the EpiPen in 2007, and at the time, only produced $200 million in revenue. However, as can be seen in Figure 8, EpiPen annual sales have increased dramatically (Koons & Langreth, 2015). Figure 8 shows the price increase through 2015. With the increase in sales came the dramatic increase in price, over a 400% price increase (Rubin, 2016). The EpiPen itself only delivers about $1 worth epinephrine, but as of 2016, it cost $600 to purchase (Koons & Langreth 2015; Rubin, 2016). It only cost $57 when Mylan acquired the product in 2007. Koons & Langreth (2015) credit Mylan with utilizing textbook branding as well as a public awareness campaign. Those campaigns include television advertisements, but they differ from the previously discussed DTC advertisements.

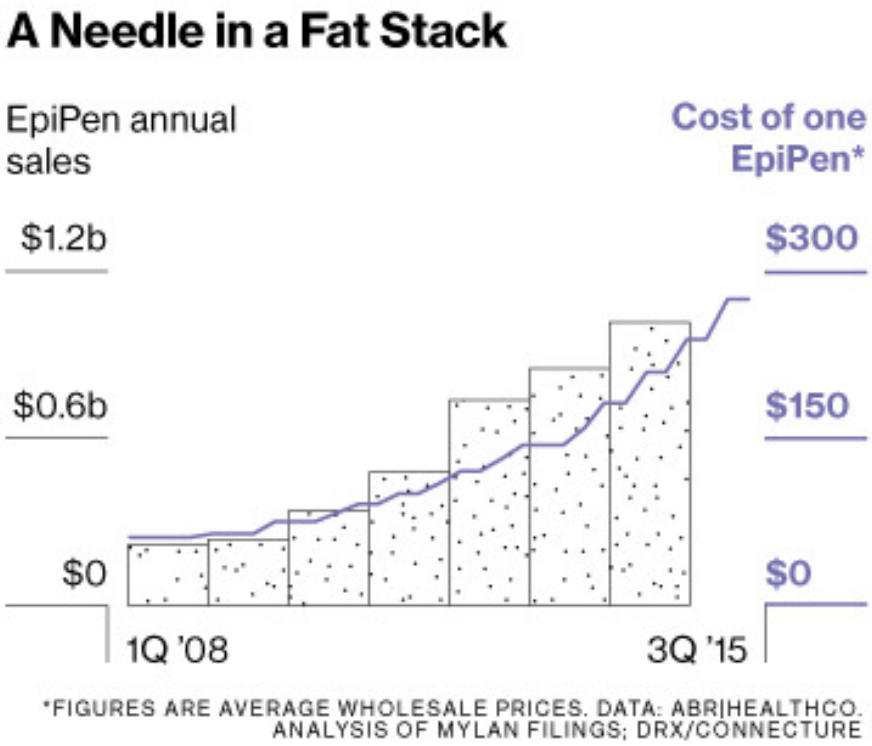


Figure 8. Data from the first quarter of 2008 to the third quarter in 2015 showing an increase in the cost of EpiPen (Koons & Langreth, 2015).

These new advertisements are called “unbranded” advertisements. These particular advertisements inform the public about a medical condition and are paid for by a company who sells a drug for said medical condition. These ads are not required to disclose side effects; instead, they inform viewers to visit the website where they will learn about the treatment options the company offers (Robbins, 2016b). While the prevalence of these ads has varied, Mylan purchased nearly $15 million worth of airtime for an unbranded campaign it launched in April 2016 (Robbins, 2016b). Mylan capitalize with these advertisements because of the increased awareness of anaphylaxis reactions. In 2010, there were new federal regulations requiring patients who experienced severe

allergic reactions to be prescribed two epinephrine doses. The FDA also changed label rules that allowed the EpiPen to be marketed to anyone at risk as opposed to those who had already experienced an anaphylaxis reaction (Koons & Langreth, 2015). As a result of these efforts, in part by Mylan, the use of the EpiPen has grown 67% in the last eight years (Koons & Langreth, 2015).

Mylan announced that it would release a generic EpiPen, but the price would still be $300 per pack of two (Rubin, 2016). Although the increase in cost for EpiPen was the result of different marketing tactics, the use of unbranded advertisements is a shift from traditional DTC advertisements. Despite informing the public about different medical conditions, they still direct people to websites that are sponsored by companies that sell the products. Even though there can be benefits to informing the public about certain medical conditions, patients should be aware as to who are the ones promoting those campaigns because the underlying message could be more about the specific treatment for the medical condition as opposed to the condition itself. Nonetheless, the use of advertisements to increase use of a specific drug does not seem to be slowing down because of the large profits companies receive, but it is interesting to note that DTC advertisements are not found worldwide.

Currently, only the United States and New Zealand allow DTC advertising. The reasons for this vary, but Guessous and Dash (2015) state that DTC advertisements have pros and cons that are regulated differently in different countries. Furthermore, constitutional factors and patient and population safety considerations also play a role. In the United States, the First Amendment protects the right to free speech, including

commercial speech (Guessous & Dash, 2015). In New Zealand, unlike other developed countries, there was never any legislation that prevented the use of DTC advertisements. Similar to the United States, there were calls to ban DTC advertisements. The New Zealand government responded in 2003 calling for a complete ban on the advertisements, but the necessary legislation was not successfully passed (Toop & Mangin, 2007). Perhaps the biggest reason why there are different regulations regarding DTC advertisements is the lack of data surrounding them (Guessous & Dash, 2015). Most of the data published is based off of surveys and opinions rather than experimental evidence. The interpretations of the results can, therefore, be subjective. Thus, there are various reasons as to why other countries do not have DTC advertisements.

While New Zealand has been unable to completely ban DTC advertisements, Europe has recently been looking to allow DTC advertisements. In 2002, the European parliament began debating about DTC advertisements except for ones that advertised drugs for diabetes, asthma, and AIDS. However, the proposal was rejected (Rutter & Gilbody, 2008). The debate then became prominent again in 2007, and the European Commission published a document that discusses the patients' rights to information. This document is significant because it discusses the Internet as a different means of providing information. Indeed, the Internet user has to actively search for information before that information is available to them. The European Commission is trying to make a distinction between advertising and information (Velo & Moretti, 2008). This distinction was important for the European Commission proposal in 2008 that was aimed at trying to provide patients with "non-promotional" information (Rutter & Gilbody, 2008). A

majority of the European Commission voted against the proposal (Direct-to-consumer advertising under fire, 2009). Currently, the debate continues about whether or not to allow DTC advertisements, and if the ban is lifted, there will be intense consideration about what regulations will be in place and what those advertisements would look like.

Europe is not alone in its consideration for allowing DTC advertisements. South Korea is also looking at allowing DTC advertising. Because of increased access to the Internet, more people are utilizing it to learn more about health information. As a result of the increased access to information, Suh et al. (2011) felt that it was necessary to survey South Koreans on their attitudes toward DTC advertisements. In South Korea, drug advertisements are regulated, but DTC advertisements for prescription drugs are generally prohibited with the exception of "professional" health journals and drugs that are considered a preventative measure for contagious diseases, such as AIDS, plague, and typhoid fever. The authors surveyed 350 subjects and addressed four different areas concerning DTC advertisements. Those are the consumers' attitude towards DTC advertisements, consumer preferences regarding regulation, consumers' expectation regarding the effects of the advertisements, and the types of credible advertisements. Although 52 respondents were excluded for incomplete questionnaires, 61.8% of those who responded felt that DTC advertisements were necessary, but only 43.3% felt that they could trust the information provided by the advertisement. Although the respondents felt that the advertisements could be potentially educational in regards to treatments and disease awareness, they also felt that the advertisements could lead to a misuse or overuse of the drug advertised. To conclude, the authors note that South Korea must take a

cautious approach when it begins to discuss DTC advertisements and whether or not they should be implemented.

Whether a country is just beginning to consider allowing DTC advertisements or the issue has been debated for years, banning the advertisements is just as difficult and contested a process as allowing them in the first place. In regards to the United States, perhaps the biggest debate about whether or not the advertisements can be banned altogether is the right to free speech argument. Advertising is considered "commercial speech" and its protection under the First Amendment dates back to the 1970s (Shuchman, 2007). The Supreme Court developed criteria, known as the "Central Hudson Test," to determine if a ban on commercial speech is allowed. The test determines whether advertising is misleading, if a ban advances government interest, and if that government interest can be reached by utilizing a less restrictive method like including a label. That is, if having a ban does not fall in line with government interest, then a ban is not necessary. One lawyer, who served as a chief counsel for the FDA from 2001 to 2004, said that because a doctor needs to intervene in the process of a patient acquiring a prescription that, it alone should prevent any ban on DTC advertising. Furthermore, he says that the drugs also have to be approved by the FDA before they can be put on the market, and because of FDA approval, DTC advertisements should be allowed. However, serious adverse side effects of a drug can be potentially unknown before there is widespread use of the drug, and thus an advertising moratorium should be put in place to allow for post-marketing surveillance (Shuchman, 2007). However, as was mentioned earlier, it is very difficult for regulations to be put in place for a moratorium to exist.

Although there is a need for post-market surveillance, a complete ban on DTC advertisements is unlikely. Furthermore, some believe that if Congress does enact a ban and it is overturned, then future attempts to control regulations on DTC advertisements would fail (Shuchman, 2007). Any efforts to completely ban DTC advertisements would have to be well thought out in a way that does not violate the First Amendment. Ultimately, if there cannot be a complete removal of the advertisements themselves, then careful considerations must be made in regards to how the advertisements could be restructured in a way that eases opponents' concerns.

Those who have studied DTC advertisements have several recommendations as to how the advertisements can be improved. There have been suggestions to have an independent agency that reviews the advertisements, but Guessous & Dash (2015) note that the FDA already has an office that reviews and controls the content of the advertisements. Because the agency is not independent, it is unclear whether or not there is potential for interests to be corrupted. However, the FDA enforcement of their policies on DTC advertisements has decreased over time. Royne & Meyers (2008) state that a policy change in 2002 now requires the FDA to obtain legal approval in order to issue a warning letter. This policy change has slowed the review process, and consequentially, less letters were issued altogether. Perhaps, a separate office or more employees need to oversee that the advertisements are still in compliance after a certain time period has elapsed. Royne & Meyers (2008) also report that there were concerns with how the advertisements are reviewed in the first place. The FDA does not have a consistent way of prioritizing the advertisements nor are there any official standards for determining

which ads would likely cause the most harm. It is evident that the FDA needs to fix its review process in order to limit the number of advertisements that may contain false or misleading information. In addition, as was mentioned earlier, the FDA is very underfunded so there also needs to be steps taken in order to ensure that the FDA is receiving adequate funding. So how can the advertisements themselves be improved?

There are several different ways in which DTC advertisements can be improved. One of those improvements has to do with providing more information about the risks associated with taking the drug. In a survey conducted by the FDA in 2002, 60% of respondents did not think that DTC advertisements provided satisfactory information about the risks (Royne & Meyers, 2008). Beyond just communicating the risks, advertisements could also communicate the efficacy of the drug. O'Donoghue et al. (2014) showed that adding efficacy information, especially quantitative information, about a drug in the DTC advertisements for both print and television potentially increased an individual's knowledge of the drug. If the patients are more aware of the effectiveness of the drug they wish to take, they may be more likely to make more informed decisions in regards to the drug. Furthermore, the authors believe this could lead to improved patient-physician communication because patients are more aware of both the benefits and the risks and thus are more educated when talking to their physicians. This differs from current advertisements that only relay risks rapidly on television advertisements.

In addition to balancing benefit and risk information, improvements need to be made on the way the information itself is presented. Information in television advertisements should be presented in "consumer-friendly" language (Kaphingst & DeJong, 2004). That

means that considerations must be made in regards to the literacy level of the recipients of the advertisements. In addition to consumer-friendly language for television advertisements, “plain language” should be used in print advertisements. The reading difficulty of the advertisements should be no higher than an eighth grade level, which is the reading level of the average American adult (Kaphingst & DeJong, 2004). So not only should DTC advertisements include more information in the first place, they should include information that is clear and easy to understand for patients with different education levels. This does not mean that the information presented will be less precise. Doctors have to find ways to present complex information in simple ways to their patients, and creators of drug advertisements should be challenged to do the same. Perhaps, by even working closely with physicians, creators of drug advertisements can find the best way to communicate the risks of a drug without compromising any specific and important information.

Lastly, there are suggestions about the way in which the advertisements are presented can be improved. That is, the way medical conditions and the treatment for those medical conditions are portrayed can be improved. Guessous & Dash (2015) state that most DTC advertisements portray medical conditions and their treatments in a very superficial, perhaps even glamorous, way. A study conducted by Frosch et al. (2010) showed that advertisement narratives for treatments for cardiovascular disease shifted perceptions of the actual cause of the disease. Participants were led to believe that high cholesterol was primarily caused by hereditary factors, thus reducing the need for lifestyle change. The authors suggest that there needs to be more scrutiny about the narratives used to show the

effectiveness of the drugs. Frosch et al. (2010) claim that less time is spent on the risks of a drug while the benefits are discusses intermittently throughout the advertisement. Thus, there needs to be more information about the risks and the effectiveness of the drugs. In addition, Kapingst & DeJong (2004) suggest that the advertisements, if they are really there to educate consumers, should also provide information about symptoms and other risk factors for the advertised disease. Essentially, the advertisements should present more accurate depictions of what the disease looks like.

A somewhat unconventional idea, but one that could mitigate some issues, is a "Patient/Consumer television control device" as suggested by Guessous & Dash (2015). This device would allow consumers to make an individualized and informed decision about whether or not they want to watch TV with DTC advertisements. The authors state that this would not only respect the First Amendment, but it would also respect the individual choices made my consumers. Furthermore, they acknowledge that now it is common practice for TV and Internet content to be profiled, and that this same practice could be applied to health related content as well. However, in regards to the Internet, this policy could be tricky as there are currently no regulations regarding online drug advertisements because they are a lot harder to control and regulate as the Internet surpasses boundaries established by different countries (Khosla, P. & Khosla, A., 2011). The issue of DTC advertisements is complicated with patients' increased use of the Internet. Patients understandably want to know more about and become more involved with their healthcare, and this medical value is called patient autonomy. Whether or not

patient autonomy inhibits or helps with physician-patient relationships will soon be discussed.

The increased role of the patient participation in healthcare was discussed briefly in Chapter III. The idea of patient autonomy itself is a relatively new idea in healthcare. It was not until 1980 that a revision in the American Medical Association Code of Ethics explicitly stated physicians are required to respect patients' autonomy. Furthermore, medical education is placing greater emphasis on physician-patient relationships that focus on shared-decision making that respects patient autonomy (Magnezi et al., 2014). Patient autonomy itself is defined as "the patient's right to involvement in the discussion and decision-making process during consultation." In addition, it is the ability for the patient to have discussions without being heavily influenced by any healthcare providers (Agarwal & Murinson, 2012). There are several reasons as to why patient autonomy has become more prevalent in healthcare, including an increased rate of chronic illnesses, the patients' rights movement, and increased Internet usage (Arney & Lewin 2013). Because of increased Internet usage, there are some patients, particularly those who are educated, who will have an increased medical knowledge. However, this is not the case for everyone. Although more people have access to the Internet and can therefore learn more about their medical conditions, it does not always mean that patients fully understand their medical conditions. Thus, there is some disparity with how much medical knowledge patients actually know despite the increase in Internet usage. In addition, the Internet does not always present accurate and correct information, and not every patient will know how to screen for correct information. Therefore, physicians have to respond

appropriately in order to develop and maintain physician-patient relationships that serve the best interest of the patient.

Thus, new models are being created to address the increased amount of information patients have, before they visit their physicians. One model proposed by Agarwal & Murinson (2012) addresses patient value, patient autonomy, and patient knowledge. The authors suggest that by utilizing this model, physicians can better interact with their patients. For example, if the patient knowledge is low, then the physician can provide more medical knowledge to the patient and in a greater context. In addition, physicians can direct patients to more reputable sources. How does this model come into play when the information the patient has is from DTC advertisements? How should doctors respond to a patient's demands for a specific drug they saw advertised?

One study conducted by Arney & Lewin (2013) looks directly at the portrayal of physician-patient relationships in DTC advertisements. The authors were trying to identify how doctor-patient relationships were depicted in drug advertisements and then also get an opinion of the types of relationships the patients themselves wanted. They analyzed DTC advertisements directly and then also conducted interviews with 36 inviduals. The researchers identified four different physician-patient relationship models while interviewing respondents to examine how consumers receive DTC advertisements. Those four models are physician-as-confidant, consumer-and- supplier, scientist-and-specimen, and patient-as-autocrat. The physician-as-confidant model shows a high emotional connection between the patient and the physician while the consumer-and-supplier showed a relationship based off of negotiation. These are the two models that are

predominantly found in DTC advertisements. The consumer-and-supplier model was found in 30% of DTC advertisements. The respondents viewed the physician-as-confidant model as an idealized relationship but one that they did not actually have. The last two model types are not found in DTC advertisements, but respondents in the interviews mentioned them. The scientist-and-specimen model places the physician in complete control, and this model was preferred by 39% of respondents. The patient-as-autocrat model is characterized by patients questioning their doctors and patients often seeking health information on their own. This model was identified by 25% of respondents. Interestingly, women preferred this model more while men preferred the scientist-and-specimen model more. Despite the four different models, respondents primarily described the physician-as-confidant model as an ideal rather than what they actually have. The authors suggest that the pharmaceutical companies are capitalizing on these types of advertisements because it encourages patients to discuss treatment options with their doctors. Although this is considered a good thing, it is solely focused on the specific treatment advertised, which may not necessarily be in the best interest of the patient.

Although there are different models and different ideas of how physicians can respond to patients' increased medical knowledge and demands for different treatments, how physicians put that into practice can vary. Getting insight from a currently practicing physician can shed some light on how physicians should respond to their patients and what should be done with DTC advertisements as a whole. Therefore, the next section

contains the summary of an interview I conducted with Dr. Robin Dickinson, who practices medicine in Denver, Colorado.

Dr. Dickinson practices family medicine. More specifically, she practices what is called community supported family medicine or direct primary care (DPC). She provides medical services to her patients, who pay a monthly membership fee. DPC differs from concierge medicine because each DPC practice fits the needs of the population it is serving. Thus, her practice is especially equipped for providing care to patients who do not have insurance and cannot otherwise afford healthcare. Dr. Dickinson first wanted to be a doctor when she was 6 years old. Growing up in an abusive home, she did not realize that being a doctor was a possibility, but it was her mother who told her that she could. She attended the University of Denver for her undergraduate education, and she went to the University of Colorado for medical school. At first she thought she wanted to be a pediatrician because of her experiences growing up, but she soon realized that family medicine is what she was the most passionate about. Through family medicine, she could address all aspects of a patient's life and provide the best possible care. She completed her residency in Pueblo and soon began working at a family medicine practice. It was while working at that practice that she thought about opening her own practice; although, at first, she never thought that she would. While at that practice, she soon realized that there were some constraints that she felt could hinder the care that she wanted to provide to her patients. Thus, she took the necessary steps to open her own practice.

Because of her unique perspective on medicine, I believe that she could provide some insight into DTC advertisements and how they are affecting doctor-patient

relationships. She first discussed how at the old practice, drug representatives would come in to talk to the doctors and would always provide free lunch. She said that the doctors were essentially trained to view the drug representatives as nice people and to like the drug representatives. That is, the physicians and staff who had been there longer than she had told her that they want her to like them; no one ever did anything differently. However, when she noticed that one of the physician assistants (PA) did not attend these lunches, she was curious as to why. This PA said that the representatives were using manipulative tactics to get the physicians to use their drugs and that it could look bad to the patients if they were receiving these free lunches from drug representatives. This was prior to the new law passed under the Affordable Care Act, the Sunshine Act. The Sunshine Act requires all pharmaceutical and medical device companies to report any payments that doctors receive to the public if the amount is over $10 (Cochran, 2014). After the law was passed, the practice actually voted on whether or not it should get rid of lunches. It decided that each doctor could individually decide whether or not they wanted to attend, and if not enough people were attending, the problem would be readdressed. Dr. Dickinson said that as far as she knew, she was the only physician who sat out those lunches.

The aforementioned narrative is what fueled Dr. Dickinson's desire to open her own practice. Most of the patients she sees now are of a lower socioeconomic status. Thus, she found that patients requesting specific prescriptions were not as frequent. In fact, Kaphingst & DeJong (2004) reported that for print advertisements, "college-level reading ability would be needed to read the average brief summary section." So even

though print advertisements are more accessible than television advertisements for people with a lower socioeconomic status, they would still be unable to comprehend the risks associated with taking certain drugs because the language used to describe the risks are above their reading level. This is why Dr. Dickinson makes it a point to thoroughly discuss with every patient why he/she came into see her because she recognizes that her patients are not going to be knowledgeable about their medical conditions or about the risks associated with certain drugs. Thus, she makes it a point to thoroughly educate her patients as much as she can about their conditions and about the drugs that they will use to help with their medical conditions. If a specific drug is requested, she goes through the entire process of why the patient may or may not need that drug. She emphasizes that her appointments are just as much about educating the patient as they are about treating the patient.

Thus, in regards to DTC advertisements, Dr. Dickinson says that the practice as a whole should be put to a stop. Even if changes are to be made, the pharmaceutical companies will most likely find ways around them. Instead, she believes that physicians should look towards educating their patients about the reasons for their visits and also educate patients about the drugs that they may be requesting. She emphasizes that treating a patient is about building a relationship and establishing trust with the patient in order to fully disclose health information, which will lead to the best treatment. Even if that means spending more time with a patient that may seem necessary, it has to be done in order to serve the best interests of the patient.

Of course, this is only the opinion of one physician, but Dr. Dickinson brings up some valuable points. Although I, myself, am not sure of what type of practice I would like to open or even the field of medicine I want to go into, I admire the way that Dr. Dickinson treats her patients. I especially like her emphasis on education and really working with patients to address their illnesses. Spending more time getting to know and educating patients is essential to providing them with the best possible care. Moving forward, with an increase in medical technology, the advent of personalized medicine and with an increase access to medical knowledge, DTC advertisements may eventually become irrelevant.

V. Personalized Medicine

Personalized medicine is the "selection of treatment best suited for an individual, involves integration and translation of several new technologies in clinical care of patients" (Jain, 2015). The term itself is used interchangeably with several other terms, including but not limited to, "precision medicine", "individualized medicine", and "stratified medicine". These terms were initially used in specific contexts but have merged together to generally identify the same thing (Abettan, 2016). Advances in chemistry, biochemistry, and genetics, among others, have allowed for personalized medicine to formulate. With the advent of genomics, the human genome project had been completely sequenced by 2001. Following the completion of that project began the ENCODE project (Encyclopedia of DNA Elements) which aimed to described all of the functional elements in the human genome (Jain, 2015). The results of these projects provided scientists with important insights into the functions of genetics and DNA, and how manipulations in the genetics code can result in various diseases. Being able to pinpoint how a disease was caused in one given individual and finding techniques to treat this particular disease on a molecular level using various molecular biology techniques lead to the birth of personalized medicine.

Since then, there is more emphasis being placed on researching personalized medicine. In 2015, President Obama announced that there would be new funding, $216 million worth for the fiscal year 2016, for the National Institute of Health, the National Cancer Institute, and the FDA. The Precision Medicine Initiative has short-term and long-

term goals. The short-term goals include more research on personalized or precision medicine for cancers while the long-term goals are focused on bringing personalized medicine to a large scale for healthcare (U.S. National Library of Medicine, 2015).

Much like the field of medicine has evolved over times, doctor-patient relationships have also changed. While direct-to-consumer drug advertisements currently serve to complicate doctor-patient relationships, personalized medicine has the potential to further complicate this precious relationship. Of course, there is also the potential for personalized medicine to strengthen doctor-patient relationships. More specific information about patients will be known by physicians, and it is what physicians do with that information that can either strengthen or weaken their relationships with patients. There is the potential for physicians to only address their patients by the information they receive. That is, patients will only be seen as their genetic information rather than as a whole person. With the specificity that personalized medicine offers, physicians have to be aware that regardless of the specific problem they are addressing, it still impacts the patient as a whole. Therefore, physicians still have a responsibility to treat and care for their patients as a whole despite the specificity that personalized medicine offers.

With that in mind, DTC advertisements will add another layer of complexity to doctor-patient relationships but in the context of personalized medicine. DTC advertisements can continue to be misleading about what personalized medicine has to offer. Although personalized medicine has the potential to radically change medicine, its full potential must not be overstated. There are still limits to personalized medicine, and patients have to be aware of that. However, as medicine continues to move towards

personalized medicine, pharmaceutical companies could further utilize DTC advertisements to capitalize on the advantages of personalized medicine for their own personal gain.

Direct-to-consumer advertisements have evolved with the field of medicine. Although the field of medicine itself has been around significantly longer than DTC advertisements, the two now coexist. The field of medicine will most likely continue to evolve, and it will be interesting to see whether or not DTC advertisements evolve with it. The direction that medicine seems to be heading is toward personalized medicine. If DTC advertisements are altered, or perhaps removed altogether, as a result of personalized medicine, what implications does that have on doctor-patient relationships? Does personalized medicine itself add to doctor-patient relationships?

It seems that because of the significant funding allocated for personalized medicine there would be benefits for the practice and many believe that personalized medicine has the potential to revolutionize healthcare. However, there are new concerns with whether or not funding will remain in place because of the new Trump administration. One article states that there is bipartisan support for personalized medicine, but this still does not completely ease concerns, as the administration could potentially not agree with either party. A 2017 appropriations bill regarding funding for the Precision Medicine Initiative was not passed, but rather, continuing resolutions that were established prior for funding were put in place until March 31, 2017 (Ray, 2016). This is not completely unusual during an election year, but some are worried that major changes will happen to the 2017 budget, which could have a significant impact on

ongoing research. In addition, some worry that funding will be cut entirely because some Republicans might see it as another effort to heighten Obama's legacy (Ray, 2016). Thus, it remains to be seen if current research, as funded by the federal government, will continue.

Personalized medicine can potentially be beneficial to many people. Abettan (2016) discusses how it could potentially be a paradigm shift in medicine. Advances in genetic knowledge can allow for more accurate prescriptions for patients. That is, prescriptions can be produced that specifically fit an individual's genotype, and in turn, adverse side effects can be greatly reduced. This would require active participation by pharmaceutical companies because they are the ones producing more effective medicines with fewer side effects (USFDA, 2013). However, if pharmaceutical companies are not willing to invest in personalized treatments, then the process could be hindered. Pharmaceutical companies would have to find new drug therapies that replace existing and profitable ones, which may not appeal to some companies (Jameson & Longo, 2015). Fortunately, it seems that more companies are wiling to invest in more personalized medications. For example, a drug used by HIV patients, Abacavir, is safe for all but 6 percent of patients who develop serious allergic reactions. Researchers found that a single genetic variant was causing the reaction and now HIV patients are screened for that genetic variant before they are prescribed Abacavir (Abettan, 2016). Personalized medicines also attempt to give patients the right drugs at the right time (USFDA, 2013). To go a step even further, supporters of personalized medicine believe that it can go from reactive to preventative medicine. By utilizing genetic testing, doctors can earlier predict

the risk for some patients of developing a specific disease (Abettan, 2016). As more of these genetic tests become available, it is likely that pharmaceutical companies will begin to put their own genetic tests on the market. However, the testing as well as the therapies that are done needs to be safe and effective, and the FDA is implementing new research regulations and standards in order to ensure this (USFDA, 2013).

As with any change in medicine, there are going to be some who do not see the benefits or have serious questions about personalized medicine and what it means for the field as a whole. One concern with personalized medicine is the cost. One study claims that healthcare costs would be reduced with personalized medicine if the focus is on prevention over therapy, but other studies have shown that genetic information can lead to an increase in physician visits which results in more laboratory tests and increases patient anxiety (Joyner & Paneth, 2015). Those increase in physician visits and laboratory tests could potentially lead to the patient paying more to cover those costs. In addition, there is also concern with the cost of the therapies themselves. Currently, new, targeted cancer drugs can cost up to $100,000 a year (Joyner & Paneth, 2015). However, it can reduce the likelihood of treatment failure thus resulting in less money spent over the long term. Also, there is a likelihood for safer clinical trials which reduces the risk of serious side effects which again, can reduce healthcare costs in the long run (Shoaib et al., 2016). It is understandable that there are concerns with the costs associated with personalized medicine, and it is a concern that would have to be monitored moving forward.

Not only are there concerns with what costs might be associated with personalized medicine, there are also some ethical concerns. One of them relates access to genetic

information. There is the possibility that individual's genetic information would be available to a wide number of people (Jain, 2015). It is also possible that patients would only be seen as genetic information as opposed to whole people who have differing opinions and emotions. This is worrisome for some physicians who argue that it could lead to a technical communication with patients as opposed to individualized communication (Abettan, 2016). There is also concern with the information patients actually receive from any genetics tests they have done. There is a potential for there to be incidental findings. In one survey, a majority of patients wanted to be asked what information they would like to receive. That is, some patients do not want to know about some information that is found in the genetic tests, and physicians have a responsibility to respect their patients' wishes (Shoaib et al., 2016).

In addition to the aforementioned concerns, there are also some ethical concerns with the information found during genetic tests and what it could mean for healthcare as a whole. There is concern with who would have access to patients' genetic information and how it would be used. To address these concerns, the U.S. Congress passed the Genetic Information Nondiscrimination ACT (GINA) in 2008. This legislation prevents insurance companies from using a person's genetic information in determining eligibility or premiums, requiring or requesting a genetic test, or employers using genetic information to make employment decisions. However, there are worries that the bill would be difficult to enforce, and it does not discuss long-term care insurers or life insurers. The Affordable Care Act would prevent insurance companies from using preexisiting conditions, whether they are genetic or not, to establish premiums (Jain, 2015). If

companies were found to be in violation of the act, they will have to pay a fee as a well as take measures to fix the mistake (Shoaib et al., 2016). Prior to the Affordable Care Act, insurance companies could deny individuals with preexisting conditions. Moving forward, this is something these are factors that will need to be considered when the laws governing healthcare have the potential to change at any time.

There are significant implications personalized medicine can have on healthcare, but more people need to actually know about the practice before some of those implications can be understood. Now, a multitude of top institutions are creating campaigns to market advances in personalized medicine (Wolinsky, 2015). These advertisements can potentially be very harmful to patients because patients can misuse the test, misinterpret the results, and not follow-up on the results with a physician. Furthermore, there is concern that the DTC genetic screening tests may not be as accurate as laboratory tests (Jain, 2015). That is, laboratory tests are done by trained professionals with access to much more precise as sophisticated tools as opposed to the DTC genetic screening tests performed at home. Much like DTC advertisements, there needs to be regulation by the FDA for DTC genetic testing. One review of marketing genomic campaigns found that many advertisements were very close to being deceptive and potentially unethical (Wolinsky, 2015). In Europe, a survey was conducted which showed that a majority of clinical geneticists do not believe that DTC genetics tests are clinically useful and that certain test should be more carefully regulated or banned altogether. They believe that DTC genetics tests should be required to undergo the same procedure that DTC pharmaceuticals do for market introduction (Jain, 2015). Ultimately, it is clear that

careful consideration needs to be put into advertisements for DTC genetic screening tests. Even institutions themselves have to be considerate of the claims they are making in regards to personalized medicine and provide full disclosure as to whether or not their therapies will benefit a particular patient.

With that in mind, it is evident that personalized medicine will have some impact on doctor-patient relationships. As was mentioned earlier, patients are taking a more proactive role in managing their healthcare because of their increased access to the Internet for information. Of course, this does not always mean patients fully understand the information that they are being presented, but there is the potential for patients to become more knowledgeable about their healthcare. If patients do have an increased medical knowledge, they may want treatments and/or therapies that are specifically designed for them or that may not be as harmful. On the other hand, some patients may not be as actively involved in their healthcare. Regardless, it is essential for physicians to remember that an important part of personalized medicine is caring for the whole person, including the patients' views and lifestyles in addition to their health (Pokorska-Bocci et al., 2014). Pokorska-Bocci et al. (2014) maintain that clinical medicine will continue to be a process of choosing the best care for the patient and that biomedical sciences will help refine the process. The best care given still has to be what is the best suited for the patient's health, preferences, and circumstances; that is determined by fostering a dialogue between the patient and the physician. Thus, personalized medicine can only be achieved when all aspects of the patient are taken into consideration (Abettan, 2016). If it is, personalized medicine has the potential to strengthen physician-patient relationships.

Patients would only be given medications that are guaranteed to better the patient, and patients would be more willing to listen to their physician and follow the treatment regimen (Shoaib et al., 2016). However, this is still dependent on a dialogue between the physician and the patient. Ultimately, even though personalized medicine may become the future of medicine, it is still dependent on an established relationship between the physician and the patient that determines the best suitable treatment for that patient. Even as personalized medicine continues to advance, physicians should still view their patients as patients as opposed to test subjects whose only purpose is to advance the field.

Final Thoughts

The field of medicine has a long history, and beginning with the Hippocratic Oath, it has developed and progressed to the practice that we recognize today. It has evolved from a practice based on primarily superstitious and religious beliefs to one guided by science and scientific research. The advent of technology has further evolved the field of medicine. With the completion of the human genome project, medicine has the potential to revolutionize how we treat patients. The field of medicine is unlike any other, and those who choose to enter the field have a tremendous responsibility. Unfortunately, there are many other factors that have influenced the field that have caused some physicians to stray away from what it really means to be a physician. Of course, this is not the case for every physician, but it has become widespread enough that it is something that needs to be addressed. One of those factors is DTC advertisements.

Beginning my research on DTC advertisements, I was not really sure what I would find. I was not even sure that I was particularly against them or what they really had to do with doctor-patient relationships. However, it soon became clear that they do, in fact, have a significant impact on the healthcare field and can be potentially disruptive to doctor-patient relationships. While I maintain that DTC advertisements should be eliminated altogether because of the overall negative impacts they can have, it does not seem like a realistic action that will happen any time soon. Therefore, I think that it becomes the duty of the physicians to ultimately negate them and decide what is best for their patients. It is necessary for physicians to develop relationships with their patients

and develop an understanding that patients are so much more than their medical condition. This becomes increasingly important with patients' increased access to healthcare information because of easier access to information found on the Internet. Physicians will have to learn to navigate and work with their patients to determine which information is actually beneficially to them.

It may seem that I am being especially critical of physicians, but in today's world, where pharmaceutical companies' sole purpose is to make a profit, physicians are challenged to rise above that notion and care for their patients regardless of any financial profit. Physicians have been given a special role in society to care for people, and they should be taking that role seriously. Physicians should be working closely with patients, educating them about their illnesses. Establishing relationships with patients makes it more feasible to physicians to successfully treat them

After completing all of my research, I feel confident working towards my goal that I have a better understanding of the medical field and the role of the physician as a whole. Although it might not be easy, I believe that being the successful physician is possible. Establishing relationships with patients and educating them is the best way to help treat them. Included in that is treating patients with the understanding, compassion, and respect that they deserve. The medical field and even the pharmaceutical industry will continue to change and evolve, but the most important thing to remember is, ultimately, what the role of the physician should be

References

Abettan, C. (2016). Between hype and hope: What is really at stake with personalized medicine? Medicine, Health Care and Philosophy, 19(3), 423-430. doi:10.1007/s11019-016-9697-2

Abramson, J. (2004). Overdo$ed America: The broken promise of American medicine (1st ed.). New York: HarperCollins.

Agarwal, A. K., & Murinson, B. B. (2012). New Dimensions in Patient–Physician Interaction: Values, Autonomy, and Medical Information in the Patient-Centered Clinical Encounter. Rambam Maimonides Medical Journal, 3(3). doi:10.5041/rmmj.10085

Arney, J., & Lewin, B. (2013). Models of Physician-Patient Relationships in Pharmaceutical Direct-to-Consumer Advertising and Consumer Interviews. Qualitative Health Research, 23(7), 937-950. doi:10.1177/1049732313487801

Background on Drug Advertising. (2015). Retrieved October 16, 2016, from http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm071964.htm

Berche, P. (2012). Louis Pasteur, from crystals of life to vaccination. *Clinical Microbiology And Infection: The Official Publication Of The European Society Of Clinical Microbiology And Infectious Diseases*, *18 Suppl 5*1-6. doi:10.1111/j.1469-0691.2012.03945.x

Boden, W. E., & Diamond, G. A. (2008). DTCA for PTCA — Crossing the Line in Consumer Health Education? New England Journal of Medicine, 358(21), 2197-2200. doi:10.1056/nejmp0801433

Bulik, B. S. (2016). With May pharma TV ad spending, AbbVie's Humira tops last year's total; Pfizer's Lyrica close behind. Retrieved December 20, 2016, from http://www.fiercepharma.com/marketing/may-pharma-tv-ad-spending-abbvie-s-humira-tops-last-year-s-total-pfizer-s-lyrica-close

Cochran, A. (2014). Does your doctor have ties to big pharma? How you'll be able to find out. Retrieved December 15, 2016, from http://www.cbsnews.com/news/does-your-doc-have-ties-to-big-pharma-how-youll-be-able-to-find-out/

Dejong, C., Aguilar, T., Tseng, C., Lin, G. A., Boscardin, W. J., & Dudley, R. A. (2016). Pharmaceutical Industry–Sponsored Meals and Physician Prescribing Patterns for Medicare Beneficiaries. JAMA Internal Medicine, 176(8), 1114. doi:10.1001/jamainternmed.2016.2765

Direct-to-consumer advertising under fire. (2009). *Bulletin of the World Health Organization*, *87*(8), 576–577. http://doi.org/10.2471/BLT.09.040809

Donohue, J. (2006). A history of drug advertising: the evolving roles of consumers and consumer protection. *The Milbank Quarterly*, *84*(4), 659-699.

Drug Advertising: A Glossary of Terms. (n.d.). Retrieved September 20, 2016, from http://www.fda.gov/Drugs/ResourcesForYou/Consumers/PrescriptionDrugAdvertising/ucm072025.htm#dtc

Ennis, B. (2011). Lipitor becomes world's top-selling drug. Retrieved December 21, 2016, from http://www.crainsnewyork.com/article/20111228/HEALTH_CARE/111229902/lipitor-becomes-worlds-top-selling-drug

Eva, K. W. (2014). Trending in 2014: Hippocrates. *Medical Education*, *48*(1), 1-3. doi:10.1111/medu.12392

Federal Drug Administration. (2016, October 24). What We Do. Retrieved February 02, 2017, from http://www.fda.gov/AboutFDA/WhatWeDo/default.htm

Federal Drug Administration. (2004). Vioxx (rofecoxib) Questions and Answers. Retrieved January 13, 2017, from http://www.fda.gov/drugs/drugsafety/postmarketdrugsafetyinformationforpatientsandproviders/ucm106290.htm

Frosch, D. L., Grande, D., Tarn, D. M., & Kravitz, R. L. (2010). A Decade of Controversy: Balancing Policy With Evidence in the Regulation of Prescription Drug Advertising. American Journal of Public Health, 100(1), 24-32. doi:10.2105/ajph.2008.153767

Guessous, I., & Dash, C. (2015). Direct to Consumer Advertising: The Case for Greater Consumer Control. *Journal of General Internal Medicine*, *30*(4), 392–394. http://doi.org/10.1007/s11606-015-3187-8

Hellín, T. (2002). The physician–patient relationship: recent developments and changes. *Haemophilia*, *8*(3), 450.

Hippocratic Oath. (2004). *Southern Medical Journal*, *97*(12), 1169-1170.

Jackson, M. (2011). The Oxford handbook of the history of medicine. Oxford: Oxford University Press.

Jain, K. K. (2015). Textbook of personalized medicine. New York: Humana Press.

Jameson, J. L., & Longo, D. L. (2015). Precision Medicine—Personalized, Problematic, and Promising. Obstetrical & Gynecological Survey, 70(10), 612-614. doi:10.1097/01.ogx.0000472121.21647.38

Jaramillo, D. L. (2006). Pills Gone Wild: Medium Specificity and the Regulation of Prescription Drug Advertising on Television. Television & New Media, 7(3), 261-281. doi:10.1177/1527476404270605

Joyner, M. J., & Paneth, N. (2015). Seven Questions for Personalized Medicine. Jama, 314(10), 999-1000. doi:10.1001/jama.2015.7725

Kaphingst, K. A., & DeJong, W. (2004). The Educational Potential Of Direct-To-Consumer Prescription Drug Advertising. Health Affairs, 23(4), 143-150. doi:10.1377/hlthaff.23.4.143

Koons, C., & Langreth, R. (2015). How Marketing Turned the EpiPen Into a Billion-Dollar Business. Retrieved November 18, 2016, from http://www.bloomberg.com/news/articles/2015-09-23/how-marketing-turned-the-epipen-into-a-billion-dollar-business

Khosla, P., & Khosla, A. (2011). Direct to consumer advertising of prescription drugs on internet: A Boon or a Curse. *Indian Journal of Pharmacology*, *43*(4), 483–484. http://doi.org/10.4103/0253-7613.83128

Lipitor Lawsuit: Litigation for Statin Drug Linked to Diabetes. (n.d.). Retrieved December 21, 2016, from https://www.drugwatch.com/lipitor/lawsuit/

Magner, L. N. (1992). *A History of Medicine*. New York: Informa Healthcare.

Magnezi, R., Bergman, L. C., & Urowitz, S. (2014). Would Your Patient Prefer to Be Considered Your Friend? Patient Preferences in Physician Relationships. Health Education & Behavior, 42(2), 210-219. doi:10.1177/1090198114547814

Mamede, S., & Schmidt, H. G. (2014). The twin traps of overtreatment and therapeutic nihilism in clinical practice. *Medical Education*, *48*(1), 34-43. doi:10.1111/medu.12264

Medication Guide HUMIRA® (Hu-MARE-ah) (adalimumab) injection. (n.d.). http://www.fda.gov/downloads/drugs/drugsafety/ucm088611.pdf

Medieval Life. (2013, July 15). Retrieved November 17, 2016, from http://www.medievalages.net/2013/07/medieval-life/

Millman, J. (2015). It's true: Drug companies are bombarding your TV with more ads than ever. Retrieved October 17, 2016, from https://www.washingtonpost.com/news/wonk/wp/2015/03/23/yes-drug-companies-are-bombarding-your-tv-with-more-ads-than-ever/

Niederdeppe, J., Byrne, S., Avery, R. J., & Cantor, J. (2013). Direct-To-Consumer Television Advertising Exposure, Diagnosis with High Cholesterol, and Statin Use. *Journal of General Internal Medicine*, *28*(7), 886–893. http://doi.org/10.1007/s11606-013-2379-3

O'Donoghue, A. C., Sullivan, H. W., Aikin, K. J., Chowdhury, D., Moultrie, R. R., &

Rupert, D. J. (2014). Presenting efficacy information in direct-to-consumer prescription drug advertisements. Patient Education and Counseling, 95(2), 271-280. doi:10.1016/j.pec.2013.12.010

Payton, A. R., & Thoits, P. A. (2011). Medicalization, Direct-to-Consumer Advertising, and Mental Illness Stigma. Society and Mental Health, 1(1), 55-70. doi:10.1177/2156869310397959

Pokorska-Bocci, A., Stewart, A., Sagoo, G. S., Hall, A., M. K., & Burton, H. (2014). 'Personalized medicine': what's in a name? Personalized Medicine, 11(2), 197-210. Retrieved January 10, 2017, from http://www.futuremedicine.com/doi/pdf/10.2217/pme.13.107

Ray, T. (2016). Precision Medicine Has Bipartisan Support, Proponents Assure Amid Trump Administration Transition. Retrieved February 23, 2017, from https://www.genomeweb.com/cancer/precision-medicine-has-bipartisan-support-proponents-assure-amid-trump-administration

Reimann, M. (2016, August 24). The story of the EpiPen: from military technology to drug-industry cash cow. TIMELINE. Retrieved February 20, 2017, from https://timeline.com/epipen-technology-drug-industry-b28d19036dee#.lrjovt8b8

Roan, S. (2011). Lipitor, best-selling drug ever, goes off patent. Retrieved December 21, 2016, from http://articles.latimes.com/2011/nov/30/news/la-heb-lipitor-generic-20111130

Robbins, R. (2016a). Drug makers now spend $5 billion a year on advertising. Here's what that buys. Retrieved from https://www.statnews.com/2016/03/09/drug-

industry-advertising/

Robbins, R. (2016b). Behind the stealth ad campaigns for the EpiPen and other drugs. Retrieved December 21, 2016, from https://www.statnews.com/2016/08/29/epipen-unbranded-ads/

Rockoff, J. D. (2016). Knockoffs of biotech drugs bring paltry savings; price increases of brand-name medicines are diminishing expected savings from biosimilars, adding to pressure on overall health costs. *Wall Street Journal (Online)* Retrieved from http://dml.regis.edu/login?url=http://search.proquest.com.dml.regis.edu/docview/1786820552?accountid=28590

Ross, J. S., & Kravitz, R. L. (2013). Direct-to-Consumer Television Advertising: Time to Turn Off the Tube? *Journal of General Internal Medicine*, *28*(7), 862–864. http://doi.org/10.1007/s11606-013-2424-2

Royne, M. B., & Myers, S. D. (2008). Recognizing Consumer Issues in DTC Pharmaceutical Advertising. Journal of Consumer Affairs, 42(1), 60-80. doi:10.1111/j.1745-6606.2007.00094.x

Rubin, R. (2016). EpiPen price hike comes under scrutiny. The Lancet, 388(10051), 1266. doi:10.1016/s0140-6736(16)31708-1

Rutter, P., & Gilbody, S. (2008). The European pharmaceutical industry: coming to a screen near you? *Journal of the Royal Society of Medicine*, *101*(10), 485–488. http://doi.org/10.1258/jrsm.2008.080259

Saul, S. (2005). Senate Leader Calls for Limits on Drug Ads. The New York Times. Retrieved January 13, 2017, from

http://www.nytimes.com/2005/07/02/politics/senate-leader-calls-for-limits-on-drug-ads.html

Say 'Yes' to Drugs? The History of Pharmaceutical Marketing. (2014). Retrieved November 16, 2016, from http://webusinessplan.blogspot.com/2015/01/say-yes-to-drugs-history-of.html

Advertisement

Schultz, S. G. (2002). William Harvey and the Circulation of the Blood: The Birth of a Scientific Revolution and Modern Physiology. Physiology, 17(5), 175-180. doi:10.1152/nips.01391.2002

Scott, D. (2015, December 11). The untold story of TV's first prescription drug ad. Retrieved November 16, 2016, from https://www.statnews.com/2015/12/11/untold-story-tvs-first-prescription-drug-ad/

Shoaib, M., Rameez, M. A., Hussain, S. A., Madadin, M., & Menezes, R. G. (2016). Personalized Medicine in a New Genomic Era: Ethical and Legal Aspects. Science and Engineering Ethics. doi:10.1007/s11948-016-9828-4

Shuchman, M. (2007). Drug Risks and Free Speech — Can Congress Ban Consumer Drug Ads? New England Journal of Medicine, 356(22), 2236-2239. doi:10.1056/nejmp078080

Sisk, B., Frankel, R., Kodish, E., & Harry Isaacson, J. (2016). The Truth about Truth-Telling in American Medicine: A Brief History. *The Permanente Journal*, *20*(3), 74-77. doi:10.7812/TPP/15-219

Suh, H. S., Lee, D., Kim, S. Y., Chee, D. H., & Kang, H. (2011). Direct-to-consumer advertising (DTCA) for prescription drugs: Consumers' attitudes and preferences concerning its regulation in South Korea. Health Policy, 101(3), 260-268. doi:10.1016/j.healthpol.2011.05.005

Taylor, R. B. (2015). On the shoulders of medicine's giants: What today 's clinicians can learn from yesterday's wisdom. New York: Springer Science Media Business.

Toop, L., & Mangin, D. (2007). Industry funded patient information and the slippery slope to New Zealand . *BMJ : British Medical Journal*, *335*(7622), 694–695. http://doi.org/10.1136/bmj.39346.525764.AD

U.S. Food and Drug Administration (USFDA). (2013, October). Paving the Way for Personalized Medicine FDA's Role in a New Era of Medical Product Development. http://www.fda.gov/downloads/scienceresearch/specialtopics/personalizedmedicine/ucm372421.pdf

U.S. National Library of Medicine. (2015). What is the Precision Medicine Initiative? - Genetics Home Reference. Retrieved January 10, 2017, from https://ghr.nlm.nih.gov/primer/precisionmedicine/initiative

Velo, G., & Moretti, U. (2008). Direct-to-consumer information in Europe: the blurred margin between promotion and information. *British Journal of Clinical Pharmacology*, *66*(5), 626–628. http://doi.org/10.1111/j.1365-2125.2008.03283.x

Ventola, C. L. (2011). Direct-to-Consumer Pharmaceutical Advertising: Therapeutic or Toxic? *Pharmacy and Therapeutics*, *36*(10), 669–684.

Wolinsky, H. (2015). Imprecise marketing of precision medicine: Advertising may be running ahead of science. Modern Healthcare . Retrieved January 11, 2017, from http://www.modernhealthcare.com/article/20150502/MAGAZINE/305029979