

Online Journal of Health Ethics

Volume 5 | Issue 2

Article 3

An Ethical Analysis of Contemporary Healthcare Practices and Issues

Gerald Mark Breen M.A.

University of Central Florida, gbreen@mail.ucf.edu

Michael Loyal M.A.

University of Central Florida, mloyalmktg@aol.com

Vanessa Littleton R.N.

University of Central Florida, vlittleton@aol.com

Binyam Seblega M.B.A.

University of Central Florida, binyamkassa@yahoo.com

Seung Chun Paek M.S.

University of Central Florida, spaek@mail.ucf.edu

See next page for additional authors

Follow this and additional works at: <http://aquila.usm.edu/ojhe>

Recommended Citation

Breen, G. M., Loyal, M., Littleton, V., Seblega, B., Paek, S. C., Meemon, N., Ellis, N., & Wan, T. T. (2008). An Ethical Analysis of Contemporary Healthcare Practices and Issues . *Online Journal of Health Ethics*, 5(2). <http://dx.doi.org/10.18785/ojhe.0502.03>

This Article is brought to you for free and open access by The Aquila Digital Community. It has been accepted for inclusion in Online Journal of Health Ethics by an authorized administrator of The Aquila Digital Community. For more information, please contact Joshua.Cromwell@usm.edu.

An Ethical Analysis of Contemporary Healthcare Practices and Issues

Authors

Gerald Mark Breen M.A., Michael Loyal M.A., Vanessa Littleton R.N., Binyam Seblega M.B.A., Seung Chun Paek M.S., Natthani Meemon M.A., Nancy Ellis Ph.D., and Thomas T.H. Wan Ph.D.

An Ethical Analysis of Contemporary Healthcare Practices and Issues

Gerald Mark Breen, M.A.

University of Central Florida
gbreen@mail.ucf.edu

Michael Loyal, M.A.

University of Central Florida
mloyalmktg@aol.com

Vanessa Littleton, R.N.

University of Central Florida
vlittleton@aol.com

Binyam Seblega, M.B.A.

University of Central Florida
binyamkassa@yahoo.com

Seung Chun Paek, M.S.

University of Central Florida
spaek@mail.ucf.edu

Natthani Meemon, M.A.

University of Central Florida
nuttanie@hotmail.com

Nancy Ellis, Ph.D.

University of Central Florida
nancy@mail.ucf.edu

Thomas T. H. Wan, Ph.D.

University of Central Florida
twan@mail.ucf.edu

Abstract

The purpose of this analysis is to examine specific segments of healthcare policy and practice, applying various ethical perspectives. We examine the economic and political influences that surround ethical behavior in health services, as well as how practitioners, patients, and families respond and act as a result of such influences. We then delve into the fundamental principles that guide ethical behavior by medical practitioners, including the Hippocratic Oath and vows of medical professionalism. Further, we analyze disparities in healthcare provisions based on gender, race, and ethnicity. Ethical theory is weaved into each of these sections, as the philosophical and ethical writings of prominent scholars illuminate how the conditions of contemporary healthcare administration are affected by the injustices and political influences that pervade the entire health services industry.

Keywords: Ethics, Health Services, Justice, Patients, Physicians, Professionalism

Introduction

The purpose of this analysis is to examine specific segments of healthcare policy and practice, applying various ethical perspectives. First, we provide a general overview of the common ethical issues that confront the healthcare industry. More specifically, we examine the economic and political influences that surround ethical behavior in health services, as well as how practitioners, patients, and families respond and act as a result of such influences. We then delve into the fundamental principles that guide ethical behavior by medical practitioners, including the Hippocratic Oath and vows of medical professionalism. To this end, we cover elements of doctor-patient communication, clinical decisions regarding administration of care and prescription medication, and the issues of direct-to-consumer drug advertising (DTCA). Moreover, we elucidate these ethical issues by providing *bona fide* examples of such situations and the ramifications they carry. Because of the vast divisions in healthcare services and differences in care across geographical and socioeconomic levels, we analyze disparities in healthcare provisions based on gender, race, and ethnicity. Such disparities represent a significant challenge to the ethical pursuit of equal and just healthcare administration for all peoples. Ethical theory is weaved into each of these sections, as the philosophical and ethical writings of prominent scholars illuminate how the conditions of contemporary healthcare administration are affected by the injustices and political influences that pervade the entire health services industry.

Literature Review

General Overview on Ethics in the Healthcare Industry

The study of ethics in the healthcare industry often focuses on issues that arise in medical and clinical settings, including: medical research, patient autonomy and care, patient health care, and professional relationships (Werhane & Rorty, 2000). The general consensus regarding the foremost professional purposes of the healthcare industry is that it provides services to society requiring medical attention, to secure and maintains the overall health of those who are healthy, and protects important healthcare values necessary to set the standard for the profession (Emanuel, 2000). Healthcare professions and professionals inherently expect out of their associates the traits of trustworthiness, accountability, personal integrity, and expertise (Emanuel, 2000). In addition, Emanuel (2000) stresses that the elements that make healthcare professions unique is the fact that the self-interests of medical professionals are subordinated by the very calling of their profession. In fact, in the healthcare industry, the need to provide professional services takes precedence over the interests of the care being provided to the organizations themselves. Emanuel (2000) identifies eight professional practice areas where healthcare professionals have the responsibility to hold expertise: 1) decision making, 2) fiduciary obligations, 3) confidentiality, 4) obligations consequential to patient vulnerability, 5) personal standards, 6) equity, 7) cultural representation, and 8) procedures for resolving dilemmas.

Political and Economic Responsibilities of the Healthcare Industry

The healthcare industry has political and economic responsibilities, too (Emanuel, 2000). The political purpose refers to the fact that citizens (both patients and professionals) are intrinsically entitled to express their own voices on how medical care and treatment are administered: in a fair, just, respectable, and personable manner. Also, there is an economic purpose to the healthcare industry; healthcare services are governed and piloted by the market, economy, and financial forces in the surroundings. Patients essentially represent the consumers, whereas the healthcare professionals or practitioners signify the purveyors. Yet, as Emanuel (2000) emphasizes, the purpose of health care in general claims precedence over the other two purposes. One main reason is that the political purpose is important in outlining the procedures through which the healthcare industry functions. Unless efforts devoted to this purpose are strictly aligned with professional objectives, these efforts can inadvertently transform into promotional methods of self-interest. The economic function is necessary for financial feasibility and affordability. Unless these protocols are guided to fall in line with the interests of both patients and the public health sector, circumstances can deviate from the intended path and become more specific toward self-promotion. As Emanuel (2000) later concludes, the political and economic purposes should stand in second place to the professional purpose. In doing so, a combination of mission statements, by-laws, and other similar structures is conveyed.

Ethical Issues Confronting Practitioners, Patients, and Families

According to Aulisio, Arnold, and Youngner (2000), healthcare providers, patients, and families are routinely confronted with ethical questions such as: competence, confidentiality, informed consent, medical futility, patient autonomy, resource allocation, rights of conscience,

and surrogate decision making. Such questions revolve around values generally accepted by societies. As history typically reveals, laws and policies reflect the values practiced by those societies. Laws often dictate decisions and ethics based on commonly accepted values. Policies, however, direct ethically-relevant matters based on internal and external environmental factors.

Ethics represents a political and social issue, as well as one that is philosophical and conceptual. Healthcare professionals need to critically examine these ethical conditions to genuinely comprehend the ethical ambiguities that exist within their professions. If healthcare organizations sense the need to promote the basic purposes for which they stand, then their very structure should be founded on such definitive ethical values. In short, the organizational structures should be consistent with the ethical values as set forth by the professional healthcare system.

Accountability in the Healthcare Field

A fundamental ethical concept in healthcare settings is accountability. According to Emanuel (2000), accountability refers to a rendering of account for responsibilities entailed by the job assumed. The purpose of this accountability helps identify rationalizations, feedback, and amendments to the appropriate parties. Accountability inherently implies reciprocity between those who are accountable and those to whom accountability is held. Accountability is a two-way relationship; that is, not a single entity is without some sort of accountability. Each entity must strive to hold others accountable for their actions. It is important to recognize that accountability is not intended to be solely applied for punitive reasons; such accountability also serves as an inherent constituent in the occupation itself. In healthcare settings, such reciprocal

accountability can be found in relationships between physicians, patients, nurses, pharmacists, clinics, hospitals, insurance companies, government, and the general public (Emanuel, 2000).

Examples of Accountability Concerns

Accountability can present mixed controversial issues and matters of questionability. A prime anecdote is the infamous case of the anencephalic infant: Baby K (Mason, Laurie, & Aziz, 2006). Anencephalic babies possess a brain stem (i.e., the Pons and Medulla) yet lack essential neurological structures – the cerebrum or cerebellum. Figure 1 comparatively depicts a normal infant brain (left) and an abnormal, anencephalic infant brain (right).

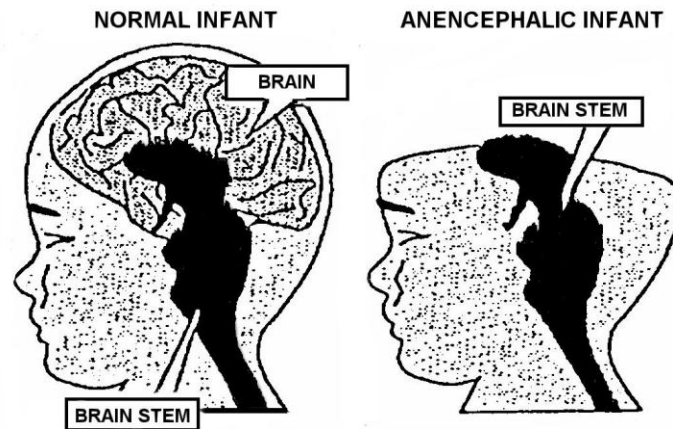


Figure 1: Normal Brain and Anencephalic Brain (Mason, Laurie, & Aziz, 2006)

Anencephalic babies are capable of breathing and heart rhythms, yet they lack important sensory components: vision, hearing, and touch. They are physically alive when at birth, but their post-partum lifespan is short-lived. In the anecdote of Baby K, this child was born in Virginia in 1992. At the insistence of the mother, Baby K received a series of aggressive life-sustaining treatments until the baby died at the age of 2. As a matter of financial importance, the treatment undertaken to prolong the life of this deformed infant cost the private insurer and Medicaid over

\$500,000USD. Under such circumstances, the notion of accountability enters into the ethical equation. Hospitals are professionally and legally obligated to place the well-being of their patients at the forefront, especially in emergency situations. Yet, common sense dictates that if the healthcare industry and insurance companies need to avoid significant financial losses (which tend to render increased premiums across the general population), there should be a restraint on such an unrestrained approach to healthcare delivery (Paris & Post, 2000). In the context of healthcare costs being as enormous as they currently are – not only are professional standards and guidelines ethically considered, but so are fiscal issues.

Shortcomings of Ethical Theories in the Healthcare Industry

Jaeger (2001) asserts that available ethical theories fall short in explaining the complex problems that exist in the healthcare industry. Jaeger (2001) defines moral sensitivity as “openness to the differences that can exist between people involved in a particular decision-making situation, and it depends on both an understanding and respect for the complexity of meaningfulness in human life” (p. 139). Moral sensitivity goes beyond understanding what others are feeling or experiencing. Being ethical requires that people comprehend and appreciate that they may not share the same value systems as others. As such, Jaeger (2001) recommends that healthcare facilities should include administrative systems that create environments that motivate workers to be both ethical and accountable.

The Hippocratic Oath: The Ultimate Ethical Foundation for Physician Practice and Patient Care

Hippocrates: The Father of Western Medicine

Hippocrates was, and still remains, a renowned physician, a pioneer in Greek medicine, and to many, the “father of western medicine”, who lived from 460 to 370 B.C. (Goldberg, 2006). Hippocrates developed the first scientific medical paradigm, led the medical field’s independence from religion and philosophical speculation, and devised an original code regarding medical ethics. Although the common method of healing the ill was to deliver them to a sacred temple for supplication to Aesculapius – the god of medicine (Stern, 2005; Sykiotis, Kallioliias, & Papavassiliou, 2005) – Hippocrates conceded that pathology generated from natural sources. Hippocrates believed that the human body, with its inherent immune system, could recover on its own, leading to healing and restoration. His direct observations of symptoms and the development of disease enabled him to describe many of today’s commonly known maladies: pneumonia, arthritis, malaria, etc.. Hippocrates exhorted like-minded physicians to strive to ensure the restoration of the sick, and that physicians should be honorable in their practice (O’Neil, 2006).

Original and Modern Version of the Hippocratic Oath

The Hippocratic Oath is a sacred vow that has been both historically and traditionally pledged by physicians with respect to their ethical practice of medicine. Because physicians have sworn to this oath for more than two millennia, this “word of honor” has been asserted to have been created by Hippocrates himself; hence the name (Goldberg, 2006; Stern, 2005). The Hippocratic Oath was initially intended to prohibit physicians from participating in abortions and

surgical procedures in which knowledge of the surgical practice itself was unfamiliar. In contemporary society, physicians pledge to a reformed version of the oath as a necessary and legal part of graduating from medical school (O'Neil, 2006). Essentially, the oath stipulates that novice physicians swear to strictly practice and uphold professional ethical standards. The most prominent element to this oath, in today's practice, is to avoid committing harm to patients.

It is crucial that the entire Hippocratic Oath, in its modern form, be iterated so that a clear understanding of its nature, seriousness, and the ethical implications it carries are fully recognized. As such, the Hippocratic Oath is as follows:

“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 [that] 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. If it is given me to save a life, all thanks. But it may also be within my power to take a life; this awesome responsibility must be faced with great humbleness and awareness of my own frailty. 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 (Lasagna, 1964).”

Surprisingly, the Hippocratic Oath has diminished in popularity among medical professions in the last several decades. As a result, in 1999, American and European medical societies formed a special committee: the Medical Professionalism Project. Too, this committee devised a renewed oath: the Charter on Medical Professionalism (O’Neil, 2006). According to Stern (2005), the professional and ethical responsibilities in this reformed oath include: 1) professional competence, 2) honesty with patients, 3) patient confidentiality, 4) maintaining appropriate relations with patients, 5) improving quality of care and access to care, 6) just distribution of finite resources, 7) scientific knowledge, 8) maintaining trust by managing conflicts of interest, and 9) professional responsibilities. These ethical obligations represent the core values of professional medical practice.

Ethical Dilemmas Regarding Doctor-Patient Communication

The delicate relationships that doctors and patients share are based on a mutually agreeable understanding regarding their purpose(s) within the clinical interaction. Essentially, the purpose of this type of healthcare interaction is to achieve an effective and realistic medical result – to manage and ensure the welfare of the patient. Keenly associated with reaching this outcome within the doctor-patient relationship is the requirement of key social and ethical elements, particularly benevolence, honesty, confidentiality, and trust (Breen et al., 2009). These fundamental traits within the doctor-patient interaction are both of moral and legal priority and

relevance. Further, the provision of an appropriate “standard of care” – that is, a form and level of care that aims to avoid or minimize patient harm – is both mandated and expected by our society’s commonly held moral convictions and governmental laws that serve to perpetuate a sense of trust within general healthcare practice. Thus, the very nature of the doctor-patient relationship must be clearly secured within tight ethical boundaries.

Clinical Decisions Regarding the Administration of Prescription Medications

Of the numerous ethical issues that surround doctor-patient relationships, the clinical communications regarding decisions over pharmaceutical prescriptions represent one such ethical concern (Petersen, 2008). Over the past century, there have been significant changes, not to mention varying expectations, in the relationships that physicians and their patients share. The traditional, paternalistic model of clinical decision-making, in which doctors dominate and preempt medical decisions on behalf of their patients, has become a decreasingly observed and acceptable practice across the country. The role of the patient within the clinical interaction has become increasingly emphasized in recent years, most notably through the adoption of a strategy known as “patient-centered” (or *patient-centric*) care (Breen et al., 2009; Stewart et al., 1995). Patient-centric care involves the physician employing active listening skills as a means to encourage patient expression regarding their own, personal agendas. In addition, this form of care seeks to understand patients’ perspectives and expectations, and aims to create a cooperative doctor-patient interaction in which to find common ground regarding clinical and case management (Stevenson, Barry, Britten, Barber, & Bradley, 2000). Therefore, patients no longer act as blind consumers, as this patient-centric practice enables them to become increasingly active in clinical participation.

Ethical Concerns Surrounding Direct-to-Consumer Drug Advertising

There is a myriad of ethical breaches and dilemmas in doctor-patient communication regarding the decisions surrounding prescription drug administration (Petersen, 2008). Interrelated ethical deficiencies are complicated even further by various intrinsic and extrinsic factors. Diverse ethical implications in doctor-patient communication cannot be clearly defined, and this communication should be accompanied by honesty, confidentiality, genuine necessity, and trust in terms of both morality and legality. Breen et al. (2009) emphasized that the existence of credibility and comfort in doctor-patient communication can improve quality of care. This credibility must be driven by ethical responsibility. According to Breen et al. (2009), there is a strong, positive correlation between increased, quality communication and improved feelings of satisfaction and trust between medical practitioners and patients. This finding represents a key lesson, one that propagates the message that doctor-patient relationships can be enhanced via mutual trust. This kind of reciprocally beneficial relationship can also positively affect care and treatment quality.

Patients' Involvements in Prescription Drug Advertising

Patients' clinical participation has also been accelerated by the rampant phenomenon known as direct-to-consumer drug advertising (DTCA), primarily spawned by the pharmaceutical industry (Loe, 2006; Petersen, 2008). Drug advertising creates a pervasive dissemination of education and information for consumers regarding new products, prompting and enabling many consumers to seek out such medication through their physicians. Since pharmaceutical companies have started mass advertisement of prescription drugs, both directly to

consumers and physicians (Petersen, 2008), understanding the clinical, psychological, and ethical impacts of drug advertising on physicians and consumers becomes critical.

DTCA has increased rapidly in the United States over last decade in particular (Loe, 2006; Mintzes et al., 2003; Petersen, 2008). Too, prescription pharmaceuticals are being ever more advertised via a variety of media outlets – television, magazines, and multimedia. Such advertising is a powerful tool, strategically designed to create widespread demand as a financial method to maximize profits (Petersen, 2008; Practice Advisory, 2001). DTCA clearly serves as an educational tool as well, providing both medical practitioners and patients with drug product information.

Primary Effects of DTCA

Despite the many benefits of DTCA, the costs are staggering. DTCA will inevitably drain healthcare dollars, dramatically increase unnecessary prescribing, and strain doctor-patient relationships (Hoffman & Wilkes, 1999). The overall influences involved in DTCA have only been critically studied for just under a decade (Bell, Kravitz, & Wilkes, 1999; Petersen, 2008). To deal with these issues, one prudent suggestion would be to ethically approach and improve doctor-patient communication. Put differently, if an open, affable, and two-sided relationship can be clinically developed in the practitioner-patient relationship, this interactive style should lead to more appropriate and necessary decisions in the prescription of pharmaceuticals. This approach should help to control and regulate healthcare expenses in general.

According to the Practice Advisory (2001), neurologists in particular may be solicited by pharmaceutical or medical device companies to participate in DTCA since general practitioners

are the targets of aggressive DTCA marketing. A keynote committee, formed by the Practice Advisory (2001), functions under the following ethical tenets:

- 1) Patient education materials produced by pharmaceutical and medical device companies may provide useful information but should also serve the purpose of advertising and should therefore be regarded as DTCA.
- 2) Mass marketing through DTCA may not promote a drug or device to an individual for whom it is unsuitable.
- 3) Participation in DTCA may have an unfavorable effect on a neurologist's professional reputation and trusted relationship with patients.
- 4) The relationship between neurologists and industry merits further analysis and improvement.
- 5) Public information about advances in therapy should be effectively conveyed from reliable, impartial sources.

Ethical Anecdotes of DTCA Administrations

Since the emergence of DTCA, more people are now requesting prescription drugs from their physicians, leading to, in many cases, physician compliance with those patient pharmaceutical requests (Kopp & Bang, 2000; Petersen, 2008). A serious issue with this situation is that misleading drug advertisements can lead to negative and dangerous consequences. For example, many prescription analgesics (pain relievers) are chemically derived

and produced from opium, the same substance that produces heroin's notoriously euphoric effects (Petersen, 2008). Drug-seeking patients may successfully pretend or feign illness in order to obtain these drugs. Similar patients may also seek to maintain a continuous supply of these drugs from their prescribing physicians. Then, as this drug consumption pattern becomes crystallized, the patient can be led to iatrogenic addiction.

Even if the pain and physical complaints are legitimate and verifiable (such as an illness related to the nervous system), repeated administration of narcotic medications for pain management can contribute to severe addiction problems and potential overdose. Fentanyl, one such powerful opiate for the relief of chronic pain conditions, has led to serious overdoses and cases of death (Borland, Jacobs, King, & O'Brien, 2007). The FDA has required Fentanyl patch producers to make special medication instructions that will accompany every box, articulating proper use of this drug. Figure 2 illustrates Fentanyl and its warnings issues by the FDA.



Figure 2: Fentanyl and FDA Warning (Borland, Jacobs, King, & O'Brien, 2007)

These kinds of examples are common occurrences in clinical practice, and represent one major way in which the ethical treatment of patients is crucial for the overall reputation and perception of healthcare delivery.

Viagra is another well-known drug that epitomizes a clash in DTCA and ethics (Loe, 2006). Viagra is clinically indicated for the use and treatment of male erectile dysfunction or impotence. Figure 3 illustrates a common DTCA of Viagra and the hyperbolized benefits of this medication.

Viagra
VIAGRA
(sildenafil citrate) tablets

Three reasons I'm *Singing* the praises of Viagra.

- It's America's most prescribed treatment for men with erectile dysfunction.
- It has an established safety record. And over a decade of research behind it.
- It helps me go and keep former erections.

Find your own reasons@viagra.com.

VIAGRA is prescribed to treat erectile dysfunction. We know that no medicine is for everyone. If you use prescription drugs, often used for chest pain (known as nitrates), don't take VIAGRA. Taking these drugs together could cause your blood pressure to drop to an unsafe level.

Talk with your doctor first. Make sure your heart is healthy enough to have sex. If you have chest pain, nausea, or other discomforts during sex, seek medical help right away.

Although erections lasting for more than four hours may occur rarely with all ED treatments in this drug class, to avoid long-term damage, it is important to seek immediate medical help.

In rare instances, men taking PDE5 inhibitors (oral erectile dysfunction medications, including VIAGRA) reported a sudden decrease or loss of vision. It is not possible to determine whether these events are related directly to these medications or to other factors. If you experience sudden decrease or loss of vision, stop taking PDE5 inhibitors, including VIAGRA, and call a doctor right away.

The most common side effects of VIAGRA are headache, facial flushing, and upset stomach. Eye symptoms are thought to be related to men who are sensitive to light. These may occur for a brief time. Remember to protect yourself and your partner from sexually transmitted diseases.

Please see our patient summary of information for VIAGRA (25 mg, 50 mg, 100 mg) tablets on the following page.

For free information, including questions to ask your doctor, call 1-888-4VIAGRA (1-888-484-2472).

Uninsured? Need help paying for Pfizer medicines? Pfizer has programs that can help. Call 1-800-PfizerCare or visit www.PfizerPatientAssistance.com.

Figure 3: DTCA of Viagra (Loe, 2006)

One major side effect of this medication is pulmonary arterial hypertension (PAH), a potentially life-threatening condition (Loe, 2006). Although this kind of pharmaceutical product can negatively affect physiological functioning, some consumers believe that the positive effects on their psychological health outweigh the risks to their physical health. The ethical circumstances surrounding the costs and benefits of this medication need to be carefully weighed. For instance, there are numerous ethical discourses concerning Viagra: 1) Is sex medically necessary or elective? and 2) Is there a physical or psychological defense that ethically

merits insurance companies to cover Viagra? Under these conditions, how physicians and patients ethically negotiate these issues represent ethics in health communication.

The History of Pharmaceutical Advertising

Regulation

Pharmaceutical advertising regulation originated in 1938 with the passage of the Federal Food, Drug and Cosmetic Act and the establishment of the Food and Drug Administration, or the FDA (Gellad & Lyles, 2007). In 1962, the act was amended to require that medications be proven both safe and efficacious before being advertised to the public (Gellad & Lyles, 2007).

According to Shaw (2008), mass media DTCA did not exist before 1980, because pharmaceutical manufacturers aimed their marketing efforts at physicians, relying on the strength of the traditional doctor-patient relationship to sell their products. An “about-face” in this marketing philosophy occurred in the early 1980s, when Boots Pharmaceuticals aired the first DTCA for the anti-arthritis drug: Rufen (Shaw, 2008). Subsequent DTCA for Pneumovax, a pneumonia vaccine, reflected Merck’s recognition that patients were taking a more proactive role in their care and the prescriptions their physicians were writing for them. These and other advertisements started to raise concerns about the ramifications of DTCA. Consequently, the FDA called for a voluntary moratorium on DTCA in order to craft a more explicit policy (Shaw, 2008). In 1985, however, the moratorium ended with revised guidelines that called for DTCA to adhere to the same rules that govern pharmaceutical advertising to physicians (Gellad & Lyles, 2007). Gellad and Lyles (2007) noted that the FDA’s decision limited DTCA because the drug manufacturers believed the *brief summary* requirement (i.e., a summary of the product label

including risk-related information in all promotional material) would dull any promotional effect of advertisements on consumers.

In 1997, the FDA reformed these policies again and allowed DTCA to appear on television (Donahue, Cevalco, & Rosenthal, 2007). New policies allowed for the removal of the brief summary requirement and permitted manufacturers to tell customers that there were alternative resources – such as web sites and toll-free telephone numbers – for obtaining that information. This policy became known as the *adequate provision* requirement (Gellad & Lyles, 2007). Another major change enabled drug manufacturers to use the drug's brand name and benefits in the same advertisement(s). Further, in 2004, the FDA stated that print advertisements were no longer required to list full prescribing information (Shaw, 2008).

DTCA Growth: 1997-2007

Following the FDA's policy change in 1997, DTCA exploded in popularity and visibility over the next decade. Pharmaceutical promotion grew at an average annual rate of 10.6% from \$11.4 billion in 1996 to \$29.9 billion in 2005 (Donahue, Cevalco, & Rosenthal, 2007). According to Donahue, Cevalco, and Rosenthal (2007), spending on DTCA increased 330% from 1996 to 2005, representing 54.4% in the total industry spending in 2005, encompassing 20 individual drugs. Gellad and Lyles (2007) also reported that, during a one-week period in Atlanta, three television networks broadcasted 907 advertisements for over-the-counter medications and 428 advertisements for prescription medications.

The Fiscal Benefits of DTCA for Pharmaceutical Companies

Pharmaceutical company's DTCA campaigns also paid off handsomely, with a major return on their investments. Boden and Diamond (2008) reported that for more than 90% of the brand name medications, 70% reaped returns in excess of \$1.50 for every \$1.00 invested. Also, 35% generated returns in excess of \$2.50 for every \$1.00 invested. Table 1 illustrates these financial gains of the top 10 prescription drug sales in the United States between 2003 and 2007.

Table 1: 2007 Top Pharmaceutical Products by U.S. Sales (Boden & Diamond, 2008)

Rank	Product	2007 Total Dollars (U.S. Billions)	2006 Total Dollars (U.S. Billions)	2005 Total Dollars (U.S. Billions)	2004 Total Dollars (U.S. Billions)	2003 Total Dollars (U.S. Billions)
1	Lipitor	8.1	8.7	8.4	7.8	6.8
2	Nexium	5.5	5.2	4.4	3.8	3.1
3	Advair Diskus	4.3	4.0	3.6	3.0	2.3
4	Plavix	3.9	3.0	3.5	3.1	2.3
5	Seroquel	3.5	3.0	2.6	2.1	1.6
6	Singulair	3.4	3.0	2.5	2.2	1.8
7	Enbrel	3.4	3.1	2.8	2.0	1.4
8	Prevacid	3.4	3.6	3.8	3.9	4.1
9	Aranesp	3.3	4.0	2.8	1.9	1.0
10	Epogen	3.1	3.2	3.0	3.0	3.1
	All	286.5	276.1	253.9	239.9	219.6

Source: IMS National Sales Perspective

The pharmaceutical companies' blockbuster DTCA budgets and drug sales, as well as the general effects of the advertisements on consumers, have not gone unnoticed. In 2007, Senators Ted Kennedy and Mike Enzi introduced Senate Bill S. 1082, the Food and Drug Administration Revitalization Act, mandating moratoriums on new prescription drugs, requiring pre-clearance of DTCA, and requiring certain language is included in these advertisements (Shaw, 2008).

The Food and Drug Administration Amendments Act (FDAAA) of 2007 became legally enacted in September 2007, but pharmaceutical advertising moratoriums were removed from the bill following "freedom of commercial speech" objections from the American Advertising Federation (Shaw, 2008). On May 20, 2008, the Pharmaceutical Research and Manufacturers of America issued a media release addressing the value of DTCA. The release reiterated PHRMA's

commitment to an “honest and open dialogue” with Congress and other stakeholders concerning the main benefits of DTCA. The statement from PHRMA (2008) essentially conveyed that increasing awareness of treatment options via DTCA advertising not only informs and educates patients potentially suffering from illness(es), but it also benefits the overall U.S.-based healthcare system by influencing patients to pursue medical attention that may assist them in the management of their conditions and in avoiding unnecessary hospital visits or procedures.

Direct-to-Consumer Drug Advertising Strategies

The Pharmaceutical Research and Manufacturers of America (2008), also known as PHRMA, defines direct-to-consumer drug advertising (DTCA) with respect to print and broadcast mediums. Each of these mediums involves unique implications. A print advertisement – whether appearing in direct mail, newspaper, or magazine publications – is paid for by a given company and is then directed to consumers for the purpose of presenting information about the company’s medicine and excludes any mention of sponsorship activities (PHRMA, 2008). Broadcast advertisement is bought by a given company for appearance on broadcast or cable television that conveys information (excluding sponsorship activities) about one or more of the company’s medicines (PHRMA, 2008). As of November 22, 2007, DTCA expanded to include medical devices, with the broadcasting of a DTCA advertisement during a professional football game that presented information about Cypher, a drug-eluting coronary stent used in percutaneous transluminal coronary angioplasty (Boden & Diamond, 2008).

The Ethics of DTCA: Helpful or Harmful?

Attitudes and opinions regarding the helpfulness or harm caused by DTCA vary – not surprisingly – depending upon one’s position within or outside the pharmaceutical, advertising,

medical, or regulatory industries. Findlay (2002) asserts that DTCA advertisements are either creating 1) a considerable, new demand for prescription medications, and/or 2) physician visits for drug requests, which represent a minor component of such visits. Further, Findlay (2002) concludes that DTCA has stimulated doctor visits and an increased awareness of new medications and medical conditions so that patients can acquire needed medications. As an “ethical” case in point, what research fails to provide is whether such doctor visits or drug requests – prompted by DTCA – are appropriate and necessary.

Almasi, Stafford, Kravitz, and Mansfield (2006) claim that DTCA aims to persuade rather than to inform, and that the information it does provide is flawed and incomplete. Boden and Diamond (2008) point out that two FDA telephone surveys conducted in 1999 and 2002 found that DTCA prompted many patients to seek out new information for available medical treatments and to ask more informed questions of their medical providers. However, Boden and Diamond (2008) temper this information-seeking benefit with concerns that DTCA television advertisements inevitably fail to completely reveal the benefits and risks that must be provided in print advertising, resulting in a diminished standard of disclosure (and one that is of significant concern to physician opponents of DTCA, not to mention congressional, supervisory committees).

Hollon (2005) reports that more than 80% of physicians believe DTCA does not provide fair and balanced information. What remains uncertain is whether DTCA helps doctors and their patients achieve the goal of improved patient health through shared decision making (Hollon, 2005). In a similar vein, Hollon (2005) revealed the reports of a randomized controlled trial involving specific drug requests from “standardized patients” and found that, while DTCA may guard against insufficient or incomplete treatment, DTCA simultaneously undermines optimal

prescribing, thereby stimulating the overtreatment for lesser conditions, and probably rendering harm in cases where the risk of therapy is not understood or is substantial.

Not surprisingly, the advertising industry's perspective on DTCA helpfulness and effectiveness differs with those of the medical community and members of Congress. Hoek and Gendall (2002) conclude that criticisms of DTCA lack any empirical foundation and the benefits of DTCA outweigh the "largely unproven disadvantages" associated with it. Mehta and Purvis (2003) surveyed 1,475 women and explored their attitudes and responses to print DTCA. Their results showed that women generally value DTCA, which seems to encourage respondents to ask their doctors about what they read (Mehta & Purvis, 2003).

Huh and Becker (2005) examined the FDA's 1999 National Survey Data and identified that DTCA exposure was strongly correlated to drug information seeking, thinking about communication with doctors, and actual communication with doctors. The study also revealed that other factors – such as prescription drug use, health conditions, demographic variables and control over health care – only indirectly affect key behavioral variables via DTCA exposure (Huh & Becker, 2005).

In a recent consumer survey (Snyder, 2008), 34% of adults aged 18 to 26 said they trust pharmaceutical companies less than they did previously. In response, the CEO of the American Advertising Federation (AAF) urged the advertising and pharmaceutical industries to regain public trust via optimized ethical advertising, an approach that provides honest, forthright, and ethical medical information to consumers who rely upon it. What can be deduced from these various propositions and statements by published authors is that DTCA is neither good nor bad. What needs to be done at this point is that policymakers must decide how to maximize DTCA

benefits, and at the same time minimize its risks, within the American free enterprise system (Almasi, Stafford, Kravitz, & Mansfield, 2006).

An Ethical Dilemma Regarding Healthcare Disparities

Racial and ethnic health disparities are one of the most challenging ethical issues currently facing the healthcare system. In a country founded on principles of equality of opportunity, the fact that race and ethnicity are associated with poor health gives rise to the question of whether or not the American healthcare system is unjust in the equitable distribution of healthcare services. Since the early 1940s, the United States has recognized that minorities have faced different health outcomes than their non-minority counterparts (Myrdal, 1996). In fact, Mays, Cochran, and Barnes (2007) reported that the health outcomes of minorities in 1990 were comparable to those of the health outcomes of the non-minorities in the 1920s, highlighting the fact that the health outcomes of African-American males living in an inner-city region of the United States were worse than those of males living in Bangladesh, one of the world's most impoverished countries (Mays, Cochran, & Barnes, 2007). Since that time, voluminous reports demonstrating disparities in rates of morbidity, mortality, disease, and injury have shown that the health outcomes of racial and ethnic minorities are consistently worse than those of the non-minority groups in several major categories (Smedley, Stith, & Nelson, 2003).

In 2003, the U.S. Congress was presented with a comprehensive report by the Institute of Medicine that provided empirical evidence that racial and ethnic minorities faced unequal treatment on several levels of the healthcare system, unequal access to healthcare services, and a lower quality of healthcare services, resulting in poorer health outcomes. Such health disparities were found in a wide range of diseases, treatments, services, recommended therapies, and

outcomes. Additionally, studies have found that racial and ethnic health disparities persist regardless of income level, education level, or insurance status (Kressin & Peterson, 2001; Krieger, 2005; Nazroo & Williams, 2006; Smedley, Stith, & Nelson, 2003). One prominent example is found in cases of infant mortality, a key indicator of a community's overall health status. The African-American infant mortality rate is over twice the rate for white infants. Even worse, the infant mortality rate for white women without even a high school diploma is better than the infant mortality rate for college-educated, African-American women (Nazroo & Williams, 2006). In light of the fact that technological, medical, and societal advancement have generally improved the health of the overall population – yet still fails to improve in the areas of racial and ethnic minorities – how does the healthcare system justify the continuation of the current structure and how do healthcare providers ensure that the system in which they operate and their manner of practice are just? These questions remain prominent ethical considerations and dilemmas for the both healthcare system and the general public.

Fundamental Ethical Considerations in United States History

The U.S. constitution posits that, as a nation – that is, as a free and independent country – the United States of America will seek to establish justice for all people. However, given the current state of health for minorities in the U.S., there is an assertion that the U.S. has fallen short in achieving the goal of justice in the equitable distribution of healthcare services. Over the years, there have been formidable debates over whether or not health care is a guaranteed right, as well as the extent of the role of government in the distribution of healthcare services (Daniels, 1985). Health and health services for the American worker are extremely important as individual and societal productivity is based upon the ability and capacity of the American worker. Individuals of ill or poor health are afforded less opportunity for social and economic prosperity,

which, in effect, reduces their quality of life. Thus, a social justice issue arises as equality of opportunity is denied when a fair and equitable healthcare system is not established for the provision of health care to those with the greatest need(s) (Smedley, Stith, & Nelson, 2003).

At the heart of the ethical dilemma is the fact that minorities often receive a lower quality of healthcare delivery than their non-minority counterparts, regardless of socioeconomic status. This phenomenon supports the idea that disparities are more about race and ethnicity than class or other statuses. The current system links affordable healthcare insurance with employment despite the fact that racial and ethnic minorities are more likely to have lower educational attainment, lower paying jobs, or are unemployed (Nazroo & Williams, 2006). Some scholars argue that the failure of the system to provide quality care to minorities, the omission of healthcare services by providers, and the resulting inferior health status of minorities serves as evidence of institutionalized discriminatory practices, representing an ethical violation of individual civil rights and a lack of fair and just treatment (Randall, 2002; Smedley, Stith, & Nelson, 2003).

Governmental Ethics in Health Services

As our first ethical consideration, we rely on John Rawls' (1971) "theory of justice". We use this theory to determine the role of government in healthcare distribution to American citizens. From an egalitarian perspective, all people should be treated as equals, and all social primary goods – including liberty, opportunity, income, and wealth – should be distributed equally, save an unequal distribution of goods is advantageous to the person(s) in the least favorable position (Rawls, 1971). In other words, there is an underlying assumption that all individuals will have access to opportunity through the provision of education and resources to

improve their individual economic status. Daniels (1985), a contemporary ethical philosopher, asserts that inequalities are unjust because they demonstrate America's inability to evenly distribute controllable resources, failing in their effort to protect equality of opportunity for racial and ethnic minorities. Since everyone is fundamentally entitled to the broadest array of basic goods and services, and because health represents a state of soundness in mental, physical, and social capacities, it is inevitably considered a basic provision. It serves as the foundation from which every activity generated by the individual occurs. As a result, health care represents a core ingredient in an individual's overall ability to pursue economic goals. A true egalitarian position requires equality in access to care, treatment, and services for all people, particularly those who are disproportionately burdened with poor health (e.g., racial minorities) (Smedley, Stith, & Nelson, 2003).

Healthcare Practitioners' Ethical Considerations

Although the overall structure of the healthcare system is important from a contextual perspective, the ethical practices of individual providers represent a critical element of health outcomes in individual patients. Currently, providers adhere to the ethical standards prescribed in the American Medical Association's (AMA) code of conduct. In establishing these standards, the AMA sought to offer an ethical framework that prioritizes the provider's responsibility to the patient first, followed by the greater society, other health professionals, and finally to the individual provider (AMA, 2006). For the purposes of this discussion, we focus on the AMA's ethical principles that state that a physician shall be dedicated to delivering competent medical care with compassion and esteem for human dignity and human rights (AMA, 2006). The principle prioritizes the need for physicians to offer services with respect for human dignity and human rights. If human dignity refers to a state worthy of respect, and if human rights are those

basic rights guaranteed by the constitution, it would appear that providers would be bound by their ethical principles to provide quality care to every patient they serve.

References

- Almasi, E. A., Stafford, R. S., Kravitz, R. L., & Mansfield, P.R. (2006). What are the public health effects of direct-to-consumer drug advertising? *PLOS Medicine*, 3(3), 284-287.
- Aulisio, M. P., Arnold, R. M., & Youngner, S. T. (2000). Healthcare ethics consultation: Nature, goals, and competencies. *Annals of Internal Medicine*, 133, 59-69.
- Bell, R. A., Kravitz, R. L., & Wilkes, M. S. (1999). Direct-to-consumer prescription drug advertising and the public. *Journal of General Internal Medicine*, 14(11), 651-657.
- Blustein, J. (2008). Who is accountable for racial equity in healthcare? *Journal of the American Medical Association*, 299(7), 814-816.
- Boden, W. E., & Diamond, G. A. (2008). DTCA for PTCA: Crossing the line in consumer health education? *The New England Journal of Medicine*, 358(21), 2197-2200.
- Borland, M., Jacobs, I., King, B., & O'Brien, D. (2007). A randomized controlled trial comparing intranasal fentanyl to intravenous morphine for managing acute pain in children in the emergency department. *Annals of Emergency Medicine*, 49(3), 335-340.
- Breen, G. M., Wan, T. T. H., Zhang, N. J., Marathe, S. S., Seblega, B. K., & Paek, S. C. (2009). Improving doctor-patient communication: Examining innovative modalities vis-à-vis effective patient-centric care management technology. *Journal of Medical Systems*.
- Daniels, N. (1985). *Just health care*. New York: Cambridge University Press.
- Donahue, J. M., Cevasco, B. A., & Rosenthal, M. B. (2007). A decade of direct-to-consumer advertising of prescription drugs. *The New England Journal of Medicine*, 357(7), 673-681.
- Emanuel, L. L. (2000). Ethics and the structures of health care. *Cambridge Quarterly of Healthcare Ethics*, 9, 151-168.
- Findlay, S. (2002). DTC advertising: Is it helping or hurting? Federal Trade Commission Health Care Workshop: Washington, D.C.
- Gellad, F., & Lyles, K. W. (2007). Direct-to-consumer advertising of pharmaceuticals. *The American Journal of Medicine*, 120(6), 475-480.

- Goldberg, H. S. (2006). *Hippocrates: Father of medicine*. Bloomington, IN: Authors Choice Press.
- Hoek, J., & Gendall, P. (2002). To have or not to have?: Ethics and regulation of direct to consumer advertising of prescription medicines. *Journal of Marketing Communications*, 8(2), 71-85.
- Hoffman, J. R., & Wilkes, M. (1999). Direct to consumer advertising of prescription drugs: An idea whose time should not come. *British Medical Journal*, 318, 1301-1302.
- Hollon, M. F. (2005). Direct-to-consumer advertising: A haphazard approach to health promotion. *Journal of the American Medical Association*, 293(16), 2030-2033.
- Huh, J., & Becker, L. B. (2005). Direct-to-consumer prescription drug advertising: Understanding its consequences. *International Journal of Advertising*, 24(4), 441-466.
- Jaeger, S. M. (2001). Teaching healthcare ethics: The importance of moral sensitivity for moral reasoning. *Nursing Philosophy*, 2, 131-142.
- Johnson, K. (2008). PHRMA Statement on DTC Advertising. Article retrieved on May 23, 2008 from http://www.phrma.org/news_room/press_releases/phrma_statement_on.
- Kopp, S. W., & Bang, H. K. (2000). Benefit and risk information in prescription drug advertising: Review of empirical studies and marketing implications. *Health Marketing Quarterly*, 17(3), 39-56.
- Kressin, N. R., & Peterson L. (2001). Racial differences in the use of invasive cardiovascular procedures: Review of the literature and prescription for the future research. *Annals of Internal Medicine*, 135(5), 352-366.
- Krieger, N. (2005). Stormy weather: Race, gene expression, and the science of health disparities. *American Journal of Public Health*, 95(12), 2155-2160.
- Lasagna, L. (1964). *Hippocratic Oath*. Medford, MA: Tufts University.
- Loe, M. (2006). *The rise of Viagra: How the little blue pill changed sex in America*. New York: NYU Press.
- Marmot, M., & Wilkinson, R. (2006). *Social determinants of health*. New York: Oxford Press.

- Mason, J. K., Laurie, G. T., & Aziz, M. (2006). *Mason and McCall Smith's law and medical ethics*. Newark: Oxford University Press.
- Mays, V., Cochran, S., & Barnes, N. (2007). Race, race-based discrimination, and health outcomes among African-Americans. *Annual Review of Psychology*, 58, 201-225.
- Mehta, A., & Purvis, S. C. (2003). Consumer response to print prescription advertising. *Journal of Advertising Research*, 11, 194-206.
- Mintzes, B., Barer, M. L., Kravitz, R. L., Bassett, K., Lexchin, J., Kazanjian, A., Evans, R. G., Pan, R., & Marion, S. A. (2003). How does direct-to-consumer advertising (DTCA) affect prescribing: A survey in primary care environments with and without legal DTCA. *Canadian Medical Association Journal*, 169, 405-412.
- Myrdal, G. (1996). *An American dilemma: The Negro problem and American democracy*. New Brunswick: Transaction Press.
- Nazroo, J., & Williams, D. (2006). The social determination of ethnic/racial inequalities in health. In M. Marmot & R. Wilkinson (Eds.), *Social determinants of health* (pp. 238-266). New York: Oxford Press.
- O'Neil, E. (2006). *Awakening Hippocrates: A primer on health, poverty, and global service*. Chicago: American Medical Association Press.
- Paris, J. J., & Post, S. G. (2000). Managed care, cost control, and the common good. *Cambridge Quarterly of Healthcare Ethics*, 9, 182-188.
- Petersen, M. (2008). *Our daily meds: How the pharmaceutical companies transformed themselves into slick marketing machines and hooked the nation on prescription drugs*. New York: Farrar, Straus and Giroux.
- Pharmaceutical Research and Manufacturers of America (2008). Article retrieved on May 27, 2008 from http://www.phrma.org/publications/policy_papers/phrma_dtc_guiding.
- Practice Advisory (2001). Participation of neurologists in direct-to-consumer advertising. *Neurology*, 56, 995-996.
- Principles of medical ethics. (2006). Chicago: American Medical Association.
- Randall, V. (2002). Eliminating the slave health deficit: Using reparation to repair black

- health. *Poverty & Race*, 11(6), 3-8.
- Rawls, J. (1971). *A theory of justice*. Cambridge: Cambridge University Press.
- Shaw, A. (2008). Direct-to-consumer advertising (DTCA) of pharmaceuticals. *ProQuest Discovery Guides*. Article retrieved on June 12, 2008 from <http://www.csa.com/discoveryguides/discoveryguides-main.php>.
- Smedley, B., Stith, A., & Nelson, A. (2003). *Unequal treatment: Confronting racial and ethnic disparities in health care*. Washington, D.C.: National Academies Press.
- Snyder, W. (2008). DTC advertising can rebuild consumer trust through third party self-regulation. Article retrieved on May 27, 2008 from <http://www.aafblog.org/blog/?p=5>.
- Stern, D. T. (2005). *Measuring medical professionalism*. Oxford, England: Oxford University Press.
- Stevenson, F. A., Barry, C. A., Britten, N., Barber, N., & Bradley, C. P. (2000). Doctor-patient communication about drugs: The evidence for shared decision making. *Social Science & Medicine*, 50(6), 829-840.
- Stewart, M., Brown, J. B., Weston, W. W., McWhinney, I. R., McWilliam, C. L., & Freeman, T. R. (1995). *Patient-centered medicine: Transforming the clinical method*. Thousand Oaks, CA: Sage Press.
- Sykiotis, G. P., Kallioliias, G. D., & Papavassiliou, A. G. (2005). Pharmacogenetic principles in the Hippocratic writings. *Journal of Clinical Pharmacology*, 45, 12-18.
- Werhane, P. H., & Rorty, M. V. (2000). Organizational ethics in health care. *Cambridge Quarterly of Healthcare Ethics*, 9(2), 145-146.