“Balancing Corporate Governance, Patients’ Interests, and Physicians’ Fiduciary Roles in the Healthcare Arena – What Would the Reasonable Person Do?”. 

rachel v rose, Stetson University
Balancing Corporate Governance, Patients’ Interests, and Physicians’ Fiduciary Roles in the Healthcare Arena – What Would the “Reasonable Person” Do?

Rachel V. Rose

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Introduction

Patients place great reliance, faith, and confidence in the professional word, advice, and acts of the physician. So, Congress should consider the relationship between the sole purpose of the medical profession, to serve the patient, and a physician’s pecuniary interests. Recently, while I was sitting in the waiting room of a physician’s office, several placards piqued my interest. The placards were visible and informed patients that their treating physician may have a financial interest in certain ancillary services (laboratory, imaging) and advised the patient to notify the physician if another service provider was preferred or required by insurance. In light of the recent collapse of the financial markets, the looming exhaustion of the Medicare Trust Fund, and the heightened scrutiny of business relationships between physicians and pharmaceutical/medical device companies, what would the “reasonable person” do in order to protect patient interests, uphold physician fiduciary duties, and provide equitable corporate governance of pharmaceutical and medical device companies? Expressly informing the patient of business interests appears a good place to start.

Oversight begins with disclosure. Physician and manufacturer disclosures of specific business relationships, which include consulting, lecturing, assisting with new product patents,
and receiving educational sponsorships/gifts, are like the disclosure of interests in ancillary services, and enable the patient to make an informed decision while ensuring that the physician is acting in the patient’s best interest.\(^3\) Oversight and disclosure, however, are meaningless without enforcement. This is because of the temptation to place individual pecuniary gain above the physical and financial interests of the patient.

From an economic perspective, the premise that people “act rationally, optimally, and in their self-interest” is known as the “rationale actor paradigm.”\(^4\) This model is used by economists to discern why individuals act in certain ways, while recognizing that changing self-interest brings on a change in behavior.\(^5\) In order for behavior to change, incentives have to change.\(^6\) Generally, manufacturers, physicians, and patients are all acting in their own “self-interest.” Thus, each faction is maneuvering to optimize its own position.\(^7\)

In light of this phenomenon, how would the “reasonable person” address corporate governance in the context of the physician’s fiduciary relationship? Originating in the law of trusts and agency, the fiduciary concept remains prevalent in American law.\(^8\) The “reasonable person” is also firmly established.\(^9\) The “reasonable person” is a hypothetical, objective standard used in judging an individual’s behavior or compensation against community standards.\(^10\) In assessing what a “reasonable person” of ordinary prudence would do in fiduciary circumstances, courts often evaluate whether the trustee abused his discretion, acted dishonestly, or was motivated improperly in the context of the acceptable community standards.\(^11\) Therefore, the actor is required to do what this ideal individual of adequate experience and intelligence would do in his or her place – suppress the selfish interest in compliance with the duties of good faith and loyalty.\(^12\) Perhaps the “reasonable person” can also find a way to balance the good faith and
loyalty duties owed to the patient with fair compensation for genuine, non-fraudulent, extraordinary undertakings such as product development or education.

Over the past several years, there has been heightened government enforcement of pharmaceutical/medical device consulting agreements, gifts, and royalty payments to physicians resulting in over $4 billion in pharmaceutical and medical device False Claims Act settlements.\(^\text{13}\) Additionally, aggressive media scrutiny by *Modern Healthcare*, *The NY Times*, *Wall Street Journal*, and local publications has brought the issue to the attention of the healthcare consumer.\(^\text{14}\) In the context of the federal anti-kickback statute on consulting, advisory, and royalty arrangements between pharmaceutical/medical device manufacturers and physicians, the parameters are murky.\(^\text{15}\)

In an effort to perhaps curtail False Claims Act settlements and increase public awareness of such arrangements, the United States Senate expanded upon the lead of a few states and proposed “The Physician Payments Sunshine Act of 2008,” which covers the pharmaceutical/medical device industries, and requires disclosure of certain financial arrangements and physician ownership interests.\(^\text{16}\) Additionally, the bill requires the Secretary of the Department of Health and Human Services to establish procedures to ensure public website accessibility with a mere $250,000 annual cap for failure to report any payment or transfer of value to a physician.\(^\text{17}\) The potential negative effects of such mild enforcement mechanisms for violations include the following: false sense of security that disclosure of the arrangements equates to immunity from Stark and Anti-kickback laws, similar failings as the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Advanced Medical Technology Association (AdvaMed) voluntary codes on interactions with healthcare professionals, and seemingly minimal incentives to change behavior.\(^\text{18}\) An unintended positive outcome of the
proposed legislation, if passed and amended, is that physicians could be better equipped as fiduciaries because of the transparency and notice available to patients.

Part I of this article addresses corporate governance in the context of financial crisis and Sarbanes Oxley. Part II highlights both the role of pharmaceutical/medical device companies in compensating physicians for the time away from their practices for educational purposes, and the consequences of physician business relationships on the fiduciary duty owed by physicians to patients. The significance of voluntary compliance programs is set forth in Part III. Present and proposed policies for the oversight of business relationships between physicians and medical device/pharmaceutical companies are discussed in Part IV. Finally, Part V concludes that a “reasonable person” would contend that physician and manufacturer disclosure of their business relationship specifics to healthcare consumers is paramount, that enforcement is essential for effective oversight, and that by aligning incentives, the impact of the “rational actor paradigm” can be mitigated.

I. Corporate Governance of Pharmaceutical and Medical Device Companies and Their Physician Relationships

The securities industry is not alone in its need for continued central oversight. In fact, if medical device/pharmaceutical companies are found to have violated the False Claims Act or agree to a settlement, Corporate Integrity Agreements are often imposed by the Inspector General of Health and Human Services (HHS) to ensure future compliance. Historically, when there is lack of oversight and enforcement, disaster results. The Stock Market Crash of 1929, scandals of Enron and World Com, and the mortgage and financial market collapse of 2008 are all examples of events that led to financial ruin. In response to the 1929 crash, the 1933 and
1934 Securities Acts were created to protect investors, and the Enron and World Com scandals led to the emergence of Sarbanes-Oxley to create accountability for executives and boards to insure that their fiduciary duties were being upheld.\(^{21}\) These scenarios suggest we are a reactive society.

The pharmaceutical/medical device industries and physicians are headed for a similar fate of decreased profits, negative publicity, and reactive regulatory oversight.\(^{22}\) However, since Congress and healthcare industry participants appear to be proactive in disclosure and oversight efforts, trepidation and suspicion from patients may be averted if an appropriate enforcement mechanism is also implemented.

**The Securities Industry**

The 1920's saw a stock market boom in the U.S. as the result of general optimism. Believing that the newly born Federal Reserve would stabilize the economy and that the pace of technological progress guaranteed rapidly rising living standards and expanding markets, economists and businessmen overzealously invested in anything. The U.S. Federal Reserve's attempts in 1928 and 1929 to raise interest rates to discourage stock speculation brought on an initial recession.\(^{23}\) It wasn’t long before the Crash of 1929 and the Great Depression changed the U.S. Markets.\(^{24}\)

The Great Depression and Stock Market Crash of 1929 led to reform as Congress enacted the 1933 and 1934 Securities Acts to protect investors by requiring disclosure. In 1933, Felix Frankfurter (a future U.S. Supreme Court Justice) and colleagues were summoned to draft the
Securities Act of 1933. Included in the Acts of 1933 and 1934 was the establishment of an oversight body for the stock market, The Securities and Exchange Commission (SEC).\textsuperscript{25}

The 1933 Securities Act was established to regulate the original issuance of interstate securities offerings and act as a prophylactic measure against misrepresentation of material facts and fraud by compelling full disclosure of material facts. This was to insure that investors had enough information about a company to make informed decisions.\textsuperscript{26}

The Securities Exchange Act of 1934 was enacted to regulate the secondary market (trading of already issued securities) and compelled ongoing disclosures similar to those required under the 1933 Securities Act by requiring registration and disclosure of financial and transactional information.\textsuperscript{27} The SEC established the Division of Enforcement in August 1972, and at the time the Securities Commission was established in 1934 oversight, investigation, and referring cases to the Department of Justice for criminal prosecution were some of its defined roles.\textsuperscript{28} In fact, after only one year there were over 2300 cases under investigation.\textsuperscript{29}

Renowned economist John Maynard Keynes once stated, “In the long run, we are all dead.”\textsuperscript{30} However, he failed to mention that we have to survive the short run. “For the first time in two generations, failures on the demand side of the economy and insufficient private spending to make use of the available productive capacity” have lead to depression economics.\textsuperscript{31} It is also important to point out that the ratio of debt-to-GDP in the early 1930’s was 264%, which was our country’s all time high – until now. “Credit-market debt now equals 295% of GDP” and in both scenarios, substantial debt contributed to these dangerous figures.\textsuperscript{32} And cheap money policies created the 1920s boom that resulted in the Great Depression.”\textsuperscript{33} As in the 1920’s, individuals and
companies are finding it difficult to maintain their purchasing power, especially in the context of healthcare.

The SEC’s Enforcement Division eventually enacted the “Access Theory” approach to enforcement, based on the rationale that because “lawyers, accountants, and securities industry professionals often participate in, or have access to, management’s decision making process, the SEC reasoned that placing pressure on these key professionals would force a closer monitoring of corporate compliance.” In doing so, it sought to hold accountants and lawyers, both of whom have fiduciary duties, responsible for providing client access to the markets “under circumstances where they knew or should have known their clients were engaged in securities law violations.” The SEC provides a central entity for oversight and establishes common goals for all participants in the securities industry: brokers, companies, the government, and the investors. The impetus for the regulations and the SEC was a desire to protect investors.

**The Sarbanes-Oxley Act of 2002**

Inspired by the gross fraud revelations of Enron, an energy-trading conglomerate, the Sarbanes-Oxley Act of 2002 (Sarbanes-Oxley) was enacted. Sarbanes-Oxley requires chief executive officers and chief financial officers of companies with annual revenues in excess of $1.2 billion to certify to the SEC that the companies’ financial statements are truthful and accurate to the best of their knowledge. Just over five years since its inception, some have described this federal securities law as “aspirational” and rooted in “deep meta-politics underlying the legal and economic criticisms of Sarbanes-Oxley.” Among Congress’ objectives in passing the Act was to insure honest securities markets and thereby promote investor confidence after the market crash of 1929 … Congress sought to substitute a philosophy
of full disclosure for the philosophy of caveat emptor and thus to achieve a high standard of
business ethics in the industry.\textsuperscript{40}

Interestingly, the HealthSouth Corporation, a healthcare company whose business
purpose was to operate rehabilitation hospitals, came under scrutiny for fraud and triggered an
SEC investigation and application of Sarbanes-Oxley.\textsuperscript{41} Ultimately, the CEO was acquitted, and
in response, questions about the punishments and enforcement adequate to deter corporate
officers from violating the act were raised.\textsuperscript{42} Pre-Sarbanes-Oxley, corporate officers were subject
to personal liability only if a plaintiff could establish breach of fiduciary duty producing a
justification for piercing the corporate veil.\textsuperscript{43} Because of Sarbanes-Oxley, both investors and the
SEC have a greater impetus to reach officers of a company and hold them personally accountable
for financial misdeeds.\textsuperscript{44}

This scenario parallels that facing physicians and pharmaceutical/medical device
manufacturers. Corporate officers and physicians both owe a fiduciary duty to an entrustor
(investor or patient).\textsuperscript{45} Sarbanes-Oxley was enacted in response to extensive fraud and the
ultimate harm suffered by investors.\textsuperscript{46} The “Physician Payment Sunshine Act of 2008” is being
proposed in response to increasing numbers of whistle blower law suits, decreased patient
confidence in the healthcare system, and heightened scrutiny by the media.\textsuperscript{47} Therefore, Congress
should consider the relationship between a physician’s monetary interests and the sole purpose of
the medical profession to serve the patient.\textsuperscript{48}

II. Balancing Physicians’ Pecuniary Interests and The Fiduciary Duties Owed to Patients

It is possible for physicians to have outside business relationships and accept
compensation for legitimate purposes while upholding their fiduciary duty to their patients. Just
as lawyers are required to stay abreast of changing common law and regulations, physicians are required to stay abreast of current technologies and techniques. A common way for physicians to gain such knowledge is through conferences, cadaver lab experience, and training from fellow physicians with experience in a given area. It is safe to assume that most patients want their physicians to be familiar with the equipment and the procedure before utilizing them on the patient. Surgical techniques are constantly evolving. Lumbar (lower back) spinal surgery and anterior cruciate ligament (ACL) reconstructive knee surgery are two examples of procedures that have evolved from “open” procedures to minimally invasive procedures. This means that surgeries that used to be performed by making a large incision and completely exposing the area are now performed percutaneously (through the skin) by making small holes then inserting cameras, instruments, and implants through them. Everything about the operation changes and surgeons are in the best position to educate their peers through conferences and practical simulations.

In order to learn, physicians must take time away from their practice. This includes the physicians who attend and the physicians who teach. Being away from the office means patients are not being seen and surgeries are not being performed; therefore, revenues are not being generated. Here, pharmaceutical companies can and do play a vital role by compensating physicians for time away from their practices. The Medical Education and Research Institute (MERI) in Memphis, TN is an example of a venue sponsored by medical device companies where physicians participate in continuing education endeavors. This 501(c)(3) facility enables physicians to learn from other experienced physicians and develop new instrumentation because physicians are in the best position to contribute to technological advancement. The key factors in determining the compensation are reasonableness and lack of fraud. These are relevant when
assessing physicians’ fiduciary duties, which relate to obtaining informed consent from the patient.

**Fiduciary Considerations**

This analysis focuses on physicians and their role as fiduciaries. A fiduciary is “one who owes to another the duties of good faith, trust, confidence, and candor.” Law, securities, and medicine are three fields that utilize fiduciary roles. However, medicine is the only field in which the provider has the ability to affect an individual’s physical well being. The role of fiduciary law is significant for it seeks to protect vulnerable people.

The physician-patient relationship is fundamentally based on the notion that the parties have inherently unequal power because of the knowledge gap and asymmetry of information. The American Medical Association (AMA) has issued numerous opinions on physician conflicts of interest arising from the relationships between physicians and pharmaceutical/medical device companies and their duties as fiduciaries. The AMA contends that treatments and prescriptions should be made solely upon medical considerations; remuneration in exchange for utilization is prohibited; direct or indirect financial interest should not influence prescribing and treatment habits; and indemnification from law suits in order to induce utilization is prohibited. Furthermore, the patient has the right “to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives … (and) to have their questions answered, to be advised of potential conflicts of interest that their physicians might have, and to receive independent professional opinions.”

The physician-patient relationship has… its foundation on the theory that the former (physician) is learned, skilled and experienced in those subjects about which the latter (the patient) ordinarily knows little or nothing, but which are of the most vital importance and interest to him, since upon them may depend health, or even life, of himself or
family. Therefore, the patient must place great reliance, faith and confidence in the professional word, advice and acts of the physician.64

The patient’s interests are paramount and must come before the physician’s individual interest. This notion, which is present in all fiduciary relationships, contrasts the legal rule of caveat emptor (“let the buyer beware”), which governs basic contract law.65 In the majority of business transactions the law assumes that the buyer and seller theoretically have the same access to information and the same bargaining power to initiate an arms-length transaction. For example, a car salesman can encourage a customer to purchase a more expensive car and emphasize certain features if he has acted in good faith and not lied about the features that contribute to the higher price of the car. The customer can always comparison-shop and seek others opinions before deciding to purchase the vehicle. Conversely, a patient is implicitly expected to rely solely on the physician’s treatment opinion or seek another opinion that may be a significant out of pocket expense if not covered by insurance.

A fiduciary duty extends to all aspects of the physician-patient relationship including financial aspects. This duty is fundamental to the Hippocratic oath: “You’re to do no harm, and you’re to put the patient’s interest first and foremost.”66 Hence, the “reasonable person” may inquire how a physician can truly put the interest of the patient first when the incentives are to utilize more of a certain company’s product to generate more income. Most patients, often unsophisticated in terms of healthcare knowledge, trust that their physician is sublimating his own interests in favor of the patient’s needs and expectations.67

As a fiduciary, the physician should be required to disclose these interests to the patient.68 This puts the consumer patient in a position to question the physician’s motives and opt for a second treatment opinion that is not biased. Relying on a 1997 opinion issued by the American Medical Association’s (AMA) Council on Ethical and Judicial Affairs, an Illinois Appellate
Court deciding *Neade v. Portes* found that physicians have the same fiduciary duty to disclose conflicts of interest as lawyers, real estate agents, and judges, and that not disclosing such conflicts deprives patients of the ability to make informed decisions about the quality of care they are receiving.\(^69\)

**Informed Consent**

The process of informed consent, which requires a physician to obtain a patient’s approval before performing a procedure, is an inter-related duty. Presently, the majority of states do not require the disclosure of financial relationships between physicians and pharmaceutical/medical device manufacturers.\(^70\) How can a healthcare consumer truly give informed consent if not informed of consulting agreements, ownership percentage in treatment centers, and investment positions in relevant pharmaceutical and medical device companies? Here, the “reasonable person” (i.e., the physician) would disclose these interests to the patient and the patient would in turn be able to ask what the motive was in doing a specific procedure or utilizing a certain laboratory or imaging center.

The doctrine of informed consent has a foothold extending back into law, jurisprudence, and philosophy. Beginning at chapter one with “*The Absolute Rights of Individuals,***” Blackstone’s COMMENTARIES ON THE LAWS OF ENGLAND (1765) notes “The right of personal security consists in a person’s legal and uninterrupted enjoyment of his life, his limbs, his body, his health and his reputation.”\(^71\) Blackstone went on to cite The Magna Carta as the foundation for the right of personal security:

Both the life and limbs of a man are of such high value in the estimation of the law of England that it pardons even homicide if committed *se defendendo* or in order to preserve them. For whatever is done by a man, to save either life or member, is looked upon as done with the highest necessity and compulsion.\(^72\)
John Stuart Mill in 1859, in ON LIBERTY, wrote:

The only purpose for which power can be rightfully exercised over any member of a civilized community, against his will, is to prevent harm to others. His own good, either physical or moral, is not significant warrant … over himself, over his own body and mind, the individual is sovereign.\textsuperscript{73}

The concepts of informed consent and what constitutes a patient’s “right” evolve from acknowledging and accepting the notion of the sanctity of an individual’s freedom over his or her body and mind. In his work THE SCIENCE OF RIGHT, Immanuel Kant defined the “rights” of persons and the meaning of personal holding by reference to the concept of bodily consent: “Anything is mine by right, or is rightfully mine, when I am so connected with it, that any other person who should make use of it without my consent, he would do me lesion or injury.”\textsuperscript{74} Furthermore, the protection of an individual’s bodily autonomy and right to self-determination (which includes the right to information that could potentially skew treatment decisions) has received judicial support.\textsuperscript{75}

An unlikely source that further developed the concept of “informed consent” of a patient in relation to the fiduciary duty owed by the physician arose during World War II at the Nuremberg Tribunal.\textsuperscript{76} The Nuremberg Code (1949) declared explicitly in its first point “\textit{The patient) should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.}”\textsuperscript{77} It is impossible for a patient to give “informed consent” when providers withhold material information such as consulting agreements, investment arrangements, and other conflicts of interest that the patient should have the ability to question. The landmark case Canterbury v. Spence further developed the doctrine of informed consent and established a patient oriented standard for disclosure (the material risks that would constitute reasonable disclosure under the
circumstances) and an objective test for causation (would a reasonably prudent patient have consented if disclosures were made). 78

Given the importance of fiduciary duties and informed consent in the law, a federal law with greater incentives to change behavior, such as greater penalties for non-disclosure of business relationships and the inability to deduct certain items on tax returns, needs to be considered. Because there is no federal law requiring disclosure of physician conflicts of interest, the effectiveness of voluntary compliance programs needs to be considered.

III. The Ineffectiveness of Voluntary Compliance Programs

It has been argued “[w]ithout proper alignment and oversight, incentives can inadvertently promote unethical behavior.” 79 Furthermore, when results are valued over honesty, and “pressure intensifies to generate better outcomes,” it is not unfathomable that an increase in unethical behavior ensues. 80 A “reasonable person” could conclude that since the potential for restitution in the amount of treble damages and a Justice Department imposed Corporate Governance Program does not seem to deter some companies, why would voluntary programs be effective? 81

**PhRMA and AdvaMed Codes of Ethics**

AdvaMed and PhRMA, the two foremost trade associations for the pharmaceutical and medical device industries, voiced their support to U.S. Senators Chuck Grassley and Herb Kohl of an initiative to create a national registry of payments to physicians by pharmaceutical and medical device manufacturers. 82 Their announcement followed recent endorsements for transparency in their financial relationships with physicians from Medtronic, Eli Lilly, and Zimmer. 83 In response to the proposed Physician Payment Sunshine Act of 2008, both PhRMA
and AdvaMed have revised their respective marketing Codes of Ethics; however, these provisions are not legally binding, but are only voluntary.\textsuperscript{84}

Both PhRMA and AdvaMed had previous Codes – PhRMA had a 2002 version as part of an ongoing effort to ensure that marketing practices complied with high ethical standards, and AdvaMed’s was adopted in April 2005.\textsuperscript{85} The federal regulations, let alone these voluntary compliance codes, apparently did little to dissuade pharmaceutical companies from engaging in behavior that resulted in over $4 billion in False Claims Act settlements.\textsuperscript{86}

**Problems With Self-Governance and No Enforcement**

The notion that physicians are supposed to provide unbiased patient care conflicts with the goals and the marketing practices of medical device and pharmaceutical companies to generate revenues. For example, in 2003, Pfizer touted to its shareholders that it had “tripled in size, adding some 80,000 new colleagues, many new products across a range of therapeutic areas and billions of dollars in sales and earnings.”\textsuperscript{87} Selling, Informational and Administrative Expenses (SI&A) had increased 41\% in 2003 due to “strong marketing and sales support for our broad portfolio of pharmaceutical products.”\textsuperscript{88} What portion of these expenses was allocated for physician consulting agreements, honorariums, or clinical trials at universities? After scrolling through over 50 pages of the annual report, this breakdown could not be found.

It is a reasonable argument that physicians are in the best position to contribute to technological advancements, but there is concern that medical device and pharmaceutical companies could exploit this position.\textsuperscript{89} This concern is what led the U.S. Attorney’s office to issue subpoenas to four orthopedic companies requesting “consulting, professional service and remuneration agreements with surgeons covering products such as artificial knees and hips.”\textsuperscript{90}
This is not the first time the Department of Justice has investigated *qui tam* (whistle blower) lawsuits brought by individuals through the False Claims Act (FCA). The government has aggressively pursued pharmaceutical and medical device companies and achieved success. Warner-Lamberts’ damages amounted to $430 million to resolve criminal and civil charges of fraudulent promotion of Neurontin®; Abbott/Ross paid civil and criminal fines totaling $614 million for paying kickbacks for enteral feeding products; Guidant paid civil and criminal penalties of $92.4 million for reportedly failing to inform the FDA of malfunctions with its Ancure Endograft System®. In 2005, the Department of Justice (DOJ) investigated the alleged payment of kickbacks to doctors by Medtronic’s Memphis-based spine division. This is after the AdvaMed Code of Ethics came into effect on January 1, 2004. More alarming is the recent FDA report criticizing oversight of medical device makers for not fulfilling their obligations to conduct studies on the safety of products once they were on the market.

Because of the roles that physicians assume in activities can directly influence patient care decisions and the financial markets, gaining consensus on what should be disclosed and how to increase compliance is imperative. Unfortunately, Medtronic provides an example of why voluntary disclosure and ethical codes do not work.

**An Example of the Present Conundrum: Medtronic**

Presently, Medtronic is “facing serious questions about its marketing of the Infuse Bone Graft®.” The question is why this has happened, given that the company entered into a settlement agreement in July 2006 over Medtronic’s consulting relationships with physicians. In a 2007 letter to Medtronic, United States Senator Charles Grassley said he was concerned that
“inordinately high consulting fees, free travel and other perks distort decision-making among physicians and obscure the best interest of the patient.”

Medtronic is already the subject of a Congressional investigation, settled a False Claims Act claim for $40 million, and was aware of the AdvaMed voluntary Code of Ethics and relevant laws. The whistle-blower lawsuit filed by two former Medtronic employees in the United States Federal District Court in Massachusetts should have been avoided. Also worth mentioning the disparity between the alleged kickbacks paid to physicians by Medtronic for promoting allegedly off-label use of Infuse Bone Graft®. The annual consulting fees range from $2,000.00 per year to nearly $500,000.00 per year. In total, it is alleged that “sham payments in 2006 alone to known physician consultants to Medtronic [spine division] exceeded $8,000,000.00.”

Some of these amounts appear excessive, unless the “reasonable person” once again considers the “rational actor paradigm,” which puts self-interests above the greater interests of patient care, investor confidence, and fiduciary duties. Therefore, perhaps a return on investment was analyzed and it was discovered that even if a substantial amount was paid out to settle government and individual claims, the amount is still not enough to justify a change in behavior. Only time will tell the outcome and whether Medtronic modifies its behavior.

IV. Government Oversight Policies

Over the past several decades, Congress has passed legislation regarding physician business interests in relation to their patient duties. Government agencies, including the Office of the Inspector General, have issued guidance in developing internal controls and procedures that
promote adherence to the applicable laws. Hence, it is important to analyze the relevant regulatory considerations.

**Present Regulatory Considerations: Stark and Anti-kickback**

Assuming the physicians’ investment terms are obtained on terms equally available to the public and the services are rendered equally to investors and non-investors, the next step is to recognize that if the business relationship between physicians and another entity such as pharmaceutical/medical device companies or hospitals are structured improperly, two Federal regulations may be implicated: (a) the anti-kickback statute section 1128A(b)(1)-(2) of the Social Security Act (the “Act”); and (b) the physician self-referral law (Stark Law), section 1187 of the “Act”.

Congress enacted two laws, the federal anti-kickback statute in 1972, and the Ethics in Patient Referrals Act (Stark law) in 1989 (Stark I) and expanded in 1993 (Stark II) to deter inappropriate physician investment in healthcare facilities. The Stark Regulations were enacted in reaction to studies released highlighting over-utilization of facilities in which physicians had a substantial ownership interest. The impetus behind the laws was to curtail financial incentives that induce over-utilization and tempt the physician to place personal financial gain before patient quality and convenience. Phase III of the Stark regulations, which became effective 90 days after publication in the Federal Register (September 5, 2007), was intended to offer “limited protection against the application of the new ‘stand in the shoes’ rule for indirect compensation arrangements.”

Anti-kickback laws make it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal health care program. Anti-kickback laws were designed to reign in
both direct and indirect investment and utilization inducement opportunities by hospitals, medical device companies, and physicians by identifying “prohibited remuneration” and providing acceptable safe harbors. \(^{122}\) Courts have interpreted the anti-kickback statute to cover arrangements where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.\(^{123}\)

The aim of the statutes is to curtail inappropriate referral incentives and provide safe harbors that detail appropriate transactions. Anti-kickback and Stark laws should be construed \textit{in pari materia} so that “the inconsistencies in one statute may be resolved by looking at another statute on the same subject.”\(^{124}\) The objective of the \textit{in pari materia} rule is to ascertain and effectuate Congressional intent by proceeding upon the supposition that several statutes were governed by one spirit and policy and were intended to be consistent and harmonious.\(^{125}\)

Therefore, when legislation dealing with a particular subject consists of a system of related general provisions indicative of a settled policy, new enactments of a fragmentary nature on that subject are to be taken as intended to fit into the existing system.\(^{126}\) Recognizing that not all investment practices would likely result in fraud or abuse, the Stark laws provide exemptions, thereby allowing physicians to have certain ownership or investment interests.\(^{127}\) The Department of Health and Human Services promulgated the anti-kickback statute’s safe harbors to further the goal of balancing referring physicians’ ownership in an entity to 40\% of the investment interest.\(^{128}\) While it is illegal to use remuneration to induce referrals, when the safe-harbors of both statutes are met in tandem, these statutes provide an investment opportunity that balances the alignment of incentives with risk of over-utilization.

\textbf{Relevant Disclosure Regulations}
In order to address increased awareness of payments made by pharmaceutical/medical device companies to physicians, the Senate Special Committee on Aging held a hearing in 2008 at which several industry participants and trade organizations voiced strong support for the Physicians Payments Sunshine Act of 2008.\textsuperscript{129} The legislation would require industry participants to publicly disclose certain pecuniary arrangements with physicians.\textsuperscript{130} In addition to input from pharmaceutical and medical device manufacturers, Congress has the benefit of relying on similar regulations already in effect in a handful of states.\textsuperscript{131}

### Comparing Existing State Disclosure Regulations to Proposed Federal Legislation

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<td>Disclosure Requirement</td>
<td>Any transfer of value to a physician when the annual aggregate amount exceeds $500, including the form and reason for the payment. Ownership information for certain MD-owned entities.</td>
<td>All expenses associated with educational programs, food, entertainment, gifts, trips, and travel, product samples not distributed free of charge to patients.</td>
<td>All expenses associated with educational programs, food, entertainment, gifts, trips and travel, product samples not distributed free of charge to patients.</td>
<td>Payments related to medical conferences, honoraria, compensation connected to research, or any payments totaling $100 or more to a physician.</td>
<td>Payments related to detailing, promotional, or other marketing activities.</td>
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\textit{Side-by-Side of S.2029 and Existing State Law}
### Exemptions

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<td>Expenses of $25 or less, free samples for patients, certain education expenses, discounts and rebates, in-kind items used for the provision of charity care.</td>
<td>Expenses of $25 or less, reasonable compensation in connection with clinical trials, certain education expenses.</td>
<td>Expenses of $100 or less, free samples for patients.</td>
<td>Expenses of $25 or less, free samples for patients, payments related to clinical trials, rebates and discounts, certain education expenses.</td>
<td>Expenses of less than $100, payments related to clinical trials, free samples for patients, certain education expenses.</td>
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<th>Penalties</th>
<th>Penalties</th>
</tr>
</thead>
<tbody>
<tr>
<td>$1,000 to $5,000, or $5,000 to $50,000 for knowing non-reporting.</td>
<td>Up to $1,000</td>
<td>Up to $10,000</td>
<td>Up to $10,000</td>
<td>None</td>
</tr>
</tbody>
</table>

* Pharma = Pharmaceutical, MD = Medical Device, MS = Medical Services. This chart can be accessed at [http://www.aging.senate.gov/record](http://www.aging.senate.gov/record) (last visited Jan. 7, 2009)

As the above chart compiled by the Senate Special Committee on Aging indicates, laws comparable to the proposed federal law, Physician Payments Sunshine Act of 2008, have already been adopted by a few states as others consider similar legislation.\(^{132}\) The biggest differences between existing state law and the proposed federal regulation include the following: manufacturers targeted, disclosure requirements, and penalty amounts.\(^{133}\) Currently, only one state, Minnesota, parallels the federal proposal and requires disclosure to the public.\(^{134}\)

“The Physician Payment Sunshine Act’s proposed establishment of a single federal reporting system for payments to physicians could simplify both industry compliance and interested consumers’ access to information.”\(^{135}\) Introduced March 13, 2008, the Physician Payments Sunshine Act of 2008 would amend part A of title XI of the Social Security Act to require quarterly transparency reports of payments to physicians or an organization in which there is a significant professional membership interest, by manufacturers of pharmaceuticals and
medical devices to the Secretary of Health and Human Services. An additionally proposed penalty for non-disclosure would amend the federal tax code “to prohibit tax deductions for the advertising, promotion, or marketing … on whom a penalty is imposed for failing to meet the requirements of this Act.”

Unfortunately, despite the benefits to patients, physicians, investors, and the industry, this bill never became law because at the end of each session, all proposed bills and resolutions that have not passed are cleared from the books. Perhaps this bill will be reintroduced in the next Congressional session and maybe it will make it to a vote versus being merely referred to a Congressional Committee.

V. Conclusions of the “Reasonable Person”

The proposed Physician Payments Sunshine Act of 2008 and comparable state laws are not substantive or forceful enough to overcome the rational actor paradigm, wherein people act selfishly and in their own best interests. The proposed penalties are paltry when considering the earnings per share of companies such as Medtronic and Eli Lilly. Perhaps this renewed interest and media attention on the issue will at least alert physicians and pharmaceutical medical device manufacturers to consider the cost of violating the False Claims Act, Anti-kickback Statute, and Stark laws. The “reasonable person” would easily conclude that a balance sheet liability expressed in a 10K filing of $40 million or $345 million is substantial and may diminish investor confidence.

The voluntary provisions promulgated by PhRMA, AdvaMed, and various government entities are a positive step in the right direction. Compliance would not only increase the confidence of patients that their physicians were acting on behalf of the patients’ physical and
financial well-being, but would also create greater transparency. Overall, consideration of existing laws coupled with a clear disclosure of remuneration to physicians enables the incentives of physician fiduciary duties, patient interests, and pharmaceutical/medical device corporate governance to be aligned. Thus, the “reasonable person” concludes that with the appropriate oversight and enforcement, certain physician and manufacturer financial relationships are possible and can represent the needs of high quality patient care.

1 Restatement (Second) of Torts §283 (indicating that to avoid negligence, an actor is required to act as “a reasonable man under like circumstances.”); see also, Joseph W. Glannon, The Law of Torts: Examples and Explanations, p. 64-66 (2nd Edition, Aspen Law and Business, New York, 2000) (explaining that a reasonable person “considers the extent of the risks posed by her conduct.”). It is necessary to understand that “a reasonable man under like circumstances” varies in the doctor/patient scenario depending on whose perspective is being considered.

Secretary Mike Leavitt said that “Foster’s update reinforced his concern that too many people view Medicare’s finances as one that is in the distant future.”


5 Id.

6 Id.


10 Id.

11 Metropolitan Life Insurance Company v. Glenn, 128 S. Ct. 2343, 2360 (2008) (“There are no gradations of reasonableness, so that one might infer that a trustee acted upon his conflict of interest when he chose a “less reasonable,” yet self-serving, course, but not when he chose a “more reasonable,” yet self-serving, course. Reasonable is reasonable. A reasonable decision is one over which reasonable minds seeking the “best” or “right” answer could disagree. It is a course that a trustee acting in the best interest of the beneficiary might have chosen. Gradating reasonableness, and making it a “factor” in the improper-motive determination, would have the precise effect of eliminating the discretion that the settlor has intentionally conferred upon the trustee with a conflict, for such a trustee would be foreclosed from making another wise reasonable decision.”).

12 Restatement (Second) Torts, section 283, Comment c; see MetLife, 128 S. Ct. at 2360.

13 Elizabeth Carder-Thompson, Aggressive Government Enforcement and Media Scrutiny, American Health Lawyers Association FRAUD and COMPLIANCE FORUM, Baltimore, MD, Sept. 23, 2007, AHLA-PAPERS P09230720, www.westlaw.com (last visited Jan. 7, 2009) (breaking the over $4 billion in False Claim Act settlements to include the following: Schering-Plough ($435 million, $345 million, $27 million); Warner-Lambert ($430 million); Serono ($704 million); Medtronic ($40 million); Abbott Laboratories ($600 million); and 7 of the 8 largest device companies were under scrutiny in 2007).

14 Id. (indicating relentless scrutiny by the media outlets).

15 Id. Although safe harbors are present in the anti-kickback statute, physicians should be aware that agreements with manufacturers may also implicate the Stark statute.

to report to DHHS payment of value to physicians for named services. If not, penalties will be assessed up to an annual cap of $250,000.

17 Id.; S. 2029 (May 13, 2008) (c) “WEBSITE: the Secretary shall establish procedures to ensure that the information is made accessible to the public through a website, with proper context given to the payments and an appeal and correction process established.”


21 Id. at C-3, C-21, “Insurance is largely exempt from federal antitrust enforcement under the McCarran-Ferguson Act of 1945, which left regulation of the industry up to the states. The Federal Trade Commission also is specifically forbidden from regulating insurance.”


27 1934 Securities Act, Title 1, Section 2(2)(2) (mirroring the 1933 Act requirement).


29 Id.

30 John Maynard Keynes, A Tract on Monetary Reform, Chapter 3 (1923) (criticizing the belief that inflation would be acceptably controlled without government intervention. “The long run is
a misleading guide to current affairs. In the long run we are all dead. Economists set themselves too easy, too useless a task if in tempestuous seasons they can only tell us that when the storm is past the ocean is flat again.”).


32 Jonathon Laing, The Debt Bomb 1,5 Barron’s, (Monday, Jan. 20, 2003) http://online.wsj.com/barrons/article_print/0,,SB1042850639116463264,00.html.


34 Id. at 3.


36 Supra n. 33 at 3.


38 Id. at 412.


41 Supra n. 32 at 412-414. Health South’s CEO, Richard Scrushy was the first CEO charged with a Sarbanes-Oxley violation. Despite the documented overstatement of financial results and fraud, but at the end of his trial on June 28, 2005, the jury acquitted him of all thirty-six counts. Therefore, no jail time was served and no fine was paid.

42 Taylor, supra n. 32 at 419-420.


44 Taylor, supra n. 32 at 419.


46 Taylor, supra n. 32.

47 Supra n. 15.

48 AHLA, supra n. 40.

49 www.floridabar.org, (last visited Jan. 30, 2009) (requiring 30 hours over a 3-year period, the Florida Bar Association monitors the requirements and compliance with continuing legal education including: 5 hours of legal ethics, professionalism, substance abuse, or mental illness
awareness. Newly admitted attorneys are required to take a basic skills course. No excess credits may roll over to next reporting period).


52 Id.


54 Daniel H. Kim, M.D., Alexander R. Vaccaro, M.D., Richard G. Fessler, M.D., Spinal Instrumentation, p. 803-805 (Thieme Medical Publishers, 2005); Alexander R. Vaccaro, M.D. and Christopher M. Bono, Minimally Invasive Spine Surgery, (C.H.I.P.S., 2007). For a comprehensive overview of the most significant advances in ACL surgery over the past thirty years see, Freddie H. Fu, M.D., Steven B. Cohen, M.D., Current Concepts in ACL Reconstruction, p. 413 (SLACK Incorporated, 2008) (“Definitely, the advent of arthroscopy for ACL surgery was a crucial point in this history [shift from open intra-articular reconstructions to minimally invasive].”).

55 Supra n. 51.

56 Id. One physician training another begins in medical school and continues in residency, where both attending physicians and upper level residents educate younger residents. Mentorship as a primary tool for learning through all phases of medical education and training extends back centuries. It is only natural that as procedures change, physicians remain the best instructors for other physicians to learn from as only practicing physicians can truly share first hand knowledge of anatomical abnormalities, procedural nuances, and navigating adverse situations. A book or journal article cannot substitute for active learning in medicine.

57 Congress Votes to Override Bush Veto on Bill Protecting Doctors From Medicare Cuts, Washington (AP), http://www.foxnews.com/printFriendlyStory/0,3566,383302,00.html, (last visited Oct. 19, 2008) (“rejecting President Bush’s veto of legislation protecting doctors from a 10.6 percent cut in their reimbursement rates when treating Medicare patients,” Congress responded with a plan that would freeze Medicare rates for physicians in 2008 and increase them by 1.1 percent in 2009. Unfortunately, Congress is merely “robbing Peter to pay Paul.” The revenues necessary to uphold the increase to physicians reduces spending on private Medicare Advantage programs which more than 9 million Americans rely on). Reduced reimbursement is an important consideration for physicians and their practices.

58 http://www.meri.org (last visited Jan. 7, 2009) (indicating that the eleoanauary MERI lab is a collective effort of the pharmaceutical and medical device companies and was established to provide an educational, hands on, unembalmed cadaver experience for surgeons to learn new techniques, procedures, and utilize new technology).

59 Id. See also AHLA, supra n. 12.

60 Metropolitan Life Insurance Co. v. Glenn, 128 S.Ct. 2343, 2357 (2008) (Scalia, & Thomas, J., dissenting) (indicating that fiduciary duties extend back to trust law and in the context of ERISA plan administration, a conflict of interest must be weighed as ‘a facto[r] in determining whether there is an abuse of discretion.’). Black’s Law Dictionary 640 (Bryan A. Garner ed.,7th ed., West 1999). “Fiduciary relationship – A relationship in which one person is under a duty to
act for the benefit of the other a duty to act for the benefit of the other on matters within the scope of the relationship. Fiduciary relationships – such as trustee-beneficiary, guardianships – such as trustee-beneficiary, guardian-ward, agent-principal, and attorney-client – require the highest duty of care. Fiduciary relationships usually arise in one of four situations: (1) when one person places trust in the faithful integrity of another, who as a result gains superiority or influence over the first, (2) when one person assumes control and responsibility over another, (3) when one person has a duty to act for or give advice to another on matters falling within the scope of the relationship, or (4) when there is a specific relationship that has traditionally been recognized as involving fiduciary duties, as with a lawyer and a client or a stockbroker and a customer.”


65 Supra n. 35 (replacing the contract theory of caveat emptor in order to define guidelines to protect entrustors).

66 AHLA, supra n. 40.

67 Healey and Dowling, Controlling Conflicts of Interest in the Doctor-Patient Relationship: Lessons From Moore v. Regents of the University of California, 42 Mercer L. Rev. 989 (1991). 1997 AMA OPINION, http://www.ama.org (“physicians must assure disclosure of any financial inducements that may tend to limit the diagnostic and therapeutic alternatives that are offered to patients or that may tend to limit patients’ overall access to care.”).

68 Therese Neade v. Steven Portes, MD, and Primary Care Family Center, 739 N.E. 2d 496 (2000); 1997 AMA OPINION, http://www.ama.org (“physicians must assure disclosure of any financial inducements that may tend to limit the diagnostic and therapeutic alternatives that are offered to patients or that may tend to limit patients’ overall access to care.”).

69 Phoebe A. Wilkinson and Karl H. Buch, N.Y. Seeks to Join States Regulating Pay to Physicians, NYLJ, Vol. 240 (Nov. 6, 2008), http://www.westlaw.com (last visited Jan. 7, 2009) (Noting that six states have adopted legislation regulating “payments, gifts, honoraria, and other items of value given to physicians by the pharmaceutical and/or medical device industries,” New York governor proposed a similar bill); see also, E.B. Solomont, Fight Erupts Over Bill on Gifts to Doctors, N.Y. Sun, (Jun. 18, 2008) (recognizing that if the federal “Physician Payments Sunshine Act” is passed, state laws may be preempted).

70 WILLIAM BLACKSTONE, COMMENTARIES ON THE LAWS OF ENGLAND (1765), Book I, Chapter I, p. 68 (Baker, Voorhis and Co. 4th ed. 1938).

71 Id. at 69.


75 Schoendorf v. Society of New York Hospital, 211 N.Y. 125, 105 N.E. 92, 93 (1914) (acknowledging that “every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient’s consent commits an assault for which he is liable for damages”).

76 See J. Katz, “The Consent Principle of the Nuremberg Code: Its Significance Then and Now,” in GEORGE J. ANNAS & MICHAEL A. GRODIN, THE NAZI DOCTORS AND THE NUREMBERG CODE 227 (1992) – “The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent, should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching or other ulterior form of constraint.”

77 Id. (emphasis added).


80 Id. at 40, 42 (recommending that in order to minimize unintended consequences, a foundation for ethical behavior must be built).

81 Supra n. 12. An excellent source for information on various violations, Department of Justice opinions, and relevant state laws.


83 Id.; PhRMA Press Release, PhRMA Statement on the Senate Sunshine Act, May 22, 2008, http://www.phrma.org (last visited Jan. 7, 2009) (commenting on the revised bill, PhRMA Chairman and CEO of Merck & Co., Inc., said, “We need to go the extra mile to allow others to see what we do, so that the public can place greater trust in us, and in our medicines and vaccines. I believe that this bill will help build a stronger foundation of trust.”).


86 Supra n. 12.


88 Id. at 13.

investments in medical device manufacturers and distributors; see also, Response Letter from Vicki Robinson to Stephen Ubl, Oct. 6, 2006, http://www.AdvaMed.org (last visited Jan. 7, 2009) (confirming that the amount of revenues generated directly or indirectly by a physician investor is a relevant factor in analyzing a joint venture under the Anti-kickback statute, 42 C.F.R. 1001.952(a), includes a provision that limits safe harbor protection to entities that derive no more than 40% of their gross revenues from investors, such as physicians.)


98 Paul A. LaViolette, MBA, Medical Devices and Conflict of Interest: Unique Issues and an Industry Code to Address Them, Cleveland Clinic Journal of Medicine, Vol. 74, Suppl. 2, p. S26-S28 (March 2007) (outlining the interaction between physicians and the medical device industry in the development of medical devices and in the context of the AdvaMed Code of Ethics).

99 Steven D. Levitt and Stephen J. Dubner, Freakonomics – A Rogue Economist Explores The Hidden Side of Everything, pp. 70-72 (Harper Collins, 2005) (“If you were to assume that many experts use their information to your detriment, you’d be right. Experts depend on the fact that you don’t have the information they do. Or that you are so befuddled by the complexity of their operation that you wouldn’t know what to do with the information if you had it …. David Hillis, an interventional cardiologist at the University of Southwestern Medical Center in Dallas, explained to the New York Times, a doctor may have the same economic incentives as a car salesman or a funeral director or a mutual fund manager.”).


101 See http://oig.hhs.gov/fraud/cia/agreements/Medtronic_and_MDS_CIA.pdf (last visited Jan. 7, 2009) (according to the press release, Medtronic was believed to have paid kickbacks to physicians in a number of forms, including fraudulent consulting arrangements, royalty agreements, and lavish trips to desirable locations. As a part of the settlement agreement, the company was mandated to maintain an internal database of its physicians and consultants.)

102 Id. (noting that as of September 15, 2008, Medtronic had still not complied completely with Senator Grassley’s request).

settlement agreement with the Department of Justice to settle allegations stemming from two whistle blower lawsuits alleging that Medtronic made illegal payments to physicians to promote its spinal products between 1998 and 2003).

104 *United States of America, Ex Rel., Jacqueline Kay Poteet and Bobbie Vaden v. Lawrence G. Lenke, M.D., et. al.*, Case No. 07 CA 1 02 37 RGS (U.S. Dist. Court, Dist. Of Mass (2008)) (seeking to recover damages for violating the Federal Civil False Claims Act by claiming that defendants violated their duty to report known errors resulting in ineligible federal payments and concealed such errors from the Government in order to keep funds to which they were not entitled. The focus of the claim, which was filed against 110 surgeons, alleges improper consulting agreements, royalties, and lavish gifts).

105 *Id.*

106 *Id.* at 24-41 (surpassing the compensation of every other physician, the alleged, combined fraudulent royalties and consulting fees paid to Kevin Foley, M.D. are said to exceed $27 million since 2001 (See p. 38 of Complaint)).

107 *Id.* at 41.

108 Supra n. 3.

109 *Id.*


111 42C.F.R. § 1001.952(a)(1)(ii) – “The investment interest of an investor in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must be obtained on terms equally available to the public trading on a registered national securities exchange, such as the New York Stock Exchange or the American Stock Exchange, or on the National Association of Securities Dealers Automated Quotation System.”

112 42C.F.R.§ 1001.952 (a)(1)(iii) – “The entity or any investor must not market or furnish the entity’s items or services (or those of another entity as part of a cross referral agreement) to passive investors differently than to non-investors).


114 42 USC 1128B –“ The anti-kickback law is a criminal statute that broadly prohibits the purposeful offer, payment, or receipt of anything of value to induce the referral of patients for services reimbursable by a federal health care program.” See MedPac, *Physician-Owned Specialty Hospitals*, p. 61, March 2005.

115 42 USC 1395nn – The Stark law is a civil statute aimed at curtailing over-utilization in facilities where physicians have a financial interest.


118 Jean M. Mitchell & Elton Scott, “New Evidence of the Prevalence and Scope of Physician Joint Ventures, 286 JAMA 80, 80-84 (1992). (This study found that at least 40% of Florida physicians involved in direct patient care have an investment interest in a healthcare business to which they may refer their patients for services; over 91% of the physician owners are collected

119 Id.  
121 Id.  
122 42 U.S.C. § 1320a-7b(b) (codified at 42 C.F.R. § 1001.952 (1997)).  
124 Black’s Law Dictionary, page 794 – in pari materia “On the same subject; relating to the same matter.”  
125 Ball v. University of Maryland, 768 A.2d 105 (2001); see also, 73 Am. Jur. 2d Statutes §103 (Sept. 2008).  
127 Stark 42 U.S.C. §1395nn(d)(3)  
128 42 C.F.R. 1001.952(a)(2)(i), “No more than 40% of the value of the investment interests of each class of investments may be held in the previous fiscal year or previous 12 month period by investors who are in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity.” (seeking to limit the percentage of ownership of referring physicians and balance their role as a fiduciary, Congress enables referring physicians to own a portion of an entity as defined under this section of the safe harbor).  
129 Support for the Physician Payments Sunshine Act, S. 2029, http://www.drugs.com/news/support-physician-payments-sunshine-act-s-2029-7838.html (last visited Dec. 29, 2008) (ironically, Medtronic believes that disclosure should be equal regardless of the size and including companies owned in whole or in part by physicians. The initial version of the bill exempted companies with yearly revenues less than $100 million and physician-owned companies).  
130 S. 2029 (2008).  
132 Supra n. 2.  
133 Id.  
134 Id.  
135 Supra n. 57.  
137 Id.  
138 Supra n. 3.  
139 Richard J. Maturi, Wall Street Words, p. 17 (Mc-Graw Hill, NY (1995)). “EARNINGS PER SHARE – Net after tax income of a corporation applicable to each share of common stock. If there are outstanding convertible securities, the unadjusted earnings per share are called primary
earnings. Earnings per share adjusted to account for convertible securities are called fully diluted earnings.”

140 Supra n. 19.

141 Id.; A Form 10-K is an annual report providing a comprehensive overview of a company’s business and financial condition, along with signed, audited financial statements. U.S. Sec. & Exch. Comm’n, Form 10-K, http://www.sec.gov/answers/form10k.htm (last visited Jan. 9, 2009).