



Points to Consider

Mike Esselman

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The availability and accessibility of medical information today is greater than it has ever been before. From online medical journals, to WebMD, to iPad apps—patients today are efficiently accessing information to take greater responsibility for medical decisions. Studies demonstrate that this behavior has its benefits: patients who are more active in their care tend to fare better. It seems that the increased availability of medical information today can be seen as a good thing, as ultimately each and everyone of us is accountable for our own health at the end of the day.

On the other hand, greater patient involvement has begun to change the paradigm of the physician-patient relationship. Recent studies are now beginning to investigate the outcomes when physicians give their patients more power in determining their medical decisions.

Results from these studies are not totally surprising, however they may provide insights to potential ethical issues surrounding this situation in the future.

A 2009 study assessed the willingness of arthritis patients to take a hypothetical ‘new’ drug that carried important benefits, but also had a small risk of serious side effects. The results showed that patients were *less willing* to try the drug when they were given complete power over the decision as compared to when a doctor advised them to take the medication. This indicates that patients are paying more attention to the risks associated with taking medications if they feel their decision is solely theirs.

So as the quantity (but not necessarily always quality) of medical information available to anyone with an internet connection continues to increase, the increasing trend

of patient involvement in determining treatment regimens will likely follow. However, the question remains if the patients granted with the responsibility to choose their care are sufficiently equipped with knowledge to assess the benefits against the risks.

- Do you see this increasing shift of power to the patient as a potential hurdle in future drug development? Will patients be less likely to enroll in clinical trials?
- Does the trend of doctors giving patients more power call for the need to reassess the direct-to-consumer marketing regulations? As it stands, DTC marketing regulations exist in order to uphold the physician-patient relationship. Does granting more freedom to patients in influencing their outcome put the patient at risk of making a potentially dangerous medical decision?

Michael_Esselman@kgi.edu



<http://bryawnt.files.wordpress.com/2009/08/stethoscope.jpg>

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KGI’s Journal Club To Be Published in *TuftsScope*

Wah Yan

The KGI Journal Club is pleased to announce the publication of an original review. “Benefits of the Orphan Drug Act for Rare Disease Treatments,” by primary student authors Boris Gites, Jessica Chang, and Mona Chughtai, will be published in the 2010 Spring Express Publication of

TuftsScope: The Interdisciplinary Journal of Health, Ethics, & Policy attached to Tufts University. The Journal Club would like to thank these three talented individuals, all members of the Journal Club for their support and editing work, and our faculty advisor, Professor M. Ian Philips for his invaluable advice.

KGI Journal Club was founded by first year students Ryan LaRanger and Wah Yan. The KGI Journal Club is dedicated to increasing KGI scholarship through the production of original reviews on different aspects of the life sciences industry. We hope to continue to foster a communal and comfortable

environment for students to explore areas of personal interest and develop their communication, writing, and team-building skills.

Wah_Yan@kgi.edu



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Economies of Health: Health Care Reform View 1

Marc Pollack

There can be no doubt that the U.S. health care system is amazing when it provides care. Nonetheless, we are faced with the stark reality that the U.S. finds itself lacking in terms of insurance coverage. Our infant death rate resides at an abysmal 33rd in the world, and our life expectancy is sitting at a dreadful 38th. This is mainly because of a lack of access to the health care system, and while this has sparked a massive debate in this country over what is the most beneficial to our country and people, I will focus on the effect on our pharmaceutical (Ph) and medical device (MD) companies.

First, let's look at what the reform does directly. The health care reform bill was passed primarily to increase the number of people with health insurance and to ensure that those who are currently covered remain so. Insurance companies will no longer be able to deny coverage due to pre-existing conditions. The "doughnut hole" in Medicare is reduced, ensuring better coverage for senior citizens by reducing the cost of prescriptions that they pay for. Medicaid will be expanded dramatically, ensuring that more low income Americans will be covered. It will also be mandatory for most Americans to have health insurance, though the bill also creates health insurance exchanges so that people can shop around, and provides subsidies to make that insurance affordable (1).

Despite worries that prices of drugs and devices would change after the passage of the bill, it allows pricing to stay the same. There is a definitive shift in "the market for prescription drugs... from healthcare providers and patients to payers, insurers, and managed plans," which is likely to change the sales strategy of Ph companies (2). While this may seem bad, it provides them an opportunity to gain a new competitive advantage in the market at a time when diversification is becoming all the more difficult (2).

This also provides new opportunities for struggling biotech companies to appeal to a new part of the market. The Ph industry has also received "12 years of protection against cheaper generic competitors," protecting 15% of pharmaceutical sales for several more years (3).

The MD industry seems to have taken a big blow through the introduction of a 2.3% excise tax on their revenues as a result of the reform bill. However, the tax was initially set far higher, meaning that companies were preparing for a more appreciable loss to their revenues, which has led to a more positive response (4). Even with the future of health care reform uncertain and a higher likelihood that things could have ended worse for the industry, the MD industry still seemed to be positive on the reform's future as of 2009 (5).

Second, let's look at the effect of the reform through health insurance providers. Health care costs were at more than \$2.3 trillion in 2008, but Ph and MD companies will see no change, especially since there will be more people with insurance coverage in the system. It is true that the number of people reliant on the government for health care coverage will increase with the reform. It is also true that hospitals will be paid more by this system (6). The addition of so many people to the system results in higher profits for hospitals than if these people were to continue to pay out of pocket, meaning that they would be able to pay for more pharmaceuticals and devices (7).

Third, let's look at the effect of adding all these people to the system via the reform. This only leads to higher profits for both types of companies, as well as insurance providers, since more people are being introduced to the system. These Companies have been waiting for this massive influx of people, anticipating increases in sales (8). MD companies anticipate that the increase in people with

health insurance will even offset the costs of their taxes (9). Even insurance companies stand to benefit from this influx, since this acts like increasing the size of their portfolio, reducing their overall risk.

My opponent (see "View 2") relates this to the housing market. However, the difference is that we already pay for their care through emergency rooms. It has been illegal since the passage of Emergency Medical Treatment and Active Labor Act (EMTALA) to turn away patients, and if they cannot pay the costs, the federal government foots the bill. According to a study by the Institute of Medicine, over half of all emergency care goes uncompensated (10). Another study concluded that uninsured people were less likely to pursue any medical care after an accidental injury or the onset of a new chronic condition. The uninsured with an injury were also twice as likely to have received none of the recommended follow-up care, and a similar pattern held for those with a new chronic condition. Uninsured patients are twice as likely to visit hospital emergency rooms as those with insurance; burdening a system meant for true emergencies with less-urgent care needs (11). The health care reform bill removes a large portion of this burden, offsetting the costs and possibly even reducing costs in the long term as more people get adequate and early care.

On the whole, companies have much to gain as a result of this health care reform bill, and there is no substantial chance of an economic collapse in the health care market. Ph and MD companies are thrilled at the prospect of introducing so many new patients to the health care system, thus increasing their overall sales. There is no uncertainty in that.

Marc_Pollack@kgi.edu

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What Does the Housing Crisis Have to do with Health care?: View 2

Thomas Tredennick

Firstly, we must note that the U.S. health care system is one of the best in the world in terms of research and innovation. Two thirds of all Nobel laureates in medicine in the past ten years are from the U.S. and over 80% of venture capital in the global health care sector was spent here in 2007 (1). This does come with a price, as we have one of the most expensive health care segments as well. Whatever happens in the future, we need to make sure our strengths are preserved if we want to maintain our position as leaders in the health care industry.

Everyone has sat in the back of their history lecture wondering, “What do these old codgers have to do with *me*?” Some would argue the reason we learn history is to not repeat the mistakes of our past. I believe the new health care bill sets the stage for history to repeat itself in the form of a boom and bust cycle much like the one we saw with the housing market in the 2000’s.

So how can insuring thirty three million extra people be a bad thing for the Pharma and Med Devices industry? On the surface, this looks great. Thirty three million extra people will have easier access to pharmaceuticals and medical devices. However, the overarching question is who will pay for this? It is obvious that taxes will have to rise and I will not belabor this point. If this method is to be sustainable, there will have to be significant wealth redistribution (read: higher taxes). The real issue will be the hidden subsidies that will be absorbed by the health care industry. The mandates from the government promises to expand Medicare and Medicaid. As a hospital, you cringe when someone walks in on Medicare or Medicaid because your profitability is -13% and -44%, respectively for each type of insurance (2). This promises to put a great strain on the health care industry because anytime you must offer a service at a price below what you need to break even, you are destined to go out of business. There is an economic distortion that prevents value-conscious decisions with any type of insurance; the government insurance options are just the worst for pharmaceu-

tical and medical device companies seeking reimbursement.

These stresses are comparable to those placed on the housing market in the early 2000’s. The government created artificial demand for houses by decreasing interest rates to almost zero. This made it more attractive and easier to finance a house. The government also created many opportunities, such as Fannie Mae and Freddy Mac, to usher low-income individuals into homes. This is directly comparable to the situation we have today. Interest rates are comparably low (which encourages consumption and not saving) and the government is mandating that thirty three million extra people, who could not otherwise afford insurance, be covered. Dropping thirty three million people into the system who cannot afford health insurance will create an initial boom fueled by artificial demand just like the one we saw with the housing market in the early 2000’s. However, like the restaurant owner who expands his store when the circus comes to town, he is left with unutilized capacity when the circus leaves. This is what happened when interest rates rose and people could no longer afford houses. They defaulted on their mortgages (which they never would have been able to afford in the first place) and the housing market crashed.

The parallel to the health care bill is the ever-increasing cost of health care and the economic distortions that remain in place. As the cost of health care continues to rise, it will become harder and harder for the government to subsidize all these people. The obvious push-back to this is that demand for health care will always be there. People will always get sick. This, however, misses a very important point. We must differentiate between demand and *desire*. People will always desire health care, just like they will desire homes and I desire a new 100 foot yacht. Demand, in an economic sense, is willingness to pay. These thirty three million extra people the government is insuring have a *desire* for health care, but lack a fundamental demand.

This is not an ethical issue, this is an economic issue. They have proven this lack of demand by not purchasing health care. This is directly comparable to the artificial demand for homes created by the government that was so perilous for the real estate market: people who had no economic demand for homes buoyed the market with artificial demand supplied by the government. Pharmaceutical and medical device companies will expand their business in expectation of increased consumption. But, when the circus leaves town (or the government can no longer afford to cover these thirty three million people), there will be an extremely painful bust.

I sincerely hope that I am wrong and this reform is indeed sustainable. I understand the housing collapse was a very complex process that cannot be pinned to one single event. This health care bill has many complex implications as well. However, it would be foolish not to at least consider the ramifications of our actions and pay heed to our history lessons. Everyone was sure there was no substantial chance of an economic collapse in the housing market. But all one has to do is take a look where we are today. I feel without addressing the underlying issue of the runaway cost of health care, this bill cannot be sustainable. My proposal for this is to treat health insurance like automobile insurance. Routine check-ups and normal wear and tear is not covered. Catastrophic or unplanned accidents should be covered. This would help remove some of the economic distortions to encourage more free-market competition and innovation. This would be good for both the consumers of health care and the pharmaceutical and medical device companies.

Thomas_Tredennick@kgi.edu

Unapproved and Unethical ... Or Is It?

Sarah Arlien

According to a March 26, 2010 article in *The New York Times*, health care providers, patients, and the FDA are concerned about marketed, but unapproved, nitroglycerin tablets (1). Wait a minute...how is an unapproved drug marketed? The FDA must have issued immediate cease and desist orders, right?

Not quite. The companies that make these unapproved drugs claim that their nitroglycerin tablets are “grandfathered” and thus do not require FDA approval; they say that their drugs are safe and that internal testing for potency is conducted. The FDA has issued warning letters to the two companies producing the unapproved tablets ordering them to stop marketing the drug immediately, to stop manufacturing the drug in 90 days, and to stop distributing the drug in 180 days (1). This means that the tablets may still be distributed until the end of September 2010.

Here’s your regulatory history lesson for the day. Starting in 1906, with the passage of the Pure Food and Drug Act, drugs had to meet certain standards of strength and purity, but had no requirements for safety or efficacy. In 1938, companies were required to prove that their drugs were safe according to the Food, Drug and Cosmetics (FD&C) Act. Drugs that were considered “identical, related or similar” to drugs approved before 1938 were not tested until the FD&C Act was amended in 1962 to require proof of efficacy. A drug is grandfathered under the 1938 grandfather clause if it was on the market before the FD&C Act was passed and its labeling indicated the same conditions of use as it did prior to the act. To be considered “grandfathered”

under the 1962 clause, a drug must have been “used or sold commercially in the United States, not a new drug as defined by the act at that time, and not covered by an effective application” (2). If a drug is “grandfathered” it means that the drug is approved under prior rules (like those just described) and the current rules, i.e. NDA review, don’t apply. You might think of it as it was good enough for your grandfather, so it’s good enough for you without any new rules. The FDA believes that the drugs on the market today likely differ from versions that meet these criteria in some way, i.e., formulation, dosage, labeling, etc. and thus do not qualify as grandfathered; the drug doesn’t meet the criteria of the early rules, so the current rules, i.e. NDA review, still apply. In 2006, the F.D.A. issued a Compliance Policy Guide further clarifying its requirements and thoughts on unapproved marketed drugs (3), (4).

So, if a company believes that its product is grandfathered, does that company have an ethical responsibility to seek at least generic approval from the FDA anyways? Or, given the expense of FDA filings and clinical trials that might be required, would the company be in violation of their responsibilities to company stakeholders by spending money on tests that might not be necessary?

I think it’s probably better to err on the side of caution and get your FDA approval. If you’re in the pharmaceutical or biotech industry, hopefully there is some part of you that wants to help people, not kill them. If you’re not sure which your drug might do, you should probably do some testing; if you’re pretty sure that it helps people you

shouldn’t have anything to fear from doing the testing. Approval will also provide some protection from the bad publicity that is likely to follow if the FDA takes enforcement action against you. On a more business focused note, if you get approved and competitors with the same product don’t, the FDA may take action on the grounds of competition with an approved product, remove the other products from the market, and leave you with market exclusivity for a generic product. For example, in the nitroglycerin case described in the first paragraph, IMS Health estimates that 80% of the 4.4 million prescriptions for nitroglycerin tablets were filled with unapproved drugs. Pfizer is the only company with an approved nitroglycerin tablet. When the unapproved tablets are removed from the market, Pfizer will gain the approximately 3.5M new prescriptions (1). Multiplying sales of a product by five-fold is generally a good thing.

So the business may be good, but an April 12, 2010, article posted on Fierce Pharma raises the concern that it may not really benefit patients. When the FDA took action against unapproved colchicine tablets, used to treat gout, it allowed URL Pharma to get approval for their version and price it as a branded drug. Although the unapproved version was priced as low as pennies per tablet, URL’s tablets may be priced as high as five **DOLLARS** per tablet. URL is even suing the



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The Ethical Concerns in Management Consulting

Sana Moosa

Management Consulting is a promising field that has caught a lot of hype over the last few decades. Its practice involves helping organizations improve the management and operation of their business, leading to better performance. Organizations hire the services offered by these consultancies to get external advice, tap into their knowledge framework and gain access to specialized expertise. In 2008, global consulting industry revenues reached about \$330 billion, with over half generated in North America alone (1). However, despite the consistent growth, the management consultant industry has attracted a significant amount of criticism and their moral standards have been questioned.

Consultants are frequently placed in situations that are characterized by ambiguity, ignorance, uncertainty and sensitivity, and cannot always apply simple ethical rules in cooperating with their clients (2). In fact, consultants face a dilemma known as 'dual ethics' where they are expected to be loyal to two separate interests that potentially conflict with each other.

To bring more light into this, let us consider some of the issues that consultancies may be accused of, which may inevitably raise ethical concerns. Critics argue that many management consultants fail to develop deliverables that are easy to execute by the client. In a sense, this serves as a 'hook' to convince

the client into pursuing another follow-on projects with the consultancy. A second criticism raised by many is the quality of the deliverables, despite the high fees that are charged by the consultants. These consultants tend to offer advice and strategies to their clients through 'prepackaged' frameworks that are not customized to the client's specific needs. Furthermore, consultants are often accused of assigning less experienced staff onto a project, in a drive to cut costs.

These concerns question the professional status of management consulting. After all, a consultant must be able to solve the organizational problem that he or she is hired to solve, and the solution must cohere with the interests of the client and sponsor (3). So what can be done to minimize the instances where consultancies may deviate from their professional status?

The British Institute of Management Consultants (IMC) is a professional and regulatory body that was formed in the mid 1950s with the aim to establish a code of professional conduct based on three main principles: 1) Meeting the client's requirements, 2) integrity, independence and objectivity, and 3) responsibility to the profession and the Institute (3). This code of conduct details the requirements to fulfill fixed standards in management consulting. Furthermore, the code of conduct describes what is seen as

unprofessional conduct by indicating the criticisms that management consultants face, such as the examples above. By doing so, the IMC is working to foster professionalism in the management consulting practice.

Should the United States consider establishing a similar regulatory body that establishes a standard that all consultancies should follow? How would such a regulatory body enforce and monitor these standards? With national revenue of over \$100 billion, can the industry sustain its steady growth, despite the increasing criticisms from both, clients and management scholars? How serious should the ethical debate be taken, in such a service-oriented field?

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KGI's First Ethics Debate

Chandana Thorat

KGI hosted its first ever ethics debate competition on Wednesday, April 14th 2010. The first debate had Ian Foti-Landis and Ryan LaRanger presenting a light argument on the efficacy and ethics of animal testing in research.

The second debate was a tough competition between well versed speakers, Marc Pollack and Juan Pablo McDonald who argued on the ethics of conducting business with countries that violate human rights. The event was judged by Professor Brian Keeley who handed out the prizes to the two winners, Ryan LaRanger and Juan Pablo MacDonald. The event was well received and greatly appreciated by the students, staff and faculty members present at the event. "We hope that this event will encourage more students to participate in the future" said Marc Pollack, one of the debate event organizers. Given the keen interest and positive response from students and faculty, the Ethics Committee plans to make this a regular event in the coming years.



<http://www.artopic.org/wp-content/uploads/2009/02/debate02.jpg>

Chandana_Thorat@kgi.edu

The Circle of KGI: A Welcoming and Farewell

Matt Verbrugge

The year is nearly complete, projects are being finished up, internships and jobs are being offered and accepted, and plans are being formulated for the summer. I'm hoping to take this time in the final edition of the 2009-2010 printing of the Kethical Dilemma to look to the future and our roles in it.

We are now about to head out on our respective paths, 2nd years to start their careers, 1st years to get a taste of their futures. Wherever we end up, remember that we are ambassadors of KGI. Everyone will need to be on their game out there, as in many cases, we will be the first person associated with KGI that our bosses and coworkers meet. How they see us will color their perspective of the institute. How they see KGI is directly related to how valuable our degrees. Therefore your

actions and conduct will have affects that range far larger than you.

I hope that the KGI curriculum and the Kethical Dilemma have given you some tools and perspectives to help with navigating the ambiguous and confusing ethical waters of industry. I caution you to always be alert and to try to always do the right thing. Once in a while, you will blow it, we all will. It will take a hundred more right calls to balance that it out, so show that you have impeccable form the rest of the time. Take responsibility for your actions, and then humbly and confidently keep going.

Our responsibilities in the future are not only to keeping a clean and positive image about KGI, the responsibilities also lie in bringing in the next class. The

class of 2010 has helped to get the class of 2011 up to speed. Soon, it will be the class of 2011 that will welcome in the students of 2012. Just as we have a responsibility in industry to spread a positive image of KGI, we also have a responsibility to bring along the following classes. There is an enormous amount of tacit knowledge that resides at KGI and it is part of the responsibilities of the incumbents to help pass that knowledge along to the newcomers.

And finally, to the class of 2012, welcome to KGI! You are in excellent hands from the class of 2011!

Matthew Verbrugge

2009-2010 Student Body President
Keck Graduate Institute of Applied
Life Sciences

MBS Class of 2010

Matthew_Verbrugge@kgi.edu

Questions? Contact the editor, Michelle Pesce (MBS '11), at Michelle_Pesce@kgi.edu.