The Ethical View
March 2006

Focus: Problem Physicians, Problem Patients

Letter from the Editor...
Laura Sedig '07

The Medical Humanities program at Davidson College challenges students to approach medicine and healthcare related issues from an interdisciplinary perspective. Under the guidance of Dr. Lance K. Stell, Ph.D., students explore the scientific, legal, political and ethical aspects of health care delivery, noting strengths and weaknesses to synthesize a more complete conception of the institution of medicine. Medical Humanities courses emphasize the analysis of ethical values that factor into defining a problem as medical and understanding opposing viewpoints. The analytical skills developed in these courses allow students to clearly think and write about the complexities of medical and institutional decision making.

The Ethical View is an annual, student-edited newsletter of the Medical Humanities program that provides a forum for discussion of current ethical issues. This issue focuses on "Problem Physicians, Problem Patients," the topic of the upcoming Frederick Womble Spears Symposium, but other topics of particular student interest are also included. Two articles are adapted from presentations given by the Bioethics Society members at the 13th Annual Bioethics Resource Group Conference and the National Undergraduate Bioethics Conference.

As editor of the 2006 issue of the Ethical View, it is my hope that this newsletter both increases awareness of current ethical issues, and provokes thoughtful reflection. It is through reflection that rational and meaningful conclusions are reached.

About the Editor...
Laura Sedig is a junior pursuing a self-designed major in Medical Ethics through the Center for Interdisciplinary Studies and a Chemistry minor. She has been a member of the Bioethics Society since her freshman year at Davidson, helping to plan the Spears Symposium all three years. She is also a frequent volunteer at the Free Clinic of Our Towns and Carolinas Medical Center. After graduation she plans to attend medical school.
Problematic Physicians, Problematic Patients
Lance K. Stell, Ph.D. Charles A. Dana Professor of Philosophy and Director of Medical Humanities

"In purity and holiness I will guard my life and my art... Whatever hazards I may visit, I will come face to face with the sick, remaining free of all intentional injustice." (The Oath of Hippocrates)

"The physician professes medicine, but he practices another art: he does not pro-" "fess... fee-earning." (Vatio, Republic).

Health care is provided to human beings by human beings. Since human beings are not angels, the care-providing relationship cannot be mediated on the assumption that each side will act responsibly. Indeed, it has always been appreciated that every medical decision, momentous or not, raises a question - will the physician put his own or patients' interests first?

Were the physician immune to "inexpensive and unhealthy" incentives, there would be no point in his vowing to guard against his unduly effecting his/her conduct. On the other hand, because "ought implies can," there would be no point in vows of vigilance were physicians (individually and professionally) totally lacking in self-control. If so, conflicts of interest which are inherent in agency, where one party bears responsibility to act in the other's best interest, must be managed, not abolished. This point applies to how physicians should normalize their interactions with the pharmaceutical industry, a source of lucrative revenue.

The drug industry develops, manufactures, markets and distributes FDA-approved products that have proven in clinical trials to provide research subjects with benefit at acceptable risk. Approximately 67 percent of biomedical R&D is funded privately.1 Drug companies fund more than 70 percent of clinical trials;2 nearly 41 percent of NIH scientists serve as consultants for industry;3 and more than one-third of interns are industry paid to assist in conducting clinical trials and to present drug talks.4

Since physicians enjoy near-monopoly control over access to prescription-only products, as approved drug cannot benefit patients unless physicians are made aware of its availability, learn about its indications/contraindications, to benefits/risk. Physicians' monopoly over access to prescription-only products imposes another duty: (1) to possess sufficient clinical knowledge and judgment to provide patients with expert counsel regarding the comparative risks/benefits of currently available treatment options and (2) to keep abreast of new additions to the treatment armamentarium when they hold in trust for the rest of us.

Since the costs of bringing a new drug to market in the United States are substantial (variously estimated between $500 million and $800 million), its manufacturer has an untenable but necessary product information dissemination framework to rapidly physician. Why? When "indications-approval" for marketing, a product's revenue potential is fairly large (4-6 years, on average).2 The patent-clock's countdown motivates drug companies to make very large expenditures to market their products to doctors. For example, in 2002, the industry spent 33 percent of its revenue on "selling and administration," variously estimated at $12 billion to $15 billion annually, or between $8,000 and $15,000 per physician. Overall, the industry spends more on marketing than on R&D. Recent years have also witnessed a dramatic increase in direct-to-consumer advertising (DTA).3

The incentive for drug companies to bias their marketing in a product-favorable direction is obvious. The bias literature is vast, but here are two examples:

- a systematic review of 30 studies comparing pharmaceutical industry-sponsored research to non-industry-sponsored research found that industry-sponsored studies were much more likely to use placebo controls and to report results favoring sponsors' products than non-industry-sponsored studies;
- a study of graph-containing advertisement claims appearing in medical journals during 1999 found that 36 percent contained product-favorable numerical data and 41 percent prohibited by FDA regulations.

That misleading graphs were accepted for publication in peer-reviewed, professional journals implies that their editors should be more vigilant and/or upgrade their analytic skills. It is unconscionable to hold journal editors responsible for negligent oversight, who should be instead... Drummond, Remmie, a long-time critic of medical journal quality and himself a medical editor finds that journals are rigid with errors and are improving only slowly. It seems, you are a time, energy, and thought to their craft."

In 2002, the [pharmaceutical] industry spent 33% of its revenues on "selling and administration," or between $8,000 and $15,000 per physician.

Drug makers' incentives to prefer placebo-controlled studies it clear. They require smaller enrollments to achieve significant results, are cheaper, and more likely to yield product-favorable results than controlled-therapy controlled studies. One product approval process is a safety-over-speed bias. This lengthens the approval process, but shortens patient-protected marketing time, increases the profit pressure on it and strengthens the incentive to economize on study design.

No Margin, No Mission

Maximizing the advantage remaining patent protection provides is the primary goal of pharmaceutical marketing. During this period, the manufacturer will attempt to recover not only the drug's R&D costs but also those associated with:

- chemical compounds (those patented and others for which patents were never sought) that seemed promising.
initially but subsequently were judged not worth the gamble of further investment.

- pay back to investors and stockholders a return sufficiently good to
  sustain their support and projecting in potential interest a maximum
  and profitable future for their money.

The competitiveness high price of drugs marketed in the U.S. additionally reflects the fact that other countries (e.g., Canada, France and Germany) refuse to pay prices that increase as a rate of a drug's R&D costs. Put in economic terms, these countries bargain for and enforce pricing reflective of "second tier" production costs, not "first pill" costs. This practice effectively (and unfairly) shifts the bulk of drug R&D costs to U.S. market consumers. Proposals to authorize drug re-importation would tend to undermine international cost-shifting, however, the current arrangement is one the industry well-understands. They have no incentive to support changing it.

Why Drug Detailing is Necessary

It is well-established that physicians sometimes neglect to prescribe the industry's products as often as they should or at doses large enough to achieve maximum benefit. However, even though physicians are not indifferent to the potential benefit that recently-approved drugs may offer to their patients, unless they are
dissatisfied with what they have been pre-
scribing, they have no incentive to care whether their learning about a product
coincides with the manufacturer's interest that they do so as early as possible within a drug's product's remaining patent protection. On the contrary, in so far as physicians inter-
pret the ethical injunction "First, do no
harm," as a precaution against novelty, they have a conservative bias against pre-
scribing recently-approved pharmaceuticals and a reason to resist exposure to the product-favorable information that pre-
dominates when a drug is newly-
approved. Nor do physicians have any incentive to lobby pharmacy benefits managers to add newly-approved drugs to the formu-

To offset physicians' indifference/resistance to learning about its new products to expend substantial resources on what has proven to win physicians' timely & favorable attention -- food, fancy, and somewhat-useful, but predictably biased product information.

No Free Lunch?

What's an ethical doctor to do? Make
sure she's prepared analytically and emo-
tionally to discount the industry's duties mentioned above? Or, should she take the
pledge: "No Free Lunch"?14 Howard
Bredy, a (physi-

ian-biotechnician) has argued that, insofar as physicians care about their profes-
sional integrity, (or, archaically, keeping
themselves and their art "holy & pure"), they should refuse to associate with drug industry representa-
tives at all:

- not to waste time listening to their
  pitches,
- not to accept pizza, pens and mugs,
  (with some waving regarding accept-
  ing product samples), and
- not to attend industry-sponsored CME
  conferences.

Why? Because, Dr. Brody argues, there is substantial empirical evidence that phar-

macists who fail to heed the danger of reps' autonomy-degrading Stern song, will in-
cure an addictions-like syndrome, "drug
company dependency." Supposedly, by
listening to reps' details, swallowing the biased-hype contenido disbursed at industry-
sponsored symposia, and gullibly grab-

...in so far as physicians interpret
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Clean Hands and Purity of Heart: Should
physicians erect Dr. Brody's integrity-
protecting firewall?

Suppose they were to do so. The follow-
ing facts remain:

- pharmaceutical companies continue their
  count-
down,
- drug makers have a powerful incenti-
  ve to maximize the advantage patient
  protection provides; and,
- given the amount Americans spend purchasing the drug industry's pro-
  ducts
(>$2 trillion in 2003)17, pa-
tients can expect to have access to

It is past-nasive to suppose that the industry would re-
spond to a profes-
sional firewall against the industry by redistributing
resources from mar-

keting toward
R&D. Given the incentives outlined above, the industry would almost certainly further expand in "ask your doctor" DTC. If we assume that patients are less well
equipped than physicians to diagnose the toxic bias with which the industry suppos-
tedly would face DTC, then to avoid de-
familizing their fiduciary responsibilities to counsel patients about their therapeutic options, physicians must somehow prepare to do so without suffering from toxic expos-
ure themselves.

How might physicians timely prepare themselves for the predictable DTC-provoked conversations? By attending non-industry sponsored educational con-
ferences for updates on cutting-edge clini-
cal practice guidelines? Problem: A survey (with a poor response-rate) found consid-
erable intersection between the author of
clinical practice guidelines and the phar-
maceutical industry11. Might physicians
instead subscribe to and regularly read a
comparatively less biased source of infor-
mation, e.g., the Medical Letter? Problem:
Dr. Brody acknowledges that very few of his colleagues curiously bias-check the
information they receive. Will the prospect of facing an increasing number of "ask
your doctor" patient inquiries in the office be sufficient incentive for already busy
doctors to do their homework? Or might
others even more often simply write the pre
scriptions patients have been prompted
to ask for? I suggest that a clean hands/poor-heart strategy is desultory and irresponsible.

**Conclusion**

In 2002, the Pharmaceutical Research and Manufacturers of America adopted a Code on Interactions with Healthcare Professionals.11 Its preamble proclaims that "ethical relationships with healthcare professionals are critical to our mission of helping patients." The Code puts out-of

boundaries egregiously compromising industries-doctor interactions that have made responsible practices on both sides crim. It specifies permissible and impermissible conduct by industry representatives while recognizing that marketing has a legitimate role to play in promoting patients' timely access to and correct use of the industry's products. It endorses industry support for professional meetings and conferences other than those organized by pharmaceutical companies themselves and affirms that control over meeting content should reside with the organizers. Proper handling of funds to enable residents, students, and fellows to attend meetings is also set out. It affirms that the host institution must retain control over selecting who receives funding. It defines ethically acceptable communicating relationships and gives criteria for determining reasonable compensation for board service (verisimul consulting services. And it limits the value of gifts to physicians to items worth $100 and specifies that these should ostensibly benefit patients (e.g., pens, notepads and stethoscopes).

The American College of Physicians has also outlined reasonable ethical constraints for dealing with industry. It now marks the Pharma's.12 Taken together these initiatives are the strongest, most helpful moves yet for guiding medical professionals who are not cognizant fund-raisers, engulfed with utopia, black/white ethical/ought and for guiding industry representatives who must now be more careful in how they market products to physicians.

Both Pharma's Code and the College of Physicians position paper are heretofy. No enforcement mechanism backs either one. But with health care costs already working at cross-purposes with access to professional services, we should remind ourselves that there tend to be a positive supply function between creating enforcement mechanisms and enforcement. When severe sanctions are authorized, offenses must be defined, standards of proof specified, and due process protections instituted. A resulting demand for a body of skill, the "certified") practices to apply standards develops, and if the core offense is "unethical influence," their numbers will be constrained only by the size of the enforcement budget. So let's be hopeful that ethical codes and reasonably conscientious compliance can promote moral progress.

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6Under current law, a patent's duration is the shorter of 20 years from the date of filing or 60 years from the parent issue. Since patent routinely take 4-5 years to issue, effectively the term is 20 years from filing. The process of product development and testing that leads to FDA approval takes roughly 10-13 years.

7Blumenfeld D. Doctors and drug companies. NEJM. 2004;351:1883-1890.

8Royenthal MB, Benoit ER, Dohmme JM, Frank FG, Epstein AH. Promotion of prescription drugs to consumers. NEJM. 2002;346:498-505.


12Some companies specialize in buying or licensing the patents of such forskoon agents, hoping to profit from further developing others' abandoned projects.

13Quality of health care delivered to adults in the United States. NEJM. 2003;349:1866-68.

14Visit www.mftresearch.org. Website master, Dr. Robert Goodman has adapted the Cage questionnaire to the diagnostic drug company dependency." His site also has downloadable Power Point presentations illustrating industry influence on physicians.


17Choudry NK, Stelfox HT, Detsky AS. Relationships between authors of clinical practice guidelines and the pharmaceutical industry. JAMA. 2002;287:612-617.


20Lance K. Stell, Ph.D., is the Charles A. Dana Professor of Philosophy and the Director of the Medical Humanities Program at Davidson College. He also serves as a Medical Ethics in the Department of Internal Medicine at Carolinas Medical Center.
“He never listens to me.”

“She’s always keeping me waiting.”

“I just can’t get him to understand what the problem is.”

These are just some of the grievances that we hear from patients about their doctors. However, these are complaints that I heard from physicians about their patients during my preceptorship at Caroline’s Medical Center this semester. While shadowing Dr. Elizabeth Abney at the Myer’s Park clinic, I saw a number of physicians who were frustrated, exhausted, confused, and angry with their patients. Most felt as though they were not making any progress with their patients because of noncompliance. Previously, while working at the Starfish Project in New York City, I saw a similar problem plaguing the HIV/AIDS specialists. Each week, at least one doctor was presented with a patient who wanted to take a drug holiday from their antiretroviral medications. And, even though the doctors had clearly explained the consequences of the action, the patients were surprised to see that their condition had worsened over the “holiday.” This pattern frustrated many of the physicians who felt that they were being blamed for their patient’s choices.

In the past, a doctor’s word was law and patients were expected to follow directions flawlessly. Over time, however, patients have become less and less compliant with their doctor’s wishes. Both the patient and his or her physician seem to have reached a stalemate where neither feels understood and each feels that they know best. In 1947, the American Medical Association released a Code of Medical Ethics that clearly establishes both the rights and the duties of each individual in the physician-patient relationship. Medicine, in its nature, is a dynamic field and the advances in technology and access to information have brought changes in the interpersonal relationships involved in this profession. The recent shift in power from the physician to the patient has had adverse effects on health care in this country, and it is essential to reestablish a balance within the physician-patient relationship.

The 1847 AMA Code of Medical Ethics begins by establishing the position of this discipline within the clinic. “Medical ethics, as a branch of general ethics, must rely on the basis of religion and morality. They compromise not only the duties, but also, the rights of a physician” (AMA 83). Even in this opening statement, the AMA has recognized that physicians not only have duties to society, but that they have a specific set of rights as well. However, the Code of Medical Ethics also stresses a balance between the two individuals in this relationship: “Medical ethics cannot be so divided that one part shall obtain the full and proper force of moral obligations on physicians universally, and, at the same time, the other be considered in such a way as to free society from all restrictions in its conduct to them; leaving it to the caprice of the hour to determine whether the truly learned shall be overlooked in favor of ignorant pretenders—persons desirous alike of original talent and acquired fitness” (AMA 85).

In any relationship, it is unacceptable for one party to carry all of the responsibility. The physician-patient relationship is no exception and shifts in either direction will inevitably create a problem. It is for this reason that the AMA outlined specific duties for both individuals in this important relationship.

Regarding the physician, there are seven specific duties, which are still applicable a century and a half later. The first is the duty to “be ever ready to obey the calls of the sick” (AMA 93). The second addresses patient confidentiality and the third encourages promptness and the avoidance of unnecessary visits. The fourth and fifth articles refer to cases of poor prognosis and futility, stating that a physician should be sensitive to the fact that “the life of a sick person can be shortened not only by the acts, but also by the words or the manner of a physician” (AMA 94). Finally, the sixth and seventh obligations are to refer patients to “whom necessary and to maintain a pleasant disposition with patients.”

Indeed, every single one of these responsibilities is expected of physicians today, and this Code of Medical Ethics is often cited when a doctor has strayed from his or her duties. The fact of responsibilities that apply to a patient, however, are not present in more recent editions of the Code. According to the original document, the patient was expected to adhere to a list of ten “obligations.” To begin with, the physician has a right to expect that his patients “exhibit a just sense of the duties which they owe to the medical attendants” (AMA 95). The second and third articles state that a patient has a right to select a doctor with a legitimate license to practice and “whose habits of life are regular” (AMA 95).

The fourth duty states that physicians should “unreservedly communicate to their physician the supposed cause of their disease” (AMA 95). It is essential for a patient to express what he or she feels is the cause of disease so that the physician can begin to make a diagnosis. Furthermore, the fifth article points out that a patient should never fear asking for a full disclosure of facts and events to his or her health care provider because anything said in the examination room will be held in confidence. These admissions will inevitably lead to a better understanding of a disease and an appropriate course of treatment. For example, one of the patients who came to the Myer’s Park clinic presented with hypertension and a history of cocaine abuse. Because a beta blocker cannot be prescribed to patients who use this drug, personal facts about this patient’s life were imperative in determining the most appropriate treatment.

The sixth duty states that, “the obedience of a patient to the prescriptions of his physician should be prompt and im-
The average patient has little or no understanding of medical arts, and ordinarily has only a physician to whom he can look for enlightenment with which to reach an intelligent decision. The patient's resistance upon the physician is a trait of the kind which traditionally has exacted obligations beyond those associated with arms length transactions. His dependence upon the physician for information affecting his well-being, in terms of contemplated treatment, is well-nigh object.

The emphasis on a patient's "subject" depended upon his or her physician underwrites the paternalistic nature of medicine at the time. From this statement, it is clear that the responsibility within the physician-patient relationship rested solely on the shoulders of the physician due to a lack of knowledge on the part of the patient.

Since the contemporary decision, however, there has been a significant change in the education of the general public. Patients today have a better understanding of basic science and unlimited access to information that was once monopolized by the medical profession. With the increased knowledge of the patient population, there has been a shift from the professional-client model to one that focuses on the "purchaser's (patient's) rights and the seller's (physician's) obligations." (J13).

Unfortunately, this shift toward patient power is just as detrimental to the physician-patient relationship as paternalism. With an increase in resources, patients can now threaten to "take their business elsewhere" (Hang 214) if they feel their needs are not being met and many have latched on to their independence as a justification for noncompliance. However, medical research shows that patients have almost as much responsibility for their health as physicians. With the relatively new technology that can treat infectious diseases, chronic diseases are becoming the newest health crisis and as we begin to understand how our behaviors affect our health, medicine is becoming more focused on preventive care than it was in the past.

Sometimes, a patient whose life is regulated by his or her disease may become angry at his or her loss of independence. This anger may be directed toward a physician in the form of inappropriate behavior or noncompliance. Just as children rebel against their parents for setting rules and guidelines, patients may act out against doctors. In this case, patients may "fail to comply as an act of medical sabotage, an undercover assertion of autonomy and independence." (Hang 214). This may have been the problem in one of the most famous cases of patient noncompliance, Poyton v. Wenatchee. c. 1974.

Amanda Poyton was a 35-year-old woman living alone and surviving on the checks she received from social security. Brenda suffered from chronic emphysema and a renal disease and began treatment with Dr. Weaver in 1975. Three years later, Dr. Weaver sent a letter to Brenda informing her that he would no longer be able to treat her because of her noncompliance behavior (including missing appointments, showing up at dialysis drunk or on drugs, and threatening nurses with a gun), which had interfered with treatment. It seems that Brenda, angered by the lifestyle she was forced to lead because of her renal failure, chose to act out against the medical institution, which she felt was ruining her life.

Another, more recent controversy involves Dr. Terri Bennett, whose medical license may be revoked for defending an obese female patient. The plaintiff alleges that Bennett said that she would never be able to find another meaningful relationship if her husband died because of her obesity. The Board of Medical Examiners has charged Dr. Bennett with misconduct and disreputable behavior, but many of the doctor's patients, on the other hand, stand against this charge. "I have been in this lady's shoes. I've been angry and left his practice. I mean, in-my-face-taking-off-angry," says Mindy Hanny, one of Dr. Ben nett's patients. "But once you think about it, you're angry at yourself, not Doctor Bennett. He's the messenger. He's telling you what you already know." (AP). Brenda Poyton's anger is similar to that felt by some patients who find it hard to accept their role in caring for an illness.

This case falls at the center of the power struggle between patients and physicians. Many of today's disease epidemics are related to the lifestyle choices of patients. Therefore, part of the treatment given by a doctor is a recommendation for a change in behavior, which is often not well-received. Now, more than ever, it is important for physicians and their patients to return to the 1847 AMA Code of Ethics to reevaluate each individual's role in the provision of health care. Physicians need to be cautious of slipping back into a paternalistic approach to medicine and to remember the altruistic nature of their profession. Patients, on the other hand, need to take responsibility for their own health as we continue to move toward a society that emphasizes preventive health care.

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-- Eikel Strachan's is a senior Spanish major with a medical humanities concentration. She is the president of the Bioethics Society and will attend medical school in the fall.
Direct to Consumer Pharmaceutical Advertisement
Bea Whigham, Davidson College '07

The pharmaceutical industry has increasingly utilized television, magazine, and other mediums to directly market their drugs to the general public. This practice, known as direct-to-consumer (DTC) advertising, has become increasingly controversial. Although the ads help to inform the public about various conditions and treatments, drug sponsors have been accused of presenting biased information, encouraging unnecessary prescriptions and undermining physician authority. While some of the arguments against the ads are valid, an outright ban may not be the best solution. If properly regulated, DTC ads might serve as a useful addition to the numerous sources of health information currently available to the public.

One of the primary concerns regarding DTC advertisement is that it will ultimately influence of physician's choice of treatment. The idea is that an ill-informed patient, having seen an ad, will decide he or she needs the advertised drug before arriving at the doctor's office. The patient will then pressure his or her physician to prescribe the drug, which may or may not be the ideal treatment. This model disagrees with several findings.

First the public is not entirely susceptible to the marketing strategies used by drug sponsors. One study found that 58% of respondents believe that the effectiveness of a drug is exaggerated in advertisements. Second, even if swayed by a DTC advertisement, most patients will still respect the physician as the decision maker. One study found that only 15% of patients would actually consider switching doctors if refused an advertised drug.

According to these numbers, the average patient will trust a physician's judgment over a 30-second sales pitch.

Instead of overriding a doctor's judgment, DTC advertising seeks not targeted to crowded markets where multiple drug companies offer nearly identical therapeutic profile. In such cases, advertisements try to build brand recognition and may give one drug an edge on the competition. Many physicians report that they will prescribe a drug requested by the patient if they consider it equal to the other drug therapy options. Such scenarios are common, since many drug classifications are crowded with "me-too" drugs that are essentially identical treatments. In this case, competing drug companies lose, but patient care does not.

A legitimate argument against DTC ads is the presence of biased information and exaggerated medical claims. The FDA established a series of requirements for DTC advertisements in the 1982 Kefauver-Harris Amendments to the Federal Food, Drug, and Cosmetic Act. According to the ad, DTC advertisements must meet four requirements, (1) They cannot be false or misleading; (2) They must present the benefits and risks of a drug in a balanced manner; (3) The advertisement must feature facts relevant to the product's advertised use; (4) Every risk from the product’s approved label must be presented in the advertisement. Except for the fourth requirement, the guidelines allow drug sponsors considerable leeway as deciding what to include in the advertisement. Also, the FDA only reviews advertisements after they have been released to the public. Between the years 1997 and 2000, the FDA sent approximately 78 notices to drug sponsors in response to promotion violations. The exaggerated claims have been optimized by a recent series of Congress commercials that featured pill-shapeq devil horns and little information regarding the risks or benefits of the medication.

Recently, however, the pharmaceutical industry has felt increased pressure to refine their advertising practices as public opinion has dropped to record lows. In large part due to the high-profile recall of the COX-2 inhibitors. Already some organizations are attempting to distance themselves from the controversial advertisements. The NFL recently opted not to renew a sponsorship with GlaxoSmithKline's heart-stiff dysfunction (ED) drug Levitra. A spokesman for the NFL cited the tone of recent advertisements as the cause of the split.

The major gastroenteric companies appear to be responding to the external pressures. Pfizer has done away with the drivel-laced Viagra campaign and recently launched an ad campaign centered on patient education. Viagra is not directly mentioned in the ads, which provide viewers with a toll-free number to call for more information on ED disorders and treatments. Additionally, the Pharmaceutical Research Manufacturers of America (PhRMA) recently adopted a new set of advertising guidelines. The advertisements for violations of the guidelines, but at least signify that the industry recognizes the need to revamp its image.

Some have called for an outright ban on DTC advertisements. Such a ban may simply cause drug companies to focus their marketing towards physicians. Drug companies already employ nearly 100,000 sales representatives to visit doctors and promote their employer's drug. A more sensible move for the FDA is to implement a pre-approval process to curtail the abuses associated with the current system.

For all the complaints leveled against DTC advertisement, their capacity to spread awareness of various conditions and treatment options should not be overlooked. Even without medical training, most patients are wary of the claims of advertisements and very few would trust a television ad over a physician. If properly regulated, the ads could help spread information about various disorders and treatments, which would benefit drug companies and the public alike.

References
HIV Positive Physicians and the Duty to Disclose
Lauren Finley, Davidson College '07 and Alice U Fletcher, Davidson College '07

This article is an adaption of a presentation that will be given at the National Undergraduate Bioethics Conference at the University of Notre Dame, March 10-11, 1996. Lauren Finley, Ben Mezes, Lauren Sedig and Alice U Fletcher created and will give the presentation.

Rooted in the principle of patient autonomy, the standard of informed consent obligates physicians to reveal all information necessary for their patients to consent to their treatment. Physicians should know and understand the different treatment options available and the risks associated with each before they make a decision concerning their treatment. While this usually pertains to the risks inherent in certain medications and operations, some risks can be associated directly with the physician. Medical students and residents, for example, do not have as much experience performing operations and therefore may not be able to provide the same outcome as an experienced physician. With the HIV epidemic, patients may now be concerned with their doctor's HIV status and the risks of transmission in the medical setting.

Does a physician have a duty to disclose his serostatus if he is HIV positive? The courts have generally agreed that doctors do not have a duty to disclose aspects of their personal lives, even though issues such as stress, sleep deprivation, and drug addictions may affect their performance in a clinical setting. An individual's serostatus is usually considered a personal matter that should not be disclosed against his will. This policy exists to protect people with HIV from unjust discrimination, stigma, and decreased employability. However, patients may argue that their physician's HIV status is a necessary piece of information in order to give their informed consent.

Physicians are required to disclose inhere risks of a procedure, but not risks that are incredibly unlikely and may lead to side effects unfound 100,000 years. This risk could be considered so small that it becomes unnecessary to disclose when obtaining informed consent.

Furthermore, there is a 1 in 20,000,000 chance of being infected by a surgeon of unknown status. In such cases, the association with disclosure could be more harmful than helpful to both the doctor and the patient.

The American Medical Association states that a physician or other healthcare provider who performs procedures and becomes HIV positive should disclose their serostatus to a state public health official or a local review committee. They also advise that an HIV infected health worker should refrain from conducting exposure-probe procedures. If they choose to perform such a procedure, they should do so with permission of the review board and the informed consent of the patient. The problem with this advice is that the term "exposure-probe procedure" is ambiguous and undefined. It is unlikely that a physician's body fluids will come into contact with a patient in any procedure, even during the most invasive surgeries.

Another problem with the American Medical Association's requirement to inform the patient is that the doctor will most likely lose patients if he follows these guidelines. In revealing his serostatus to the patient, a doctor risks losing the patient because of the stigma with which the patient is likely to associate him. Even though it is common knowledge that the HIV virus cannot be spread through touch or breathing, many patients are still extremely fearful of infection. This fear could lead someone to abstain from any interactions with a patient who has a known HIV infection. People with limited understanding of HIV transmission may lose faith in the medical profession if they feel betrayed by their doctor due to a lack of disclosure. In some cases, it may even lead them to sue their doctor.

In one case, Faya v. Almanzar, two patients brought suit against their physician for failure to disclose his serostatus. Although the patients did not contract the disease after having operations performed by the infected physician, they claimed that the physician had behaved negligently. The court found that the potential harm was not likely enough to confer upon the physician a duty to disclose.

In another case, a physician was struck with a needle during his neurological residency and later tested HIV positive. The University of Maryland Medical System Corporation forbade the doctor from surgery. The physician in turn sued the corporation under the Americans with Disabilities Act and Equal Protection Clause of the Fourteenth Amendment. The court found that he could not claim discrimination under the ADA and equal protection clause since the CDC guidelines stated that HIV positive physicians should not perform high-risk procedures.

Clearly, there has been debate over whether the possibility of virus transmission from doctor to patient warrants mandated disclosure of physician status in obtaining informed consent. There is enough information verifying that the possibility of this transmission is so small that the physician should not have to sacrifice his privacy and integrity in the medical profession. Once a physician becomes debilitating by AIDS, strict standards already in place are sufficient to ensure that a physician does not continue his practice beyond the point at which he is capable of doing so.

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Death with Dignity: Eight Years of Physician Assisted Suicide in Oregon

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Over the past 8 years, one out of every 1000 deaths in Oregon has resulted from a lethal prescription for a terminally ill patient. The practice, known as physician-assisted suicide (PAS), has been legal in Oregon since the implementation of the Death with Dignity Act (DWDA) in 1998. The act has been controversial, and only recently did the Supreme Court block an attempt by the US attorney general to overturn it. DWDA is portrayed as a protection of end-of-life rights by its supporters and a Pandora's box by its critics. This article summarizes the provisions of the DWDA law as well as the results of its first seven years in practice.

The Law

The applications of the Death with Dignity act are narrowly defined. For a patient to be eligible for physician-assisted suicide, they must meet four requirements. The patient must be: 1. An Oregon resident; 2. 18 years or older; 3. Terminally ill; and, 4. Capable of communicating their wishes. Failure in any of these categories precludes PAS as a treatment option.

The law also lays out strict guidelines that must be adhered to. The patient must make two oral requests for a lethal dose of medication. These requests must be at least 15 days apart. Beyond the oral requests, the patient is required to provide a signed statement requesting the lethal dose. The written request must be completed in the presence of two witnesses, one of which must be unrelated to the patient.

The attending physician must, at all times, be certain that the patient is competent to make medical decisions. This opinion must be backed by a consulting physician. Any suspicion of a psychological disorder necessitates a refusal of the medication.

The physician must inform the pharmacist of the nature of the prescription. The pharmacist, like the physician, is not obligated to participate in the undertaking.

Every completed PAS case must be reported to the Department of Human Services, which has led to a quick accumulation of data on the practice.

The Patients

Individuals with higher levels of education are far more likely to request PAS. For example, college-educated patients are, on average, 8.7 times as likely to request physician-assisted suicide than individuals who never completed high school. Other factors, such as marital status and age, factor into the likelihood that a particular patient will request PAS. Patients that are divorced or that never married are far more likely to request PAS. Younger patients are more likely to request PAS than older patients.

Surprisingly, men and women appear equally likely to request a lethal dose of medication when all other factors are held constant.

Among the reasons for choosing PAS, the terminally ill patients consistently list several concerns. The most common reasons for choosing PAS were an inability to participate in enjoyable activities (92%), a loss of autonomy (87%), and a loss of dignity (78%). Of the recorded reasons, financial concerns were the least common reason for electing PAS.

The DWDA has been employed by patients with a wide range of terminal illnesses. Some illnesses were more likely to elicit the decision to end it all than others. Patients with neurological-degenerative disease, amyotrophic lateral sclerosis (ALS) are the most likely to choose PAS (252.0 per 10,000), Patients with HIV/AIDS (234.7 per 10,000), and malignant neoplasms (58.4) were the second and third most likely groups to request PAS.

The Future

The number of PAS events in Oregon increased annually from 1999 to 2003, but declined in 2004. For now, it appears the upward trend has ceased, with only a small fraction of patients electing to end their lives.

The slowing of PAS expansion in Oregon has not silenced its critics. The Death with Dignity act has many opponents, including the current administration in the White House. Some critics have presented disturbing statistics as to the use of PAS. For example, studies have shown that nearly half of the terminally ill patients that consider suicide will change their minds after treatment with antidepressants. At the same time, the percentage of PAS requesting patients that are referred to specialists for psychological evaluation has declined from 31% in 1998 to 5% in 2004.

Some claim that PAS will ultimately lead to euthanasia, in which the doctor injects the lethal dose of medication. However, the emphasis on patient autonomy found within the Death with Dignity Act is not consistent with the practice of euthanasia. While the debate is not settled, PAS might not be the slippery slope that some of its critics claim.

Although the Supreme Court rejected the White House's attempt to revoke the DWDA, the controversy will continue. Like the cases of Nancy Cruzan and Terry Schiavo, the Death with Dignity Act has been effective in turning the public eye towards an unsavory issue. We can all hope that public awareness will benefit as a result of the controversy.

References:

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Controversy Envelops South Korean Stem Cell Researcher Woo Suk Hwang

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The scientific community has watched with a mixture of shock and dismay in the past few months as the controversy regarding South Korean researcher Woo Suk Hwang's fabrication of data unfolded. Scientific American's editor in chief, John Rennie describes the scandal in one word: "Thalberg-mingling." Woo Suk Hwang was born in the poor town of South Chungcheong, South Korea. He financed his education by farming, earning a doctorate in veterinary medicine and eventually becoming a professor of veterinary medicine at Seoul National University. He also obtained a doctorate in Theriogenology, the science and practice of animal reproduction. His initial goal upon entering the field of research was to develop superior cows for South Korea. His work soon, however, branched further into embryonic stem cell research, a field that stood to benefit from his knowledge of the cloning process. No one could have predicted that the workaholic national hero would eventually be embroiled in controversy.

The conflict began in November 2005, when University of Pittsburgh professor Gerald Schatten ended his two-year collaboration with Dr. Hwang, citing concerns with the manner in which Hwang's laboratory obtained eggs for his research. Shortly thereafter it was found that Hwang's own researchers had, in fact, donated eggs used in his experiments. In addition, Hwang's collaborator Rob Sungenis, the head of a hospital, admitted to paying women approximately $1,400 each to donate eggs.

While Hwang initially denied knowledge of these practices, he eventually revealed that he knew about them, but lied to protect his researcher's privacy. After this initial scandal, a wave of sympathy and support poured in for Hwang, even resulting in an increase in egg donations for his work. It seemed South Korea was rallying around the famous scientist, who had long been a household name and the pride of the nation.

However, in December of 2005, concerns began to surface that would ultimately deal a devastating blow to his country's—and indeed, the world's—confidence in his research. The focus of the concerns was one accomplishment in particular that Hwang reported in the June 2005 issue of Science: that is, the development of patient-specific embryonic stem cells from a process called somatic cell nuclear transfer (SCNT).

SCNT is used in both reproductive and therapeutic cloning. The nucleus from a somatic cell is injected into an enucleated egg and the egg is "tricked" into dividing as if it had been fertilized. In reproductive cloning, this embryo would be implanted into the womb of a surrogate mother; however, in Hwang's process, therapeutic cloning, the cloned embryos are used as a source of embryonic stem cells. The diagram explains both of these processes. Researchers seek to develop therapeutic cloning methods for obtaining stem cells because it would allow them to make "patient-specific" cells that decrease the likelihood of immunorejection.

The paper Hwang published on the creation of these patient-specific stem cells claims that "Eleven human embryonic stem cell lines were established by somatic cell nuclear transfer (SCNT) of stem cells from patients with disease or injury into donated oocytes." However, on December 15, 2005, the Seoul National University Investigation Committee announced that they were beginning an investigation into Hwang's findings after several scientists (including Dr. Ian Wilmut, famous for the cloned sheep Dolly) questioned the credibility of his data. In their announcement, the SNU Investigation Committee revealed that Hwang's 2005 paper contained at most data from two embryonic stem cells lines—not the eleven he had asserted—and even these were of questionable origin.

On January 10, 2006, the SNU Investigation Committee released their anxiously awaited final reports on Hwang's alleged misconduct, and the transgressions proved more serious than originally thought. The Committee found that even the two lines used to produce data for the paper "originated from frozen fertilized eggs and not from cloned blastocysts." The report goes on to say, "The data in [the] 2005 article [...] have all been fabricated."

Hwang attempted to resign from Seoul National University on December 23, 2005, perhaps to avoid being terminated from his position when the investigation was completed, but his resignation was denied. Instead, he and six other co-
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Applying Ethical Principles to Public Health Emergencies
Laura Seig, Davidson College '07

This article is an adaptation of a presentation given on November 13, 2005 at the 13th Annual Bioethics Resource Group Conference in Charlotte, NC. Brad Deme- ter, Lauren Finley, Laura Seig, Cecily Stohes-Pandit and Ella Strachan created and gave the presentation with research assistance from Carolyn Mohr and Kend- all Williams.

The tragedy of Hurricane Katrina exposed the shortcomings of the local and national medical communities to care for New Orleans’ poorest residents. It also demonstrated the difficulties doctors face when making ethical decisions in a public health emergency. Traditional medical ethics focuses on the individual physician-patient relationship, emphasizing patient autonomy, beneficence, non-maleficence, and justice. These principles must be recon- sidered to provide a framework for ethical decision making during a public health emergency.

To define ethical principles for a public health emergency, the concept of “patient” must be reconsidered. In traditional ethics, the patient is the individual presenting at the doctor’s office for personal care. The physician treats the parts of the patient that are not functioning correctly for benefit of the whole. In an emergency, the entire affected community becomes the patient. Each member of the community is treated as part of the patient and decisions are made to benefit the community as a whole. Ethical principles must be redefined in reference to the larger patient body.

“I injected morphine into those patients who were dying and in agony. If the first dose was not enough, I gave a double dose. And at night I prayed to God to have mercy on my soul.”
—An Anonymous Doctor in New Orleans

Public health is easy to justify on the community level, but may be difficult to enforce on an individual level. For exam- ple, while a patient may understand that there is a shortage of flu vaccines, he may have a hard time accepting that he will not receive a vaccine that year. A patient may feel that his reasons for needing a vaccine are justifying enough to warrant his doctor overriding the eligibility requirements set forth by the state. How- ever, the physician is responsible for a much larger population in this case, and he must follow the regulations to ensure that those most endangered from forgetting vaccinations are able to re- ceive them. This is counterintuitive to many physicians who have been trained to act with beneficence and provide all care possible to their patients.

The flu shot shortage demonstrates the need for a shift in the application of beneficence from individual good to utilitarianism. Instead of the physician being re- quired to treat every patient to the fullest extent possible, he must consider treating the entire community. Realizing that the greatest good for the greatest number will be achieved by refusing to vaccinate pa- tients who are not in a group at high risk of serious complications from the flu, he must act against the desires of his individ- ual patient to better care for the commu- nity. In this case, beneficence can be demonstrated in the physician’s advocacy on the patient’s behalf to the local medical board if he believes that the patient should be vaccinated even though he does not meet the eligibility requirements.

Another conflict in public health ethics is between autonomy and public good. Under the auspices of patient autonomy, doctors are required to inform the patient of the risks and benefits of a procedure and the patient chooses whether or not she wants to proceed. In a public health emer- gency, patients are often not given the same degree of choice, if they have a choice at all. Consider the mandatory smallpox vaccinations that took place in the early 20th century in Massachusetts. All residents of Boston and the surround- ing towns were required to receive the vaccination in an attempt to rid the community of smallpox, or to pay a fine. One citizen’s refusal to have the vaccine or pay the fine on the grounds that forced vaccina- tion was unconstitutional made it all the way to the Supreme Court. The Court found the law constitutional, stating “Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of dis- ease which threatens the safety of its mem- bers.” (Jacobson v. Massachusetts, 1905). Autonomy occasionally must be sacrificed for the greater public good.

A sacrifice of the decision-making branch of patient autonomy and informed consent is not grounds to disregard the adequate disclosure leading up to that deci- sion. Even in public health emergencies, when the patient may have little or no de- cision-making power, the physician must still provide adequate disclosure. The typical informed consent discussion be- tween patient and physician is reduced to adequate disclosure that should include the physician’s acknowledgement that he is infringing on the patient’s autonomy, an explanation of the public health concerns that led to this decision, and justification of the decision for that particular patient.

In an emergency situation, these shifts in principles come down to the third- second decisions made as a health care worker triages the victims. Triage at- tempts to create order out of a chaotic situation to ensure that as many people survive as possible, the ultimate utilitarian exercise. Victims are divided into three categories: those who cannot be saved, those who can be saved with immediate attention, and those who can wait for medical treatment without too much furt- her damage. The determination makes
Public health emergencies require reconsideration of the traditional principles of medical ethics to accommodate a change in the definition of a patient. Individual beneficence is replaced by beneficence to the community as a whole in the form of utilitarianism. A patient's ability to make healthcare decisions may be compromised, and the informed consent discussion between patient and physician is reduced to adequate disclosure. Triage ethics change the physician's thought process while making treatment decisions and questions of resource allocation test the principle of justice. Despite these changes, the underlying principles of medical ethics apply to emergency situations as a guide for ethical decision making.

Selected References:

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Jacobson v. Massachusetts, 191 U.S. 11 (1904)

