

The Medical Humanities program at Davidson College, chaired by Lance K. Stell, Ph.D., promotes an interdisciplinary approach to medicine and health care. It enables students to appreciate the legal, political and ethical issues involved in the production, distribution and delivery of health care services. The *Ethical View*, a student-edited newsletter published annually, serves as a forum not only to highlight current ethical issues but also to generate discussion concerning these important topics.

A significant number of Davidson students enroll in at least one course in the medical humanities curriculum. A large number also participate on extracurricular activities in the field. This newsletter is a vehicle to showcase the experiences of these students. Through mentorships, internships and various conferences Davidson students are able to continue their education even after classes have ended.

As the editors of the 2003 issue of the *Ethical View* we hope that the articles contained herein serve to increase the awareness and consideration of the important ethical and legal issues surrounding the delivery of health care. It has been, and continues to be the philosophy of the editors of this publication that participation in creating a learning environment often holds the key to understanding.

About the Editors.

Susanne Francis is a senior pre-medical student at Davidson College, with a double major in biology and Spanish. She will be attending medical school next year at the University of Texas Health Science Center at San Antonio, and will pursue a career as a surgeon in the United States Navy. In addition to being a co-editor of the "Ethical View," Susanne has served as of the Bioethics Society, and currently has an internship with Carolinas Laparoscopic and Advanced Surgery Program at Carolinas Medical Center in Charlotte.

Virginia Nimick, a member of the class of 2004, is a Center major in Ethics in Law and Medicine with a minor in Philosophy. She is a member of the Davidson Bioethics Society and, for the past two years, she has interned with the Ethics Committee at Carolinas Medical Center, assisting members with research regarding ethical decisions affecting both patients and policy. During the summer of 2002 Virginia worked with Rosamond Rhodes, Ph.D. at Mount Sinai Hospital in New York City. After graduation she plans to attend law school.

Volume II1, Issue 1

Letters from the Editors...

By Susanne Francis '03 and Virginia Nimick '04

March 2003

2001

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Inside This Issue:

The Ethical View

A Publication of the Medical Humanities Program of Davidson College

"No physician, in so far as he is a physician, considers his own good in what he prescribes, but the good of the patient; for the true physician is not a mere moneymaker."

"Every physician-patient encounter is a conflict of interest. Every physician-payer encounter is also a conflict of interest."

The license to practice entitles the physician to hold himself out to the public as a competent and trustworthy guardian of patients' health interests. He evaluates their complaints, outlines his findings, identifies care options and the expectable consequences associated with pursuing them. If his best medical judgment is that the patient's condition is self-limiting or will respond to self-doctoring, he has a duty to say so. On the other hand, if his best medical judgment is that the patient requires further professionally supervised diagnostic procedures or treatment, he must say so. Whatever medical recommendation he makes, the physician is in a position marginally to benefit himself, or his employer.

Payer-status, may bring the physician's financial interests into conflict with those of some of his patients, but into convergence with other of his patients. Patients covered by fee-for-service reimbursement give him an incentive to recommend marginally beneficial diagnostic and therapeutic options. Despite that they will sacrifice their time and be exposed to increased iatrogenic risk, patient's tend to pursue the promise of marginal benefit, especially when their physician makes the recommendation. The physician benefits from their doing so. By contrast, patients covered by capitated prepayment contracts create the opposite incentive. Whether reduced exposure to iatrogenic risk under a prepayment scheme off-sets patients' foregoing some marginally beneficial interventions is unclear. Unsponsored patients in his practice give the physician and incentive to cost-shift their unpaid charges to sponsored patients to whatever degree possible.

Obviously the physician's interests may converge with patients' interest but conflict with 3rd party payers interest. Sponsored clinical research (both for-profit and non-profit) complicates physicians' conflicts of interest still more.

The Ethical Importance of Conflicts of Interest

A conflict of interest presents a judgment-biasing risk to a physician's medical decision making. Depending on the physician's susceptibility to its associated incentives at any particular time, a conflict of interest will have some tendency to motivate decisions that subordinate patients' interests to the physician's interests, or to other interests the physician is in position to promote at the patient's expense.

Motivation and Motives

The incentives associated with a conflict of interest may influence a physician's conscious motives by insinuating a new one that tends to crowd out of his consideration faith-keeping motives that are ordinarily present and effective. More indirectly, a conflict of interest may weaken the physician's faith-keeping motivations, or strengthening his trust-betraying motivations, or some combination.

A conflict of interest may color a physician's judgment and exert marginal motivational influence on his medical decision making irrespective that it does not present among the motives consciously present to his deliberation. For example, the success of a pharmaceutical company's efforts to influence physicians' prescribing behavior is not gauged by the extent to which advancing the company's interests becomes one of physicians' conscious motives. On the contrary! Thus is it is not necessarily disingenuous for a physician to disclaim that promotion of a drug company's interest is one of his conscious motives, despite that his prescribing behavior reveals a clear preference shift toward that company's products after attending their sponsored CME sessions.

Here are some further examples:

****Surgical extraction of cataracts is performed on 1.4 million patients per year. It is Medicare's largest expenditure. The procedure is performed at higher rates under fee-for-service reimbursement than under pre-paid reimbursement. No data support that medical indications for cataract extraction vary with reimbursement model.**

**In 1991, Genentech, a for-profit biotechnology industry leader, contributed \$2.5 million to the American Heart Association (a non-profit corporation) for construction of its national headquarters in Dallas, Texas. In the mid-1990s, the AHA launched a health care initiative to reduce morbidity and mortality secondary to “brain attack,” its campaign term for acute ischemic stroke. The AHA touted the promising results of a clinical trial of new bioengineered fibrinolytic agent, tPA, (tissue plasminogen activator). The AHA estimated that tPA might save as many as 400,000 lives per year, could reduce stroked-related morbidity, perhaps even reverse paralysis secondary to stroke. During the 1990s, Genentech’s contributions to the AHA exceeded \$11 million. Genentech’s support was not disinterested. It developed, patented and wanted to market tPA. In 1996, the FDA approved tPA (*Alterplase*) for use in ischemic stroke. The expert panel that issued the favorable recommendation (8-1) contained only one member not known in advance to favor tPA approval. His professional history was uniquely devoid of ties to Genentech. By contrast, 6/8 supporting panel members had financial ties to Genentech. 4/8 supporting experts were members of Genentech’s paid-speakers bureau. 2/8 had received research support from Genentech. The American Heart Association never published the dissenter’s opinion which pointed out that the AHA’s initial enthusiasm for tPA was based on only one trial and that a statistical analysis of that trial’s results showed that chance alone could explain its finding of tPA’s apparent efficacy. Subsequently, no fibrinolytic trial demonstrated that tPA confers a mortality benefit in treatment of acute ischemic stroke. On the other hand, several studies found an association between tPA and increased mortality. More worrisome, one fifth of patients initially diagnosed with stroke by expert-teams were found subsequently not to have suffered stroke. Patients falsely diagnosed “positive” for stroke who receive tPA emergently are exposed to risk unbalanced by benefit. Nevertheless, in August of 2000, the AHA upgraded its recommendation for tPA from “optional” (class II b) to “definitely recommended (class I). Having won FDA approval and treatment-guideline support from the AHA, Genentech perceives no advantage in funding a comparative efficacy study matching tPA against streptokinase (a very cheap, generic fibrinolytic agent). One of its scientists explained, “We don’t know how another trial would turn out. And if we don’t come out ahead, we would have a tremendously self-inflicted wound.”

**Clinical trials sponsored by drugs companies are much more likely to report positive results than trials that have non-profit sponsors. Does this show that physicians who conduct drug company sponsored clinical trials have a conflict of interest which increases the likelihood of their producing positive results for a fee? Perhaps. However, it is estimated that drug development costs that eventually lead to FDA approval average \$500 million. If so, wouldn’t a drug company have a strong incentive to use adverse selection to disfavor submitting for clinical trials a drug antecedently regarded as less likely to win approval? Similarly, if a study sponsor were comparatively indifferent whether a study yielded negative results, wouldn’t it be reasonable to predict that more of its sponsored studies will be negative? Too, non-financial conflicts of interest may distort investigators’ judgment too. An interest in winning desirable academic appointments, in securing tenure and promotion, in publishing articles in prestigious journals, in vindicating one’s pet theories, etc., may present judgment-biasing incentives as powerful as any financial incentive.

**Phase I clinical trials are conducted to establish safety. Consent forms for these trials avoid any mention of direct benefit for research subjects, other than their contributing to socially useful knowledge. Consent forms also emphasize the seriousness of any risk as well as its unpredictability. Nevertheless, only about one third of research subjects understand the nature of the trial and most anticipate direct clinical benefit from participation. Are research subjects misled by physicians who are compensated on a capitated basis for enrolling them in the study? Or is the power of wishful thinking so strong in people who have failed conventional therapy that no disclosure, however candid, can eradicate it?

Managing Physicians’ Conflicts of Interest

The main strategies for managing physicians’ conflicts of interest are “professionalism,” civil and criminal liability and external regulation.

By candidate selection, education, and peer socialization, the professionalism strategy inculcates a sense of ethical integrity resulting in physicians’ adherence to the fiduciary principle – to put patients’ and research subjects’ interests first when these conflict with the physicians’ interests or interests of others the physician is in position to advance. The advantages of the professionalism strategy: integrity motivated self-control is cheap and economizes on social monitoring and enforcement costs. Self-control and peer review are routinely criticized as inadequate to control conflict of interest problems.

It is commonly asserted that 10% of health care spending (\$1.15 billion in 1998) is lost to fraud, waste and abuse. Since this “common wisdom” percentage never changes, aggregate loses from “fraud and abuse” must grow inexorably with increases in health care spending.

Federal anti-kickback and fraud and interpretations given to them by the federal courts makes it unlawful for a provider to pay or receive any “remuneration” in exchange for purchasing, prescribing, or recommending any item or service, or referring any patient for treatment for which payment may be made under Medicare or Medicaid. Additionally, HIPAA criminalizes any “scheme or artifice” to defraud, or obtain money by false pretenses from any health plan (federal or

not). The prohibitions are sweeping in their scope. For examples:

**Federal law is violated if even one purpose (as opposed to a primary or sole purpose) of a payment, whether received or given, is in exchange for or to induce the referral of patients or the ordering, purchasing, or recommending of items or services. It *may* be a defense that the improper purpose was “incidental,” “minor,” or “not material;”

**Although courts recognize that some benefits received or given by providers may be *de minimis*, any payment or other benefit may violate the law when the amount is sufficient to influence the physician’s reason or judgment;

**The fact that a fee charged is reasonable will not serve as a defense if the intent underlying the arrangement that generated it can be shown to be an exchange of payment for referrals;

**There need not be proof of an agreement to make referrals, or to order, purchase, or recommend medical items or services. Intent may be inferred from the circumstances of the case.

**The mere potential for increased charges to, or a payment to be made by a federal health care program may be sufficient to violate the law; no actual payment is necessary so as long as the challenged charge for an item or service might be reimbursed by a federal health care program;

**The fact that an arrangement is “common” in the health care industry is not a defense to a kickback violation.

These prohibitions are so sweeping that virtually every financial relationship in the health care industry potentially violates federal law. Not actually, of course, but the resulting uncertainty where the line is between permissible/criminal has added a substantial increment to physicians' agency costs. The magnitude of threatened penalties, despite the unlikelihood of their imposition on any one of the million health care providers in the United States, create an incentive for each to direct resources toward reducing the hazard of federal prosecution. Indeed, the sweepingly broad definition given to unlawful conduct in federal law implies that the only restraint on the number of enforcement actions is the size of the enforcement budget.

The federal government encourages providers to adopt "voluntary compliance programs" and to self-disclose improper billing. Law firms market protective services to their client-providers. There are at least two competing trade associations that credential compliance officers. Hospitals purchase insurance against the consequences of filing false claims – an irony, since a predicate of insurance is uncontrollability of risk.

It might be argued that these anti-kickback and anti-fraud provisions effectively *reduce* physician's agency costs by making physicians more trustworthy. But if the number of law enforcement actions are an index to trustworthiness, physicians and other providers seem to be less and less trustworthy. For the past 6 years, civil, criminal and administrative fraud enforcement has logged an increasing number of cases.

Despite that this federal remedy for alleged physician untrustworthiness has failed to make physicians more trustworthy, it promises inexorable increases physician's agency costs. Resources that might have been directed to improving quality of care to increasing access to health care and toward enhancements in professional competence are consumed by the compliance industry instead.

Conflicts of Interest in the Conflict of Interest Industry

Comparatively high public confidence in the medical profession makes it comparatively "bullet-proof." Achieving political victories against it is harder as a result. Winning legal victories against its members in medical malpractice cases tends to be harder too.

Making the public more fearful of (or angry at) physicians because of their alleged conflicts of interest makes winning political and legal contests with the medical profession easier. Any economic or political interest that would gain by discouraging utilization of physicians' services has an incentive to make the public more doubtful about physicians' competence and trustworthiness. Painting a discouraging picture of physicians' competence and trustworthiness will have some tendency to encourage patients to pursue and form allegiances with "alternative providers" who are currently spared scrutiny by the conflict of interest detection and treatment industry.

Increasing the public's anger about physicians' conflicts of interest makes the provision of service environment more adversarial. It also stimulates demand in the public policy market for the "safety products" offered by advocates favoring increased regulatory oversight of the health care environment and the medical profession. Selling the public regulatory oversight as a precautionary measure to offset concern about physicians' conflicts of interest creates employment opportunities for a wide array of political interests. It also creates employment opportunities for

consultants who specialize in minimizing the resulting harm to physicians' interests.

Cost-Effective Management of Physicians' Conflicts of Interest

2500 years ago, Plato gave the fiduciary principle prominence in medical ethics because he recognized that conflicts of interest cannot be eliminated from the physician-patient relationship. Zero-tolerance for physicians' conflicts of interest is equivalent to zero-tolerance for physicians. If so, strategies for reducing patients' or research subject risk associated with physicians' conflicts of interest should be assessed in terms of their cost-effectiveness.

There are large information costs associated with monitoring and suppressing conflicts of interest. If physicians must gather and submit it to an external authority, the scheme requires that they forego alternative uses of their time and skill which might better advantage patients. If external authority must gather and evaluate the information, the quality of the information will depend on the knowledge and skill of those who do this work. The social costs to the health care system might be lower than having physicians do it themselves, but it also might be more costly still. It is a truism that physicians are not perfectly competent and fully trustworthy. We incur risk when we trust them more than they deserve. We also incur costs when we trust them less than they deserve. James Madison succinctly characterized the basic ethical problem: *If men were angels, no government would be necessary. If angels were to govern men, neither external nor internal controls on government would be necessary. The great difficulty lies in this; you must first enable the government to control the governed; and in the next place oblige it to control itself.*

Notes

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Lance K. Stell, Ph.D., is the Charles A. Dana Professor and Director of the Medical Humanities Program at Davidson College. He also serves as the Medical Ethicist in the Department of Internal Medicine at Carolinas Medical Center.

Physicians' Conflicts of Interest

By Lance K. Stell, Ph.D., Charles A. Dana Professor of Philosophy and Director of the Medical Humanities Program, Davidson College

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Risk Management and Ethics Consultations: The Lawyer's Dilemma

By Virginia Nimick, Davidson College '04

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Davidson College is one of the few liberal arts institutions that offer such a unique program in Medical Humanities. Although such programs are common in medical schools, Davidson brings the field of bioethics to the undergraduate level. The Medical Humanities Program operates under the guidance of the Medical Humanities Advisory Council, composed of practicing medical professionals. This program promotes an interdisciplinary understanding of medicine and health care, and provides students with opportunities to appreciate the strengths and limits of the sciences as they apply to disease, illness, and suffering. Students are able to recognize the roles that ethical values, politics, economics, and legal issues play in the medical atmosphere. The program develops and promotes intense discussion by encouraging students to think for themselves and by probing the morals and values to which we as a Davidson community adhere.

Coordinated by Doctor Lance K. Stell, the Medical Humanities faculty and staff consist of Davidson College professors committed to a standard of excellence in undergraduate education. This group of authors, biomedical researchers, and public policy proposers is intricately involved with the Davidson community and meet regularly to discuss current issues in bioethics. Their work is supported by the college and by external bodies like the Fullerton Foundation, the Hobbie Charitable Trust, and the Duke Endowment. The faculty organizes both lectures and conferences related to bioethics by noted speakers. They also administer a "Healthcare-Professionals-in-Residence" Program and work closely with the Premedical Program, providing students with

many internship possibilities.

Davidson also works in connection with the Carolinas Medical Center, creating an alliance that provides opportunities for students only possible at large teaching hospitals. Beginning in 1990, these two institutions made it their purpose "to cooperate and share their resources toward the common betterment of health care, education, and training of physicians and improved understanding of the relationship between medicine and society." Davidson's Medical Humanities Program also works cooperatively with the Bioethics Resource Group, Ltd., Charlotte Area Health Education Center, and the Mecklenburg County Medical Society to provide information related to health care and ethics to the public. It is through these united efforts that students are able to work and gain valuable experiences outside of Davidson.

Christin Raimondo is a junior biology major and medical humanities concentrator who plans on attending medical school after Davidson. She is member of the Davidson Lacrosse team, the Davidson Pre-Med society, and the national honor society Alpha Epsilon Delta.

Our Own Track: Davidson's Medical Humanities Program

By Christin Raimondo, Davidson College '01

THE ETHICAL VIEW

Have you ever met someone whose intelligence and strength of character fills a room? Those of you who know Dr. Stell would not hesitate to describe him as one of these people.

Lance Stell loves what he does; anyone who talks to him can see his enthusiasm. He is not only the Director of the Medical Humanities Program and the former Chair of the Philosophy Department at Davidson but is also a nationally recognized philosopher and medical ethicist. He has published hundreds of articles on topics ranging from health care reform to medical futility (which some of his colleagues would argue he is the "Father" of!), and is an authority on controversial issues like gun control and 'right to die.'

Stell also plays an active role at Carolinas Medical Center, where he is Director of the Ethics Consultation Service and Vice-Chair of the Institutional Ethics Committee. On the advisement of CMC, Stell spent his sabbatical (1989-90) studying the intricacies of medicine and health care management via a teaching/research fellowship. He describes this as an "invaluable opportunity" to "interact with physicians and develop a knowledge base."

In the little spare time that Stell has between teaching, writing, consulting, advising, and lecturing, he enjoys activities like hunting, shooting, and tennis (as an undergraduate at Hope College, competing against Davidson on the tennis court was his first introduction to the College). As a motto, Stell employs "safety first, fun second" when he takes his students to the shooting range. He also publishes articles on dueling (yes, dueling!), one last year in the International Encyclopedia of Philosophy and Law.

What is unique about Dr. Stell is his ability to foster a classroom environment that embraces independent thought. "I feel an obligation not just to indoctrinate people with information," says Stell. "The only way isn't the way that I think about it. And there are no 'forgone conclusions' or standards of 'political correctness' in any of my courses. Thinking for yourself — well, I think that's part of the way to being free." Dr. Stell invokes this sense of discovery in his students. One lesson in particular stands out in my mind: "You can't begin to understand how to change something until you have a clear understanding of its history." According to Dr. Stell, the ability to define clearly both the components of health care and their evolutions and purposes is critical to speculating about changes in its future.

My final questions to Dr. Stell were “What has been your most coveted accomplishment to date? What are you most proud of?” I was not surprised by his answer. He paused for a moment and replied, “Teaching classes that students want to take. That is number one on my list.”

I cannot fit all of the praise that has been heaped upon Dr. Stell into this article. The list of students he has influenced is long and will continue to grow for many years to come. Knowing Dr. Stell is knowing someone who will teach you something every time you speak with him. His ability to convey his passion for the study of law and medicine is remarkable. Any and every student who has taken Medical Ethics with him knows that indeed, class size restrictions *can* be broken, and they will continue to be broken because students will sit on the floor for all of drop/add until they can get a desk. Demand is high. For Dr. Stell, demand has always been high. Stell says, “I wouldn’t do anything else or be anywhere else. I belong here at Davidson.” We are glad to hear that, Dr. Stell.

A Portrait of Lance K. Stell

By Jennifer N. Higgins, Davidson College '02

Lance K. Stell, PhD, Charles A. Dana Professor of Philosophy and Director of the Medical Humanities Program
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Resources on Medical Futility

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Chambers Building, Davidson College

Resources from Futility Articles:

1. [Eric Knoche] Stell, Lance K. *The Regional Review*. Charlotte: Bioethics Resource Group, Ltd. Winter, 1993.
2. [William Porter] <http://www.nejm.org/content/2000/0343/0004/0293.asp>
3. [William Porter] In the Matter of Baby “K.” U.S. Ct. of App. 4th Ct. 1994.

Books:

- 1) *When Doctors Say No: The Battleground of Medical Futility* by Susan B. Rubin. Indiana University Press, 1998.
**Recommended for health care professionals and members of ethics committees.*
- 2) *Medical Futility and the Evaluation of Lifesustaining Interventions* by Marjorie B. Zucker and Howard David Zucker. Cambridge University Press, 1997.
**A broad introductory overview for beginners who want to learn more about the issue of medical futility in a formal manner.*
- 3) *The Dark Side: Thoughts on the Futility of Life from the Ancient Greeks to the Present* by Alan R. Platt. Citadel Press, 1994.
**A thinking person's guide for existence and a guide to the intellectual tradition on futility.*
- 4) *Wrong Medicine: Doctors, Patients, and Futile Treatment* by Lawrence J. Schneiderman and

Nancy S. Jecker. Johns Hopkins University Press, 2000.

**Discusses the doctor-patient relationship and the economic, demographic, and historical factors that affect health care; discusses what constitutes futile medical treatment.*

Source: Amazon.Com Books. 4 Oct. 2000 <http://www.amazon.com>.

Journals:

- 1) *"The Rise and Fall of the Futility Movement"* by P.R. Helft, M. Siegler, and J. Lantos. *The New England Journal of Medicine* Vol 343, No. 4, July 27, 2000. 293-6.

Case Law:

- 1) *Gilgunn v. Massachusetts General Hospital*. No. 92-4820. *Mass. Sup. Ct.*, 1995.
- 2) *McCullough v. State*. 657 P.2d 1157. *Supreme Ct. of Nevada*. 1983.
- 3) *Barber v. Superior Court*. 147 Cal. App. 3d 1006. *Ct. of App.* 1983.
- 4) *In re Wangle*. No. PX-91-283. 4th Judicial Dist., Minnesota. 1991.
- 5) *Matter of Dinnerstein*. 380 N.E. 2d 134. *App. Ct. of Mass.* 1978.
- 6) *In re Quinlan*. 355 A. 2d 647. *Sup. Ct. of New Jersey*. 1976.
- 7) *Cruzan v. Director, Missouri Department of Health*. 110 S. Ct. 2851. *Sup. Ct. of U.S.* 1990.

Websites:

- 1) *The Internet Journal of Emergency & Intensive Care Medicine*
<http://www.ispub.com/journals/IJEICM/Vol3N2/ethics.html>
**International medical publishing house over the web. Provides articles, reviews, multimedia presentations and case reports that are peer-reviewed.*
- 2) *The San Francisco Medical Society*
<http://www.sfms.org/sfm/sfm800q.htm>
*** Guest Editorial on Medical Futility: *When the Time Comes to Just Say No More* by Steve Heilig, MPH.**
- 3) *FindLaw*
<http://www.findlaw.com>
**Website that aids lawyers and legal professionals for communicating with their clients in legal news, law cases and codes; aids students with information on law schools and career development; assists businesses with information understandable to non-lawyers and small business owners.*
- 4) *American Medical Association*
<http://www.ama-assn.org>
**Provides information on the history and mission of AMA, E&M Guidelines, legislative*

initiatives, new scientific

discoveries, and medical ethics knowledge. Provides research from JAMA and specialty journals and provides information on litigation affecting medicine, AMA membership, and other products and services.

5) *American College of Physicians-American Society of Internal Medicine*

http://www.acponline.org

**Gives practice tips, educational publications, information about ACP-ASIM, positions and statements on ethical issues, and links to discussion groups.*

6) *The Institute of Medicine*

http://www.iom.edu

**Provides information on consortiums, studies, and fellowships; ongoing studies on current medical issues; recent reports on current ethical debates; a search engine; and upcoming events in IOM.*

If you would like to respond to the issues in this edition of *The Ethical View*, please send responses to:

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If you prefer, send e-mail to:

ethicalview@davidson.edu

If you know someone who would like to receive *The Ethical View*, please contact the Medical Humanities Program by mail or e-mail, using the contact information above.

Focus:

Conflict of Interest

This story can fit 100-150 words.

The subject matter that appears in newsletters is virtually endless. You can include stories that focus on current technologies or innovations in your field.

You may also want to note business or economic trends, or make predictions for your customers or clients.

If the newsletter is distributed internally, you might comment upon new procedures or improvements to the business. Sales figures or earnings will show how your business is growing.

Some newsletters include a column that is updated every issue, for instance, an advice column, a book review, a letter from the president, or an editorial. You can also profile new employees or top customers or vendors.

This story can fit 150-200 words.

One benefit of using your newsletter as a promotional tool is that you can reuse content from other marketing materials, such as press releases, market studies, and reports.

While your main goal of distributing a newsletter might be to sell your product or service, the key to a successful newsletter is making it useful to your readers.

A great way to add useful content to your newsletter is to develop and write your own articles, or include a calendar of upcoming events or a special offer that promotes a new product.

You can also research articles or find “filler” articles by accessing the World Wide Web. You can write about a variety of topics but try to keep your articles short.

Much of the content you put in your newsletter can also be used for your Web site. Microsoft Publisher offers a simple way to convert your newsletter to a Web publication. So, when you’re finished writing your newsletter, convert it to a Web site and post it.

This story can fit 75-125 words.

Selecting pictures or graphics is an important part of adding content to your newsletter.

Think about your article and ask yourself if the picture supports or enhances the message you’re trying to convey. Avoid selecting images that appear to be out of context.

Microsoft Publisher includes thousands of clip art images from which you can choose and import into your newsletter. There are also several tools you can use to draw shapes and symbols.

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This story can fit 150-200 words.

One benefit of using your newsletter as a promotional tool is that you can reuse content from other marketing materials, such as press releases, market studies, and reports.

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This story can fit 75-125 words.

Selecting pictures or graphics is an important part of adding content to your newsletter.

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THE ETHICAL VIEW

Fetal surgery: A hotbed for maternal-fetal conflict issues

Verna M. Case, Professor of Biology, Davidson College

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For the past several years Davidson students have been privileged with the opportunity to attend the monthly meetings of the Ethics Committee at Carolinas Medical Center. Under the supervision of Dr. Lance Stell and other committee members the students gain experience and also contribute through various research projects. These meetings provide a wealth of experience that cannot be acquired from a textbook.

I have attended these meetings for the past two years. Each month the committee, comprising MDs, PhDs, nurses, social workers and lawyers, discuss the new ethics consultations. Obviously there are innumerable conflicts of interest that arise during patient care and the majority of these have been identified and discussed in numerous forums. One dilemma, however, that has not received as much attention is that of the lawyer.

Typically, when we associate lawyers with hospitals we think of them as risk managers. It is inevitable that mistakes will be made in the delivery of health care and the hospital hires lawyers to act in both a preventative capacity and to minimize liability should a lawsuit arise. In hospitals all across the country many of these lawyers also serve a third role as members of the hospital's ethics committee. In many cases, the recommendations that these lawyers make, both as risk managers and as members of the committee may be similar but there are, no doubt, certain instances in which they are conflicted.

For example: an elderly man in the ICU has been designated "DNR." The decision was a difficult one and, although the order has been entered into the chart, several family members are still uneasy. They want to be bedside when the man expires. The physicians, however, are uncomfortable with this and do not want the room to be too crowded. Physicians are often weary of the fact that the more people see, the more questions they will ask. Most of us would not understand why the vast majority of things are being done to a patient. This ignorance often sparks apprehension and causes friends and family members who might be present to begin to second-guess the doctor's decisions.

As a member of the ethics committee a lawyer might suggest that the family be allowed to stay in the room. Watching a loved one die, especially after such a difficult decision as to whether to

designate him as DNR, is hard enough and the hospital staff ought to do whatever they can to make the situation more comfortable. On the other hand, in his capacity as a risk manager, the lawyer might think it best to have as few people bedside as possible.

The legal profession plays an important role in any hospital setting. It is clear that lawyers are needed but it is equally clear that they are faced with a major conflict of interest. So how can the problem be solved? As part of an ethics committee should lawyers completely disregard their role as risk managers? It seems that is asking too much. It is nearly impossible to be totally unbiased. In order to give truly effective and objective advice in either situation, lawyers must choose; risk management or ethics consultations. Without this clear distinction advice given in one arena may only have been offered because of considerations in the other. A lawyer serving on the ethics committee might suggest a solution motivated not by ethical considerations but instead by desires to minimize the hospital's liability should something go wrong.

Should lawyers continue to serve as both ethical advisors and risk managers it is important that everyone involved recognize the conflict. It must be openly acknowledged and should be both offered and received with that in mind.

It is a powerful and compelling image – the fetus seeming to reach out of the uterus to grasp the finger of the heroic surgeon. The story accompanying the image reads, “The baby is literally hanging on for life. For this is one of the most remarkable photographs taken in medicine and a record of one of the world's most extraordinary operations.”

Dr. Michael Harrison performed the first human fetal surgery in 1981 at the University of California San Francisco. Since then, this new surgical technique has spread to other major medical centers throughout the United States. Recent headlines applauding fetal surgeries for spina bifida have solidified a place for this new specialty on the cutting edge of the medical frontier. While these medical “miracles” are impressive and even unbelievable, there is a side to this new area of medicine that is disturbing. Web images of these surgeries, like the one cited above, symbolize the subtle and gradually shifting focus during pregnancy...from mother to fetus. In these photographs, the exposed and accessible fetus is portrayed as the patient in need of rescuing, while the mother, represented only by her uterus, is reduced to a vessel for developing and delivering the fetus.

The problem with these changes in our perception of pregnancy is that the fetus is far from a typical patient. It is not capable of making autonomous decisions and it has no independent legal rights. Further, treatment of the fetus can only be accomplished through a person who is autonomous and who does have rights...the mother. So, by opening the womb and “separating” fetus from mother, fetal surgery sets the stage for the next chapter in the maternal-fetal conflict saga.

But why should there be conflict between mother and fetus? One source reports that over 200 surgeries have been performed on fetuses with spina bifida since 1997. Doesn't that number indicate that mothers will accept risks to help their fetuses? Yes and no. Most mothers will take any steps they feel necessary to deliver a healthy baby. However, some very competent mothers may refuse fetal surgery based on religious beliefs or because they disagree with their physician's recommendation for other reasons. What happens then?

Because fetal surgery is classified as experimental, it is unlikely that a mother's refusal of a “recommended” fetal surgery would be challenged at this time. However as our technology advances, the experimental procedures of today become the standard procedures of tomorrow. If surgical innovations are developed that reduce the risks of the procedure, e.g., the new robotic technology for fetal surgery, then fetal surgery may become as “routine” as Caesarean sections or hysterectomies. When fetal surgery becomes standard care, will mothers be morally and legally obliged to undergo treatments for the sake of their fetuses?

Serving as an advocate for the pregnant woman, the American College of Obstetrics and Gynecology's

Committee on Ethics recognizes that a mother has the right to choose or refuse treatment, while the physician has an obligation to promote both maternal and fetal health. The ACOG committee feels that court orders to resolve maternal-fetal conflict are almost never warranted. A slightly different view held by the American Academy of Pediatrics states, "If fetal intervention is one of proven efficacy and has a concomitant low maternal risk, the physician should recommend the procedure and emphasize, if necessary, the responsibility of the mother to accept some personal risk for the potential benefit to her fetus." Both the AAP and the American Medical Association feel that it is morally acceptable for physicians to request court-ordered intervention on behalf of a fetus, when treatment risks for the mother are low.

But aren't court interventions a drastic step? Does the fetus have a right to treatment that would override a mother's right to refuse treatment? Technically, the courts have never given rights to the fetus itself, even in the *Roe v. Wade* decision. However, the courts have recognized claims against third parties who harm a pregnant woman's fetus and have extended criminal liability to include injuries inflicted on an unborn fetus by third parties or by the mother. Actions resulting in the death of a viable fetus may be considered homicide and the use of drugs or alcohol during pregnancy may constitute child abuse or neglect. Since 1985, thirty-four states have obtained criminal prosecutions of pregnant women; however, many of these prosecutions were reversed upon appeal. In 1992, Cornelia Whitner was charged with criminal child neglect in violation of the South Carolina Children's Code, based on the fact that her baby was born with cocaine metabolites in its system. She pled guilty to endangering the life and health of her child and was sentenced to 8 years in prison. The Supreme Court of South Carolina upheld her conviction stating that a viable fetus is a "child" or a "person," and is thereby entitled to legal protection. The U.S. Supreme Court denied review of the case in 1998. In 2001, the same South Carolina law allowed the courts to convict Regina McKnight of homicide and to sentence her to 12 years in prison for killing her unborn child by using crack cocaine during her pregnancy. How will the courts view a mother's refusal to have fetal surgery, if her physician argues that the surgery is necessary for fetal well being? Will this refusal be considered child neglect? If a child's death at birth could have been prevented by fetal surgery, could a mother be convicted of homicide?

What about the mother's rights? Courts have upheld a competent individual's constitutional right to privacy, including the right to refuse treatment and right to informed consent. However, in *Roe v. Wade* and other decisions, the U. S. Supreme Court recognized that the constitutional right to privacy is not absolute and that states have the right to intervene in order to preserve life and protect third parties. Precedent cases where pregnant women have refused Caesarean sections may indicate how the courts might respond to a mother's refusal for fetal surgery. Many of the compelled C-section cases involved hastily obtained court orders. *In re Madyun*, a court ordered C-section was performed and both mother and baby recovered without complications. In other cases, court orders for C-sections were never carried out. One woman avoided the court ordered C-section by not checking into the hospital, another woman went into hiding, and a third got a second physician's opinion causing the court to revoke its original order. In the most famous case involving a forced C-section, *In re A.C.*, the Court of Appeals for the District of Columbia argued that the fetus could not have rights superior to the mother. Tragically, this decision was handed

down after the C-section was performed and after the death of Angela Carder and her baby. The impact of this Court of Appeals decision and the publicity surrounding the case have played a major role in reaffirming a woman's right to refuse invasive medical treatment.

It is only a matter of time until cases of compelled fetal surgery come before the courts. As we continue to view the fetus as the primary patient, a healthy, defect-free life will grow and will gain support from physicians and the general public. We must proceed cautiously in our judgments – clinically, legally and ethically – and not give the fetus rights at the expense of maternal autonomy. As Pamela Harris states, "The pregnant woman's right to be free from coercion in making reproductive decisions is once again at stake with this rapidly advancing technology." We need to keep the mother in focus in our fetal surgery "picture", for it is she who has the right to choose or refuse!!

Notes

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Verna Case, PhD., is the Chair of the Biology Department at Davidson College and teaches an annual seminar on issues in reproductive medicine.

This year, the Davidson College Bioethics Society is proud to host The Frederick Womble Speas Symposium, marking this the second year that the Bioethics Society has hosted such a forum. Now included as part of the Speas Symposium instead of just a pre-conference workshop, the bioethics forum drew students and physicians from a wider region of the country.

With the hopes of increasing participation, many of the structural changes made by the Bioethics Society improved upon last year's forum. For example, invitations to undergraduates were extended to a greater number of students at a greater number of institutions. Instead of including only neighboring schools in the Carolinas, invitations were extended to schools all over the Southeastern United States. This produced a more diverse group of students with a wider range of ideas and background in medical ethics.

In addition to inviting a greater array of students, physicians also attended this year's conference. While leading panels and delivering lectures, these physicians also participated in breakout sessions with the undergraduate students. This interaction was of particular interest due to the different backgrounds and career stages among the participants.

Coupled with the structural improvements in the forum, this year's topic, Conflicts of Interest, also generated endless debate. The two keynote speakers, Professor Hall and Professor Kopelman, started the debate by discussing the conflicts of interest in health care and research, respectively. Both keynote speakers were followed by breakout sessions on topics ranging from insurance and gate keeping to the religious differences between doctors and patients. These breakout sessions proved to be immensely thought provoking due to the unique composition of the forum's participants.

The intimate interaction between physicians and undergraduates separated The Frederick Womble Speas Symposium from other bioethics forums around the country.

Megan Shafer is a senior at Davidson College majoring in Bioethics. She is President of the Bioethics Society and hopes to attend law school to pursue a career in health care law.

Frederick Womble Speas Symposium 2003

By Megan Shafer, Davidson College '03

This is based on an article recently published in *Law and Contemporary Problems* (Duke University Press), which retains the copyright (c).

Law professors, as a whole, are rather worldly and cynical about financial, political, and other suspect forms of motivation. I was therefore surprised to find that, as managed care was taking hold in the early 1990s, several of my colleagues at Wake Forest University were genuinely startled to learn that Health Maintenance Organizations ("HMOs") commonly reward physicians for saving costs, which often entails withholding care. My colleagues first learned of this when Wake Forest required all of its employees to switch from Blue Cross insurance to its own newly established HMO, created to keep the University's physicians and affiliated hospital from losing business. As the resident expert on managed care, I was peppered for several months with anxious questions and angry comments about this change. The reaction that most surprised me was the dismay over learning that our HMO, like most others, uses a risk pool to reward its physicians for staying within budget.

In a recent commentary, health economist James Robinson observed that "the fundamental flaw of managed care, in retrospect, was that it sought to navigate the tensions between limited resources and unlimited expectations without explaining exactly how it was so doing." As my experience reflects, this is certainly true for HMOs' use of physician incentives, one of managed care's major tools. HMOs routinely pay physicians in a manner that rewards them for saving costs, in sharp contrast with the inflationary incentives of traditional fee-for-service reimbursement. Other features of managed care are visible to all members, such as a limiting patients to a network of providers or requiring they obtain approval before expensive treatment. Physician incentives, however, are entirely behind the scenes. Most HMOs, until recently, have made no effort to call financial incentives to people's attention.

This situation has changed rapidly in the past few years, in response to several legal pressures. Now, there is widespread consensus that physician incentives under managed care should be disclosed. However, there is little agreement on what exactly should be disclosed, when, and by whom. One reason for this uncertainty is the multiple purposes that disclosure serves. Under one view, disclosure is meant to warn patients that their physicians have a conflict of interest that may affect their clinical judgment. Under another view, disclosure is intended to make patients better informed consumers of health insurance, so that they choose the type of insurance that best fits their preferences. Under a third view, disclosure is meant only to provide a general understanding of what managed care insurance is about, so that people are more willing to accept limitations designed to promote efficiency.

Fortunately, it is not necessary to arrive at a single theory and purpose of disclosure. There need not be only one

solution to this problem because disclosure can be done through a multistaged approach, one in which information is revealed at different times and in different contexts. This layering approach allows people to learn what they want in response to their varying levels of interest, concern, and ability to absorb the information. What follows is merely one suggestion about how this might be accomplished:

- (1) Prior to insurance enrollment, potential subscribers can be told simply whether health plans use physician incentives in any fashion to contain costs, as one aspect of distinguishing managed care generally from traditional fee-for-service indemnity coverage, and potential subscribers can receive additional, more detailed information if they request it.
- (2) Following enrollment, managed care members can be given fairly detailed descriptions of the various physician incentive arrangements used in the network, as part of the plan's legal documents and explanation of how it operates. This detailed level of disclosure exists primarily as a contractual formality, to meet basic legal requirements and to provide an opportunity to learn the facts about incentives for those who desire this information.
- (3) When a patient chooses a specific physician, either the health plan or the physician's clinic can inform the patient in writing of the incentive arrangements directed to the particular group and within the group.
- (4) At any point, a person who wants additional information should be told whom to contact, including their personal physician, and that contact person should be prepared to discuss candidly the general structure, purpose, and potential effects of various physician incentives. With respect to medical treatment decisions, this means that it is up to each individual how to assess the impact incentives might have on a physician's recommendations and whether to raise these issues or to request more information about incentives or treatment options before consenting to particular procedures. If raised even indirectly, physicians should be sensitive and receptive to these inquiries rather than defensive or obtuse.
- (5) At each of these stages, all that is required is a description of the basic structure of the incentive and perhaps the direction in which it potentially biases decisions, not a full articulation of all the dimensions and possible effects of payment incentives. This leaves to individuals the decision of whether they wish to seek more information and whether and to what extent to take this information into account when making decisions and evaluating courses of action.

This approach attempts to provide as much information as most people are likely to want, at the point at which they need it, and it has sufficient flexibility to allow people to learn more as their understanding and information needs change. It also attempts to meet the major objectives of disclosure while avoiding the major objections. Nevertheless, this is merely a preliminary sketch and therefore leaves many issues of implementation unaddressed. It remains to be seen how well this and other approaches actually succeed in these ambitions, and what impact these disclosures will have on patients' understanding of incentives and trust in their physicians.

The Theory and Practice of Disclosing Physician Incentives under Managed Care

By Mark A. Hall, JD, Fred D. and Elizabeth L. Turnage Professor of Law and Public Health, Wake Forest University

This article reviews some of the practical ethical challenges associated with clinical research in medicine. The article takes the position that the professional researcher typically finds her- or himself in a professional milieu

with considerable checks and balances to prompt and be accountable for ethical issues and challenges in their work. It is more likely that physicians who conduct research in more applied settings- for our purposes the “moonlighting researcher,” [i.e. those practicing clinicians for whom research is not their primary professional identity] will have to be a bit more thoughtful about some of the implicit ethical considerations in conducting their work.

Professional full-time biomedical researchers are usually employed by research universities or institutes, with an expectation that researchers compete for funds from extramural sources such as private foundations or government agencies. Because funding occurs in such a rarified atmosphere of competitiveness and competence, there is a rigorous infrastructure for regulating the ethical activity of full-time professional researchers. Full-time researchers submit research protocols to Institutional Review Boards [IRB] to protect the interests of patients, sign non-conflict-of-interest documents, clearly specify their protocols and techniques to other research scientists reviewing their techniques, justify their [non-profit] budgets, promise to maintain the integrity of their data, and otherwise march through accountabilities demonstrating that they are smart, skilled, well-informed, and honorable people. These loftily perched researchers are expected to submit proposals that address virtually all threats to the integrity of their ethics or data. The preparation of a competitive extramurally funded grant is often a full-time job in itself. In these major leagues of competitive research, the small minority of researchers who are found guilty of ethical violations have usually transgressed out of some perceived pressure to advance a particular theory or to be competitive for further funding, seemingly knowingly violating a protocol or standard to do so.

A more typical profile of a clinical researcher would be a practicing clinician who is intellectually aggressive, who has had the training to conduct research, and is willing to take on research projects as after hours activities. Most clinicians who are inclined toward research with their interventions, protocols, or patients -*scientist-practitioners*- will doubtlessly find themselves with modest economic resources for conducting their studies. For the practicing clinician in today’s cost-conscious health care venues, conducting research will require a series of cost-benefit decisions. At their first contemplation of conducting research, clinicians conducting research in “the real world” probably do so as a “moonlighting” activity. Most clinics and hospitals are not, of course, designed to support research as their primary mission. To the contrary, the economic pressures on physicians are toward providing less costly health care. Health care systems keep careful accountings of physicians’ time, so it is likely that a physician wanting to conduct research will do so after practice hours, during lunch breaks, or during some time that she or he “makes up” elsewhere. A first ethical issue a practicing clinician faces, then, is some sort of professional and economic prioritizing as to whether or not she or he has the time and energy to conduct research- as well as the ethical concern of whether or not the benefit to patients is offset by the value of the research question, and whether the implicit costs of patients not diagnosed nor treated are worth the time invested in research. Practicing clinicians must at the same time consider whether or not the research will ultimately benefit patients. There should be some demonstrable link between the research question and patients’ well being.

Practicing clinicians face choice points about the economic bases of their work, and they should consider the differences between *Clinical Trials* versus *Outcome Studies*.

Practicing clinicians have more protocol responsibility and control in Outcome studies. Outcome studies are typically projects where the clinician originates the question, creates the study design, and seeks out economic resources to support the project from funds created within their medical center, clinic, or hospital. Most clinicians do not have the time and resources to pursue developing a major competitive extramural proposal, so they typically apply for funds within some pool of money created by medical billings or extramural funds developed within their home clinical setting. A medical center or hospital usually has two standing committees to review these research projects. The IRB reviews protocols for risks to patients, liabilities to the institution, and informed consent. Here, as in larger research projects, the physician must protect her or his patients. It is likely that the hospital’s or medical center’s IRB will review the protocol to ensure that the consent form protects patients’ interests. The typical challenge to physician-patient relationships in a relatively modest clinical outcome study is that patients often feel that their care might be somehow jeopardized if they don’t participate and support their physician’s work. Clinical researchers should take pains to ensure that patients experience freedom from coercion or a desire to please their physician by their participation.

A Scientific Review Committee typically evaluates the merits of the research question itself, another form of ethics. The Scientific Review Committee will evaluate if the research design is adequate to pose and test a clinical question, and provide a relatively unambiguous answer. Will the risks to patients’ care or their confidentiality be justified by the merits and integrity of the research question?

Ordinarily, Clinical Outcome studies require cost-benefit analyses of several sorts. The scope of these projects is usually such that the researcher must try to form the research question within existing hospital assessment or intervention protocols, routine record keeping processes, or archival record searches. Data collection must take place without compromising the medical center or hospital's principal mission of patient care. Physicians are usually Principal Investigators on Clinical Outcome studies, which means they must include in their budgets time to compensate the Hospital or Medical Center for any time they spend on research activity that compromises their more primary medical care role. Correspondingly, physicians must also think through how to compensate the practice or medical center for time they claim from other personnel (e.g. nurses as study coordinators, database managers conducting archival record searches).

There is a robust social psychology describing risks for experimenter effects that contaminate research (Rosenthal, 1966). To summarize some of the main concerns of decades of research, it appears that researchers should be blind to the experimental or quasi-experimental conditions of their patients, and should not take too active a hand in scoring or coding the data. Decades of research show that researchers can unknowingly influence the outcomes of studies in the direction of their hypotheses when they are too close to collecting or interpreting their data. For the moonlighting outcome researcher then, there is the practical problem of how to gather and/or score data from patients too directly, given the limited resources to conduct the study.

Depending on the design of Outcome studies and Clinical Trials, researchers can be faced with practical difficulties about control groups or conditions. Given that researchers generally have a sense of which treatment condition is going to be most efficacious, a decision rule about how to assign research participants to conditions can be challenging. Random assignment eliminates some of this concern, but poses additional ethical questions of whether or not to offer participants the more clinically efficacious treatment condition once the study data have been collected. Clinical researchers must also have some assurances that patients' conditions won't significantly deteriorate if the most efficacious treatment is withheld, or even delayed.

By definition, Clinical Trials occur when a pharmaceutical or equipment manufacturer recruits a clinician to implement the drug or equipment with his or her patients. Ordinarily, the representative from the pharmaceutical or equipment company approaches the moonlighting clinical researcher with a "turnkey" package: the protocols for recruiting and assigning subjects, offering interventions, collecting data, and even analyzing data are typically provided. These studies can offer the potential to provide treatments for patients who have been unresponsive to more proven regimens, or for those who can't afford them. The studies might also provide sources of income for study coordinators within practices, physicians themselves, or a hospital setting.

Clinical Trials studies can offer the most pitfalls for the ethical conduct of research, however. First, rare is the case when there is a dispassionate question being posed in the protocol: generally these studies are designed to prove the efficacy of some type of drug or equipment from the study sponsor. Not infrequently, contracts for Clinical Trials require that the data collected in the studies are the property of the manufacturer [i.e. not under the control of the moonlighting researcher], and/or the manufacturer reserves the right for editorial oversight of any research reports. Moonlighting clinical researchers should be wary about contract arrangements that might minimize the reporting of adverse events such as side effects, or suppress findings of ineffective treatments.

Any clinical researcher, any time, should have his or her research protocols reviewed by an IRB. Study sponsors will often suggest that a "Centralized IRB authorize the protocol for the study" since an independently practicing clinical researcher may not be associated with an organization that supports its own. Sometimes these Centralized IRBs are supported by consortiums of the very manufacturers being represented in the studies, creating high potential for conflict of interests.

Physicians agreeing to conduct Clinical Trials may have to be even more vigilant to ensure that the selection criteria proposed by the study's sponsor are appropriate to the needs of their patients. Potentially the sponsor's desire for information may exceed patients' needs, and the risks to their health or confidentiality may not be warranted by a protocol aggressively recruiting patients as participants.

In sum, then, the more modest circumstances experienced by the moonlighting clinical researcher challenge him or her to do a more thoughtful review of their own research proposals. Managing hidden costs economics, minimizing risks to patients, managing the accuracy and completeness of information, running cost-effective protocols without contaminating the results by being too close to the data, and making sure that there are fair third party reviews for patient protection and scientific quality are but some of the most apparent challenges to conflict of interest- there are doubtlessly others.

This is not to suggest that clinical researchers should be discouraged from conducting research, but rather that they may need to recruit additional people and support resources beyond the more tangible technical tools required to run the study. Hopefully these considerations will lead researchers to creative solutions, ethical qualities matching their data.

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Cole Barton, Ph.D., is a Professor of Psychology at Davidson College. He is a licensed clinical psychologist, and is the Director of the Clinical Research Institute at NorthEast Medical Center. He conducts research on psychosocial dimensions of medical problems.

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THE ETHICAL VIEW

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Conflicts of Interest in Clinical Research: Potential Issues for the Moonlighting Clinician-Researcher

By Cole Barton, Ph.D., Psychology Department, Davidson College

Free medical clinics face a unique set of challenges in providing for the care and treatment of patients. One of these challenges is balancing the cost of medical treatment with the quality of care. Clinics often

provide prescription medication for patients. Deciding which medications to give can be a difficult task. Doctors would like to be able to prescribe to the indigent the same range of medications they provide to paying patients on a daily basis. But unfortunately, most clinics must rely on donations of medications. Stocking enough medications to support a small free clinic is nearly impossible.

Most clinics have a small volume of patients, seeing somewhere between 10 and 50 patients a week. Some medication needs, such as those for high blood pressure and diabetes, and antibiotics can be predicted. Other medications are rare, but crucial, such as those for migraines and epilepsy. Stocking all the medications that might be needed at any one time would be economically impossible. Instead, clinics must optimize their resources by having available the medications that will be used with a greater frequency.

Many of the physicians at local free clinics would like to have the freedom to prescribe brand name drugs for indigent patients, especially in instances where treatment with generic medications has proved less effective. The cost of these medications is exorbitant for both the clinics and the patients. In order to provide these medications clinics are forced to rely on one of two sources: samples or indigent medication programs.

Clinics often receive drug samples from local doctors' offices and drug company representatives. The supply of these medications is sporadic at best. This unpredictable supply can inhibit the progress of treatment for patients who rely on these samples for chronic conditions. Even if a medication is available it may not be in the right strength for a patient. Some clinics also stock expired medications because it is all they have. While a certain grace period exists after the expiration date in which a medication can still be effective, there are both legal and medical risks associated with this practice. Any discontinuity in treatment can threaten the quality of care provided.

Indigent medication programs clearly involve a prohibitive amount of paperwork in order to protect the interests of both the patient and the provider. However, the majority of patients seeking treatment at a free medical clinic come in search of immediate relief of their symptoms. They are less interested in a wellness-care program, and thus have the tendency to delay treatment until their conditions are exacerbated to a critical level. Patients with chronic conditions are often deterred by the lengthy paperwork. Nevertheless, indigent medication programs can be very effective for patients who meet the requirements set out by the drug companies that sponsor them. Some programs will give as much as a three-month supply at one time and have a system for easy renewal. However, many of these programs require that a patient provide proof of their income. Numerous patients at free clinics do not hold jobs. Without an income, they are not eligible for many indigent medication programs.

Another population at risk is the Hispanic community. Many immigrants come to the United States illegally as migrant workers. Illegal immigrants in need of medications cannot provide proof of income without disclosing their citizenship status. As a result, many Hispanics in need are excluded from indigent drug programs. In addition, providing medications through these programs requires continued contact with the clinic. Following up with Hispanic patients is difficult because many do not speak English. Moving is a frequent occurrence and patients rarely remember to change the phone number listed in their medical records.

Immigrants from rural areas of their countries may also adhere to a belief in holistic or traditional medicine. A fundamental distrust for modern medicine exists in patients who seek cures from these spiritualist healers. Only when treatment from the healer fails does a patient come to a modern doctor. At this point, the condition is usually grave and there is little that can be done. Unfortunately, this only reinforces the distrust. As a result, immigrants from rural areas have been taught to go to a modern clinic only when it is absolutely necessary. Furthermore, they are not interested in following up with their care at the clinic.

Free medical clinics are attempting to bridge geographical, cultural, and economic gaps all across the country that prevent patients from receiving adequate medical treatment. Because these clinics are generally funded by donations, their resources often are minimal. Within the economic limitations of the clinic, doctors do everything possible to give optimal care to the indigent population. At the same time, they assume a certain liability, as their care can only be as good as their resources.

Ashley Crimmins is graduating from Davidson College in May with a major in Chemistry and a concentration in Medical Humanities. A frequent volunteer at several of the free medical clinics around Davidson, she is hoping to attend medical school after working for a year.

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Balancing Cost and Care: Challenges Facing Free Medical Clinics

By Ashley Crimmins, Davidson College '03

Ordinarily, Clinical Outcome studies require cost-benefit analyses of several sorts. The scope of these projects is usually such that the researcher must try to form the research question within existing hospital assessment or intervention protocols, routine record keeping processes, or archival record searches. Data collection must take place without compromising the medical center or hospital's principal mission of patient care. Physicians are

usually Principal Investigators on Clinical Outcome studies, which means they must include in their budgets time to compensate the Hospital or Medical Center for any time they spend on research activity that compromises their more primary medical care role. Correspondingly, physicians must also think through how to compensate the practice or medical center for time they claim from other personnel (e.g. nurses as study coordinators, database managers conducting archival record searches).

There is a robust social psychology describing risks for experimenter effects that contaminate research (Rosenthal, 1966). To summarize some of the main concerns of decades of research, it appears that researchers should be blind to the experimental or quasi-experimental conditions of their patients, and should not take too active a hand in scoring or coding the data. Decades of research show that researchers can unknowingly influence the outcomes of studies in the direction of their hypotheses when they are too close to collecting or interpreting their data. For the moonlighting outcome researcher then, there is the practical problem of how to gather and/or score data from patients too directly, given the limited resources to conduct the study.

Depending on the design of Outcome studies and Clinical Trials, researchers can be faced with practical difficulties about control groups or conditions. Given that researchers generally have a sense of which treatment condition is going to be most efficacious, a decision rule about how to assign research participants to conditions can be challenging. Random assignment eliminates some of this concern, but poses additional ethical questions of whether or not to offer participants the more clinically efficacious treatment condition once the study data have been collected. Clinical researchers must also have some assurances that patients' conditions won't significantly deteriorate if the most efficacious treatment is withheld, or even delayed.

By definition, Clinical Trials occur when a pharmaceutical or equipment manufacturer recruits a clinician to implement the drug or equipment with his or her patients. Ordinarily, the representative from the pharmaceutical or equipment company approaches the moonlighting clinical researcher with a "turnkey" package: the protocols for recruiting and assigning subjects, offering interventions, collecting data, and even analyzing data are typically provided. These studies can offer the potential to provide treatments for patients who have been unresponsive to more proven regimens, or for those who can't afford them. The studies might also provide sources of income for study coordinators within practices, physicians themselves, or a hospital setting.

Clinical Trials studies can offer the most pitfalls for the ethical conduct of research, however. First, rare is the case when there is a dispassionate question being posed in the protocol: generally these studies are designed to prove the efficacy of some type of drug or equipment from the study sponsor. Not infrequently, contracts for Clinical Trials require that the data collected in the studies are the property of the manufacturer [i.e. not under the control of the moonlighting researcher], and/or the manufacturer reserves the right for editorial oversight of any research reports. Moonlighting clinical researchers should be wary about contract arrangements that might minimize the reporting of adverse events such as side effects, or suppress findings of ineffective treatments.

Any clinical researcher, any time, should have his or her research protocols reviewed by an IRB. Study sponsors will often suggest that a "Centralized IRB authorize the protocol for the study" since an independently practicing clinical researcher may not be associated with an organization that supports its own. Sometimes these Centralized IRBs are supported by consortiums of the very manufacturers being represented in the studies, creating high potential for conflict of interests.

Physicians agreeing to conduct Clinical Trials may have to be even more vigilant to ensure that the selection criteria proposed by the study's sponsor are appropriate to the needs of their patients. Potentially the sponsor's desire for information may exceed patients' needs, and the risks to their health or confidentiality may not be warranted by a protocol aggressively recruiting patients as participants.

In sum, then, the more modest circumstances experienced by the moonlighting clinical researcher challenge him or her to do a more thoughtful review of their own research proposals. Managing hidden costs economics, minimizing risks to patients, managing the accuracy and completeness of information, running cost-effective protocols without contaminating the results by being too close to the data, and making sure that there are fair third party reviews for patient protection and scientific quality are but some of the most apparent challenges to conflict of interest- there are doubtlessly others.

This is not to suggest that clinical researchers should be discouraged from conducting research, but rather that they may need to recruit additional people and support resources beyond the more tangible technical tools required to run the study. Hopefully these considerations will lead researchers to creative solutions, ethical

qualities matching their data.

Rosenthal, R. (1976). *Experimenter effects in behavioral research*. New York: Irvington.

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THE ETHICAL VIEW

Lance K. Stell, PhD, Charles A. Dana Professor of Philosophy and Director of the Medical Humanities Program

“But aren't court interventions a drastic step? Does the fetus have a right to treatment that would override a mother's right to refuse treatment?”

“It is only a matter of time until cases of compelled fetal surgery come before the courts.”

“Will the risks to patients' care or their confidentiality be justified by the merits and integrity of the research questions?”

“Physicians are often weary of the fact that the more people see, the more questions they will ask.”

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A Gallery of Pictures from the Frederick Womble Speas Symposium, 2003

Frederick Womble Speas

(Davidson, '43), was a student at Bowman Gray Medical School in 1947 when his promising career in medicine was cut short by leukemia. His foreshortened life embodied the ideals of compassion and caring to an extraordinary degree.

The Frederick Womble Speas Memorial Lecture and Seminar was established by

R. Dixon Speas in memory of his brother. The event in medical ethics focuses on the analysis and discussion of issues relevant to the provision of healthcare in our complex society.

Megan Shafer, Mark Pustay, Ashley Price and Erin Cobain assisted participants with registration.

Above, keynote speakers, Mark Hall, J.D. and Loretta Kopelman, Ph.D.

Lance Stell with members of the Speas family (Dirk, Tom and Ruth).

John Little, M.D., and Lewis Sigmon, M.D., in a breakout session.