Loma Linda University Center for Christian Bioethics

LOMA LINDA UNIVERSITY
Center for Christian Bioethics

Update

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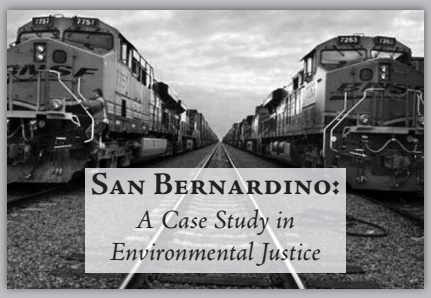

According to a recent state analysis, the San Bernardino rail yards presents one of the greatest cancer risks to nearby residents of any rail yard in the State of California. This was the perfect topic to cap off the 19th annual Contributor's Convocation. The case study in environmental justice brought together the mayor of San Bernardino, a leader of the Center for Community Action and Environmental Justice, a spokesperson of the Burlington Northern Santa Fe railroad, and faculty of Loma Linda University who are conducting a study of 900 homes surrounding the rail yard. The roundtable was chaired by Roy Branson, director of the Center for Christian Bioethics.

From left is Susanne Montgomery, PhD, MPH, LLU School of Public Health; Tom Dolan, PhD, Inland Congregations United for Change; Patrick J. Morris, mayor of San Bernardino; Roy Branson, PhD, moderator; Samuel Soret, PhD, MPH, LLU School of Public Health; and David Seep, Burlington Northern Santa Fe Railway Company.

Quid Pro Quo, Quid Vadis

Conflict of Interest Policy of Loma Linda University School of Medicine

Richard E. Chinnock, MD, FAAP
Professor and chair of pediatrics
School of Medicine, Loma Linda University, Loma Linda, California
Chair, task force on industry and academia

Over the 2009–2010 school year, the School of Medicine at Loma Linda University invested a great deal of time and effort developing and adopting a policy regarding conflict of interest. The School of Medicine adopted this policy to advance the value of integrity integral to its declared aim "to make man whole." [1]

The scope of the issue of conflict of interest is large, with 95 percent of all physicians reporting having had some interaction with industry. And the estimated amount spent each year in the United States is estimated at between $40 to $60 billion dollars.

Loma Linda University School of Medicine (LLUSM), as a Seventh-day Adventist Christian institution, has long had a tradition of valuing ethical standards and adhering to a strong ethos of mission and service. There was, however, less consensus on campus regarding the necessity and/or advisability of enacting a policy aimed at oversight of physician relationships with industry. Comments received during the process ranged from those who believed that, as a Christian institution, we were unlikely to have a problem with disreputable relationships, to those who believed that a Christian institution should embrace the most restrictive elements of the debate.

In 2008, the Association of American Medical Colleges (AAMC) released its task force report on Industry Funding of Medical Education. It was at this point that most medical schools, Loma Linda University included, began in earnest to develop its own policies.

In order to mediate between these competing interests and to address a topic that was gaining increasing notice in the academic world, in 2008 the dean of the LLU School of Medicine appointed a task force chair to develop a policy for the school. This paper will describe the history of financial relationships between industry and medical school academia, and describe the conflicts of interest in an academic health center. It will also explore the scientific basis of influence and reciprocity. And lastly, it will describe the process of developing the policy and the rationale for the components of the Loma Linda University School of Medicine "Vendor Policy."

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Editorial

Thank you, Mark Carr—Welcome, Roy Branson!

Loma Linda University is proud that the founding of the Center for Christian Bioethics, in 1984, took place early in the rise of bioethics in the United States. One reason the center continues to make a contribution to the field is the continuity of its leadership—three directors in the center's first 26 years: Dr. Jack Provonsha, a physician and theologian, who founded the center; Dr. David Larson, a theological ethicist, whose 15 years as director saw national conferences and the establishment of a significant endowment; and Dr. Mark Carr, also a theological ethicist, whose nine years at the helm have seen several innovations.

This year, Dr. Carr decided to move on from being director to devote more time to writing in the field of ethics. I want to celebrate Mark Carr's years as director and welcome the center's new director, Roy Branson, who has been involved in bioethics since the beginnings of the field.

As director, Dr. Carr worked particularly closely with three schools to enrich their ethics offerings. The center provided office facilities for the executive director of the American Society for Dental Ethics. Dr. Carr helped design ethics courses for the newly founded School of Pharmacy and served on its admissions committee. He also cooperated with the School of Public Health in integrating ethics into a national public health conference. While Dr. Carr directed the MA degree in bioethics, students enrolled in schools across the campus also earned master's degrees in bioethics.

Dr. Carr hosted the center's first-ever Bioethics Summer Camp and started the Claritas Essay Contest, which has drawn many Loma Linda University undergraduate and graduate students into reading, thinking, and writing about bioethics. Under Dr. Carr's leadership, the Provonsha Lecture became a lecture series with new, associated courses. He is editing the lectures into printed volumes.

When Dr. Carr resigned as director, Loma Linda University, in the spring of 2010, invited Dr. Branson to serve as permanent director. Dr. Branson has a rich background in both teaching ethics and fostering centers of writing and research. He started the ethics program at the Seventh-day Adventist Seminary at Andrews University, where he introduced the field to several of the ethics professors at LLU. Soon after the Kennedy Institute of Ethics was founded at Georgetown University, Dr. Branson was invited to join as a full-time senior research scholar. Later, he started and directed the Center for Law and Public Policy, affiliated with Columbia Union College, until he joined the LLU School of Religion as associate dean, in 2008. Dr. Branson has already led the center in presenting several well-attended roundtables on issues of bioethics in the public square.

Continuing as associate director of the center is Dr. Robert Orr, both a physician and ethicist. Dr. Orr directs the clinical ethics consultation service in the LLU Medical Center and is training five physicians, who are fellows of the center, in the field of clinical bioethics. His recent volume, *Medical Ethics and the Faith Factor: A Handbook for Clergy and Health-Care Professionals,* will be featured in the next issue of Update.

With its strong faculty of professors trained in ethics, Loma Linda University continues its commitment to being one of the country's outstanding centers of bioethics in the clinical and health care settings.

Jon Paulien, PhD
Chair, administrative committee
Center for Christian Bioethics

Historical context

A pivotal event in American medicine occurred in 1999 when a patient, Jesse Gelsinger, died during a gene transfer experiment. Controversy was provoked when it was revealed that the principal investigator for the trial also had ownership interests in the company making the product. Prior to 1999, the number of articles in the medical literature concerning conflicts of interest between industry and medical institutions averaged about 5 to 10 annually. After this point the number of journal articles increased more than 10-fold.

Disclosure of financial relationships between industry and physicians took a new turn when the U.S. Department of Justice agreed to a deal with orthopedic device companies to disclose payments to physicians on the Internet. (An entry on *The Wall Street Journal's* health blog cheekily asked, "Hey, orthopedic surgeons: Check out how much your pals are making in consulting fees from companies that sell orthopedic implants."[2]

It is true that the history of financial dealings between industry and academia has had many success stories. For example, Eli Lilly worked with researchers at the University of Toronto to develop insulin. However, concerns about undue influence from drug manufacturers date back at least 100 years. A review of the *Merck Manual* from the early 1900s noted that "although this book is gotten out by a manufacturing firm and with some view towards its advertising value, it nonetheless is of such merit that it is deserving of mention."[3]

A pivotal series of events occurred in the 1940s when the American Medical Association began marketing its physician

database information to the pharmaceutical industry. The pharmaceutical companies used the information to study the effectiveness of various marketing techniques on physician prescribing patterns. This led to the practice of pharmaceutical representatives entering physicians' offices to provide clinical information related to their products. Marketing practices included providing free food and items with company logos, such as pens, note pads, etc.

In 1959, pharmaceutical company marketing practices were the subject of a U.S. Senate hearing led by Senator Estes Kefauver. In 1981, in an attempt to promote research without an infusion of federal dollars, the U.S. government provided tax credits to companies if they invested in university-based basic research. In 1983, a California state commission found that a number of University of California faculty had financial interests in companies funding their research.

The medical literature addressed these issues in 1984 when *The New England Journal of Medicine* announced a policy on conflict of interest. Four years later, the International Committee of Medical Journal Editors (ICMJE) developed a statement of requirements for authors regarding financial disclosure. In 1993, Minnesota was the first state to limit drug company gifts.

Organized medicine joined the discussion in 1990, when the Association of American Medical Colleges (AAMC), the American Medical Association (AMA), and the American College of Physicians (ACP) all published guidelines and position papers regarding conflicts of interest and gifts to physicians.

What is a conflict of interest?

A conflict of interest is defined as a set of circumstances that creates a risk that professional judgment or actions regarding a primary interest will be unduly influenced by a secondary interest. Primary interests are those elements of first importance, such as the welfare of patients, integrity of research, and quality of education. Secondary interests are issues such as financial gain, professional advancement or recognition, personal achievement, and favors to family or friends. Secondary interests are not inherently unethical. But when a secondary interest has inappropriate weight in a decision and distorts the pursuit of a primary interest, it exerts undue influence.

Conflicts of interest can be dealt with in various ways. There is disclosure, prohibition, and "management" of the conflict of interest. Most conflicts of interest in the academic setting have historically been handled by disclosure agreements. More recently, prohibition has been used more aggressively.

In developing conflict of interest policies, the following factors must be considered.

***Proportionality*:** Is the policy efficiently directed at the most important conflicts?
***Transparency*:** Is the policy comprehensible and accessible to the individuals and institutions that may be affected?
***Accountability*:** Does the policy indicate who is responsible for enforcing and revising it?
***Fairness*:** Does the policy apply equally to all relevant groups within an institution?

Arguments against conflict of interest policies have come from both sides of the ideological spectrum. There are those who believe that policies have become too strict. They worry that financial disclosure invites ad hominem attacks, shifts focus away from the merits of work to the biography of the author, and develops a new "Scientific McCarthyism" wherein research is tainted merely by association with industry. Those who believe that the new policies are too lax note that the policies are weak and inconsistent and that they are inadequately administered and enforced. Most tellingly, there have been few, if any, studies evaluating the implementation or effectiveness of conflict of interest policies.

The core principles of professionalism are autonomy, objectivity, and altruism. And there is an expectation that medical professionals can behave in the best interests of their patients regardless of any financial or other beneficial relationship with industry. But some are concerned that there is a "bias of rationality." David Blumenthal from Mass General Hospital in Boston states, "Doctors don't want to hear that there are things going on in their heads that they are not aware of."[4] A recent editorial in a medical journal more pithily put it as, "Your soul for a pen?"[5] Are physicians influenced by being given trinkets, by support for medical education, by provision of drug samples, and by consulting relationships with industry?

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Every time a physician sees a patient, except in free clinic situations, there is a financial transaction that takes place. A charge is generated and a payment is received for services. There has always been the concern that a physician could be more interested in the payment than in the patient. Indeed, the Hippocratic Oath states in part that a physician should prescribe regimens for the good of his patients according to his ability and judgment and never to do harm to anyone. The LLUSM

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Physician's Oath states that "the wholeness of my patient will be my first consideration." It is understood that physicians should be appropriately compensated for the services, but this should never overshadow his or her responsibility to the patient.

LLUSM conflict of interest basic principles

The LLUSM policy provides guidance for gifts and compensation, drug samples, drug detailing activities, educational and other professional activities, disclosure, and logistics of the policy.

Disclosure: Justice Louis Brandeis (1914) noted that "Sunshine is said to be the best of disinfectants."[6] But there is a growing concern that though disclosure is an essential element of conflict of interest policies, it is probably an insufficient element.

> "Disclosure relies on the honesty of the discloser."

The first challenge for disclosure policies is that there is not a sufficient policing process. In a study of articles on coronary artery stents, it was noted that of 75 authors who disclosed as least one potential conflicting relationship, only two authors disclosed their relationship in every article that they published.[7] Disclosure relies on the honesty of the discloser. There have been several reports regarding well-regarded scientists who failed to disclose hidden payments from pharmaceutical companies.[8] In addition, disclosure does not resolve conflicts of interest, but rather places the onus for evaluation on the person receiving the disclosure. For example, disclosure of possible conflicts of interest in patient research has been shown to not have a significant effect. And it may be counterproductive if the investigators who have disclosed their conflict of interest, believe that they can be more aggressive in promoting a therapy.[9]

Disclosure does not deal with the unconscious biases involved in human relationships. I know that I have come to doubt my ability to evaluate those actors or agencies that seek to influence me. Indeed, most physicians are subject to the "Lake Wobegon Effect." In his semi-mythical hometown of Lake Wobegon, Garrison Keillor reports that "all the children are above average." Similarly, a study of Swedish drivers reports that 90 percent of them believe that they are better drivers than the average.[10] Most physicians claim that marketing and "trivial" gifts do not influence them. But, most physicians believe that the same tactics work on the majority of other physicians.

Influence: Let me describe the challenges of influence by referring to several experiments. Influence is described as "a power affecting a person, thing, or course of events, especially one that operates without any direct or apparent effect." And reciprocity is the "quality of state of being reciprocal; mutual dependence, action, or influence."[11] The subconscious effects can be seen in many different ways. We miss what we aren't looking for, and we are influenced by financial sponsorships. Even honest persons will sometimes behave unethically (at least up to a point). Well-intended persons will give themselves some "wiggle room."

In a classic 1979 study, Ulric Neisser showed a video clip to study subjects. Two teams of players were passing a basketball back and forth. The subjects were asked to count the number of passes made by the team dressed in black. About two-thirds of the way through the clip, a woman with an umbrella unexpectedly walks through the teams. Only 21 percent of the video-watching subjects noted the woman. In other words, many don't see what they are not expecting to see.[12]

In a study that evaluated the influence of fictional sponsors, study subjects in a functional MRI (fMRI) were shown paintings and asked to rate them. The investigators were able to correlate brain responses with the subjects' ratings of paintings. Then the subjects were informed that a (fictional) company had sponsored the research and provided a cash reimbursement to the experimental subject. Prior to the next phase of the test the subjects were shown the company's logo, which subsequently appeared randomly near paintings. The mere presence of the sponsoring logo near a painting changed the subject's passive brain fMRI response and led to the subject's more positive rating of the painting. We are subconsciously influenced by incentives.[13]

Honesty: In a test of honesty, researchers devised a test of general knowledge. Students were told that they would receive a certain amount of money for each correct response. The first group of students marked their test sheet with their answers, then transferred the answers to a second answer sheet, and turned both sheets in to the investigator. The second group of students was given an answer sheet with the correct answer in grey. They could choose to transfer their own answer or choose to change their answer to the correct answer, and then turned in both sheets to the investigator. There was the possibility that their deception would be found out. The third group of students was given the answer sheet with the correct answers in grey, but this time they were allowed to shred their original answer sheet, eliminating the ability of the investigator to determine if they were cheating. A separate fourth group of students was asked to predict how much cheating in this last group there would be.

Surprisingly, the amount of cheating that occurred was significantly less than predicted. The amount of cheating was very similar between the second and third

groups. It has been posited that the students cheated less than the maximum amount they may have gotten away with in order to maintain their self-concept that they were basically honest. They would thereby avoid receiving a negative self-signal. In other words, they would cheat, but "just a little." When the same experiment was conducted using tokens rather than cash, the amount of cheating doubled. A non-cash "gift" increases the likelihood of unethical behavior.[14]

Another experiment evaluated unconscious influences. Two groups of study subjects were told to place a drop of saliva on a test strip. The first group was told that a change of color of the strip showed the presence of disease. The second group was told that a change of color showed the absence of disease. The second group waited twice as long to see whether the strip would change color. The implication is that we work hardest for what we want to see.[15]

In a money-sharing game between two players, one player was designated as the "dictator." This player was given the option of giving $6 to himself and $1 to the "other," or the option of giving $5 to himself and $5 to the other. The dictator made the altruistic distribution of the money in 74 percent of cases. In the next phase of this experiment the amount given to the other was randomly assigned at $1 or $5. That is, if the dictator received $6 the other could receive $1 or $5. If the dictator received $5, the other could receive either $1 or $5. The dictator was given the option to see the randomization result before deciding on the distribution. Surprisingly, only 44 percent of the dictators chose to see the results beforehand, depriving themselves of the opportunity to choose the fairest option. And, in this scenario only 38 percent of the others received $5. The implication is that people are good at not looking when they don't want to see.[16]

Biases: Let's look at self-serving biases. In a study of work effort versus work reward, subjects were asked to complete the task of filling out surveys. They were then given money and an envelope to pay themselves and another "employee" who had already left. The subjects were told one of four different scenarios. The scenarios and how the subjects allocated the money is as follows. When the other "employee" worked half as much time and filled out half as many surveys, study subjects allocated the money in the expected 2/3 to themselves and 1/3 to the other "employee" —a simple merit principle. When told that the "employee" had worked half as much time but completed twice as many surveys or that the other "employee" had worked twice as much time but had completed half as many surveys the study subjects allocated 60 percent of the money to themselves and 40 percent to the other "employee." The experiment results illustrate a merit principle that advantaged the study subject, whether they had spent twice as much time or completed twice as many surveys.

In the last scenario, the other "employee" worked twice as much time and completed twice as many surveys. This is the reverse of the first scenario. However, this time the study subject allocated 50 percent of the money to themselves and 50 percent to the other employee, presumably because both had worked and therefore both should be paid the same—an equal division principle. Interestingly, nearly all of the study subjects actually sent money via mail to the other "employee." However, when free to choose among competing principles of fair behavior, they tended to gravitate toward those principles that most favored their own interests.[17]

Other experiments reveal how people apply different standards when evaluating a proposition they wish to be true. To an agreeable proposition people ask, "Can I believe this?" To a disagreeable proposition people respond, "Must I believe this?" For example, a physician may evaluate evidence that a particular treatment is effective. If that physician stands to gain financially by prescribing that treatment, the motivation of financial gain may make the physician more likely to regard the drug as effective.

Teaching someone the concept of the bias "blind spot" helps them to recognize it in others but not necessarily in themselves. We "know" that we aren't biased. However, in others whose thoughts we do not know, we can believe that they are biased. The bias blind spot may explain why there are such strong disagreements about whether conflicts of interest are problematic.

"Some fairly egregious examples of unethical behavior have taken place within medical education."

Awareness: Finally, there is the effect of increasing awareness of moral standards. A study divided students into two groups. The first group was asked, just prior to the exam, to recall 10 books from high school. The second group was asked to recall as many of the 10 commandments as they could. No one asked about the 10 commandments cheated. Some among those asked to recall high school books did cheat. The researchers concluded that the mere fact of having a policy regarding conflicts of interest might decrease questionable behavior. [18]

Loma Linda University School of Medicine conflict of interest policy—specific requirements

We began the process of developing a policy at LLUSM with these values in mind: the process should be transparent, inclusive, and deliberative. The following is the timeline and tasks accomplished in developing the policy (Table 1.)

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Gifts and compensation

The AMA policy on gifts notes that it is the responsibility of the individual physician to minimize conflicts of interest. Gifts should be of minimal value, should benefit patients, or should relate to a physician's work (e.g. pens, notepads). Faculty and physician trainees (either post-graduate or medical students) at LLUMC may not accept gifts from industry. However, an unrestricted educational grant may be given to a department or division. Individuals with a conflict of interest may not participate in institutional purchasing decisions. Faculty and trainees may not accept payment for attending an educational event, and industry may not supply food to LLUSM events.

Table 1: Development of conflict of interest policy for Loma Linda University School of Medicine—a chronology

6/07	Initial meeting with Dr. Hadley, dean, School of Medicine (SOM)
2/08	Dean appoints task force chair
6/08	Association of American Medical Colleges (AAMC) releases report
9/08	General call for volunteers from SOM faculty
9/08	Dissemination of AAMC, Pharmaceutical Research and Manufacturers of America (PhRMA) information, and presentation to School of Medicine executive committee (SMEC)
1/09	First meeting of task force (TF) • Discusses comparisons between AAMC, PhRMA and Riverside County Regional Medical Center (RCRMC) policies; examples of policies from UCLA, Stanford, University of Pittsburgh
1/09	Presentation to Clinical Science Faculty Advisory Council (CSFAC)
2/09	Second meeting of task force • Discussion of feedback regarding comparisons
3/09	Third meeting of task force • Discussion of proposed policy
3/09	Proposed policy is disseminated to entire SOM faculty for review and comment
5/09	Fourth meeting of task force • Finalization of policy (again using ARS)
6/09	To general counsel for review
7/09	Response to general counsel review
7/09	Policy presented to CSFAC for review and comment
9/09	Final approval by MSEC and then to LLU Board of Trustees

Drug samples

The rationale for providing drug samples is that short-term use allows for assessment of potential side effects and benefits before prescribing a full course. And they can provide access to meds for low-income patients.

However, many problems have been documented. A large majority of drug samples are given to insured patients. Physicians, their patients, and staff often use the samples, even if they may not be the best choice for a particular condition. Poor patients may not be able to afford the follow-on course of a newer, non-generic medication. Accordingly, the LLUSM policy states that samples are discouraged. If samples are to be given, then they must be logged, used solely to enhance patient care, and not merely for convenience. No samples are to be used by faculty, staff, trainees, or their families.

Drug detailing

A pharmaceutical representative engages in drug detailing when the representative provides information to a physician about particular medications. Drug detailing is a $20 billion a year business practice. While drug detailing can be a valuable information service, it inevitably co-mingles information with gifts from a drug company to a physician; also, trainees may not be able to discern information from hype.

Accordingly, the LLUSM policy states that drug company representatives may have access to physicians only by appointment. They are not permitted in a patient care area except to provide in-service training or to demonstrate use (e.g. of a blood sugar monitor) for patients. A faculty member must be present whenever a pharmaceutical representative is interacting with a trainee. Faculty must thoroughly vet any device training program. Indeed, the overall activity of industry representatives is subject to oversight by faculty leaders, as well as the LLU hospital and Loma

Linda University Adventist Health Sciences Center (LLUAHSC).

Educational and other professional activities

There are many opportunities for conflict of interest in not only the formal medical education curriculum, but also in the informal or hidden curriculum (the attitudes and behaviors modeled by faculty).

Academic medical centers are increasingly dependent on industry support for education. One half of physician continuing medical education is paid for by industry. Medical students are masters at delayed gratification and finish medical school with average indebtedness of $150,000. It is unfortunate, but probably not unexpected, that when queried, 80 percent of medical students believe that they are entitled to gifts from industry. It is for these and similar reasons that academic medical centers have been targeted to be the vanguard of the conflict of interest culture change in medicine.

Some fairly egregious examples of unethical behavior have taken place within medical education. In 2004, the drug company Warner Lambert was fined $430 million for paying doctors unreasonable fees to attend "consultant" meetings, for sponsoring expensive dinners to discuss off-label uses of their drugs, and for planting people in audiences to ask questions highlighting benefits of their drugs. In 2007, Orphan Medical was fined $20M for paying exorbitant speaker's fees to promote their product. And in 2008, Merck was fined $58M for company use of ghostwriters and for non-disclosure of company ties to speakers at medical meetings. A 1998 study found that 13 percent of journal articles had been ghostwritten (that is, an article written by an industry writer would then have a faculty person's name assigned to it as the author).[19]

Speakers' bureaus provide speakers free of charge to educational institutions. The lecturers receive honoraria and expenses, paid by a drug company. In and of itself, this practice may not be a problem. But an ongoing payment over a number of years creates the risk of undue influence. Also, a company may exert substantial control over content by: 1. providing slides and answers to questions; 2. insisting that a presenter avoid mentioning a competitor's product; and 3. providing answers to possible questions raised about the drug.

With the foregoing considerations in mind, the LLUSM policy on industry support for education proscribes direct interaction between industry and trainees. The department chair must determine educational merit for all educational programs and must have sole discretion to determine how any funds provided by industry are used. There must not be an implicit or explicit quid pro quo. All continuing medical education (CME) events must comply with Accrediting Council for Continuing Medical Education (ACCME) standards for commercial support. This applies whether the educational program is on- or off-campus. Any educational activities must be administered by departments and not by individual faculty. Finally, industry may not directly provide meals either on- or off-campus.

LLUSM acknowledges that speakers' bureaus may be just an arm of the marketing department of the commercial sponsor, and therefore are discouraged. Any compensation provided to a faculty member involved in speakers' bureaus must be at fair market value, the source of compensation fully disclosed by the meeting sponsor, and the content of the lecture solely the responsibility of the lecturer. The lecture must be fair and balanced, and the slides and educational materials must be prepared by the lecturer. The meeting organizer must be free from influence by industry. The lecturer must also make sure that the content reflects his or her view, and not necessarily that of LLUSM or any other LLUAHSC entity.

Consulting

LLUSM recognizes that an LLUSM faculty member's special knowledge and expertise may be invaluable in developing new products. But consulting arrangements cannot be gifts in disguise. Compensation must be at fair market value, paid through the employing corporation for specific tasks.

"There are many opportunities for conflict of interest…Academic medical centers are increasingly dependent on industry support for education."

Conclusion

During the last several years, the academic health center community has increasingly debated the proper relationship between academia and the health industry. Collaborative and productive relationships between academia and industry have provided numerous advances in health and the treatment of disease. Simultaneously, an intertwining of finances between academia and industry has created the potential for physicians to regard financial gain as the primary interest, rather than serving the best interests of the patient. In some cases, physicians have stepped over the line. Loma Linda University School of Medicine has developed a policy that attempts to keep those relationships that benefit the patient, while eliminating those that create conflicts of interest. There is still more work to be done. Other schools within the university will need to address their own unique considerations with this issue. There will need

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to be ongoing education of faculty and physician trainees. Further work needs to be done to "operationalize" the policy and to determine consequences for non-adherence.

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Richard Chinnock, MD , FAAP, is professor of pediatrics and the Robert F. Chinnock chair of pediatrics at Loma Linda University School of Medicine. He has published 73 refereed articles, 12 book chapters, and 129 non-refereed articles. He is the principal investigator of three IRB-approved protocol research projects and co-investigator on three others. Dr. Chinnock received the Whole Person Care Award in 2008, "in recognition of a physician who provides compassionate care as exemplified by the Good Samaritan."

CLARITÁS

Clarity in Ethics

ESSAY CONTEST

First-place 2009 graduate essay winner

HEALTH CARE: BUSINESS OR SERVICE?

Mark Warren, School of Medicine, Loma Linda University

Health care is arguably the most important domestic issue that the United States is facing in this blustering economy. A major political platform for both democrats and republicans alike, the health care debate has inspired heated controversy, artistic expression, a global search for answers, and most importantly, some difficult questions about the core values of American citizens.

The topic for this paper is ethically charged and invigorated by true stories and horrifying facts. In a tumult of political opinions and the quagmire of a broken health care system, the central ethical question emerges: is health care a basic human right? If not, then the question of whether health care is a business or a service is simply academic. But if, in fact, health care is a right, then it becomes a discussion not simply about economics but about values. It becomes a matter of urgent domestic and global priority and ultimately a discussion about what it means to apply a Christian worldview to this pressing issue.

In *The Pearl*, John Steinbeck weaves the tale of Kino, the indigent pearl diver, his wife Juana, and their newborn son Coyotito. When Coyotito is stung by a scorpion, Kino and Juana take him to visit the local doctor. At the gate of the wealthy doctor, Kino pleads with a servant for an audience with the physician. In anger, the doctor replies to the servant turned intercessor, "Has he any money? No, they never have any money. I, I alone in the world am supposed to work for nothing—and I am tired of it. See if he has any money." When Kino predictably produces nothing of any value, he is left with his sick child, tormented by his own inferiority and shame to find his own desperate way.[1]

Kino's experience is fictional in this context, but in the broader context of modern medicine, at least in the United States, his story is frighteningly true. As citizens of the world's most powerful nation, we rub shoulders with 46.3 million Kinos everyday within our own borders.[2] The circumstances vary, but they are linked by a shared obstacle. The business of medicine has become exclusive and you cannot participate unless you can pay. Studies show that some 20,000 Americans die for lack of access to adequate health care each year.[3] Further, it is estimated that 700,000 Americans face bankruptcy every year due to medical bills.[4] Add to this the fact that no other nation on the planet burns through a larger percentage of GDP on health care and it is not difficult to see that something is wrong.[5]

In most places in the United States, health care is a business. At Loma Linda, we have conspicuous and shining examples of clinics that are primarily service oriented. Take the SACHS clinic system for instance.[6] And there are others, pockets all over the United States where medicine is more service than business. Not only in the United States but abroad, there are organizations actively answering the primary ethical question. But on the whole, in the United States, medicine is primarily a busi-

Please turn to page 10

ness. As a business there are many advantages. High-tech innovations and life-saving novel medications are all market-driven. Without monetary incentive, some argue that cutting-edge research and development would be unlikely, if not impossible. Capitalism drives creativity and excellence. But there can be a downside to the business of medicine.

In a free market economy, there are going to be inequalities. And if a society chooses to uphold a free market economy, it must decide which inequalities it is willing to tolerate. While the practice of high-tech medicine in the free market undoubtedly drives innovation, it may also come to represent a dangerous conflict of interest. The introduction of powerful, profit-driven third-party payers has come to represent, in many cases, a monolithic business enterprise standing between patient and provider. The Achilles heel of the free market system, when it comes to health care, is that it leaves millions without access to the very innovations and life-saving medications and procedures that it inspires.

"The Achilles heel of the free market system…is that it leaves millions without access to the very innovations…that it inspires."

Insurance companies notoriously avoid "adverse selection" of customers by hiring experts to review applications, deny coverage to risky investments, and at times cancel coverage that might interfere with the bottom line. Business is business. In order to secure and keep coverage, customers often have to wade through the quagmire of pre-existing conditions, of rescission, of denied claims, and of cessation of coverage upon employment change. Some, not finding a provider willing to accept them, are forced to hide assets or spend down to be considered for Medicaid.

T.R. Reid, in *The Healing of America*, argues that the health care debate is often simply a financial debate. Since our national identity is strictly tied to our primarily free market economy, any discussion of universal access to health care is wildly rhetorized as socialism. However, the heart of the issue, he maintains, is the central question we have identified. He offers this:

> Should society guarantee health care, the way we guarantee the right to think and pray as you like, to get an education, to vote in free elections? Or is medicine a commodity to be bought and sold, a product like a car, a computer, or a camera? This is the key question facing any nation as it designs a health care system […][7]

Citing Professor William Hsiao, the Harvard economist who has "helped design health care systems for more than a dozen nations,"[8] he goes on:

> 'Before you can set up a health care system for any country,' Hsiao told me, 'you have to know that country's basic ethical values. The first question is: Do people in your country have a right to health care? If the people believe that medical care is a basic right, you design a system that means anybody who is sick can see a doctor. If a society considers medical care to be an economic commodity, then you set up a system that distributes health care based on the ability to pay. And then the poor, pretty much, are left out.'[9]

So then, as Reid and Hsiao argue, the central question in the health care policy for any developed nation with a means to provide for its citizens is an ethical one. Arguments about market-based vs. government-based solutions are secondary.

Some argue very powerfully that a nation that allows access to every one of its citizens does so at the expense of quality of care, patient preference, innovative excellence, and over-involvement of the government in the form of taxation and regulation. Informed by our political isolation, our perceived superiority, and our pervasive individualistic culture, it is very easy for us as Americans to dismiss universal access to health care as a threat to our national identity. Unwilling to look around the world, and more importantly to realize that the socialism many fear in health care has already been here for decades, we fail to address seriously the fundamental ethical question.[10] While it is beyond the scope of this paper to deal with a comparative analysis of world health care systems, it is worth noting that every wealthy nation has both raised and answered the central ethical question. All wealthy nations have decided that every one of their citizens deserves, as a matter of basic human right, access to health care. All that is, except the United States.

As Christians, whose worldview is central to ethical considerations, the principles surrounding the health care issue gain even more clarity. When it comes to health care access, both domestically and abroad, it is the women, the children, and the downtrodden who are marginalized. The message of Christ has undeniable social implications and imposes unequivocal responsibilities. Christ clearly asserted that the central issue in authentic Christianity is our treatment of those he refers to intimately as "the least of these my brethren." Conspicuous among those are the sick.[11] Tracy Kidder, speaking of Paul Farmer, a physician made famous by his dedication to the underserved, offers this: "He's still going to make these hikes, he'd [Farmer] insist, because if you say that seven hours is too long to walk for two families of patients, you're saying that their lives matter less than some other's, and the idea that some lives matter less is the root of all that's wrong with the world."[12]

So as we face a broken U.S. health

care system with its tragic inequities, the central ethical question needs to be addressed. If we fail to address the question of health care as a basic human right, we will be unprepared to confront the urgent global priority of our world's deplorable inequities. But if we have the courage to answer this call to moral responsibility, regardless of its implications on the business of medicine, we will find that we are doing exactly what Jesus asked us to do, and we will redefine modern medicine, not as a business, but as a service.

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4. Ibid., p. 31.
5. Ibid., p. 9.
6. For more on SACHS clinic visit: http://www.llu.edu/central/sachs/index.page
7. Reid, p 212.
8. Ibid., p. 212.
9. Ibid.
10. As Reid points out in his comparison of the world's major health care systems, the United States has elements of all of them. We have a hybrid of the Bismarck model, the Beveridge model, the National Health Insurance model, and the Out-of-Pocket models in one dysfunctional conglomerate, p. 16-27.
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Mark Warren, MD, is a 2010 graduate of Loma Linda University School of Medicine. This was the second time Mark finished as a finalist. In 2008, Mark competed amongst an equally impressive field of essayists when he wrote on physician-assisted suicide. Mark is now at Mayo Clinic for his residency.

First-place 2009 undergraduate essay winner

Service or Business?

Sidney E. Irving, School of Nursing, Loma Linda University

Today, health care lies at the forefront of modern debate in the United States. No one disagrees that reform is necessary; rather the issue is how the reform should be structured. The question of whether health care is a business or a service appears to be at the root of this debate. As a newly licensed registered nurse, I firmly believe that health care is a service.

What exactly does service mean? According to the Oxford Dictionary, service is "the organized system of providing labor, equipment, etc., to meet a public need such as health" (2002, p. 2768). It is the idea that one does something to help others without making a profit. Business lies on the other end of the spectrum. A business, according to Oxford, is a commercial transaction (2002, p. 313). Health care in this view implies that the investors or owners will make a profit.

Our current health care system is run as a business, although it has not always been this way. Hippocrates, the father of medicine, proclaimed in his famous oath, "do no harm." Then, in the Dark and Middle Ages, monks and nuns were the main providers of health care. This tradition of religious organizations providing health care is alive today (*The History of Health Care*, 2008). In the United States, especially during the Great Depression, there were rural doctors who provided a service to their community.

In the late 1940s, President Truman advocated universal health care. The American Medical Association (AMA) was a powerful opponent to his idea. Additionally, citizens felt this proposal was akin to communism and it was dropped (Barlett & Steele, 2004). Then, in 1965, Medicare and Medicaid were created to assist the elderly and poverty-stricken to receive health care. At that time, Americans had a sense of solidarity that allowed them to use the government to do something for the common good (*In It Together*, 2009).

In the 1980s, under President Reagan, there was a move from a non-profit to a profit-based system of health care, transforming health care from our historical service model into a business model. Reagan and his supporters firmly believed in the market economy. Competition, as well as supply and demand ruled our health care arena. It was believed that this change would lower costs, while improving the quality of care.

In fact, today we spend more on health care than any other nation. There has been a rapid increase in our spending, with no increase in value or quality. When I was a student at Cabrillo College, a fellow student fell ill. He was an athletic 19-year-old with cardiomyopathy and desperately in need of a heart transplant. Fundraisers were conducted to pay for his medical bills. Sadly, he is not an anomaly. There are families that have gone bankrupt because of their medical bills. In the business model, the health company shareholders and insurance companies are the ones who profit.

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A market economy and health care do not mix. We must not rely on a decentralized market process to produce an efficient and equitable allocation of health care at the individual level (Baily, 2004). We know this does not work. The U.S. Census Bureau reported that, in 2008, there were 47 million Americans with no health insurance. Eight in ten uninsured people came from working families (Facts about health care, health insurance coverage, 2009). This number appears to be on the rise.

President Obama is working to change this situation. He believes that, simply on the basis that we are all human, we are obliged to give access to health care to all Americans. Other countries believe health care is a human right, while Americans have categorized it as a consumer item (In it together, 2009).

In a market economy, competition and free choice rule. However when most people become ill, they are unable to exercise free choice. The doctor that they see, or do not see, will depend on their health care insurance or lack thereof. When a patient in California gets cancer and wants to go to a specialty hospital in a different state, the patients' finances, as well as his insurance, will make the choice for him. Besides insurance companies, there is government regulation that limits competition. Due to the Office of Statewide Health Planning and Development (OSHPD) regulations, it is more expensive to build a hospital in California than in other states.

There are those that argue this type of regulation is stopping the market from working properly. The purported need for governmental oversight and regulation clashes with the individual patient's demand for greater privacy and freedom of choice (Johnson, 2006). Health care should be a free market entity. If the market is allowed to work properly, it will lead to innovation, better products, and decreased costs. It is a matter of getting the government less involved in health care, which will reduce waste and remove inefficiencies.

In our capitalist economy, we have the best health care system in the world; top-notch equipment, well-trained doctors, highly skilled technicians. Health care is provided for those that live in poverty through Medicaid, while Medicare is available for senior citizens. As it is a limited resource, health care should be allocated in the most efficient way possible, with supply and demand as the ruling force. According to Victor Fuchs (as cited in Johnson 2006), it is economically impossible to give every person in need of medical care all the treatment that would be of potential benefit to him or her. As health care is not a service, we must seek the financial viability of hospitals and health care institutions.

"Health care is not a consumer item where we want to increase sales."

According to Porter & Teisberg (2004), competition is the root of the problem in our health care system. However, they believe competition is also the solution. They advocate continuing with our model of health care as a business, but with some important changes. Today, there exists a practice of cost-shifting rather than reduction leading to a zero increase in net value. Competition should exist in the prevention, diagnosis, and treatment of individual conditions or comorbidities, instead of among health plans, networks, and hospitals. There is no rationale for the discounts given to large businesses for health care. It costs the same to treat someone employed by the school district as it does to treat a self-employed lawyer. This is a cost-shifting measure that limits competition.

Competition should be allowed on a national level. Medicare reimbursement costs vary depending on the treatment location. Yet, according to studies by Dartmouth Medical School (as cited by Porter & Teisberg, 2004), "higher costs are not associated with better medical outcomes and cannot be explained by differences in age, sex, race, rates of illness, or cost of living." According to Porter and Teisberg (2004), if true competition is allowed, a business model would work well for health care.

I believe, however, that health care as a service is the model we should adopt. The American health care system is stuck in Piaget's egocentric mode: as long as I have health care, that's all that matters. Under today's business model, we provide the best health care, but only for a few Americans. Competition simply doesn't work. Health care is not a consumer item where we want to increase sales.

A focus on preventive care would decrease overall health care costs. Currently, most people have little or no access to preventive care. They are unable to get an early diagnosis of their disease, increasing the cost to treat it. Money is also spent on unnecessary emergency department visits. These scenarios exclude the cost to society for letting our fellow humans suffer.

The utilitarian theory guides us to consider the consequences of our actions. If health care is a service, more Americans will receive health care. Fewer citizens will experience hardships related to a lack of coverage. Under the business model, society ends up paying more monetarily, and in human costs, by not providing health care.

Regardless of the cost, the deontological view states that it is our duty as humans to help others. The consequences are not important, yet it is intrinsically right to provide health care. Virtue theory

also supports health care as a service. This theory states that one should do good in this world. It would be difficult for most to live well while others are needlessly suffering because they lack access to health care.

With the recent health care debates, Obama has challenged our tradition of individualism; we need to be able "to stand in other people's shoes" (In it together, 2009). We must adopt or listen to the standpoint of the most marginalized and vulnerable persons involved: the uninsured and underinsured. These people are unable to purchase health care or adequate health care. As a society, we should provide this service.

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Sidney E. Irving is a 2010 graduate of Loma Linda University School of Nursing.

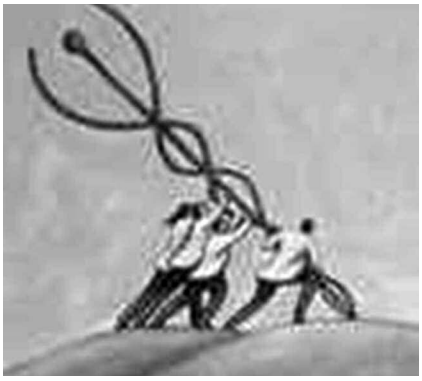
2009 Contributor's Convocation: A New View

The 2009 Center for Christian Bioethics Contributors Convocation took full advantage of the new Centennial Complex. Roy Branson, PhD, director of the Center for Christian Bioethics, began the convocation by inviting Gerald Winslow, PhD, vice president for spiritual life and wholeness, LLUAHSC, and Robert Orr, MD, associate director, Center for Christian Bioethics, to provide an overview of clinical ethics in the United States and at LLU.

With the return of Dr. Orr to the position of associate director of the center, weekly case conferences have returned as well. In addition, Dr. Orr has instituted, in cooperation with Loma Linda University Medical Center, an ethics fellows program designed to train physicians in clinical ethics.

Throughout the morning, ethics fellows, ethicists, and center associates engaged in spirited exchanges as they reviewed classic ethics cases.

Following the case consultations, the essay finalists presented their essays. The first Claritás essay contest was in 2008. It was designed by Mark F. Carr, PhD, former director of the center, to spark interest in



ethics across the disciplines. The 2008 contest generated 17 entries; the 2009 contest generated 21 entries. At the end of each presentation, the authors answered questions from the audience. The convocation attendees then decided the winners of the contest.

First place went to Mark Warren; second place, to Gregory Lammert; and third place, to Cordel Anderson. This year, an undergraduate division was added to the essay contest. The winner was decided by the associates of the center and went to a nursing student, Sidney Irving. A special thank you goes to Dr. Garry FitzGerald, who generously donated Alaska Airlines flight miles for our essayists to enjoy as part of their winnings.

Lunch was served on the second floor of the Centennial Complex. The design of the building provides magnificent views of the San Bernardino and San Gabriel mountains from every floor.

Following lunch in the Frank Damazo Amphitheater, Dr. Branson moderated a roundtable, "God and the American Health Care System." Could health care reform spell disaster for local hospitals? Are Christian beliefs at stake in legislation moving through the U.S. Congress? Do Seventh-day Adventists have anything at stake? These and other questions were addressed by members of the roundtable, including Ruthita Fike, CEO of the Loma Linda University Medical Center; Daniel Giang, MD, Loma Linda University School of Medicine; Joan Sabaté, MD, PhD, Loma Linda University School of Public Health; and Nicholas Kockler, PhD, Loyola Marymount University, Los Angeles.

The roundtable was open to the general public and was attended by about 170 people.

2010 Contributor's Convocation: Ethics in the Inland Empire

Ethics is everywhere; that was especially true in the Inland Empire on Saturday, November 6, 2010, as the Center for Christian Bioethics turned its focus on "Ethics in the Inland Empire" for the 19th annual Contributor's Convocation.

Roy Branson, PhD, director of the Center for Christian Bioethics, opened the day's activities with interviews of School of Religion alumni. Robert Kiger received his MA in biomedical and clinical ethics in 1985, as well as earning his DDS from LLU School of Dentistry in 1970. Dr. Kiger continues to pass the ethics torch to LLU dental students by teaching many of the School of Dentistry ethics courses.

The next alumna up was Ruthanne Williams. Ms. Williams received her master's in 2002. She is currently a social worker at Redlands Community Hospital, but prior to that, Ms. Williams served many years at Loma Linda as a social worker and as a clinical ethicist. Ms. Williams has been a presenter at the center's Bioethics Grand Rounds and at past Contributor's Convocations.

The morning presentations transitioned from former students to current fellows. Each of the ethics fellows presented the area he or she has been researching. Gina Mohr, MD, a family medicine practitioner and director of palliative care, presented "Ethical Issues in Palliative Sedation." Tae Kim, MD, is an emergency medicine physician and leads the fourth year medical student ethics elective. His presentation covered "Ethics in Disasters." Grace Oei, MD, is an internal medicine and pediatric physician, as well as a pediatric critical care fellow. Her presentation was "Ethics of Resource Allocations." And finally, Steve Hardin, MD, internal medicine and ethics, has been associated with the center for years, and when he returned to California he was quickly recruited for the fellows program. His presentation covered his specialty of hematology-oncology, "Ethical Issues in Oncology."

To round out the morning presentations, Robert Orr, MD, focused on "The Endangered Right of Conscience." In other words, does a health care professional have the right to refuse to do a procedure based on religious beliefs?

The year 2010 featured the third annual Claritás: Clarity in Ethics Essay Contest. This essay contest was created to encourage all full-time students to participate in the ethics discussion by writing on the topic of the year.

This year's topic for the essay contest was "Moral Distress and the Conscience of the Health Care Professional"—clearly relating to the final topic of the morning session on right of conscience. The three finalists included two medical students and a psychology student. It was again a difficult decision between first and second place, but ultimately first place was awarded to Gregory Lammert. His prize is a roundtrip ticket anywhere Alaska Airlines flies within the United States, Canada, and Mexico. Second place was awarded to John Park, who will enjoy a roundtrip ticket anywhere Alaska Airlines flies within the United States. Both airline tickets were generously donated by Dr. Garry FitzGerald. Third place went to Andrew Wa (LLUSM) and runner-up went to Ileana Galvin (LLUSPH.)

Dr. Branson started a new tradition with the 2009 Contributor's Convocation by following the event with a roundtable. This year's roundtable was based on the award of a two-year, nearly $1 million grant to Loma Linda University School of Public Health to generate data on the health status of neighborhoods closest to the one railyard in California (located in San Bernardino) deemed to present the highest public health risk by the California Air Resources Board. It was a lively debate concerning the moral, health, and public policy aspects of an immediate environmental hazard. Roundtable participants included Pat Morris, mayor of San Bernardino; Susanne Montgomery, PhD, MPH, Loma Linda University School of Public Health; Samuel Soret, PhD, Loma Linda University School of Public Health; Davis Seep, BNSF Railway; and Tom Dolan, PhD, Inland Congregations United for Change (ICUC). The roundtable was recorded and can be viewed online at <www.vimeo.com/16841068>.

LOMA LINDA UNIVERSITY
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UPDATE

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For more information, contact:

E-mail: bioethics@llu.edu
Website: bioethics.llu.edu
Phone: (909) 558-4956
FAX: (909) 558-0336

Letters to the editor and comments may be sent to:
24760 Stewart St., Loma Linda, California 92350

ETHICS ALUMNI UPDATES

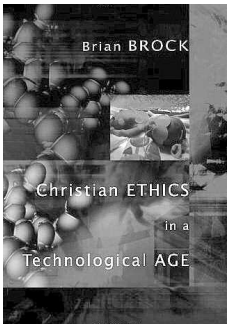
Brian Brock, MA, DPhil, is a 1996 alumnus of the Loma Linda University School of Religion biomedical and clinical ethics master's program. Since his graduation from LLU, he has earned a DPhil from King's College, London.

Dr. Brock is currently a lecturer in moral and practical theology at the School of Divinity, History, and Philosophy, King's College, University of Aberdeen, Scotland. Practical theology in Aberdeen, as Dr. Brock describes it, "begins and ends with inquiries focused on practices. Our task is to think through faith not as 'belief' but as lived." He finds theology most interesting when it is "done in relation to the concrete questions of daily life." It is not surprising that he has the same practical approach to Christian ethics.

Dr. Brock has written several books on Christian ethics:

- *Theology, Disability and the New Genetics: Why Science Needs the Church* (London: T&T Clark, 2007)
- *Singing the Ethos of God: On the Place of Christian Ethics in Scripture*, (Grand Rapids: Eerdmans, 2007)
- *Evoking Lament: A Theological Discussion* (London: T&T Clark, 2009)

And in his most recent book, *Christian Ethics in a Technological Age* (Grand Rapids: Eerdmans, 2010), Dr. Brock develops a theological ethics that addresses moral challenges surrounding new technology.



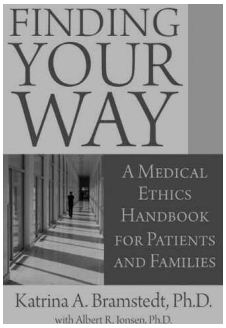
Katrina Bramstedt, PhD, is a 1998 alumna of the Loma Linda University School of Religion biomedical and clinical ethics master's program. After graduating from LLU, she moved on to UCLA. In the School of Medicine, she was an ethics fellow training in bioethics consultation with a specialty focus in heart transplantation and research ethics. She moved to Australia and, in 2002, earned her PhD in community medicine and general practice, with a bioethics emphasis, from Monash University, Victoria, Australia.

Dr. Bramstedt was formerly on staff at the Cleveland Clinic, where she worked in both inpatient and outpatient settings, performing more than 800 consultations.

She is currently chair of the ethics committee for NATCO (The Organization for Transplant Professionals.) She also works as an ethics consultant to the California Transplant Donor Network (CTDN), a San Fransisco Bay Area non-profit organization dedicated to saving and improving lives through organ and tissue donation for transplantation. Dr. Bramstedt also serves as an ethics consultant, living donor advocate, and philosophical counselor at her own practice found at AskTheEthicist.com.

Dr. Bramstedt is a prolific writer and has published more than 75 articles in peer-reviewed medical and ethics journals. She also has a long history of presentations, teaching, and research.

Dr. Bramstedt co-authored her latest book with Albert R. Jonsen, PhD, a pioneer in the field of clinical ethics, *Finding Your Way: A Medical Ethics Handbook for Patients and Families*, (NY: Hilton Publishing, 2011).



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