

Bioethics Matters

A Newsletter for the Friends
of Biomedical Ethics at UVA



VOLUME 16 ISSUE TWO Summer

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Director's Letter

Perhaps the summer of 2009 will eventually be known as the time when meaningful changes in the financing of health care in the United States were made possible through the concerted, democratic wrestling of the people and our leaders. The debates and maneuverings, and the voiced concerns on all sides, provide certain, if somewhat paradoxical, evidence of both the robustness and the fragility of the social contract that holds us together as a nation. Also evident are the many forms leadership can take and how crucial thoughtful, committed leadership is, not only in times of major change but also in the daily organization of our lives together.

Leadership has been much on our minds here in the Center. Earlier this summer we had the pleasure of meeting together with several recognized leaders in ethics from

healthcare institutions in Virginia and West Virginia to talk about obligations of and challenges to moral leadership in our medical centers. One point of interest that arose in our conversations is a recent change in the organization of information required by The Joint Commission: reports about specifically ethical aspects of the institution—consistent attention to ethical practices, processes available for ethical deliberation, etc.—now are included within the larger category of “leadership.” We are exploring the implications of this rearrangement and the opportunities it may provide for all of us healthcare “ethics-identified” people. We’ll relay our conclusions and recommendations to you in various ways, including at least one session in the March 2010 DSHEP Conference.

Here in the Center, several of our faculty have been demonstrating their leadership within the wider discipline of bioethics, as well as in the UVA Health System. Lois Shepherd’s thoughtful and accessible book about issues in the care of persons who are “permanently vegetative” or “minimally conscious,” *If That Ever Happens to Me*, continues to spark interest nationwide. Patti Tereskerz’ article in *Accountability in Research* (April-June, 2009), revealing the disheartening extent of the influence wielded by industry on the content, methods, and publication of biomedical research, was immediately noted and has

inspired editorial commentary in a variety of journals, including the *Hastings Center Report*. Three faculty members served on subcommittees reviewing proposals for presentations to this October’s annual meeting of the American Society for Bioethics and Humanities (ASBH): Ann Mills in organization ethics, Donna Chen in research ethics, and Margaret Mohrmann (as subcommittee chair) in religion and spirituality.

We are in the midst of a major overhaul of the Center’s website to make our cyberface better reflect who we are and what we do, and to provide the necessary base for our planned innovative educational and informational offerings. As part of this move to a more useful and user-friendly web presence—and, of course, as part of the budget constraints we’re all dealing with—future editions of *Bioethics Matters* will be posted on-line rather than printed and mailed. Please be sure that Carrie Gumm (cg2b@virginia.edu or 434-924-5695) has your current e-mail address so we can notify you when the next issue appears. If you do not have access to the internet, let Carrie know so we can mail a copy to you. ♦

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BIOMEDICAL ETHICS

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Recent Faculty Publications/Presentations/Activities

Donna Chen

Publications

+ Chen DT, Shepherd LL, Mohrmann ME. Substituted Judgment (letter to the editor). *J Gen Intern Med.* 2009 Jan;24(1):145; author reply 146.
 + Chen DT, Shepherd LL. When, why, and how to conduct research in child and adolescent psychiatry: practical and ethical considerations. *Psychiatr Clin North Am.* 2009 Jun;32(2):361-80. (Invited, peer-reviewed)
 + [Chahal H](#), Chen DT. Invited book review of *Neuroethics*, by Neil Levy for *Journal of Neuro-Ophthalmology*, 2009;29(2):166-167.

Presentations

+ Maloney R, **Chen DT**, Wynia MK, Alexander GC. *Physician knowledge of the FDA-approved indications of commonly prescribed drugs: results of a national survey.* SGIM 32nd Annual Meeting. Miami FL. May 15 2009 (oral presentation by Maloney)
 + Debate moderator: *Ethical Issues in Stroke Care.* 2009 International Stroke Conference. San Diego, CA. February 19, 2009 (Moderators: Chen D, Schwamm L. Speakers: Furlan A, Becker K, Mayer S, Haley EC.)
 + *Capacity and Competency in Behavioral Health.* Scattergood Ethics Summer Institute for the Applied Ethics of Behavioral Health. University of Pennsylvania. July 23-24, 2009.

Other

+ ASBH (2009) Sub-committee Reviewer: Research Ethics

Ann Mills

Publications

+MV. Rorty, PH Werhane, and **AE Mills**, (2009) The Third Face of Medicine: Ethics Business and challenges to Professionalism, in *Ethics and the Business of Biomedicine.* Ed. Denis G. Arnold. Cambridge University Press p. 198-219.

Other

+ ASBH (2009) Sub-committee Reviewer: Organization Ethics

Margaret Mohrmann

Publications

+Chen DT, Shepherd LL, **Mohrmann ME.** Substituted Judgment (letter to the editor). *J Gen Intern Med.* 2009 Jan;24(1):145; author reply 146.

Presentations

+“Bioethics for Babies: Are There Guides for the Perplexed?” Matthew Vandevier Sims Lecture, Indiana University, Bloomington, IN, April 16
 +“Thinking Differently,” Keynote address, Conference on Health Disparities, Ethics Committees of Roper/St. Francis Bon Secours Hospital and the Medical University of South Carolina, Charleston, SC, May 21
 +“Future Directions in Medical Ethics” and “Theodicy for Hospital Chaplains,” Annual Clergy Symposium, Chaplaincy Service, Roper/St. Francis Bon Secours Hospital, Charleston, SC, May 22
 +“Personal Integrity in the Medical Profession,” Keynote Address, Baylor Medical Ethics Symposium, Baylor University, Waco, TX, June 12

Other

+ASBH (2009) Sub-committee Chair: Religion and Spirituality
 +Member, Editorial Board, *Journal of Religious Ethics*

Lois Shephard

Book

Janet L. Dolgin & **Lois Shephard**, *Bioethics and the Law*, 2d ed., Aspen Publishers, Inc., 2009.

Publications

+ Donna T. Chen & **Lois L. Shepherd**, When, Why, and How to Conduct Research in Child and Adolescent Psychiatry: Practical and Ethical Considerations, *Psychiatr Clin N Am* 32 (2009) 361–380.
 + Chen DT, **Shepherd LL**, Mohrmann ME. Substituted Judgment (letter to the editor). *J Gen Intern Med.* 2009 Jan;24(1):145; author reply 146.

Presentations

+ Presentation sponsored by Health Law and Policy Initiative, "If That Ever Happens to Me...": Making Life and Death Decisions after Terri Schiavo," Virginia Commonwealth University, April 1, 2009.

Other

Media

Guest on call-in talk show, "Charlottesville—Right Now," NewsRadio 1070 WINA, June 11, 2009.

Guest blog spot

Guest blog for UNC Press on rationing, health care reform, and the end of life entitled "More talk, less action: toward sensible health care reform." Available <http://uncpressblog.com/2009/05/21/more-talk-less-action-toward-sensible-health-care-reform/>.

Patti Tereskerz

Publications

+ Patricia M. Tereskerz; Ann B. Hamric; Thomas M. Guterbock; Jonathan D. Moreno, Prevalence of Industry Support and its Relationship to Research Integrity, [Accountability in Research](#), 16(2): March 2009: pages 78 – 105.

Other

Center faculty Lois Shepherd, Preston Reynolds, and Donna Chen undertook to answer a request for assistance from the Student Affairs office of the Medical School about ethics related to medical student blogging. With the help of several medical student students, they prepared a "tip-sheet" for the Student Affairs office to hand out to medical students on blogging. ♦

Ethics Conundrums: The Programs for Biomedical Ethics in the Center for Biomedical Ethics and Humanities are proud to announce two recent publications by members of its faculty. Both publications are garnering national attention and should be of interest to readers of ***Bioethics Matters***. *They are discussed below.*

Lois Shepherd

This spring, the second edition of Lois Shepherd's co-authored legal casebook (with Janet Dolgin, of Hofstra University School of Law) was published by the leading legal publisher, Aspen Publishers, Inc. ***Bioethics and the Law, Second Edition*** presents a revealing survey of the full range of contemporary healthcare issues—from cloning to health care access to research ethics—along with the various conflicts and confluences that surround them. The book takes a multidisciplinary approach that combines sources of law with scholarship from philosophy and sociology. It follows a cradle-to-grave organization that traces a typical individual's experience in the healthcare system starting from birth and continuing through adulthood. A detailed Teacher's Manual accompanies the book.

Patti Tereskerz

Patti Tereskerz, and study authors (Ann B. Hamric, PhD, RN, of the UVA School of Nursing, Thomas M. Guterbock, PhD, of the UVA Center for Survey Research and Jonathan D. Moreno, PhD, who holds faculty appointments at both UVA and the University of Pennsylvania in Philadelphia, PA) have found that academic medical researchers who are highly reliant on industry support are most likely to have experienced questionable pressure from sponsors and to have first-hand knowledge of integrity breeches within their work environment. Those breeches not only compromise the well-being of medical research participants but also impact research initiatives, publication of results, interpretation of research data and scientific advancement.

Funded by the National Institutes of Health, through the Office of Research Integrity, the UVA study, **Prevalence of Industry Support and its Relationship to Research Integrity** was published in the March 2009 issue of *Accountability in Research* and marks the first attempt to acquire updated empirical data about financial arrangements and conflicts of interest between industry and investigators at academic research institutions.

The study was conducted via a survey mailed to 1,548 clinical and nonclinical researchers at the 33 U.S. universities that receive the most research funding. To encourage candor and protect anonymity, the survey did not ask respondents to report their own behavior. Rather, it asked about their first-hand knowledge of questionable research integrity practices in their institutions and departments. Findings which may be interest to our readers include:

Most prevalent forms of industry support - Sixty-six percent of respondents reported receiving industry support, the most prevalent forms of which were: research contracts or grants, honoraria, biomaterials, trips to professional meetings, support for staff or study coordinators, support for students or fellows, discretionary funds or gifts to the researcher's institution, equipment, funds for publication costs and personal gifts of more than \$100.

Questionable requests from industry sponsors – A minority of the 231 respondents funded by industry reported receiving questionable requests from their sponsors – 13 percent were asked to delay publication of research; nearly 8 percent were asked to present findings to favor a sponsor's drug or product; seven percent were asked to keep research secret; and, 4 percent were asked to withhold results from publication.

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However, the frequency of questionable requests was considerably higher among the 80 survey respondents who received several forms of industry support and rated that support as very or extremely important. Patti Tereskerz commented, "We found that 28 percent of these investigators had been asked either to withhold results, delay publication, present results more favorably or keep the project secret."

Questionable practices by industry sponsors - Only a small minority of survey respondents reported first-hand knowledge of questionable practices by industry sponsors, but knowledge of such practices was significantly higher among the subset of respondents who rated industry support most important. Within this group of 94 researchers, 25 percent had knowledge of sponsor-initiated publication delays, 17 percent knew about results reporting that favored a sponsor and 11 percent were aware of instances when sponsors had suppressed publication.

Compromises by colleagues supported by industry - Fifty-nine percent of respondents reported that colleagues within their department or work unit were receiving industry support. This group was more likely than respondents without colleagues supported by industry to have first-hand knowledge of delayed publication, results presented to favor a sponsor and suppression of results. This group attributed other integrity breaches to industry sponsorship, including compromises in the publication of research results, in the interpretation of data, in research initiatives and in scientific advancement.

Compromises to well-being of research participants – Of the

173 respondents with colleagues supported by industry, fifteen had first-hand knowledge that sponsorship had caused compromises to the well-being of research participants at their institution. Forty percent of these cases involved serious or significant well-being compromises.

"Although such compromises occur infrequently, our concern is that they occur at all," notes Patti. "There should be zero tolerance for compromising the well-being of human research participants in any study, regardless of how the study is funded."

Disclosure practices – Responses from 139 medical researchers indicate that many institutions do not require investigators to disclose their relationships with industry to research participants. Disclosure practices at such institutions vary considerably.

To read the essay, which addresses the most prevalent forms of industry support and how they might affect academic researchers, please follow visit Accountability in Research: <http://www.tandf.co.uk/journals/titles/08989621.asp>. (Portions reprinted with permission from the University of Virginia's Health Care System)◆

DSHEP 2010

The Center for Biomedical Ethics and Humanities, in cooperation with UVA's Office of Continuing Medical Education, is pleased to announce the **2010 Developing Skills for Healthcare Ethics Programs (DSHEP), March 17-19, 2010** at the UVA Jordan Hall Conference Center.

This three-day advanced program introduces different models of ethics programs, as well as of services that ethics programs provide, and enhances skills of those institutional representatives already serving in ethics programs. The program supplies tools to participants interested in identifying areas in their institutions where ethics programs might play a larger role. **Program registrants are expected to have already obtained the basic education expected of most ethics committee members.** The program's faculty and presenters include members of the UVA Center for Biomedical Ethics and Humanities and its affiliated faculty, the UVA Ethics Consultation Service, and ethics programs from other institutions.

Program registration will be limited to allow registrants to interact with colleagues and faculty. The cost of the program is \$650 per registrant. The fee includes breakfast and lunch on each of the three days, CMEs or CEUs, and conference materials.

This year the program will include a discussion of The Joint Commission's "Leadership" standard and associated performance requirements, and what they may mean for healthcare ethicists.

There are still a limited number of scholarships available, on a first come, first served basis, for representatives of institutions that were Virginia Healthcare Ethics Network (VHEN) members.

For registration or scholarship information, please contact Carrie Gumm at cg2b@virginia.edu, or 434-924-5695. ◆

Intensive Scholars Institute - 2010

This summer the Program in Ethics and Policy in Healthcare Systems will hold its fourth annual month long Intensive Scholars Institute. The institute seeks to attract young men and women who are interested in a career in the healthcare industry—either as physicians, nurses, administrators or lawyers—with the goal of initiating the development of a generation of leaders capable of identifying, clarifying and managing conflicting values in healthcare systems. Students meet and study in daily seminars focused on the moral issues confronting the health care system – and the conflicting values that have made forming a consensus on these issues so difficult. Students “shadow” physicians, attend weekly ethics consultation service meetings, as well as meet leaders from the research, business, academic and policy communities involved in healthcare. The diverse backgrounds and interests of its students, as well as the commitment of the Institute’s core faculty, have ensured the program’s continued success and enthusiastic endorsement by previous students. This year the Institute will take place from June 1 to June 27 at the Center for Biomedical Ethics and Humanities at the University of Virginia. More information can be found on the Center’s website or by emailing Patti Tereskerz, Director of the Program in Ethics and Policy in Healthcare Systems, at pjm7s@virginia.edu or by calling 434-243-6659. ♦

**Questions, comments
and items of interest**
should be sent to:

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