

# Health Advocates in Research

## A Participatory Conference

*We are here ... to promote and protect the rights of individual research subjects and to strengthen our voice as advocates for everyone who depends on the results of research to live a healthier life.*

—Marsha Hurst

*How do we talk to each other and how do we become more than the sum of our parts?*

—Gwen Darien

On January 14, 2005, more than 100 health advocates gathered at Sarah Lawrence College for a day-long participatory conference on “Health Advocates in Research.” This was the first in an annual series of conferences about current health issues and new arenas of advocacy. The conference celebrated the 25<sup>th</sup> anniversary of Sarah Lawrence’s pioneering Health Advocacy Program.

The organizing committee for the conference represented many different institutions and concerns. Attendees included advocates working in research settings; members of voluntary associations; advocates from disease-specific and issue-oriented organizations; advocates from government programs and institutions; educators; and the students, faculty, and graduates of Sarah Lawrence’s Health Advocacy Program.

The consensus of the planners was that the conference met a strong need for health advocates involved in research to exchange ideas and experiences, reflect, and envision the future. They decided to focus on two core questions:

- What are the roles of health advocates in research and what should these roles be?
- What ethical principles should guide our participation in research?

The morning sessions explored the roles of health advocates; afternoon discussions centered on ethical issues. At the end of the day, the major points that came out of



Gwen Darien

the conference were summarized by Ngina Lythcott, Dean, Mailman School of Public Health, Columbia University. Byllye Avery, founder of the National Black Woman’s Health Project, closed the day on a high note with a “Call to Action.”

### THE CONFERENCE IN CONTEXT

The growth in research involving human subjects has been explosive. More than 41,000 clinical trials are now conducted annually in the U.S.<sup>1</sup> and it is estimated that as many as 19 million people participate in these trials each year<sup>2</sup>. Almost every day, high-profile news stories lauding scientific progress in diagnosis and treatment share space with reports about misconduct in medical research—stories of falsification of data, conflict of interest, use of unethical financial incentives, plagiarism, violation of informed consent protocols and failure to report adverse events.

*All research subjects really want is to be able to trust the system. Because of the secretive and conflicting influences on clinical research, the average research subject has little hope of understanding and giving truly informed consent.*

—Paul Gelsinger

The explosion of scientific research promises improved health for millions of people. At the same time, more research means greater risk for millions of human participants. It is therefore not surprising that so many health advocates are becoming involved in protecting the rights of patients and the general public in research situations.

### Health Advocacy at Sarah Lawrence College

Twenty-five years ago, Sarah Lawrence College pioneered the field of health advocacy. The program educates graduate master’s-level students to become professional patient advocates and health advocates and plays a leadership role in defining and expanding the profession of health advocacy. [www.sarahlawrence.edu/health\\_advocacy](http://www.sarahlawrence.edu/health_advocacy).

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## ROLES ADVOCATES PLAY

Throughout the conference, attendees explored the variety of roles advocates play in research and offered examples from their own organizational work and individual experience.

At present, health advocates are working on research-related issues both from within and from outside the health care system. They work in disease-specific groups, clinical settings, research organizations, the media, oversight agencies and local communities.

*My view of advocacy is trying to give voices to the voiceless, give a face to the faceless.*

—Susan Matsuko Shinagawa

Advocates in research are finding more effective ways to safeguard human subjects and to educate patients, consumers and the general public. They formulate and reformulate research questions, design and redesign studies,



Susan Shinagawa, Karen Joy Miller

insure informed consent, monitor the protection of human subjects, oversee regulations and policies intended to safeguard research participants, assure public access to research results and increase researchers' accountability to the public.

The many roles of advocates in research can be divided into three broad levels: advocacy on behalf of individuals and families, advocacy on behalf of communities and advocacy on behalf of systems.

Just a few examples: Individual or family-level advocacy might involve protecting human subjects or facilitating access to a clinical trial. Community-level advocacy might assure communities a central role in formulating research questions or in gathering data. System-level advocacy could target reallocation of research dollars, legislation for a publicly accessible national databank of clinical trial information, or full disclosure of adverse events in clinical research.

## ETHICAL ISSUES

The afternoon discussions focused on the multitude of ethical issues that arise in clinical research: those that are endemic in the system; those that concern individuals, families, and communities; and those that are raised by the involvement of advocates themselves.

*Bioethics is an abstraction until it becomes a reality when it hits you personally.*

—Adil Shamoo

**Issues that are systemic.** All advocates, particularly those who work at a systemic level, need to keep in mind two fundamental and far-reaching ethical issues: First—though this point may seem obvious to many—we must remain vigilant about the financial stake that providers and funders have in medical research. Second and less obvious is the growing danger of a medicalized society in which screening, testing and certain interventions are rationalized as “risk reduction.” Speakers and participants explored examples of the public harm that results from medicalization. For example, the widespread prescription of estrogen for healthy women has now been shown to have been based on weak and incomplete research.

**Issues that concern others.** Conference participants raised a wide range of ethical questions regarding their work with patients, families and communities:

- How can we improve informed consent? It is especially important to educate prospective research subjects about the “therapeutic misconception” (the mistaken belief that the purpose of medical research is therapeutic and that the subject will necessarily directly benefit from participation).
- How do we ensure appropriate oversight of ongoing research trials involving human subjects? How do we monitor adherence to agreed-upon ethical standards or principles?
- How can we best protect the public against financial and professional conflicts of interest in research settings?
- How can we make sure that the best information possible—e.g., evidence-based medical information and complete information about drug trials—is accessible to patients and is guiding providers' decisions?

*Control of knowledge is a very big problem that we're dealing with right now. A lot of [study] results aren't published or made public in any way.*

—Kay Dickersin



Deborah Collyar, Sallie Bernard, Rachel Grob

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*Issues for advocates.* Advocates themselves also face numerous ethical issues in their work. For instance, some may overemphasize the value of medical research for possible future benefits as compared with the value of spending the same resources on improving access to existing medical care. Others may focus on short-term, tangible benefits of research without paying adequate attention to the need to build cumulative scientific knowledge. Sometimes, too, advocates allow their personal experience with disease to skew their perspective at the expense of the research needs of a broader community.

## SUMMARY OF THEMES

*Advocates are becoming key figures in decision-making about biomedical research—decisions that have important ethical and policy implications.*

—Rebecca Dresser

After a day of considering how advocates participate and should participate in research Ngina Lythcott, a health advocate and Dean of the Mailman School of Public Health at Columbia University, pulled together the day's discussions and compiled a list of nine major themes.

- 1. The importance of learning from history.** Health advocates need knowledge and understanding of historical health advocacy movements and of the history of the use of human subjects in research. This knowledge will keep advocates from spending time “reinventing the wheel” and will enable us to be better educators of future advocates.
- 2. The need for agreement about advocacy terms and concepts.** For example, the word *advocacy* evokes different pictures and models in people's minds. *Community*, and specifically diversity within the community, needs to be defined so that those in a specified “community” are not misrepresented. A clear definition of *research* enables advocates and others to decide whether a specific project constitutes research or not. (Some people call any form of study “research,” while others fail to identify as research such activities as analyzing the blood of newborns for genetic disorders.) *Availability* needs to be defined so that it is clearly differentiated from *accessibility*.
- 3. The value of having many different kinds of advocates.** Participants agreed that a wide variety of advocates brings a broader range of ideas to the table, enables different models of learning and action to be shared, enhances leadership development, and increases the passion for advocacy exponentially.
- 4. The costs of having many different kinds of advocates.** The wide variety of advocates can also create enormous competition for finite resources. Broadening the research agenda can divert attention and resources from specific needs and

concerns. In particular, competition can be created between advocates seeking prevention and those seeking treatment.

- 5. The importance of connecting personal stories to broader issues and movements for change within advocacy.** Lythcott encourages advocates to keep stepping back to widen their scope of concentration — for example, from personal story to all of breast cancer to all of cancer to whole-body health.
- 6. Development of guiding principles for advocates.** Among the values that need close consideration:
  - a. Balancing bottom-up with top-down advocacy;
  - b. making health care and health care information not just accessible but available, wherever possible;
  - c. recognizing the importance of humility and skepticism;
  - d. empowering individuals, communities and leaders;
  - e. practicing advocacy that is evidence-based;
  - f. encouraging full disclosure of research results.
- 7. The importance of gaining legitimacy for advocates.** Advocates should consider two questions when seeking legitimacy: Are advocates more powerful with more legitimacy? Are advocates more professional with more legitimacy? If we step back to a broader perspective on advocacy, we can increase our strength in the struggle for increased legitimacy.
- 8. The importance of building alliances, coalitions and partnerships.** It is critical for advocates to create relationships with a wide range of other advocates so we can educate each other and assist one another in moving shared agendas forward.
- 9. Thinking about what is next.** During the conference, many of the breakout groups raised the question, “How will we move to the coming together?” Some suggested using the 2005 conference and /or Sarah Lawrence College as the starting point.

## CONTINUING THE CONVERSATION

The conference ended with great energy and a commitment to continue the conversation that more than 100 participants had begun. Many voiced a clear need to be aware of the work of their colleagues in other research arenas and in other areas of advocacy and, potentially, to share that work. Networks or coalitions can help build knowledge about how to promote patient-centered research. Networking also facilitates potential alliances that can expand the pie rather than compete for slices.

*We can throw all the money in the world at cancer research, but if we don't change the way the system works and the mindset of the scientists who actually do the work, we're not going to make the progress that we want to make.*

—Deborah Collyar

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Besides networking and coalition building, conference participants felt it was important to be open in sharing and discussing ethical concerns, possibly with a view toward developing ethical principles for advocates in research. Conferees agreed that at the very least, openness about ethical concerns was important both for advocates and in the research arena itself.

There was general agreement, too, that advocates need to be leaders—not just in protecting the rights of research subjects, but in *promoting* the rights of research subjects and in encouraging research that addresses a broad range of health concerns.

Bylye Avery ended the conference with her compelling call to action:

*Put your energy towards helping to use the information that you've learned in your advocacy and in your specialty to help create a whole new system that helps meet the needs of everybody. We are our sisters' and brothers' keepers; we owe that to each other. We are all advocates: we have the power, and it belongs to us. So, take it!*

[Full Conference Proceedings are available online at [www.sl.c.edu/health\\_advocacy](http://www.sl.c.edu/health_advocacy).]

## UPDATES

### ETHICAL GUIDELINES FOR ADVOCATES IN RESEARCH

At the “Health Advocates in Research” Conference there was discussion among participants about the need to develop ethical guidelines for advocates in research. These guidelines or principles will be helpful to many: to advocates, who may find themselves in difficult situations that they could manage better if they had a sense of what their peer advocates felt was ethical in the circum-

stance; to the research community, who would be assured that advocate(s) they work with share a sense of ethical standards; and to the larger public, who — whether they become re-



Bylye Avery, Ngina Lythcott

search subjects or not — will have the assurance that advocates who become involved in research have addressed important ethical issues. A small group of advocates has indicated a willingness to work on this project, first gathering together any ethical guidelines that may already exist and then proceeding to draft and circulate proposed guidelines for ethical practice that can form the basis of on-going conversation and action. If this working group interests you, please contact Marsha Hurst at (914) 395-2371, [mhurst@sarahlawrence.edu](mailto:mhurst@sarahlawrence.edu).

### A CURRICULUM IN APPLIED RESEARCH ETHICS

Since the conference in January of 2005, Sarah Lawrence College has received an implementation grant from the Ford Foundation, through the Council of Graduate Schools, to develop a curriculum in “Applied Research Ethics.” This timely grant will be used to create curriculum and internship opportunities for HAP students, Human Genetics students and others in the health care field who are interested in careers as advocates in medical or health research arenas.

1 T. Abate, “Special Report: Experiments On Humans,” *San Francisco Chronicle*, August 5th, 2002.

2 A. Shamoo and F. Khin-Maung-Gyi, *Ethics of the Use of Human Subjects in Research* (NY: Garland Science Publishing, 2002), 197.

## CONFERENCE SPEAKERS AND PLANNING COMMITTEE MEMBERS

**Bylye Avery**, Founder and President, Avery Institute for Social Change; Founding President, National Black Women’s Health Project

**Sallie Bernard**, Executive Director, Coalition for Safe Minds; President, ARC Research; Executive Director, New Jersey Cure Autism Now

**Deborah Collyar**, President, Patient Advocates In Research and Program Director, SPORE Patient Advocate Research Team Program

**Gwen Darien**, Director, Department of Survivor and Patient Advocacy, American Association for Cancer Research\*

**Kay Dickersin**, Professor, Department of Epidemiology and Director, Center for Clinical Trials, Johns Hopkins University, Bloomberg School of Public Health and Director, U.S. Cochrane Center.

**Rebecca Dresser**, Professor of Law and Ethics in Medicine, Washington University School of Law\*

**Paul Gelsinger**, Vice President, Citizens for Responsible Care and Research (CIRCARE)

**Rachel Grob**, Associate Dean of Graduate Studies and Faculty, Health Advocacy Program, Sarah Lawrence College\*†

**Joyce Hunter**, Co-Director, Community Collaborative Care, HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University

**Marsha Hurst**, Director, Health Advocacy Program, Sarah Lawrence College\*

**Ngina Lythcott**, Vice Dean and Dean of Students, Mailman School of Public Health, Columbia University \*

**Abbey Meyers**, President, National Organization for Rare Disorders (NORD)\*

**Karen Joy Miller**, Founder and President, Huntington Breast Cancer Action Coalition

**Jane Nadel**, Consumer Advocate,\*†

**Maryann Napoli**, Associate Director, Center for Medical Consumers\*

**Barbara Seaman**, Women’s health advocate, journalist and author; Co-Founder, National Women’s Health Network

**Jane Baker Segelken**, Breast Cancer Advocate \*†

**Adil Shamoo**, Professor, University of Maryland School of Medicine; Co-Founder, Citizens for Responsible Care and Research\*

**Susan Matsuko Shinagawa**, Community Director, Asian American Network for Cancer Awareness, Research and Training; Co-Founder and Co-Coordinator, Asian Pacific Islander National Cancer Survivors Network

\*Planning Committee

† Health Advocacy Program graduate