

Health Advocates in Research

A Participatory Conference

INTRODUCTION

“Twenty-five years ago the Health Advocacy Program was started by hospital-based advocates who believed that promoting and protecting patients’ rights was a serious business deserving of serious professional study,” said **Marsha Hurst**, Director of Sarah Lawrence College’s master’s program in Health Advocacy, in her opening remarks. “We are here with a similar purpose: to promote and protect the rights of research subjects and—in a larger vision—to strengthen our voice as advocates for all, including ourselves, who depend on the results of research to live healthier lives. This, too, is a serious business deserving of substantive study, serious discussion, and continuing professional education.”

On January 14, 2005, in celebration of its 25th year, the Health Advocacy Program at Sarah Lawrence College sponsored a national conference, “Health Advocates in Research.” The conference goals were to consider two central 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?

Participants attended lectures and presentations at morning and afternoon plenary sessions, and breakout discussion groups. The Conference provided the opportunity for a diverse group of advocates—including students, researchers, academics, representatives from public and private organizations, and leaders of both grassroots and professional advocacy groups—to discuss the differences among their fields of interest, and how they might make use of these differences to collaborate most effectively to achieve shared goals. The conference encouraged dialogue about medical research issues and about what steps might be collectively taken after the conference. It promoted the formation of valuable connections among advocates and the development of shared ideas about the role of health advocacy in research.

Major themes and issues presented for discussion included: community participation in research advocacy and

clinical trials; ethics and conflicts of interest—particularly with respect to corporate and institutional funding; principles of truth-telling and transparency in advocacy in research; how advocates influence research at each stage of the process; cooperation and competition among advocacy groups; and responsibilities of advocacy groups to their constituencies and to the larger society.

FRAMING THE CONFERENCE

“Sarah Lawrence is in the fortunate, as well as difficult, position of being the only program in the country offering a master’s degree in Health Advocacy, and thus has the responsibility to take the leadership role in facing a challenge to define as well as help lead the field,” said **Gwen Darien**, Director of the Department of Survivor and Patient Advocacy at the American Association for Cancer Research. Planning for the conference began the previous year with discussions about how Sarah Lawrence’s Health Advocacy Program had transformed over time. What had started as almost exclusively a “one-on-one patient advocate educational program” now “encompasses a larger definition of advocacy,” Darien said.

Through her work as a cancer advocate, Darien said she realized that sometimes people don’t talk to each other even when they are dealing with similar issues. “We could all learn a tremendous amount from each other. And as befitting a Sarah Lawrence conference, you will learn as much from each other as from the people at the podium or on the stage.” She spoke also about how Sarah Lawrence, as the host of this conference, will be in the position to rally and bring together groups from across the spectrum of disease-specific and issue-oriented advocacy groups to have discussions about what individuals are doing in advocacy; how to help and learn from each other; and how participants can form coalitions to pursue mutual goals. In conclusion, she posed two interrelated critical and overarching questions to the diverse group of advocates at the conference: “How do we talk to each other? And how do we become more than the sum of our parts?”

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.

Health Advocates in Research: A Participatory Conference

KEYNOTE

Paul Gelsinger provided one answer to Darien's question through a description of his experiences and the advocacy work in which he has subsequently been engaged. He is currently Vice President of Citizens for Responsible Care and Research (CIRCARE) and is active in other organizations and committees to promote ethical research. In 1999, his 18-year-old son Jesse, who was diagnosed as a young child with Ornithine Transcarbamylase Deficiency (OTCD), died in a gene therapy experiment. Gelsinger has worked tirelessly to understand how Jesse's death occurred and to advocate for protection of human subjects in research. He was a working group member on informed consent for the National Human Research Protections Advisory Committee (NHRPAC), and is currently serving on the board of directors of Partnership for Human Research Protections (PHRP). Gelsinger has shared Jesse's story with audiences around the world in an effort to prevent what happened to Jesse from happening to others.

Gelsinger shared a few of the many violations of the informed consent process that he discovered while investigating Jesse's death.¹

- The clinical investigators painted a misleading picture of the safety and efficacy of their work. Their enthusiasm blinded them to the ill effects that they were witnessing and inhibited forthright communication with subjects (and their families), with the research institution's Institutional Review Board, and with the government agency (the FDA) that oversaw their work. Some of that "blindness," however, appears to have been intentional. Following Jesse's death, the University of Pennsylvania (U Penn) researchers continued to misinform Gelsinger about what they

knew, telling him only what would "keep him on their side."

- The Conflict of Interest Committee at the University of Pennsylvania failed to prevent conflicts of interest from compromising the integrity of the research process. The lead investigator, James Wilson, represented himself as an "unpaid consultant," but in fact he had substantial personal financial interests in the gene therapy trial he was conducting.
- The bioethicist who advised the clinical research team, Arthur Caplan, committed a serious error of judgment: He advised the researchers that since they could not obtain informed consent from the parents of dying infants, they should instead test the vector on relatively healthy carriers and partially affected OTC patients. This was a serious violation of the Declaration of Helsinki because it entailed serious risk with no benefit to the research participant. The institutional review boards and the Recombinant DNA Advisory Committee (RAC) also missed this ethical violation, and the consent forms did not make clear the actual situation with respect to risks and benefits.
- The study coordinator, who was the nurse who had acted as the informed consent witness when Jesse was first considered for participation in the clinical trial, resigned her position some ten days prior to Jesse's actual participation because of her own discomfort with how the trial was being conducted. She did not, however, act as subject advocate by making public her concerns. A more independent and persistent advocate may have helped put the brakes on the study.

In addition FDA investigation revealed specific protocol violations by the study's sponsors, who:

UPDATE: Settlement for the Jesse Gelsinger Case

On February 9, 2005, the government reached civil settlements for the Jesse Gelsinger case brought by the Justice Department against the research institutions and scientists involved. The settlements intend to cover the alleged false statements and claims made by the University of Pennsylvania and the Children's National Medical Center from July 1998 through September 1999.

The University of Pennsylvania (U Penn) agreed to pay \$517,496 and the Children's National Medical Center (CNMC) agreed to pay \$514,622 to the federal government to resolve the government's allegations. Additionally, the three named investigators, Drs. James Wilson, Mark Batshaw, and Steven Raper, currently have restrictive controls on their clinical research activities. The restrictions placed on Dr. Wilson are more severe given his primary role as sponsor of the clinical trial in which Jesse Gelsinger participated. The government determined that Wilson would not be allowed to lead any trials regulated by the Food and Drug Administration for five years and that he must have a designated monitor for any human research for three years. Batshaw and Raper have a three-year research restriction as a result of the settlement.

Paul Gelsinger said he is dissatisfied with this settlement. He wanted a public apology from Dr. Wilson as well as a release of all of the documents from the case. Gelsinger states in a CIRCARE press release:

We received none of what we asked for and therefore do not support this settlement. There will be no further legal action by the Justice Department in this matter, and the public should be dismayed that the responsible parties were let off so easily. In my conversations with the Justice Department it was evident that Justice does not have statutory authority to go after researchers for wrongful death or manslaughter charges. They are only able to pursue charges related to fraud. Congress needs to work on legislation that will give our national law enforcement agencies the authority they need to curb the type of behavior demonstrated by these researchers and their institutions.

Health Advocates in Research: A Participatory Conference

- did not adequately document the process of informed consent for some of the patients;
- did not submit to the FDA a report of the death of two monkeys in a similar study “in a timely manner” (the paperwork was filed Oct. 27, 1999, nearly a year after the animal study concluded);
- failed to halt the human study and immediately notify the FDA after two previous patients developed severe toxic reactions;
- did not have documentation for the training of study staff;
- failed to properly document the eligibility of all eighteen patients when they were admitted into the study. Eligibility forms were not developed until the fall of 1999, after Jesse’s death;
- included Jesse in the study even though the ammonia levels in his blood were too high to meet the eligibility criteria the day before the drug was administered;
- admitted Jesse to the study even though the protocol required that the next patient be a female.

The National Institutes of Health (NIH) bears significant responsibility for the ethical conduct of gene transfer research. Gelsinger discovered, however, that noncompliance with federal guidelines was widespread. In ninety clinical trials that used viral vectors similar to the one given to Jesse, fewer than 6 percent of nearly 700 required adverse event reports were filed with the NIH.

Gelsinger is concerned about the peer review process itself in terms of its ability to provide oversight on quality and ethical conduct of research. Conflicts of interest, for example, may prevent data about adverse reactions or other issues revealed by trial data from being published. “What is wrong is that a growing ambitious minority of researchers and institutions have compromised their ethics for profits and prestige, mostly as a result of industry’s inappropriate financial influence on them and our government,” Gelsinger said. “I still support our need for clinical trials, but with this caution: Informed consent is only possible if all facets of the research endeavor are ethical and in the open.”

Gelsinger concluded with a warning and a goal: “Because of the secretive and conflicting influences on clinical research, the average research subject has little hope of understanding and giving truly informed consent. All research subjects really want is to be able to trust the system.”

RESPONSE TO KEYNOTE

Adil Shamoo is a Professor at the University of Maryland School of Medicine and the Co-Founder of Citizens for Responsible Care and Research (CIRCARE). In response to Gelsinger’s personal story, Shamoo talked about the mission of CIRCARE, the advocacy group on whose board Gelsinger sits: to raise the ethical and professional levels of human subject research and medical treatment to those that are compatible with the principles that ought to be incorporated in the National Human Research Protections Act (NHRPA).

“Bioethics is an abstraction until it becomes a reality when it hits you personally,” said Shamoo, who co-founded CIRCARE because he had personally encountered violations of patients’ rights in research. CIRCARE brings the concerns of the informed public to the government’s attention. “We unearthed all these abuses, we testified in congress, we had hundreds of reports in newspapers, and we pushed the federal government to greater oversights.”

The three primary goals of CIRCARE are:

- to enact a national human subject protection act
- to require the majority of members on each IRB to be from the community from which subjects are recruited
- to improve adverse event reporting

Shamoo told the conference participants that there is a systematic failure to protect human subjects in research. “It will come as a surprise to you that if you do research with animals, 100 percent of all research, regardless of the source of funding, is regulated by the U.S. government.” He explained that this is not the case with human subjects, where 30 to 40 percent of research with human subjects is not regulated in any way.

Shamoo has written about the huge growth in the public and private research industries. “The pharmaceutical industry spends \$36 billion annually on research. This compares to nearly \$15 billion for NIH as recently as 2000.(NIH 2000).” In the past few years funding for NIH research has nearly doubled, from \$ 15 billion to \$ 30 billion. “This huge growth in human testing has really outpaced society’s ability to control it and oversee it. . . . The total number of human subjects enrolled in research in both the public and private sectors can be estimated as high as 19 million.”²

Shamoo concluded by saying that “good science and good clinical practice are compatible with sound ethical principles

“Adverse Events Reporting—The Tip of an Iceberg”³

- The overall number of human subjects enrolled in research is between 10-19 million per year.
- Deaths in the thousands are not reported every year.
- Adverse events in the ten of thousands go unreported every year.
- Research institutions bear the legal and moral responsibility for failing to report adverse events, including deaths, to authorities.
- The federal government (NIH, OHRP, and the FDA) bears the legal and moral responsibility for failing to provide enforcement of accurate reporting.

Health Advocates in Research: A Participatory Conference

that respect the rights and dignity of human subjects.” He warned, “If we don’t conduct clinical trials, desperate patients will put pills that are not tested in their mouths. . . . We need to pursue clinical trials. However, conducting them in an ethical manner is something we all as a society can and should do.”

MORNING PLENARY SESSION

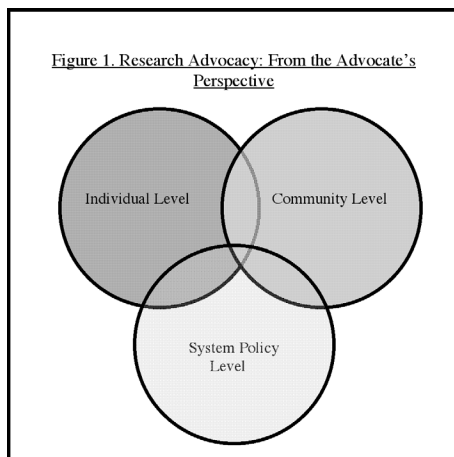
“To explore the many approaches to research advocacy and to examine their commonalities and differences.”

Rachel Grob began the morning plenary session by noting that, “As advocates, many of us move from our own experience with illness to a more organized advocacy effort. And we may go from this personal experience to a professional advocacy mode, or be taken there because of the many we know and love and are connected to who suffer from illness.”

Grob then presented a conceptual framework for research advocacy that she and Marsha Hurst had developed. She

explained that the framework was in draft form, and that they were seeking feedback about how it might be fleshed out.

The conceptual framework makes explicit and brings together the various interconnected levels that must be considered in terms of research advocacy.



Individual Level

Research advocacy from the advocate’s perspective requires thinking through ways that change is targeted at the individual level, including protecting individual human subjects and facilitating individual access to participation in research studies or to the results of research studies.

Community Level

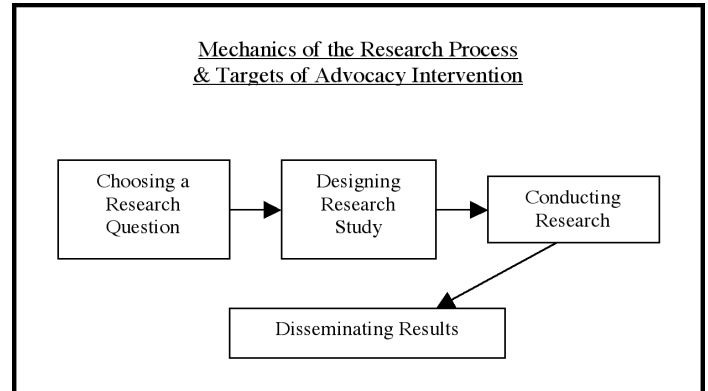
Grob explained this may mean enhancing the ability of the community to have input into the research process by, for example, enabling the community to formulate its own research questions. It is important for the community to have the resources necessary for this level of meaningful action and participation.

System Policy Level

As Gelsing and Shamoo exemplified during their presentations, the policy level needs to be a combination of individual experience and system-wide considerations. Grob said advocates need to address the existing system,

where those with most control over the research process are often also answering the demands of industry.

Next, Grob presented a broad conceptual view of the fluid, cyclical process of research advocacy.



Choosing a Research Question

Grob said that advocates need to think about the ways they can influence how research questions are selected, formulated, and conceptualized. She suggested a few important considerations advocates might keep in mind with respect to choosing a research question:

- What do we, as a society, think is important to research?
- Are we looking at prevention and causality as well as cure?
- Are we looking at research to benefit those who have been less empowered in the country?
- How do we, as advocates, gain and use influence?

Panel Participants

- Rachel Grob, Associate Dean of Graduate Studies and a faculty member of the Health Advocacy Program at Sarah Lawrence College. *Moderator.*
- Sallie Bernard, Executive Director of Coalition for Safe Minds, President of ARC Research, and Executive Director of New Jersey Cure Autism Now“
- Deborah Collyar, President of Patient Advocates In Research and Program Director of SPORE (Specialized Program of Research Excellence) Patient Advocate Research Team (PART) Program
- Joyce Hunter, Co-Director of Community Collaboration Core, HIV Center for Clinical and Behavioral Studies, New York State Psychiatric Institute and Columbia University
- Karen Joy Miller, Founder and President of Huntington Breast Cancer Action Coalition
- Susan Matsuko Shinagawa, Community Director of Asian American Network for Cancer Awareness, Research and Training, and Co-Founder and Co-Coordinator of Asian Pacific Islander National Cancer Survivors Network

Health Advocates in Research: A Participatory Conference

Designing a Research Study

Once the research question is formulated it is important to ask questions such as:

- Is it scientifically valid?
- Is it sensitive to the needs of the community?
- Is it something that is going to protect those who are involved as well as those who will gain from the results of the research later?
- Is the current standard of evidence-based research—the “gold standard” of the randomized controlled trial—the only acceptable standard for constructing scientific knowledge about health, illness and disease, or do we need additional ways of thinking about research as well?

Conducting and Monitoring Research

The next step is the actual process of doing the research, which involves consideration of:

- Who is involved?
- What are the conflicts of interest of those involved?
- How does the research team relate to the research subjects?
- Who might be there to advocate on behalf of research subjects as they navigate the process?
- Are there advocates of any kind who are present to guide the research subjects throughout the process, not just to witness the consent but to monitor safety and human subject protection, and to answer questions that arise?

Disseminating Results

In the process of releasing information about the study, a new list of concerns arises.

- Are advocates getting the results of studies out to policy makers and journalists?
- How might the publication process itself be biased and what can advocates do to correct that bias?
- What is required to be published and how do advocates help build capacity for others to disseminate findings widely and effectively?

- How does the process of critiquing results influence the formulation of new research questions?

Turning the session over to the panelists, Grob asked that each explain her own advocacy role; where her role might fit within the conceptual model just presented; and how her role might be different from and/or similar to those of other advocates.

Sallie Bernard, the mother of an autistic son, began the panel discussion by speaking about her role as Co-Founder and Executive Director of SafeMinds, an advocacy group started in 2001 to investigate the role of mercury in neurodevelopmental disorders such as autism. Its mission focuses on facilitating scientific research, parent support and networking, and regulatory and legislative remedies. SafeMinds has been instrumental in raising awareness of the dangers of mercury to children from all sources, but particularly from the mercury preservative thimerosal in infant vaccines and medical products given to pregnant women.

Bernard explained that research-related advocacy at SafeMinds involves:

- directly funding research
- promoting public access to relevant databases
- doing research studies
- functioning as a clearinghouse and resource center to connect scientists with each other, parents with scientists, and scientists with resources
- trying to “influence the influencers”

Bernard explained that SafeMinds focuses on the environmental causes of disease because “most diseases result from environmental exposure. . . . We try and see justice served for the plight of our children.”

Deborah Collyar has been involved as an advocate in research for many years, including her current work as President of Patient Advocates in Research and Director of the SPORE (Specialized Programs of Research Excellence) Patient Advocate Research Team (PART) program. PART helps SPORES (there are 56) work more collaboratively with patient advocates.

UPDATE

On February 17, 2005, HR881, the “Mercury-Free Vaccines Act of 2005” was introduced in the US House of Representatives by Dave Welson, MD (R-FL) and Caroline Maloney (D-NY). The bill, if passed, would “amend the Federal Food, Drug, and Cosmetic Act to reduce human exposure to mercury through vaccines.”

Sallie Bernard said about HR881: “Since 1999, SafeMinds has fought to get mercury, a known neurotoxin, out of vaccines, especially those given to children. This legislation will achieve this goal. SafeMinds appreciates the leadership that Representatives Dave Weldon, MD and Caroline Maloney have taken in introducing a bill to assure the removal of mercury from all vaccines. All scientific research points to the fact that mercury exposure has the potential to alter brain and immune functions, especially in the unborn and the very young.”

HR881 prohibits children under the age of three and pregnant women from receiving flu vaccines that contain more than one microgram of mercury beginning in the 2006-2007 flu season; the following year the age for children will be raised to six. By 2009, the cap on the maximum acceptable amount of mercury will be applied to all vaccines, including childhood, pediatric, adolescent, and adult. The legislation would urge the Centers for Disease Control and Prevention to actively discourage any medical professional from administering vaccines that contain mercury-based preservatives.

Health Advocates in Research: A Participatory Conference

How do SPORE Patient Advocates work?*

- Participate in research discussions and strategy meetings
- Ask results-oriented questions that help SPOREs focus on ways to move discoveries toward clinical applications for people
- Facilitate discussions among disparate scientific disciplines to create collaborations
- Serve on SPORE executive committees
- Help review small, “seed” grants that SPOREs can fund
- Help identify gaps and barriers in the research system, and facilitate discussions with federal agencies, national organizations, companies, and institutions to streamline the discovery-development-delivery process
- Learn why tissue is important to researchers and patients, and help researchers get what they need while respecting patients’ privacy
- Improve consent and collection processes involving human tissue
- Review surveys, instruments, consents, websites, projects, and cores
- Serve on local Institutional Review Boards
- Bring awareness of the SPORE program and its clinical trials to patient and community organizations
- Hold educational forums between patient & research communities
- Brainstorm on ways to improve the clinical trial system for participants
- Give input into clinical trial development and design
- Develop plans and tools that help explain clinical trials better

[*from http://spores.nci.nih.gov/part/index_part.html#patient_accomplishment; accessed 12-11-05]

SPORE is a “translational research” program, which funds research for a specific kind of cancer and then tries to turn scientific discoveries based on that research into something that can be used for patients. The goal of the SPORE program is “to bring to clinical care settings novel ideas that have the potential to reduce cancer incidence and mortality, to improve survival, and to improve the quality of life. Laboratory and clinical scientists work collaboratively to plan, design, and implement research programs that impact on cancer prevention, detection, diagnosis, treatment, and control.” Collyar said, “We [patient advocates] are conduits, connectors, and problem solvers.”

Collyar said she sees advocacy as a five-piece puzzle that includes:

- political advocacy
- fundraising
- direct patient support
- watchdog advocacy
- research advocacy

Research advocacy can touch on all of these pieces. “We want to be involved with the research,” Collyar said. “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—not just the principal investigators but also the people in the labs doing the work—then we’re not going to make the progress that we all want to see.” She often refers to the work advocates do with SPOREs in this way: “We’re infiltrating cancer centers all across the country.”

Patient advocates working with SPORES focus on the results end of the research: how can research results be improved, and how can they be made more useful for patients?

Joyce Hunter is Co-Director of the Community Collaboration Core at the HIV Center for Clinical and Behavioral Studies. “One of the things we have to remember about advocacy,” explained Hunter, “is that it really means empowerment.” The Community Collaboration Core has two goals:

- To initiate and sustain successful partnerships in order to conduct HIV prevention and treatment research and program activities related to sexuality, gender, and mental health that are of mutual interest and benefit to communities and researchers.
- To develop and disseminate theoretical models and methods that advance the science of the collaborative process in the field of HIV prevention and treatment, and may then be applied to other areas of health-behavior research.

She also explained that there are essential characteristics of community-based research.

- Collaboration, i.e., working together towards commonly valued goals. Communication between scientists and the public is essential in the advocacy field. “There needs to be a bi-directional exchange between the researchers and the community.”
- Participation, i.e., researchers and the community are equal stakeholders in the outcome.
- Action orientation, i.e., being driven by a mutual desire to create change that has a constructive impact on the quality of life within the community (in other words, empowerment).

The nine points that Hunter finds crucial to consider in advocacy are:

- entry
- a shared agenda

Health Advocates in Research: A Participatory Conference

- logistics
- patient privacy rights
- ownerships
- deliverables (i.e., researchers' needs, community-based organizations' needs)
- how the client is impacted
- remedies for problems
- an escape course

Karen Joy Miller, Founder and President of the Huntington Breast Cancer Action Coalition (HBCAC) calls herself a grassroots community activist and believes the main problem surrounding health advocacy is that "we are a reactive society at every level." She said that we need "to change society from becoming a reactive, pill-driven society into an active society."

In the late 1980s when Miller was diagnosed with the breast cancer, she was shocked because she was healthy and there was no history of cancer in her family. She went to her U.S. Congressman's office in Huntington, Long Island, to "find out what caused my disease if I did not have any of the known risk factors." She was looking for action and advocacy on the part of her Representative. To her surprise, the Congressman responded by contacting Miller within a few days and shortly thereafter holding Congressional hearings for the Long Island Breast Cancer Study Project.⁴

Reflecting on her role as an advocate, Miller said, "You engage people by saying, 'I care about you, this is my story, and we need to do [something] before people are dying. That's what I'm here to learn about, that's what I'm here to talk about."

Miller said she wants to be part of an integrated and caring society. "It has always been [HBCAC's] 'M.O.' that everyday you wake up and you say, 'what can we do in our community at the grassroots level to make a difference?' And what we have learned is to be really good listeners," Miller said. By listening, she said, you can find out what it is that the neighbors want to know.

The mission of the Huntington Breast Cancer Action Coa-

lition (HBCAC) is to focus on prevention methods while actively helping those who are faced with a positive diagnosis. Their focus on prevention is linked to an interest in the environment as it impacts on cancer. The Coalition strongly believes that "Prevention is the Cure,"⁵ and that the Precautionary Principle⁶ should govern use of potentially toxic substances.

"I didn't choose advocacy, advocacy chose me," said **Susan Shinagawa**, Community Director of Asian American Network for Cancer Awareness, Research and Training, and Co-Founder and Co-Coordinator of Asian Pacific Islander National Cancer Survivors Network.. Shinagawa was diagnosed at 34 with breast cancer. "My advocacy started out by just talking about my breast cancer." She had gone to a doctor who told her that Asian women don't get breast cancer, and that statement motivated her to focus her advocacy on cancer in the Asian American communities. She has been active as a breast cancer advocate not only with Asian communities but with communities of color and poor communities. Currently her focus is on health advocacy and the government's involvement.

Shinagawa agreed with Joyce Hunter, saying that the community must be informed before becoming involved in participatory research. "A community participatory approach is so important [as is] engaging the community before . . . you start doing anything. It has to be a real partnership and there has to be a level of trust and a level of respect."

In terms of Asians in America, she pointed out that 65 percent of the Asians are first-generation immigrants and that there are 35 different ethnicities and over 2,000 variations of languages and dialects. "Health literacy becomes very important," she said, explaining that in terms of language, it is important for those who don't read or speak English to have alternatives for health advocacy and education.

"The western biomedical paradigm is completely different from the eastern philosophic view," she said. "What we're trying to do now is to get more minorities into clinical

UPDATE

In the "President's Message" of the Huntington Breast Cancer Action Coalition's Spring 2005 Newsletter, Karen Joy Miller presents the New York State Breast Cancer Network's position on prevention:

"Mounting evidence reveals that toxic environmental exposures may be contributing to the rising rates of breast cancer and other chronic diseases. In the face of such evidence, preventing disease must become our highest priority. To do this effectively, we must identify the causes of disease and understand how to change the conditions that permit illness to occur.

"A growing recognition is emerging within the scientific community that health must be viewed as an integrated response of all body systems to the environment and that, in many cases, the interaction of toxic environmental exposures with our genes is directly related to the onset of disease. Indeed, many world renowned scientists now believe that cancers, birth defects, asthma, diabetes, Parkinson's disease, heart disease, neurodegenerative and developmental disorders, and autoimmune disease result from our exposure to adverse environmental agents. These researchers calculate that environmental exposures account for well over half of human cancers—perhaps as many as 80–90%....

"As an informed public, we must support environmental health research and disease prevention. Given the complexity of cancer and other debilitating diseases, the crawl to a cure remains illusory. Under these circumstances, preventing the start of such illnesses may well be the most practical and meaningful solution to dealing with such diseases. Indeed, the greatest gain in stemming illness and saving lives would result from the long overdue recognition that Prevention Is The Cure."

Health Advocates in Research: A Participatory Conference

trials; we're talking about changing the paradigm in this sense."

Shinagawa said she is working with her advocacy group to change the paradigm of consent and to deal with the language barriers. "My view of advocacy is trying to give voices to the voiceless, give a face to the faceless."

Morning Breakout Groups

AFTERNOON PLENARY PANEL

"To explore the ethical issues that confound⁷ us, and the principles that should guide us."

In introducing **Rebecca Dresser**, a lawyer and bioethicist from Washington University School of Law in St. Louis, Marsha Hurst told conference participants that Dresser's talk at Fordham Law School last year on research ethics had planted the seed for this conference.

Rebecca Dresser began the afternoon session with a presentation based on her study of advocates in research, from a bioethical standpoint.⁸ Dresser said one of her major interests has been research ethics and policy. HIV/AIDS activists of the 1980s set a model for all forms of health advocacy. "Many scientists began to regard HIV/AIDS activists as having valuable knowledge that should be considered in decision making about research, design, funding, and policy." Using the HIV/AIDS model of advocacy, other patient advocates became active in research arenas. "Advocates were becoming key figures in decision making about biomedical research, decisions that had important ethical and policy implications, but people in my field of bioethics weren't paying much attention to this."

Dresser's first concern about advocacy in research is "advocates don't always convey the uncertainties involved in research. There isn't always a clear distinction made between investigational interventions and accepted medical therapies, where the risks and benefits are more clearly known."

Panel Participants

- Rebecca Dresser, Professor of Law and Ethics in Medicine, Washington University School of Law. *Moderator*
- 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
- Paul Gelsinger, Vice President of Citizens for Responsible Care and Research (CIRCARE)
- Abbey Meyers, President of the National Organization for Rare Disorders (NORD)
- Maryann Napoli, Associate Director of the Center for Medical Consumers and writer of the CMC newsletter, *Health Facts*.
- Barbara Seaman, women's health advocate, journalist, author, and Co-Founder of National Women's Health Network

She perceives this to be a danger because when the distinction is blurred, people run the risk of enrolling in research trials without a good idea of the tradeoffs involved. She also thinks that advocates' focus on funding research for specific illnesses can impinge on productivity of research for other, broader health benefits. "Sometimes advocates imply that if we only get more money for more research we will develop a cure, a cure is inevitable. There is no question, of course, that research can lead to health care improvements, but almost always it takes many years and many false starts before effective practical applications become available." She said that this could take the focus away from helping those in need who are currently burdened by illness. "So sometimes we might question whether proportionate emphasis is placed on research, versus access to existing medical care."

Second in Dresser's areas of concern are the ways that advocates evaluate the quality of research and how that can influence their work as advocates. "The ultimate purpose of biomedical research is to produce concrete health benefits and this is what health advocates emphasize." She said this could be positive in that advocates can help keep scientists from becoming so immersed in their research investigations that they become detached from the desired health endpoints and forget about the people they are working to help. There is sometimes, however, also a negative side effect: "Advocates can become so caught up in this desire to produce concrete health benefits that they hinder the actual process of the research or at least make it more difficult. This is letting hope get the better of us." Efforts by advocates to lobby for clinical access to new investigational interventions that are still being tested may hamper enrollment in clinical trials to evaluate those interventions. "It's important to not get so focused on the desire to produce benefits for your constituents that the actual process of determining what is beneficial is hampered."

A third point that Dresser discussed was the uneven quality of abilities and expertise, as well as range of representative legitimacy of patient advocates. She said that many advocates have a close personal connection to the disease or group they represent because they or a relative or close friend has the disease. Some advocates become "lay experts,"⁹ gaining extensive knowledge about the scientific and medical dimensions of the relevant health problem. Others rely solely on knowledge acquired through personal experience with illness. Dresser explained that some advocates receive guidance from their constituents. Other advocates appear to take positions based primarily on their own assumptions about what would be best for patients. Dresser concludes that advocates vary in their abilities and qualifications to act as a particular group's representative when making research decisions and this can affect the ways they advocate, including leaving out some populations due to personal bias.

In addition, Dresser addressed the issue of fairness. People who don't have advocates representing them at the

Health Advocates in Research: A Participatory Conference

UPDATE: Fair Access to Clinical Trials (FACT) Act

Since the Sarah Lawrence Health Advocacy in Research conference in January 2005, the drug trial legislation that Kay Dickersin spoke about was introduced in Congress by Senator Christopher Dodd (CT) as a bill amending the Public Health Service Act to expand the clinical trials drug data bank. The Fair Access to Clinical Trials Act of 2005, or the FACT Act, was brought to the Senate in February 2005 with these purposes:

- to create a publicly accessible national data bank of clinical trial information comprised of a clinical trial registry and a clinical trial results database
- to foster transparency and accountability in health-related intervention research and development
- to maintain a clinical trial registry accessible to patients and health care practitioners seeking information related to ongoing clinical trials for serious or life-threatening diseases and conditions
- to establish a clinical trials results database of all publicly and privately funded clinical trials results regardless of outcome, that is accessible to the scientific community, health care practitioners, and members of the public

The FACT Act is currently sitting in the Senate Health, Education, Labor, and Pensions Committee (S.470).

In June 2005 the FACT Act was introduced in the House by Representative Henry Waxman (CA) as HR 3196. It was referred to the House Subcommittee on Health of the House Committee on Energy and Commerce in July 2005.

See <http://thomas.loc.gov> for updates.

table don't have a say when it comes to decision-making about policy and funding. "When officials and researchers consider only the views of advocacy organizations that are proactive" and have the funding, know-how, or persistence to be present, the people or groups without proactive advocates are under-represented. To correct that imbalance, Dresser thinks that it is important to provide education and financial support to those who don't have access and representation.

Having framed some of the ethical issues raised by the growing involvement of advocates in research, Dresser concluded by suggesting three ethical principles advocates should follow and three challenges they face.

Kay Dickersin¹¹ began her presentation by saying, "I want to call us, as advocates, to action." Dickersin defines her work in the field of evidence-based healthcare (EBHC) as the integration of the best research evidence with clinical expertise and patient values. She warned, "There is a threat to evidence-based health care and the threat is how our knowledge is controlled." Dickersin emphasized that knowledge is controlled by people and situations. The health care

industry manipulates information through:

- missing and biased evidence
- deliberate creation of misunderstanding, lack of understanding, and obfuscation
- lobbying for profit
- determining the research questions asked

Policymakers, providers, and consumers also control knowledge for their own benefit through both greediness (including taking money from industry either directly or indirectly) and complacency (including failure to become educated about new information from high-quality research).

"Control of knowledge is a very, very big problem," according to Dickersin. She gave two examples of knowledge control that she happened upon: a hotel door key with an advertisement for a drug printed on the key, and a taxi cab receipt with an ad for a drug, but with an existing FDA warning about dangerous side effects.

Dickersin's main interest is to get all clinical trials published and information about them public, with no exceptions. "We have a problem in that a lot of results aren't published or made public in any way. When participants

Ethical Principles and Challenges for Advocates, proposed by Rebecca Dresser¹⁰

Three Ethical Principles:

Advocates should

1. Be accurate and realistic when communicating with their constituents about research
2. Consider the educational and economic diversity of their constituents, including their ability to access information electronically
3. Reject parochialism—focusing on a single disease or population—in funding and policy work

Three Challenges:

1. Determining whether HIV/AIDS advocacy should continue as a model for research advocacy
2. Developing responses to growing industry-sponsored research
3. Formulating positions on new "exotic areas of research," such as stem cell research and xenotransplantation, areas that require an understanding of new scientific knowledge as well as of societal controversies over the new science

Health Advocates in Research: A Participatory Conference

agree to be in a clinical trial, they sign a consent form that almost certainly says, 'one of the benefits of your participation is that you will be contributing to medical knowledge.' If those results, or even the existence of the trial, aren't made public, then the participant isn't contributing to anything. That person's contribution is going down a black hole and we have a real ethical problem here."

Dickersin explained that federal legislation mandating trial registration is being proposed. [See insert, "Fair Access to Clinical Trials Act"] This is a start and important to support, but it is inadequate as it now stands because it focuses heavily on drug and device trials and does not consider the other types of trials.

Paul Gelsinger spoke earlier at the conference about his son Jesse's death as a result of ethical and legal violations in a clinical trial. As a follow-up to his morning presentation, Gelsinger said, "Back then I was dad and I was very involved in Jesse's care. I had great knowledge about his illness. I always wanted the best for him. I felt like I was always acting in his best interests. But I failed in that capacity when he entered that clinical trial because I didn't get all the information I needed. I trusted that the system was trustworthy, and it is not." Gelsinger said that not all of the guidelines for ethical research were followed in Jesse's trial, including those laid out in the Declaration of Helsinki. "Our system is inadequate and very conflicted right now," Gelsinger spoke in particular about the advocate who was supposed to be involved in Jesse's trial, and who left her job without telling the Gelsingers about the violation of ethical principles in the conduct of the trial. "I feel like it's our government's responsibility to come up with a program where advocates are available to oversee these clinical trials so that they are conducted ethically, so that when the stop signs are reached, there is somebody there to press that button that says, 'everybody stop.' And that program does not exist. We need something like that out there."

Abbey Meyers is President of the National Organization for Rare Disorders (NORD), an advocacy organization that was formed by a group of voluntary health organizations for rare diseases. These advocates banded together to promote legislation that would encourage drug companies to do research for rare diseases. Drug researchers had overlooked rare diseases because drugs developed for people who suffered from these diseases would not have a large market and would therefore not be profitable. This coalition passed the Orphan Drug Act in 1983, "and ever since then there's been an influx of very important breakthrough drugs for rare diseases, called orphan drugs," Meyers said. She describes NORD as a clearinghouse for information. The organization has an office in Washington, DC, and concentrates fulltime on public policy. NORD also helped pass an amendment to the User Fee Law for the FDA that requires all clinical trials to be registered and made public on a government-sponsored database. This became

ClinicalTrials.gov, but it included only clinical trials that involved federal funds. The pharmaceutical industry initially refused to participate in ClinicalTrials.gov. Meyers outlined five of what she perceives to be the most serious ethical problems:

1. **Different kinds of consumer groups represent different constituencies and have different and sometimes conflicting interests.** There are consumer groups that represent healthy people who have very common conditions, such as high blood pressure, high cholesterol, headaches, etc., and they want to lengthen the drug-approval process to ensure maximum safety. But there are also groups of consumers, like those represented by NORD, with very serious diseases who want their treatments to be approved by the FDA as quickly as possible. They are willing to take risks that are proportionate to the possible benefits. "The sick people want something different than the healthy people and that has a very intense political effect on the public servants in government, especially the FDA."
2. **Therapeutic misconception.** "You can say anything you want to a family that is sitting through an informed consent session about not expecting to personally benefit from whatever they are testing, but the only reason they are going into the trial is because they expect to personally benefit." Meyers feels that the public perception of research reinforces false hopes, primarily because the press writes about research successes and omits the failures.
3. **Conflicts of interest.** Meyers described the various conflicts of interest that involve all aspects of clinical trials. Not only are there obvious conflicts with the investigators, but also IRBs and research institutions have built-in conflicts of interest because they want to attract drug-company funding. The IRBs are reluctant to be too tough for fear that the researchers may be denied funding from the pharmaceutical industry. "I wish there were a way to keep the IRB from being composed of staff at the institution," Meyers said. She pointed out that until a year ago, the FDA—the only entity that regulates privately funded research—didn't have a bioethicist on staff. Even support groups can have conflicts of interest because they can get immersed in their personal battles and lose sight of the overall cause.
4. **Lack of enforcement mechanisms.** "There's no way to punish anybody who violates human protection rules," Meyers said. She re-emphasized the point Shamoo made earlier, that there are very good laws to protect animals who are subjects in research studies, but no laws—only regulations—to protect humans.
5. **Difficulty in rising above personal interests to represent the whole group in coalition work.** It is difficult to train people who are doing advocacy out of the goodness of their heart, but who are focused on one disease because they desperately want their families to benefit. "A lot of people become arrested at that initial stage of

Health Advocates in Research: A Participatory Conference

lobbying for their own family member,” Meyers said, emphasizing that people need to lobby for principles affecting all diseases, not just the one that is of personal interest.

Maryann Napoli has an investigative reporter’s view of the medical care system and how it seems bent on making us all into patients. She began her presentation by noting, “We have an entrepreneurial health care system that’s all about making us feel like we could get sick, that we’re just a walking bundle of risk factors.” Napoli writes the newsletter *HealthFacts* for the Center for Medical Consumers, a non-profit advocacy organization founded in 1976. Its mission is to encourage people to consider the supporting research when making medical treatment decisions. The Center has chosen to concentrate its efforts on hospital patient safety and informing the public about the potential harms associated with excessive medical care. “We have been slowly sold the idea that healthy people should be tested and monitored and that’s the way to stay healthy. So I do see this as an enormously important ethical issue,” Napoli says.

Napoli addressed the problems of randomized controlled trials, saying that there are many influences that have corrupted these trials. “The danger, of course, is that people will take risky drugs that can’t benefit them.” Inappropriate testing often leads to inappropriate lifelong drug therapy, Napoli said, and she reminded people of the recent media attention given a clinical trial concerning the C-reactive protein test for heart disease. The newly published trial did show a benefit to giving people the CRP test, but the benefit was only observed in people with severe heart disease. Yet the lead author was quoted all over the media, saying, “This test is better than the cholesterol test,” implying that even people without heart disease should be given the test. If the test were given to everyone, regardless of whether they had heart disease, said Napoli, then many more healthy people would take cholesterol-lowering drugs for the rest of their lives. The lead author, it turns out, had a major conflict of interest. He co-owned the patent to this drug, but this fact was printed in small type at the end of his published study in the *New England Journal of Medicine*. Unfortunately, most of the media reporting his overly optimistic comments neglected to mention this conflict of interest. One notable exception was the *New York Times*, whose reporter noted his conflict each time she quoted him. Napoli saw this as a small victory for consumer advocacy. “As far as I know, only one other consumer advocate besides me had complained to the *New York Times* several months beforehand about not mentioning doctors’ conflicts of interest in their reporting, especially when they are quoting experts who appear to be neutral because of their university affiliation.”

Another problem Napoli discussed is withholding information about serious adverse effects in published drug trials that are sponsored by drug companies. She learned that few trials adequately report the seriousness of the adverse ef-

fects. “In a medical system where we’re encouraging millions of healthy middle-aged people to take cholesterol-lowering drugs, we’re not informing them of the adverse effects.” The fact that data about serious adverse effects has not been reported should be noted prominently in the abstracts of medical journal articles, which is only part of the study but is the part that most people read because it is freely available in medical databases such as Medline. Napoli gave one example of how this information can be “buried” even when acknowledged. In one review of all cholesterol-lowering drug trials that included women, the authors concluded that the drugs had a benefit to women with heart disease but not to healthy women without heart disease. “How, I ask you, can these authors come to any conclusion when they’re working with incomplete data, when they give just one sentence to note a crucial point, and they place it in the “discussion” section, which is at the end of their review of all trials?”

“Troubled as I am about trusting the information from clinical trials,” she said, “it is our mission as consumer advocates to keep medical researchers honest, to point out these glaring omissions, and to critique these studies for our respective constituencies.”

Barbara Seaman is a women’s health advocate, journalist, and author who “pioneered efforts to allow women to take control of their own health care decisions.”¹² She is also Co-Founder of National Women’s Health Network, founded to be the “eyes, ears, and voice of the female patient.” The Network is an activist organization that aspires to a health care system that is guided by social justice and reflects the needs of diverse women. The organization is supported by its grassroots membership and, as part of their ethical foundation, accepts no money from pharmaceutical or device manufacturers.

“The very idea of giving healthy people a drug to take for long term that hasn’t been tested long term is in my view a triumph of marketing over science,” Seaman said. She discussed two ethical issues, selective disclosure and informed consent, through events she documents in her newest book, *The Greatest Experiment Ever Performed on Women: Exploding the Estrogen Myth*.¹³ “I particularly wrote this book for advocates because I hoped it would give some clues that would stay in their mind about what to look for when we’re being snookered.”

Regarding selective disclosure, Seaman talked about a randomized research trial done in the early 1980s for Premarin, an estrogen drug for menopause. The trial tested the drug’s efficacy in preventing osteoporosis in three groups of women: one group was given a low dosage, one a higher dosage, and one a placebo. The group with the highest dosage of the drug had the lowest bone loss of the three groups. However, the women in the study were all young women in their twenties, thirties, and early forties, who were still

Health Advocates in Research: A Participatory Conference

menstruating when they had their ovaries removed during hysterectomies. Not a single woman in the study was a woman going through natural menopause.¹⁴ “You have to be very careful when you hear any study ballyhooing the long-term use of any drug. You have to be very careful of missing elements,” Seaman said, and argued that people should look into the original studies themselves, the pros and cons, the possible conflicts of interest, before getting involved or taking any kind of long-term drug.

Seaman illustrated a problem with informed consent and full disclosure by telling the story behind the extension of warning information, which was first presented with birth control pills (since 1970) and then with other estrogen products (in 1977), to all prescription drugs. In 1996, when the National Women’s Health Network, arguing for patient inserts for all prescription drugs, and the AMA, arguing against this full disclosure to patients, presented their arguments to the FDA, the AMA acknowledged that their opposition had nothing to do with the value of full disclosure for FDA-approved use. “The reason that the AMA and drug companies are opposed to the full disclosure of patient labeling is that 40 to 60 percent of prescriptions are written for off-label prescriptions—that is, prescriptions not approved by the FDA,” Seaman explained. If there were packets warning, for example, that “this drug has been *approved for*,” or “this drug is *under study for treating*” or “this drug has *not been proven for* or *has not been approved by the FDA for*,” then there would be a huge drop in patients willing to take the drug, and, according to the AMA, there would be a huge increase in lawsuits because the patients would know they were being given drugs that are off label.

Afternoon Breakout Groups

WRAP-UP

Ngina Lythcott, Vice Dean and Dean of Students, Mailman School of Public Health, Columbia University, and breast cancer liaison for the Black Women’s Health Imperative (formerly the Black Women’s Health Project) gave a wrap-up that summarized and tied together the issues that were raised at the conference. She considered what was presented through the morning and afternoon plenary sessions as well as what was discussed in the breakout groups. Lythcott compiled a list of nine points of concern, interest, and activity that were predominant themes of the conference.

- 1. Knowing and understanding historical health advocacy movements and 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. Using clearly defined and commonly understood advocacy terms.** 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. Recognizing and valuing the wide range 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. Understanding the “costs” of having a wide variety 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. Connecting personal story driven advocacy to a broader health or wellness driven 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 and wellness.
- 6. Developing guiding principles for advocates.** Among the values that need to be more closely considered:
 - a. Balancing bottom-up with top-down advocacy
 - b. Making health care and health care information are not just accessible but available, wherever possible
 - c. Recognizing the importance of humility and skepticism
 - d. Empowering individuals, communities and future leaders
 - e. Practicing advocacy that is evidence-based
 - f. Encouraging full disclosure of research results
- 7. Gaining legitimacy as 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 gain numbers and increase our strength in the struggle for increased legitimacy.
- 8. 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

Health Advocates in Research: A Participatory Conference

using the 2005 conference and/or Sarah Lawrence College as the starting point.

CALL TO ACTION

Billye Avery, who founded the National Black Women's Health Project in 1981, has been a women's health care activist for over 25 years. Avery gave the "Call to Action" at the end of the conference to wrap up the day on an inspirational note and to motivate participants to push forward. As with many of the speakers throughout the day, Avery brought up the issue of trust and asked, "Whom do we trust?" and "How do we regain or build trust?" She went on to agree with Lythcott that terms need to be defined more clearly, asking, "What does consumerism mean when we say health is a human right?"

Avery argued that advocates may be beyond "fixing" the system. "I think this system is so messed up that there is no more fixing, the band aids are falling off We have 45 million people without health insurance—and increasing; how many of us can sit around and allow that to happen? Most of us are only a job away from being uninsured."

What advocates must do, said Avery, requires a rebuilding process. "The only way we all can reach the other side

together is we have to absolutely dismantle this health care delivery "system" that we have. We have to create a new one, and it has to be something that is created using all that we know here [the conference]."

Avery challenged the audience to "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. Be ready, because the grassroots movement is coming." She reiterated Lythcott's encouragement to step back to a level that reveals the potential connections among more people, and added, "We need to go back and establish who we are. That means we have got to have a mass mob consciousness change. Our heads have to change around. I don't know how that's going to happen and I don't know what that act is that's going to get things going. All I know is that it's going to happen," she said, then referred back to her earlier example of Rosa Parks' activism during the Civil Rights movement. "You might not know what you're going to do, but make a commitment to doing something," she urged. "We are all advocates and what we have to do is just know within ourselves that we have the answers, we have the power, and it belongs to us. So, take it!"

Notes

¹ Portions of this section of Gelsinger's talk can also be found in *Jesse's Intent* by Paul Gelsinger. <http://www.wramc.amedd.army.mil/departments/dci/downloads/Tri-Srv-CI-May02/Jesse's%20Intent..doc> <accessed September 22, 2005>

² "Adverse Events Reporting—The Tip of an Iceberg" published in 2001 in *Accountability in Research* 2001: 8(3):197-218.

³ Ibid

⁴ <http://epi.grants.cancer.gov/LIBCSP/> <accessed September 22, 2005>

⁵ <http://www.preventionisthecure.org/> <accessed September 22, 2005>

⁶ The Precautionary Principle, as formulated at Wingspread (Racine, WI) in 1998 states: When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. In this context the proponent of an activity, rather than the public, should bear the burden of proof. [http://www.biotech-info.net/rachels_586.html; accessed December 11, 2005]

⁷ One panelist felt that these issues that "confound" us are also the issues that confront us, and must be faced.

⁸ See Dresser's book published on this subject, *When Science Offers Salvation: Patient Advocacy and Research Ethics* (Oxford, 2001).

⁹ For an in-depth discussion of "lay experts" in advocacy, see Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (University of California, 1998).

¹⁰ Adapted from her conference presentation and the recommended conference reading by Dresser, "Patient Advocates in Research: New Possibilities, New Problems," Washington University Journal of Law and Policy (2001) <http://law.wustl.edu/journal/11/p237Dresserbookpages.pdf> (accessed September 25, 2005)

¹¹ At the time of the conference, Kay Dickersin was Professor, Department of Community Health, and Director, U.S. Cochrane Center, Brown University.

¹² Carolyn B. Maloney, *Congressional Record*, October 17, 2005.

¹³ *The Greatest Experiment Ever Performed on Women: Exploding the Estrogen Myth* (Hyperion, 2003).

¹⁴ Harry Genant, MD et al, "Quantitative Computed Tomography of Vertebral Spongiosa: A Sensitive Method for Detecting Early Bone Loss after Oophorectomy," *Annals of Internal Medicine*. 1982 Nov; 97 (5):699-705.