GENETIC ALLIANCE MONOGRAPH SERIES NUMBER 1

GENOMICS, CANCER CARE & ADVOCACY

Terry, SF, Genetic Alliance

Zeitz, K, Arizona Breast Cancer Coalition

Majumder, MA, Baylor College of Medicine

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PUBLISHED BY GENETIC ALLIANCE

Genomics, Cancer Care & Advocacy

Published by: Genetic Alliance, 4301 Connecticut Avenue, NW, Suite 404, Washington, DC 20008

ISSN 1933-4168

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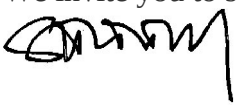
Preface

I am excited to launch this monograph series–designed to give access to the incredible work of disease-specific advocacy organizations. The face of advocacy is changing—as these organizations revolutionize translational research and service delivery on all levels and in all venues, the need for increased communication, sharing of current best practices and 'how-to' guides drives our decision to begin this monograph series.

This monograph describes the Genomics and Cancer Care and Advocacy Workshop, which formulated a proactive plan for advocacy involvement in the application of genomics into cancer care. Many people worked to make the workshop a meaningful and productive event, and have subsequently executed on the many recommendations. Genetic Alliance is particularly grateful to Patrick Terry, Director of Advocacy, Genomic Health; Kathleen Zeitz, Arizona Breast Cancer Coalition, Mary Anderlik Majumder, Baylor College of Medicine, and Kathy Hudson, Genetics and Public Policy Center, for their thoughtful planning, organization and support.

We also thank these organizations for their participation in crafting the recommendations:
Alliance for Lung Cancer Advocacy, Support, and Education
The Children's Cause, Inc.
Facing Our Risk of Cancer Empowered (FORCE)
Inflammatory Breast Cancer Research Foundation
Marti Nelson Cancer Foundation
National Alliance of Breast Cancer Organizations
National Breast Cancer Coalition
National Coalition for Cancer Survivorship
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Patient Advocates in Research (PAIR)
Research Advocacy Network
Self-Help for Women with Breast or Ovarian Cancer (SHARE)
Sisters Network, Inc.
The Leukemia and Lymphoma Society
The Wellness Community
US TOO! Prostate Cancer Support Groups
Y-ME National Breast Cancer Organization
Young Survival Coalition

We invite you to share this monograph!



Sharon F. Terry, MA
President & CEO, Genetic Alliance
Washington, DC
16 November 2006

In the past several decades, oncologists and cancer researchers have come to recognize the importance of the role of advocacy organizations in cancer research and treatment. With genomics poised to become a major force in cancer care, advocacy organizations have an important role to play in traditional areas of concern such as patient education about new genomic technologies. Advocacy organizations also have the potential to serve as partners with clinicians, researchers, policy makers and others in developing an agenda for further research, creating guidelines for practice, and working for the passage of legislation to address problems such as genetic discrimination. With this in mind, we organized a workshop on Genomics, Cancer Care and Advocacy, with the sponsorship of the Genetics and Public Policy Center at John Hopkins University and Genetic Alliance. This report provides an overview of the workshop content and the proactive plan for advocacy involvement developed by participants. Participants in the Genomics and Cancer Care and Advocacy Workshop formulated a proactive plan for advocacy involvement in cancer care.

Representatives from patient advocacy organizations, drug companies, academia and policy institutes worked to develop a comprehensive set of action steps that can capitalize on the value advocates have to offer in the translation of basic science to services. The morning session included an overview by Francis S. Collins, M.D., Ph.D., Director of the National Human Genome Research Institute, National Institutes of Health, on the directions of research in genomics; a presentation by Nicholas Dracopoli, Ph.D., Vice President, Clinical Discovery Technologies, Genomics, Bristol-Myers Squibb, on the potential uses of biomarkers in refining and facilitating treatments; and a discussion by Janet Warrington, Ph.D., Vice President, Molecular Diagnostics and Emerging Markets Research and Development, Affymetrix Inc., on the fundamental need for standardization of new tests and assays used in this new era of genomic medicine.

The afternoon session included more specific presentations and the establishment of action plans in key areas such as education, collaboration, and best practices. Daniel Hayes, M.D., Professor of Internal Medicine at the University of Michigan and clinical director of the Breast Oncology Program at the University of Michigan Comprehensive Cancer Center, gave his perspective as a clinician on realistic expectations for genomic medicine. Sharon Terry, M.A., President and CEO of Genetic Alliance, reported her perspective and experience as an advocate with interests in

genomic medicine, while Kathy Hudson, Ph.D. Founding Director of the Genetics and Public Policy Center, Johns Hopkins University, elucidated policy challenges and opportunities in the era of genomic medicine that are ripe for the intervention of disease advocates.

The Application of Genomic Discoveries to Human Health

The National Human Genome Research Institute (NHGRI) developed a vision for the future of genomics research over the course of 18 months and included advocates in many meetings.(1) This blueprint covers three areas of focus: biology, health, and society. Six critically important crosscutting elements are relevant to all three thematic areas: resources; technology development; computational biology; training; ethical, legal and social implications; and education. In the *Nature* article describing this vision, 15 challenges were proposed that, if accomplished, would revolutionize the way disease is understood, treated, and indeed, prevented. In the presentation that opened the workshop, NHGRI Director Francis Collins highlighted the challenges that were particularly relevant to cancer care:

Genomics and Biology

Knowing the full sequence of the human genome is useful only in as much as it can become a tool for better health. Building upon the foundation laid by the Human Genome Project, an international consortium led by NIH is creating a map of common human genetic variation, called haplotypes, which will speed the search for genes involved in common, complex diseases, such as cancer, diabetes, and heart disease. Collins said the International HapMap Consortium, like the Human Genome Project, is making all of the data publicly available to researchers around the world.

Genomics and Environment

It would be helpful to identify how genetics and the environment interact to increase the risks of common diseases, including cancer. Collins drew specific attention to how the retrospective case-control studies traditionally used for these sorts of analyses have built-in bias related to participants' selective recall. It would be more reliable to have access to large-scale prospective cohorts that could be followed over the course of many years. Even better still would be to have one very large cohort study in the United States that would gather information on the genetic and environmental factors involved in all major diseases,

including cancer. Such a study would also permit observation of interactions between diseases. While Collins said he thinks that such a study would be extremely informative, he cautioned that there would be many logistical problems to solve beforehand.

Genomics to Society

Collins described the need for federal genetic anti-discrimination legislation as particularly urgent. Without uniform, national protections against genetic discrimination, it is difficult to enroll enough participants into research studies involving genetic testing. Collins urged advocates to wisely use their considerable clout in pressing for the passage of such legislation

In closing, Collins pointed out that the new NIH Roadmap for Medical Research (2) strongly supports public-private partnerships – including advocacy efforts – and he is excited about these partnerships accelerating the future of genomic medicine.

Clinical Applications of Genomics

Nicholas Dracopoli, Bristol-Myers Squibb, spoke from an industry drug development perspective. He described a biomolecular level approach, particularly with regard to the issue of molecular profiling (3). Several steps are involved when a normal human cell becomes malignant. Molecular profiling involves the recognition of molecular patterns that consistently identify certain pathways of changes that result in malignancies. These molecular patterns can then be used as markers for identifying abnormal cell changes very early on in the malignant process.

Optimal dose selection

Traditional approaches to identifying the dosages for cytotoxic drugs are ‘tolerance’ based, i.e., the maximum tolerated dose is identified in exploratory clinical studies. Tolerance, however, does not correlate directly with optimal efficacy. Using a molecular approach, the effectiveness of a particular drug dose or schedule can be determined directly from monitoring the changes at a molecular level – the level at which the drug exerts its effects. In this way, it may be possible to identify a biologically effective dose at which the drug is having its full effect below the maximum tolerated dose. This lower biological dose could be

used to treat patients effectively while reducing some of the side effects encountered at the higher maximum tolerated dose.

Biomarkers and Surrogate Biomarkers

If a drug is presumed to interrupt a particular molecular pathway, measuring its effect directly on this pathway will provide effectiveness information well in advance of any clinical applications. Following on from that, biomarkers that correlate with the molecular pathway targeted by that drug would serve to identify those patients who would respond to the particular drug and those who would not based on whether the particular biomarker is present in the tumors. Thus it will be possible to predict responsiveness to therapy even before therapy is given. Biomarkers and surrogate biomarkers (surrogate biomarkers are alternative endpoints that may be gathered in a shorter timeframe or evaluated with more confidence) could provide means of measuring the impact of a new drug in the actual clinical situation.

Targeted Therapy

Profiling technologies can potentially be used in predicting diseases early, and this could translate into improved therapeutic potential. The idea of 'targeted therapy' at a molecular level is that the therapy is "aimed" at patients with a molecular "target" involved in the development of the tumor. These targeted therapies are likely to have fewer side effects as the drug's effect is specifically aimed at molecular changes in the tumor cells and will largely spare normal cells which do not have these changes.

Translation of Basic Scientific Genomic Knowledge into Practical Clinical Use

Janet Warrington, PhD, Vice President, Emerging Markets and Molecular Diagnostics Research and Development for Affymetrix Inc., explained that many steps are involved in the translational process.

Basic Scientific Developments

Warrington used the example of B-cell lymphoma to illustrate how the measurement of gene activity (RNA) could be useful. Researchers used gene expression arrays to measure differences in molecular activity in lymphomas from different patients. Eventually distinct

gene expression patterns can be identified that distinguish lymphomas into different types based on differences in the oncogenic mechanisms underlying an individual's disease. From this information, patients could be sub-classified into those expected to have better and worse responses to treatment and those expected to have better and worse prognoses. Affymetrix is working with a diagnostic company, Roche Molecular Systems, to develop these findings into a diagnostic tool that can be used in clinical practice.

The actual reading of the DNA sequences is important in identifying DNA variants that are associated with specific conditions, or simply with susceptibility to some conditions. The 0.1% differences in DNA sequences between two people could have significant effects on how people respond to their environments. Drug metabolism is one example of this. Genes involved in the cytochrome P-450 pathway are involved in drug metabolism and variants in these genes have implications for drug dosing, hence affecting drug efficacy and side effects. Affymetrix has developed, with Roche Molecular Systems, a cytochrome P-450 array that is still only a research tool.[†] Large-scale studies will be required to ascertain the reliability and usefulness of this tool.

Standardization Issues

Dr. Warrington emphasized the need for standardization and the developments of standard controls and best practice guidelines in order to move discovery research to clinically useful applications. The External RNA Control Consortium is a concerted effort involving more than 50 organizations, including the National Cancer Institute (NCI), the Food and Drug Administration (FDA), the National Institute of Standards and Technology (NIST), the US Department of Agriculture (USDA), many microarray and reagent manufacturers, and diagnostic and pharmaceutical companies. The goal of the Consortium is to develop a common reference set of external RNA controls, protocols and analytical tools for use in expression assays (http://www.affymetrix.com/community/standards/index.affx.)

Policy Issues

Affymetrix supports public education about genetics. It is also interested in exploring consumer needs. Advocacy groups have important functions in both activities.

[†]Late in 2004, the FDA approved this array for clinical use.

> Further, the company supports genetic nondiscrimination legislation as well as government engagement in funding for translational research. Moreover, the company believes that basic scientific information should be freely available to researchers in order to ensure scientific progress (http://www.affymetrix.com/corporate/outreach/ethics_policy/ethics_policy.affx).

With regard to the role of advocates, Warrington expressed her view that public education and correcting misinformation are areas in which advocates have been very useful. She also thought that advocates could be very useful in promoting the Genetic Information Nondiscrimination Act, which is currently pending in Congress.

Clinical Genomic Medicine

Daniel R. Hayes, MD, Professor of Internal Medicine at the University of Michigan and Clinical director of the Breast/ Oncology Program at the University of Michigan Comprehensive Cancer Center shared his perspective, as a clinician, on genomic medicine. His concerns essentially revolve around how information is translated into clinical usage. Contrary to some scientists' vision of a future when cancers are viewed as molecular pathway changes rather than organ specific entities, Hayes believes that organ-specific management of cancer is unavoidable.

For Hayes, tumor markers define risks – risks of being more susceptible to developing a cancer, or to developing recurrent disease. So tumor markers could be used to screen at-risk populations for the purpose of either providing earlier treatment, or closer monitoring.(4)

Hayes reported that while molecular imaging is exciting, thus far, the American Society of Clinical Oncology's patient guide only recommends use of a few tumor markers to assist providers in trying to make meaningful treatment decisions.

Using breast cancer as example, Professor Hayes went on to propose that breast cancer mortality reduction in recent years has much to do with the use of systemic treatment. However, it is not going to be similarly efficacious in every patient and not every patient would need it to reduce disease recurrence.

Prognostic factors give an indication of how likely the cancer is to recur independent of therapy. By grouping patients into different prognostic groups, clinicians could tailor their recommendations to patients concerning therapy based on the likelihood of benefit. However, the magnitude of benefit might be perceived quite differently by different patients, to the extent that some might be willing to accept significant toxicity from therapy in return for a rather insignificant magnitude of benefit.(5)

Predictive factors, on the other hand, predict if a therapy is likely to work and are particularly useful in deciding on the type of therapy that might be suitable.

For genomic medicine to be genuinely useful, it must be able to identify significant prognostic and predictive factors that can be translated into meaningful clinical usage with acceptable outcomes. With all the tests being done in different manners by different laboratories, standardization is a primary critical component.

Hayes asserted that any application of technology must first be supported by clinical evidence. He offered PSA testing to screen for prostate cancer as an example of an application that lacked the clinical science to back up its routine use, which has resulted in men having unnecessary preventative treatments and associated complications.

With regard to the role of advocates, Hayes admitted that the scientific community was naïve [dismissive?] at first about the ability of advocates to contribute productively to clinical research, especially when people seemed to want different things. However, scientists often don't agree amongst themselves, and so it was unreasonable to expect that advocates should be of a single mind/speak with a single voice. That said, the value of any decision about cancer care should be weighed in terms of priorities, based on the premise that people with different interests, different perspectives, can come to agreement.

The Challenge for Policymakers

Kathy Hudson, PhD, Director of the Genetics and Public Policy Center, a partnership of John Hopkins University and The Pew Charitable Trusts, described the policy challenges that must be addressed to move new genetic and genomic diagnostics and treatments into mainstream

medicine. In the research context, there are three critical issues on which advocates have had and can continue to have a substantial impact: ensuring adequate research funding, prioritizing the use of precious research resources, and safeguarding the interests and rights of research participants. As genetics moves increasingly from research to clinical use, ensuring the quality of the tests and treatments and quality of the health care becomes paramount.

The Center's evaluation of the social and policy environments for genetic testing has included an analysis of the social implications, ethical concerns, safety issues, and regulatory landscape as well as an in-depth assessment of the public's attitudes and opinions. The potential social impacts of greatest concern to the public are that (1) genetic testing and selection of the genetic attributes of our children will change the way we view children, (2) testing will lead to diminished tolerance of and support for those with genetic diseases and disabilities, (3) testing will be available only to the wealthy, resulting in a 'genetic underclass,' and (4) genetic testing results will be used in discriminatory ways by insurers and employers.

Of these, the social concern most amenable to an immediate, targeted, pragmatic policy solution is the fear that insurers and employers will use genetic information in detrimental ways. Thus, protecting against genetic discrimination is ripe for short-term policy solution and, echoing previous speakers, Hudson called for enactment of strong protections against genetic discrimination.

There is virtually unanimous agreement that clinical genetic tests should be accurate and reliable before they are provided to patients. Indeed, all of the Center's public opinion research shows that Americans place a high priority on the safety and accuracy of genetic technologies and that they support—even expect—that the government will ensure test safety and accuracy. Yet, the Center's detailed legal and regulatory analysis has shown that government oversight is inadequate and that there are few mechanisms in place to ensure even the basic accuracy and reliability of genetic tests through either government regulation or private sector oversight.

Using the cystic fibrosis carrier testing as an example (6), Hudson highlighted how the safety and quality of genetic testing depends on four underlying factors: (1) the *laboratories* that conduct the tests must have quality control and personnel standards in place to prevent mistakes; (2) the

tests themselves must be valid and reliable – that is, they measure what they say they measure accurately over time; (3) *health care providers* must understand when to order the tests, how to in interpret them and what to do with the results; and (4) *uses and outcomes* must be evaluated over time in order to pinpoint any problems that may require attention, particularly as new tests enter wider use.

Improvements in genetic testing oversight and enhancements in the quality of genetic services have been identified by numerous groups over the past decades but these calls for change have largely gone unheeded. Dr. Hudson suggested that adding a strong voice of advocates could make all the difference in making sure that policies keep pace with the science and ensure that advances in genetics are translated safely and effectively into improved health care.

Advocacy and Genomics

Sharon Terry, M.A., President & CEO of Genetic Alliance, offered insight into the advocate's perspective about genomics and cancer care. Her perspective results from the diagnosis of a rare genetic disorder in her children, pseudoxanthoma elasticum (PXE), and the subsequent founding of a nonprofit organization dedicated to research on that condition – PXE International. In their endeavor to find the best medical information for their children, she and her husband discovered various inadequacies in biomedical research.(6) In her position at Genetic Alliance, she works with hundreds of advocacy organizations and knows first hand the struggles of the various cancer groups as they work to accelerate the translation of basic research into cancer therapies.

Ms. Terry was particularly concerned that biomedical investigations focus on health outcomes. On this front, she expressed concern that, although a significant part of research should be basic science, a portion should be goal-orientated with clear objectives that would fit into a well-developed strategic plan. This would ensure the most efficient use of resources.

Ms. Terry described some tensions in the system including:

- Researchers and drug companies need research participants, results, funding, recognition, and profits.
- Research participants need benefits from research, and to understand how resources are being used.

- Amidst the various interests, advocacy groups serve well as facilitators. To fulfill this role, advocates must:
  - Acquire the ability to identify urgent healthcare needs in a more global context;
  - Develop the ability to understand the challenges facing the research community;
  - Acquire information so that they make appropriate decisions; and
  - Adhere to defined standards of best practices.

As an advocate, Sharon has been very pragmatic in her approach – establishing agreements and specific objectives in the various partnerships she has forged. In 1996, PXE International became the first advocacy group to own its own blood and tissue bank, primarily to create a leveragable commodity. Subsequently, Ms. Terry, with her husband Patrick Terry and Joan Scott, Deputy Director of the Genetics and Public Policy Center, co-founded the Genetic Alliance BioBank. The Genetic Alliance BioBank is built upon this new paradigm: advocacy organization-owed and managed biological samples and data. Under this model, the advocacy organization retains control of the management of and access to its sample bank. Benefits are reaped by all of the players: patients can be recruited and engage in an informed decision-making process in an atmosphere of support and trust, with ongoing educational support. Researchers, approved by the organization, are assured that they have access to all available samples and that no other research groups are performing redundant work. The advocacy organization retains control of how patients are recruited, which researchers are granted access to samples, and has sole access to all patient-identifiers: all samples are blinded to the central repository and to collaborating scientists. Most importantly, placing control in the hands of advocacy organizations brings the focus and energy of people living with genetic conditions to bear in the laboratory, where answers will be found.

Ms. Terry believes that advocates can contribute significantly to the definition of success in the research enterprise. Patients do not always share the same goals as researchers or health care providers, particularly with regard to the definitions of disease and health with the whole person in mind. However, collaborations among all the interested parties, including patients and patient advocates, will result in an atmosphere that accelerates translation.

Major Areas of Action Identified at the Workshop

The workshop concluded by laying out areas in need of concerted efforts by advocates to accelerate translation. Small group discussions surrounding these issues resulted in a series of action plans.

The participants broke into four groups: Education; Accountability; Collaboration and Best Practices; and Renewing the Energy of Advocacy Organizations. They discussed practical actions to move from discussion into productive advances. Each of the breakout groups offered recommendations at the close of the day.

1. Education

General Recommendations*:*

- Patients should develop tools, i.e., language and appropriate questions, to alert them to relevant information that affects the decision-making process.
- Advocacy communities should develop best practice guidelines that enable them to understand information relevant to genomic science, strategies to deal with the media, and methods of efficient communication.

Specific recommendations:

- Advocates should coordinate educational materials to provide a comprehensive overview, without any critical gaps. This committee determined that it would work on creating a genomics manual.
- Advocates should set standards for accurate and accessible materials development and dissemination. Those generating materials should be accountable to set standards.
- Materials should be audience-specific (public, advocates, patients, health care providers and researchers) with appropriate degrees of complexity.
- Advocates should acquire basic and cancer-specific science education. This should include fundamental information and an understanding of scientific methods, clinical trials, designs and statistical methods. Advocates should understand how to analyze and interpret scientific papers, particularly in the specific areas, such as genomics.

- Scientists and health care providers, probably thorough their professional associations, should be informed of topics of particular importance to individuals and families. Feedback mechanisms should be created to give them feedback from both patients and the public.
- Centralized agencies coordinating relevant information should be created. This should include not just breaking news but discussions and perspectives of relevance.
- Advocacy organizations should attend scientific meetings and be integrated into these meetings. The San Antonio Breast Cancer Symposium mentorship program offers a good model.
- Key communities should be identified and/or established. Mailing lists could provide forums for ongoing discussions. An online community that can be sufficiently updated and function on a day-to-day basis will be a product of such an endeavor.

Actions taken to date:

- Work has progressed on a peer-reviewed genomics manual – specifically focused on presenting accurate and accessible to the average advocate.
- Advocacy Workshops were presented throughout 2005. Genetics 101, an online listserv discussion, featuring an 'expert' in a particular area presenting information and answering questions, ran from February to June 2005. These "CyberChats" were archived [www.geneticalliance.org]. In addition, the Genetic Alliance Annual Conference provided an opportunity to learn from academic researchers, industry, and regulators about the research process; many of the examples used were cancer-specific.
- The San Antonio Breast Cancer Symposium's Mentor series (advocates are sponsored to attend the meeting and attend a briefing each evening, then write reports to share with the advocacy community) has been used as a model in the creation of the American Society of Human Genetics & Genetic Alliance Advocacy Training Partnership and the American College of Medical Genetics Partnership Program.
- An online Resource Repository has been created to allow advocates to share and access information and educational materials.

2. Accountability

Advocates and others should have some sense of the evolution and the direction of research in general, and the research agenda should be held accountable to the emerging needs of cancer

patients. Advocates could act as ‘honest brokers’ to facilitate and negotiate research concerns amongst involved parties.

Areas in Need of Attention:

- Advocates and partners should define conflicts of interest for advocates, researchers, academic institutions and industry.
- Scientific communities should interact with advocacy organizations more frequently and both parties should be held accountable for informing the other.
- Genetic tests should have oversight.
- Advocates should be held accountable for the information they provide to patients, the public and the media.

Actions to date:

- A working group is founding a professional advocacy organization and it is exploring what constitutes a conflict of interest for advocates.
- The Genetics and Public Policy Center has received funding from The Pew Charitable Trusts for a project to improve the overall quality of genetic testing, and to develop and promote recommendations where appropriate.

3. Collaboration and Best Practices

This working group identified a number of critical steps in building collaborations among stakeholders and developing and disseminating best practice standards:

- Identify priority issues;
- Centrally gather relevant information;
- Share resources;
- Collect best practices from the Department of Defense, American Society of Clinical Oncology, Genetic Alliance and other stakeholders and disseminate them; and
- Collect evidence of effective advocacy models that accelerate research.

Actions to date:

The group has begun to collect best practices and is archiving them to be used in the Resource Repository described above. In addition, several successful advocacy models have been replicated and are being prepared for dissemination

4. Perpetuating and Renewing Energy of Advocacy Organizations

This breakout group expressed concern that with so many cancer advocacy groups, they lack sufficient focus. In addition, in some instances, individual interests drive the organizations. It is not enough to just have discussions, focused action should result. Genetic Alliance has created Action Teams – seven of them each focused on an issue: Education, Access, Disparities, Research, Public Health, Genetic Nondiscrimination and Youth to Adult Transition issues. These teams allow advocates across organizations to concentrate their energy on specific interests in a concerted activity. Grouping individuals with an issues-specific passion allows the identification of common elements and creates actionable items that can be productive and sustained.

This group called for an electronically accessible Resource Repository. They recommended that this resource be easily searchable and should accept contributions from members that are then reviewed by an editorial board before publishing to the repository. It was also recommended that the archive allow some kind of rating system so that highly valuable information would be easily identifiable.

Actions to date:

Genetic Alliance's Action Teams have had variable effectiveness. The philosophy has been to allow the community to animate the work of the teams with minimum input from Genetic Alliance staff. This has been very successful for the Research Team – they have founded a BioBank. The Diversity Team has established a coalition of federal and community organizations working on making family history tools available to underserved and underrepresented communities. The Public Health and Newborn Screening Team has made public comment at a number of federal advisory committees. The Genetic Nondiscrimination Team has 'staffed' the Coalition for Genetic Fairness and helped the Genetic Information

Nondiscrimination Act pass by a unanimous vote in the Senate. Still, this bill has not yet passed in the House, and the Coalition continues its efforts to recruit new allies to assure that this important bill becomes a law (http://geneticfairness.org/).

Genetic Alliance has responded to the call for a resource repository, and launched it in 2006.

This meeting, and the resulting activity, point to an important trend. Advocacy organizations are moving to a new position in the research to clinical services continuum. Anxiously awaiting return on the Country's billions of dollars investment in basic science, advocates are increasingly advancing sophisticated methods to accelerate that return. The work begun at this workshop has created strong partnerships that will deliver important products over the next few years.

Financial Disclosure

Funding provided by an educational grant from Genomic Health, Inc.

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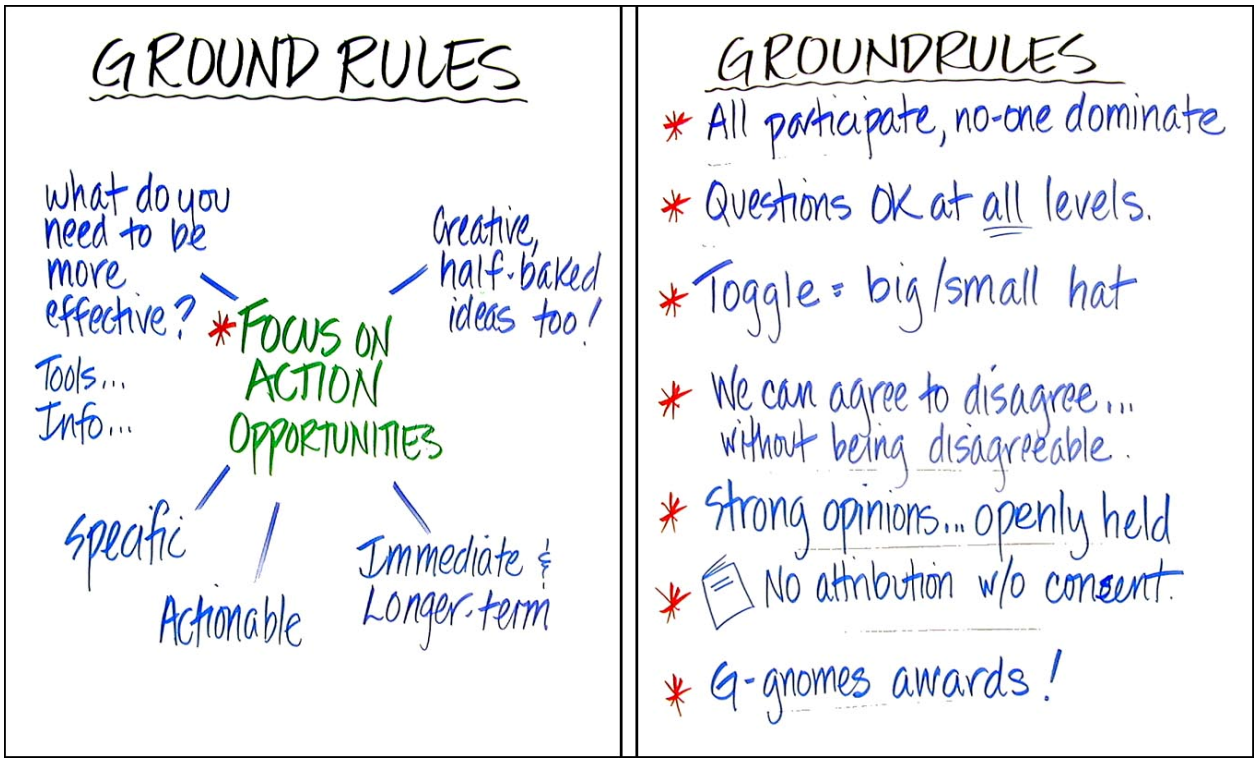
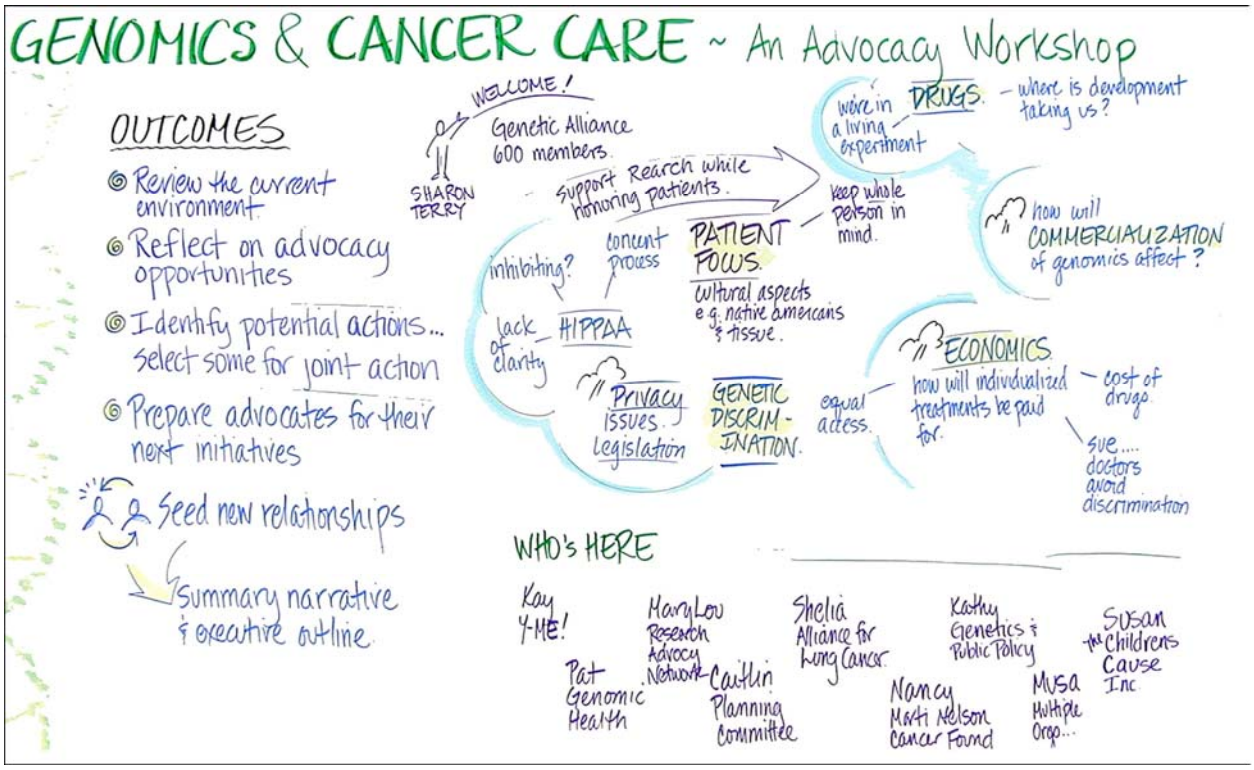
Corresponding author: Sharon F. Terry, sterry@geneticalliance.org

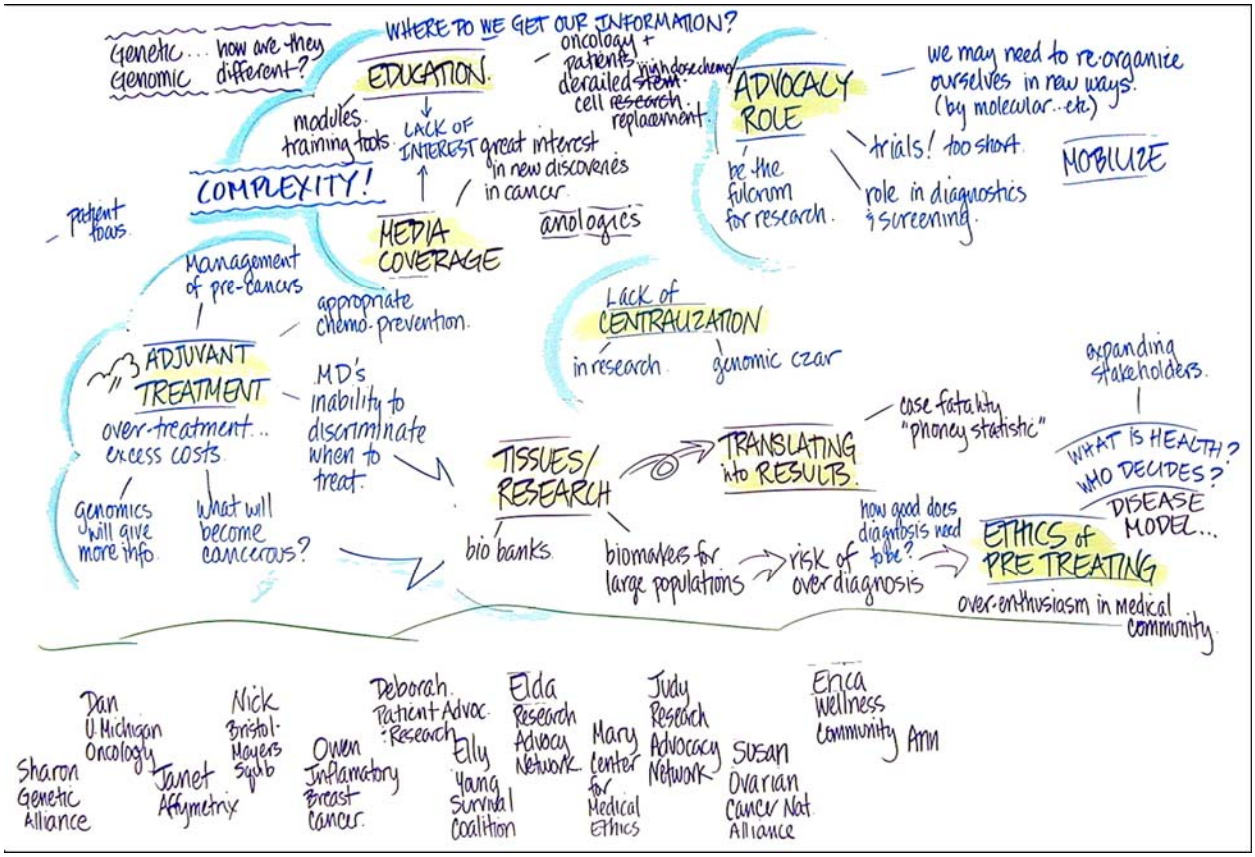
Appendix

Ground Rules

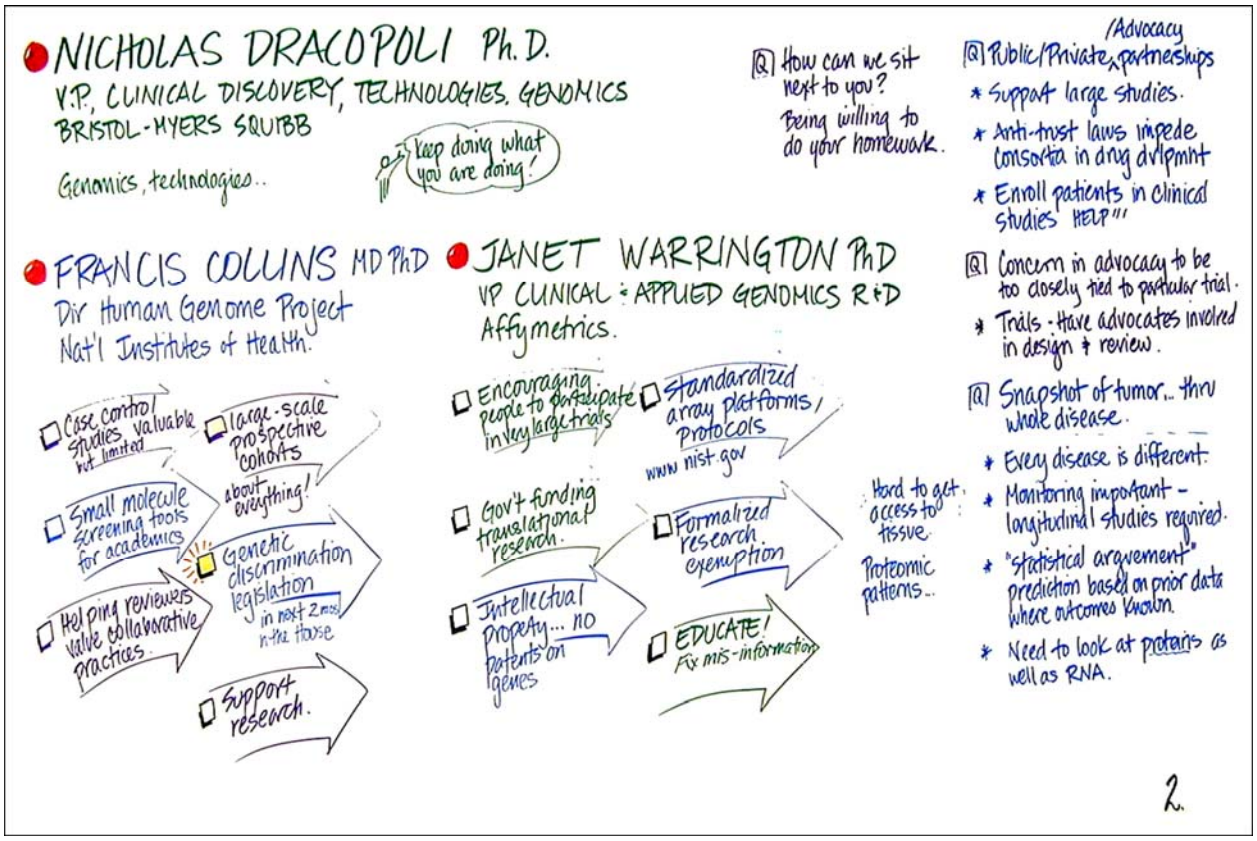


Issues


GENOMICS & CANCER CARE ~ An Advocacy Workshop
OUTCOMES
Review the current environment
Reflect on advocacy opportunities
Identify potential actions... select some for joint action
Prepare advocates for their next initiatives
Seed new relationships
Summary narrative & executive outline
WELCOME!
Genetic Alliance 600 members
SHARON TERRY
Support Rearch while honoring patients.
PATIENT FOCUS
cultural aspects e.g. native americans & tissue.
concent process
inhibiting?
lack of clarity
HIPPAA
Privacy issues. Legislation
GENETIC DISCRIM-INATION.
equal access.
DRUGS
where is development taking us?
we're in a living experiment
keep whole person in mind.
how will COMMERCIALIZATION of genomics affect ?
ECONOMICS
how will individualized treatments be paid for.
cost of drugs
sue.... doctors avoid discrimination
WHO's HERE
Kay Y-ME!
MaryLou Research Advocy Network
Pat Genomic Health
Caitlin Planning Committee
Shelia Alliance for Lung Cancer
Nancy Marti Nelson Cancer Found
Kathy Genetics & Public Policy
Musa Multiple Orgs...
Susan The Childrens Cause Inc

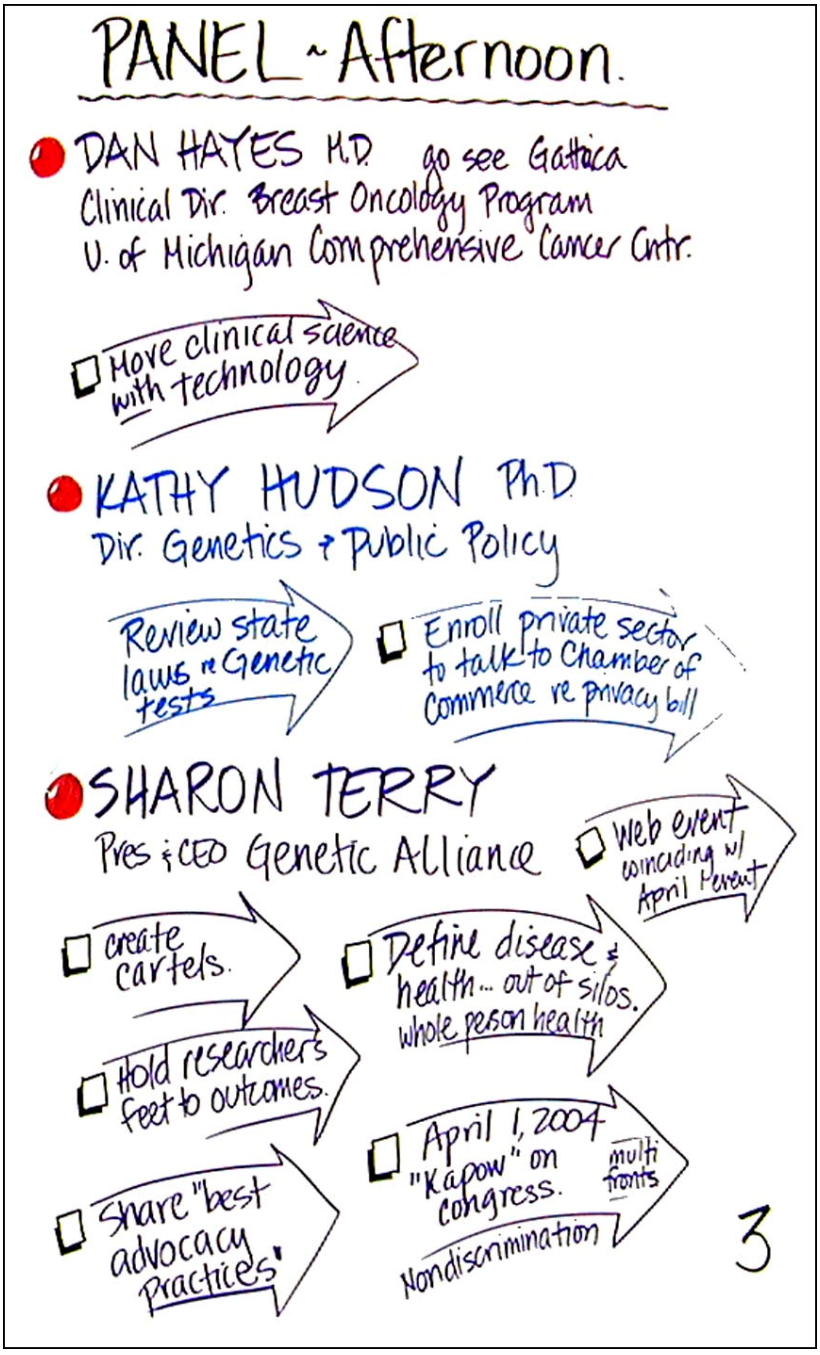

Genetic... how are they different?
Genomic
WHERE TO WE GET OUR INFORMATION?
EDUCATION
oncology + patients
high dose chemo
derailed stem cell research
replacement
modules training tools
LACK OF INTEREST
great interest in new discoveries in cancer
COMPLEXITY!
MEDIA COVERAGE
analogies
patient focus
ADVOCACY ROLE
we may need to re-organize ourselves in new ways. (by molecular... etc.)
be the fulcrum for research.
trials! too short
role in diagnostics & screening.
MOBILIZE
Management of pre-cancers
appropriate chemo-prevention.
ADJUVANT TREATMENT
over-treatment... excess costs
MD's inability to discriminate when to treat.
genomics will give more info
what will become cancerous?
Lack of CENTRALIZATION
in research
genomic czar
TISSUES/ RESEARCH
bio banks
biomarkes for large populations
risk of over diagnosis
TRANSLATING into RESULTS.
case fatality "phoney statistic"
how good does diagnosis need to be?
ETHICS of PRE TREATING
over-enthusiasm in medical community
expanding stakeholders.
WHAT IS HEALTH? WHO DECIDES?
DISEASE MODEL...
Sharon Genetic Alliance
Dan U Michigan Oncology
Janet Affymetrix
Nick Bristol-Myers Squib
Owen Inflamatory Breast Cancer
Deborah Patient Advoc. Research
Elly Yang Survival Coalition
Elda Research Advocy Network
Mary Center for Medical Ethics
Judy Research Advocacy Network
Susan Ovarian Cancer Nat. Alliance
Erica Wellness Community Ann

Morning Panel



Afternoon Discussion Panel

Discussion Panel


PANEL ~ Afternoon.
DAN HAYES M.D. go see Gattaca
Clinical Dir. Breast Oncology Program
U. of Michigan Comprehensive Cancer Cntr.
Move clinical science with technology
KATHY HUDSON Ph.D
Dir. Genetics + Public Policy
Review state laws re Genetic tests
Enroll private sector to talk to Chamber of Commerce re privacy bill
SHARON TERRY
Pres + CEO Genetic Alliance
Web event coinciding w/ April Prevent
create cartels.
Define disease + health... out of silos. whole person health
Hold researchers feet to outcomes.
April 1, 2004 "Kapow" on congress.
multi fronts
Share "best advocacy practices"
Nondiscrimination
3

Actions


ACTION
EDUCATION Education
- Multi-layer
- Build on Existing Sources
- Genetics Centers
- Clinical Trials
Determining topics priorities
Advocacy science education across all cancers
Target audiences
① Patients - language, raise awareness
② Advocacy Community
media training
critical thinking skills
communicating complexity
Genetic Alliance Host
Judy Moderate
Judy Peretti
Send an email "I'm interested"
Accountability
Advocates in design, etc...
CONFLICTS OF INTEREST
- for advocates
- keep focus on patient
More accountability for research dollars — and transparency (report results)
of research
Advocacy sub-mtng at ASCO-type mtng
Expand model of prof. orgs who open mtngs inexpensively to advocates
mentoring program on research accountability
- share expertise across cancer types
Scientific funding
Pancreatic cancer model
mapping portfolio. who's doing what
stimulate research in gap areas
⇨ Create a map now for genomics as the field grows
Elda Railey
Collaboration
BEST PRACTICE
Action Teams - focus on a specific area
Website updates
Caitlin
Ways to continue dialogue
PAIR model.
website.
correct
BEST
PRACTICES
Gathering place for evolving/emerging info AND perspectives on it
Focal Points
Segmentation
Fragmentation
WEBSITE
Summary docs & meeting follow-up.
e-mailing list.
jump start a conversation = priorities survey
Interactive Guide
Lay Advocacy "How To"
interactive
Caitlin
GENOMIC STDS FOR Protocols & CONSENT (IRB + PATIENT ed)
TISSUE issues
- IP
- HIPAA
barriers to progress
I.P.
Mary Lou : what is available?
STANDARDS
Calls → develop outline for a proposal. Committe
Create a white paper for genomics SPORE is model
Deborah Collyar
WE ALL MOTIVATE our constituencies
HR 1910/S1053
Constituents in Hastert District - call his office to make recommendations to Committee
4


Genetic Alliance