International Genetic Alliance

"Seeks a world where genetic conditions are understood, prevented, treated, ameliorated and cured"

2010

For members and interested parties

 # 9

EDITORIAL

Written by: Jessica A. Ritsick (Health Policy Intern) and Sharon Terry (President and CEO) of Genetic Alliance

The Changing Genetic Landscape in the United States

The past decade has seen numerous advances in genetics and genomics in the United States. Especially since 2003's completion of the Human Genome Project, the advances in all areas of genetics have seen a dramatic upswing. In 2008, the United States passed the Genetic Information Nondiscrimination Act (GINA), prohibiting discrimination in insurance and employment based on an individual's genetic information. In the past year, the U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) launched the Joint Leadership Council on Regulatory Science, to accelerate much-needed regulatory science. NIH created a genetic testing registry to expand access to information that will be critical to accessing the quality of genetic tests, much like the CE mark registration in Europe. FDA is also working with stakeholders to accelerate drug development for rare diseases. Most recently, the FDA has launched an initiative to examine oversight for laboratory developed genetic tests (LDTs), and direct-to-consumer genetic tests (DTCs). The genetic landscape in the United States is changing rapidly. This editorial provides a brief overview of all the many changes going on in the United States, propelling the genetics community further and faster through the 21st Century.

GINA has been hailed by many as the first civil rights legislation of the 21st Century. This legislation prevents health insurers and employers alike from taking discriminatory action against individuals based upon the individual's predictive genetic information. Thus, if an individual has a genetic test, or has a family history predisposing him to a genetic condition, he cannot be denied health insurance or employment based on this information. Employers are forbidden from requesting or acquiring an employee's genetic information, and face penalties if they do so – especially if they use this information to the employee's disadvantage. Further, insurance companies may not deny someone health insurance coverage, or decide someone's insurance rate, based upon predictive genetic information. Genetic Alliance led the Coalition for Genetic Fairness, the advocacy that worked to get GINA passed.

The rare disease community has recently benefitted from US Congressional legislation requiring the FDA to do more for the rare disease community. The Brown-Brownback Amendment tasks the FDA with establishing review groups within the agency to "recommend…appropriate preclinical, trial design, and regulatory paradigms and optimal solutions for the prevention, diagnosis, and treatment of rare diseases," both domestically and in the developing world. The FDA recently held a public meeting to get the perspectives of various stakeholders in the rare disease community to better inform how FDA will tackle this task. The meeting was productive and informative, and is a positive step to making needed changes to help speed and streamline the approval process of pharmaceuticals to treat rare diseases.

Finally, the FDA is in the process of clarifying oversight for LDTs and DTCs. As the genetic testing landscape has grown by leaps and bounds in recent years, the regulations have failed to keep pace with the scientific advancement. FDA wants to make sure the genetic tests administered are as safe and as accurate as they can be for patients, while at the same time recognizing that innovation is essential in this area, and must not be hampered. FDA's great attention to this area is welcome and laudable, and shows the Agency's commitment to accelerating genetics integration into medicine.

Genetic Alliance is working with the federal agencies and some of their complements in

Europe, and we are excited by the various and positive changes taking place in the United States at this time. It is also significant that each of these things are not being done in a vacuum – the global systems within which we all work are able to communicate priorities so that U.S. policy can be productive and collaborative. The 2010 International Congress on Rare Disorders in Buenos Aires enhanced our ability to collaborate and we look forward to more.

UPCOMING EVENTS

International Federation of Human Genetics Societies (ICHG/ASHG 2011), Montréal, Quebéc, Canada, 11-15 October 2011

The International Federation of Human Genetics Societies (IFHGS) ensures that an International Congress of Human Genetics will take place every five years and that a credible forum for the sharing of ideas about human genetics is provided. The purpose of The International Federation of Human Genetics Societies is to provide a forum for organised groups dedicated to all aspects of human genetics, including research, clinical practice, and professional and lay education. The Federation will enable communication between its member groups and encourage interaction between workers in genetic fields and related sciences and will make itself available to promote meetings and publications and other forums which support human genetic research and practice."
For more information visit:
www.ichg2011.org

1st European Congress 2010 Preconception Care and Preconception Health, Brussels, Belgium, 6 – 9 October 2010

For decades, progress in neonatology, obstetrics and perinatology led to major reductions in fetal, newborn and maternal morbidity and mortality.

The next step in improving maternal and newborn health with measurable results is to focus on the time just before or around conception. That is the purpose of preconception care.

The objects of this congress are:

- To introduce preconception care into primary care services in Europe
- To give information about preconception care interventions to medical and psychological providers
- To increase public awareness of the medical salience of preconception health services in the prevention field
- To sustain people's involvement in this important medical matter

For more information visit:
www.preconception2010.one.be

From New Zealand
The Global Genes Project

As part of World Rare Disease Day 2009, a video began circulating on You Tube that was developed by a rare disease parent advocate. The video showed the natural connection between jeans and genes. Here you can look at the video:
www.globalgenesproject.org/videos.php

Using that video as inspiration, a group of individuals and organisations decided to take this connection to the next level by creating the Global Genes Project, a grassroots effort to use jeans to raise awareness for rare genetic disorders.

This group has grown and continues to add individuals and organisations that want to be involved. Our hope is that the rare disease community as a whole will view this initiative as an opportunity to build unity around this important cause. Creating a platform for collaboration, while building awareness,

educating and engaging support from the general public.
You can find the website at: www.globalgenesproject.org *This article has been derived from the LSDNZ newsletter of May 2010.*

From Europe

Play and Decide on your preferred rare disease (genetic disease) policy scenario!

National rare disease patient groups have started to organise Play Decide sessions and are finding unique ways to encourage others to do the same.

In Romania the Romanian National Alliance (RONARD) played the game with staff members, volunteers and medical students on the topic of neonatal screening. Play Decide made the team members more aware of the ethical and moral issues surrounding genetics and prenatal screening. The experience was an eye-opener for the medical students who realised that they needed more information on rare (genetic) diseases.
In Denmark a Play Decide session was organised with patient representatives and Danish politicians from three different parties, to play a game on neonatal screening. The session resulted in a heated debate and the politicians were forced to take stand on burning questions like: What should we screen for and who should decide? The debate was observed by a journalist from a Danish newspaper, who ran a story on neonatal screening and its implications for rare diseases.

You can look at an instructive video on Play Decide and see people in action at: www.eurordis.org/content/play-and-decide-your-preferred-rare-disease-policy-scenario (at the bottom of the web page).

A special website on Play Decide has recently be launched and can be found at: www.playdecide.eu *This article has been derived from the EURORDIS website.*

NEWS

Genetic Alliance President Joins Prestigious Fellow Program for Global Organization

Sharon Terry, president and chief executive officer of Genetic Alliance, was just announced as an Ashoka Fellow, a distinguished lifelong position attained only after a rigorous selection process. Ashoka is the largest association of leading social entrepreneurs in the world that strives to enable the world's citizens to think and act as changemakers.

Terry was selected as an Ashoka Fellow for her efforts in leading an organization that helps improve health outcomes for patients who have genetic diseases by aligning incentives and structures so that they facilitate, rather than obstruct, the continuum of research, drug development, treatment, advocacy, and support.
"Being named as an Ashoka Fellow is both humbling and empowering. It calls me to live entrepreneurship very personally, and thereby align and focus my energy on deep personal and organizational transformation," stated Terry. "I am thrilled to collaborate with some of the best minds in the world to address serious global health issues. I will approach this task with the same dedication I have put into advancing the understanding of genetic disease over the past 15 years. The teams at both Genetic Alliance and PXE International are phenomenal collaborators; they, and my family, are what have catapulted me to this high honor."

Ashoka Fellows are leading social entrepreneurs with innovative solutions to social problems. Working in over 60

countries around the globe in every area of human need, Ashoka Fellows demonstrate an unrivaled commitment to bold new ideas through a combination of compassion, creativity and collaboration. Ashoka Fellows working in the health field focus on areas such as securing much needed medicines, developing mechanisms for knowledge transfer, building robust public health systems and delivering a holistic approach to health. All Fellows must undergo a rigorous search and selection process in which they demonstrate that they fully meet Ashoka's selection criteria.
For more information, please visit: www.ashoka.org/fellows
You can share Sharon's Ashoka journey by following her on Twitter at @sharonfterry

BOOKS

THE VOICE OF 12,000 PATIENTS
This book on the experiences and expectations of rare disease patients on diagnosis and care in Europe can be ordered or downloaded from the Eurordis website at: www.eurordis.org/publication/voice-12000-patients

IT'S MY LIFE
The book portrays a revolution that is taking place now! Stories of twelve patients with a rare genetic disorder show a determination to take charge, to make a real difference. This book can be ordered at any local bookstore. Copies ordered via the **European Genetics Alliances' Network** (EGAN) will bring a donation for each copy towards patient support activities. Your order can be send to egan@egan.eu
The price for each book will be € 15 (± US $ 20) excluding shipping costs.

BECOME A MEMBER OF

The international multidisciplinary community genetics network. It facilitates communication between all those working in the field of community genetics (and genomics). To become a member you only need to send an e-mail mentioning this desire to commgennet@gmail.com.

The **Genetic Alliance Network** offers a wide array of programmes, resources, and events for all the individuals and organisations in our network, including: - Annual Conference, - Genetic Alliance Webinars, - Member Forum, - Discussion listserv, - Weekly Bulletin, - Policy Bulletin, and quarterly newsletter, - WikiAdvocacy and WikiGenetics, - Disease InfoSearch
To join the network, please visit: www.geneticalliance.org/join

International Alliance of Patients' Organisations (IAPO) represents patients of all nationalities across all disease areas and promotes patient-centred health care around the world. To receive IAPO's newsletter, please go to this website: www.patientsorganizations.org/index.pl?n=210;section=3 to submit your request.

RELEVANT WEBSITES

ORGANISATIONS:

BIO – a biotechnology industry organisation whose members are involved in research and development of innovative healthcare
Website: www.bio.org/healthcare/issues/

EGAN – focuses on genetics, genomics and medical biotechnology and their implications.
Website: www.egan.eu

International Alliance Patient Organizations (IAPO) - global alliance representing patients worldwide across all disease areas
Website: www.patientsorganizations.org

International Genetic Alliance (IGA)
Website: www.intga.org

March of Dimes – is an organisation for pregnancy and baby health
Website: www.marchofdimes.com

UNESCO – gives information on life sciences and the implications on all species.
Website: www.unesco.org/shs/bioethics

WAO – for the prevention and treatment of genetic and congenital conditions.
Website: www.world-alliance.org

Genetic Alliance UK – is a national alliance of patient organisations of genetic disorders.
Website: www.geneticalliance.org.uk

Erfocentrum – Dutch national genetic resource and information centre.
Website: www.erfocentrum.nl/english.php

WHO – its Genomic Resource Centre provides information and raises awareness on human genetics and human genomics.
Website: www.who.int/genomics/en

MAJOR PROJECTS with International dimension and genetic alliances' engagement:

CAPABILITY – Capacity Building for the Transfer of Genetic Knowledge into Practice and Prevention
Website: www.capabilitynet.eu

PATIENTPARTNER – to promote the role of organisations in the clinical trials context.
Website: www.patientpartner-europe.eu

EuroGenGuide – contains information about genetic testing, counselling and research across Europe.
Website: www.eurogenguide.eu

EuroGenTest – harmonizing genetic testing across Europe.
Website: www.eurogentest.org

Human Genome Project Information – informs about project facts, education, medicine and the new genetics.
Website: www.genomics.energy.gov

RARE DISORDERS:

Orphanet – the portal for rare diseases and orphan drugs
Website: www.orpha.net

International Birth Defects Information Systems (IBIS) – to promote better care and prevention of birth defects through information sharing
Website: www.ibis-birthdefects.org

IGA MEMBERS:

Europe: European Genetic Alliances' Network (EGAN), Website: www.egan.eu
Central & Eastern Europe: Central & Eastern European Genetic Network (CEE GN), Website: www.ceegn.org
Asia: Indian Genetic Society
Africa: Southern African Inherited Disorders Association (SAIDA), Website: www.saida.org.za
Latin America: Brazilian Genetic Alliance, Website: www.abg.org.br
North America & International: Genetic Alliance, Website: www.geneticalliance.org
Middle East: Iranian Genetic Alliance of Parent/Patient Organisations & Gulf State Alliance
Australia and New Zealand: Association of Genetic Support of Australasia (AGSA), Website: www.agsa-geneticsupport.org.au & New Zealand Organisation for Rare Disorders (NZORD), Website: www.nzord.org.nz

UPCOMING INTERNATIONAL EVENTS with IGA - involvement and partnering

6 – 9 October 2010, Brussels, Belgium
1st European Congress 2010 Preconception Care and Preconception Health

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11 – 15 October 2011, Montréal, Canada
International Federation of Human Genetics Societies (ICHG/ASHG)

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