



Organization Profile

Genetics Policy Institute

Genetics Policy Institute (GPI) is a nonprofit, public interest organization recognized as a leading promoter and defender of stem cell research and other cutting-edge medical research targeting cures. Since GPI's inception in 2003, its mission has focused on establishing a positive policy, regulatory and societal framework to enable research to flourish, under the highest ethical and medical standards. We seek to accelerate the discovery and development of lifesaving cures, therapies, diagnostics and research technologies, with an overarching goal to alleviate human suffering from chronic afflictions.

Headquartered in the Village of Wellington, Genetics Policy Institute (GPI) is located in the heart of Palm Beach County, FL, USA, which has become a burgeoning center of biotechnology, with the recent expansions of The Scripps Research Institute and the Max Planck Institute to the area. GPI maintains satellite locations in Summit, New Jersey and San Francisco.

GPI is the catalyst and a leader of the 'Pro-Cures Movement', an influential global network of stakeholders from patient-advocacy, science and industry.

We maintain science and legal advisory boards of more than 100 experts and advisors, comprising leading stem cell researchers, disease experts, ethicists, industry leaders and attorneys. GPI has a fulltime staff of policy, business, science and communication experts (Box 1). We rigorously study and analyze laws and, with the aim to remove unreasonable roadblocks and to propose solutions to bring about cures, sooner rather than later.

GPI is often referred to as the 'voice of the stem cell community.' While we are perhaps best known as the organizer of the annual World Stem Cell Summit, we have many other projects. Through GPI's action network, world report, speaking engagements, renowned advisory boards, educational resources, teaching initiatives and strategic relationships, GPI serves as the foremost channel of knowledge

between the world's leading stem cell experts, patient advocates and those who make policy for the general public.

In the beginning: the Cloning Case

Florida attorney, Bernard Siegel, founded the GPI to become a persuasive voice on behalf of the stem cell community.

He was introduced to the field in a most unusual way. In December 2002, Clonaid, the self-proclaimed 'human cloning company', made an announcement in Broward County, FL, USA, that it had cloned the first baby, referred to as 'Baby Eve.' In the ensuing media firestorm, many pundits believed that Clonaid had the scientific wherewithal and intent to accomplish the task. Its founders, part of a UFO sect called the Raelian Movement, had been somewhat validated. Its leaders appeared before a committee of the United States Congress and at the National Academy of Sciences, where they declared their intention to clone a baby.

While many journalists and the public were uncertain as to the validity of Clonaid's cloning claims, only Bernard Siegel took action to test the truth. He filed a lawsuit, seeking to have appointed a temporary guardian of the alleged cloned child. He reasoned that reproductive cloning was unsafe and principles of child protection and welfare should

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Box 1. Genetics Policy Institute's key executives.

- Bernard Siegel, JD, Founder and Executive Director
- Robert Margolin, Associate Director
- Alan Fernandez, Director of Public Outreach & Development
- Sarah A Haecker, PhD, Director of Strategic Projects

govern. The case would compel Clonaid to appear before court to testify as to the whereabouts and existence of the alleged cloned child.

The legal matter became a 30-day 'cause celeb'. CNN's Connie Chung described the case as 'unlike any other in human history.' Siegel uncovered through sworn testimony that Clonaid lacked a board of directors and even a street address. The case was widely viewed as discrediting the cloning claim and demonstrating that Clonaid was nothing more than a 'sham', and its representatives mere publicity seekers.

The case exposed the would-be cloners as 'cartoon scientists', defusing the cloning hysteria and thus dampening the enthusiastic lawmakers from enacting overly broad legislation that would ban nuclear transfer.

During and immediately after the cloning case, prominent researchers requested that Siegel remain engaged in the cloning debates and serve as a 'legal mouthpiece' to defend freedom of legitimate scientific research against those who sought to scare the public or cloak their political agenda by using misleading scientific jargon.

With encouragement of supportive scientists and inspired by patient-advocates, Bernard Siegel (a cancer survivor himself) left his law practice and formally launched the organization, originally named the Human Cloning Policy Institute, with its initial goal to defend nuclear transfer. He recruited an initial Science Advisory Board including Rudolf Jaenisch, Ian Wilmut, Douglas Melton, Lawrence SB Goldstein and Alan Trounson.

Stem cell science under siege

In order to understand the context of GPI's impact one must remember that in early 2003, the 'Stem Cell Wars' in the public arena was in full swing. Cloning hysteria was the prevalent zeitgeist. The ascendant social conservative forces were pouring resources into US policy 'think-tanks' with bioethics agendas. Organizations such as the Family Research Council, Ethics

and Public Policy Center and Discovery Institute provided the political talking points, op-ed editorials and formulated legal initiatives geared to stymie human embryonic stem cell research (hESCR). Certain lawmakers were proposing bills in the US Congress that called for imprisonment and imposition of heavy fines on scientists engaged in nuclear transfer, with even patients being placed in legal jeopardy. The Bush Administration's funding policy created in August 2001 relating to hESCR severely limited the research grants needed to advance the field.

As its first initiative, GPI became engaged in the United Nations where there was a global treaty under consideration which sought to impose a global ban and moral condemnation on nuclear transfer (therapeutic cloning), a promising area of research that scientists believed might produce pluripotent stem cells. The attack on nuclear transfer, cloaked in a broader ban on human reproductive cloning, was an effort to delegitimize all hESCR. It was evident that many of the same forces aiming to derail hESCR in the US were harnessing support in the UN in an international effort to accomplish their mission.

GPI proposed a novel approach to the process. It launched a 'World Court Initiative' seeking an advisory opinion from the International Court of Justice declaring reproductive cloning only as a violation of international law. The goal was to distinguish and isolate the unethical cloning of 'people' from therapeutic cloning of stem cells. The initiative was modeled on a citizens' movement to have the World Court declare illegal the threat of nuclear weapons.

In fall 2003, while the 'World Court Initiative' was being discussed with various UN delegations, the matter on the cloning treaty came up for a swift vote before the Legal Committee of the United Nations. Media observers predicted that the treaty was on a fast track to pass.



GPI became a prominent ‘whistle-blower’ alerting the world stem cell community of scientists and patient groups about the impact a cloning treaty would have on stem cell science should it be enacted with a ban on nuclear transfer. We served as a principal organizer of the response to this threat. A massive grassroots letter writing campaign was launched, resulting in more than 35,000 faxed letters to the United Nations missions. GPI’s intervention proved pivotal. The Legal Committee saved the research by a single vote in October 2003 and the General Assembly continued the matter for further deliberations to the following year.

In 2004, GPI was asked by the Belgian ambassador to the United Nations to present a science conference to educate the UN delegates about cloning and stem cells. GPI presented ‘Human Cloning Issues in all its aspects’ co-sponsored by the Asian Group Legal Experts Meeting in the Dag Hammarskjöld Auditorium at UN headquarters. The conference showcased some of the pre-eminent researchers and clinicians who ably explained the promise of hESCR and described how reproductive cloning differed from nuclear transfer. The conference received global media coverage.

Later in October 2004, GPI organized a patients’ press conference with the Washington-based Coalition for Advancement of Medical Research (CAMR). Both meetings featured a stirring video message from stem cell advocate Christopher Reeve, which GPI produced.

Finally, in 2005, after extensive lobbying pressure (throughout the campaign GPI worked closely with the Washington-based Coalition for Advancement of Medical Research, Cures for California, the Luca Coscioni Association and the Stem Cell Action Network) the treaty ban was derailed for the foreseeable future. A vaguely worded, undefined and unenforceable declaration was substituted opposing ‘human cloning’ instead.

Michael J Werner, then Chief of Policy of the Biotechnology Industry Organization, wrote that the GPI was ‘instrumental in galvanizing into action patient groups, scientific organizations and ordinary citizens into a powerful voice in favor of legitimate scientific research’ [PERS. COMM.].

The rise of a consumer movement

The United Nations campaign underscored the political challenges to advance hESCR. GPI’s successful advocacy was a result of our outreach to those impacted by stem cell research. We helped organize grassroots advocates who were often overlooked by policy-makers and unrepresented by mainstream organizations.

Through its efforts, GPI became a recognized leader of the nascent ‘Pro-Cures Movement.’ In presentations around the world, Bernard Siegel explained that public support for stem cell research had created large consumer demand for stem cell therapies. The public viewed stem cells as a matter of personal health, for themselves and their loved ones. That consumer demand is now transformed into a powerful consumer movement driving the field forward. GPI’s goal was to increase public support and translate that support into action. In almost every jurisdiction, GPI became a resource for identifying proposed laws for and against stem cell research and creating strategies with a goal to foster funding and remove legal roadblocks.

GPI was involved in all the policy battles educating the public, inspiring grassroots efforts and assisting the scientific community to communicate exciting research in ways to engage public interest and increase support. We specifically developed platforms to promote societal impact, build constituencies, educate, publish and communicate.

Societal impact: GPI summits & meetings

GPI created and organized a series of novel conferences hosted with major academic institutions and open to all stem cell stakeholders, including medical philanthropies, the patient community and general public. The meetings are educational and media events and serve as a platform for pre-eminent researchers, Nobel laureates, political leaders and other luminaries. We plan to expand our conference programming outside the USA in 2010.

Some of our more notable events include:



- June 2004: ‘Human Cloning Issues in all its aspects for the United Nations’ at UN headquarters, NY, USA.
- June 2004: ‘First International Stem Cell Action Conference’ at the University of California, Berkeley, CA, USA, co-organized with the Stem Cell Action Network.
- August 2004: ‘Stem Cell Awareness Day with Janet Reno’ at the Miami Project to Cure Paralysis, Miller School of Medicine, University of Miami, FL, USA.
- October 2004: ‘Patients Press Conference for the United Nations’ at UN headquarters, New York, USA, co-sponsored by the Coalition for Advancement of Medical Research, featuring a video appeal from Christopher Reeve.
- June 2005: ‘Stem Cell Policy & Advocacy Summit: Sustaining the Mandate for Cures’ in partnership with Baylor College of Medicine, Houston, TX, USA.
- June 2006: ‘Stem Cell Policy & Advocacy Summit II: Empowering the Pro-Cures Coalition’ co-sponsored with the Center for Biomedical Ethics, Stanford University, Palo Alto, CA, USA.
- October 2006. ‘Stem Cell Town Hall Meeting with Governor Jennifer Granholm’ at the University of Michigan-Dearborn, MI, USA.
- October 2007: ‘The Stem Cell Summit’ organized with the Harvard Stem Cell Institute and Burrill Life Sciences Media Group at the Hynes Convention Center, Boston, MA, USA.
- September 2008: ‘World Stem Cell Summit’ co-hosted by the University of Wisconsin Stem Cell & Regenerative Medicine Center and WiCell Research Institute at the Alliant Energy Center, Madison, WI, USA.

2009 World Stem Cell Summit

GPI will stage its most comprehensive conference on 21–23 September, 2009, at the Baltimore Convention Center in Baltimore, MD, USA. Hosted by John Hopkins University and the University System of Maryland, this flagship networking meeting will bring together

researchers, academics, industry leaders, policymakers, regulators, advocates, students, legal experts, investors and philanthropists to illuminate the critical issues and together chart the future of regenerative medicine. The event brings to the table all the major funding partners, including disease-specific medical philanthropies. The 2009 summit introduces a science track of the highest level, to complement the tracks devoted to economic development, commercialization and policy/regulation. It will target more than 1200 attendees, 75 exhibitors and sponsors and 120 supporting organizations and media partners. For more information visit www.worldstemcellsummit.com.

Public awareness & education

■ NABT/GPI Stem Cell

Education Summit

The GPI is partnering with the National Association of Biology Teachers (NABT) to produce an educational stem cell conference in conjunction with the annual NABT meeting. To enhance stem cell education in the US and abroad, the conference will enable more than 5000 teachers to engage in dynamic learning platforms and interact with today’s world renowned stem cell thought leaders. Through these teachers we hope to reach hundreds of thousands of students and their households. GPI will provide, create and disseminate authoritative educational tools to serve classroom teachers at the high school and introductory university level.

■ Stem Cell Public Awareness Day

Each year, the World Stem Cell Summit kicks off with a public celebration of stem cell research with activities designed to inform, educate, stimulate and entertain students, teachers, patients, families, and citizens of all ages and interests. The event includes expert panels, documentaries, hands on workshops, live music and a student stem cell career fair. The 2008 event, entitled ‘Lab on the Lake’ brought together more than 700 attendees to learn about stem cells. In 2009, GPI will produce ‘Lab on the Harbor’ in conjunction with the 2009 World Stem Cell Summit at the Maryland Science Center in Baltimore.



Constituency building

■ Stem Cell Action Campaign

GPI is undertaking a campaign to enlist 1 million supporters of stem cell research through an extensive online movement. The 'Stem Cell Action Campaign' serves as a persuasive force dedicated to removing unreasonable policy roadblocks to stem cell research. The campaign is focused on the repeal of the Dickey–Wicker Amendment (a US law that restricts funding for hESCR), the promotion of a uniform regulatory scheme that will foster global research collaboration, public education and support for increased research funding. One tool of the campaign is the *Stem Cell Action News*, an online bimonthly newsletter to inform advocates about policy shifts, scientific advancements and industry news.

■ Stem Cell Action Awards

Through the Stem Cell Action Awards, the GPI recognizes organizations and individuals who have most positively impacted the stem cell community. This recognition and corresponding publicity is seen as an empowering tool encouraging positive advocacy. Past honorees include Wisconsin Governor Jim Doyle, Christopher and Dana Reeve Foundation, National Association of Biology Teachers, Brooke Ellison, Ben Kaplan, Michael J Fox, Dr Ralph Dittman, Missouri Coalition for Life Saving Cures, Bob Klein, Hadassah, Don Reed, Student Society for Stem Cell Research, Luca Coscioni Association, Danny Heumann, Coalition for Advancement of Medical Research and Texans for Advancement of Medical Research. GPI honorees are recognized at the annual awards dinner at the World Stem Cell Summit.

Communications & publications

■ Stem Cell Action

Speaker Series

GPI offers leading experts in cutting-edge science, policy, law, business, ethics and advocacy to participate as speakers and debaters at academic centers and conferences around the world to further stem cell education. Bernard Siegel, who currently co-chairs the Government Affairs

Committee of the International Society for Stem Cell Research, is a frequent lecturer, panelist and keynote speaker and has addressed such notable institutions as the United Nations, the Salk Institute, James Baker Institute of Public Policy at Rice University, New York Biotechnology Association, Diabetes Research Institute Foundation, Seoul National University, International Stem Cell Forum (Beijing), World Congress for Freedom of Scientific Research (Rome), Stem Cells European Business Summit (Edinburgh), Stem Cells Europe (Amsterdam), World Parkinson Congress and Association of American Law Schools, American College of Trial Lawyers.

■ World Stem Cell Report

International and interdisciplinary in scope, GPI's annual *World Stem Cell Report* assists leaders and decision-makers to stay abreast of the latest developments relating to stem cells. This report mirrors the ecosystem of the stem cell community, with more than 35 illuminating articles written by leading thinkers. The 2009 Report will focus on the translation of stem cell research and the birth of the ReGEN industry.

■ Editorials, interviews & media

GPI experts have been featured and published in leading scientific journals, biotechnology trade publications, newspapers and have appeared on radio, television and the Web.

Industry & law

■ ReGEN Industry Forum

Through GPI's ReGEN Industry Forum the regenerative medicine industry will have a new platform to serve its needs. Planned for launch in 2010, the Forum will provide educational programs to promote industry solutions and forge a new identity for the field geared to capture the public's imagination. Cell therapy companies and related businesses have unique issues impacting the commercialization, including regulatory hurdles and reimbursements. GPI will use its expertise to expand public awareness and support for the ReGEN industry and thereby encourage investment, stability and growth of these innovative and pioneering enterprises.



■ Legal Forum for Regenerative Medicine

'Stem Cell Law' presents many new regulatory and intellectual property challenges. There is a growing demand for a specialized understanding of the legal issues relating to regenerative medicine. GPI interacts with leading lawyers and academics. Our Legal Forum for Regenerative Medicine engages our existing network to provide a service to the international legal community by offering programs geared to educate legal professionals as to the relevant issues, thus empowering them to understand the legal and regulatory barriers slowing the advance from bench to bedside and find solutions to move the field forward.

Conclusion

While in 2009 the political climate for stem cell research has changed for the better, the work for stem cell proponents continues. Since its inception, GPI's mission has steadily expanded to embrace the entire

universe of regenerative medicine. We are considered a foremost thought leader, progressing the entire field with an overarching goal of promoting effective treatments and cures.

The economic engines driving the GPI are charitable gifts, grants, conference sponsorships, registration fees and advertisements in the *World Stem Cell Report*. All gifts are tax deductible in accordance with the United States Internal Revenue Code Section 501 (c)(3).

Financial & competing interests disclosure

The author is the Founder and Executive Director of the Genetics Policy Institute. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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