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Expert Panel to Examine Health Effects of Assisted Reproductive Technologies on Children

Genetics and Public Policy Center Partners with American Academy of Pediatrics and American Society of Reproductive Medicine to Assess Health Risks

One million children have been born worldwide as a result of assisted reproductive technologies (ART), yet the effects of these procedures on the health and development of the resulting children is unclear. While some medical studies suggest that ART children are as healthy as their naturally conceived peers, others associate ART with a higher incidence of cancer, birth defects and genetic diseases.

"Parents and healthcare providers need access to accurate information on the health and developmental risks associated with these technologies," commented Kathy Hudson, Ph.D., director of the Genetics and Public Policy Center at Johns Hopkins University. To assess current medical knowledge about the health and development of ART children and make recommendations for future research priorities, the Genetics and Public Policy Center has established the ART Children's Health Panel. This expert panel, co-sponsored by the American Academy of Pediatrics (AAP) and the American Society for Reproductive Medicine (ASRM), will carefully review the scientific literature and produce a report outlining its findings and recommendations. The report is expected by fall 2003.

The ART Children's Health Panel will evaluate scientific and medical studies on the health of children born through *in vitro* fertilization (IVF), intracytoplasmic sperm

injection and embryo cryopreservation, and those born after having preimplantation genetic diagnosis. The panel's report will identify where current data are conflicting or inconclusive and make recommendations for future research.

The five panelists are leading experts in pediatrics, obstetrics/gynecology, epidemiology and genetics. The panelists are:

Steven N. Goodman, M.D., M.H.S., Ph.D., **Panel Chair**, Departments of Oncology, Pediatrics, Biostatistics and Epidemiology, Johns Hopkins University

Marcelle I. Cedars, M.D., Divisions of Reproductive Endocrinology, Infertility and Embryology Laboratory, University of California San Francisco

Judith Hall, M.D., Department of Pediatrics, University of British Columbia

Joe Leigh Simpson, M.D., Departments of Obstetrics and Gynecology, and Molecular and Human Genetics, Baylor College of Medicine

Arnold W. Strauss, M.D., Department of Pediatrics, Vanderbilt University

"This study is intended to provide greater clarity on the safety and efficacy of IVF, the underlying technology that feeds all advanced reproductive techniques," said Sandra Carson, M.D., president of ASRM.

"Through this study we hope to understand the impact of ART on children's health and development in a way that will inform and guide future research, its use, and the oversight of ART–based therapies," added Russell Chesney, M.D., FAAP, chair of the AAP Committee on Pediatric Research.

The Genetics and Public Policy Center is a part of the Phoebe R. Berman Bioethics Institute at Johns Hopkins University and is funded through a grant from The Pew Charitable Trusts. The mission of the Genetics and Public Policy Center is to create the environment and the tools needed by decision makers in both the private and public sectors to carefully consider and respond to the challenges and opportunities that arise from scientific advances in genetics.

The American Academy of Pediatrics is an organization of 57,000 primary care pediatricians, pediatric medical subspecialists and pediatric surgical specialists dedicated to the health, safety and well being of infants, children, adolescents and young adults.

The American Society for Reproductive Medicine, founded in 1944, has almost 9,000 members who are devoted to advancing knowledge and expertise in reproductive medicine and biology. ASRM-affiliate societies include the Society of Reproductive Surgeons, the Society for Reproductive Endocrinology and Infertility, the Society for Male Reproduction and Urology, and the Society for Assisted Reproductive Technology.

ART Children's Health Panel FAQ's

Why is ART being examined?
There have been a number of reports in recent years on the health and developmental outcomes of children conceived through Assisted Reproductive Technology (ART). These reports have generated news and opinion pieces in the popular press[1] that have caused some concern and confusion among patients, the public, and policymakers.

Some reports on ART outcomes have noted a possible link between children conceived through ART and certain clinical conditions, including: congenital defects such as cerebral palsy[2]; cancers like retinoblastoma[3] and genetic disorders such as Beckwith-Wiedemann syndrome[4], while other studies indicate ART children are born similar to those naturally concieved[5]. The Panel will study scientific and medical literature published in both the U.S. and abroad.

The Genetics and Public Policy Center is looking at genetic testing procedures that can be performed throughout the human reproductive cycle. Genetic testing of early embryos, called preimplantation genetic diagnosis (PGD), can detect genetic abnormalities in embryos. Since PGD is not possible without utilizing ART procedures to create these embryos, we must study the underlying technology – ART – before we can assess the health and safety risks associated with PGD.

Why form a partnership?
The Genetics and Public Policy Center has formed a partnership with the American Society of Reproductive Medicine (ASRM) and the American Academy of Pediatrics (AAP) to study the health and developmental outcomes of ART children. Both ASRM and AAP have considerable expertise in this area, and a significant interest in determining whether ART has an impact on children's health. ASRM is devoted to advancing the knowledge and expertise of reproductive medicine, while AAP is dedicated to the health and safety of children. The Genetics and Public Policy Center's mission intersects with both organizations' pursuits – by studying the medical, ethical, legal and policy issues related to reproductive genetic technologies, with the goal of

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[1] Skloot, R.L. (2003, February 22). *The Other Baby Experiment*. The New York Times, p. A17; Robotham, J. (2003, February 1). *Test-Tube Time Bomb*. Sydney Morning Herald, p. 30; Horowitz, J.M., Park. A, and Song, S. (2002, March 18). *Risky Business?* Time, p. 68; Brown, D. (2002, March 7). *Test-Tube Babies Face Higher Health Risks*. The Washington Post, p. A3; Mishra, R. (2002, March 7). *Study Ties Birth Defects to In Vitro Fertilization*. The Boston Globe, p. A1; Griffith, V. (2002, March 7). *Questions Raised Over Infertility Treatments*. The London Financial Times, p. 10. (2002, March 7).

[2] Blickstein, I. and Weissman, A., *N. Engl. J. Med*., 1999; 341: 1313-1314; Ericson, A., *et al.*, *Hum. Reprod*. 2002; 17: 929-932; Stromberg, B., *et al.*, *Lancet.* 2002; 359: 461-465.

[3] Anteby, I., *et al.*, *Arch. Ophthalmol.* 2001; 119: 1525-1529; Cruysberg, J.R. *et al.*, *Arch. Ophthalmol.* 2002; 120: 1773; Moll, A.C., *et al.*, *Lancet.* 2003; 361: 309-310.

[4] DeBaun, M.R., *et al.*, *Am J. Hum. Genet*., 2003; 72: 156-160; Gicquel, C., *et al.*, *Am. J. Hum. Genet*., 2003; 72: 1138-41; Maher, E.R., *et al*., *J. Med. Genet*., 2003; 40: 62-64; Sutcliffe, A.G., *et al.*, *Hum. Reprod.* 1995; 10: 3332-3337.

[5] Bernasko, J., *et al., Obstet. & Gynecol.* 1997; 89: 368-372.; Minakami, H., *et al.*, *Hum. Reprod.,* 1998; 13: 2005-2008; Reubinoff,B.E., *et al., Fert. and Ster.*, 1997; 67: 1077-1083.

developing policy options to help shape and guide the development of these technologies. By working collaboratively, these three organizations are in the unique position to accurately and objectively assess the health and developmental outcomes for children born from ART procedures and propose tangible next steps.

What is Assisted Reproductive Technology?
Assisted reproductive technology (ART) is commonly referred to as the set of medical and laboratory procedures used to help couples that are having difficulty conceiving children. While various definitions of ART exist, the Genetics & Public Policy Center's *ART Children's Health Panel* will focus solely on those procedures involving manipulation of both egg and sperm outside the human body in order to create embryos. The ART procedures that the Panel will be reviewing include: *in vitro* fertilization (IVF) and embryo transfer (ET), embryo cryopreservation, preimplantation genetic diagnosis (PGD), and intracytoplasmic sperm injection (ICSI).

Why do people use ART?
Couples typically utilize ART services because they are experiencing some form of infertility and cannot conceive naturally. However, since the development of PGD, some fertile couples that are at risk of having a child with a genetic disease such as cystic fibrosis, have used ART.

Common ART Procedures

***In Vitro* Fertilization (IVF) and Embryo Transfer (ET)** are the most common procedures used in ART. The IVF-ET process involves: stimulating the woman's ovaries to produce mature eggs; retrieving the eggs; fertilizing the egg with sperm; and implanting fertilized, developing embryos into the woman's uterus. Fertilization of the egg occurs *in vitro* (meaning "in glass"), rather than inside the woman's body.

Intracytoplasmic Sperm Injection (ICSI) is the *in vitro* process of using a microscopic glass needle to inject a single sperm directly into a mature egg to achieve fertilization. ICSI utilizes IVF procedures for egg retrieval and embryo transfer.

Embryo Cryopreservation is the process of freezing and storing human embryos. Following an IVF cycle, couples sometimes have excess embryos. Embryo cryopreservation allows couples to save their embryos for future attempts at pregnancy, while avoiding the costs and invasive procedures associated with subsequent IVF. Other possible uses for frozen embryos are donation to scientific research or donation to other couples attempting to have children.

Preimplantation Genetic Diagnosis (PGD) is used by both fertile and infertile couples that are at risk of transmitting a genetic disease to their offspring. There are two types of PGD. The first involves testing one or two cells from a developing embryo (2-4 days after fertilization) prior to implantation for chromosome abnormalities, single gene mutations or sex-linked disorders. The second method of PGD involves testing a polar body after biopsy. A polar body is a product formed during egg maturation that contains

a single set of maternal chromosomes. During polar body biopsy analysis, only the maternal chromosomes are tested from the egg.

Additional Web Resources

Genetics and Public Policy Center

American Academy of Pediatrics

American Society of Reproductive Medicine

Resolve

American Infertility Association