

**Comments by Kathy Hudson at the June 12, 2003 meeting of the President's Council on Bioethics.**

**DR. HUDSON:** Dr. Kass, members of the council, thank you very much for the invitation to speak before you today.

I'm Kathy Hudson, the Director of the Genetics and Public Policy Center at Johns Hopkins University.

The center is a little bit over a year old, and we were created to build tools and resources to help policy makers and the public address issues emerging from advances in human genetics.

Our first project is on reproductive genetics, funded by the Pew Charitable Trusts. As this committee knows and has discussed, the fusion of advances in genetic science and advances in human reproductive medicine have brought forth new technologies that give parents unprecedented new powers to identify, select, and perhaps in the future to modify the genetic characteristics of their children.

The specific aims of our attention to reproductive genetics are listed here. We want to understand what the public is thinking about reproductive genetics. We want to engage them in a conversation about reproductive genetics.

We would like to create objective, comprehensive, and hopefully comprehensible information resources, and ultimately to develop a set of policy options that can be considered by the public and its representatives.

We will not be creating individual recommendations, but rather, an array of options with robust underlying analysis that can be used by others in making decisions.

Dr. Kass, in the center's written comments, we responded to the council's request for information about the current regulatory and legal landscape. This morning I would like to make two points.

The first is that I think it's quite clear that safeguarding and improving human health is the key motivation and key principle that guides genetics not only in the research laboratory, but in the clinical context, and similarly reproductive medicine research and its practice. And yet I believe there are weaknesses in the current system.

Second, I'd like to point out that public participation must be a core principle that guides policy development, process, and choices.

So of the core values or principles that should guide reproductive genetics policy, safeguarding human health is perhaps the easiest to identify, to understand, and ostensibly to address, and yet there are weaknesses in the current system of policy, and I use the term "policy" quite broadly to include research policy, that have significant implications for human health.

As Pam addressed, as did Robert, there are now over a million babies that have been born worldwide through assisted reproductive technologies. And yet in the United States, we do not have an effective system to monitor the health and developmental outcomes of these children.

There have been a number of studies that have produced sometimes confusing, sometimes contradictory, and often incomplete information about the health status and developmental outcomes of these children.

To make sense of this information, the center this week convened a panel co-sponsored by the American Academy of Pediatrics and the American Society for Reproductive Medicine to evaluate the current medical knowledge and to make recommendations for future research to resolve uncertainties and fill gaps in our knowledge.

The second example of a weakness in the current reproductive genetics policy is the absence of a well paved and clearly marked road that genetic tests must traverse in moving from the research laboratory into widespread clinical use. While the accuracy, reliability, and interpretability is important for all genetic tests, it is particularly critical in the reproductive genetic testing context.

There are now over 900 genetic tests that are available clinically or that are in development, and it's possible to do genetic testing at virtually every point in the human reproductive cycle. We can test parents. We can select gametes based on the presence of sex chromosomes. We can test embryos, fetuses, and newborns.

In the reproductive context, it is often the genetics test alone that is the sole clinical information available for making important decisions. Attempting a pregnancy or not, implanting an embryo or not, continuing a pregnancy or not, these are profoundly important decisions, and thus we need to have the very highest degree of confidence that the genetic test results and their interpretation are accurate.

So I believe there are weaknesses in the current system of oversight and policy that result in an inadequate understanding of the health risks of these technologies and an inadequate assurance of the health and safety of their use.

Briefly, on the second point, I would like to propose that a fundamental core principle that should govern the process by which policy decisions about reproductive genetics are made in the United States, and that principle is the

public's participation. The public should have a voice in public policies about reproductive genetics.

The goods and values that are advanced and embodied by policies governing reproductive genetics should be the goods and values that are held most dear by the citizens in this democracy, and yet we have only the faintest glimpse of what our citizens hope for and fear in this new realm.

We don't know largely because we haven't asked. As you have heard from other speakers during the course of your deliberations, other nations when trying to develop a regulatory framework for these issues have turned to its citizens. Both Canada and the United Kingdom consulted with tens of thousands of citizens in their consideration of human genetics policies.

The Genetics and Public Policy Center is engaged in a modest effort to understand and listen to the voices of the public. We took an initial pulse through a survey last fall. We recently completed 21 focus groups with Americans in five cities around the country, and we're now conducting over 200 interviews with individuals who have special experience, expertise, or perspective.

The themes and hypotheses emerging from this work will be validated and tested in a very large survey of citizens this fall, and in addition, this winter we will be engaging groups of citizens to learn about genetics, to learn about reproductive medicine, to learn about governance, and then provide to us their ideas and input about how we should move forward.

The center will use this input along with our extensive policy analysis to construct an array of options that can be considered as society grapples with the development and use of these technologies.

In closing, I'd like to quote Thomas Jefferson, who certainly had some interesting perceptions of genetics and the nature of families, and he said, "I know no safe depository of the ultimate powers of society but the people themselves, and if we think them not enlightened enough to exercise their control with wholesome discretion, the remedy is not to take it from them, but to inform their discretion by education."

Thank you for your attention.