

POLICY AND STRATEGY BREAKOUT SESSION 2

Moderator: Susan Fogel

Rapporteur: Eric Hoffman

Introduction by Susan Fogel:

- What are the issues we believe are important and strategically useful? What policies are needed at the domestic and international levels? What initiatives must be taken in the short term and long term?
- Everyone please put on the sticky notes the top three issues that you believe need national or international policy. These will be posted on the wall, organized by topic or theme; then we'll break into groups of two for a few minutes of discussion.

Topics were organized into these categories:

- The largest category was composed of issues related to **how to create spaces and frameworks for public debate**. Specific issues: creating a public debate, bringing people together, collaborating, educating scientists and students of science, encouraging open debates on medical technology, raising public awareness, creating space for critical thinking, creating an international community, the relationship of bioethics to other forms of public deliberation, the problem of focusing on technological solutions instead of addressing root causes, creating a larger framework to deal with ethical and social knowledge beyond specific issues, raising public awareness.
- **Public policy, especially in the sphere of assisted reproduction:** Women's eggs, surrogacy, personhood, informed consent, data collection, regulation in the fertility industry, who owns us, how to make the FDA accountable, global governance.
- **Gene-related technologies and practices:** Genetic engineering, gene patents, human cloning, protections against exploitation of genetic material, synthetic biology, DTC gene testing.
- **Race and ethnicity** in genetic science, the reemergence of race as a biological category.
- **International perspectives** on cloning, human trafficking, trafficking of human tissue.

Discussion

Speaker 1

- Issues around proper regulations have come up a number of times. We don't know how long we'll have the present administration but there are changes happening in the regulatory agencies that govern this country.
- The FDA has reemerged with different people with a different philosophy. We need to recognize this change and take advantage of this new and unique opportunity. For the first time since the 1980s, we have a government that is responsive and has the ability to get things done.

Speaker 2

- The question of regulating technologies depends on people's ability to recognize the long-term consequences of these technologies.
- How do we theorize eugenics in the 21st century? Most people in college and law classes have never heard this term and there is no theory or description of what this new form of eugenics looks like. We need to learn from the history of eugenics.

- We need to show what a lack of regulation around these human biotechnologies means, in a way that is accurate and that people can feel a visceral level.

Speaker 3

- Some of the issues listed are actionable and some are not.
- To pass certain regulations, you need the corresponding cultural norms that accept what the regulation is attempting to do.
- For example, we cannot ask for the end of exploitation if our cultural forms are not there.
- We need to pick two or three issues to focus our energy on.

Speaker 4

- There now may be opportunities to push for regulations and move our issues. The FDA has not regulated direct-to-consumer genetic testing yet but there has been an effort to push for regulation of clinical genetic testing.
- The FDA does not have the tools they need or the expert knowledge.
- Is this an opportunity to move other issues not normally under the FDA's portfolio, to incorporate issues and our expertise into FDA practices in order to change the larger framework?

Speaker 5

- We cannot talk about regulation without the intent to follow through with implementation of the laws we fight for. Having a law on paper is not enough.
- We need to give power to regulators to evolve so we can watch over them.
- What is needed is a statement we can use to address these evolving technologies and regulations.

Speaker 6

- There are two parallel discourses: those saying we need to regulate ART and the powerful forces pushing against the call for regulation.
- Those doing ART procedures already think they are over-regulated.
- Unless we can combine these two discourses we will not be able to move on these issues.

Speaker 7

- What do we do with the case of Octo-mom? She was not an outlier as the media portrayed.
- People in industry have good intentions yet we do not communicate well together. Patients also feel overregulated in terms of costs of services.
- What are we as a society willing to pay and what aren't we, and how does this influence policy?

Speaker 8

- We should be careful when proposing to strengthen certain agencies.
- For basic legal issues we need to make changes to the actual laws, especially in the case of genetic testing. Legal issues need a legal response, not a regulatory one.

Speaker 6

- The FDA can't regulate without the laws passed by Congress

Speaker 9

- It would be useful to include more scientists in these conversations: There are not many people engaged in actual research here at the meeting. This would allow us to get scientists who are involved with these technologies to think about the issues we are concerned about.
- It would also be useful to talk with scientists about the potential for regulations to see what they would oppose or support, and to highlight areas that may need regulation.
- This would also help us become more aware of what is in the pipeline so we can begin thinking of the appropriate responses and regulations to technology – so we aren't always in the reactive mode.

Speaker 1

- One the dangers at meetings like this is reinventing the wheel for the first time.
- At a meeting like this we need to compensate for the lack of depth that happens because we all come from very different places.
- I sympathize with the idea of having more scientists here but don't agree with the idea of tackling these issues with scientists without addressing what it means to have scientists at the table.
- If scientists don't have STS studies, they won't have rudimentary knowledge of policy, constitutional system, etc.
- Scientists should have to engage in extensive ELSI (ethical, legal, social implications) training and education starting at the very beginning of their science education – even undergrad, but certainly in grad school.
- If you have NIH funding, for example, you should be required to take bioethics classes. We will just reproduce the same structures unless we address these issues.
- Terms need to be created and defined before inviting people.
- Differences in laws and regulations between the U.S. and Europe arise since these two regions live in two very different legal worlds. Americans say we are over regulated, but when we say overregulated what are we talking about? Actually we are the least regulated when compared to other societies. For example, pre-implantation genetic diagnosis is regulated in every other developed other country but not U.S.
- We are a diverse but parochial people.

Speaker 6

- The market harms our ability to legislate.
- There are two models, regulation versus legislation.
- Europe has bioethics law. We can learn from the European model.

Speaker 1

- The European and American ways of creating laws are not the only models. There are creative and productive strategies to bring in other experiences and other people from around the world in how they deal with problems.
- Progressives make a huge mistake if we buy into the same idea of regulation that the conservatives propagate.
- It is not just about making laws and rules. Regulation is the space in which we can bridge the words of the law and the policies that we want.
- Regulations create a flexible and creative space, making the law is just the beginning.

Speaker 3

- We need to address the elephant in the room: much of what we are discussing is the proposal to restrict women's reproductive freedom. Many proposals we talk about fit under this idea. Someone needs to figure out how to deal with this tension.

Speaker 10

- That is not the elephant in the room, there are a number of panels talking about ART and appropriate policies would look like. This is very much on the table.

Speaker 3

- For example, it should be illegal to clone yourself. Pro-choice groups would agree but see it as ammunition for the right and may not support this policy on paper.

Speaker 6

- We have to question the language of limiting women's reproductive freedom. The language we should use is that no procedures should be allowed that alter the nature of being human.

Speaker 11

- The FDA is charged only to consider safety and efficacy. These symbolic concerns are an entire different set of issues.
- To what extent do we want to take on these symbolic causes, which may be hopeless, versus winnable causes?
- What are these symbolic concerns that we are worried about that can be used to persuade fellow citizens to be concerned as well? These concerns must be more explicitly spelled out.

Speaker 4

- It would be worthwhile to spend time telescoping what the dominant discourses are and the ways these issues are framed.
- How do we produce counter-claims or defend counter-claims? We won't get anywhere if we use the frame of limiting reproductive freedoms.
- It is not helpful to create the distinction between winnable and symbolic causes.

Speaker 10

- Reproductive justice groups have developed a different frame which rejects relying on the autonomy and choice frame in favor of a more human rights framework that takes into account the impact of individual decision making for not just the individual but also society at large.

Speaker 7

- The framework needs to change from one of choice to empathy. I have worked with a cognitive linguist to discuss how mental models are used to talk about issues.
- There are mental models of discussions on personhood and we need to use models that the public will use or we will lose them.

Speaker 11

- Empirical claims that cloning harms what it means to humans can go against the rights of the gay community and the idea of creating new families.

Speaker 10

- We do not have a very clear empirically evaluated argument of how we get from reproductive freedom to being against cloning. There is no difference between sex and ART in a lab with a couple that wants to reproduce.
- We can still make the argument that there are boundaries, whether they're about cloning or trait selection.

Speaker 1

- Individual versus collective responsibility. Women's reproductive rights are often a red flag in the movement. Given that reproduction is a social act, do you think new forms of social arrangements should also be restricted?
- There is a disconnect between those who see people acting in a society and those who see people as individuals acting on themselves.

Speaker 3

- If we say one thing fundamentally damages how we treat each other, then it should be regulated. There are exploitive forms of reproduction.

Speaker 8

- We need an argument as to why we are against something – cloning is dangerous to the health of the child is one such argument.

Speaker 2

- There are some things that can never be experimented on in humans and should never be legitimized.

From papers on wall:

- Regulation:
- Eugenics and looking at long-term consequences of policies
- Opportunities now
- Perspective of those being regulated
- Changing cultural norms
- FDA: New forms of expertise and frameworks, accountability, is FDA only answer?
- Costs, Benefits, and Access: Health disparities, access to fertility treatments/services
- Who is at the table? Researchers, doctors?
- Reproductive freedom vs progressive belief that certain reproductive choices may need to be limited (i.e. cloning)

Post-session note from Susan Fogel:

Here are several "bigger-picture" themes to add to the session notes:

1) Same sex families: There was a fairly intense interchange between Speaker 6 and Speaker 3 over whether same-sex couples/people should be able to create families through ART. Speaker 6 appeared to be willing to say same sex couples shouldn't use ART - only "natural families." The discussion was not so much about cloning as reflected in the notes, but whether there should be limits on ART: Do the desires of same-sex couples to have biological children cross those limits?

2) Reproductive freedom: Speaker 3 started one part of the conversation with the assertion that he was willing to limit women's reproductive freedom. He then explained that what he meant was that he would ban reproductive cloning. There was a lot of pushback to his framing, along the lines of asking why he sees banning cloning as a reproductive freedom issue. There was general agreement that we would all ban reproductive cloning, and that we did not see this as a limit on reproductive freedom. He then said that he had worked with a lot of mainstream reproductive rights organizations that are unwilling to support a ban on cloning because of the potential impact on reproductive freedom.

3) Science education: There was a lot of support for Speaker 1's call for ELSI training for scientists and students of science. There was wide agreement that one part of the problem is that scientists are too narrowly in the lab, looking only at the science, and not being educated about where science lives in the world and how the implications of the uses of scientific information are equally if not more important.