POLICY AND STRATEGY BREAKOUT SESSION 6
Moderator: James Rusthoven
Rapporteur: Molly Maguire

After introductions, James Rusthoven invited the group to consider, personally, what the issues are; how to prioritize them; and how we cab create, amplify, and develop new initiatives in strategy. He suggested that each person, in turn, say what are their three key areas/issues, and what priority each should be assigned.

[The suggested areas/issues are bolded and bulleted in comments below. A cumulative list was generated but is not available at time of posting. Some speakers made other comments, included but not bulleted. Discussion followed, see below.]

Speaker 1

- **Symbolic harms** — one priority how to create a space for taking these issues seriously within the policy arena.
- **Synthetic biology** — there is a very tidy way in which concerns can be ignored and we don't yet have the language or the space in which these concerns can be aired and taken seriously.
- **Communications** — this piece is key; we need clear communication while being aware that medium can be message. Consider using electronic technologies and what can be embedded in those technologies.

Speaker 2

- **Regulation** — which governmental agencies should be involved in regulating genetic information; how we characterize this field has implications for how people think about potential harms.
- **Privacy**.
- **Access to funding**, private or public.

Speaker 3

- **Low cost IVF in developing countries** — cloning researchers may be based there too.
- **Role of media** — how to deal with conflicts of interest within science? Creation of scientist-entrepreneurs inherent in many issues. Points out CIRM article and how it misleads public by its use of the words 'clinical trials' and 'treatments.'
- **Problem of transparency** — as with CIRM.

Speaker 4

- **Regulation/oversight of repro health industry** generally.
- **More ethical oversight of gamete donation process** — follow-up health history of egg donors; adequate counseling of egg and sperm donors and recipient parents at front end of donation.
- **Accountability and responsibility within repro health industry** — need more of both, including accurate record-keeping; monitoring and tracking of births; no medical info shared among donor families; multiple births per donor.

Speaker 5

- **Conflicts of Interest** — need for policy decisions that articulate social purposes/social benefit that particular science serves; disclosure of scientists' financial interests.
- **Suppression of information/lack of communication of information** to those who need it, such as policymakers, the public, patients, et — risks of technologies not revealed.
- **Educational gaps in training of scientists and non-scientists** so that public can make intelligent choices and help set priorities.

Speaker 6

- **Bottom-up: Engaging public**, which entails health information communication, social marketing strategies, translation of information, particularly women and medical professionals.
- **Top Down**: **Transnational governance**; scientific entrepreneurship travels and these are global issues.
- **Middle (us): 'Rights'** are really just the starting point; **We need to be able to speak about responsibilities from the position of a rights-holder**. Not all of these activities are other-regarding; liberty is about self-regarding. But everything we do here is other-regarding and cannot be extracted and cannot be individualized. We are talking about a relational autonomy which brings us back to the notion of responsibility as an ethic of care. Important for us to be moving forward and adding to and building from of the human rights discourse, that what we do has implications: a way to counter the market consumerist ideology that dominates. Start talking about relationships and responsibility.

Speaker 7

- **Surrogacy** — doable and its already begun.
- **Gene patent** — ACLU lawsuit.
- **Egg donation** — a way to engage and involve a younger generation because it's a personally relevant issue for many; really gets to the need to control practicing physicians who are unregulated.

Footnote: Sterilization abuse (i.e. from eugenics movement) as a learning tool.

Speaker 8

- **Transnational regulation**.
- **Lack of information and lack of informed choice in US context**.
- **African perspective: how they view new genetic technologies**; practices banned in US can be transferred to Africa.

Speaker 9

These are places where resources need to be placed today, to lay the foundations for when these issues emerge in next couple of years:

- **Personalized medicine** — the challenge is that it's a bundle of technologies.
- **Human enhancement tech's** — pay attention now rather than later. The longer these technologies develop without conversation and debate, the more we are building precedents for sets of interventions that will be evidence for future sets of interventions. Consider the use of off-label pharmaceuticals for human enhancement purposes — then the argument is that "this is nothing new because people have been using Adderall for 20 years and no one has paid any attention to it." We should approach these technologies in an anticipatory mode.

- **Regulation Improvement Including Laboratory Level** — A lot of conversation about regulation occurs at the interface between the provider and the consumer. But the laboratory itself can be a site of governance, and by working with scientists as they are doing their research and alerting them to the fact that instruments of governance exist, and their decisions matter for broader public policy and welfare, can lead to them making those decisions somewhat differently.

Speaker 10

- **Improve the national regulatory system** — it's such a mess that there isn't a good process for discussing regulation of the issues.
- **Direct-To-Consumer Testing** — a very current issue that is getting traction and raises deep regulatory issues.
- **Patents**.

Speaker 11

- **Intellectual property regime as a site of governance** — in absence of legislation or regulation, or only very weak legislation or regulation, this has implications, i.e. who has access, who benefits, how is ownership disbursed, etc.

Speaker 12

- **Surrogacy** — In India, surrogacy capital of world, there needs to be careful thinking about the legal status of children that are born to surrogates. All the battles that have taken place in India are over the recognition of citizenship of such children. The women offering themselves as surrogates do not have agency. There is an assumption that they are victims and that they are being coerced — not the case. They see it as a chance to do well for their families — altruism combined with pragmatism. Regulation becomes part of that discussion.
- **Global tourism** — Reproductive and medical tourism as a whole have been spurred by GATT, which the Indian government openly promotes. Can they use the same instruments to promote a global governance aspect that draws on some of the other international instruments, such as the Universal Rights Declaration? But it's difficult because, who regulates? Who enforces? It's important to not just have education but legislation that allows people to invoke the law in their fight.
- **Testing:** Testing out; not even permitted. Jurisdictional issues very important.

Discussion

Rusthoven: Are there strategies that people would like to raise? Any new initiatives? Are there thoughts worth contributing that have been mentioned over last day?

Speaker 7: There is a NOW/CRG alliance about surrogacy, committing one of largest women's organizations to this issue — a pre-existing group of activists. This should be a global strategy, including working with and in India.

Speaker 4: My issues are regulation, national and international. I am very clear about what the issues and problems are, but I hit a ceiling when it comes to dealing with a for-profit industry that is unregulated, has no interest in being regulated, and I feel ineffective because I can't

make any change. That's why I'm here. How do you get regulation in an industry that is self-serving and profit driven? How do you make change? In all of these issues, this dilemma comes up.

Speaker 13: Look at the history of the FDA — there have been changes in FDA decision-making and direction due to various stakeholders' influence. How much do they appeal to evidence vs. political pressure? Things are so wrong that we need to do something. OR, start changing people's minds so that law becomes less vital, as people have begun to think in a healthier way.

Speaker 4: We need to be speaking to people and employing communication strategies, but it's a frustratingly slow process.

Speaker 6: On the surrogacy regulation issue: people are using Indian surrogates but using white eggs and white sperm. Eggs, sperm and genes travel. Point of leverage: area of safety of bio-products. When we get a public health disaster around this moving around of bio-products, that's when people are going to wake up. Look at the European Directive about storage and transfer of bio-products. This angle might be a point of leverage into this market.

Speaker 13: Bioethics is a reactive discipline. The FDA was created due to disasters and whistle-blowing. We have to fix things at the front-end; regulation is helpful to a point, but if you don't fix at the front-end, the pattern is set.

Speaker 6: Medical individualization versus collective sensitivity to societal needs — I think we need to put this in a public health context and lift it out of the language and paradigm of personalized medicine, because this is where the market is taking us. We are looking at these issues from a social justice/public health approach. We don't want to divide and conquer, we want to come together over the issues that concern us collectively.

Speaker 10: DTC testing is becoming the issue it is right now because the big players are opposed to the little players for "messing it up" for the big ones, who are concerned that abuse will ruin their industry. We should look for a point where there are very large forces, with whom we can cynically engage.

Speaker 3: Do you mean grassroots? Do you mean large forces?

Speaker 10: I mean both grassroots and big capital.

Speaker 3: Need for public watchdogs complementing agency regulation — we won't get anywhere without grassroots. You can have all the regulation you want, but those agencies will be taken over by the large interests unless you have grassroots to hold them back. Look at OSHA and Becky McClain, the Pfizer researcher infected by recombinant DNA. OSHA ruled that intellectual property protection trumps worker protection. You can build grassroots support around a law, and if it fails it's almost better, because in that case, the grassroots movement gets more agitated.

Speaker 7: New FDA leadership gives hope for public interests over corporate wishes — we will always need grassroots but that isn't always sufficient. We presently have a few open doors at FDA. Margaret Hamburg is a different kind of commissioner and Josh Sharfstein under her, who

has an interesting track record. There is an opportunity, and monied interests will always try to infiltrate, but you have to look for a moment when there are people in place whose sympathies are in line with public welfare and public mandate rather than making sure that corporations get their due.

Speaker 3: But can't you get those regulations by letters and petitions?

Speaker 7: Leveage points as coalitions to help regulators keep public good in sharp focus — all that is essential, but it isn't enough unless you have key leverage points so this is a good moment to form coalitions and move forward and try and keep the honesty. You have to be there constantly with a savvy media person, for example, Jesse Reynolds at CGS with the CIRM.

Speaker 3: You have to have the public and plunk these issues in front of the public.

Speaker 5: Archive of experiences, accumulated wisdom for future problem avoidance — need for explicit histories on these issues, on specific cases, to inform the present. What are the patterns? Is there some wisdom we can gain? Some clues that we can give ourselves? This can't remain private knowledge.

Speaker 13: Within situations, you can capitalize on pre-existing tensions, for the right reasons, as in the DTC case.

Speaker 9: The point about getting ahead of things, anticipatory governance is one aspect of that. Public engagement at upstream level is both possible and very effective. CSPO held series of meetings about nanotechnologies in human enhancement across country and our results are significant.

About anticipation itself — when we are talking about emerging technologies, things are not quantifiable and predictable, there are uncertainties. We need different techniques for trying to think about the future as an object of governance, using scenario development workshops where you can bring together multiple stakeholders, mediators, lay and expert.

You can generate some really robust visions of potential socio-technical futures, not necessarily what is going to happen, but exercises or trainings for things that might happen. This situates governance back in the laboratory and our experience has been that scientists and engineers that have participated begin to tweak their experiments based on the knowledge.

Speaker 3: Is the public represented in these experiments? Are they figured in as stakeholders?

Speaker 9: Lay public are included in the engagement section of our workshops. We had 74 people off the street, with well-matched demographics, in a process that lasted over a month.