Insights on Bioethics Council Meeting in Boston

An Exclusive Interview with

Sonny Ramaswamy (Bioethics Council) and **Verena Hellwig** (Law Business Partner Pharma)

"Following an extremely productive council meeting in June, we interviewed two of the key figures involved in the exciting discussions about their impressions. Meet Verena Hellwig from Bayer Legal, who led the debate around “Informed consent in acute care”, and Sonny Ramaswamy, an agricultural scientist and member of Bayer´s independent Bioethics Council whose insights provided a unique and external perspective on the topical bioethical questions that we are discussing at Bayer." (Bayer Bioethics Office)

Sonny Ramaswamy
President of the Northwest Commission on Colleges and Universities in Redmond, WA, USA; Member of the Bayer Bioethics Council

Verena Hellwig
Senior Counsel at Bayer AG and Law Business Partner for Bayer Pharma Clinical Development & Operations

Sonny, what motivated you to enter the collaboration with Bayer in the first place? What did you expect?

It was a pleasant surprise to receive the invitation to serve on Bayer’s Bioethics Council.

As President Barack Obama’s political appointee as director of the National Institute of Food and Agriculture, the USDA’s science funding agency, I was involved in supporting vital innovations in food and agriculture needed to address the existential societal challenges such as climate change, hunger and obesity, nutritional and food security, environmental degradation. Much of the innovations we supported are in the areas that Bayer is interested and investing in.

I was taught early on by my mentors, that part of one’s professional responsibility is to support the efforts of organizations for the benefit of society – the invitation from Bayer was congruent with my knowledge, experiences, skills, and my passion to make difference, and I accepted the invitation to serve on the Council. During the last several months, my expectations have been met.

Verena, this was also your first time to join a meeting with our independent Bioethics Council: What was your topic and why did you want to discuss it in the Council?

We develop products to treat typical acute care syndromes of patients on the intense care unit, such as lung failure, a coagulation disorder or sepsis. Clinical trials are a crucial step on the way to product registration and one cornerstone is that the patient

is duly informed about benefit and risks of the trial and on that basis consents to participate.

However, clinical trials in acute care are difficult to conduct because patients in an acute care situation are usually no longer capable to provide such an informed consent. Often, they do not have a legal representative who could make such decision. Thus, it can take many days until a court would have appointed someone. The treatment, however, needs to start quickly to be effective. In these situations, laws provide exceptional rules allowing to include a patient into a clinical trial without an immediate consent under certain conditions. Certainly, the question under which conditions it is ethical and even required to include a patient into a clinical trial without an informed consent, is a very sensitive one and Bayer should have clear standards for the conduct of these trials. An important topic we considered worthwhile discussing with the independent experts of the Bioethics Council.

Verena, how did you perceive the interaction with the Council?

I really liked the atmosphere. All Council members were very engaged and gave great input. We received impulses on data safety, medical law, research ethics, but also very practical advice from a hospital's or physician's point of view. The diverse background of the Council members is a big advantage given that our patients are also not a homogeneous group.

Sonny, you as an agricultural scientist also participated in the discussion on ´informed consent in acute care´ – what is the most crucial point for you in this context?

From my perspective, informed consent is shared decision making, i.e., a collaborative process that allows patients and / or their families to have as much a say in their health outcomes as their doctors, nurses, and the healthcare providers. This shared decision making allows patients and their families to exercise their unique backgrounds, preferences, and priorities for their well-being, based on the best scientific evidence.

I found the discussion facilitated by Bayer on informed consent was in line with my own perspective and offered me insights regarding challenges people face in dealing with their health.

Verena, what is your main take-away from the meeting?

Council members are world-wide thought leaders from leading universities and institutions. With their broad experience they came up with ideas and approaches we have not thought of yet. Therefore, the discussion has been very valuable for us. We are currently considering how to implement the input into our study protocols and the global consent templates. Additionally, we will update our whitepaper on ethical conduct of clinical trials in acute care at Bayer.

Overall, the discussion took place not on an abstract, theoretical level, but really led to concrete, forward-looking ideas. I strongly believe that many Bayer research projects facing an ethical dilemma can benefit from consulting the Bioethics Council.

Verena, can you share one suggestion by the Council members that you found particularly helpful?

The aspect of shared decision making by all stakeholders of clinical trials – highlighted by Sonny – was a very important one in the discussion. The council members brainstormed with us on how we could foster general understanding about the relevance and specific needs of clinical trials in acute care settings. Patient centric initiatives could be one cornerstone. As Patient centricity is a key element for Bayer in designing and planning clinical trials, we will certainly look into this more closely.

Sonny, in our next meeting, we intend to discuss Bayer´s approach to gene technologies in agriculture from an ethical perspective, what do you expect from the discussion?

Gene technologies have been part of the global agricultural landscape for almost three decades and proven to enhance farm productivity and profitability, while offering excellent environmental benefits.

The technology is slowly, but surely morphing from the use of transgenic approaches, i.e., transfer of genes of interest between unrelated species, to one of precision gene editing to create excellent new traits such as, for example, improved water and nutrient use efficiency, excellent plant protection, enhanced root growth, increased fruit and grain set, and excellent (food and feed) nutrient profile. All these characteristics will be critical as we consider addressing the existential societal threats imposed by climate change, diminishing land and water resources, hunger, and need for improved health outcomes.

I am looking forward to the discussion of these matters by Bayer – both scientific and regulatory, as the issues of ethics, regulation, technology, human welfare and well-being, and farmer profitability are critical to create a workable path forward.

If you would like to learn more about how we engage with the independent Bioethics Council at Bayer please visit our webpage.