# Societal Issues Arising from Synthetic Biology: What Lies Ahead

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We hope to spend November 8<sup>th</sup> and 9<sup>th</sup> exploring the unexpected events, innovations, convergences and results that often falls off the table at many workshops -- game changers within and outside the field of synthetic biology that may give rise to new societal issues. Here is some initial food for thought.

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# Some thoughts on systemic risks, early warnings, surprises, and disruptions

# Systemic Risks

Systemic risks have characteristics that differentiate them from ordinary risks. One of the most important is that actions taken by individual actors or single institutions to address frequent, low-impact events can actually predispose a system to fail when a low-probability and high impact event occurs.<sup>1</sup> For example, the overuse of antibiotics to combat common infections has created a system prone to larger-scale bacterial outbreaks. Parsing, rationalizing, and addressing the risks from synthetic biology in 'safety' and 'security' components or addressing the risks piecemeal though uncoordinated regulations or policy could create and/or exacerbate systemic risks. Disaggregated solutions to individual risks won't add up to effective or lasting solutions, because the risks stem from the interactions within the system and its structural characteristics, i.e., the way we do science or create institutional regimes for regulation.<sup>2</sup>

#### Predictable Surprises and Early Warnings

Systemic risks often result in a predictable surprise or event "that takes an individual or group by surprise, despite prior awareness of all the information necessary to anticipate the events and their consequences."<sup>3</sup> Many times, people in the field are aware of the problem; it is getting worse over time; and existing policies and behaviors perpetuate the status quo. Not

<sup>&</sup>lt;sup>1</sup> Another example is the construction of levees in New Orleans designed to deal with intermediate storms that failed catastrophically during Katrina, a low-probability, extreme event. From: NRC 2007. New Directions in Understanding Systemic Risks, Washington, DC: National Research Council.

 $<sup>^2</sup>$  Despite attempts to reform the financial markets, hidden structural flaws at a systems level left us susceptible to the "flash crash" that occurred on March 6, 2010, when the Dow fell 600 points within a few minutes.

<sup>&</sup>lt;sup>3</sup> Bazerman, M.H. & Watkins, M.D. 2008. Predictable Surprises, Cambridge, MA: Harvard Business School Press.

only do we ignore early warnings, but we ignore what have been termed "late and loud warnings."<sup>4</sup> As former CIA director George Tenet so famously noted prior to the 9/11 attacks, "the system is blinking red." So, are there any warnings in the synthetic biology community that we are ignoring – the red blinking lights (or even yellow)?

# Surprises

Then, or course, there are the things we are not even paying attention to, that are outside of our peripheral vision (intellectually or geographically), obscured by cognitive biases, or hidden by institutional restrictions to our thinking. They could have these characteristics:

- 1. The event shocks us (Wow! How did that happen? Why now?).
- 2. The event has a major impact on the development of synthetic biology (negative or positive unintended consequences accelerating the development of the field or putting the brakes on).
- 3. After the fact, the event would be rationalized by hindsight, as if it had been expected. Probabilities could be run ex post facto, but not ex ante.<sup>5</sup>

In this situation, prediction is not the answer or even possible. We need to figure out how to build robust systems and strategies that mitigate bad things and exploit positive occurrences. What would these systems and strategies look like? Who is responsible for creating them?

# Disruptions

When disruptive technologies appear, they often perform at a level that is actually below what is already on the market. This is exactly what makes it difficult to perceive their potential. Think about digital photography versus film; e-commerce versus bricks-and-mortar retailing; classroom educations versus internet-based, distance learning – all greeted with yawns and skepticism. But these disruptive technologies created new market opportunities, especially for people focused on higher performance options, and that is what drove their adoption.

The strategic inflection point occurs sometime after the introduction of the new technology but before its advantages are obvious or market-tested. The new technology does not replace the old, it provides new capabilities. Schematically, this is represented in Figure 1 (based on the work of Clayton Christensen at Harvard).<sup>6</sup> Figure 2 appeared in a recent DOE-supported study on synthetic biology and shows the anticipated performance increase of the enabling tools of synthetic biology compared to traditional recombinant DNA techniques.<sup>7</sup>

<sup>&</sup>lt;sup>4</sup> EEA 2001. Late lessons from early warnings: the precautionary principle 1896–2000, Brussels, European Environmental Agency, Report No. 22.

<sup>&</sup>lt;sup>5</sup> Taleb, N.N. 2007. The Black Swan, Penguin.

<sup>&</sup>lt;sup>6</sup> Christensen, Clayton 1997. The Innovator's Dilemma, NY: Harper Business.

<sup>&</sup>lt;sup>7</sup> Bio-Era 2007. "Genome Synthesis and Design Futures: Implications for the U.S. Economy, Cambridge, MA: Bio Economic Research Associates, p. 38,



This may look like interesting management theory, but disruptive shifts in technologies can have large implications for governance. Rapid technological change often leaves the science of risk assessment catching up with the risks, outstrips the ability of governments to provide adequate oversight, and leaves little time for democratic deliberation and public dialogue. As Charles Fine at MIT's Sloan School has pointed out, when the "clockspeed" of government falls far behind industry, public policies can either become irrelevant or badly designed as policymakers rush to close the governance gap.<sup>8</sup> It makes better sense to assume possible disruptive effects and plan for them rather than react after the fact.

<sup>&</sup>lt;sup>8</sup> Fine, Charles 1998. Clockspeed: Winning Industry Control in the Age of Temporary Advantage, NY: Perseus Books.