

Good morning Chairperson Gutmann and Vice Chair Wagner, and to all assembled.

My name is Damon Terrill, and I'm with Integrated DNA Technologies or "IDT." I'm IDT's General Counsel for international affairs, and also coordinate its work in the area of biosecurity matters relating to gene synthesis.

Joining me is my colleague Dr. Ralf Wagner, CEO and Chief Scientific Officer of GeneArt. Geneart works with IDT and the other member companies of the International Gene Synthesis Consortium, or "IGSC," on whose collective behalf we both appear here today. I speak for all them when I thank the Commission for affording us this opportunity to introduce you to the work our companies are doing to promote biosafety and biosecurity in commercial gene synthesis.

I'll begin with what I hope will be a useful summary of how and why our companies – competitors when in pursuit of our commercial missions – came to cooperate, and then collaborate, in pursuit of a common, public interest: namely, protecting public safety and national security, while promoting the beneficial application of gene synthesis, a technology fundamental to synthetic biology.

Dr. Wagner will focus his remarks on

Introducing the IGSC

In September of 2009, five of the world's leading gene synthesis companies came together to form the IGSC.

Member Companies

As the use of synthetic genes in vital research grew dramatically in the first decade of the new century, Blue Heron Biotechnology, DNA2.0, Geneart, GenScript, and Integrated DNA Technologies had each developed our own systems to prevent the potential misuse of genes, and we each had contributed actively to the public discussion of how best to promote biosecurity.

The IGSC member companies had then, and share now, two primary goals.

IGSC Goals & Objectives

(1) First, we knew that a common protocol to screen both the sequences of synthetic gene orders, and the customers who place them, would help us all to ensure that people who obtain genes from us with sequences related to potentially dangerous organisms are engaged in beneficial research and have a legitimate need to use them; our commitment has been to establish and put in place that protocol, and over time to improve it as the technology evolves.

(2) Second, the IGSC member companies committed to devote their common resources to working with governments and others concerned to promote the beneficial application of gene synthesis technology, and to safeguard biosecurity. We shared the belief that the broadest

possible understanding and adoption of biosecurity practices among synthetic gene providers would most directly advance those objectives.

It's this second charge that brings us here today.

Some additional background will help the Commission to understand how exactly we have acted to advance the biosecurity agenda in the past, and what the IGSC member companies are doing now to ensure the safe exploration of all that synthetic biology has to offer.

Industry Collaboration Toward Biosecurity: A Brief History

Even before the 2006 publication by the NSABB of its report, "Addressing Biosecurity Concerns Related to the Synthesis of Select Agents,"

NSABB Report Cover

the IGSC member companies then engaged in gene synthesis were using sequence and customer screening methods to identify potentially hazardous genes and to limit their sales to customers able to work with them safely and legitimately.

As the NSABB report suggested, however – and as the use of synthetic genes in biomedical and other research expanded – it had by then become clear to the academic, regulatory, law enforcement, and gene synthesis communities that the risks associated with the potential misuse of synthetic genes, however latent or theoretical, required systematic evaluation and eventually a framework for practices by both producers and users of synthetic genes that would limit those risks.

From then to the present day, the IGSC member companies have played a leading role in that evaluative process, working closely with our colleagues in government, private industry, and academia.

From the NSABB Report to the Framework Guidance and the FBI Reporting Program

In general terms, the IGSC member companies' contributions took three concrete forms:

First, our members participated actively in the discussion of the policy changes most likely to achieve real gains to biosecurity. That policy discussion took place over more than four years, and in a variety of fora, including, for example, in panel meetings hosted by AAAS, by the U.S. federal government, and perhaps most notably by the group that produced the "Options for Governance" report,

Options for Governance Cover Report

including MIT, CSIS, and the Venter Institute.

That policy conversation involved the broadest possible collection of stakeholders, of whom commercial gene providers were only one, producing a rich literature on which lawmakers and regulators have been and will be able to draw as they consider the most promising policy choices. We've been pleased to contribute to that body of knowledge as we could, and will look forward to helping it keep up with changes to the industry, and in technology, over time.

Second, the IGSC member companies have collaborated to engage together with the U.S. Government agencies, in particular the Department of Health and Human Services, responsible for drafting the Screening Framework Guidance for Synthetic Double-Stranded DNA Providers.

First Page of Draft Guidance

As it happened, our collective engagement in that process contributed significantly to bringing the member companies together within the IGSC. We welcomed the publication of the draft Guidance

IGSC Statement Welcoming Draft Guidance

and continue to support its final adoption. Each of us has committed to incorporating that final Guidance fully into our sequence and screening practices, including insofar as it may suggest changes or improvements to our current practices as they are reflected in the IGSC's Harmonized Protocol, which I'll describe in a moment.

Collaboration with Federal Bureau of Investigation – FBI Reporting Program

Finally, the IGSC member companies have worked closely with federal law enforcement, most especially with the Federal Bureau of Investigation as it developed its Pilot Program for reporting by gene synthesis companies of problematic orders.

Two of our companies, Blue Heron and IDT, hosted agents from the FBI for visits to our facilities and meetings with our managerial and scientific staff. Those visits were extraordinarily useful to us as we learned how law enforcement approached the subject; we've been told they also helped the FBI better to understand the technology and the reality of how synthetic genes are ordered, produced, and distributed around the country and around the world.

Their concrete result is that each of us now knows exactly whom to contact and how within the FBI, should our customer and sequence screening ever produce significant concern about a particular order or prospective customer. We have confidence too that the agents with whom we'd speak in that event are well-informed of the issues surrounding biosecurity and synthetic genes, and could respond appropriately. I'm pleased to report that, so far, none of our companies has ever had occasion to take advantage of the FBI's readiness in this regard.

Dr. Wagner may describe similar notification procedures in place in Europe.

The FBI deserves credit in another respect: While Blue Heron, DNA2.0, Genart, GenScript, and IDT were all participating in the FBI's conference in San Francisco, in the fall of 2009

Cover of FBI Conference Brochure

it became clear that we should combine our efforts at effective sequence and customer screening.

We agreed then what almost seems obvious in retrospect: that by taking advantage of the IT resources we each deploy, by sharing our experience with customer screening, and by collaborating to refine how we identify potential matches of ordered gene sequences against the various databases of pathogen sequences, we could simultaneously benefit from the economies of shared work while improving the end result for safety and security in the industry.

Together, the five IGSC member companies account for roughly 80% of the commercial gene synthesis capacity globally. We compete vigorously against one another, and the rest of the industry, for the opportunity to provide those genes to the scientists who need them.

We absolutely do *not* compete for the business of customers who would misuse synthetic genes, and we all have an especially acute interest in common with law enforcement, our governments, and with the public at large to do all we can to prevent the misuse of this vitally important technology.

The first result of that shared interest, and of the work among us that's followed, is the Harmonized Screening Protocol,

Cover Page of Harmonized Protocol

or more precisely the harmonized sequence and customer screening practices that the Protocol describes. The IGSC announced that the member companies had adopted and were applying the Protocol almost exactly a year ago, on November 19, 2009.

Press Release of Harmonized Protocol

In it, the IGSC member companies describe for all to see how we each apply the Protocol's five core components to promote the safe synthesis and sale of synthetic genes.

Those five components are:

1. [Gene Sequence Screening]: The screening of the complete DNA sequence of every synthetic gene order against a Regulated Pathogen Database developed by the IGSC and one or more of the internationally coordinated sequence reference databanks [i.e., NCBI/GenBank, EBI/EMBL or DDBJ] and, for orders originating in the United States, against the U.S. Select Agents list.
2. [Gene Customer Screening]: The screening of each potential gene synthesis customer to establish identity and clearance for delivery of genes, in accordance with national guidelines.
3. [Record Keeping]: All of the IGSC companies keep all screening, customer, and order records for at least eight years.
4. [Order Refusal & Reporting]: The IGSC member companies reserve the right to refuse to fill any order, and to notify authorities, most notably in the U.S., the FBI, upon identifying potentially problematic orders.

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5. [Ongoing Regulatory Compliance]: The IGSC companies comply with all applicable laws and regulations governing the synthesis, possession, transport, export and import of gene synthesis and other products.

What's Next?

As we made clear when we announced the Harmonized Protocol, its launch was not an end, but rather a beginning. It marked the first step of a process of collaboration amongst our member companies that will continue with others in the industry, with our customers in the academic, government, and private sectors, and with the regulatory and law enforcement communities whose job it is to ensure the safety and security of the public.

For ourselves, we are at work now to improve our own sequence screening methods and to adapt them to growing order volumes and increasing complexity. In particular, we face the challenge of developing – we hope with the support of others within and outside government – sequence databases designed specifically for sequence screening, and the software needed to perform that screening more effectively.

In addition to whatever recommendations the Commission may make, our first opportunity to engage with the regulatory community, with an eye to the future, will likely come as we implement the U.S. government's final screening Guidance, and incorporate its detail into our own Harmonized Screening Protocol.

With others, we'll hope to engage in a process to evaluate what other steps governments could take to encourage adoption of sound sequence and customer screening practices by gene synthesis providers across the globe, and the resources needed to advance that objective.

Specifically, (a) we believe that the U.S. and other governments ought to consider seriously supporting a centrally-curated database of problematic gene sequences for use by gene providers who must screen their orders. Such a database would need to be designed for use in sequence screening and maintained to incorporate new sequences as they become known.

(b) The U.S. and other governments might also choose to require verification of best sequence and customer screening practices as a condition of the use of public funds for research purchases of synthetic genes.

(c) Finally, governments should evaluate whether public funding of independently-developed gene sequence screening software could encourage its ready availability to companies and others who could put it to legitimate use.

For more discussion of those issues, and to describe in some greater detail the vitally important uses and applications of synthetic genes, I give the floor to my colleague Dr. Ralf Wagner of GeneArt.

Q&A Notes:

Q. *Why is the IGSC's "Regulated Pathogen Database" private?*

A. The databases and sequence contents that the IGSC draws upon for gene sequence screening are public. We don't add or subtract from those databases on our own initiative. However, we've not been asked to make the common dataset public, and would be reluctant to make a single compilation of those databases publically available, on our own initiative, out of concern that it could be misused.

It goes without saying that were we to receive a request from an appropriate authority to disclose it, we most certainly would.

Indeed, we'd welcome the creation -- by or with the support of governments -- of a single, authoritative database, designed for sequence screening by gene synthesis providers and others, and would be pleased to provide whatever help we could to support such a project.