Implementation of Synthetic DNA and Security Policy Actions

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Synthetic Genomics

- Advances in chemical synthesis of specialized nucleotide sequences open new possibilities
  - Ubiquitous and critical reagents and tools for life sciences research
  - Potential benefits to medicine and public health
  - Basis of a growing global industry of synthetic providers
- Concerns regarding potential misuse
  - Relatively small risk of misusers out of given pool of users;
  - How best to identify and address potential misuse?

NSABB Recommendations

- Examined biosecurity concerns of synthesis of select agents and recommended strategies:

  *Addressing Biosecurity Concerns related to the Synthesis of Select Agents (*Dec. 2006)

- 4 overarching areas:
  - Harmonize existing guidance (Select Agent Regulations etc)
  - Modify current laws and regulatory frameworks
  - Implement a framework for screening
  - Conduct studies, analysis and outreach

Dual Use Technologies

"Proposed Framework for the Oversight of Dual Use Life Sciences Research: Strategies for Minimizing the Potential Misuse of Research Information." (June 2007).

And associated draft Guidance on:

1) Criteria for Identifying Dual Use Research of Concern,

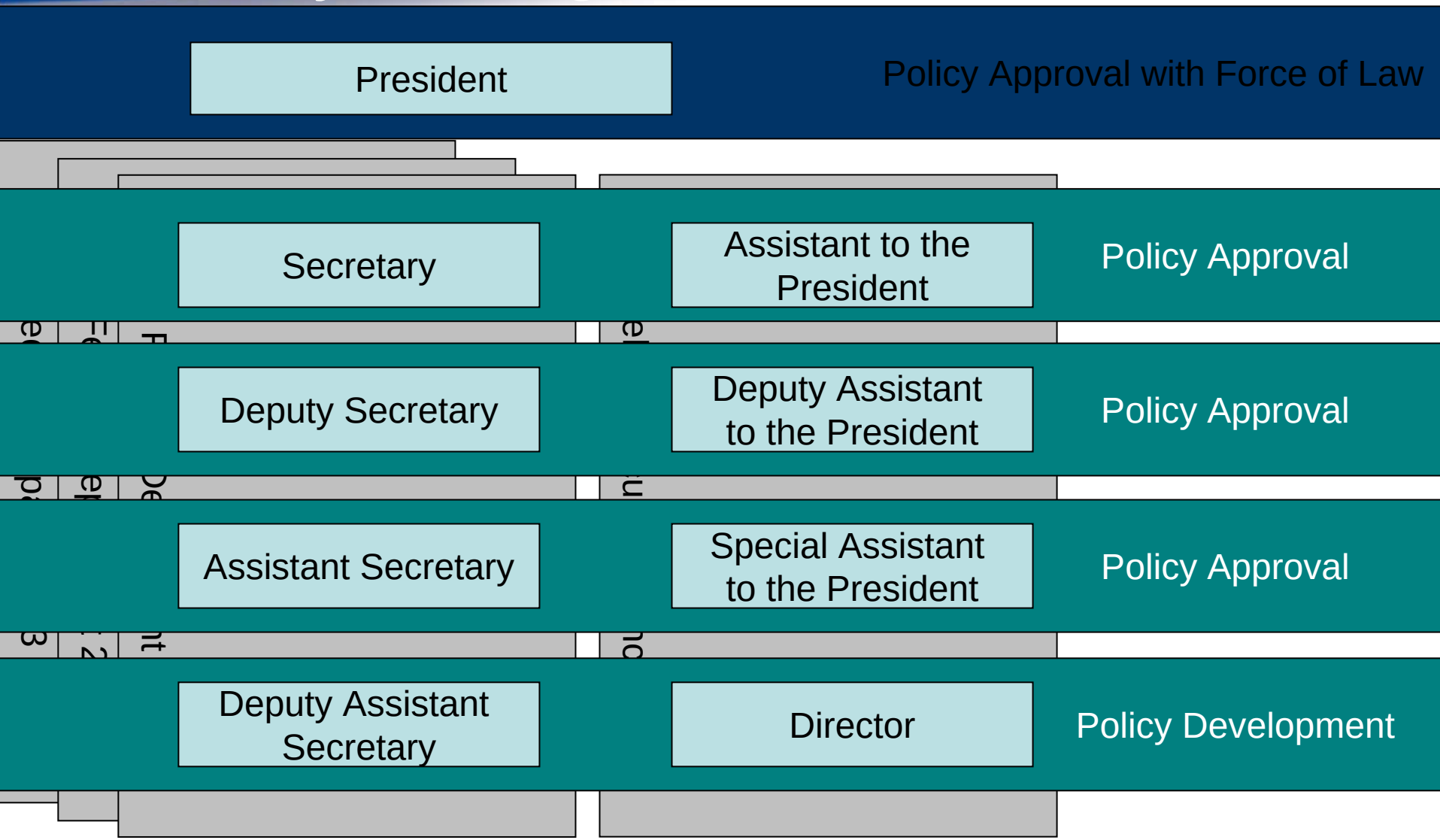
2) Tools for the Responsible Communication of Research with Dual Use Potential, and

3) Considerations in Developing a Code of Conduct for Dual Use Research in the Life Sciences.

Policy Coordinating Committees

"PCCs shall be the main day-to-day fora for interagency coordination of national security policy. They shall provide policy analysis for consideration by the more senior committees of the NSC system and ensure timely responses to decisions made by the President. Each NSC/PCC shall include representatives from the executive departments, offices, and agencies represented in the NSC/DC."

Executive Branch Long-Range Policy Making



Sub-PCC tasks on synthetic DNA

1. Develop harmonized guidance on SAR; revise regulations?
2. Develop screening framework for providers and users
3. Conduct international dialogue and outreach on synDNA
4. Legal interpretation of 18 USC 175c (smallpox)
5. Update *NIH Guidelines for Research involving Recombinant DNA Molecules* and *Biosafety in Microbiological and Biomedical Laboratories*
6. Reconcile Commerce Control List (CCL) with SAR
7. Convene panel to revise SAR with synDNA advances
8. convene panel to develop *predictive* oversight system

Guidance on SAR

Task Lead: USDA/HHS, partner with DOC

- Guidance document to clarify existing language has been completed and was communicated to stakeholders August 2008;
- Advanced Notice of Proposed Rulemaking (ANPR) in draft has cleared sub-PCC review. Must now go through OMB prior to Federal Register publication. (expected June 2009)

Develop Screening Infrastructure

Pillars of Customer Screening

- Customer Verification
- Biosafety Verification
- USG Restricted Entities Lists
- Restricted Sequences

Develop Screening Infrastructure

Task Lead: HHS

How to screen for misusers of synDNA?

- Proposed framework approved by the PCC;
- HHS/USDA jointly established an interagency working group - task of the IWG is to create a plan, including a timeline and milestones, for the development of a comprehensive set of screening guidance for the synthetic nucleic acid provider community.
- Lead and support departments and points of contact were established for six sub-working groups, focused on addressing the key elements of the framework.
- HHS and USDA, as co-chairs of the IWG, anticipate the completion of the plan for guidance development by mid-January for transmission to HSC.

International Outreach

Task Lead: State

Develop coordinated and consistent US Government message to international community on synthetic DNA:

- State has drafted an outreach strategy and is aiding elevation of topic in international settings;
- Begin sharing US experiences Sept. 2008
- Begin sharing US Policies January 2009

Resolve 18 USC 175c

Task Lead: DOJ, Partners HHS/DoD/DHS

- DOJ completed Office of Legal Counsel (OLC) Opinion Letter
- Disseminated by the CDC to Select Agent Officials/institutions and posted on the website:

http://www.selectagents.gov/infoBoard.htm

Update Biosafety Guidelines

Task Lead: HHS

- The biosafety issues raised by synthetic genomics have been addressed through a deliberative process involving consultation with the scientific community and the public, via the NIH Recombinant Advisory Committee (RAC) and has resulted in proposed amendments to the *NIH Guidelines for Research Involving Recombinant DNA Molecules* to address research involving synthetic nucleic acids.
- A federal register notice outlining the proposal and requesting public comment is at OMB review and should be published shortly. *BMBL* revisions will follow along those to the *Guidelines*.

Reconciliation of CCL and SAR

Task Lead: DOC, partners HHS/USDA

- Will be addressed upon completion of tasking on SAR guidelines;
- CCL undergoing revision by BIS/DOC via ETRAC

Predictive Oversight Framework?

Task Lead: HHS

What scientific advancements are needed to create a predictive oversight framework?

- HHS contracted with National Academies to conduct a study to identify the scientific advances needed to enable prediction of biological function from primary nucleic acid sequence.

Dual Use Framework

Report delivered to EOP and Briefings received;

During transition there will be decision made as to “home” for USG deliberation of Dual Use framework, at present it will occur via the Biotechnology Subcommittee, within the Committee on Science within NSTC. (January, 2009)

NSTC

Environment and Natural Resources	Science	Technology	Homeland and National Security
Air Quality Research	Aquaculture	Aeronautics	Decontamination Standards &Technology
Disaster Reduction	***Biotechnology***	Biometrics	Foreign Animal Disease Threat
Global Change Research	***Education***	Nanoscale Sci, Engineering	International
Ecosystems	***Human Subjects Research***	Networking IT	National Security R&D
Ocean Science & Technology	***Research Business Models***	Hydrogen	Standards
Toxics and Risks	***Social, Behav., Economic***	Infrastructure	WMD Medical Countermeasures
US Group Earth Observations	Digital Data	Manufacturing	
Water Availability and Quality	Domestic Animal Genomics		
	Obesity Research		
	Physics of the Universe		
	Prion Science		
	Plant Genomes		
	Scientific Collections		
	Trans-Border Movement		
	Export Controls		
	Food and Ag Research		

Questions?