“Broader Impacts”
“Ethical, Legal, Societal Implications”
“LEEDR”

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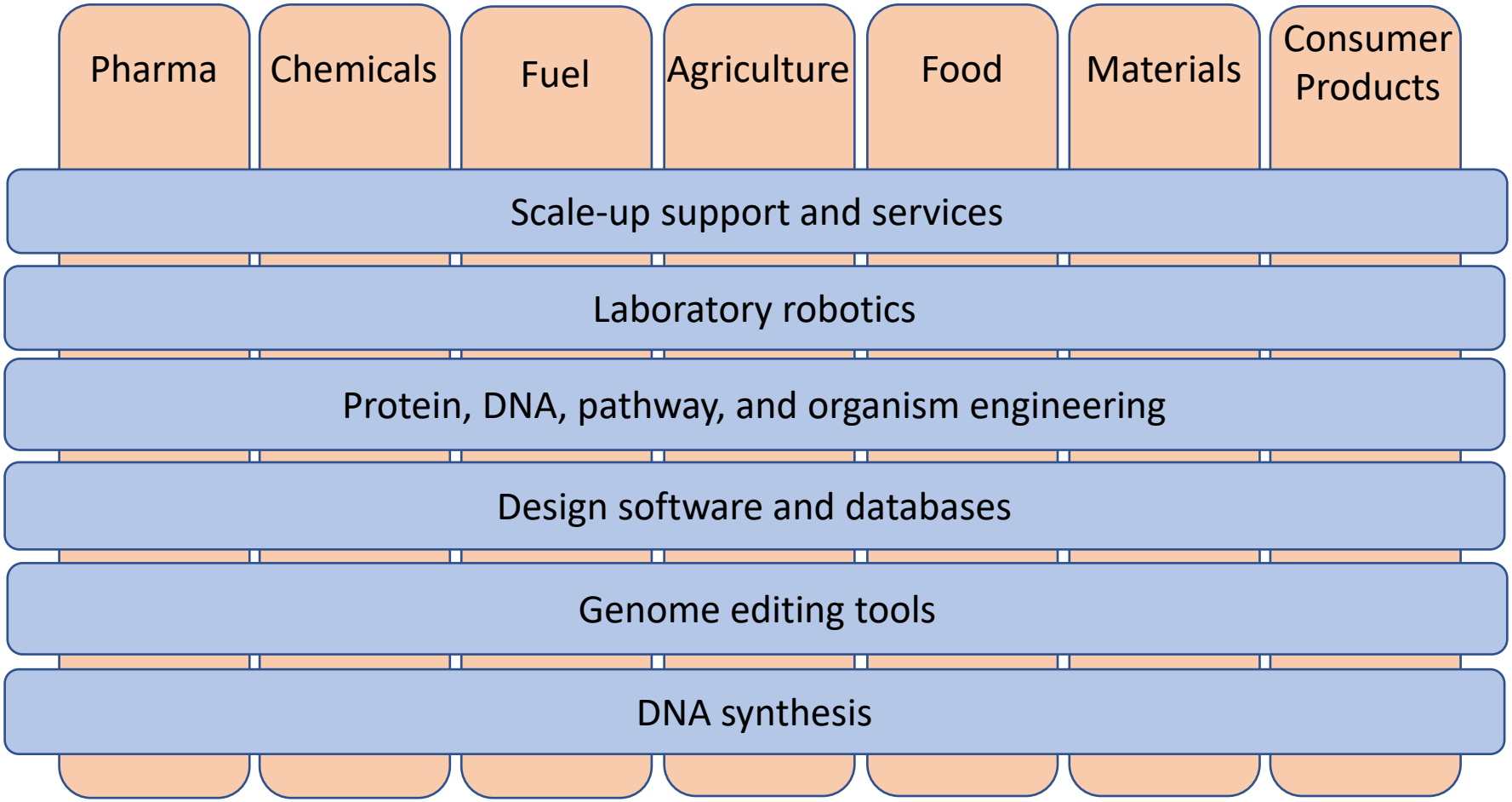
Things to Keep in Mind

Societal implications of biotechnology are broad and diverse because biotechnology is broad and diverse.

For some biotechnology,
the societal hurdles are as big as the technical hurdles.

Army is a stakeholder in these conversations.

Syn Bio Industry Ecosystem



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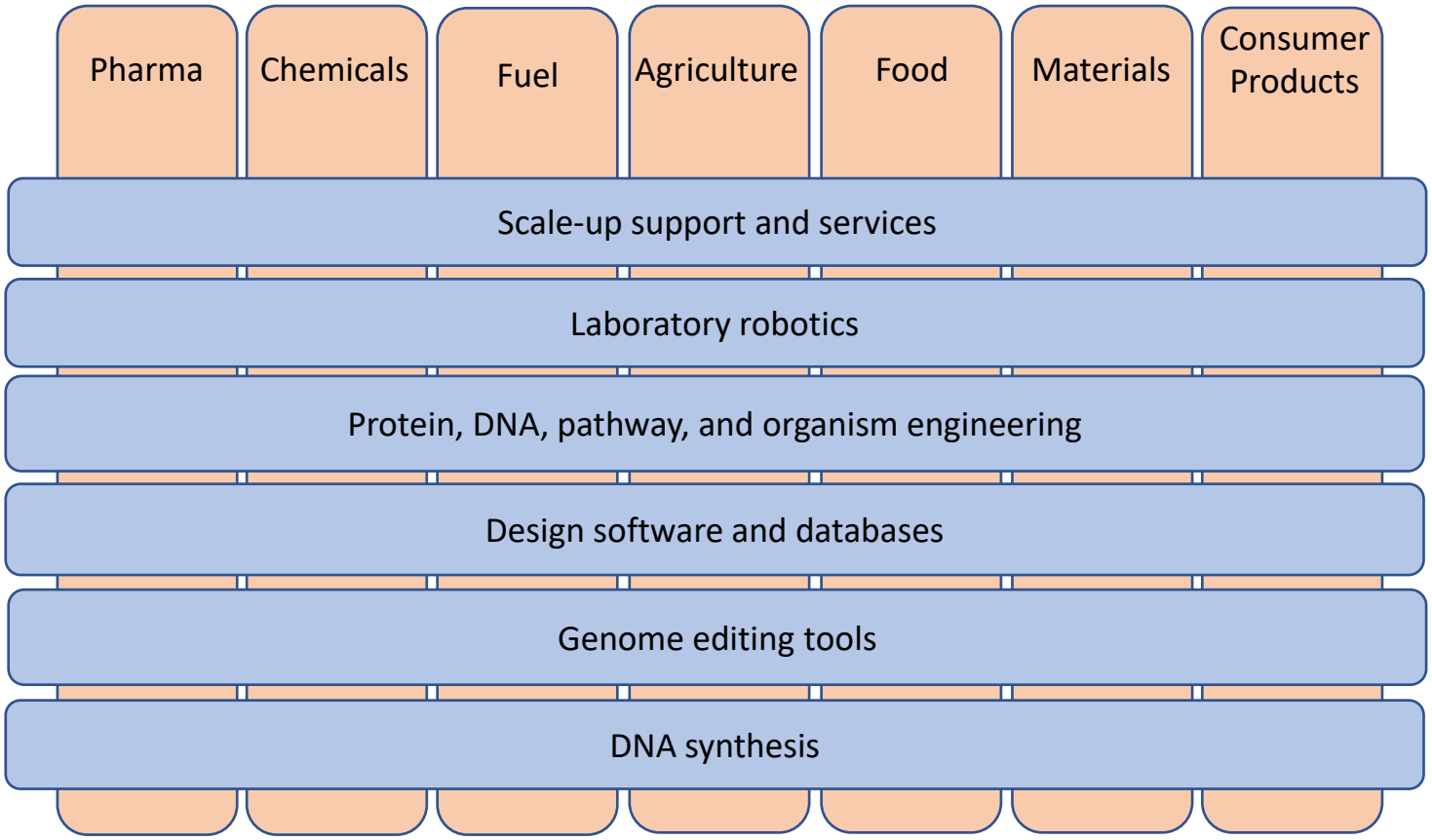
Capabilities vs. Products

Syn Bio Products of interest to DoD: Acquisitions



Syn Bio Capabilities: Investments

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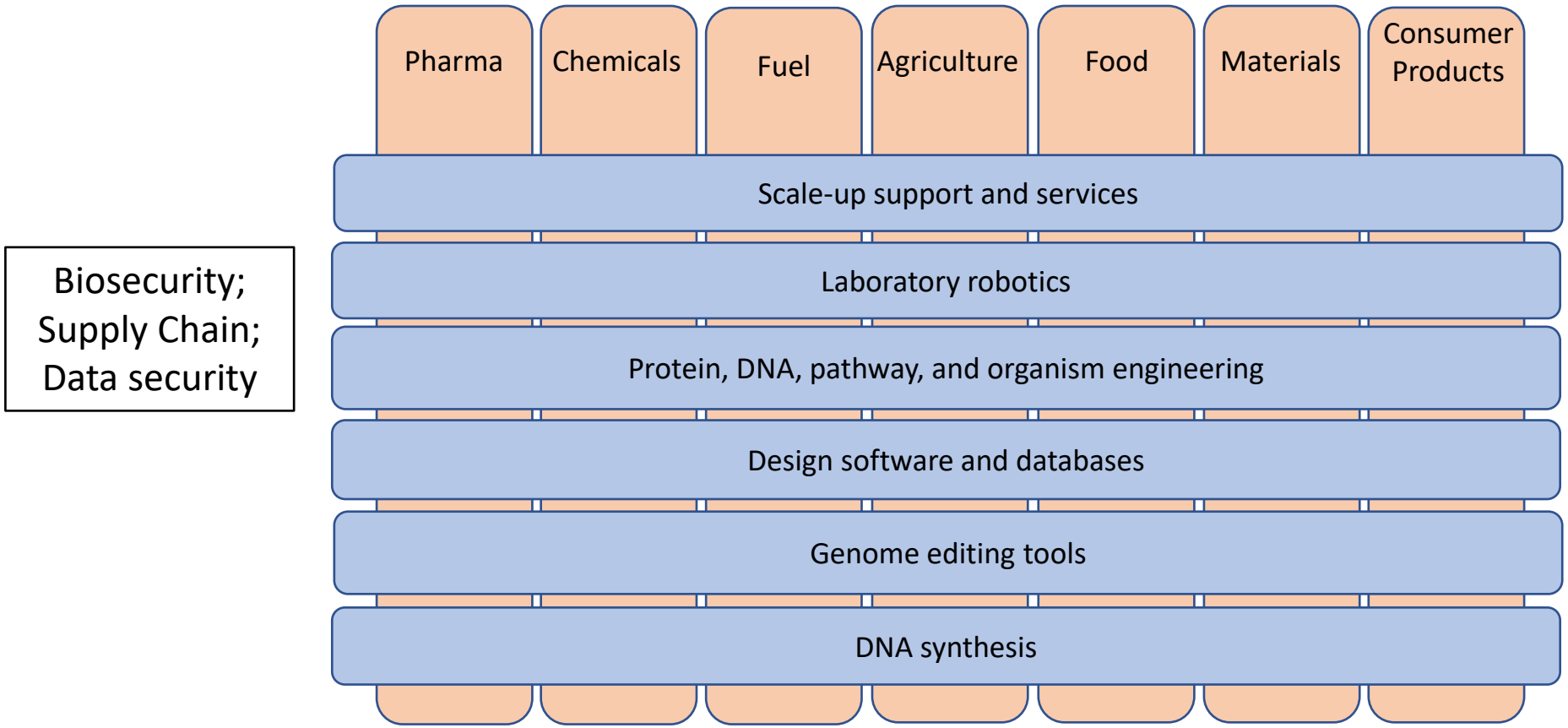
Capabilities vs. Products

Regulation; International Responsibilities



Biosecurity; Supply Chain; Data security

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Biotech Products

U.S. Biotech Regulatory System:

- FDA, USDA, EPA and the Coordinated Framework
  - Product-based system using existing authorities within these agencies
  - Often, is based on claims (What is the intended use of your product?)

- Well established regulatory pathways for some products
  - pharma, crops with transgenes, E. coli grown in bioreactors

- Uncertain or inconsistent regulatory approaches for some newer products
  - GE mosquitoes (Oxitec saga)
  - GE cattle and other mammalian agriculture (USDA vs. FDA)
  - Genome edited plants and animals (USDA vs. FDA)

- DoD has its own biosafety and containment rules for field testing GE organisms on DoD lands (and perhaps more general environmental guidelines)

Biotech Products

Regulatory Challenges for Novel Products:

- Human applications – genome editing, neurotech

- Intentional environmental persistence
  - GE Chestnut trees, GE biocontrol insect agents
  - Gene drives (DARPA Safe Genes)
  - Sensors (microbes or plants – e.g. DARPA APT, NRL ocean sensors)
  - Environmental microbiome engineering (DARPA BRICS)
  - Structures (DARPA ELM)

- Potential environmental impacts from non-environmental products
  - GE salmon (AquaBounty lawsuits)
  - Engineered human microbiome; gut, skin (DARPA ReVector), etc.

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Requires forethought, engagement with regulators, other measures

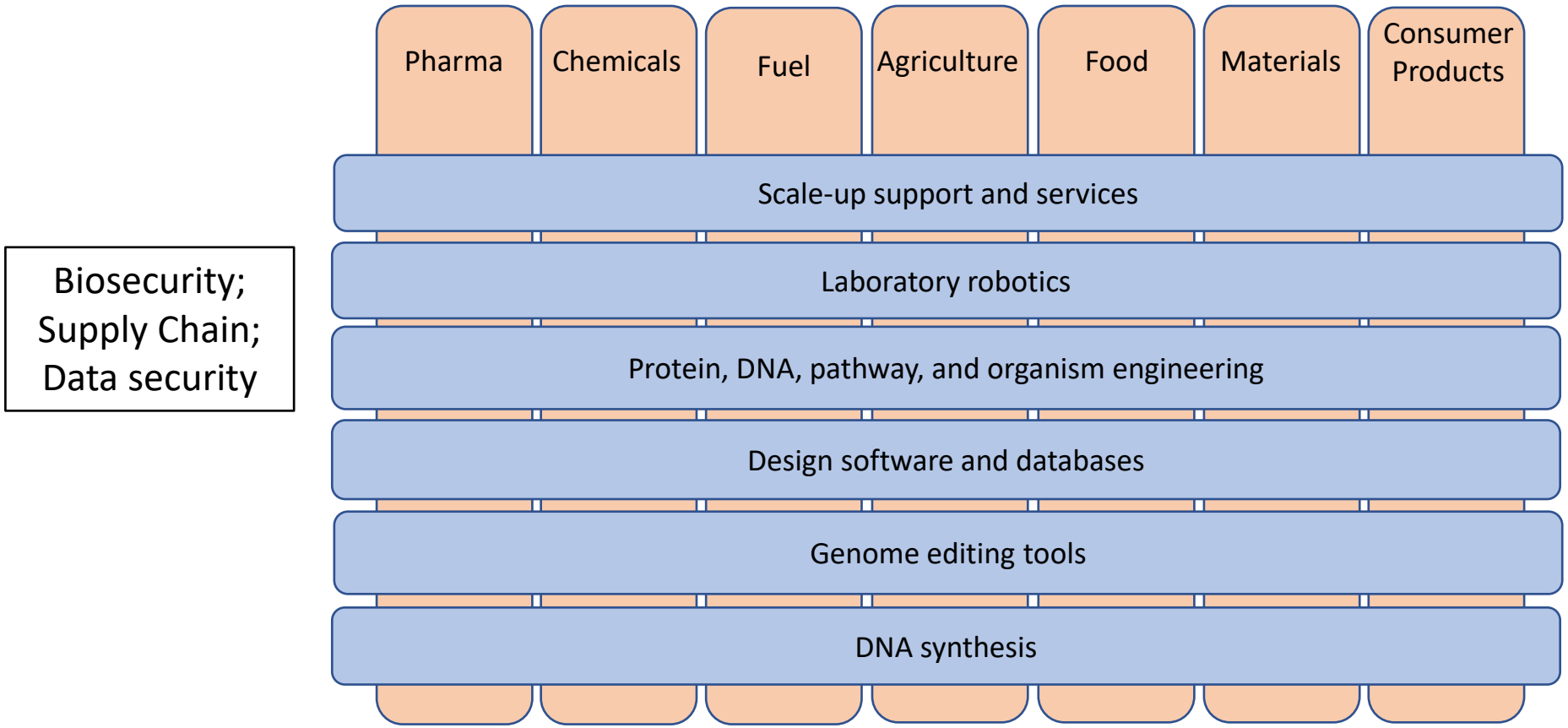
**Gaps in the regulatory system do not remove responsibility (e.g. non-agricultural uses of plants, FDA environmental oversight)

International Responsibilities

- Biological Weapons Convention, WHO containment guidance, etc.
- Convention on Biological Diversity and “living modified organisms” rules (Cartagena Protocol)
  - Gene drives and other environmentally persistent applications
  - Microbes for sensing in international waters (Naval Research Lab)
- Convention on Biological Diversity and genetic resources and benefits sharing (Nagoya Protocol)
  - Does digital sequence information count as “genetic resources”?

Capabilities vs. Products

Regulation; International Responsibilities



Biosecurity; Supply Chain; Data security

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Capabilities

Biosecurity Concerns:

- Primary concerns
  - Misuse of capabilities to generate or "enhance" pathogens or toxins
  - Misuse to otherwise harm people, animals, or the environment
  - Accidental release or unintended consequences

- Second-order concerns
  - Backlash by public, lawmakers, regulators, funders
  - Mistrust of science and industry

Biosecurity Challenges:

- Rapid pace of development of capabilities

- Democratization, accessibility of tools (though most powerful remain restricted)

- Cumulative nature of information hazards

Capabilities

Supply Chain and Competitiveness:

- Elements of supply chain:
  - Physical infrastructure (e.g. laboratories, bioreactors)
  - Human infrastructure (e.g. innovators, technicians)
  - Intellectual property (e.g. patents, trade secrets, data, DNA sequences)

- Objectives:
  - Maintain control of supply chain (within U.S., if possible)
  - Protect supply chain elements from hackers, adversaries, etc.

Capabilities

Challenges for Supply Chain and Competitiveness:

- Competing on costs, other incentives
  - Off-shoring of manufacturing, etc.
  - Start-ups and acquisitions – opportunities for strategic investment (CFIUS)

- Distributed nature of syn bio industry ecosystem
  - Internationally – different rules (e.g. DNA data asymmetry)
  - By tools and capabilities – data and products may flow through multiple companies

- Early days for syn bio
  - Few established standards – data sharing, subcontracting
  - Uncertain industry structure (behemoths vs. niches)

Additional Societal Obligations?

- Products with novelty, persistence, uncertainty
  - But how novel is novel?

- Engagement with stakeholders – NASEM reports on:
  - Gene drives, 2016
  - Human genome editing, 2017
  - Forest biotech, 2019
  - Future products of biotech, 2019

- DoD has additional hurdles
  - "Why is DoD doing that?"
  - Perceptions for some specific cases
  - Cultural issues and trust

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societal hurdles are as big as the technical hurdles.

Army is a stakeholder in these conversations.

What Army can do

- Track and participate in broader discussions on standards, biosecurity, oversight, digital sequence information, etc.
- Understand the broader context (including industry) of investments.
- Incentivize biosecurity-by-design and biocontainment in tech development.
- Provide funding for engagement with regulators and others.
- Provide funding for environmental risk assessment science.
- Reconsider tech transfer and acquisitions structures.