Comments, NSABB Meeting, Session I

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Summary, Highlights

- Working Paper Findings: lack resolve, fail to address a clear need in the face of 'difficulty' (i.e., to describe studies that should not be funded)
- Attributes 'of concern': transmissibility 'trumps' countermeasure resistance
- Safety and security assessments are based on faulty and dangerous logic, unjustified assertions; risks are underestimated

Findings are too tentative (and hence, unhelpful)

"Key Finding 1: There are many types of GOF studies and not all of them have the same level of risks. Only a small subset of GOF studies--GOF studies of concern--entail risks that are potentially significant enough to warrant additional oversight" (lines 81-83)

Comment:

- Why "potentially"? ...Define a subset that <u>does</u> warrant additional oversight

Findings are too tentative (and in this case, says nothing)

"Key Finding 4: There are life sciences research studies that should not be conducted on ethical or public health grounds if the potential risks associated with the study are not justified by the potential benefits" (lines 90-92)

Comment:

- Re-states the starting premise!
- What are those studies?? (Why then the RBA?)

NSABB fails to address a clear need, abdicates responsibility

"There may be GOF studies that should not be funded on ethical grounds, but it is difficult to identify or describe such studies, particularly based on general or hypothetical descriptions." (lines 1159-60)

Comment:

- "Guiding principle 9": "NSABB will consider whether there are certain studies that should not be conducted under any circumstances, and if so, articulate the critical characteristics of such studies" (lines 320-1)
- Yes or no? (This is actually not so difficult!)
- If yes, the studies need to be identified now (will not get easier!)

Attributes of concern?

"the working group identified the attributes of GOF studies of concern, which are studies that could generate a pathogen that is: highly transmissible, highly virulent, and resistant to public health control measures" (Recommendation 1, lines 110-112)

Comment:

- Public health measures, despite being effective in theory, often cannot control highly transmissible pathogens! (Note: influenza A(H1N1)pdm09 virus)
- High transmissibility renders control measure resistance irrelevant (acknowledged in RBA 8.4.4.3)
- Any 2 of these phenotypes are sufficient for concern

Findings are unsupported

"Key Finding 2: The U.S. government has effective policy frameworks in place for managing risks associated with life sciences research"

Comment:

- Effectiveness has not been demonstrated
- On the contrary, framework may be flawed:
  - players, institutions affected by conflicts of interest
  - process non-transparent (acknowledged…line 891)
  - local oversight = haphazard, inconsistent, non-standardized, unfunded

RBA: poorly justified assumptions, flawed, dangerous logic (security)

"interestingly, risks associated with information from future GOF studies with influenza, SARS and MERS appear small...because most of the information of interest is already published, or non-GOF information relating to pathogens that are more attractive agents of harm is already available" (lines 472-4)

Comment:

- Not true! Optimized phenotypes have not been described (e.g., further enhancements in mammalian adaptation, transmissibility; combinations)
- Presumes to know motivations and goals of all mal-actors in all circumstances, assumes others will act as we would = grossly irresponsible guesswork!

RBA: poorly justified assumptions and flawed logic (safety and security)

"If currently mandated biosecurity systems are effective, outsiders have little chance of causing harm on their own." (lines 471-472)

Comment:

- Do we really think they are always effective?? And if not...?

"...risk associated with the wild-type 1918 strain is already so great it is difficult to increase risk substantially" (lines 457-458)

Comment:

- On what basis is this asserted?? (none)
- Why use 1918 strain as comparator?

RBA: poorly justified assumptions and flawed logic (safety and security)

Comment:

- Analysis of laboratory safety assumes that all work takes place in U.S. or in high-containment labs = Not true
- Fails to recognize that freely-available information allows re-creation of strains 'of concern' in very different laboratory settings, with lesser degrees of physical security and safety
- Safety and security risks are greater than asserted (assumed) in RBA

Confusion about biosecurity?

"Key Finding 5: The biosafety and biosecurity issues associated with GOF studies are similar to those issues associated with all high containment research..."

Comment:

- Meaning unclear, possibly confused
- 'High containment' is not necessarily relevant
- Information-associated risks can occur in other settings

RBA: poorly justified assumptions, assertions (benefits)

"Most GOF studies provide benefits in the form of new scientific knowledge, and many of these benefits are unique" (lines 475-6)

Comment:

- Scientific knowledge, per se (alone), does not justify large risks
- Uniqueness is over-stated, and/or specific attributable benefits (attributable to unique knowledge) minimal (and not justified)
- In fact, benefits are less 'unique' than risks!