

## Session 4: Roundtable Discussion

Facilitated Discussion Leader: Leon Bruner (Gillette)

### General Conclusions / Answers to Questions Posed:

- The main barriers identified fit into the following categories:
  - Funding / Resources:
    - Government agency priorities for funding.
    - *Recommendation: Individuals need to keep pressure on agencies to fund focused research on validating and implementing alternative test methods.*
  - Scientific:
    - Lack of data availability from industry libraries – proprietary information, influence of global competition, etc. Outside of a government mandate to make data available and compensation companies for releasing data, not much can be done.
    - Data in industry libraries may be abundant, but it is not uniform and some is archived in hard copy format and not easily available.
    - Publishing in the peer-reviewed literature does not provide the individual animal data that is needed to run statistical models for predictive toxicology.
    - Agencies need proof-of-concept.
    - *Recommendation: Research needs to be focused on elucidating mechanism of action, validating new methods, and translating them to an applied risk assessment use. More reference data on biomarkers is also needed.*
  - Education:
    - Level of comfort with alternative assays in regulatory community
    - SOT (and its members) need to provide a platform for education on alternative methods within the toxicology community to promote translational research and move alternative methods from the bench to an application that can be used in risk assessment and benefit society.
    - *Recommendation: All interested parties need to keep pressure on the toxicology community to provide forums for all stakeholders to participate and educate on the use of alternative methods.*
  - Coordination / Leadership / Regulatory Change:
    - NICEATM has an issue with outreach. Not as many submissions or nominations for method validation have come in as expected.
    - The Animal Welfare Act does provide that investigators should consider alternatives to animal testing and use them when appropriate, however awareness of regulatory requirements is low.
    - *Recommendation: The NTP could provide a coordinating agency within the federal government.*
  - Clarity of Objectives:
    - *Recommendation: Need to identify short term and long-term objectives.*

- Questions that panelists were asked to consider include:
  - Does the community have a collective understanding of the research now in progress? Is research focused in the correct areas?
    - No, individuals do not have a wide breadth of understanding. There needs to be national coordination to gather data and present it.
  - The agencies have implemented many programs aimed at the development of new methods – Is it clear what agency strategies in this area are? Is there a need for an overarching federal strategy for prioritizing this research?
    - A few agencies (EPA, FDA, NTP) have begun to implement alternative methods programs. There is a need for an overarching strategy that could be provided through NTP’s Roadmap. Short and long term goals need to be clarified.
  - Is funding of research directed to the right targets? Does the funding ensure transfer of new methods from the bench to practical use in a regulatory framework?
    - Funding sources for this area are unclear and there is a need for a guiding agency to focus and allocate funding.
  - Are current regulatory frameworks too rigid for the substitution of validated methods? Should regulatory frameworks be changed in a way that makes them more flexible with regard to the adoption of new methods?
    - Yes, current frameworks are too rigid. The rigidity is provided by current law and guidelines, and furthered by the fact that regulators are uncomfortable in changing the structured framework. Some flexibility is starting to creep in, *i.e.* OECD acceptance of *in vitro* eye/skin corrosivity testing.
  - Is the federal decision making approach designed in a way that facilitates the incorporation and use of valid test methods? Can the acceptance process be improved? If so, how?
    - No good answer to this question; this is the area that is most unclear.
  - What are the barriers to removing animal testing methods from federal guidance once a validated replacement method becomes available – method preference, historical data, legal barriers, inertia?
    - There wasn’t a clear answer to this question. Discussion focused on where methods have been deleted, *i.e.* OECD removed animal tests for skin/eye corrosivity and therefore, member countries were forced to remove their requirement; OPPT is also removing the chronic dog assay.