My name is Kelvin Lee and I am the Gore Professor of Chemical Engineering at the University of Delaware and serve as the Director of the Delaware Biotechnology Institute - a successful public, private, academic partnership in Delaware. Together with my close colleague, Michael Betenbaugh, Professor of Chemical and Biological Engineering at Johns Hopkins University, we are in the early stages of leading a new industrial consortium related to genome-scale technologies to foster innovation in the biomanufacturing area. Our consortium includes academic members (primarily from the United States, but complemented by institutions in Europe and Asia), industrial members (many of the large biotechnology and pharmaceutical companies as well as start-up and medium-sized companies), as well as some federal agencies (with support from NIST and NSF).

We very much appreciate the opportunity to provide input on the AMTech initiative and offer some thoughts related to the questions posed by NIST as outlined below.

Sincerely,
Kelvin H. Lee
Director, Delaware Biotechnology Institute
Gore Professor of Chemical Engineering

c c Dr. Michael Betenbaugh, JHU

Comments from Kelvin Lee (Univ Delaware) and Michael Betenbaugh (Johns Hopkins Univ)

1. Should AMTech consortia focus on developments within a single existing or prospective industry, or should its focus be on broader system developments that must be supplied by multiple industries?

We believe that each AMTech funded consortium should focus on a single existing industry; although we further believe that the AMTech program should provide support for multiple industries. By allowing each funded effort to focus on a single industry, one can maximize the impact on that particular industry. There is a risk that funded programs that have too broad of an emphasis will not have the desired impact on our manufacturing infrastructure and future.

2. Who should be eligible to participate as a member of an AMTech consortium? For example, U.S. companies, i.e., large, medium, and/or small; institutions of higher education; Federal agencies; state, local, and tribal governments; and non-profit organizations?

Any organization capable of dealing with government contracts of the scope proposed by AMTech should be able to serve as the primary contracting institution. Given the emphasis on a consortia model,
the institution should have the capacity to administer subcontracts as needed. It is important to keep
the opportunity to participate as broad as possible given that innovations can come from a variety of
sources: academic, state and federal agencies, non-profits, and businesses. For these same reasons, we
believe that consortium memberships should be open to both large and small companies as innovations
will come at all levels. Indeed, a consortium involving company members of different sizes together
with academia and government will enable synergies to develop between and across these different
levels. There may be developments in the small company domain that could be relevant to large
companies and vice-versa. Giving flexibility in the structure enhances interactions between entities.

3. Should AMTech place restrictions on or limit consortium membership?

No restrictions should be placed on consortium membership.

4. Who should be eligible to receive research funding from an AMTech consortium? For example, U.S.
   companies i.e., large, medium, and/or small; institutions of higher education; Federal agencies; state,
   local, and tribal governments; and non-profit organizations?

All of the eligible members of a consortium should be able to receive funding from an AMTech
consortium provided they can administer those funds in a reasonable way. However, it is reasonable to
expect that the academic institutions, federal agencies, and smaller companies should receive the
majority of the funding. Many of the larger companies will not be interested in the financial support as
much as access to intellectual capital generated by the consortium. These companies will often possess
the financial muscle but may lack the innovation available in the consortium. Thus the consortium
funding can be structured in such a way to adjust funding according to financial capacity of the members
but make membership open to large and small entities.

5. What criteria should be used in evaluating proposals for AMTech funding?

Vision of a consortium for an industry, ability to make that vision a reality, industries with potential to
make an impact on the national industrial competitiveness, structure of the consortium that is capable
of accomplishing mission.

6. What types of activities are suitable for consortia funding?

We believe that research and development activities relevant to moving the innovation economy
forward and particularly important to fund. These may be activities related to specific research targets
and development milestones. These will also include activities related to bringing consortium members
together (travel and meetings) as well as activities that provide, perhaps in a limited way, connections to
innovation concepts in other countries.

7. Should conditions be placed on research awards to ensure funded activities are directed toward
   assisting manufacturing in the U.S.?
One possible condition is that funds be expended only in the US or to support US-based activities.

8. What are ways to facilitate the involvement of small businesses in AMTech consortia?

Require each consortium to have at a specified (one, two, etc.) number of start-up or small business.

9. What are best practices for facilitating the widest dissemination and adoption of knowledge and technology through consortia?

Websites and meetings. Also creating a single or a few physical sites as the leader or hub of the activity will ensure that this is the focal point of the program. Having a leader site will enhance the capacity to facilitate interactions between members during meetings, annual retreats, etc.

10. While it is expected that the research efforts of AMTech consortia (including participants from the Federal, academic, and private industry sectors) will take place largely at the pre-competitive stage in the development of technologies, the generation of intellectual property is possible, and even likely. What types of intellectual property arrangements would promote active engagement of industry in consortia that include the funding of university-based research and ensure that consortia efforts are realized by U.S. manufacturers?

The most successful models in our industry are ones in which the university-based research is funded both by government and consortium members and funding consortium members have first rights for the utilization of these technologies. Indeed, incentivizing companies to join would require that each contributing consortium member has rights. Outside entities would only have ability after the consortium members have refused their opportunities. In contrast, work taking place at companies should be the privilege of that company according to conventional approaches. When the work is done in partnership with an academic institution and if the academic institution holds the lead on intellectual property, there is a clear path forward for the administration and sharing of intellectual property after agreement on licensing terms. If multiple competitive for-profit members of a consortium share rights to a single piece of intellectual property through their participation in the consortium, challenges can emerge that could limit the impact of the work.

11. Would planning grants provide sufficient incentive for industry to develop roadmaps and initiate the formation of consortia? If not, what other incentives should be considered?

Planning grants offer an excellent first step to develop roadmaps and initiate consortia. Companies are eager to leverage these activities but only after seeing the government put in seed funding to initiate such an effort.

12. Should each member of an AMTech consortium be required to provide cost sharing? If so, what percentage of cost sharing should be provided?

Each for-profit member of a consortium should be required to make a commitment to the effort.
However, the types and levels of cost sharing should recognize the different sizes of businesses that may participate. For example, a start-up company will not be able to provide the same level of commitment that a large, multinational, company might be able to provide. Thus, in kind cost sharing, should be an option.

13. What criteria should be used in evaluating research proposals submitted to an AMTech consortium?

The quality of the science and technology, the potential impact on the community (not just the consortium, but also other companies working in the same technology base), the quality of the team, and the impact on a variety of technology areas achieved by addressing a spectrum of activities.

14. What management models are best suited for industry-led consortia?

Each consortium should be able to suggest their own management model and these should be evaluated in the proposal process (perhaps with a special section dedicated to management). Ultimately, a single institution should serve as a primary contractor and will be required to develop an effective management model to ensure that the group meets the proposed milestones.

15. Should the evaluation criteria include the assessment of leadership and managerial skills?

Assessment of leadership and managerial skills should be a relevant component but not the single most dominant criterion. The quality of the research plan, potential for impact, and the relevance of the members to the field are all more important. For example, this should not be an opportunity to enable a contractor to join a program without any previous experience in the targeted industry.

16. Should limitations be placed on the duration of consortia?

No limits should be placed on the duration of the consortia. The government funding may be expected to have some sunset clause but only after sufficient time for consortium to get solid and consistent industrial base.

17. How should an AMTech consortium’s performance and impact be evaluated? What are appropriate measures of success?

Relatively straightforward ways to evaluate the initiative are to examine the (a) amount of matching funds raised (b) industrial members in the consortium—broken down by both large and small companies (c) publications generated by academic/govt/industrial participants (d) patents issued by the initiative (e) rate of change of membership with time (increasing versus decreasing). Longer term measures such as growth of an industry or implementation of technology may be years in the making.

18. What are the problems of measuring real-time performance of individual research awards issued by an industry-led consortium? What are appropriate measures of success?
Most of the impact typically comes several years after the initiative has made investments so there will inevitably be a lag between funding and measurable impact. After that period, these consortia should be accountable using quantitative measures described above.

19. How should the NIST AMTech program be evaluated?

The AMTech program could be evaluated based on the size of the industries that are supported as well as their growth rates. The program should support programs with a large and expanding industrial base. These measures can be estimated by market capitalization, number of firms, growth rate over the past 10 years versus measures of growth over the next 5 to 10 years.

20. What are lessons learned from other successful and unsuccessful industry-led consortia?

The lessons learned are that these consortia can be successful if they are initially kick-started as a joint government-private industry initiative. As the consortia mature, the government could ease out and then let the private companies take over. These initiatives also seem to be more successful if there is both a physical and conceptual focal point for the initiative. If it is a focused area, then members will remain committed to the program but if it becomes too diffuse or too expensive, members will fail to renew. It will also be useful if there is a central location for the headquarters of the initiative. While members may do research at different locations, it will be useful to have a place where members can meet and to serve as the focal point or “home” for the consortium.

21. How can AMTech do the most with available resources? Are there approaches that will best leverage the Federal investment?

Some type of matching program would be reasonable. The larger companies are much more willing to provide funding and other resources if they discover that the government is matching these initiatives. It seems like matching programs with the government open doors to funding that are not available without it. Government funding also provides the stamp of approval on an initiative. A requirement for co-funding by private enterprises (perhaps not at a 50-50 level but some other level) is one mechanism to consider. Another mechanism is that membership in a consortium requires an annual fee. Small companies could be asked to participate through in kind contributions or other mechanism more appropriate to their scale of operation.

22. How should AMTech interact with other Federal programs or agencies?

Many of the most successful programs are interagencies programs and AMTech should be encouraged to cosponsor initiatives with other federal agencies such as NSF, DOE, or NIH. Also, investigators at these agencies as well as NIST investigators could certainly be a part of any specific initiatives-by in kind contributions as consortium members or by receiving funding directly.

23. What role can AMTech play in developing, leading, or leveraging consortia involving other Federal
agencies?

No comment.