STATE OF ARKANSAS
MIKE BEEBE
GOVERNOR

December 5, 2011

Dr. John P. Holdren, Director
Office of Science and Technology Policy
Executive Offices of the President
725 17th Street, Room 5228
Washington, DC 20502

Dear Dr. Holdren:

The State of Arkansas, along with the United States Food and Drug Administration (FDA), has recently undertaken a bold initiative to meet the "grand challenges", as set forth in the Request for Information on Building a 21st Century Bioeconomy, by partnering to create the Center for Excellence for Regulatory Sciences. I offer my support for the attached responses from the FDA's National Center for Toxicological Research (NCTR) to the Request. I am confident that this partnership is an important component in helping the Office of Science and Technology Policy (OSTP) develop a successful National Bioeconomy Blueprint.

I am convinced that the work being accomplished by the professionals at the NCTR is critical to meeting the national objective of creating a strong 21st Century Bioeconomy. The expanded sharing of resources, facilities, and education initiatives supports the goal of utilizing the embedded resources in Arkansas to meet the opportunities of the emerging bioeconomy.

As stated in the Request, biological research underpins the foundation of a significant portion of our economy. I look forward to strengthening the partnership with the federal government through this important economic development initiative.

Sincerely,

Mike Beebe

MB:jb
Enclosure

UALR

OFFICE OF THE SPECIAL ADVISOR TO THE
CHANCELLOR FOR ECONOMIC DEVELOPMENT

December 6, 2011

The Honorable Dr. John P. Holdren,
Director of the Office of Science and Technology Policy
Executive Office of the President
725 17th Street, Room 5228
Washington, DC 20502

Dear Dr. Holdren:

I am pleased to submit a reply to the Request for Information on Building a 21st Century Bioeconomy. Arkansas Governor Mike Beebe has asked me to take a leadership role in this activity, a task which I have eagerly accepted. I am excited about our activities in Arkansas, especially those that work to collaborate with and extend the effectiveness of FDA's National Center for Toxicological Research. I have worked with NCTR for years and have the highest regard for its scientific excellence and its vision for improving public health through collaboration with academia and industry. Those of us in academia have enjoyed their collaboration and have utilized the excellent staff in teaching and research collaborations.

I believe we have a set of suggestions that can have a profound effect on speeding commercialization within the bioeconomy. As Co-chair of our Center of Excellence in Regulatory Science, I will look forward to more discussion and exciting new interactions.

Sincerely,

Mary L. Good

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AN ARKANSAS RESPONSE
To A Request for Information from OSTP
Building A 21st Century Bioeconomy

Introductory Statement:

There is one major impediment to harnessing biological research innovations for the bioeconomy. Research resources have not been directed to the science of rapidly assessing the toxicity of those innovations. Cutting edge research leading to product development is essential but not sufficient. We also need cutting edge research into understanding potential toxicity early in the development process. Without that capability, product approvals are lengthy, expensive, animal-intensive and the cause of enormous levels of uncertainty. Uncertainty leads to lack of investment and lack of commercialization.

Arkansas is home to the one facility dedicated to that mission, the internationally acclaimed[1] National Center for Toxicological Research (NCTR)[2]. Properly funding the practical research at NCTR would have a very large, positive impact on the bioeconomy, especially in the biomedical, food, cosmetic, and veterinary product areas.

Arkansas has taken a strong step to contribute its resources to the resolution of this problem. Arkansas has entered into a Memorandum of Understanding[3] and a subordinate Collaborative Supplemental Agreement[4] with the Food and Drug Administration. The agreement establishes a Center of Excellence in Regulatory Science that will focus on research in the area of nanotechnology, especially developing rapid indicators of toxicity; doing so in collaboration with industry, academia, government and public partners; establishing data mining techniques utilizing the latest information technology; providing certificate- and masters level training courses; analyzing policies and procedures leading to commercialization; aiding commercialization through providing business advice and suggesting funding sources; and an accountability/review process with FDA and others. A Working group consisting of representatives from federal and state government, academia, industry and the public has been established to coordinate the activities of the Center of Excellence.

(1) *Identify one or more 'grand challenges' for the bioeconomy in areas such as health, energy, the environment, and agriculture, and suggest concrete steps that would need to be taken by the Federal government, companies, non-profit organizations, foundations, and other stakeholders to achieve this goal.*

The "grand challenge" Arkansas wishes to address includes experimentation, novel ideas, improving the regulatory process, consideration of research priorities, use of public-private partnerships, reduction of barriers to commercialization, workforce development, technology transfer and more.

- It understands the critical importance of the practical research conducted at NCTR and supports it in a program that combines Arkansas assets with those of NCTR; focuses them on one component of the bioeconomy, *i.e.,* understanding and providing the tools to rapidly and accurately detect the toxicity of products derived from nanotechnology; instructing participants regarding the regulatory processes; speeding commercialization; improving decision-making; and doing so in a collaborative effort with government, academia and industry.
- It establishes a collaborative effort between Arkansas's medical research facilities at the University of Arkansas for Medical Sciences (UAMS) along with other Arkansas research universities, state government, NCTR, the Food and Drug Administration, private industry, organizations whose purpose is to help emerging technologies become successfully commercialized and a major volunteer effort devoted to improving the regulatory science base and enhancing commercialization in this area related to nanotechnology.

- It continues—and increases—support for research leading to new therapies, diagnostics, cosmetics, food and agriculturally related products and others derived from nanotechnology, incorporates and supports the co-participation by NCTR to provide safety assessments, incorporates private industry into a draft standards-setting process and data sharing, creates masters-level and certificate-granting courses in Regulatory Science, incorporates the science of data reduction and computer modeling to provide more access to- and validation of- data from diverse sources, and develops proposals for concurrent scientific peer review to assure the highest level of scientific assessment.
- It recognizes global development of products using nanotechnology, but nowhere else is there the collection of resources like those in Arkansas to assess their safety. NCTR has a unique nanotoxicology capability with world-class expertise. NCTR has the decades of experience required to conduct safety studies using an internationally recognized "gold-standard," one that very few are capable of meeting. When combined with the drug, diagnostic and other product development in our academic institutions, we have the opportunity to pull resources together in a unique manner and to work within this defined area, nanotoxicology.
- It understands that the proof of value for this experiment will be its practical, measurable impact on facilitated commercialization of safe and effective products. Accordingly, it focuses heavily on detection of barriers to this process. Barriers, whether technical, policy, social or other will be identified, proposals for improvement will be developed, and meetings will be held with regulatory policy-makers to refine and implement recommendations. The transparency of this process will provide the means to measure success and accountability.
- It is intended in part, to test the premise that since old models of regulatory approval are proving inadequate for today's global technology and markets, new models are possible in which the regulatory agencies work cooperatively with industry, academia and the scientific community. Our desire is to create such a model in Arkansas and offer successful components to other regulatory agencies and a broader line of technologies.
- It mobilizes the private sector's abilities in business planning, capital formation, business management to work with the academic and government laboratories to reduce barriers to commercialization.
- It invites the participation of other federal agencies into this process, including those from Commerce, Defense, NIH, USDA, EPA, and others to join in with FDA and Arkansas to create a council for barrier reduction.

RESEARCH AND DEVELOPMENT:

(2) What should be the Federal funding priorities in research, technologies, and infrastructure to provide the bioeconomy?

- We need a re-direction of some research into predicting safety. This research is applicable across products and is beyond the ability of industry to conduct. When government is not doing enough, the consequences are delayed product approval.
- Providing adequate funding for NCTR is the most important step for the U.S. to be successful in the bioeconomy. NCTR helps develop the latest technology and applies it to predicting harmful effects. It develops tools such as those looking for early predictors of harm in saliva, blood, and urine; understanding the ways in which genetic variations affect metabolism and toxicity; understanding the relationship between nutritional status and harmful reactions; understanding the effect of variations (based on diet and geography) in intestinal microflora on drug metabolism; developing rapid (less than an hour) means of identifying micro-organisms; developing computer models; extrapolating results from animals to humans; refining models of risk assessment; etc.

- Within that need is recognition of the enormous impact on the bioeconomy of nanotechnology. Medical diagnosis and treatment, food production and packaging, cosmetics, manufacturing processes, and interactions with daily life we have not yet recognized will be dramatically different in the future. A review of the proportion of research funds devoted to nanotechnology devoted to safety assessment is an indication of the larger need for re-direction of research funds.
- Without a vastly different research focus, current regulatory capabilities and procedures will impose a barrier to the capabilities of nanotechnology and delay implementation at a huge impact on the bioeconomy, delaying cost-lowering diagnostic and therapeutic agents and adding to the existing high levels of uncertainty.
- The tools needed to assess the toxicity of nanomaterials are sophisticated and rare. NCTR has an excellent nanotoxicology facility, but its excellence is only relative to what is available elsewhere. More is needed to be responsive to the pull of the bioeconomy. More importantly, more scientists are needed. Exciting new drugs and cancer detection models based on nanotechnology are being developed in Arkansas academic facilities and elsewhere, but the current NCTR resource levels do not allow them to perform the needed assessments of toxicity. The need is magnified by the national scope of the NCTR task.

(3)(a) What are the critical technical challenges that prevent high throughput approaches from accelerating bioeconomy-related research?

- Nanotechnology presents new challenges in toxicity assessment.
  - Traditionally, chemical structure has been the primary determinant in this assessment process. With nanoparticles, one must consider a host of other attributes including particle size, particle charge, shape, purity (much more difficult at the nanoscale), agglomeration, surface area and much more.
  - Understanding the chemical, physical and biological aspects of these particles is essential in determining impact within the body, dissemination and the multiple sites that may be affected, biological activity, metabolic properties, excretion patterns, effects on excretory processes and environmental impact.
  - Manufacturing processes must be understood in order to determine purity and variability.
  - The laboratory equipment necessary is both highly sophisticated and requires unique capabilities.
  - Facilities to house equipment such as electron microscopes with added spectrometers and other detection devices must be specialized to eliminate vibrations and control other conditions.
  - Expertise in this area requires specialized training and is not widely available.
  - The work requires some work with animals in facilities certified to provide only first-class animal care along with tightly controlled and measured diets and environments.
- Scientific papers and the press often report on small studies with apparent alarming results. The public sometimes has difficulty understanding that it takes huge studies with statistical power and years of experience and qualifications to conduct the level of study required to make responsible regulatory decisions. Many of these "alarming" results are found not to pose a human hazard, but only after damage may have been done to an industry. NCTR has the very rare capability to make these determinations properly. There is also a sophisticated, multi-layered, scientific review structure in place to provide external analysis of results. It would be inefficient to duplicate this capability elsewhere.

(b) What specific research priorities could address those challenges?

- The needed research encompasses more than the understanding of nanomaterials. It also includes bioinformatics, biostatistics, predictive computer modeling and others. All of these disciplines are housed at NCTR, but their utility could be much more powerful if funded adequately. (This

Arkansas effort will combine these capabilities in our universities with that of NCTR to accomplish more than is now possible.)

(c) Are there particular goals that the research community and industry could rally behind?

- Industry is certainly interested in innovative tools to predict toxicity early in the product development process and later during the variable conditions of use, *e.g.,* physical and metabolic interactions, multiple genetic variations, etc. Currently, these tools are evolving too slowly to quickly cull out "bad actors" during development, cut development costs, provide sufficient certainty in knowing whether products may be approved, and reducing the time required for approval and tests to be submitted for approval. These factors are major for the venture capital community. The lack of predictive tools can also lead to more concern that patients may be harmed which also adds massive liability concerns. Without these tools, consumers and businesses are both at risk to unproven claims of risk based on small, poorly designed tests, leading to fear and commercial impact when it may not be justified. Business and consumers need reliance on solid, proven methods to detect potential harm.
- If we are able to show positive impact, industry may want to help exploit available technology to mine data from all sources, public and private. In nanotechnology, we cannot afford the situation we have in other areas where massive amounts of data relevant to determining toxicity are unavailable for use. With new imaging and other technologies, standardized approaches to collecting and arraying massive amounts of data could be developed in a manner similar to the NCTR-developed ArrayTrack™ – a DNA microarray data management, mining, analysis, and interpretation software tool.
- Similarly, we believe there may be opportunities with closing of military bases and other areas to collaborate in developing a much more robust super-computing capability that could use existing expertise in modeling complex data to develop more predictive models.
- There is an opportunity to experiment with a process of sharing concerns and needs between researchers and industry, an effort that could impact some research agendas and lead to research efficiency and efficiencies in the development of regulatory standards.
- Creating a cadre of trained professionals who understand the intricacies of regulatory science could also be a common goal. This would seem to be even more attractive to industry if the training brings current issues to the discussion with a procedure to raise those issues to the level of regulatory consideration.

(4)What new multidisciplinary funding efforts could revolutionize predictions of protein function for genes?

- Understanding the protein-coding function for genes is an intricate part of the NCTR work since it is so critical to understanding individual reactions to drugs. As more therapies are being personalized for individual genetic characteristics, this area is of increasing importance. This will be true for those therapies based in nanotechnology as well as others. This work is also receiving strong emphasis at our medical school (UAMS) as well as other Arkansas universities, thus funding the NCTR effort to develop safety procedures would serve as a multi-disciplinary effort through our Center of Excellence.

<u>MOVING LIFE SCIENCES BREAKTHROUGHS FROM LAB TO MARKET</u>:

(5) What can be done in the way of encouraging experimentation with new private-sector-led models for funding commercialization of life sciences research?

(a) What barriers are preventing biological research discoveries from moving from the lab to commercial markets?

- By far, the primary barrier is uncertainty in detecting down-stream toxicity and uncertainty in knowing if a product is approvable.

There are other barriers that could be addressed:

- Traditional granting procedures are a significant barrier to this work for Arkansas institutions. As the academic work proceeds, there is a need to engage the NCTR component to define the limits of toxicity. As HHS employees, NCTR employees may not be paid on NIH grants. Because the NCTR is underfunded, it often cannot provide resources to participate in this important work with our universities. If they were allowed to be funded on the grants, the hiring of postdocs, technicians and other staff would enable a huge amount of important work that simply cannot be accomplished under the present set of rules. The rules do not allow funding that would speed safety assessment and thus needed products are left undeveloped.
- NCTR has had many successful Cooperative Research and Development Agreements (CRADAs) with industry partners. Perhaps there could be a study of whether regulatory agency restrictions in those CRADAs should apply to NCTR since it has no regulatory responsibility.

(b) What specific steps can Federal agencies take to address these shortcomings (in academic labs, government labs or both)?

- Re-envisioning and re-positioning NCTR to be a facility where industry, academia and government come together to apply the latest technology to develop innovative, predictive procedures is the most important thing that could be done.
    - This recommendation was made previously by a Subcommittee of the FDA Science Board in November, 2007[5]. The report argues the FDA cannot fulfill its mission due to an eroded scientific base. It recommended the establishment of the type of facility we are recommending for NCTR. Also, The Subcommittee chair recommended that NCTR be considered for this designation[6].
    - The fact that NCTR it has no regulatory responsibilities and has worked collaboratively with numerous agencies and firms including Pfizer, AstrZeneca, Litmus, Sigma Tau Research, RxGen and others is important to this decision.

With respect to other steps:

- Perhaps OSTP could study this specific situation to look at options for resolution such as: when a grant application is successful and includes NCTR collaborators, a separate funding for the NCTR portion could be provided through an interagency agreement; or a separate funding track that rewards an NCTR researcher for a program with commercialization potential;
- Review and alter policies that fail to encourage collaboration between government, academia and industry. Legitimate industry knows that regulatory protection is essential to protect against fraud and to provide standards every manufacturer must meet. At least for the purposes of this Arkansas Center of Excellence, let us consider approaches that open some doors in the wall between the regulator and the regulated. Help us find ways to provide transparency, proprietary protection, and the highest quality scientific review.

(6) What changes to Federal Small Business Innovation Research and Small Business Technology Transfer programs would help accelerate commercialization of federally-funded bioeconomy-related research?

- Agencies could contribute representatives to work proactively with participants to become more deeply involved in the day-to-day process. The effort could become a program in which all federal agencies impacting this area of technology in this region could unite behind one comprehensive federal government presence, all devoted to adding to the experiment, focusing on problem-solving and barrier reduction in all of the areas covered by this Request for Information.

- Technology Transfer has too often become a slow, burdensome process. The Arkansas group plans to work with NCTR to remove barriers to more rapid implementation of technology transfer provisions. The intention is to facilitate the process while reducing the burden on both the laboratory (NCTR) and those seeking to transfer the technology. It would be more effective if a federal representative were to be an active participant.
- Since NCTR has no regulatory responsibilities, it seems prudent to review the policies and procedures that restrict NCTR compared to NIST and other facilities.
- The Arkansas Research Alliance, with a Board consisting of the chancellors of Arkansas's five research universities and top management from 16 major Arkansas corporations, with support from the Winthrop Rockefeller Institute, the Walton Family Foundation, instituted research conferences based on promising research focus areas. These conferences connect researchers and business leaders for three day conferences. Perhaps Small Business and Technology Transfer programs could offer assistance to ARA in this or similar programs and to participants in these programs. It may also be possible to extend their reach by bringing some of the excitement from technologies discussed at these conferences to students in order to stimulate interest.

(7) What high-value data might the government release in the spirit of its open government agenda that could spur the development of new products and services in the bioeconomy?

- Much more could be done in the area of data mining and in identifying both the significance of- and gaps in- available data. It may not be so much a matter of releasing data as finding it in order to release it. The Arkansas Center of Excellence will establish a program seeking widely distributed data using advanced information management tools, particularly those associated with bioinformatics and modeling.
- Most importantly, the effort would engage the research community in an effort to establish a data repository. It would also require a validation and information arraying capability, another part of the Arkansas vision. This step would be followed by sharing and peer review, leading to the refinement of a nanotoxicology research plan.

(8) What are the challenges associated with existing private-sector models (e.g. venture funding) for financing entrepreneurial bioeconomy firms and what specific steps can agencies take to address those challenges?

- Providing much less expensive, more rapid tools to demonstrate safety early in the process of development will reduce the huge barriers of uncertainty, and thus encourage investors.
- Stronger grant programs for small businesses to either validate their technology or demonstrate safety should be considered.
- Incentives for entrepreneurial development at the universities might be considered. If, for instance, a new grant program were to be established for validation and safety testing of promising products, intellectual property may become more recognizably valuable more quickly. This may also be attractive to the venture capital community.

<u>WORKFORCE DEVELOPMENT</u>:

(9) What modifications should be made to professional training programs to better prepare scientists and engineers for private-sector bioeconomy jobs?

- Many entrepreneurs and scientists are unfamiliar with both the policy and the science required to obtain product approval. Therefore, the Arkansas Center of Excellence provides programs in Regulatory Science including a Certificate program, a Masters in Public Health focused on Regulatory Science and a Masters in Regulatory Science.

- If this Center of Excellence could receive federal funding, the educational component could be developed fully and also expanded to other campuses and sites with individual programs and/or feeder programs. The University of Arkansas at Pine Bluff, an HBCU in the Lower Mississippi Delta (and very close to NCTR) has offered a Bachelors degree in Regulatory Science for several years.
- This program is designed to be a part of a feedback loop in association with researchers, regulators and entrepreneurs to provide students with experience handling current issues. It incorporates this educational program into a policy review group that ties all of the programs together. Using that approach, as researchers and entrepreneurs work through the regulatory process, barriers found, approaches discussed and policy solutions may be matters for class discussion. Students may then have the opportunity to analyze identified problems and recommend policy and procedural changes that would be incorporated into reports and meetings with the federal agencies.

(10) What roles should community colleges play in training the bioeconomy workforce of the future?

- Community colleges could build construct small versions of facilities used in the bioeconomy for training purposes. This would allow them to instruct the traditional "trades" of pipefitters, electricians, mechanics and others to understand issues related to areas like biofuel production, bioconversion, reaction chambers, etc. The effort would focus on training current students, but also vigorously focused on re-training unemployed workers.
- Community colleges could work more vigorously with high schools to design programs that begin in the high schools and continue into the community colleges to train students for the type of work mentioned in the previous bullet. Such programs would also provide the opportunity to begin developing entrepreneurial interests in high school, and perhaps help students understand the need for STEM courses and develop interest in them.

(11) What role should the private sector play in training future bioeconomy scientists and engineers?

- More participation by the private sector is essential. In all of our training programs, particularly considering today's pace of technological development, the private sector must be available to give-real time examples of issues. It will also be important for the private sector to have a forum for evaluating various training programs with a feed-back loop to assure that graduates meet their needs.
- The private sector may be asked to allow access to facilities, equipment and expertise when efficiency indicates that such use would be in the best interest of the overall effort. By doing so, the private sector will enhance their voice in guiding the training programs.

(12) What role might government, industry, and academia play in encouraging successful entrepreneurship by faculty, graduate students, and postdocs?

- It is important to introduce the concept and the mindset for entrepreneurship early in the educational process and to continue it throughout. The county in which NCTR resides is developing a program in which high schools, a community college and a university (UAPB) combine resources to stimulate students, encourage entrepreneurialism, and engage faculty, postdocs and graduate students.
- NCTR participates vigorously with training, especially with its adjacent universities, primary among which is UAMS where many scientists serve as adjunct faculty, but also has very strong international participation. As this role increases, there will be more graduate students, post-docs, and faculty participating in NCTR research activities. The government might review incentives to determine if they are sufficient for assisting the process of commercialization.

REDUCING REGULATORY BARRIERS TO THE BIOECONOMY:

(13) What specific regulations are unnecessarily slowing or preventing bioinnovation? Please cite evidence that the identified regulation(s) are

a) slowing innovation, and

This effort is larger than one focused on a specific regulation. It encompasses an entire range of regulations enforced by FDA. Toxicology studies are often very time-consuming, especially if they require animal studies. Their results often require sophisticated statistical analysis, adding to the time required, but also adding significant uncertainty. Long time periods mixed with uncertainty become huge barriers to potential investors and certainly slow innovation.

b) could be reformed or streamlined while protecting public health, safety, and the environment.

- The entire NCTR mission is focused on public health. The re-direction of research is needed to assure protection of the public health. Part of that mission includes getting life-saving and life-improving therapeutics to the public as quickly as possible. Everything in this reply is directed to that end.

(14) What specific steps can Federal agencies take to improve the predictability and transparency of the regulatory system?

- Reducing the uncertainty in the approval of drugs, crop treatments, alternative fuels and chemicals as is the goal of the Arkansas Center of Excellence in Regulatory Science would be an enormously effective step.

(15) (a) What specific improvements in the regulatory processes for drugs, diagnostics, medical devices, and agricultural biotechnology should federal agencies implement?

In addition to funding of the science that provides the bases of regulatory review …and therefore product marketability… the Arkansas Center of Excellence in Regulatory Science is piloting a list of such improvements as previously listed.

(c) What challenges do new or emerging technologies pose to the existing regulatory structure and what can agencies do to address those challenges?

In additions to re-thinking scientific funding priorities;

- Finding ways in which industry is not threatened by a process of sharing data and working to establish safety standards. Such a process would need to be carefully crafted to protect proprietary developments, and clearly not all data would be available for sharing, but making industry a partner in standard-setting would provide a base incentive.
- Looking for ways to apply resources being down-sized from other activities to help with this effort. For example, DoD may have enormous expertise in developing computer models of complex data. The Arkansas experiment is working to find ways to make this happen. Perhaps more capabilities could be matched to more needs.
- There are many known toxicity issues to be resolved in the realm of nano-medicine. However, the same or similar issues will likely arise when considering the future of nano-agriculture. Consider nano-fertilizer: This could revolutionize crop production to feed the world, but numerous agencies with numerous responsibilities would slow progress unless we are able to develop new models of cooperation—and new scientific and computer capabilities.

<u>PUBLIC-PRIVATE PARTNERSHIPS</u>:

(16) (a) What are the highest impact opportunities for public-private partnerships related to the bioeconomy?

To meet the "grand challenge" articulated in this response, public-private partnerships are essential and central to our Center of Excellence. It involves all of us working together, dedicated to finding new solutions and approaches...

(b) What shared goals would these partnerships pursue, which stakeholders might participate, and what mutually reinforcing commitments might they make to support the partnership?

- An over-arching goal is the safety of the public. The participants in this activity know up front, that there will be no short-cuts that risk harm to the public. The effort will be to find smarter ways to achieve the essential level of safety.
- The second goal is related to the first. The best interest of the public is not served if life-saving or otherwise helpful therapies or products are kept from them. Accordingly, a second goal is to facilitate the commercialization of such products.
- Diverse groups are engaged to support the entrepreneur.
    - As an example, Arkansas has funded a very successful program run by WinRock International called Innovate Arkansas. In this program, a group of professionals help guide the development of business plans and provide advice and assistance in obtaining capital and overcoming other barriers.
    - Innovate Arkansas is but one example of the impact of one volunteer organization of professionals from across the state who are very much involved in this Arkansas experiment. That group, Accelerate Arkansas has created not only Innovate Arkansas, but also the Arkansas Research Alliance, the Risk Capital Matching Fund, a STEM fund and numerous tax credits, teacher loan forgiveness programs and many others. This resource of over 70 volunteers is a major asset Arkansas offers to participate and lend experience to the Arkansas experiment. It is an indication of a spirit of cooperation and participation that can solve even the most difficult problems.

(17) (a) What are the highest impact opportunities for pre-competitive collaboration in the life sciences, and what role should the government play in developing them?

- This reply has previously identified the opportunity for pre-competitive collaboration in safety standard-setting. It should support regulatory science and it should pull agencies together. Participating in the Arkansas Center of Excellence to pilot new ideas would be a helpful approach.

(b) What can be learned from existing models for pre-competitive collaboration both inside and outside the life-sciences sector?

- We need only look to our global competitors to see that they are not following our model, and their success rates seem to be astounding compared to future projections for our own. We simply must do some things differently. If we want to stimulate entrepreneurship, we must think and act with an entrepreneurial spirit ourselves.
- Another example is the level of success attained by NIST, both in innovation and in transferring their technologies to the private sector. Re-evaluating the technology transfer capabilities of these national labs at NCTR might have a huge impact.

(d) What are the barriers to such collaborations and how might they be removed or overcome?

- Clearly, anything that sounds like increased funding will be a barrier. The need may be a matter of re-direction rather than new funding. We believe that there is sufficient recognition by the biomedical industry that this issue would be understood and supported. We would hope for a non-partisan, industry-supported effort that recognizes this approach is the most practical, efficient, least expensive (because it is non-duplicative) approach to removing huge barriers to successful product commercialization.
- Public fear could be another barrier. Proposing that industry and government cooperate could be a rallying cry for those who fear possible consequences. Bi-partisanship directed to the ability to develop new technology into an economic stimulus will be important.

APPENDIX--Footnotes

1. NCTR is called to participate and lead many important international scientific activities including:
   a. Joint FAO/WHO Expert Committee on Food Additives (JECFA)
   b. International Agency for Research on Cancer (IARC) of WHO
   c. National Institute of Food and Drug Safety, Republic of Korea
   d. Several universities in China
   e. The fact that there are over 50 postdocs and other PhD's from across the world at NCTR
   f. NCTR hosted a Global Summit on Regulatory Research in Little Rock, August, 2011 attended by over 40 scientists from 17 different countries representing Asia, Australia, Europe, Africa, South America and Canada
   g. Many, many university collaborations too numerous to list--all over the world
2. NCTR is described at http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofScientificandMedicalPrograms/NCTR/ucm2006206.htm
3. The Memorandum of Understanding is at http://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm267896.htm
4. The Collaborative Supplemental Agreement can be emailed upon request from arnorris@swbell.net
5. The report may be found at: http://www.fda.gov/ohrms/dockets/ac/07/briefing/2007-4329b_02_01_FDA%20Report%20on%20Science%20and%20Technology.pdf The discussion relevant to this point begins on page 26. The subcommittee was chaired by **Gail H. Cassell, MS, PhD, DSc (Hon)**, Vice President, Scientific Affairs and Distinguished Lilly Research Scholar for Infectious Diseases, Eli Lilly and Company
6. Transcript of the May 30, 2008 Science Board meeting. http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4365t1-01.pdf beginning on p. 94 and continuing at http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4365t1-02.pdf/ on pages 21-24.