Putting the Bioeconomy Blueprint to Work

April 26, 2012

Today, a number of departments and agencies announced initiatives aimed at helping to attain the strategic objectives outlined in the National Bioeconomy Blueprint. Among them:

Expanding the biobased products purchasing program: Today the US Department of Agriculture (USDA) announced that it will issue a rule that will expand upon a Presidential Memorandum signed in February that called upon Federal agencies to more effectively execute Federal procurement requirements for biobased products through the BioPreferred program. That program was established by Congress to increase Federal procurement of biobased products to promote rural economic development, create new jobs, and provide new markets for farm commodities. The new rule will add a procedure for designating intermediate materials and feedstocks—the chemical building blocks of biobased products—as acceptable for the BioPreferred program. The change will make it easier for companies to choose raw materials that will help ensure that their final products will qualify for the BioPreferred program. In addition, the rule will provide a streamlined procedure for designating as biobased those products composed in significant part from such intermediate materials and feedstocks, and it will create a procedure for designating as biobased certain complex assembly products that cannot be tested for biobased content in the laboratory due to their heterogeneous nature. The rule will also broaden USDA's efforts to provide information on the environmental and public health benefits of biobased materials during the designation process. Together, these actions will provide significant support for the goal of reducing our reliance on petroleum-based products, and will drive the creation of new innovative new products, markets, and jobs in rural communities.

Building support for biofuel production facilities to create jobs and expand the use of alternative energy: Earlier this month, foreshadowing key priorities in the Bioeconomy Blueprint, Agriculture Secretary Tom Vilsack announced USDA approval of a $5 million payment to Western Plains Energy, LLC, to support the construction of a biogas anaerobic digester in Oakley, KS. The completed project will utilize waste energy resources from a local cattle feedlot to replace the vast majority of the fossil fuels currently used by Western Plains Energy. The funding of this project is expected to create 15 full-time positions and almost 100 additional construction opportunities. The digester, which will be fully operational by next year, is expected to produce enough biogas to replace 89 percent of the fossil fuel that Western Plains currently uses to provide process heat at its Oakley ethanol plant, which produces 50 million gallons of ethanol annually. Animal waste from a local feedlot will be the primary feedstock that Western Plains will use for the digester. It also will use grain dust as well as waste from a variety

of industrial food and municipal facilities. Western Plains expects to be able to produce more than 100 million BTUs of renewable energy per hour daily.

Transforming the FDA archives into a driver of discovery and development: The Food and Drug Administration (FDA) currently houses one of the largest known repositories of clinical data, including safety, efficacy, and performance information, and an increasing amount of post-market safety surveillance data. Integrating and analyzing these data, with appropriate patient privacy protections, could revolutionize the development of new patient treatments and allow researchers to address fundamental scientific questions about how different patients respond to a therapy, but many of these data are today not organized in ways to allow them to be plumbed for the full value they contain. In order to harness the power of these data, FDA is rebuilding its information technology and data analytic capabilities and establishing "science enclaves"—virtually networked IT environments where multi-disciplinary teams can work together to analyze large sets of data extracted from the vast FDA data resource while complying with applicable law concerning proprietary information and patient privacy. This approach promises to not only speed the development of new therapies for patients but also result in significant reductions in costs to drug and medical device developers.

Science enclaves are a response to the fact that in the emerging bioeconomy, data sharing, and management will catalyze research and product development in unprecedented and unanticipated ways. The ability to integrate big data sets and collaborate both internally and with external partners—under non-disclosure agreements, for example—will generate new insights into product development and use. The enclaves can also be used to design new software that should enhance the quality, efficiency, and accuracy of FDA regulatory reviews.

Training the power of induced pluripotent cell technology on blood-related and neurological diseases: The recent discovery that adult skin or blood cells can be reprogrammed to produce induced pluripotent stem (iPS) cells—which have the ability to become nearly any type of cell in the body—promises to revolutionize understanding of disease, spur progress in drug discovery, and pave the way for new cell-based therapies. The National Institutes of Health (NIH) recently launched its new Intramural Center for Regenerative Medicine (NIH CRM) to support advancement of iPS cell technologies. Building on that foundation, NIH CRM and its partners are exploring the development of iPS cell therapies to treat blood-related diseases, such as leukemia and metabolic diseases, including the devastating lysosomal storage diseases that affect children. In addition, researchers will investigate whether iPS cells can be used to develop blood products that could help meet the demand for blood transfusions during medical emergencies and surgeries. NIH also recently embarked on a major effort to use iPS technology to advance research into neurodegenerative diseases. That effort already has developed and made widely available neural cell lines for Parkinson's disease, amyotrophic lateral sclerosis, and Huntington's disease. NIH CRM plans to expand its iPS cell efforts in the near future, with an

eye towards accelerating discovery of new candidate drugs to treat or prevent Parkinson's disease.

Growing the economy and rural jobs by supporting biomass production: Today, as a down payment on fulfillment of the objectives outlined in the National Bioeconomy Blueprint, the USDA is releasing a whitepaper describing progress to date and emerging opportunities for the United States to transition from fossil- and petroleum-based sources of carbon to renewable biomass from sustainable agricultural practices. The White Paper notes that rural America will play a significant role in this transition since the raw materials needed to grow the biobased products industry are largely produced on farms and forests. It also notes the importance of (1) using USDA's data and economic analysis capacities to guide decisions about workforce development; (2) developing strategic partnerships with the private sector to enhance technology and knowledge transfer; and (3) supporting financial and technical assistance programs to identify the bioproducts that hold the most promise for expanded markets, rural economic development, and solutions to societal grand challenges.

Forging new relationships to provide FDA device review staff with real-world knowledge: This week, FDA launched its new Experiential Learning Program (ELP), a new educational program within the agency's Center for Devices and Radiological Health (CDRH), designed to enhance medical device review staff's real-world knowledge of existing and emerging technologies. Because medical device technology continuously evolves, it is essential that CDRH review staff stay abreast of new technology developments and improvements in how devices are developed, clinically tested, manufactured, and utilized. The ELP will include visits to academic institutions, device manufacturers, research organizations, and healthcare facilities. The program will address knowledge gaps and help FDA better understand innovative devices, with the goal of improving the quality and timeliness of product reviews. The ELP is just one of the several innovative initiatives that FDA has recently implemented for medical devices this year, including the Innovation Pathway 2.0—an evolving effort to test ways to shorten the overall time for the development, assessment and review of medical devices by enhancing premarket interactions between FDA and innovators—and the Entrepreneurs-in-Residence program, which allowed CDRH to bring in vision leaders in business process innovation, decision science, medical device innovation, venture partners, and information technology to work alongside agency staff and leadership.

Expanding Medicare's evidence development program to drive innovation: Medicare payment for medical treatments is a powerful driver of industry investment. Under the Coverage with Evidence Development (CED) program, Medicare pays for promising new technologies that do not currently meet the evidence threshold for broader coverage. The CED program furnishes payment while simultaneously requiring the collection of more evidence to determine the full potential impact of a new health care technology. Although the CED authority has existed for more than a decade, it has been applied sparingly. The Centers for Medicare & Medicaid

Services (CMS) is now poised to implement a new phase of CED by better defining the parameters and guidance for CED so it can be used more widely and effectively as a driver of innovation. Specifically, CMS will convene its Medicare Evidence Development and Coverage Advisory Committee next month to consider input on how to update CED based on lessons learned to date, with the goal of increasing this program's use to create predictable incentives for innovation while providing greater assurance that new technologies fulfill their initial claims of benefit.

Creating a step-by-step guide to turning discoveries into treatments: The NIH's newest center, the National Center for Advancing Translational Sciences (NCATS), recently teamed up with Eli Lilly to create a step-by-step playbook to help researchers from all sectors translate their basic findings into potential treatments for patients. The Assay Guidance Manual, which will be available as a free e-book in early May (http://preview.ncbi.nlm.nih.gov/bookshelf/booktest/br.fcgi?book=assayguide), reflects the wisdom of more than 100 authors from around the world who contributed content to this free tool. The book will guide researchers through the complex process of turning basic research findings into tests that can be applied to thousands of compounds to screen for and identify potential new drug candidates. This collaborative project embodies the NCATS mission to improve the process by which therapeutics are developed and make translational sciences more efficient, and less expensive.

Collaborating to reduce the need for nitrogen fertilizer inputs: The National Science Foundation (NSF) has developed an "Ideas Lab" collaboration with the United Kingdom's Biotechnology and Biological Sciences Research Council (BBSRC) to identify novel approaches to design and engineer agricultural systems that will maintain or increase crop yields with minimal input of nitrogen fertilizers. Ideas Labs are innovative approaches to devising potential solutions to complex problems that have not been solved despite long periods of research. The approach features an intensive interactive workshop involving up to 30 participants brought together from around the world, with the aim of developing new and bold approaches to address grand challenges—all with a promise made in advance to provide funding for research projects that emerge from the process. In this case, NSF and the UK's BBSRC have each committed to contribute $8 million over three years.

The new Ideas Lab takes aim at the fact that nitrogen is critical to plant growth, but only a limited number of plants have the capacity to obtain nitrogen from non-biological sources—a process generally accomplished with the help of nitrogen-fixing bacteria. Farmers have compensated for this deficit through increased application of nitrogen-based fertilizers, a costly and often environmentally damaging approach since much of the applied nitrogen is lost as run-off into water courses or as greenhouse gases. Because global food production needs to increase significantly to feed a growing human population, the Ideas Lab collaboration will explore new opportunities to decrease the inputs of nitrogen fertilizer while increasing the efficiency of its

use, and investigate exciting approaches to develop plants that can fix their own nitrogen in the absence of helper bacteria. In addition to using synthetic biology to design plants with these desired characteristics, NSF envisions that inspirations from marine and soil nitrogen fixation mechanisms could also provide new ways to engineer plants.

Improving homeland security through biological research: Because a genome provides the most definitive signature for an organism, it can be used to distinguish an organism from all others. As a consequence of this, genome sequencing is a foundational technology for microbial forensics. The Department of Homeland Security's Science and Technology Directorate (DHS S&T) is developing a genomics-based approach to microbial forensic analysis to allow identification and characterization of any microbial organism, including "unknown" organisms such as emerging, chimeric, or synthetic organisms. This new effort involves development and refinement of several intersecting technologies, including bioinformatic analysis, metagenomic analysis, and comparative genomics. The largest impediment to the success of this approach remains the lack of an adequate comparative genomics database. To address this issue, DHS S&T is working with the National Center for Biotechnology Information and others to establish a comprehensive catalog of genomes that covers a diverse array of pathogens. To integrate genomic information with additional information for successful identification of pathogens, DHS plans to leverage other promising "omics" technologies (proteomics, metabolomics, transcriptomics) to generate profiling methods for microbial organisms. The integration of information gleaned from the multiple "omics" methodologies constitutes a systems-based approach to microbial characterization that will be a first-of-its-kind capability and promises to have important applications to the fields of public health, food safety, medical diagnostics, and homeland security.

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