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The Future of Biotechnology: Solutions for Energy, Agriculture and Manufacturing
Subcommittee on Research and Technology
Committee on Science, Space and Technology
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Good morning Chairwoman Comstock, Ranking-Member Lipinski, and Members of the House SubCommittee on Research and Technology.

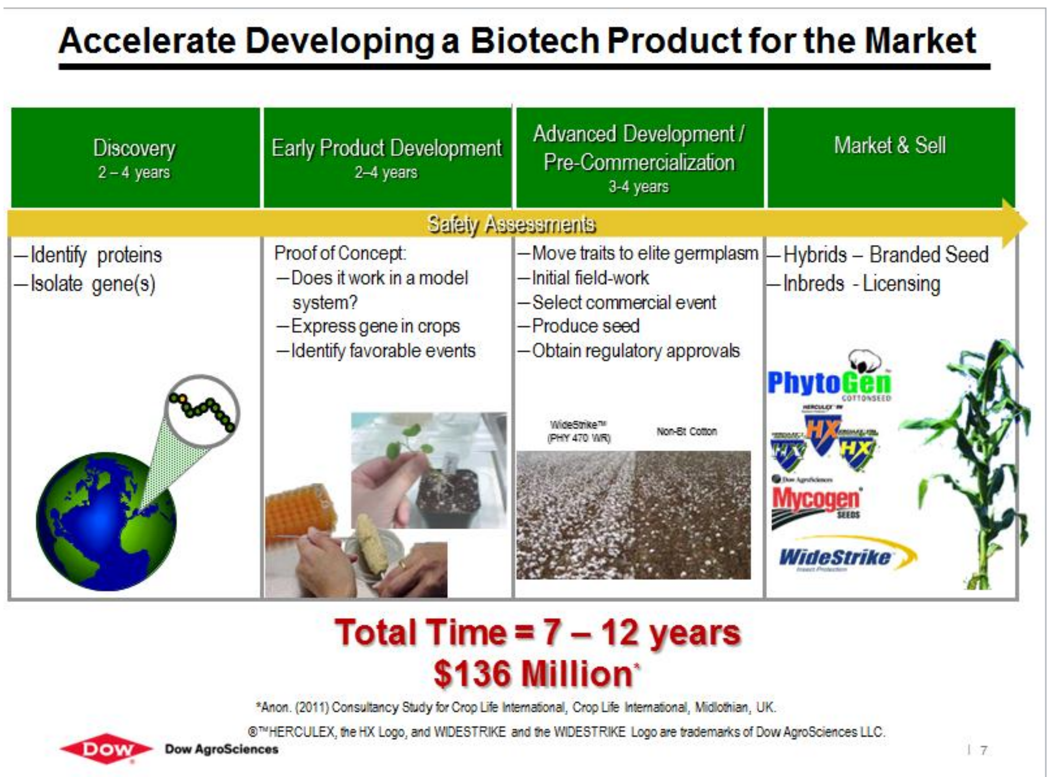
Thank you for inviting me to represent my company, Dow AgroSciences, in this hearing on emerging biotechnology applications. We trace our roots in agriculture back 60 years and emerged from within The Dow Chemical Company – a company that has been transforming technology into viable product solutions since 1897.

The drivers for application of biotechnology to agriculture are clear. The global demands for food, feed, fiber and fuel are strong and rising. The solutions to meet this global need must be met within increasing constraints and unpredictability, reinforcing the need to make newer product offerings even more sustainable. We have all heard the challenge set forth for global needs in 2050. To meet the global need in 2050, agriculture will need to produce more food in this timeframe than the sum total of what it has produced in the last 10,000 years. Since their introduction in the mid-1990's agricultural biotechnology offerings have made significant contributions to global food security, and a long term reviewer of the field argues that biotechnology-based crops are the fasted adopted crop technology in the history of modern agriculture.

If you were to visit the early stage R&D laboratories at Dow AgroSciences, you would see tools and techniques in use that are common to other bioscience endeavors. Early stage Ag biotechnology research benefits from the same molecular biology, bioinformatics, DNA sequencing, high throughput analytical systems and other tools that benefit labs involved in basic life sciences to biopharma. For this reason, we are able to directly incorporate many of the advances in basic life science development funded by federal research.

One of the ways that Dow AgroSciences has benefited from advances in related fields, and helped provide industry input to shape outcomes, is by participation in NSF Engineering Research Centers, or ERCs. The SynBERC ERC brings together 37 professors in 18 universities with 47 companies with the stated mission “to make biology easier to engineer”. As past Chair of the Industrial Advisory Board I can affirm that a portion of the participating companies represent both established agricultural entities and startups with concepts in the agricultural space. The ERC has provided a unique pre-competitive venue to allow both industry participation and influence in technology development. Some of the inventions and technologies created by the universities within SynBERC are already present in offerings by several tool and technology suppliers and are used by Dow AgroSciences today in our research. From an examination of recent patent activity by large agricultural biotechnology companies, it is clear that such tools and technologies are being broadly adopted in the early R&D efforts disclosed by patent applications. But to form a realistic expectation for the timeline for appearance of such technology in products, it is important to understand the general Ag biotech development timeline.

The typical range of development spans 7-12 years and comes at an average investment price tag of over $130 million per product. While the laboratory tools and



technologies just described play an important role in performing and even accelerating the front end of developing products we still face multiple challenges within the national and international regulatory framework. Companies understand and can manage risks related to product performance and customer choice. However, because our time horizon is approximately a decade and the cost of development well over $100 million, to make informed investment decisions we need to have an regulatory approval process that is predictable to enable realistic planning. The regulatory process needs to be science based and proportionate to risk.

We can illustrate potential impact of this uncertainty by considering an area of very active research, development and federal investment today which has roots dating to the 1980s. Recent advances in tools and technologies allow researchers to understand the microbes associated with other living organisms to a degree simply not possible even five years ago. These are the so-called microbiomes. Most famous are human microbiomes, but plants, insects and other systems relevant to agriculture have associated microbial communities. The recent "Report of the Fast-Track Action Committee on Mapping the Microbiome"[1] identified $300 million in annual funding for this area, with some research already aimed at agriculturally or environmentally relevant areas. The ability to understand and ultimately positively manipulate these naturally-occurring microbial communities could have profound effects on plant or insect health. Early stage academic researchers are obviously interested in using biotechnology tools to manipulate these microbial communities to improve their agricultural utility.

However, my personal history in this area dates back to small biotech companies in the late 1980's and early 1990's which sought to do just this – use what was then the newest tools of biotechnology to manipulate plant associated bacteria for new agronomic properties – only on a much smaller scale than currently being investigated. Half dozen or more companies were engaged in developing products for the agricultural or environmental space utilizing genetically engineered plant associated microbes. The pathway through the regulatory environment for deliberate release of live, engineered microbes was uncharted. My company, Mycogen Corporation, solved the problem by developing an industrial scale technology to kill the engineered microbes after fermentation, thus releasing a formulation containing dead microbes as the ultimate product. While successful for a particular purpose, the real benefit from such products would have been maximized if they were able to be released as live microbes.

Nearly 25 years later, there are still few if any examples of commercial products destined for environmental release based on live, genetically engineered microorganisms. And so, cutting edge research being funded today in the area of agriculturally or environmentally relevant microbial communities will undoubtedly produce intriguing and impactful product concepts that could be critical components of a sustainable agricultural offering in the ramp up to 2050 (for instance, by increasing nutrient availability, impacting soil fertility, improving plant vigor). However, these

[1] https://www.whitehouse.gov/sites/default/files/microsites/ostp/NSTC/ftac-mm_report_final_112015_0.pdf

product concepts likely will not be adopted and commercialized because of regulatory approval uncertainties or excessive regulation that is not proportionate to risk if there is not a parallel investment in developing and publishing new, fundamental research assessing scientific questions related to deliberate release of engineered microbes which is informed by the experiences of the past 25-30 years.

In addition to using biotechnology to develop modern crops that are offered to the farmer, Dow AgroSciences is a leader in commercializing agrochemicals derived from natural products. These are substances produced by organisms and are important products because they have benefit to the farmer or other producers in the Ag value chain. Taken together, products and chemistries inspired or derived from natural products account for one quarter of global Ag chemical sales. Historically one challenge in developing natural products, whether for pharma or for Ag, is attaining sufficient productivity in fermentation to make the process economically viable. Another is genetically engineering the organisms to increase their production of the intended organic substance, again at an economically viable level. Today the advanced techniques being developed and deployed to tackle these challenges stem from the field of engineering biology. Dow AgroSciences' platform to integrate biotech tools from both external sources and internal capabilities is aimed at rationally engineering our strains to solve these productivity challenges. Nationally funded research has enabled key technological milestones in this field, but the United States is not alone in recognizing the economic and environmental benefits to be derived from commercial manufacturing of novel natural products or of chemistry inspired by them. Unlike the biotech concepts destined for direct release into the environment, here the engineered organisms are designed for use in contained fermentation facilities. The timelines for commercialization are still surprisingly similar in length than previously described for biotech crops (around a decade) but the investment cost is over $250 million.

Finally, I will propose that a framework for involvement of the Federal government can be understood in terms of Three C's. 1) Continue to support exceptional science, 2) Convene forums for discussion on development and risk-proportionate oversight, and 3) Create a strategic vision to ensure U.S. biotechnology investments produce exceptional solutions for the world's most pressing needs. These actions are important to maintain a U. S. position of leadership in development and application of this technology in an increasingly competitive, global race. Within our field, these investments help provide technology, a workforce of new skilled talent and a predictable, science based regulatory framework from which companies like ours can make informed investment decisions for products taking over a decade to bring to market.

Thank you.

National Needs – Three C's

- National scientific funding agencies:
  - > Continue to support exceptional science that is foundational for biotechnology
    - Deployable tools in many areas of application
    - Serves the public good
  - > Convene forums for discussion on development and oversight to include public engagement, dialogue, outreach and education
    - Bringing science to policy venues and to the public
    - Input can drive new research programs providing science based, proportionate risk analysis tools benefiting all interested parties
  - > Create a strategic vision to ensure this US biotechnology investments move in a direction that is responsible and produces exceptional solutions to pressing needs
    - Technical, societal, regulatory, policy integration
    - National and International presence