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Hearing on Fueling Innovation: The Role of Small Businesses in America's Bioeconomy

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SENATOR YOUNG, DISTINGUISHED MEMBERS OF THE COMMITTEE AND GUESTS,

Thank you for the opportunity to testify on the efforts in Indiana to create the foundation for formation of startups to support America's bioeconomy. In response to the clarion call to accelerate reshoring of biomanufacturing, Catalyze Indiana is an initiative to establish Indiana as the national hub for Advanced Chemistry manufacturing and innovation. Building on Indiana's unique strengths—including global industry leaders like Eli Lilly, Elanco, and Corteva, world-class research universities, and the nation's highest concentration of manufacturing jobs—this initiative addresses critical gaps in domestic supply chain resilience for food and medicine production. The initiative has been shaped via extensive stakeholder engagement over six months with industry CEOs and university leaders. CICP is presently developing a detailed funding proposal for implementation of Catalyze Indiana's foundational programs.

> **Catalyze Indiana aims to position Indiana as the default destination for invention, development and implementation of next generation technologies to enable the reshoring of manufacturing of the supply chains for medicine and foods.**

Supported by a $69.4 million grant from Lilly Endowment Inc. to the CICP Foundation Inc. and matching commitments from participating universities, the Catalyst Scholars Fund, spearheaded by CICP and powered by its branded initiatives, BioCrossroads and AgriNovus Indiana, will enable these Indiana higher education institutions to recruit 25-45 world-class faculty and their teams over five years to tackle industry informed grand challenges in key platform technology areas. Successfully implemented, this Catalyze Indiana phase will position Indiana at the forefront of national efforts to bring Advanced Chemistry manufacturing to the United States to secure the nation's supply of food and medicine. This catalytic investment will establish Indiana as a destination for top research and workforce talent; as a magnet for industry manufacturing investments; and as an engine for innovation in horizontal production technologies to ensure American leadership in Advanced Chemistry manufacturing across a wide range of sectors.

It is the full expectation that many of the faculty recruited through the Catalyst Scholars Fund, will serve as scientific and technical founders of startups further developing and ultimately commercializing the Scholars' technology and inventions to ensure that their research has real-world impact. BioCrossroads, amongst a spectrum of partners in Indiana's innovation ecosystem, have developed and deliver a portfolio of programming and initiatives to inspire and support startup

founders in their respective journeys to develop and commercialize impactful technologies and inventions. A critical gap that continues to exist is the lack of venture capital funding for bioscience startups in regions such as Indiana. Despite having promising discovery and inventions born in Indiana, the overwhelming concentration of necessary capital to fuel their development and growth is found in Massachusetts, California and New York. The federal government can play a role to facilitate the broader dispersion and increased access of venture capital to communities such as Indiana, which are hotbeds for innovation vital to the national security.

II. INTRODUCTION

Amid uncertainty and vulnerability, Advanced Chemistry supply chains dictating the nation's supply of food and medicine have emerged among business leaders and policymakers as an exigent priority for creation of resilient domestic manufacturing capabilities in Advanced Chemistry. Indiana is uniquely positioned to establish and act on a national ambition to secure critical U.S. food and medicine supply chains. Indiana's nation-leading research universities and institutes and strong life science industry presence—with global industry leading corporations spanning human health, animal health and plant science-- make the State a natural home for efforts in this space. Via investment in new programming and infrastructure alongside strong coordination of robust existing efforts, Indiana can cement and grow its national leadership in Advanced Chemistry clusters while addressing gaps in national security and domestic economic resilience through the expansion and innovation-enhanced, technology-driven advancement of domestic supply chains for critical goods.

Overview of existing assets and opportunities

Indiana possesses exceptional foundational assets positioned to address this national challenge. The state's Advanced Chemistry ecosystem generates over $43 billion in annual revenue and employs nearly 40,000 Hoosiers across leading companies including Eli Lilly and Company, Elanco Animal Health, Corteva Agriscience, and others. Indiana ranks as a top-five performer nationally in pharmaceutical manufacturing and maintains strong positions across agrochemicals, advanced materials, and emerging sectors like sustainable chemistry. These industry stakeholders not only position the State as a national leader; they represent globally recognized brands that symbolize leading innovation in pharmaceuticals, animal health, and agriculture. Their leaders are naturally positioned as thought leaders in business and policy matters related to their respective fields.

Adding to Indiana's prowess in human, plant, and animal health is its unique strength as a manufacturing powerhouse. BLS data show that Indiana has the highest intensity of manufacturing jobs of any U.S. state with a location quotient of 2.04, indicating a concentration double the national average. Manufacturing accounts for 19.8% of Indiana's jobs, employing over 540,000 people. This historical strength in manufacturing is in large part what has enabled Indiana to maintain and grow its manufacturing presence among major pharmaceutical, agricultural, and specialty chemical producers, even as research and development sites have proliferated elsewhere. Like the U.S., the size of Indiana's manufacturing employment base is diminishing year-on-year; However, Indiana is best poised among any U.S. state to lead the return of national manufacturing capacity.

Leading Indiana institutions of higher education, Indiana University, Purdue University, the University of Notre Dame, and Rose-Hulman Institute of Technology, bring world-class capabilities in chemical biology, synthetic biology, analytical chemistry, and biomanufacturing. Purdue's William D. Young

Institute for Advanced Manufacturing of Pharmaceuticals represents a center of excellence for next-generation pharmaceutical production, and Purdue's analytical chemistry is the nation's top graduate program. IU is deeply engaged in Advanced Chemistry initiatives like IU LAB and its significant $250 million investment in life sciences. The Notre Dame-led Center for Bioanalytical Metrology promote strong industry-academic partnerships. These institutions collectively produce over 4,000 chemistry graduates annually and maintain research portfolios generating significant patent activity and commercialization outcomes. Rose-Hulman, with its primary focus on education and training, has pioneered an innovative model for faculty work experience that has not only enhanced job-relevant education, but has also led to invaluable workforce and talent pipelines to top Indiana employers. For example, its enablement of faculty sabbaticals to key State industry employers has enhanced the job relevance of education, while simultaneously creating strong network connections that have promoted retention of student talent in Indiana.

However, academic and industry stakeholders have emphasized both tremendous opportunity and clear challenges. Universities and industry organizations have expressed strong receptiveness to coordinated Advanced Chemistry efforts, while noting that current activities remain fragmented across institutions and lack critical infrastructure and scale. Industry partners have likewise noted limited engagement with Indiana-based research institutions despite strong desire for deeper collaboration in academic-industry peer research collaborations, faculty attraction, student retention, and innovation partnerships. Similarly, universities have identified numerous opportunities, many unrealized until now, to deepen their respective industry collaborations and formalize their participation in business attraction and supply chain development efforts.

A national "whitespace" for action

While federal place-based investment efforts to-date have focused on other hot-button priorities such as semiconductor and chip manufacturing, policy focus on Advanced Chemistry has been comparatively under-developed despite its importance. Recent publications from Indiana leaders, including Lilly CEO Dave Ricks' *Business Roundtabl*e study on critical supply chains and Senator Todd Young's National Security Commission on Emerging Biotechnology report, have drawn attention to the critically needed onshoring and technological enhancement of global Advanced Chemistry supply chains to secure U.S. economic resilience and assure national security. A lack of both focused federal efforts or any competing efforts by other U.S. states in this space, coupled with Indiana's unique ability to lead come together in this moment to position the State as an obvious epicenter for renewed and ambitious efforts within the U.S.

Enabling American leadership in Advanced Chemistry manufacturing

Where the U.S. is a long-standing incumbent leader in the Advanced Chemistry manufacturing value chain, America's levels of production and economic profile in the space have undoubtedly declined over the last three decades. According to former FDA Principal Deputy Commissioner Janet Woodcock, "as of August 2019, only 28 percent of the manufacturing facilities making APIs to supply the U.S. market were in our country." Similarly, sector experts like the Atlantic Council and the U.S. Pharmacopeia Medicines Supply Chain Map have documented acute challenges due to reliance on external countries, particularly those without strong U.S. geopolitical alliances. China is now the fourth largest pharmaceutical importer to the U.S. after Ireland, Germany, and Switzerland.

However, multiple challenges must be addressed in order for the US to reshore both precursor chemicals and active pharmaceutical ingredients. Production economics fundamentally disadvantage domestic manufacturing, with U.S. labor, energy, and compliance costs far exceeding those in India and China—disparities particularly acute in commoditized generic APIs where razor-thin margins cannot support price premiums and low-capacity utilization drives costs to be prohibitive. Capital requirements compound these challenges, as GMP-compliant facilities demand hundreds of millions in upfront investment plus technological upgrades from batch to continuous flow processing that Asian competitors have already scaled. The U.S. also sees regulatory barriers create multi-year permitting timelines due to EPA hazardous waste requirements and community opposition. Major incumbent supplier countries have spent more time building the pipeline of chemical engineers, process chemists, and other operations talent that the U.S. must expand. Finally, onshoring requires coordination action across the manufacturing value chain; reshoring API production without the entire supply chain—from basic chemicals through excipients—merely shifts vulnerability upstream while risking retaliatory disruptions from China or India that could compromise other pharmaceutical supplies.

Catalyze Indiana must address technology, human capital, and infrastructure challenges that – because unaddressed to date – have previously diminished the business case for undertaking manufacturing of complex chemicals in the United States. This involves development of new innovations that enhance efficiency, mitigate waste, and support agile production; workforce training to ensure that Indiana students are prepared to engage in future Advanced Chemistry manufacturing; and supply chain infrastructure that can incentivize in-State production. Because of its capital- and labor-intensive nature, Advanced Chemistry leadership is closely linked to efficiency, which is in turn linked to advances in technology platforms that enhance productivity.

Industry leaders have reflected that restoring national leadership in Advanced Chemistry will require continual innovation in production technologies and processes. Efforts to bring manufacturing onshore cannot rely on traditional processes or technologies alone. Rather, they must be crafted to scale transformative innovation that can subvert the economic model that has drawn manufacturing to low-cost countries and that anticipate disruptive trends such as artificial intelligence. Necessarily, Catalyze Indiana should prepare Indiana's workforce and industry to lead the next generation of agile and efficient manufacturing in the U.S.

Long-promised paradigm shifts to advanced and continuous manufacturing could vastly enhance the operational and material efficiency of manufacturing but have not yet arrived at scale. Investment in deployment of technology platforms aligned to industry-informed "grand challenges" can create opportunities across clusters involved in Advanced Chemistry manufacturing, including pharmaceuticals, agriculture, advanced polymers, and energy storage. While Catalyze Indiana focuses primarily on food and medicine, its focus technology platform areas will enable expansion of Advanced Chemistry manufacturing across sectors.

Technology areas for Catalyze Indiana were driven by an analysis of existing grants and patents, broader innovation trends, and industry needs. The four focus areas of technology are: (1) Automation; (2) Analytical chemistry; (3) New macromolecular chemistries, including those enabling waste mitigation; and (4) Artificial intelligence and computation.

III. Envisioning Catalyze Indiana

Catalyze Indiana seeks to establish Indiana as the default destination for the expansion and innovative technology advancement of Advanced Chemistry manufacturing in the U.S. As policymakers and business leaders seek to enhance the domestic supply chain to secure the nation's supply of food and medicine, Indiana is uniquely positioned to serve as a global model for rapid and agile Advanced Chemistry production and related scientific and technology innovation at the scale necessary to meet the nation's growing demand for increasingly complex and biologically inspired molecules. This effort seeks to coordinate and scale Indiana's existing assets – its three R1 research institutions with high degrees of specialization in chemistry and chemical engineering, Rose-Hulman Institute, a unique engineering school with a history of collaborative industry partnerships, Indiana's Fortune 500 companies who serve as leaders in Advanced Chemistry clusters, and its storied track record of manufacturing and production. If successfully implemented, Indiana will be a go-to hub for talent seeking abundant workforce opportunities; for innovators seeking to bring new technologies to market; and for industry seeking to expand and technologically advance their domestic manufacturing operations. Building out this vision at meaningful scale will necessarily include all of the following:

- Enhancing Indiana's ability to **commercialize and advance innovation** emanating from its leading universities and research institutions;
- Supporting attraction and retention of **top faculty, student, and workforce talent**; and
- Creating **infrastructure** to support critical U.S. policy and business priorities, including sustainability in Advanced Chemistry, efficiency of manufacturing, and global leadership in AI and biotechnology.

When fully and successfully implemented, Indiana will be home to the world's top research talent in Advanced Chemistry production and manufacturing technologies, such as biocatalysis, membrane separations, and process analytical technologies. The State will also be a magnet destination for top student and early-career talent seeking robust and competitive jobs in Advanced Chemistry fields. Finally, anchored by these innovation and workforce efforts, Indiana will be a top candidate for any company seeking to make substantial investments in onshore manufacturing across Advanced Chemistry sectors, including biopharmaceuticals, agrisciences, advanced polymers, and energy storage.

Based on feedback from Indiana Advanced Chemistry stakeholders to the prior report and ongoing interviews, the full potential Catalyze Indiana program should span four strategic pillars of interrelated activity: would

(1) Developing, attracting, and retaining talent to support research and workforce needs

(2) Enabling innovation that supports technology grand challenges and industry needs

(3) Establishing supply chain resilience through infrastructure, business readiness, and connectivity

(4) Enhancing Indiana's profile as a technology and policy leader in domestic Advanced Chemistry onshoring and growth

IV. CONCLUSION

The imperative to secure America's supply chains for food and medicine has never been more urgent, and Indiana stands uniquely positioned to lead this national mission by leading the country in technological innovation, workforce development, and infrastructure creation. This initiative establishes the foundation for Indiana to become the nation's hub for Advanced Chemistry manufacturing and innovation.

If successfully implemented, Indiana will be home to the world's top research talent in Advanced Chemistry technologies; will be a magnet for top workforce talent seeking jobs and growth opportunities; and will attract substantial private investment through companies seeking to build onshore manufacturing facilities. In order for this vision to be fulfilled, it will be critically important that sufficient capital can be attracted to support the resulting startups who will translate the promising innovation into impact. Government support of enhanced access to capital outside the conventional hubs of investment – Massachusetts, California, and New York – to the Heartland would be highly enabling and welcomed.

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