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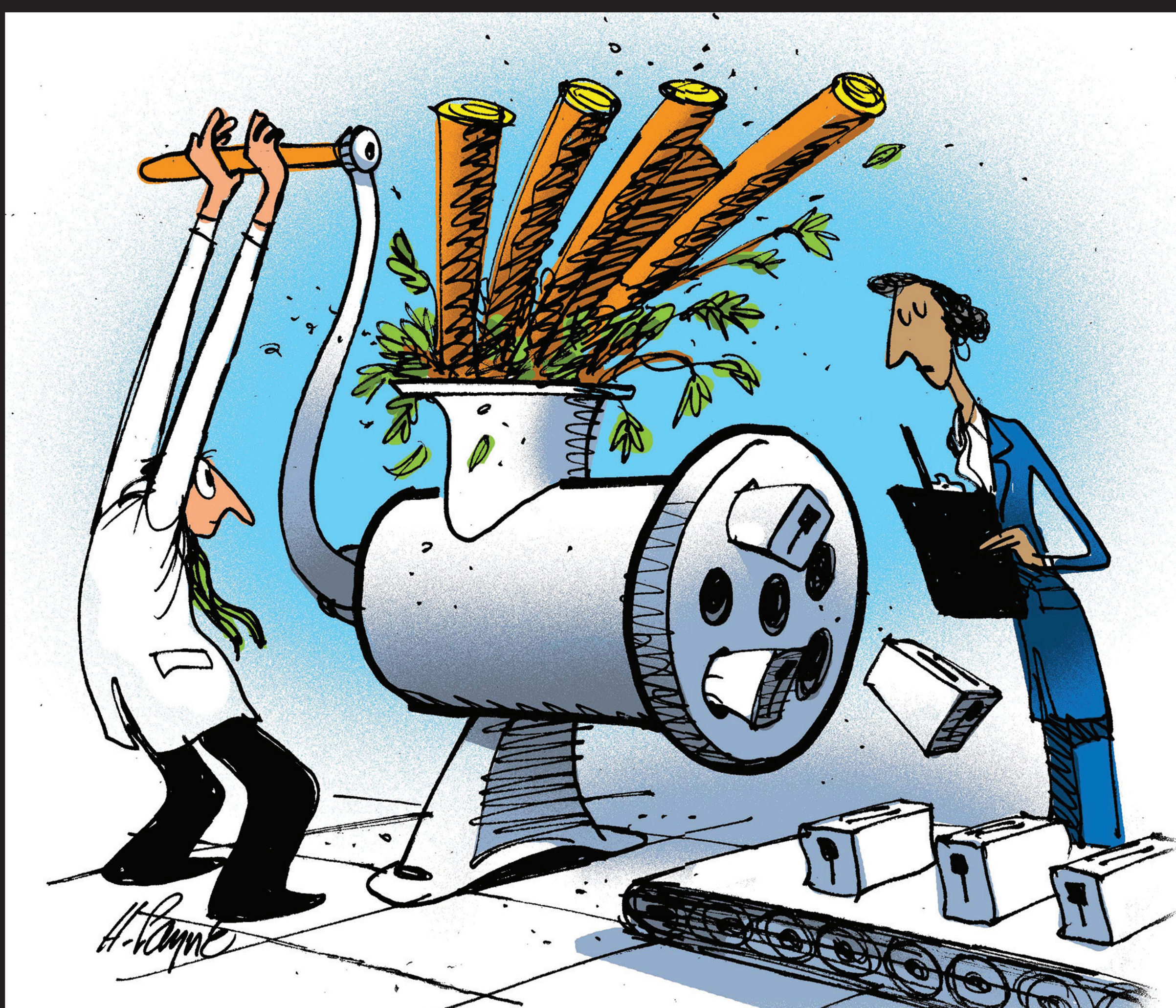

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Bioengineering the Future

A sustainable, circular economy may depend on solutions coming from life itself. So think of today's biology not as just a science, but as a precision-manufacturing platform — digitally interconnected, increasingly automated, flexible, and cost-effective

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In 1898, the British chemist William Crookes gave a talk before the British Association for the Advancement of Science entitled simply, "The Wheat Problem." Crookes is best remembered for his work on vacuum tubes, and lenses that were precursors to today's sunglasses, so his focus on wheat production probably startled his audience. Especially since his thesis was alarming: wheat was extracting more nitrogen from the soil than we could replenish, which resulted in ever lower yields and "a life and death question for generations to come."

It took another decade, but in 1908, the German chemist Fritz Haber (later referred to as the "father of chemical warfare") provided a solution to the wheat problem by demonstrating that ammonia, the main component for nitrogen fertilizers, could be synthesized. The manufacturing of ammonia for fertilizer is one of the great innovations of the 20th century. Some researchers estimate that its introduction in agriculture has since supported over 40 percent of global births.

But, as has been the case for many technological leaps, there were downsides. Today, the synthesis of ammonia accounts for a quarter of the annual greenhouse gas emissions of the entire chemical sector, as well as increasing nitrogen pollution of waterways through agricultural run-off. Other options are being explored — from synthesizing ammonia using plasma to low-temperature electro-catalysis — but the most intriguing solution is biological.

Some plants, mainly legumes like beans, have microbial partners with an amazing capability to extract and "fix" nitrogen directly from the atmosphere for immediate use by plants. What if that genetic function could be transferred directly to plants like corn? And that is exactly what is happening. Hundreds of millions of dollars are being poured into new approaches, and firms like PivotBio are making plants that they hope in the future will be self-fertilizing, addressing both environmental and food security challenges.

Over the last decade over $12 billion has been invested in new biotech startups and existing companies, with around $4 billion put forward in 2018 alone. The pandemic has riveted our attention on health care applications, but as a recent report from McKinsey notes, "More than half of the potential direct economic impact from biological technologies . . . is outside of health care, notably in agriculture and food, materials and energy, and consumer products and services."

Some of these emerging applications you may have already heard about, or even tasted. Memphis Meats and Mosa Meat are growing beef, pork, chicken, and

even duck meat from cultures in the lab, just two of the over 80 companies now working on cultured meat and seafood protein products using a process broadly referred to as cellular agriculture. These approaches are being applied to a broad spectrum of dietary products. Finless Foods, for example, is applying cellular agriculture technologies to grow fish cells in the lab. It isolates cells from fish tissue, feeds the cell cultures with nutrients to grow and multiply, and structures them into seafood products — all in local facilities, which further reduce transportation-related environmental impacts.

As another example, researchers at the Joint BioEnergy Institute, funded by the Department of Energy, have recently developed a plant biomanufacturing platform that was used to synthesize a new-to-nature biopesticide with novel antifungal properties. This suggests that plants can be used to sustainably manufacture molecules not possible with traditional chemical methods.

This all is the tip of the revolution in what is termed *engineering biology* and signals a shift from chemical to biological synthesis — to a new manufacturing paradigm. An inventory maintained by ELI to track emerging biotech products and applications now contains over 300 examples stretching across almost two dozen categories, from food to fuel to threat detection.

People are beginning to build with biotechnology. The sustainable building materials startup bioMASON injects microorganisms with sand in an aqueous solution to create bricks and other construction materials, a process that is not only faster than the traditional kiln-fired process, but it also releases no carbon because it does not require fuel or heat. Traditional brick making not only emits CO_2 and other gases into the atmosphere, but often involves the removal of agriculturally productive topsoil. That can reduce agricultural yields by 60-90 percent. Another innovative and sustainable materials startup, Cruz Foam, uses one of the most abundant natural polymers on Earth, chitin from shrimp shells, to sustainably manufacture packaging materials, automotive parts, and consumer electronics.

Novel solutions to tackle indoor air pollution are in the pipeline. Researchers at the University of Washington have inserted a mammalian gene (CYP2E1) into ivy plants to increase their detoxifying potential. The gene "codes" for an enzyme that breaks down some of the volatile organic compounds found in homes. The researchers estimate that a biofilter made of these genetically modified plants could deliver clear air at rates similar to commercial home filters.

Next-generation biotech firms are exploring new avenues to address old, intractable environmental challenges. A new effort at Allonnia, backed by Gates Ventures and the Battle Memorial Foundation, will search for enzymes or microbes that could tackle the long lasting risks from so-called "forever" chemicals — per- and poly-fluoroalkyl substances found in thousands of nonstick, stain repellent, and waterproof products.

Biotech is starting to provide promising solutions aimed directly at the global carbon cycle that could help address the 37 gigatons of carbon released annually into the atmosphere — creating carbon-neutral or de-carbonization options for a number of economic sectors, such as agriculture, construction, and some forms of transportation — aviation, for example — that are less amenable to the adoption of traditional carbon-neutral strategies. Aviation currently accounts for 2 percent of global carbon emissions. Unfortunately, plane fuel weight restrictions eliminate many of the other carbon-neutral options being considered for the transportation sector, such as electric motors or fuel cells. But researchers at the University of Manchester in England have re-engineered the genome of a bacterium (*Halomonas*) that grows in seawater to produce next-generation bio-based jet fuels.

Research is also targeting direct interventions in the carbon cycle, by increasing the carbon capture efficiencies of plants and trees. Today, around 120 gigatons of carbon is removed by terrestrial photosynthesis on an annual basis. So even small improvements could have large impacts on carbon removal while simultaneously improving crop yields and food security. Research is underway to redesign photorespiration and CO_2 fixation pathways, optimize light reactions during photosynthesis, and transfer carbon-concentration mechanisms from algae and bacteria into other plant chloroplasts.

Biotech is creating new avenues for climate change adaptation — for instance, the engineering of drought- and disease-resistant crops. Researchers at the Innovative Genomics Institute at Berkeley have developed cacao plants engineered to thrive as the climate warms and dries the rain forests where they normally grow the crop. As many as 50 million people worldwide make their living from the industry.

Long term, biology can be a key to creating a circular economy, where decentralized and distributed biomanufacturing systems are designed to use a variety of inputs. These include chemicals from industrial off-gases; syngas generated from municipal solid waste, organic industrial waste, forest slash, and agricultural waste; or reformed biogas. These systems provide a variety of outputs, from fuels to food or vaccines. This kind of production flexibility is one objective of the new BioMADE initiative developed by the Department of Defense and the Engineering Biology Research Consortium. The seven-year award includes $87.5 million in federal funds and is being matched by more than $180 million from non-federal sources, including state governments.

This future rests on the increasing ability to engineer biology to enable what researchers at the firm Zymergen have coined *biofacturing*. Jason Kelly, the CEO of Ginko Bioworks, predicts, "As we get better at designing biology, we'll use it to make everything, disrupting sectors that the traditional tech industry hasn't been able to access."

Old biotech was messy, expensive, and imprecise. It would often take large companies hundreds of millions of dollars and years to change the properties and behavior of one molecule. No more. To paraphrase Stanford University economist Paul Romer, the new biology is about better recipes, not just more cooking.

Today's biology goes beyond the "study of complicated things," as the British evolutionary biologist Richard Dawkins once put it. Over a decade of significant investments by organizations like the National Science Foundation, the Department of Energy, and the Defense Advanced Research Projects Agency have turned biology into what some have termed a *Type 2 innovation platform*, similar to the Internet, which "consists of technological building blocks that are used as a foundation on top of which a large number

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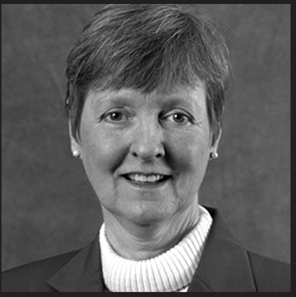
Reinventing Biotechnology Regulations



Barbara J. Evans

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"The real problem is not the occasional gap in an otherwise well-functioning regulatory model, but with the regulatory model itself."

Clayton Christensen's theory of disruptive innovation saw new technologies as mere enablers of transformative change. Making a splash requires two more things: business model innovation and new value networks to deliver the technologies in ways that are profitable, affordable, safe, and accessible to consumers. New business models require new regulatory models. Gene editing promises to cure rare forms of hereditary blindness but at prices above $500,000 per eye, if approved using FDA's last-century biologics regulations. Can the blind afford that?

Instead of passing biotechnology-specific legislation, the United States adopted a Coordinated Framework for Regulation of Biotechnology in 1986, with revisions in 1992 and 2017. The CF tapped existing federal regulators like the Food and Drug Administration, Department of Agriculture, and Environmental Protection Agency to oversee new biotech products using legal powers they already had. The CF agencies are safety regulators, protecting consumer, patient, environmental, agricultural, workplace, and other types of safety. The CF ignores other regulatory concerns, including infrastructure policy.

Regulatory scholar Jose Gómez-Ibáñez conceives "infrastructure" as "networks that distribute products or services over geographical space." Biology-based manufacturing demands diverse new infrastructures: data commons, facilities, and service networks, some exhibiting economies of scale that make shared assets superior to fragmented efforts.

The United States relies on private-sector infrastructure but subjects it to economic regulations that incentivize investments, promote responsible operation, and capture economies of scale while controlling monopolies to ensure fair access and pricing. Our current infrastructure regulatory model emerged in 1887 to regulate railroads and fostered the development of national infrastructures as varied as stockyards, telecommunications, electricity, and aviation. Modest reforms late in the 20th century harnessed market incentives to sweeten command-and-control tactics. Can this 150-year-old regulatory model call forth vast new infrastructures to support biology-based manufacturing? Perhaps, but not until policymakers recognize infrastructure as a crucial biotechnology policy issue.

Even as a safety framework, the CF falls short. It is a patchwork of antiquated statutes, some dating to the early 20th century and not designed for today's biotech industry. There are legal gaps where novel products slip through with no safety oversight. Fortunately, the CF agencies are nimble in interpreting old laws in new ways to enable basic safety and environmental oversight for many products. The real problem is not the occasional gap in an otherwise well-functioning regulatory model, but with the regulatory model itself. The concept of "safety regulation," as practiced in the last century, was designed for industries that have a fairly small number of large manufacturers selling mass-marketed products and operating at a scale that covers the costs of generating evidence to support detailed premarket review.

Today's biotech industry upends old regulatory models in ways also seen in the sharing economy, exemplified by people who rent their homes through platforms like Airbnb. When millions of people rent their homes for a night, how can a hotel regulator find them to regulate them? The platform that holds the information regulators need (who rented a room?) does not itself provide lodging and is beyond the reach of hotel regulators. New biotechnology business models pose analogous challenges for CF agencies like the FDA. Business functions once integrated together are split across multiple players, some beyond the reach of CF regulators. It is neither practical nor cost-effective to inspect thousands of decentralized facilities and service providers. Ponderous regulatory reviews of the past could destroy the economic viability of precision-manufactured products.

Regulatory models tailored for the last Industrial Revolution will not fit this one. The CF was a bridge. Biotechnology crossed it to a new shore. New models and types of regulation are now required.

of innovators can develop complementary services or products." Think of today's biology not as a science, but as a precision-manufacturing platform — digitally interconnected, increasingly automated, flexible, and cost-effective.

These novel biological engineering approaches share one critical characteristic — the ability to run experiments quickly, testing hypotheses, learning, adjusting — what some have termed the Design-Build-Test-Learn cycle. Making things faster has been lauded as the single most important determinant of manufacturing productivity and was historically a critical focus of companies such as IBM (via Continuous Flow Manufacturing), Motorola (Short Cycle Management) and Westinghouse (Operating Profit Through Time and Investment Management). Jack Newman, a co-founder of the biotech firm Amyris, observed that the DBTL cycle "was transformational, allowing the operational translation of fundamental science into stuff."

These new capabilities have spawned radically new business models, allowing the disaggregation of the historical value chains that have long dominated medical and agricultural biotech. This is happening even at a time when large first-wave biotech firms are tending toward consolidation, bordering on monopolistic aggregation, such as the recent mega-merger of Monsanto and Bayer. But simultaneously, what some term *de-verticalization* is creating viable business niches in new economic ecosystems, where many new firms work to design the molecules that can be scaled by larger firms downstream in the value chain.

But going to scale remains a large challenge facing the bioengineering community. This will mean moving from a few milligrams of a novel microbe in the lab to kilograms, kilotons — and beyond in the case of commodity products. Going from lab to commercial-scale production will require a bridge, a distributed and sharable infrastructure that can be co-developed with industry. It will need a new workforce with the necessary skills to engineer large-scale, distributed, and flexible production facilities and the ability to build life cycle and sustainability considerations into manufacturing processes and their associated supply chains.

And going to scale with potentially hundreds or thousands of large-capacity bioreactors will bring the new biotechnology face-to-face with the public and media, raising questions about safety, security, and governance. Moving forward, there is an urgent need for regulatory and policy reinvention. There is an old adage in Silicon Valley that innovation requires a combination of "rich people," "nerds" and "risk taking." That may not be enough. There are some important ways in which biology differs from other innovation platforms. The most crucial are the regulatory, security, and public perception barriers that may hinder the introduction of new products into the market.

Regardless of these challenges, over a decade of progress and emerging business opportunities have motivated many countries to develop bioeconomy strategies designed to expand their industrial base and accelerate the commercialization of biotech innovations. There are now nearly 60 bioeconomy strategies for nations and for a number of macro-regional areas like the European Union and East Africa. Thousands of people now attend the biennial Global Bioeconomy Summit held in Berlin (virtual this year). The United States was an early leader, developing a government-wide National Bioeconomy Blueprint in 2012 under the Obama administration. It emphasized the role of the biosciences and biotechnology in creating new economic opportunities.

The 2012 Blueprint was the first and for the better part of a decade the only bioeconomy strategy that featured biotechnology as a critical platform technology to drive economic benefits in the biomedical, agricultural, environmental, energy, and industrial sectors. The Blueprint promotes making strategic and non-overlapping research and development investments, facilitating transitions from lab to market, increasing regulatory efficiency, enabling public-private partnerships, and supporting strategic workforce development. In the years that followed the release of the Blueprint, the Obama administration realized a number of outcomes relating to all five of its strategic objectives.

For instance, significant research investment enabled the discovery of CRISPR/Cas9, which became a genome-editing technology that has significantly accelerated the ability to quickly and precisely edit genomes of microbes, plants, and animals. The Department of Agriculture expanded the BioPreferred Program, the federal biobased procurement system that aims to provide market certainty for the growing industry sector. Then in 2015, Executive Order 13693, titled Planning for Federal Sustainability in the Next Decade, required federal agencies to set biobased procurement targets. The Office of Science and Technology Policy convened the Food and Drug Administration, EPA, and USDA to execute the 2017 Update to the Coordinated Framework for

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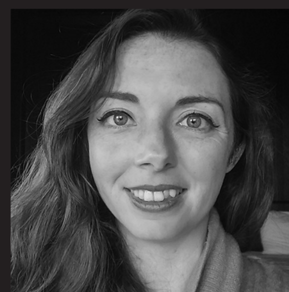
Good for Ag, Good for the Bioeconomy



"*Policies that recognize the sustainable intensification of agriculture as a cornerstone of the bioeconomy will help realize the full potential of this rapidly growing industry.*"

Keira Havens
Sustainability Program Manager
Pivot Bio

PRODUCTION agriculture is a cornerstone of the trillion-dollar bioengineering industry, yet it is often overlooked and underfunded. In other sectors, private equity investment and national-level initiatives have worked hand-in-hand to jump start research, tool development, and novel applications of biology. Programs like U.S. Department of Agriculture's BioPreferred ensure that the government is a ready and willing market for novel products manufactured with sustainable practices. However, agriculture itself is often discussed in isolation from the bioeconomy, and could benefit from a national-level focus on the development of new tools and markets for the production of sustainable, resilient, and domestic feedstocks.

Investment in agricultural research and economic support for growers implementing sustainable practices are essential to realizing the promise of a circular bioeconomy. American commodity crop growers cultivate millions of tons to provide the biomass that is converted into fuel, feed, food, and fiber. Crops like corn also provide the sugar for fermentation that drives much of the bioeconomy. A national discussion that includes commodity growers as an essential element of the bioeconomy integrates inputs critical to the successful trial and deployment of new agricultural tools, with the potential to change the definition of best practice in the field.

Synthetic nitrogen fertilizer is one of the oldest tools available to farmers. But it presents a catch for the bioeconomy. Even when used with best practices, half of nitrogen fertilizer never reaches the plants; it's lost to the environment.

Fertilizer production and loss to the environment account for up to half of the global warming potential of an acre of corn. Without the downside of synthetic nitrogen, corn is one of the plants best suited to capture carbon from the air and serve it up as biomass and sugar feedstocks for the bioeconomy. As long as synthetic nitrogen fertilizer is required for productive agriculture, nitrogen loss will offset the benefits of a robust and sustainable bioeconomy.

There are systemic benefits to re-thinking tools and best practices in light of the unique advantages biotechnology offers. For example, nitrogen-fixing microbes, developed using tools and knowledge from other sectors of the bioeconomy, are part of the solution to the synthetic nitrogen fertilizer dilemma. The microbes bring cutting-edge biology to the field and facilitate the previously impossible: a transition away from petroleum-based synthetic nitrogen fertilizer, allowing growers to maintain productivity while operating with a lighter environmental footprint.

Microbes as a nitrogen source can reduce greenhouse gas emissions associated with fertilizer manufacturing by 98 percent Furthermore, emissions reduction for commodity row crops like corn ripple through both traditional markets like animal feed and essential biomanufacturing pipelines like fuel production and fermentation. This innovation brings us closer to realizing the full potential of the bioeconomy by examining the essential needs of growers and working with biology to eliminate barriers like nitrogen loss.

When we invest in technologies — biological or otherwise — that benefit growers through both improved agricultural productivity and improved sustainability, we reap benefits in the bioeconomy at large. Each innovation that makes production agriculture more sustainable means that the bioeconomy can further distinguish itself as a long-term solution to provide essential goods and services without compromising our resources. Biology advances beyond the static, linear expectations of traditional chemistries and offers dynamic tools that cultivate resilience as well as reliability.

Innovation is the key to delivering clean water, clean air, and a healthy planet to the next generation. When we make use of new tools, powerful algorithms, and models that allow us to rapidly test our understanding of interconnected systems, biology becomes a source of innovation with the capacity for unrivaled impact. Policies that recognize the sustainable intensification of agriculture as a cornerstone of the bioeconomy will help realize the full potential of this rapidly growing industry.

the Regulation of Biotechnology, aimed to increase transparency, ensure safety, streamline regulatory processes, and accelerate the translation of bioinventions to market. There was also a successful public-private partnership between LanzaTech and Pacific Northwest National Laboratory that resulted in the development and testing of the first bio-jet fuel, used to power a Virgin Atlantic Airlines flight from Orlando to London. Finally, in addition to launching a technical roadmap in 2019, progress has been made toward the Blueprint's workforce objective through a public-private partnership known as the Engineering Biology Research Consortium, which established a four-month industry internship program for Ph.D. candidates to help train the next generation workforce for engineering biology.

Since the National Bioeconomy Blueprint was released, a number of additional important advances have occurred. In 2019, the House of Representatives passed legislation, the Engineering Biology Research and Development Act of 2019, with the aim of directing the Office of Science and Technology Policy to implement a national engineering biology research and development program that would coordinate relevant federal agency investments and activities. The Senate followed with the Bioeconomy Research and Development Act of 2020, with a similar aim. Also in 2020, the National Academies for Science, Engineering, and Medicine released a study, "Safeguarding the Bioeconomy," that articulated — for the first time — the value of the U.S. bioeconomy, which it estimated at $959 billion annually. The report argued that the United States needs a White House-level standing committee of scientists, economists, and national security experts to develop a strategic plan to promote and protect the United States' biology-based industry.

These actions portend a future wherein a strategic, coordinated federal effort is possible. Toward this end, additional steps are needed. For instance, the Biden administration should consider creating an office to coordinate interactions between the government and businesses, large and small, on bioengineering. It should be a one-stop shop — similar to what the National Nanotechnology Coordinating Office did for the National Nanotechnology Initiative.

To realize a strategic, coordinated U.S. bioeconomy, policymakers will need to advance not only authorization for a national engineering biology research and development program, but also appropriations to fund it. Any appropriations should be linked to regular evaluation of program impacts and proactive anticipation and management of emerging risks to help ensure public confidence in new and novel products and applications. A recent meta-analysis of the national bioeconomy strategies found that, "Only a minority . . . even mention the potential negative consequences of bio-based transformations."

Significant strategic infrastructure investments are needed. For example, a new constellation of state-of-the-art, networked biomanufacturing facilities, positioned near sources of biomass, could not only maximize the use of renewable resources but also create high-tech jobs in rural areas. Facilities in Iowa, for instance, could use agricultural waste from corn as a feedstock, those in southeastern states could utilize switchgrass, and coastal production plants could take advantage of marine species such as seaweed and various kelp varieties. This biomanufacturing "commons" could also serve to reduce greenhouse gas emissions and the generation of toxic waste as compared to traditional chemical manufacturing. And it would create value from problematic wastes such as forest slash and agricultural residues.

Building on the progress started by the National Bioeconomy Blueprint developed during the Obama administration, the incoming Biden team has a tremendous opportunity for a renewed commitment to the U.S. bioeconomy as an important pillar of its commitment to climate action. Its new "Made in All of America" effort is aimed at revitalizing domestic manufacturing with inclusive policies and environmental stewardship,

Working together with the 117th Congress, the new administration has potential to realize a Clean Manufacturing Act, aimed to mobilize the diverse talent of the American workforce, accelerate sustainable manufacturing innovation, maximize the use of the billion tons of sustainable, renewable biomass the United States has the ability to produce, and significantly reduce negative environmental impacts of manufacturing.

As nearly sixty countries around the world try to refine their bioeconomy strategies to include biotechnology to help reboot economies crippled by the coronavirus pandemic, the United States has little time to waste in developing strategies to keep its leadership position in biomanufacturing. Over a decade ago, Neri Oxnam at MIT's Media Lab observed that "the biological world is displacing the machine as a general model of design." That revolution has happened. The future of manufacturing has arrived. **TEF**

SIDEBAR

Need a National Program to Scale Up

Douglas Friedman
Chief Executive Officer
BioMADE

"Companies, universities, nonprofits, as well as environmental health, safety, security, and other professionals will work together to establish an ecosystem responsive to the call"

IMAGINE a world with a closed loop of sustainably manufactured products, all within 200 miles of your home. Now imagine those products are made with waste from local communities and organic matter that would otherwise be landfilled. This is the future that will be enabled through distributed industrial biomanufacturing.

The bulk of industrial chemical production (by volume) in the United States comes as byproducts of energy-intensive petroleum refining. These chemicals are produced in billion-dollar refineries and then transported throughout the country to manufacturers that bring higher-value goods to market. The drivers of this system are inefficient. Fuel consumption, not chemical use, drives energy markets, and shortages and surpluses are commonplace with decoupled supply and demand.

Distributed biomanufacturing can help avoid these problems. First, with the capital cost of a biomanufacturing facility a fraction of that of a petroleum refinery, we can build them in a distributed network throughout the country — bringing jobs to communities. Just think of the number of craft breweries that have appeared in nearly every major city over the last two decades. Manufacturing facilitates can use local feedstocks that don't need to be shipped long distances: corn in the Midwest, sugar beets in Michigan, switchgrass in Virginia, and almond hulls in the central valley of California. Even trash from municipal waste is contemplated as a biomanufacturing feedstock. These facilities then produce products for businesses in the region and can be directly responsive to local demand.

Three things are holding us back. One is an inability to predictably reach commercial-scale production. A second is a lack of a national bioeconomy strategy. Last is a state of regulatory confusion.

Biology can be used to make almost any molecule imaginable, but only ounces at a time. Commercial industrial products often require tons of material. The Pentagon recently awarded a $275 million cooperative agreement to establish a nonprofit bioindustrial manufacturing innovation institute; I am proud to be CEO of this creation. BioMADE will focus on developing technologies necessary to achieve scale more predictably as well, through investments not only in discrete scale-up opportunities but downstream processing and data analytics. Companies, universities, nonprofits, as well as environmental health, safety, security, and other professionals will work together to establish an ecosystem responsive to the call.

Predictable technology development is not enough; a national strategy is critical. To get there, the federal government should develop a National Bioeconomy Strategy focusing on transitioning our world-leading biotechnology capabilities from research into economic development. In the last Congress, the Bioeconomy Research and Development Act of 2020 passed out of Senate committee. This legislation would have established an initiative and created an office to coordinate these national objectives. The new Congress should take up these ideas again and establish a national program to expand biotechnology for the bioeconomy.

Finally, the regulatory environment for products of biotechnology is confusing and a challenge for new entrants into the market. The Coordinated Framework for the Regulation of Biotechnology, which explains the complex set of laws and regulations that apply to biotechnology, was originally published in 1986. Despite the efforts of the executive branch to clarify the legal environment for biotechnology products, the underlying legislation has not kept up with advances in science and engineering and should be reviewed. I make no statements about what the results should be other than it be clear to companies in the industry so they can develop their products within a known set of parameters.

Bioindustrial manufacturing is at an inflection point. Global competition is peaking, and the United States is well positioned to compete in the new bioeconomy, but it will take concerted action to do so. It is not too soon to start.