National Commission on Innovation & Competitiveness Frontiers

A Council Plan to Redefine 21st Century Productivity, Prosperity and Security

Optimizing the Environment for the National Innovation System

Working Group 3 Charter

Setting the Stage for the Commission Working Groups

Despite significant strengths in its innovation capabilities and capacities—documented in the Council on Competitiveness *2018 Clarion Call for Competitiveness*—U.S. competitiveness is dynamic and ever transforming. And our nation's comparative position in the global competitiveness arena can change rapidly.

Now and into the future, U.S. companies, industries and our national and regional economies that expect to compete will have to rise to the challenge of this dynamic, and reorganize for an age of growing technological, economic and political disruption. Our government, communities and our education system must be prepared to support rapid change, and help those who are displaced or negatively affected by technological and competitive change.

When the United States controlled the global direction of technology, we were positioned to control our economic destiny. That is no longer guaranteed.

The United States must take stock. We must assess if our innovation ecosystem and its investments are enough to maintain our global economic and technological leadership. And, as technology seeps into nearly every aspect of American life, our national leaders and our governments at every level must bolster their knowledge and response capabilities to match the strengthening global competition, technological change and coming disruptions.

What will the United States do in the face of challenges at home and coming from abroad?

Will we plan for the long term, transforming challenge to opportunity? Will we put in place the talent, innovation capital and infrastructure necessary for continuing success in the decades to come? Will we recognize the multifaceted nature of today's global innovation race, and come together across all sectors to form a new "innovation compact" for economic growth, productivity and inclusive prosperity?

To confront and overcome critical challenges facing the U.S. innovation engine…

To create momentum in the United States to outpace the rest of the world in innovation capacity, capability and competitiveness…

To build on the Council's history of work in defining, articulating and activating America's innovation movement…

And to develop new partnerships and efforts to launch and scale innovation-based research, businesses and ventures in the United States.

The Board and Executive Committee of the Council has formed the National Commission on Innovation & Competitiveness Frontiers (Commission) to prepare the Nation for a new, unfolding and evolving innovation reality that will shape the Nation's prosperity for the next half century.

In the first year of the Commission's work, the Council will build a powerful set of recommendations with **Working Groups focused on three core pillars:**

1. **Developing and Deploying at Scale Disruptive Technologies.**
2. **Exploring the Future of Sustainable Production and Consumption, and Work.**
3. **Optimizing the Environment for the National Innovation System.**

Working Group 3: Optimizing the Environment for the National Innovation System

Mission

Innovators start with an idea of what is needed by a society, market or individual. Like inventors, they create—but they also apply their creations. And those applications, in turn, generate further innovations, giving rise to new industries, and national and global markets; spurring productivity and economic growth; fueling wealth creation and profit; generating high-value, higher-paying jobs; and raising the standard of living for everyone touched by the innovation.

The **Optimizing the Environment for the National Innovation System Working Group** will examine the physical and policy structures that support innovators, including intellectual property protection; business regulation; structures for collaboration; capital availability (venture capital, federal funds, foreign investment); standards; new, emerging trading systems; etc.

To accomplish these aims, the Working Group will discuss ways in which to support and optimize the entire system in which the nation's innovators and enterprises operate. And though the private sector takes the lead—applying strategies, technologies, business models and capital that address genuine market needs—there are critical roles local, state and federal governments must play.

Timeframe

The Working Group will:

- Form in late summer and fall 2019, following the launch meeting of the Commission.
- Convene physically in early 2020 for cross-Working Group level set conference.
- Continue virtual engagement in spring 2020, with potential physical meetings hosted by a Commissioner.
- Target delivery of final recommendations at a summer 2020 Commission meeting.

Background

There are many factors that affect a country's ability to innovate and compete. This includes levels of investment in R&D, the availability of capital to fuel start-ups and innovation at critical stages, the availability of talent, the environment for entrepreneurship, and the general business environment including taxes, the level of business regulation, government support of business and the environment for global trade. These elements often vary in different countries around the world, playing a significant role in a country's competitiveness and capacity for innovation.

U.S. competitors around the world seek to build and strengthen knowledge and technology-based economies as the basis for advancing productivity, job creation, raising standards of living and, in some cases, advancing their geopolitical goals. As a result, many deploy policies and programs to stimulate innovation, and create a business environment to achieve this impact. These countries are instituting their own distinctive innovation ecosystems, which may not be compatible or friendly with U.S. systems of innovation.

Potential question for the Working Group to consider:

- Should the federal government perform a "whole of government" review of the federal role in creating a business environment for innovation?

Issues

Capital and tools to invest in innovation from start-up to scale-up. The U.S. financial system—including financing for small and medium-sized enterprises and the availability of venture capital, both crucial for U.S. innovation—is considered among the very most, if not *the* most, competitive in the world.

Nevertheless, obtaining capital at critical points in the innovation development life cycle can be challenging for innovating entrepreneurs, and small and medium-sized enterprises. There are two key investment gaps. In the first, entrepreneurs and small firms—including those developing technologies transferred from universities and federal labs—often lack funding to develop prototypes, and to test and validate their innovations. Lacking adequate resources at this critical juncture in the innovative life cycle, these technologies may fall into the "valley of death," stalling or terminating their development toward commercialization, and increasing their vulnerability to foreign acquisition. A second area of challenge is securing adequate financing to scale-up to full production in the United States, when risk has been significantly lowered, but investment needs are significantly higher.

To capture the full fruits of the U.S. innovation ecosystem, the United States must bridge both gaps.

Venture capital. Venture capital plays an indispensable role in funding U.S. innovation, supporting the development of some of the most innovative and successful U.S. companies. Recognizing the powerful role U.S. start-ups and venture capital have played in U.S. innovation and competitiveness, other nations have adopted this model, and the U.S. lead in venture capital is shrinking. While the absolute level of venture capital coming to the United States has increased, the U.S. share of the growing global pool of venture capital—which has increased by more than 200 percent since 2010—has eroded sharply from more than 90 percent in the 1990s, to about half in 2018.[27] Moreover, venture capital investment is highly concentrated in certain geographic regions of the United States—particularly California, New York and Massachusetts—which, together, accounted for 79 percent of venture dollars invested in the United States in 2018.[28] Also concentrated, more than half of venture capital in the United States goes to software (36 percent) and life science (18 percent) companies.[29]

U.S. venture capital appears to be shifting, with capital increasingly concentrated in bigger funds and bigger investments, with fewer companies receiving investments. For example, the number of companies receiving venture capital has been on a downward trend since 2015, reaching a six-year low in 2018.[30] Large investments are taking a significant share, with investments of $100 million or more in venture-backed companies accounting for 47 percent of

27 National Venture Capital Association 2019 Yearbook.

28 ibid.

29 ibid.

30 ibid.

venture capital invested in the United States in 2018; unicorns—venture-backed companies valued at $1 billion or more—accounted for 35 percent of the total venture dollars invested, but only two percent of the deals.[31]

Federal government funding for innovation. Efforts to advance innovations by start-ups and small firms are supported by some government funding, but that funding can decrease abruptly after a technology is created, right when a company or entrepreneur needs funds to test and begin commercializing the technology. Some federal R&D grant programs have extended some funding further into the development life cycle. For example, the Small Business Innovation Research Program (SBIR) has a three-phase, merit-based R&D grant program. In Phase I, small businesses can receive up to $150,000 to establish the technical merit and commercial feasibility of their innovations. In Phase II, those who have participated in Phase 1 may compete for up to $1 million to further their R&D or to develop a prototype. In Phase III, SBIR awardees pursue commercialization, but there is no SBIR funding. Federal departments and agencies have authority to offer financial support beyond the first Phase II award, however, matching funds may be required. Through the SBIR program in 2018, federal departments and agencies awarded or obligated $3 billion in more than 5,600 awards to about 3,000 small firms.[32]

In another example, the Department of Energy awards merit-based grants for research and development to advance clean energy and energy efficiency technologies. Grants can range from several hundred thousand dollars to 10 million dollars or more. However, cost-sharing is often required and grant applications are complex, a challenge to cash- and time-strapped small businesses and start-ups.

Foreign investment in U.S. innovation. Foreign investment in start-ups and innovating companies is increasing. China and Russia—both considered strategic competitors to the United States—have interests in acquiring U.S. technologies by both licit and illicit means. For example, China is targeting development of the entire semiconductor ecosystem, including spending more than $150 billion over 10 years for investments and acquisitions.[33] Also, China is increasingly playing the role of venture capitalist, while U.S. investors' share has declined. In 1992, U.S. investors led 97 percent of the $2 billion in venture finance and accounted for about three-quarters just a decade ago. However, in 2017, U.S. investors led 44 percent of a record $154 billion in venture finance, with Asian investors (with China leading) accounting for 40 percent.[34]

The Foreign Investment Risk Review Modernization Act of 2018 reforms the national security reviews made by the Committee on Foreign Investment in the United States (CFIUS), broadening its scope to include certain noncontrolling transactions (as opposed to those that could result in foreign control of a U.S. business), and requiring mandatory declarations for both controlling and noncontrolling transactions that involve a foreign investor that fall into

31 ibid.

32 SBIR Dashboard, https://www.sbir.gov/analytics-dashboard.

33 Made in China 2025: Global Ambitions Built on Local Protections, U.S. Chamber of Commerce, 2017.

34 Silicon Valley Powered American Tech Dominance—Now it has a Challenger, Wall Street Journal, April 12, 2018.

a critical technologies pilot program that includes industries advancing a range of important emerging technologies, including aircraft and aerospace manufacturing, computer-related industries, R&D in nanotechnology and biotechnologies, and semiconductors, among others. CFIUS reviews potentially can discriminate among investors from certain countries that are determined to be a country of "special concern" that has a "demonstrated or declared strategic goal of acquiring a type of critical technology or critical infrastructure that would affect U.S. leadership in areas related to national security."

Potential questions for the Working Group to consider:

- Does the geographic concentration of venture capital prevent the United States from harnessing its full capacity for innovation? Do we need a more geographically inclusive venture financing system?
- Does the industry concentration of venture capital prevent the United States from fully exploiting a broader range of emerging technologies that could result in additional jobs and industrial expansion? Do we need a more industry inclusive venture financing system?
- Does the shift in venture capital to larger investments in fewer firms have the potential to undercut U.S. innovation by reducing the venture capital available to a broader, more technologically diverse set of start-ups? Or, does the U.S. benefit from larger infusions of capital into new firms that are perceived as more attractive to drive their scaling more quickly? What might be the shorter-term and longer-term impacts on technology-driven U.S. economic growth?
- Should the federal government play a larger role in providing capital at critical stages of the innovation life cycle, for example, to help bridge "the valley of death?" Are current federal programs—such as SBIR, Department of Energy R&D grants and the Manufacturing USA Institutes—the right kinds of tools to accelerate U.S. innovation by providing critically-timed financial support?
- What other kinds of investment tools—both public and private—are needed?
- Do crowdsourcing models have greater potential? Should we find ways to expand the scope of U.S. investors in innovation, or does that present too much risk?
- How can more private companies take a greater role in investing in innovations developed outside of the company that could potentially be of future interest and utility?
- Many state and local economic development agencies seek foreign investment to create new jobs. How should those needs be considered?
- Given both the U.S. interests in national security and global competitiveness, how do we balance the risk of losing critical technologies to foreign competitors with the need for funds for U.S. fast-growing industries, and start-ups and other companies advancing new technologies?

Tax incentives and tax treatment that foster innovation. While other nations have steadily lowered their corporate tax rates since 2001, the United States had a tax rate highest among all OECD countries. The Council has long advocated for lowering the U.S. corporate tax rate to 23 percent, in line with the upper quartile of OECD economies. The Tax Cuts and Jobs Act of 2017 reduced the

corporate income tax rate from 35 percent to 21 percent—making doing business in the United States significantly more attractive and freeing more private sector funds for investment.

The U.S. Research and Experimentation Tax Credit is a significant incentive for investment in R&D. The tax credit was permanently extended in 2015, and its provisions were expanded to further reach U.S. innovators. For example, prior to the changes, the R&E tax credit did not benefit start-up firms with no federal corporate income tax liability. Now start-up businesses with no federal income tax liability and gross receipts of less than $5 million can take the R&E tax credit against the employer portion of payroll taxes, creating a refundable credit capped at $250,000 for up to five years.

In addition, some states and localities have additional tax benefits and inducements for investing in R&D and to attract R&D facilities and high-tech companies.

Potential questions for the Working Group to consider:

- Is this basic tax structure adequate and/or optimal for getting the most innovation out of the U.S. system as possible?
- Do we need to do more to inform U.S. small businesses about the benefits available to them through the R&E tax credit, given the wide range of research, development, testing, manufacturing process advancements and other activities that qualify for the credit?
- Are there other opportunities for using tax or other financial incentives to encourage innovation?

Intellectual property in a hyper-diverse innovation economy. Is the U.S. intellectual property regime out of date—configured as a "one size fits all" model in a world riddled with diversity? The U.S. patent system was established and evolved for a simpler economy that was very different from today's hyper-competitive, hyper-paced, knowledge-driven, global economy. This is reflected in the 1790 U.S. Patent Act's very definition of the subject matter of a U.S. patent: "any useful art, manufacture, engine, machine, or device, or any improvement thereon not before known or used." Rather than built on mechanical devices, today's economy; its growth industries—such as microelectronics, software and biotechnology—company value, and competitive advantage are based on the generation, control and use of knowledge. These knowledge-based technologies and industries also enable a wide range of other industries in the economy, contributing to their growth and competitiveness. For example, retail industries gain advantage from big data and software that manages logistics, while the oil and gas industry depends on computing and seismic imaging.[35] Moreover, emerging technologies—such as synthetic biology—have the potential to create new types of intellectual property, for example, a new gene sequence.

Moreover, the U.S. patent system is "one-size-fits-all," while the needs of intellectual property (IP) holders and the ways in which they use IP protections are increasingly diverse. For example:

- The microelectronics industry, where product life cycles have collapsed, requires speed and shorter-term protection before products are commoditized

35 Needed: A New System of Intellectual Property Rights, by Lester Thurow, Harvard Business Review, September-October 1997.

and it turns to the next generation technology, while the pharmaceutical industry needs long-term protection to recover the billions spent on R&D, clinical trials, long-term studies, regulatory approvals and project failures.

- Securing patent protection is a complex and costly process that large firms are financially equipped to handle, while many small firms and start-ups without such resources tend to seek protection for trade secrets because it is cheaper and simpler.
- Some entrepreneurs, small firms and start-ups secure IP protections to attract financing or for a stronger position when seeking out a joint venture. Others do not intend to scale and commercialize their innovations, but seek IP protection for a stronger negotiating position in attracting potential suitors for an acquisition or licensing agreement.
- Large firms may use patents to keep competitors at bay.
- Different forms of IP protection may be important at different stages of the innovation life cycle, for example, trade secrets during R&D, before it is known if a new technology is worth patenting.

Also, challenging globally, different countries have different ideas about IP rights, for example, what can be protected, as well as the balance between what should be free to society and what can be sold by the private sector.

Potential questions for the Working Group to consider:

- Is it time to remake the U.S. system of IP protection more aligned with today's knowledge economy and diverse needs? What would be some of a new system's key features?
- Should greater consideration in IP protection be given to the benefits of faster, more widespread distribution of new knowledge and technology? Where is the balance between faster, more widespread distribution and incentives for the private sector to advance technology? Would faster dissemination drive greater ancillary and associated innovations, new firm entry, and speed up the transformation of the economy around new technologies?

Challenges business face in engaging universities in technology transfer and IP. U.S. technology transfer laws—which include provisions for patenting and licensing IP created with federal government financial support—are considered a U.S. competitive advantage. However, the challenges of negotiating IP agreements with universities is a continuing trouble spot for U.S. industry. In the Council's Technology Leadership and Strategy Initiative, many participants confirmed that industry-university collaboration falters most often over IP differences. Due to IP or other issues, U.S. business partners with universities on only a small percentage of its research, about 1.2 percent of business research funding.[36]

While a few U.S. universities are state-of-the-art in negotiating with start-up companies and established firms, there are often mismatches between the goals

36 National Science Foundation.

of a firm and a university, and over how each party values the IP in question. The entrepreneur or firm often has to acquire, license or create several patents in order for the whole IP package to generate value, and it is often difficult to determine the royalty stream appropriate for each IP component. This is pointed to as a significant barrier to industry-university collaboration.

Many universities employ master agreements that are "one-size-fits-all," despite vast differences in the market realities of different industries. Company-university collaboration may also suffer from current laws that incentivize universities to pursue more rigid profit-making IP strategies than would be best for commercialization. Most research universities overseas have a greater bias for commercialization, far fewer IP barriers to collaboration, and many offer greater IP flexibility.

Potential questions for the Working Group to consider:

- How can we reduce costs and delays in negotiating and transferring IP from universities and federal laboratories to businesses?
- How can we encourage universities to offer more flexible and attractive IP terms in corporate-university partnerships? Should the federal government use its leverage in funding university R&D to encourage more R&D engagement with industry and more favorable IP terms?
- Can we create model master agreements that offer greater flexibility for different industries and different types of projects?

A recent Department of Justice indictment reveals China's efforts to steal technology from Micron Technology, Inc., a global leader in semiconductors and the only U.S.-based company that manufactures DRAMs. According to the indictment, a Chinese individual illegally obtained Micron's trade secrets, valued at up to $8.75 billion.

USTR 301 Report

- Should we show preference to potential licensees in the best position to commercialize federal research and technology, even if that means a waiver to the small business preference?

Protecting U.S. intellectual property. The theft of U.S. IP is a continuing concern. IP is foundational to economies built on knowledge and technology, and its theft can be a serious blow to an individual company. The Commission on the Theft of American Intellectual Property estimated that the annual cost of IP theft to the U.S. economy exceeds $225 billion, and could be as high as $600 billion.[37]

37 Update to the IP Commission Report, The Theft of American Intellectual Property: Reassessments of the Challenge and United States Policy, Commission on the Theft of American Intellectual Property, 2017.

China remains the world's principal IP infringer. As it is committed to industrial policies that include maximizing the acquisition of foreign technologies, particularly in high-tech sectors, these policies could drive even greater IP theft. Collectors are especially interested in U.S. technologies vital to competitiveness and national security (Table 1).[38]

The Trump Administration has raised the protection of U.S. IP to a top-tier priority and made it a top goal of U.S.-China economic negotiations. The Foreign Investment Risk Review Modernization Act of 2018, which added new bite to the CFIUS processes, and the Export Control Reform Act of 2018 are measures that are expected to increase protection of U.S. IP. Also, several new government reports are bringing the China IP threat into sharper focus.[39]

The administration is using tariffs and the threat of more tariffs to compel China to respect IP rights, curtail IP theft by its companies and cease other unfair trade practices. However, some U.S. manufacturers are concerned that these tariffs will reduce their competitiveness, present a tough challenge for small businesses affected, lead to higher costs for Americans and lost jobs. After the G20 Summit in Buenos Aires in December 2018, where President Xi and President Trump said they would begin negotiations on IP protection, China announced a crackdown, releasing a list of 36 punishments for companies that engage in IP theft.

China is not the only county where IP protection and enforcement is inadequate. For example, long standing IP challenges facing U.S. businesses in India include those which make it difficult for innovators to receive and maintain patents in India, particularly for pharmaceuticals. Numerous other countries present a variety of IP protection and enforcement problems such as patentability criteria, inadequate protection for trade secrets and lack of IP enforcement.

Potential questions for the Working Group to consider:

- Is the level of theft of U.S. IP and emerging technologies an existential threat to U.S. global technology leadership and national security? Is the federal government giving the issue appropriate priority?
- Given the landscape of global commerce and scope of U.S. business transactions with foreign entities known to pose IP risks, how can we help U.S. businesses better understand the level of risk they face when doing business with a foreign entity?
- How can we use market mechanisms to encourage foreign companies to comply with laws and values that protect IP?
- Are there other sources of leverage the United States has to seek to compel foreign entities to provide adequate and effective protection and enforcement of U.S. IP rights?

38 Foreign Economic Espionage in Cyberspace, National Counterintelligence and Security Center, 2018.

39 How China's Economic Aggression Threatened the Technologies and Intellectual Property of the United States and the World, White House Office of Trade and Manufacturing Policy; Findings of the Investigations into China's Acts, Policies, and Practices Related to Technology Transfer, Intellectual Property, and Innovation under Section 301 of the Trade Act of 1974, U.S. Trade Representative; 2018 Report to Congress on China's WTO Compliance, U.S. Trade Representative; China's Technology Transfer Strategy: How Chinese Investments in Emerging Technology Enable a Strategic Competitor to Access the Crown Jewels of U.S. Innovation, Defense Innovation Unit Experimental, U.S. Department of Defense.

Table 1. U.S. Technologies Vital to Competitiveness and National Security

Industry	Priority Sectors / Technologies	
Energy / Alternative Energy	• Advanced pressurized water reactor and high-temperature, gas-cooled nuclear power stations • Biofuels • Energy-efficient industries	• Oil, gas and coalbed methane development, including fracking • Smart grids • Solar energy technology • Wind turbines
Biotechnology	• Advanced medical devices • Biomanufacturing and chemical manufacturing • Biomaterials	• Biopharmaceuticals • Genetic modification and reprogramming • Infectious disease treatment • New vaccines and drugs
Defense Technology	• Aerospace and aeronautic systems • Armaments	• Marine systems • Radar • Optics
Environmental Protection	• Batteries • Energy-efficient appliances • Green building materials	• Hybrid and electric cars • Waste management • Water / air pollution control
High-End Manufacturing	• 3D printing • Advanced robotics • Aircraft engines • Aviation maintenance and service sectors • Civilian aircraft • Electric motors • Foundational manufacturing equipment	• High-end computer numerically controlled machines • High-performance composite materials • High-performance sealing materials • Integrated circuit manufacturing equipment and assembly technology • Space infrastructure and exploration technology • Synthetic rubber
Information and Communications Technology	• Artificial intelligence • Big data analysis • Core electronics industries • E-commerce services • Foundational software products • High-end computer chips	• Internet of Things • Network equipment • Next-generation broadband wireless communications networks • Quantum computing and communications • Rare-earth materials

- Should the government take greater punitive measures against foreign entities that are directly benefitting from U.S. IP theft, such as denying access to the U.S. market or banking system, or public reporting of the use of stolen IP when foreign entities seek to be listed on U.S. exchanges? What other kinds of sanctions could be levied against foreign entities that steal U.S. IP?
- Are other countries concerned about IP theft adequately engaged in showing a unified front in confronting IP thieves and enforcing IP laws? Should there be harmonized national and international legal and regulatory approaches?
- How can we improve coordination, intelligence gathering, and information sharing on IP threats and incidents among nations, and the public and private sectors?

Shaping the standards and regulations around critical technologies that will be the future of innovation. The disruptive technologies that will shape the economy for decades to come will require the development of a wide range of standards and some regulations. For example, artificial intelligence, machine learning, and autonomous and semi-autonomous systems will require technical standards for safety, interoperability, detecting bias, trustworthiness, human factors, privacy, transparency, and to protect these systems from malicious attacks and cyber intrusions that could have profound consequences for security. Since these systems will be used in transportation, health care and the military, failures could be catastrophic. Novel approaches may be needed, for example, for testing and verification to ensure that AI-based systems meet their specifications. Robots have been used for years in controlled industrial settings. As robots become more commonplace in a wide variety of venues, such as homes, hospitals and retail establishments, their exposure to humans will increase substantially in more intimate interactions, with implications for standards in areas such as safety, trust and human interfaces.

> The pace of innovation in automated vehicle technologies is incompatible with lengthy rule-making proceedings and highly prescriptive and feature-specific or design-specific safety standards. Future motor vehicle safety standards will need to be more flexible and responsive, technology-neutral, and performance-oriented to accommodate rapid technological innovation.
>
> **Preparing for the Future of Transportation, Automated Vehicles 3.0**
> U.S. Department of Transportation

Auto and high-tech companies are racing to get driverless vehicles on the road for passengers and goods transport and delivery. Standards must support the safe and effective operation of automated

vehicles that may not have steering wheels, pedals, mirrors or human controls; may have drastically different passenger seating; may rely on networks for their operations; must adhere to rules; and must react to unpredictable roadway conditions, interaction with other vehicles and pedestrians who may not always adhere to traffic laws or behave in unexpected ways. These may require new approaches to motor vehicle safety standards and regulations, and for when humans are and are not present in the vehicle. Also, as intelligent highways deploy and smart cities develop, standards will be needed to integrate into these platforms.

Standards and regulatory development is a critical aspect to commercializing nanotechnologies. As nanotechnology advances and is used more widely, there may be implications for protocols, standards and regulations throughout the product life cycle—in raw material production, consumer product manufacturing, worker exposure, industrial emissions, consumer use and exposure, ecological exposure and at product end-of-life in landfills and incinerators. For example, workers within nanotechnology-related industries have the potential to be exposed to uniquely engineered materials with novel sizes, shapes, and physical and chemical properties.

Concerns have increased about ethical guidelines and safety standards for gene-editing, and the scientific and international communities are getting discussions underway. Areas include the use of gene-editing in health care and disease mitigation, food production and environmental applications. Focus is particularly strong on germ-line editing and genetic enhancement. International guidelines and standards could be used for countries to set their own national regulations. However, ethical principles that could underpin domestic guidelines and standards vary across countries and regions, and the roles of public institutions and private companies in different countries.

Personalized medicine creates a different set of challenges. Standards of care have been developed based on the effects of treatments and medicines as observed in clinical trials involving large cohorts of individuals. But, in personalized medicine, addressing a patient's health is based on a range of an individual's specific characteristics and will increasingly include a person's unique genetics. This is expected to lead to an era of individualized diagnostics, therapy and medication, with dramatic implications for the development of standards of care.

Standards are often embodied in national regulations. While conforming to standards is voluntary, compliance with regulations is mandatory. Nations can craft standards and embody them in regulations to disadvantage competitors, impeding market access or sometimes requiring excessive testing or redesign of products. U.S. innovation and its global competitive position will benefit from an international environment of standards that reduces barriers and underpins open markets for the use and commercialization of these technologies. This involves both regulatory and non-regulatory approaches. Since the U.S. system of standards development is distributed and private sector-led, the development of U.S. standards and U.S. participation in international standards development will involve numerous actors, including government, industry, academia and society. Standards-related bodies are beginning to address these new needs. R&D for new metrology and instrumentation and new test-beds are needed.

Potential questions for the Working Group to consider:

- Are standards and regulations for new, disruptive technologies being developed in a timely fashion to match the rapid pace of technological advancement, and to fully capture the economic opportunities and societal benefits these technologies present? Where are we lagging, where are we leading?
- Is greater government leadership and coordination needed to drive, accelerate, and optimize standards development and deployment in the United States—to match the pace of new technology development and the challenges from strong competitors?
- How do we manage and/or prioritize both cross-cutting standards development for new technologies and for sector specific applications?
- How do we balance risk in promoting safety and rapid innovation?
- What is the degree to which we can draw from current standards to accelerate standards development for these new disruptive technologies?
- Will new R&D be required? If so, in what areas?
- What is the role of U.S. values and societal issues in developing standards, for example, in biotechnology and gene-editing? Will the willingness to push the envelop beyond internationally accepted guidelines and standards be a determinant in a country's global competitiveness?

Challenges in the global environment for trade and new mercantilism. The United States has long championed fair and equitable market access, and the reduction of non-tariff trade barriers, unfair government preferences for domestic producers, or demands for localized manufacturing. Non-tariff barriers can pose significant competitive and business challenges to U.S. firms and globally-leading U.S. industries. For example, the United States is a world leader in pharmaceuticals and medical device innovation. The pharmaceutical industry invests about $100 billion in R&D—no industry invests more. In addition, the federal government invests about $40 billion annually in life science R&D, which has supported the U.S. competitive edge.[40] U.S. pharmaceutical firms have raised concerns about policies and practices in several trading partners, for example, pressure for compulsory licenses, which can undermine incentives to invest in R&D, be used to advantage domestic companies, or to gain leverage in pricing negotiations. Other challenges faced include unreasonable regulatory approval delays, non-transparent reimbursement policies, and outright bans on some imported pharmaceutical products and medical devices in favor of local products.[41]

In another example, digital trade, U.S. firms have faced restrictions on cross-border data flows, data localization requirements, bans on foreign companies directly providing cloud computing services in domestic markets, web filtering and blocking of web sites, the prospect of tariffs on digital products transmitted electronically, and a EU proposal to single out

40 National Science Foundation.

41 2018 Special 301 Report, Office of the United States Trade Representative.

China currently blocks 10 of the top 30 global websites, and more than 10,000 domains in total, affecting billions of dollars in potential U.S. business.

digital services for taxes on revenues which would apply almost exclusively to U.S. firms. These have the potential to hurt U.S. start-ups and small innovators particularly. Data analytics, cloud computing and online platforms allow small businesses to keep costs low, scale up quickly without costly infrastructure investments and compete against larger, more established firms.[42]

When small countries deploy non-tariff trade barriers, the impact is relative to the size of their market. It is a different story entirely when a large, strategic competitor to the United States deploys these practices. In this regard, China presents a range of trade challenges to U.S. firms with respect to market access, foreign investment, government interference in private sector technology transfer decisions, and investment and other regulatory requirements that promote the acquisition of foreign technology by Chinese firms.

U.S. firms face requirements or pressures to transfer their technology in exchange for market access, or obtaining investment and regulatory approvals. For example, the 2018 China Business Report of the American Chamber of Commerce in Shanghai reported that 21 percent of member companies had felt pressure to transfer technology in exchange for market access. This pressure was particularly notable in high-tech industries, with 44 percent of aerospace and 41 percent of chemical companies reporting pressure to transfer technology. While these measures are sometimes meant to incentivize domestic "indigenous innovation," in practice they disadvantage U.S. companies, requiring them to give up their IP as the price of market entry.

Other long standing concerns include non-discriminatory access to China's standards setting processes; foreign ownership restrictions and foreign equity limitations; regulations that force U.S. companies seeking to license technologies to Chinese entities to do so on non-market-based terms that favor Chinese recipients; Chinese government facilitation of systematic investment in, and acquisition of, U.S. companies and assets by Chinese companies to obtain cutting-edge technologies; and using cyber security as a pretext to force U.S. industries to disclose IP to the government, to transfer it to a Chinese entity, or to require associated R&D be conducted in China.[43]

On an even broader front, China seeks to shape large swaths of the 21st century global economic and trading system. China's Belt and Road Initiative is staggering in scope; a new Silk Road of railways, energy pipelines, highways, shipping lanes and special economic zones, fueled by $1 trillion in Chinese investment. The initiative would touch more than

42 Fact Sheet on 2019 National Trade Estimate: Key Barriers to Digital Trade, Office of the United States Trade Representative, March 29, 2019.

43 2018 Special 301 Report, Office of the United States Trade Representative.

4 billion people in 65 countries, and $23 trillion in GDP. While the initiative has the potential to develop the infrastructure needed to drive global trade, investment and economic development, it also serves China's economic and geopolitical goals. It could serve as a route for its military expansion, a platform for Beijing-controlled institutions, align a large part of the world economy toward China, and position China to shape the rules and norms of economic activity in the region.

Potential questions for the Working Group to consider:

- Are we confronting new trading (mercantilist) systems in our global competitors? Can we compete with those systems? If not, what do we need to do as a nation to ensure U.S. made goods and services can compete in the global market place?
- The administration has taken a more muscular approach to trade, non-tariff trade barriers, the pressure to transfer (and the theft) of U.S. intellectual property, and other barriers to foreign market access. Is this the right approach; is the level of pressure appropriate? What are alternatives?
- How concerned should the United States be about China's Belt and Road Initiative? Does the United States need more aggressive investments and policies in that part of the world to counter-balance China's actions?

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