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March 15, 2021

The Honorable Todd Young
Finance Committee
U.S. Senate
Washington, D.C. 20510

Dear Senator Young:

The COVID-19 pandemic has affected nearly all aspects of American life. As you move forward examining what policies are needed to strengthen America and stimulate our economy, I wanted to share my suggestions on policies affecting the device industry. It has been my privilege to be associated with Cook for more than 50 years and I offer these thoughts in that context, but also as a husband, father, grandfather, patient, and, finally, as an employee myself.

Since 1963, Cook has grown from its birth in a spare bedroom in Bill and Gayle Cook's apartment to a world leader in advancing medical care for patients worldwide. There were many setbacks and countless challenges that threatened the success of Cook as our founder, Bill Cook, sought to build an innovative American company that would improve patient care. But Bill was resilient and had the same entrepreneurial spirit that makes this country so unique. These traits, combined with his focus on the patient, are the foundation of Cook's success. The company has been the first to introduce new medical devices contributing to more than 70 new procedures.

For over 50 years, Cook Medical has been inventing, manufacturing, and delivering a unique portfolio of medical devices to healthcare systems around the world. We work closely with physicians to develop technologies that improve patients' lives. Serving over 40 medical specialties and every area of the hospital, we provide treatments in almost every body system. Because we remain family owned, we have the freedom to focus on what we care about: our patients, our employees, and our communities.

Cook is headquartered in Bloomington, Indiana with its U.S. manufacturing plants in Indiana, Pennsylvania, North Carolina, Illinois and California. We also have manufacturing facilities in Ireland, Denmark and Australia. We have direct sales in most of the world where the health care system is developed. Our company employs about 11,600 people around the world with approximately 9,600 of these

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employees based in the United States. While more than 56 percent of our sales are outside the United States, more than 72 percent of the devices are manufactured in this country.

The Medical Device Industry

In my lifetime, health care has advanced from limited antibiotics and vaccines, exploratory surgery, go-home-and-rest following a heart attack to modern medicine that includes more targeted, minimally invasive medical procedures and treatments that extend lives, improve the quality of life often with better outcomes and greater value. The device industry has been at the center of these advances and offers clean, well-paying jobs with benefits. It is the envy of the world and countries around the world are competing to dominate this industry and workforce and have made gains in recent years.

For many decades, the U.S. medical device industry was one of the few manufacturing and technology industries that consistently maintains a trade surplus. However, that surplus is threatened by competition from other countries that have put in place policies to provide favorable tax, reimbursement and regulatory treatment. As Congress looks to enact policies that stimulate our economy and make America more competitive and resilient, policymakers on both sides of the aisle agree that a key component is to invest in technology, manufacturing, and growth industries of the future.

Cook Policy Suggestions

Supply Chain

As a global company, Cook serves patients around the world, which depends on and benefits from a global supply chain. In some cases, there are certain inputs that we, through our suppliers, must source from outside the United States. The global pandemic tested—but did not break—the supply chain for medical devices. Of course, certain products were in short supply, and I urge policy makers to consider future steps to mitigate the risks and severity of such shortages in future events. Any policy changes related to the supply chain should be targeted to the specific problem that we are seeking to address. Please see the below suggestions:

- **Products used in the critical care setting should be Made in America**—By definition, those products used in the critical care setting are essential to caring for patients in dire circumstances. To ensure that we have ongoing access to these needed products, these most essential of products should be

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- domestically manufactured, with critical inputs also domestically sourced or inventoried in sufficient quantities to support defined surge capacity.
- **Medicare payment should recognize and incentivize those products to be Made in America**—Medicare, due to its size and scope, exerts a great deal of influence in the U.S. health care market. To encourage more domestic manufacturing of needed medical products, there should be an added incentive for those products made in the U.S. via increased reimbursement.
 - **The United States should invest in capacity to manufacture critical items**—Not only do we need to ensure that we as a country have access to needed products, we need to ensure that we have the ability to manufacture them in the U.S, and be able to handle a surge capacity situation. This can be encouraged through increased grant opportunities, tax credits and consideration of strategic, long-term contracts for maintenance and upkeep of critical production surge capabilities beyond existing market requirements.

Tax Incentives

Our tax structure should support U.S. manufacturing of devices and these incentives should apply to all, not just those who re-shore. Incentives drive jobs and investment, and because wages and benefits are much higher in the U.S. these countries start with a cost advantage, other countries are increasing their efforts to attract jobs and investment through the use of various incentives, including cash grants.

- **The NOL carryback provision should be maintained**—Cook strongly supports the current net operating loss (NOL) carryback provision, which has been key to infusing cash into mid-size companies as it allows losses generated in tax years 2018, 2019, and 2020 to be carried back five years. While the Paycheck Protection Program (PPP) for smaller companies and other liquidity measures for larger companies were generally very successful, the Main Street Program, which was targeted to create liquidity for mid-sized companies, was not very effective as intended so the NOL provision really filled that void. We remain concerned about the House-passed HEREOS Act provision resurfacing in future reconciliation legislation or an infrastructure bill that would include a revenue offset to significantly curtail the CARES Act NOL provision and require companies to pay back money that might have already been spent to stay afloat during the pandemic.
- **The U.S. must keep a competitive tax rate**—It is important the U.S. keep a competitive tax rate in order to encourage domestic manufacturing. The Tax Cut and Jobs Act (TCJA) change lowered the U.S. corporate rate to 21% making the U.S. competitive with the rest of the

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world, which today the OECD rate average is below 24%. Maintaining this rate will help the U.S. continue to be competitive.

- **R&D should be supported through the tax code**—Cook supports the “American Innovation and Jobs Act” as introduced by Senators Hassan, Young, Cortez Masto and Portman. As written, the legislation would restore immediate deductions for research and development (R&D) investments and expand the refundable R&D tax credit for startups by raising the existing credit cap. Based on an OECD analysis, the U.S. ranks twelfth in government funding and tax support for R&D trailing such countries as Russia, the UK, and Italy. The U.S. ranking likely decreases further if companies are required to capitalize and amortize R&D expenses. Manufacturing and jobs located where research develops new technology.
- **Cost recovery model should be examined.** An immediate cost recovery is arguably the best policy to spur economic growth and jobs according to the Tax Foundation’s General Equilibrium Model. Cook supports an extension of 100% expensing for qualifying equipment purchases.

Finally, thank you for your efforts to repeal the medical devices excise tax. It has made a difference, particularly during 2020 when elective procedures came to a halt.

Medicare reimbursement

Seniors are the biggest end-users of medical technology given both the acute and chronic needs of this more fragile demographic. As a result, Medicare is our most important payer and the private sector looks to Medicare’s reimbursement models for guidance. Suggested reforms that would improve seniors’ access to innovative technologies and encourage domestic manufacturing include:

- **Telehealth should be expanded and incentivized**—Since last March, Medicare providers can use telehealth services for certain medically reasonable purposes from offices and places of residence. This has enabled patients to consult with their physicians on needed health issues and in rural areas it has provided improved accessibility. Congress should consider further easing Medicare telehealth restrictions, expanding these services in the future and incentivizing physician offices to adopt needed technology, including programs that will assist seniors when accessing these virtual appointments.
- **The Coverage for Evidence Development (CED) process should be reformed**—While Medicare provides certain conditional coverage for medical devices or services while additional clinical or scientific information

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is collected, the system needs to become more transparent and predictable so safe, innovative technologies reach patients in a more timely manner.

- **Coordination is key for patients**—Finally, we need to improve the collaboration between CMS and FDA on reaching Medicare reimbursement decisions more timely using agile principles and updated digital transformational processes. When FDA approval or clears a device then CMS should accept the approval for coverage and determine reimbursement.

FDA/Regulatory

The Coronavirus pandemic has had a huge impact on the healthcare system and has required all stakeholders to transcend traditional boundaries and work together. The FDA has stepped up to lead through these challenges and should be commended for its work to get safe and effective COVID-related tests and treatments to patients, all while continuing its non-pandemic work.

In addressing the pandemic, FDA has reassessed its models and practices, related to its evaluation of a product's safety and effectiveness. For those treatments with demonstrated safety, the Agency has permitted accelerated clinical development using agile principles, regulatory flexibility, new trial designs using real world data, and integrated evidence generation in a test, learn and scale mode with the hopes of saving more lives.

As one example of changes in the process, FDA has established The Coronavirus Treatment Acceleration Program (CTAP) which uses every available method to move new treatments to patients as quickly as possible, while at the same time assuring those treatments are helpful and not harmful. Clinical trials are being expedited for COVID patients who need urgent care—more than 420 reviewed by FDA as safe to proceed. Product authorizations under Emergency Use Authorizations (EUAs) have permitted thousands of lives to be saved. New vaccines approved in record time are now available globally.

As we move into a new stage of the pandemic, it is important to keep in mind that there are thousands of patients who are in desperate need of new medical technologies and treatments designed to alleviate suffering. We need to be able to deliver these treatments to patients with a continued mindset of urgency. To that end, we suggest:

- **FDA use lessons learned from the pandemic in its approach to regulation of medical devices in general**—There are numerous patients with horrible diseases who suffer daily with serious and deadly unmet clinical need. These patients could benefit from efforts to use every available method to move

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new treatments to patients as quickly as possible.

- **FDA continue efforts to support development of devices specifically indicated for use in pediatric populations**—This important group of patients is being underserved by the current device regulatory framework, but their needs are just as urgent as other groups of patients.
- **Congress should fund the Pediatric Device Consortia**—Cook has long supported increased funding for the Pediatric Device Consortia (PDC) Grant Program at the Office of Orphan Products Development at the FDA. We recognize the significant achievements of the PDC and the ongoing needs of children, where medical devices often lag five to ten years behind those for adults due to factors that include differences in size, weight and metabolism rate. Increased funding for the program is necessary to achieve continued improvements.

Education and Workforce Development

While many factors impact the strength and competitiveness of U.S. manufacturing, none is more important than access to a highly prepared workforce. This requires a high-quality educational system starting in early childhood and extending through high school graduation to postsecondary education and beyond, including effective employer-driven workforce development strategies.

This means America’s employers have a vested interest in the caliber and opportunity offered by the schools in their communities—including elementary schools. For example, it is well established that students who can’t read proficiently by grade three have dramatically diminished potential for future success and are far more likely to drop out of high school. The ability to read well is a critical early building block and one we must all support to secure collective success and individual opportunity for all children.

At Cook, we have worked hard to grow our business, positively impact the healthcare industry and the patients it serves and develop a skilled and ready workforce. We have learned that we will only succeed if we can reach all potential pools of talent. In Indiana, that meant finding ways to elevate the 29,000 people age 18-64 in our multicounty employment region without a high school diploma or equivalency.

As part of our “My Cook Pathway” employee development effort, we created a targeted program that hires eligible candidates without a high school diploma and offers them a full-time, 40-hour paycheck while they work toward their high school equivalency certificate. They spend half their time working at Cook and half their

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time in classes studying for the high school equivalency exam. Cook pays for tutors, materials and test taking and upon successful completion of their HSE testing, those employees move into full time, full benefit positions throughout the company.

We also have learned that the key to company and individual success in today's economy depends on employees who are able and willing to advance their knowledge and move to higher levels of interest and potential. For that reason, we added critical components to our "My Cook Pathway" program that support employees' continued advancement in our company, including up-front tuition assistance to help employees earn up to a master's degree at virtually no out-of-pocket cost. Cook works with the higher ed institutions to pay upfront (up to max of \$5,250 annual support limit) or to defer payment until completion. The results of this initiative have been truly impressive: The number of Cook employees continuing their education has grown from 100 per year to more than 1,000 per year. The need for a trained educated workforce depends on the nations ability to get working age individuals to pursue certificates, HSE, complete the secondary education. How do we incentivize them? We have found connecting the job with the training or education is essential.

Our efforts at Cook along with those of many important education and workforce partners are elevating the importance of aligned and high-quality education and workforce development—for individuals, communities and our nation's economy. In our opinion, the COVID-19 pandemic has exacerbated the challenge and created an additional sense of urgency to focus on these issues.

We would propose that the critical elements of focus on the workforce development front include the following:

- **Increase the maximum allowable annual tuition assistance support.** The maximum allowable support for tuition assistance programs has not been increased from the \$5,250 level since 1996 (Section 127 – in today's dollars would be \$8,700). Increasing that number would be a key first step in advancing important continued advancement for our individuals and industries.
- **Support direct industry engagement with educational partners.** Many examples exist of industry working collaboratively with educational partners to align curriculum, provide awareness, relevancy and work-based learning opportunities for students. These best practices should be supported and duplicated pervasively across the country. At the K-12 level in Indiana, career and technical education programs have been realigned to focus on high-demand industry sectors and embed industry and workforce certificates.

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- **U.S. Manufacturing sector needs more industry-recognized credentials.**
There should be a coordinated effort to advance more targeted manufacturing industry recognized credentials in addition to AA, BA, BS higher education degrees. A coordinated effort between the leading US manufacturing industry organizations and U.S. Department of Education among others should promote and incentivize best practice programs across the country. As an example, Indiana through its Next Level Jobs initiative offers Hoosiers high-demand industry certifications in five key sectors, including advanced manufacturing, tuition free.
- **Advance upskilling of the current generation of working age adults.**
In Indiana alone there are 500,000 adults with no HS diploma/GED/HSE and more than 1.5M without education beyond high school. We must advance programs and support efforts to completion. As an example, the Indiana Commission for Higher Education in conjunction with Indiana's colleges and universities have developed a successful program called You Can. Go Back. that helps adults return and finish degrees they started. .Additionally, Governor Holcomb's Next Level Jobs initiative has helped more than 21,000 Hoosiers earn certificates in high-demand industries at no cost.
- **Expand experiential work-based learning programs and requirements.**
Experiential learning is critical for both individual success and overall American competitiveness – internships, apprenticeships, co-ops, etc., must become the norm rather than the exceptions at both the high school and postsecondary level. All programs within higher education should include some required element of career experience/engagement.
- **Expand digital learning and awareness.**
American competitiveness is dependent on our ability to lead in the digitally enabled economy; we must focus on expanding experience and basic skill development for all students. Indiana, as an example, is working to embed digital literacy skills and competencies into its statewide college core (30 general education college-level credits that transfer seamlessly to any public state institution).
- **Align leadership of education and workforce development leadership.**
As we are doing in Indiana, our K-12, higher education, workforce development and industry leadership must be totally aligned and focused on achieving collective goals to grow our economy and improve the lives of individuals and families.

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Thank you for all that you are doing for our country. I am passionate about this industry, our country and the patients we serve. I stand ready to be helpful in any way that I can.

Respectfully,



Stephen L. Ferguson
Chairman of the Board