

"Mini" U.S. Innovation & Competition Act Senate Passage This Month

Package Is A Bipartisan Win, Plus for Life Sciences

- **We think the new “mini” U.S. Innovation & Competition Act will pass the Senate this month.** The bill passed a test Senate vote (64-34) earlier this week that allowed for the inclusion of science-related provisions in the original “chips-only” package. Senator Schumer (D-NY) is expected set up a Senate vote later this week, but final passage may be delayed to next week if there are pushbacks during the debates.
- **The repassage of a “mini” USICA package through the Senate became necessary after conferencing of the House & Senate innovation bills fell through earlier this summer.** Major chamber differences, including trade provisions, were left out of the “Chips + Endless Frontiers” package. While the chips package and its tax incentives dominated Senate discussions, bipartisan support for science-related provisions (which were present in both bills) ultimately drove its inclusion in the final package.
- **The life science wins remain largely intact.** The bill will still create a technology directorate (\$20 B over 5 years) within the National Science Foundation (NSF) and authorizes key research and development programs within the NSF (\$81 B over 5) and Dept. of Commerce (\$11 B over 5). Private industries are expected to have access to new opportunities to collaborate with federal and educational institutes and could receive assistance for accelerated commercialization efforts.
 - **The NSF Directorate for Technology, Innovation and Partnership (TIP)** will fund technical research aimed at meeting practical goals, reduce barriers to technology transfers (through new research/industry intellectual property frameworks), and increase research diversity through partnerships at higher education institutions. *Biotechnology, medical technology, genomics, and synthetic biology* are listed as a key technology focus area that will take precedence in funding and research opportunities.
 - **A national engineering biology research and development initiative** will facilitate public-private partnerships in engineering biology research, and support proof of concept activities and the formation of startup companies.
 - **20 regional technology hubs** will provide development opportunities for private companies that are not located in key tech heavy localities (CA, MA, and DC). The federal government is aiming to bring jobs to smaller communities and increase geographic diversity in tech. Funding remains consistent with previous USICA text (\$10 B over 5 years).
- **“Mini” USICA is part of a larger federal biotech and life science agenda (ARPA-H, Cancer Moonshot).** The House passed its standalone ARPA-H bill in June and the agency has its \$1 B in initial funding from the FY2022 budget. While states bid to host the new agency and the White House seeks an inaugural director, we note that the agency’s structure has not been finalized as the Senate has not acted on their ARPA bill, which made it out of the HELP committee in March as part of the Pandemic Preparedness Act.
- **Despite bipartisan support for research, all bets are off right now as Republicans grow increasingly discontent with the reconciliation process.** Last week, we alerted to the release of a “clean” FDA User Fee bill from Senator Burr (R-NC). This GOP version excluded the VALID Act, and the cosmetics and dietary supplement regulations that were integral to the Senate user fee package that was voted out of the HELP committee (13-9 vote). Election year politics & conflict over drug

reforms in BBB are creating negotiation breakdowns in typically bipartisan processes. A bare bones FDA bill is unlikely to pass and we expect to see a final package that may include provisions on accelerated approval, therapeutic equivalence, domestic and foreign inspection reporting, orphan drug reform, and interchangeable biosimilar reform.

- **NEXT STEPS:** Following Senate passage, the “mini” USICA will move to the House which is expected to vote on the measure before August recess. We expect FDA User Fees passage by Oct. 1, which could be a slimmed down text with fewer riders.. We note that Reconciliation is expected to undergo a Parliamentary review and we expect it to pass with 75/25 odds. Inflationary rebates may be first on the chopping block if the commercial provisions fail to pass the Byrd test. We expect ACA subsidies to be included, perhaps even 3 years.

Background (Original USICA)

Senate bill summary below and CBO score is [here](#)

S. 1260 would authorize appropriations and provide direct appropriations for programs to improve U.S. competitiveness in technology and communications.

USICA

- Division A would, among other things, provide appropriations aimed at strengthening the domestic industry for semiconductors and microelectronics.
- Division B would establish a technology directorate within the National Science Foundation (NSF) and would authorize other programs within the NSF, the National Institute of Standards and Technology, and the National Aeronautics and Space Administration (NASA).
- Division C would specifically authorize appropriations of about \$38.5 B over the 2021-2026 period for international affairs programs, primarily for the United States' contribution to the Inter-American Development Bank, foreign assistance programs for the Indo-Pacific region, and Department of State operations.
- Division D would establish a Made in America Office to prioritize federal procurement of materials produced in the United States, establish a Cyber Response and Recovery Fund to coordinate with nonfederal partners to assess risks of a cyber-attack, and provide resources for response and recovery.
- Division E would establish sanctions to counter illicit trade and forced labor, cyberattacks, and intellectual property theft.
- Division F would create or amend and reauthorize several elementary, secondary, and higher education grants programs, amend the statutes authorizing the Truman and Madison Foundations, require institutions of higher education to disclose certain gifts from and contracts with foreign sources, and establish requirements that institutions of higher education with certain types of cultural partnerships must meet in order to be eligible to participate in the federal student aid programs. This division also would change the structure for filing fees collected from some businesses that are considering a merger or acquisition.

House bill summary is below and CBO score is unavailable.

COMPETES Act

The America COMPETES Act includes investments for:

- Supercharging investments in semiconductor chips with \$52 billion to support U.S. production of semiconductors — a key component in consumer electronics, cars, healthcare, defense systems and other key products.
- Strengthening supply chains and manufacturing at home with \$45 billion to improve our nation's supply chains and strengthen our economy and national security by preventing shortages of critical goods and ensuring that more of these goods are made right here in the United States.

- Advancing American scientific research and innovation excellence with a suite of bipartisan science, research and technology bills to increase American innovation.
- Promoting U.S. global leadership by positioning the interests and values of the United States to win on the world stage, including strong action to hold the People's Republic of China accountable for its trade abuses and human rights violations.