



For Immediate Release
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Contacts: Steven Grossman 1-301-539-9660
Ladd Wiley 1-202-549-3595

In response to media inquiries following the Senate Appropriations Committee's May 24 mark-up of the FY 19 Ag/FDA Appropriations Bill.

- Information reflects bills approved by the House and Senate committees, but not yet scheduled for floor time.
- Numbers may change as additional information becomes available from the House and Senate Appropriations Committees.
- The comparison (below) covers \$259.5 million of the **House-proposed increase of \$308 million** in budget authority (BA) spending. Additionally, \$30 million would go to programs to address opioids and another approximately \$19 million is aimed at other programs that are not identified in the House bill or committee report.
- The comparison (below) covers \$88.5 million of the **Senate-proposed increase of \$159 million** in BA spending. Additionally, \$59 million would pay for opioid programs and \$15.5 million for food safety. The food increases would go for FSMA cooperative agreements with states, food import safety, food safety outbreaks and testing antibiotic resistance in imported seafood. Programs increases total \$163 million and there are \$4 million of offsets elsewhere in the FDA budget.

FDA has requested FY 19 funding for a number of new medical product initiatives. Thus far, the House and Senate have both shown support for the agency, but at different levels and with somewhat different priorities.

- **Promote Domestic Manufacturing.** The House committee bill would provide \$38.5 million; the Senate committee bill would provide \$11.7 million.
 - New technologies have great potential to accelerate new, more targeted therapies, enhance product quality and bolster stability in the U.S. drug supply to meet domestic and global needs. These new manufacturing platforms may be especially important in the development of personalized medicines and innovations in cell- and gene-based therapies and vaccines.
- **New Domestic Drug Industry.** The House committee bill would provide \$12 million; the Senate committee would not provide any new funding.
 - With these resources, FDA will expand engagement with outsourcing facilities and states to help the pharmacy outsourcing industry grow to meet its intended function and adhere to higher quality standards to protect patient health.

- **MedTech Manufacturing.** The House committee bill would provide \$12 million; the Senate committee bill would provide \$6 million.
 - As medical devices become more complex – and given the frequent modifications made to devices – spurring advanced manufacturing and creating a competitive marketplace for device quality is critical for both driving technological innovations and assuring patient safety. FDA is already working collaboratively with industry, patients, providers, and payers through the Medical Device Innovation Consortium to develop the parameters of this program.
- **New Medical Data Enterprise.** The House committee bill would provide \$60 million; the Senate committee bill would not provide any new funding.
 - Advance the use of real-world experience to better inform patient care and provide more efficient, robust, and potentially lower-cost ways to develop clinical data that can inform product review and promote innovation. The effort will cover a broad range of medical products, including drugs, biologics, and medical devices.
- **Growth and Transformation of Digital Health.** The House committee bill would provide \$40 million; the Senate committee bill would not provide any new funding.
 - FDA will work with stakeholders to establish a new risk-based regulatory paradigm for digital health technologies that would allow companies to market lower-risk products without FDA premarket review and market higher-risk products following a streamlined FDA premarket review. Two benefits of an improved regulatory framework would involve better access to postmarket data and the opportunity to focus more on the cybersecurity issues inherent in digital health.
- **New Platform for Drug Development.** The House committee bill would provide \$45 million; the Senate committee bill would provide \$8.2 million
 - Rapidly advancing science in drug development requires FDA to have up-to-date scientific standards and assessment tools, as well as evolving technologies, methods, and approaches. Without these tools, the Agency’s ability to support innovation and review applications will lag behind the latest science and inhibit innovation.
- **Modernizing Generic Drug Development and Review.** The House committee bill would provide \$27 million; the Senate committee bill would provide \$37.6 million.
 - Create a new review platform that will significantly modernize generic drug review from a text-based to a data-based assessment with structured submissions and FDA assessments. This more automated system will improve clarity for generic sponsors, making initial reviews more efficient and decreasing the risk of refuse-to-file letters, increasing the rate of first-cycle approvals, and greatly increasing overall efficiency
- **FDA’s Oncology Center for Excellence and Investment and Innovation for Rare Diseases.** Both House and Senate committee bills would provide a \$5 million increase to fully fund the Oncology Center for Excellence and add \$20 million for investment and innovation in rare diseases.

The Alliance for a Stronger FDA is a multi-stakeholder advocacy group that unites more than 150 patient and consumer groups, biomedical research advocates, health professions societies, individuals and industry to work to increase FDA's budget authority appropriations.

More information about the Alliance can be found at www.StrengthenFDA.org.

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