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Senate HELP Committee Convenes Third and Final Cures Markup

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This morning the Senate Committee on Health, Education, Labor, and Pensions (HELP) will hold its third and final markup for its biomedical innovations package. This package is a compliment to the House-passed 21st Century Cures Act, which the House passed in July of 2015. The previous two hearings HELP held on this issue have gone relatively smoothly, with the committee agreeing to move the legislation largely by voice vote. However, a number of unresolved issues remain and hold the potential to send the entire package up in flames.

While this hearing should be no different when it comes to the legislation being discussed, this will be the committee members final opportunity to offer amendments or raise issues before the legislation moves to the Senate floor for consideration. Issues relating to drug pricing and mandatory funding for NIH will likely be discussed at length today. In addition, funding for these measures, including the Administration's Precision Medicine Initiative, will be up for debate.

Here is a preview of the legislation to be considered:

S. 2700, the FDA and NIH Workforce Authorities Modernization Act

S. 2700 would update the workforce authorizing provisions relating to the National Institutes of Health and the Food and Drug Administration. Specifically, this legislation would enable the FDA to more fully participate in the Biomedical Research Service to attract more qualified scientists to its ranks. Currently, the Biomedical Research Service is used primarily by NIH. This legislation would also increase the number of people eligible for the Biomedical Research Service at both agencies.

This legislation would also:

- Establish a pilot program to test the best ways to boost communication and information sharing between different centers at the FDA.
- Strengthen policies that would enable FDA and NIH scientists to attend scientific conferences so they can stay informed on the latest developments and achievements in science.
- Make it easier for FDA scientists and regulators to partner and collaborate with those in the private sector.
- Exempt NIH research from relying on the voluntary data collection from the Paperwork Reduction Act.

S. 185, the Promise for Antibiotics and Therapeutics for Health (PATH) Act

The PATH Act would enable the FDA to expedite an antibacterial drug's approval on the condition that it is for an identifiable, limited patient population. Additionally, the drug would have to treat a serious or life-threatening condition and address unmet needs. The bill would also require the drug's label to include a special designation indicating its intended use in limited, high-risk populations.

S. 185 was introduced by Senator Orrin Hatch (R-UT) with five bipartisan co-sponsors.

S. 2713, the Advancing Precision Medicine Act of 2016

This legislation would provide the Secretary of HHS with processes for the implementation of the Precision Medicine Initiative. The responsibilities of HHS would include:

- Developing a network of scientists to assist in carrying out the Initiative.
- Developing new approaches for addressing scientific, medical, and public health issues, among others.
- Applying genomic technologies to provide data on the molecular basis of disease.
- Collecting information voluntarily provided by a diverse cohort of individuals.
- Coordinating with the Secretary of Energy, the private sector, and others to identify and address the advanced super computing needs of the Initiative.

Here is the **full text of the legislation** for more information.

S. ____, the Promoting Biomedical Research and Public Health for Patients Act

This legislation would update reporting requirements across NIH to ensure that Congress receives a more cohesive and comprehensive report of the agency every three years. It would establish processes which would require directors at the agency's 27 institutes and centers to be reappointed every five years to allow for evaluation and increased accountability.

This legislation would also require NIH to evaluate reporting requirements on researchers and to eliminate requirements seen as duplicative or irregular. It would also direct the Office of Management and Budget to establish a board to look at the impacts of federal regulation on research and recommend improvements. Lastly, it would allow universities and others participating in the National Center for Advancing Translational Sciences (NCATS) supported clinical research to conduct later-stage clinical trials in an effort to foster greater private investment in public biomedical research.

S. ____, the NIH Strategic Plan and Inclusion in Clinical Research Act

This legislation would promote the inclusion of minorities in clinical research by requiring NIH, when developing its strategic plan, to assemble accurate data on public health burdens, and on progress to reduce health disparities among women, minorities, and certain age groups. This data would then be used to assess research priorities. Additionally, this legislation would make it easier for individual centers and institutes to encourage research which would achieve the goals of NIH relating to minority health and addressing health disparities. This legislation would also establish a task force on research specific to women, with a focus on pregnant and lactating women.

Authors