Health Law Daily Wrap Up, TOP STORY—Bills advance, aiming to improve the “health of virtually every American”, (Apr. 7, 2016)

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The Senate took a big step towards advancing medical innovation as the Senate Committee on Health, Education, Labor and Pensions (HELP) advanced the final five of 19 bipartisan pieces of legislation that will become the Senate companion to the 21st Century Cures Act passed by the House late last year. The bills are aimed at speeding up the FDA’s approval of new drugs and devices, as well as advancing President Obama’s Precision Medicine Initiative and Vice President Biden’s National Cancer Moonshot program.

Senator Lamar Alexander (R-Tenn), chair of the HELP committee, said “Because our Innovation—or ‘Cures’—legislation will affect virtually every American, it will be the most important new law enacted this year. The legislation would create a breakthrough path for new medical devices like the breakthrough drug path approved in 2012 that has already attracted 384 applications and led to 39 approvals. It would give the FDA new authority to attract talented researchers, and reduce the administrative burden on NIH and researchers.” Alexander noted that the legislation would target rare diseases, including diseases resistant to antibiotics, require researchers who use NIH funds to share their data, and encourage interoperability of electronic medical records, reducing excessive physician paperwork. It would also clarify each patient’s right to own their own medical record, and discourage information blocking.

The HELP committee’s April 6, 2016, mark-up meeting was the final meeting specifically dedicated to discussing and approving bipartisan bills that provide quick funding opportunities for health care technology innovations. According to the press release, the proposed legislation from the meetings is “intended to move safe and effective drugs, treatments and devices more rapidly, and at lower cost, through the investment and regulatory process and into the doctor’s office and the medicine cabinets for the benefit of patients.”

Political roadblocks. Despite the bipartisan effort, politics remain a roadblock on the road to successful passage. One element still has not been worked out, according to Patty Murray (D-Wash), the top Democrat on the Senate HELP committee. She believes that “we need stronger mandatory investments in the NIH and the FDA, and we need additional steps to prioritize consumer safety and protection, especially when it comes to monitoring devices once they’re on the market.”

Both sides remain optimistic about providing NIH funding. The starting point for those negotiations is $9 billion over five years established in the House’s 21st Century Cures legislation. We continue to work to find an amount that the House will agree to, the Senate will pass and the president will sign,” said Senator Alexander (see House welcomes 21st century medicine and hopes Senate is forward looking too, July 10, 2015).

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