

H.R. 6, 21st Century Cures Act/Innovation for Healthier Americans

Key Takeaway: *The Alliance of Specialty Medicine supports the bipartisan effort to improve the discovery, development and delivery that support continued innovation in our health care system.*

The Alliance thanks House members for their overwhelming support in passing H.R. 6, the 21st Century Cures Act. We look forward to continue to work with the Senate as they craft language for their Innovation for Healthier Americans initiative.

Specialty physicians encourage support for medical innovation that integrates the patient's perspective into the regulatory process; facilitates responsible communication of scientific and medical developments; modernizes clinical trials; fosters the future of science, including encouraging young scientists; invests in advancing research; incentivizes the development of new drugs and devices for unmet medical needs; promotes interoperability; and supports 21st Century digital medicine by facilitating data sharing and the use of new technologies.

Issues of Interest

The Alliance has watched the development of legislation in this area and is particularly interested in the following:

- Reauthorizing the National Institutes of Health (NIH);
- Establishing a streamlined process for qualifying and utilizing surrogate endpoints in clinical research trials;
- Permitting data sharing without relinquishing data ownership;
- Facilitating responsible communication of scientific and medical developments, including off-label uses (see the Alliance's position statement entitled "[Physician Directed Applications](#)"¹);
- Creation of an innovation fund to foster the discovery, development, and delivery of medical innovation;
- Standardizing data in clinical trial registry data banks;
- Developing a centralized institutional review board (IRB);
- Fostering telemedicine/telehealth;
- Promoting interoperability; and
- Clarifying the continuing medical education (CME) exemption for the Sunshine Rule.

¹ http://www.specialtydocs.org/files/Alliance_Off-label_Statement_5.2.14.pdf