Comparison of Senate Package of 19 Bills with House 21st Century Cures Act

Bill	Bill No.	Short Title	Comparison to H.R.6, House-passed 21st Century Cures Act
1	S. 2511	The Improving Health Information Technology Act	Sec. 3001, Interoperability
2	S. 1622	The FDA Device Accountability Act of 2015	Sec. 2223, Training and oversight in least burdensome appropriate means concept Sec. 2262, Use of non-local institutional review boards for review of investigational device exemptions and human device exemptions Sec. 2228, CLIA waiver study design guidance for in vitro diagnostics
3	S. 2030	The Advancing Targeted Therapies for Rare Diseases Act of 2015	Sec. 2041, FDA Precision Medicine Guidance Sec. 2051 of January 2015 discussion draft, Genetically Targeted Platform Technologies for Rare Diseases, not included in H.R. 6
4	S. 849	The Advancing Research for Neurological Diseases Act of 2015	Sec. 1122, National neurological diseases surveillance system
5	S. 2014	The Next Generation Researchers Act	Companion bill, H.R. 3466, was introduced in Sept. 2015, after H.R. 6 had passed the House
6	S. 800	The Enhancing the Stature and Visibility of Medical Rehabilitation Research at NIH Act	Companion bill, H.R. 1631, was introduced in Sept. 2015, after H.R. 6 had passed the House
7	S. 2503	The Preventing Superbugs and Protecting Patients Act	Subtitle D—Disposable Medical Technologies Sec. 3061. Treatment of certain items and devices

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8	S. 1878	The Advancing Hope Act of 2015	Sec. 2151 Extension of exclusivity periods for a drug approved for a new indication for a rare disease or condition Sec. 2152 Reauthorization of rare pediatric disease priority review voucher incentive program
9	S. 1101	The Medical Electronic Data Technology Enhancement for Consumer's Health (MEDTECH) Act	Similar to Subtitle N (Sec. 2241, 2243, and 2243), the Sensible Oversight for Technology which Advances Regulatory Efficiency Act or the "SOFTWARE Act"
10	S. 2055	The Medical Countermeasures Innovation Act of 2015	No provision in HR 6, no companion bill in the House
11	S. 1767	The Combination Products Innovation Act of 2015	Sec. 2181 of HR 6, Enhancing combination products review
12	S. 1077	The Advancing Breakthrough Medical Devices for Patients Act of 2015	Sec. 2201 of HR 6, Priority review for breakthrough devices
13	S. 1597	Patient Focused Impact Assessment Act of 2015	No provision in HR 6, no companion bill in the House
14	S. 2512	Adding Zika to the Priority Review Voucher Program Act	S. 2512 passed the Senate on March 17, passed the House on April 12, and was enacted on April 19

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15	S. 2700	FDA and NIH Workforce Authorities Modernization Act	Sec. 2. Silvio O. Conte Senior Biomedical Research Service	Sec. 2281, Silvio Conte Senior Biomedical Research Service
			Sec. 3. Hiring Authority for Scientific, Technical and Professional Personnel	Sec. 2285, Hiring authority for scientific, technical and professional personnel at FDA centers
			Sec. 4. Establishment of FDA Intercenter Institutes	(No legislation on intercenter institutes)
			Sec. 5. Scientific Meetings	Sec. 1025, Sense of Congress on NIH participation in scientific meetings Sec. 2282, Enabling FDA Scientific Engagement
			Sec. 6. Reagan-Udall Foundation for the FDA	Sec. 2283,Reagan Udall Foundation for FDA
			Sec. 7. NIH Research Information Collection Exempted from Paperwork Reduction Act	Sec. 2284, Collection of certain voluntary information exempted from Paperwork Reduction Act
			Sec. 8. Studies	(No legislation on removing mandated studies)
			Sec. 9. Summary Level Review	(No legislation on summary level reviews)
			Sec. 10. Drug Surveillance	(No legislation on drug surveillance)
			Sec. 11. Biological Product Innovation	(No legislation on biological product innovation)
			Sec. 12. Expanded Access Policy	Sec. 2082, Expanded access policy
			Sec. 13. Finalizing Draft Guidance on Expanded Access	Sec. 2083, Finalizing draft guidance on expanded access
			Sec. 14, Amendments to the Orphan Drug Act	Sec. 2151, Orphan Product Exclusivity Period Extensions
			Sec. 15, Standards for Regenerative Medicine and Advanced Therapies	(Companion bill, H.R. 4669, was introduced in Mar. 2016, after H.R. 6 had passed the House)
			Sec. 16, Technical Corrections	

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16	S. 2713	Advancing Precision Medicine Act of 2016	Sec. 2, Precision Medicine Initiative Sec. 3. Protection of Identifiable, Sensitive Information Sec. 4. Data Sharing Sec. 5. High-Risk, High-Reward Research	 Sec. 1028, High Risk, High Reward Research
17	S. 185	Promise for Antibiotics and Therapeutics for Health Act ("PATH Act")	Sec. 2. Antibiotic Resistance Monitoring Sec. 3. Limited Population Pathway for Anti-Bacterial Drugs	Sec. 2121, Approval of certain drugs for use in a limited population of patients Sec. 2122, Susceptibility test interpretive criteria for microorganisms Sec. 2123, Encouraging the development and use of DISARM drugs
18	S. 2745	Advancing NIH Strategic Planning and Representation in Medical Research Act	Sec. 2. NIH Strategic Plan Sec. 3. Collaboration to Enhance Diversity in Clinical Research Sec. 4. Promoting Inclusion in Clinical Research Sec. 5. Research Related to Sexual and Gender Minority Populations Sec. 6. Improving Coordination Related to Minority Health and Health Disparities Sec. 7. Enhancing the Rigor and Reproducibility of Scientific Research Sec. 8. Task Force on Research Specific to Pregnant and Lactating Women	Sec. 1021, NIH Research Strategic Plan Sec. 1029, Sense of Congress on increased inclusion of underrepresented communities in clinical trials Sec. 1083, Appropriate age groupings in clinical research

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19	S. 2742	Promoting Biomedical Research and Public Health for Patients Act	Sec. 2. Triennial Reports of Director of NIH	Sec. 1022, Increasing accountability at the National Institutes of Health
			Sec. 3. Administrative Burden on Investigators	Sec. 1023, Reducing administrative burdens of researchers
			Sec. 4. Reimbursement for Research Substances and Living Organisms	
			Sec. 5. Streamlining NIH Reporting Requirements	Sec. 1024, Exemption for the NIH from the Paperwork Reduction Act requirements
			Sec. 6. National Vaccine Injury Compensation Program	Sec. 2141, Timely review of vaccines by the Advisory Committee on Immunization Practices
			Sec. 7. Vaccine Meetings, Report on Vaccine Innovation	Sec. 2142, Review of processes and consistency of ACIP recommendations Sec. 2143, Meetings between CDC and vaccine developers
			Sec. 8. Technical Updates to Clinical Trials Database	Sec. 1101, Standardization of data in Clinical Trial Registry Data Bank on eligibility for clinical trials
			Sec. 9. Compliance Activities Reports	
			Sec. 10. Appointment of Directors of National Research Institutes and National Centers	
			Sec. 11. National Center for Advancing Translational Sciences	Sec. 1027, NCATS phase IIB restriction