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## Preventing Patient Harm in 21<sup>st</sup> Century Cures and Beyond

### Worst Provisions in HR 6 (and Senate Companions):

- **Section 2151.** Could increase drug prices and cost taxpayers up to \$12 billion over 10 years<sup>1</sup> by extending monopolies on brand-name blockbuster drugs that receive additional approval to treat orphan diseases. (Orphan Product Extensions Now Accelerating Act. S. 1421, H.R. 971)
- **Section 2201.** Creates overly-broad category of “breakthrough” devices and pressures the FDA to approve these based on lower-quality evidence. (Senate: Advancing Breakthrough Medical Devices for Patients Act, S. 1077)
- **Section 2221.** Allows device manufacturers to make changes to high-risk devices without FDA oversight, monitored only by a new system of private contractors accredited by FDA but paid by industry.
- **Section 2222.** Encourages approval of highest-risk medical devices based on low-quality evidence.
- **Section 2121.** Pressures FDA to approve antibiotics, antifungals, and possibly other drugs, under lower FDA standards, putting patients at risk of being treated with unsafe and ineffective drugs (Senate: Promise for Antibiotics and Therapeutics for Health Act, S. 185)
- **Section 2123.** Encourages antibiotic resistance by paying hospitals to use (& over-use) new antibiotics.
- **Section 3041.** Opens a gaping hole in the Physician Payment Sunshine Act for “educational” gifts.

### Other bills to watch out for in a 21st Century Cures Package:

- **Reliable and Effective Growth for Regenerative Health Options that Improve Wellness (REGROW) Act.** Allows FDA to conditionally approve cellular therapeutic products without adequate testing to ensure the products are safe and effective.
- **In vitro clinical testing bill.** Undermines FDA’s ability to regulate high-stakes diagnostic testing (discussion draft).
- **Combination Product Regulatory Fairness Act (S. 1767).** Pressures FDA to regulate combination drug/device products as devices, leading to weaker oversight.

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<sup>1</sup> Public Citizen Report: House Orphan Drug Proposal. [www.citizen.org/hrg2289](http://www.citizen.org/hrg2289)