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21st Century Cures: Summary

The 21st Century Cures (CC) draft is a reactionary assault on safety and science. It would undermine the FDA, drive up health care costs, and harm patients and public health. Its worst provisions are:

1. Dismantling clinical trials, the gold standard for drug safety Title I, Subtitles C and D

Clinical trials are the gold standard for assessing drug safety and effectiveness, developed by scientific consensus over decades. Large, well-designed, randomized controlled Phase III clinical trials are critical for weeding out bad drugs: over a third of the drugs that enter Phase III testing fail to gain FDA approval, with nearly 90 percent of failures due to safety and efficacy problems.[1,2] The 21st CC would abandon the Phase III testing requirements and undermines the drug approval process. Without these trials, nearly one in three drugs approved under the 21st CC pathways could be unsafe, ineffective, or both.

2. Lengthening drug company monopolies to gouge consumers and drive up costs Title I, Subtitle L

21st CC triples and strengthens the monopoly period available for most drugs, replacing 5 years of data exclusivity with 15 years of data exclusivity plus extended patents. Such anti-competitive monopolies drive up health care costs and hurt patients. They are also unnecessary, as drug companies continue to make record-breaking profits.

3. Removing dangerous high-risk medical devices from FDA oversight Title V, Subtitle D

21st CC guts already-weak FDA regulation of medical devices. The bill worsens problems by allowing companies to make changes to the highest-risk devices (like brain stents or artificial heart valves), after which an unlimited number of such changes could be made without even notifying the FDA. Even simple changes can be dangerous, as illustrated by recent cases of catastrophic bone and tissue damage caused by changes to the material used in hip implants.[3] Self-regulation for these types of changes would be disastrous.

4. Forcing the FDA to base high-risk device approvals on unreliable data Title V, Subtitle D, Section 5062

21st CC would require the FDA to approve new high-risk devices based on articles from medical journals. The FDA would have to take the articles at face value and would be blocked from digging deeper or asking questions, even in cases where articles leave out information or rely on mistakes, misrepresentations, or outright fraud.

5. Encouraging hospitals to overuse antibiotics, speeding the rise of superbugs Title I, Subtitle D

21st CC exacerbates the spread of drug-resistant diseases by paying hospitals bonuses for using new antibiotics. This provision encourages hospitals to overuse rather than conserve the most powerful antibiotics, accelerating the development of antibiotic resistance. This is extremely dangerous and would shorten the period for which new antibiotics are effective.

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[1] DiMasi JA, Feldman L, Seckler A, Wilson A, Trends in risks associated with new drug development: Success rates for investigational drugs. *Clin Pharmacol Ther* 2010;87(3):272-7.
[2] Arrowsmith J. Trial watch: phase III and submission failures: 2007-2010. *Nat Rev Drug Discov* 2011;10(2):87.
[3] Meier B, Concerns over “metal on metal” hip implants. *New York Times*. March 3, 2010. http://nyti.ms/1A4k85S.