

21st Century Cures Act: A Deregulatory Trojan Horse

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The U.S. Congress just passed a revised version of the 21st Century Cures Act, one of the most far-reaching health bills under consideration since the Affordable Care Act (ACA). Achieving widespread bipartisan support, the bill is expected to be approved by the White House by the end of the year. Supporters tout the legislation as making it easier for life-saving drugs and device innovations to reach the bedside along with bringing huge increases in federal funding for biomedical research. Representing a total earmark of \$6.3 billion, the bill, among its many stipulations, would appropriate \$1 billion for opioid abuse and addiction programs over 2 years, \$4.8 billion in additional funding over 10 years for the National Institutes of Health which has a current budget of \$31.3 billion, and \$500 million in additional funding over 10 years for the Food and Drug Administration (FDA) [1].

Naturally, any measure achieving such broad-based consensus among both parties in the current political climate merits skeptical reexamination. Indeed, the bill's provisions have faced considerable criticism from consumer advocacy groups and some prominent politicians, including Senators Bernie Sanders (D-VT) and Elizabeth Warren (D-MA), for being too yielding to the financial interests of private industry [2-3]. As has been noted by some observers, the Act represents one of the most lobbied bills in recent history [4]. Per the Center for Responsive Politics, almost 1500 lobbyists serving over 400 organizations including major research universities and multinational pharmaceutical corporations were involved [5] (Table 1).

Industry	Example
Insurance	BCBS Aetna
Research University	MIT Northwestern
Pharmaceutical	GSK Eli Lilly
Medical Device Industry	Smith & Nephew Medtronic
Physicians Groups	American College of Cardiology American Assn. Neurological Surgeons

Table 1: Multiple industries participated in the massive lobbying campaign leading up to the 21st Century Cures Act.

For physicians concerned with patient safety, skyrocketing prescription drug costs (i.e. for patients), and reducing systemic expenditures, it's worth asking how the bill's proposed measures address or affect these issues in any meaningful way. Not surprisingly, the answers are quite revealing. It is evident that one of the bill's principal aims is to reduce barriers to market for drug and device companies by easing safety standards in no uncertain terms. Regulators would be free to approve new uses or indications for drugs already on the market that have not been evaluated using randomized controlled trials. Instead, the FDA would be permitted to use "real world evidence" obtained from observational studies, patient registries, and other data not obtained by traditional methods. For new drugs and devices, the FDA is encouraged to use biomarkers and other surrogate endpoints to evaluate technological efficacy as opposed to conventional

clinical outcomes such as morbidity, restoration of function, or death [6]. These are but two among a host of additional deregulatory schemes embedded in the bill [7].

It is argued that the goal of such deregulation is to shorten the approval process in order to bring much needed interventions to market. Senator Majority Leader Mitch McConnell (R-KY) offers the rhetoric: “Too many people are waiting for the promise of a cure or a medical advancement to combat a life-threatening disease. Cutting back on bureaucratic red tape, advancing lifesaving research and tackling the scourge of cancer would move our country forward and help millions looking for more than hope, but a chance at long, healthy lives [8]”. However, the myth of the regulatory “bottleneck” was formally debunked years ago after a much longer period of suspicion [9]. In 2015, the FDA’s approval rate for new drugs was 89 - 96% [10]. Furthermore, the FDA approves drugs faster than its counterparts in Europe and Canada and, in most cases, earlier [11]. There is no “innovation crisis” in the pharmaceutical market as has been conceded by industry-employed analysts [12]. Existing literature indicate that most new drugs brought to market are rarely better than drugs already available, sometimes harmful, and manufactured as minor biomolecular variants in order to generate patent rents. Nevertheless, the myth serves a useful purpose: namely, to invite favorable legislation.

The risks of loosened safety standards are not hard to elucidate given the available literature examining off-label use of prescription drugs. When physicians prescribe drugs “off-label”, they are prescribing them for indications that have not been approved by the FDA. An example would be the use of a selective serotonin reuptake inhibitor, which is approved for the treatment of depression, to treat premature ejaculation. In a recent article published in *JAMA Internal Medicine*, Egualé, *et al.* showed, dramatically, that off-label prescribing was associated with significantly higher rates of adverse drug events, with the highest rates achieved by indications lacking strong scientific evidence [13]. While physicians are free to prescribe off-label, it is illegal for manufacturers to promote drugs for off-label indications. Most notoriously, Merck agreed to pay close to \$1 billion to resolve criminal and civil charges pertaining to the illegal promotion of their drug Vioxx, a COX-2 inhibitor estimated to have caused over 100,000 excess cases of serious cardiovascular disease and causing close to 50,000 excess deaths. There are countless other examples of other companies engaging in similar illicit activity [14].

The point is that industry leaders are driven by perverse incentives which minimize concern for patient safety. Deregulation makes it easier for drug and device companies to sell more product for an expanded array of indications in order to generate more profit. Government-granted patent monopolies represent the central feature underlying both the ability and the incentive to engage in this behavior. The Cures Act may carry \$6 billion in new funding, but prescription drug spending tops \$300 billion in the United States i.e. 10% of national health expenditures [15]. Drugs are expensive because patent protection allows manufacturers to sell drugs for exorbitantly high prices. Making minor modifications to the biomolecular structure of a drug enables companies to submit new applications for approval by the FDA under a new patent lease. By virtue of these dynamics, the deregulatory measures in the Cures Act is probably harmful for patients and are likely to increase costs. Naturally, profits will climb, hence the lobbying by industry and criticism by consumer advocates.

Even new drugs that are useful do not address the most important obstacle: affordability. National health expenditures are rising and will continue to do so [16]. Per capita prescription drug spending in the U.S. vastly exceeds analogous spending in comparable advanced economies: over twice as much on average [17]. Furthermore, new drugs are prohibitively expensive. To take the most egregious examples, Novartis charges \$14,000 per month for Zykadia, indicated for lung cancer. Amgen charges \$64,000 monthly for Blincyto, indicated for leukemia. High prices for prescription drugs really hurt people. The National Center for Health Statistics reported last year that to save money, almost 8% of adults did not take their medication as prescribed and 4.2% used alternative therapies. Approximately 16.9% of total drug expenditures in 2014 (\$300 billion) were out-of-pocket expenses [18]. According to health policy researcher and Memorial Sloan Kettering physician Peter Bach, “Drugs are so expensive that once they flow through our ragtag insurance system, we have patients who can’t afford them, or they can barely afford them, so they’re not getting therapies [19]”.

Harvard researchers Ameet Sarpatwari and Michael Sinha concluded that although “there are some positive provisions,” the Cure Act’s “potential benefits and modestly enhanced funding for scientific advancement are far outweighed by the increased risk of patient harm, and added pressure on the FDA to rush new products to market without adequate evidence. The current 21st Century Cures Act would not drive innovation. Instead, it represents a poor deal for patients [20].”

The “positive provisions” and “potential benefits” refer most likely to the sums earmarked for opioid abuse and addiction programs and increased NIH funding totaling over \$5 billion, an ostensible victory for public health advocates. However, there are major problems with these provisions which lend credence to the suspicion that the bill was primarily designed as a giveaway to industry in response to a massive lobbying blitz. Namely, the bill also requires a compensatory \$3.5 billion decrease in funding for the Prevention and Public Health Fund which was established under the ACA to support education and prevention of Alzheimer’s Disease, diabetes, infections, smoking, immunizations, and other miscellaneous chronic conditions.

Leaving aside the issue of reciprocal cuts, another concern is that the \$5.8 billion in new funding is not even guaranteed. Though it was in an earlier version of the bill, it shifted to “discretionary funding” in the most recent iteration. In other words, Congress will actually have to approve the funding annually in order for the FDA, the NIH, or opioid abuse and addiction programs to receive any money. Given the outcome of the November elections, it is impossible to prognosticate the distribution of these funds. Nevertheless, with the bill passed, the deregulatory mechanisms are mandatory, rather than discretionary. That is to say, the windfall for the drug and device industries is secure whereas, for at least the next two years, the programs that might actually benefit patients and society (i.e. more biomedical research, better staffing at the FDA, addiction and treatment programs) will be subject to annual review and possible termination by a Republican leadership which has traditionally viewed biomedical research initiatives and substance abuse treatment with suspicion and contempt [21].

There is no question that the 21st Century Cures Act, which is likely to become law, represents a tremendous victory for the pharmaceutical and medical device industries with regards to potential cash earnings and profit. It is, in fact, plausible that the bill’s core purpose was engineered to reflect the interests of specific industrial sectors and investor groups. However, it is also evident that there are hidden costs to be borne by the general population in the form of increased drug prices, reduced safety standards, and economic inequality. A rollback of this magnitude merits careful consideration by the compassionate and policy-minded investigator. Although additional funding for biomedical research and opioid addiction is a worthy goal and should continue to be pursued, the Cures Act offers no guarantee and any potential benefits are dramatically overshadowed by the harms it will do to people and society.

Bibliography

1. Lupkin S and Findlay S. “Grab bag of goodies in 21st century cures act”. *Kaiser Health News* (2016).
2. McGrane V. “Warren splits with party, Mass. interests over drug bill”. *The Boston Globe* (2016).
3. Sanders B. “Sanders statement on the 21st century cures act” (2016).
4. Lupkin S. “Legislation that would shape FDA and NIH triggers lobbying frenzy” (2016).
5. “Clients lobbying on H.R.6: 21st Century Cures Act”. *OpenSecrets.org* (2016).
6. Avorn J and Kesselheim AS. “The 21st Century Cures Act--Will It Take Us Back in Time?” *New England Journal of Medicine* 372.26 (2015): 2473-2475.
7. “Preventing patient harm in 21st century cures”. *Public Citizen* (2016).
8. Steinhauer J and Tavernise S. “\$6.3 billion measure aims to cure ailing health care policies”. *The New York Times* (2016).

9. Light DW and Lexchin JR. "Pharmaceutical research and development: what do we get for all that money?" *British Medical Journal* 345 (2012): e4348.
10. Herper M. "The FDA is basically approving everything". *Forbes* (2016).
11. Downing NS., *et al.* "Regulatory review of novel therapeutics--comparison of three regulatory agencies". *New England Journal of Medicine* 366.24 (2012): 2284-2293.
12. Schmid EF and Smith DA. "Keynote review: Is declining innovation in the pharmaceutical industry a myth?" *Drug Discovery Today* 10.15 (2005): 1031-1039.
13. Eguale T., *et al.* "Association of Off-label Drug Use and Adverse Drug Events in an Adult Population". *JAMA Internal Medicine* 176.1 (2016): 55-63.
14. Katari R and Baker D. "Patent monopolies and the costs of mismarketing drugs". *Center for Economic and Policy Research* (2015).
15. IMS Health Study: U.S. Drug Spending Growth Reaches 8.5 Percent in 2015 (2016).
16. Martin AB., *et al.* "National Health Spending: Faster Growth In 2015 As Coverage Expands and Utilization Increases". *Health Affairs (Millwood)* (2016).
17. Kesselheim AS., *et al.* "The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform". *Journal of the American Medical Association* 316.8 (2016): 858-871.
18. "Table 16 Retail Prescription Drug Expenditures; Levels, Percent Change, and Percent Distribution, by Source of Funds: Selected Calendar Years 1970-2013". *Centers for Medicare and Medicaid Services* (2016).
19. Walker J. "Patients struggle with high drug prices". *The Wall Street Journal* (2015).
20. Sarpatawri A and Sinha M. "The current 21st century cures legislation is still a bad deal for patients". *Health Affairs Blog* (2016).
21. Republican Platform: Great American Families, Education, Healthcare, and Criminal Justice (2016).

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