

# Public Citizen Wants You Dead- Not Bacteria



By *Josh Bloom* — December 7, 2016



Public Citizen Just Loves Bacteria.  
People? Not So Much. Image:  
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It would be absolutely impossible for something as huge and comprehensive as [The 21st Century Cures Bill](#) <sup>[1]</sup>, which is expected to become law after it passes the Senate, to be without major controversy. There is so much at stake, and virtually everyone has a complaint about who is getting what and how much.

Much criticism has (big surprise) perennially been directed at America's pharmaceutical industry, usually by know-nothings, and this time is no different. There is no shortage of complaints. Here are a few; none particularly enlightening or original:

- [Huffington Post](#) <sup>[2]</sup>
- [Elizabeth Warren](#) <sup>[3]</sup>
- [Bernie Sanders](#) <sup>[4]</sup>
- [The Centre for Research on Globalization](#) <sup>[5]</sup>

But, no one gets it more wrong than Public Citizen, especially their stance on new antibiotic research. The group wants to take us back precisely to the time where excessive FDA requirements pushed all the major drug companies out of the antibiotic business—perhaps the principal cause for today's antibiotic resistance crisis. What are they thinking?

Perhaps the better question is who is thinking. It's [Sarah Sorscher, JD, MPH](#), <sup>[6]</sup>Researcher with Public Citizen's Health Research Group. Yes—a lawyer who knows nothing about antibiotics, which should become rather evident soon.

Lets examine some of Sorscher's contentions, and then the facts. There is quite a difference.

Sorscher: *"No antibiotic with a truly novel mechanism of action has been discovered since the late 1980s. Yet this drought is not the fault of the Food and Drug Administration."*

Fact: Dead wrong. Twice. 1) Ever hear of daptomycin (2003) or avibactam (2015)? And, the fault lies with the [biostatisticians](#) [7] in the infectious disease division of the FDA: (Emphasis mine).

*"The problem began with a rethinking of clinical trials, catalyzed by a group of 'radical skeptic statisticians' who doubted whether antibiotics were actually effective for bacterial infections. The new rules and regulations rendered clinical trials for antibiotics virtually impossible to conduct, and prohibitively expensive... [f]or example, regulations **barred patients from taking part in clinical trials if they had taken antibiotics prior to enrollment.**"*

Sorscher: *"Many of the antibiotics approved over the past decade have suffered from safety and effectiveness problems. For example, Tygacil, an antibiotic that received special accelerated FDA approval in 2005."*

Fact: Again, wrong. Tygacil was, in fact, the last antibiotic that was approved under the FDA's prior guidelines **(1)**. Newer (and useless) guidelines required more statistical power in antibiotic trials, which made these trials prohibitively long and expensive. It took American Council advisor, Dr. Dave Shlaes and the Infectious Disease Society of America (IDSA) two years to convince the FDA to treat Tygacil like antibiotics had been treated in the past.

Sorscher: *"[Tygacil] was slapped with a black-box warning in 2013 stating that the drug increases the risk of death."*

Fact: Big deal. [More than 140 prescription drugs](#) [8] currently carry black box warning. Sorscher also fails to mention how many lives Tygacil may have saved.

Sorscher: *"If bacteria have developed resistance to the drug being used for the comparison. If an old drug is ineffective, proving that the new drug is not worse by comparison is hardly evidence of anything."*

(Comment with eyes bugging out of head): She must be kidding. It takes two days to see if a new drug will work against a resistant organism.

Sorscher: *"[The 21st Century Act is] yet another accelerated approval pathway to pressure the FDA to use even smaller clinical trials, more surrogate endpoints and potentially even more questionable forms of evidence, casting further doubt on the safety and effectiveness of antibiotics approved during the coming century."*

Comment: This is precisely the point that Sorscher is missing. Regressive regulations like the ones that were slapped on antibiotics in the 1990s drove all the major companies out of AB research in the first place. Public Citizen wants to go back to the exact point in time when the

system began to fail. Brilliant.

Sorscher: *"Another troubling provision will allow the FDA to outsource important decisions involved in determining when the microorganism that has caused an infection is antibiotic-resistant and therefore requires newer antibiotics.*

Comment: The current focus of antimicrobial research is to discover novel, narrow-spectrum antibiotics to treat specific resistant infections. Yes, it would be very nice to actually know what will successfully treat what. And this is about using an organization like The European Committee on Antimicrobial Susceptibility Testing (2) to recommend breakpoints just like the European Medicines Agency does. What could possibly be wrong with that? Nothing.

In summation:

1. It is no secret that Public Citizen hates all drugs.
2. But not bugs.
3. If you guys are going to open your yaps, maybe you should know what you're talking about.
4. Otherwise, go measure gas mileage, or count the number of Necco Wafers in a roll.



Note:

- (1) David M. Shlaes, "Antibiotics: The Perfect Storm" (Springer, 2010) Pages 32-34.
- (2) See: <http://www.eucast.org/> [9]
- (3) The European Medicines Agency is essentially the European equivalent of the FDA.

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**Links**

- [1] <https://www.congress.gov/bill/114th-congress/house-bill/6>
- [2] [http://www.huffingtonpost.com/jonathan-galland/hfcs-soda\\_b\\_1581123.html](http://www.huffingtonpost.com/jonathan-galland/hfcs-soda_b_1581123.html)
- [3] [https://www.warren.senate.gov/?p=press\\_release&id=1307](https://www.warren.senate.gov/?p=press_release&id=1307)
- [4] <http://www.sanders.senate.gov/newsroom/press-releases/sanders-statement-on-the-21st-century-cures-act>
- [5] <http://www.globalresearch.ca/urgent-alert-the-21st-century-cures-act-that-will-expand-the-use-of-coerced-drug-treatments/5560117>
- [6] <http://www.citizen.org/documents/critique-dangerous-antibiotics-21st-century-cures.pdf>
- [7] <http://www.asm.org/index.php/programs/2012-05-30-14-11-35/88-news-room/journal-tipsheets/91799->

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[8] <http://www.bad-drug.net/bad-drug-list>

[9] <http://www.eucast.org/>