On December 13th, 2017 President Obama signed the 21st Century Cures Act which passed both the House and the Senate nearly unanimously. There were 5 Senators who stood up against big Pharma:
Elizabeth Warren – MA
Jeff Merkley -OR
Ron Wyden – OR
Mike Lee -UT
Bernie Sanders -VT

Although 1000s of calls were made legislators did not listen to their constituents. Why? Because these legislators were bought. Over the last two years 1400+ lobbyists and $525+ million influenced their vote. These legislators are BOUGHT. Each and every one of them has had two years' worth of wheeling and dealing, horse-trading and funds being put in their bank account. They also each had their “wish” amendment or section added in so they are all invested. This is how our legislature works these days. We the people have a week to undo the work that has been done for the past two years. If we want to make a change we need to wake up more people so that there are more people in these fights. We need all of the health freedom groups to come together and fight together on all these issues, even if they are not the primary issue for that person/group. That is what we need to do while we are playing in their sandpit, but at the same time we need to build our own sandpit and share the truth so that people find our sandpit more appealing.

So what do we do now? We get off the bus! We vote with our dollars and feet and quit going to traditional medical doctors and using traditional medical care except in temporary rare acute times such as accidents, broken bones, stitches, etc. The power of the consumer is amazing and we need to show them that we are not OK with what they are pedaling. We need to boycott the Pharma industry and the industries that support them. Emergency drugs or hospital visits are one thing, but the fact that the average number of drugs a senior takes in this country is 13 is a problem. The fact that the US consumers 75% of the pharma drugs globally is a problem. The fact that we are one of two countries in the world that allow TV advertising for Pharma drugs is a problem. These companies are not going to stop and the legislature is not going to stop until we either get the money out of politics or lessen the size and power of these Pharma corporations. The big corporations just have too much lobbying power right now. So go out and talk about your Chiropractors, Acupuncturists, Naturopaths, Homeopaths etc. to your
friends and family and share the issues with this bill. Talk about the chronic addiction to fix it pills this country has. Open their eyes because most are asleep.

**ACTION NEEDED:**

1. Tweet/Facebook and call the 5 no votes and thank them for standing up against Big Pharma (@SenWarren @SenSanders @SenJeffMerkley @RonWyden @SenMikeLee). You can retweet AVFCA’s tweet (https://twitter.com/avoiceforchoice/status/806616233034424320)

   Sanders (202) 224-5141
   Warren (202) 224-4543
   Merkley (202) 224-3753
   Lee (202) 224-5444
   Wyden (202) 224-5244

2. Then vote with your Dollars and educate others so they can know why they should be concerned about our government’s and the Big Pharma’s influence.

**Legislative Details:** On November 30th 2016, the House of Representatives passed the 21st Century Cures Act (HR34) nearly unanimously (392-Yay; 26 Nay) (https://www.govtrack.us/congress/votes/114-2016/h592), and on December 7th 2016 it passed the Senate also nearly unanimously (95-Yay; 5 Nay)

The 21st Century Cures Act legislation was originally passed in the house last year on July 10, 2015 as HR 6. After passing the house in 2015, the legislation stalled. Many of the provisions of HR 6 were broken up into several smaller bills, but over the Thanksgiving holiday, the legislation was quickly reassembled into a new version including some sections from HR 6 and adding some new sections, amending them all onto bill HR 34. HR 34 was originally a bill that only addressed “Tsunami Warning, Education, and Research”.

A few legislators spoke out against it. They include:

**Rep Rosa DeLauro**

**Sen Elizabeth Warren**

**Rep Jim McDermott**

**Sen Bernie Sanders**

**Sen Jeff Merkley**

**Bill Details:** Although this is coveted as a wonderful bill that is needed in the US so that drugs and medical devices can be fast tracked, if you read the nearly 1000 pages it is clear this is dangerous bill that is has the best interests of the Pharmaceutical industry at heart, NOT its consumers. Over 1400 lobbyists were involved in the creation of this bill. “The 21st Century Cures Act is a drug company stockholder’s dream and a consumer’s worst nightmare,” said Barbara Loefisher, NVIC Co-founder and President.

“Making experimental drugs quickly available for the sick and dying, who voluntarily choose to use them, is one thing but Congress should not be greasing the skids to license experimental vaccines that government will recommend and legally require healthy children and adults to use. It is a prescription for disaster.”
Here are some of the issues with this bill:

**Informed Consent (or lack thereof) in HR34:** The 21st Century Cures Act would no longer require the informed consent of the subjects for medical devices or drugs. All patients receiving treatment by any medical doctor may be, WITHOUT THEIR KNOWLEDGE, enrolled in a clinical trial for drugs and devices as long as there is “minimal risk” to the patient and the practitioner, and as long as there are “safeguards”. This means that the person being given the drug or having the medical device used on them does NOT have to be informed that they are entered into the clinical trial or of the adverse side effects or risks. This provision makes no sense logically, or scientifically, and is dangerous. We use clinical trials not only to study the efficacy of drugs and devices, but also to determine their safety profiles. Under the 21st Century Act, no clinical trial can proceed unless the safety profiles are known. The effect of this act is to leave “safety” to guesswork and rationalization, and to allow the medical establishment to assess harm in drugs and devices in a manner in which (1) the patients are not informed that they are in a clinical trial, and (2) they have no right to say “No” to being part of an experiment. If they are harmed during the trial, they cannot know that they should sue because any ill effect of the experimental drug or device cannot be traced to the experiment. This allows the medical establishment to experiment on the population with impunity. The act does not specify “minimal risk”. *(This is probably one of the ones that resonates most with staffers)*

**Vaccines in HR34:** The 21st Century Cures Act would fast track the approval of all vaccines, and shields drug companies and vaccine administrators from liability for fetal injuries and deaths caused by vaccines marketed for and given to pregnant woman. It also allows the approval of drugs by the FDA vaccines “with the least BURDENSOME means.” Drugs should require the MOST rigorous testing, not the least burdensome means.

**Health Information Privacy (or lack thereof) in HR34:** The 21st Century Cures Act would allow the government to access and use your private health information and records without your authorization.

**Big Brother for Disability Care in HR34:** The 21st Century Cures Act would create big brother mechanisms in (IHSS) In Home Supportive Services for home care providers with the creation of the electronic visit verification system.

**Electric shock “therapy” in HR34:** The 21st Century Cures Act would fast track Electric shock “therapy” as a cure for maladaptive behaviors and seizures.

**Reduced Funding of NIH and FDA in HR34:** The 21st Century Cures Act would trade temporary additional funding for the National Institutes of Health and the FDA for permanent weakening of the FDA’s approval process.
**Removes Requirement to Report Payments to Physicians:** The 21st Century Cures Act would remove the requirement that manufacturers of medical products report payments to physicians for certain “educational” activities.

**Prescription Drug Price Increases:** The 21st Century Cures Act would likely increase prescription drug prices and make them less accessible to lower income patients.

**CDC surveillance of neurological diseases:** The 21st Century Cures Act would increase surveillance of neurological diseases and with the question of what would they do with that information and how would it negatively influence laws in the future.

**HR34: 21st Century Cures Act in the media and related articles**

“David Hilzenrath at the [Project on Government Oversight](http://www.pogo.org) reports that at least 39 of 42 patient advocacy groups who participated in discussions with the FDA over agency review processes for prescription drugs received funding from pharmaceutical companies. And at least 15 have representatives of drug or biotechnology companies on their governing boards.

“Kaiser Health News reviewed the lobbying records filed by the Pharmaceutical Researchers and Manufacturers of America, the trade group representing drug makers, and found the industry group spent up to $24.7 million lobbying on the bill. (On some of the lobbyists’ disclosure forms, multiple healthcare laws are listed, and it was not clear how the industry’s lobbyists divided their time.) The mega-drug maker AbbVie — which manufacturers Humira, one of the most lucrative pharmaceuticals marketed for multiple uses — spent up to $7.7 million. The U.S. Chamber of Commerce spent up to $136.5 million.

The bill also had support from the US. Oil and Gas Association — which spent $293,000 on lobbying — since some of the new funding for research would come from selling oil crude from the Strategic Petroleum Reserve.”  


National Vaccine Information Center (NVIC) Calls 21st Century Cures Act “A Wolf in Sheep’s Clothing” and Urges Presidential Veto to Protect Public Health | Business Wire  


[https://www.facebook.com/vaccineinfo/posts/10154708664460891](https://www.facebook.com/vaccineinfo/posts/10154708664460891)

21st Century Cures Act Eliminates Vaccine Safety Science  

House lawmakers passed the biggest health reform bill since the Affordable Care Act
To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes

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This new version still contains many of the sections of concern that were in the original version outlined in Barbara Loe Fisher’s commentary from 7/21/15, [Here Comes the 21st Century Cures Act: Say Goodbye to Vaccine Safety Science](https://www.thestreet.com/story/13911755/1/21st-century-cures-act-flies-through-house-senate-set-to-give-its-blessing-next-week.html).

UPDATE: 9/14/2016 – [https://www.congress.gov/bill/114th-congress/house-bill/6/cosponsors](https://www.congress.gov/bill/114th-congress/house-bill/6/cosponsors) HR 6 has not moved since passing the US House and being referred in the Senate to the Committee on Health, Education, Labor, and Pensions. HR 6 is a federal bill that has passed the US House and is now in the US Senate assigned to the Senate Committee on Health, Education, Labor, and Pensions Committee.

[http://www.senate.gov/general/committee_membership/committee_memberships_SSHR.htm](http://www.senate.gov/general/committee_membership/committee_memberships_SSHR.htm) – Senate HELP Committee information


The title of this bill is An Act To accelerate the discovery, development, and delivery of 21st century cures, and for other purposes.

This legislation includes a section that would fast track newly licensed vaccines for approval by the ACIP (Advisory Committee on Immunization Practices). The ACIP makes recommendations for the use of vaccines, then states follow by requiring them or mandating them.

In her commentary, Barbara Loe Fisher says:

*The 21st Century Cures Act is being sold as a way for the FDA to quickly license experimental pharmaceutical products for people suffering with rare or life threatening diseases, whether or not those products have been adequately tested.* However, greasing the FDA licensure skids to make experimental drugs available for the sick and dying, who voluntarily choose to use them, is one thing, while greasing the skids to bum rush experimental vaccines to licensure that government will legally require healthy children and adults to buy and use, is something quite different.
Nearly every single vaccine that the pharmaceutical industry creates and the FDA licenses for child use is eventually recommended for all children and mandated by state governments for daycare and school entry. And, now, many adults are being brought into the vaccine mandate net as well. The 21st Century Cures Act is a prescription for disaster. Vaccine research, development and fast tracking should not be a part of it.


HR 6 adds the following new laws:

Full text of HR 6, vaccine section begins on page 162 — https://www.congress.gov/114/bills/hr6/BILLS-114hr6hrs.pdf

subtitle H — Vaccine Access, Certainty, and Innovation

SEC. 2141. Timely review of vaccines by the Advisory Committee on Immunization Practices.

Section 2102(a) of the Public Health Service Act (42 U.S.C. 300aa–2(a)) is amended by adding at the end the following:

“(10) ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES.—

“(A) STANDARD PERIODS OF TIME FOR MAKING RECOMMENDATIONS.—Upon the licensure of any vaccine or any new indication for a vaccine, the Director of the Program shall direct the Advisory Committee on Immunization Practices, at its next regularly scheduled meeting, to consider the use of the vaccine.

“(B) EXPEDITED REVIEW PURSUANT TO REQUEST BY SPONSOR OR MANUFACTURER.—If the Advisory Committee does not make recommendations with respect to the use of a vaccine at the Advisory Committee’s first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee, at the request of the sponsor of the vaccine, shall make such recommendations on an expedited basis.

“(C) EXPEDITED REVIEW FOR BREAKTHROUGH THERAPIES AND FOR USE DURING PUBLIC HEALTH EMERGENCIES.—If a vaccine is designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act, and is licensed under section 351 of this Act, the Advisory Committee shall make recommendations with respect to the use of the vaccine on an expedited basis.

“(D) DEFINITION.—In this paragraph, the terms ‘Advisory Committee on Immunization Practices’ and ‘Advisory Committee’ mean the advisory committee on immunization practices established by the Secretary pursuant to section 222, acting through the Director of the Centers for Disease Control and Prevention.”.

SEC. 2142. Review of processes and consistency of ACIP recommendations.

(a) Review.—The Director of the Centers for Disease Control and Prevention shall conduct a review of the process used by the Advisory Committee on Immunization Practices to evaluate consistency in formulating and issuing recommendations pertaining to vaccines.

(b) Considerations.—The review under subsection (a) shall include assessment of—

(1) the criteria used to evaluate new and existing vaccines;

(2) the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach to the review and analysis of scientific and economic data, including the scientific basis for such approach; and

(3) the extent to which the processes used by the working groups of the Advisory Committee on Immunization Practices are consistent among groups.

(c) Stakeholders.—In carrying out the review under subsection (a), the Director of the Centers for Disease Control and Prevention shall solicit input from vaccine stakeholders.

(d) Report.—Not later than 18 months after the date of enactment of this Act, the Director of the Centers for Disease Control and Prevention shall submit to the appropriate committees of the Congress and make publicly available a report on the results of the review under subsection (a), including recommendations on improving the consistency of the process described in such subsection.

(e) Definition.—In this section, the term “Advisory Committee on Immunization Practices” means the advisory committee on immunization practices established by the Secretary of Health and Human Services pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.
SEC. 2143. Meetings between CDC and vaccine developers.
Section 310 of the Public Health Service Act (42 U.S.C. 242o) is amended by adding at the end the following:

“(c)(1) In this subsection, the term ‘vaccine developer’ means a nongovernmental entity engaged in—
“(A)(i) the development of a vaccine with the intent to pursue licensing of the vaccine by the Food and Drug Administration; or
“(ii) the production of a vaccine licensed by the Food and Drug Administration; and
“(B) vaccine research.
“(2)(A) Upon the submission of a written request for a meeting by a vaccine developer, that includes a valid justification for the meeting, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall convene a meeting of representatives of the vaccine developer and experts from the Centers for Disease Control and Prevention in immunization programs, epidemiology, and other relevant areas at which the Director (or the Director’s designee), for the purpose of informing the vaccine developer’s understanding of public health needs and priorities, shall provide the perspectives of the Centers for Disease Control and Prevention and other relevant Federal agencies regarding—
“(i) public health needs, epidemiology, and implementation considerations with regard to a vaccine developer’s potential vaccine profile; and
“(ii) potential implications of such perspectives for the vaccine developer’s vaccine research and development planning.
“(B) In addition to the representatives specified in subparagraph (A), the Secretary may, with the agreement of the vaccine developer requesting a meeting under such subparagraph, include in such meeting representatives of—
“(i) the Food and Drug Administration; and
“(ii) the National Vaccine Program.
“(C) The Secretary shall convene a meeting requested with a valid justification under subparagraph (A) not later than 120 days after receipt of the request for the meeting.
“(3)(A) Upon the submission of a written request by a vaccine developer, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall provide to the vaccine developer any age-based or other demographically assessed disease epidemiological analyses or data that—
“(i) are specified in the request;
“(ii) have been published;
“(iii) have been performed by or are in the possession of the Centers;
“(iv) are not a trade secret or commercial or financial information that is privileged or confidential and subject to section 552(b)(4) of title 5, United States Code, or section 1905 of title 18, United States Code; and
“(v) do not contain individually identifiable information.
“(B) The Secretary shall provide analyses requested by a vaccine manufacturer under subparagraph (A) not later than 120 calendar days after receipt of the request for the analyses.
“(4) The Secretary shall promptly notify a vaccine developer if—
“(A) the Secretary becomes aware of any significant change to information that was—
“(i) shared by the Secretary with the vaccine developer during a meeting under paragraph (2); or
“(ii) provided by the Secretary to the vaccine developer in one or more analyses under paragraph (3); and
“(B) the change to such information may have implications f