ALEC EXPOSED

"ALEC" has long been a secretive collaboration between Big Business and "conservative" politicians. Behind closed doors, they ghostwrite "model" bills to be introduced in state capitols across the country. This agenda–underwritten by global corporations–includes major tax loopholes for big industries and the super rich, proposals to offshore U.S. jobs and gut minimum wage, and efforts to weaken public health, safety, and environmental protections. Although many of these bills have become law, until now, their origin has been largely unknown. With **ALEC EXPOSED**, the Center for Media and Democracy hopes more Americans will study the bills to understand the depth and breadth of how big corporations are changing the legal rules and undermining democracy across the nation.

ALEC's Corporate Board --in recent past or present

- AT&T Services, Inc.
- centerpoint360
- UPS
- Bayer Corporation
- GlaxoSmithKline
- Energy Future Holdings
- Johnson & Johnson
- Coca-Cola Company
- PhRMA
- Kraft Foods, Inc.
- Coca-Cola Co.
- Pfizer Inc.
- Reed Elsevier, Inc.
- DIAGEO
- Peabody Energy
- Intuit, Inc.
- Koch Industries, Inc.
- ExxonMobil
- Verizon
- Reynolds American Inc.
- Wal-Mart Stores, Inc.
- Salt River Project
- Altria Client Services, Inc.
- American Bail Coalition
- State Farm Insurance

For more on these corporations, search at www.SourceWatch.org.

DID YOU KNOW? Corporations VOTED to adopt this. Through ALEC, global companies work as "equals" in "unison" with politicians to write laws to govern your life. Big Business has "a VOICE and a VOTE," according to newly exposed documents. **DO YOU?**

Did you know that global pharmaceutical company Bayer Healthcare was the corporate co-chair in 2011?

Clinical Trial and Results Registries Act

Section 1. {Short Title} This Act shall be known as the "Clinical Trial and Results Registries Act."

Section 2. {Summary} This bill establishes an agreement for [insert state] to adopt and abide to federal legislation for Clinical Trial and Results Registries (CTRR).

Section 3. {Background} In 1997, the FDA Modernization Act (FDAMA), Section 113 ("FDAMA 113") mandated the posting of Phase II to Phase IV industry-sponsored clinical trials conducted under an Investigational New Drug (IND) application for serious and life-threatening illnesses onto a public registry, maintained by the National Library of Medicine within the National Institute of Health. The intent was to provide patients with information on clinical trials and provided a means for those patients to contact participating physicians.

On September 28, 2007, the FDA Amendments Act (FDAAA) ("the Amendment") was signed by President George W. Bush with an effective date of October 1, 2007. Title VIII of the Amendment extended the mandate for clinical trial sponsors (public or private) to register all Phase II to Phase IV trial information and subsequent results information, regardless of clinical trial outcome. The intent of sharing results is to foster the scientific enterprises' knowledge around human clinical trials, with an understanding that even failed clinical trials that do not produce the expected results can add value to science and medicine.

A number of respected bodies have adapted their own position around clinical trial and results registries, including the World Health Organization (WHO) and the International Committee of Medical Journal Editors (ICMJE).

Since the original FDAMA 113 mandate, a number of individual states have proposed, and in some instances (for example, Maine) passed into legislation additional requirements above and beyond federal legislation. In some instances, the additional requirements were value-adding for patients and health care providers, because the additional information required to publicly post provided useful decision-making information. However, these state-specific proposals/requirements often overlap with federal mandates and/or confuse the clinical trial enterprise (private and public) about what is required due to different terminology, timelines and expectations.

Section 4. {Legislation}

A. So that [insert state] can have the most value-adding impact to its constituents, it is proposed that [insert state]:

1. Determine if the FDAAA Regulation, Title VIII, includes appropriate information for [insert state's] patients and health care providers to make meaningful medical decisions. In instances where it is determined that additional information should be included in the clinical trial or result public registry (based on the federal legislation), [insert state] shall participate and provide comment to the FDAAA legislation, as appropriate.

B. [Insert state] shall not propose or enact CTRR requirements specific to [insert state], nor shall [insert state] preempt the federal legislation.

C. If [insert state] would like to provide CTRR information to its constituents, [insert state] must agree to provide a link to the federal databases so as to ensure patients and health care providers have access to timely and consistent information.

Section 5. {Definitions} As used in this Act, the following definitions from Title 21 of the Code of Federal Regulations and/or the FDA Amendments Act of 2007 apply:

A. "Clinical trial" means a controlled clinical investigation; other than a Phase I investigation, of a drug.

B. "Sponsor" means a person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.

Section 6. {Applicability and Scope}

A. Provisions of this Act shall apply to all states where clinical research is conducted by public or private sponsors.

B. {Severability Clause}

C. {Repealer Clause}

D. {Effective Date}

Were *your* laws repealed?

Endnotes

A. Gulmezolglu M., Pang, T., Horton R., Dickersin K. WHO Facilitates International Collaboration in Setting Standards for Clinical Trial Registration. The Lancet, 2005. 365:1829-1831.

B. Deangelis C., Drazen J.M., Frizelle F.A., Haug C., Hoey J., Horton, R., et al. Clinical trial registration: a statement from the International Committee of Medical Journal Editors. Ann. Intern. Med. 2004; 141:477-8. Sept. 2004. (published electronically Sept. 2004: www.icmje.org).

C. World Health Organization. International Clinical Trials Registry Platform (ICTRP). www.who.org.

D. Joint Industry Position on the Disclosure of Clinical Trial Information. www.phrma.org.. Jan. 2005.

E. FDA Amendments Act of 2007 (FDAAA). www.fda.gov.

Adopted by the Health and Human Services Task Force at the States and Nation Policy Summit, December 8, 2007. Approved by the ALEC Board of Directors, January 2008.