CODE-BREAKING: TRANSLATING THE LAW

One Hundred Thirteenth Congress of the United States of America

AT THE FIRST SESSION

Begun and held at the City of Washington on Thursday, the third day of January, two thousand and thirteen

An Act

To amend the Federal Food, Drug, and Cosmetic Act with respect to human drug compounding and drug supply chain security, and for other purpose a

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Drug Quality and Security Act".

SEC. 2. REFERENCES IN ACT; TABLE OF CONTENTS.

- (a) References in Act.—Except as otherwise specified, amendments made by this Act to a section or other provision of law are amendments to such section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).
- (b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:
- Sec. 1. Short title. Sec. 2. References in Act; table of contents.

TITLE I-DRUG COMPOUNDING

- Sec. 101. Short title.
- Sec. 102. Voluntary outsourcing facilities.

- Sec. 103. Penalties.
 Sec. 104. Regulations.
 Sec. 105. Enhanced communication.
- Sec. 106. Severability.
- Sec. 107. GAO study.

TITLE II-DRUG SUPPLY CHAIN SECURITY

- Sec. 201. Short title.
- Sec. 202. Pharmaceutical distribution supply chain.
- Sec. 203. Enhanced drug distribution security. Sec. 204. National standards for prescription drug wholesale distributors.
- Sec. 205. National standards for third-party logistics providers uniform national
- Sec. 206. Penalties.
- Sec. 207. Conforming amendment. Sec. 208. Savings clause.

TITLE I—DRUG COMPOUNDING

SEC. 101. SHORT TITLE.

This Act may be cited as the "Compounding Quality Act". SEC. 102. VOLUNTARY OUTSOURCING FACILITIES.

(a) In General.—Subchapter A of chapter V (21 U.S.C. 351 et seq.) is amended—

TABLE OF CONTENTS.

The Table of Contents of this Presentation is as follows:

Sec. 1. The Problem.

Sec. 2. The Solution.

Sec. 201. The Idea.

Sec. 201a - 202. The Tools.

Sec. 3. The Plan.

Sec. 4. Feedback.

SEC. 101 THE PROBLEM.

Right now our laws look like this:

H. R. 2775—3

SEC. 109. Notwithstanding any other provision of this joint resolution, except section 106, for those programs that would otherwise have high initial rates of operation or complete distribution of appropriations at the beginning of fiscal year 2014 because of distributions of funding to States, foreign countries, grantees, or others, such high initial rates of operation or complete distribution shall not be made, and no grants shall be awarded for such programs funded by this joint resolution that would impinge on final funding prerogatives.

SEC. 110. This joint resolution shall be implemented so that only the most limited funding action of that permitted in the joint resolution shall be taken in order to provide for continuation of

projects and activities.

SEC. 111. (a) For entitlements and other mandatory payments whose budget authority was provided in appropriations Acts for fiscal year 2013, and for activities under the Food and Nutrition Act of 2008, activities shall be continued at the rate to maintain program levels under current law, under the authority and conditions provided in the applicable appropriations Act for fiscal year 2013, to be continued through the date specified in section 106(3).

(b) Notwithstanding section 106, obligations for mandatory payments due on or about the first day of any month that begins after October 2013 but not later than 30 days after the date specified in section 106(3) may continue to be made, and funds shall be available for such payments.

And our regulations look like this:

meat from all of Uruguay to the United States is prohibited until at least 12 months have elapsed since the depopulation, cleaning, and disinfection of the last infected premises. [The current requirement for fresh beef is that FMD has not been diagnosed in Uruguay within the previous 12 months.]

- The meat came from animals that originated from premises where FMD has not been present during the lifetime of any animals slaughtered for the export of meat to the United States.
- The meat came from animals that were moved directly from the premises of origin to the slaughtering establishment without any contact with other animals.
- The meat came from animals that received ante-mortem and post-mortem veterinary inspections, paying particular attention to the head and feet, at the slaughtering establishment, with no

SEC. 101 THE PROBLEM.

Legale§e is not pointless...



... but it can leave people confused and frustrated

SEC. 102 THE PROBLEM (CONT'D).

Many organizations exist to help, but...



Cost money



Need money



SEC. 103 PRO BONO PROBLEMS

300,000 cases in 2012

44,000 civil cases



400,000 requests for civil case assistance

THE SYSTEM IS DAMAGED

Thanks to interviews and research generously provided by

Professor David Johnson

Professor Beth Noveck

The Legal Aid Society of New York

DoTank

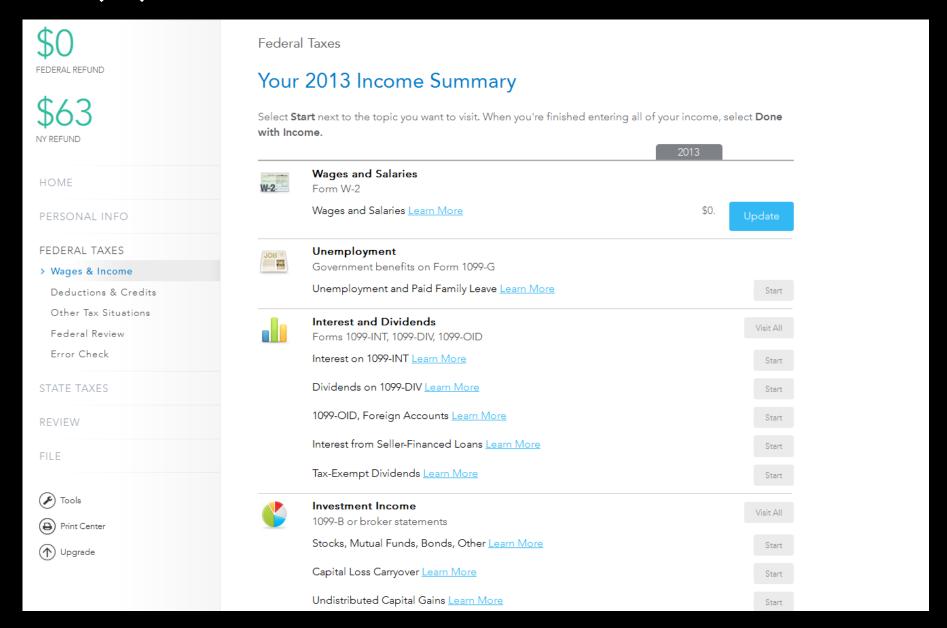
The Sunlight Foundation

A way to help began emerging

SEC. 2 CODE-BREAKING IT DOWN

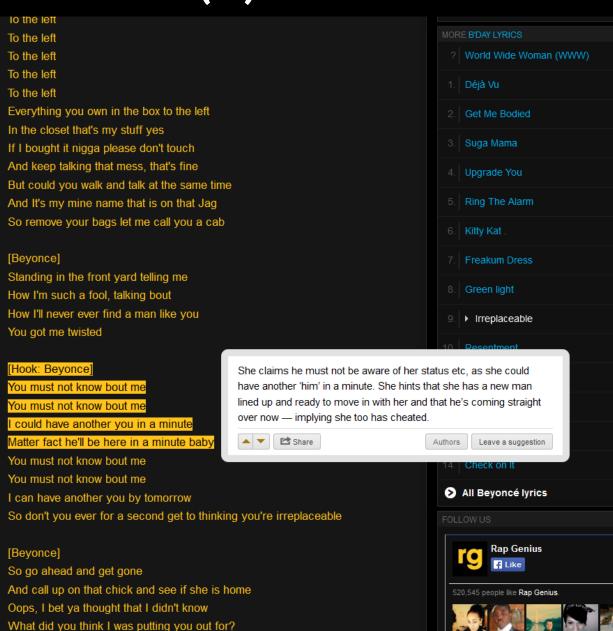
Codebreaking is about breaking down and translating the law

SEC 201(A) STEP-BY-STEP WALKTHROUGHS.

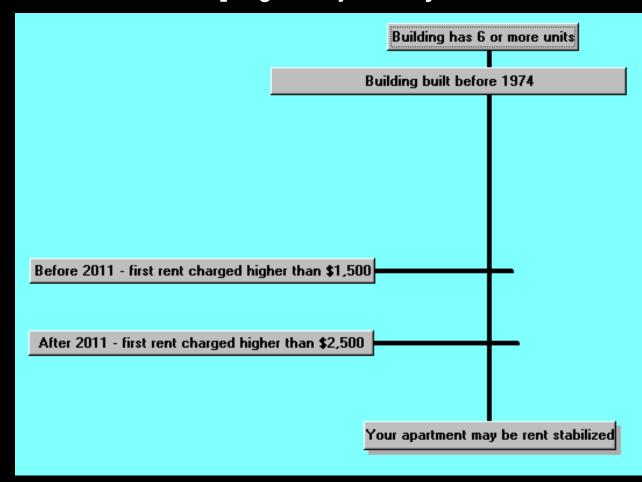


(Source: TurboTax.com)

SEC 201(B) ANNOTATIONS AND VISUALS.



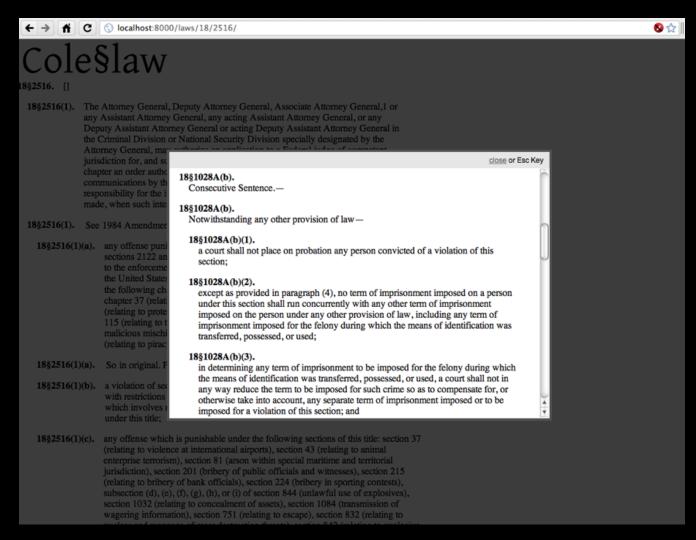
Clickable Statutes program by David Johnson & DoTank



http://dotank.nyls.edu/clickable-statutes

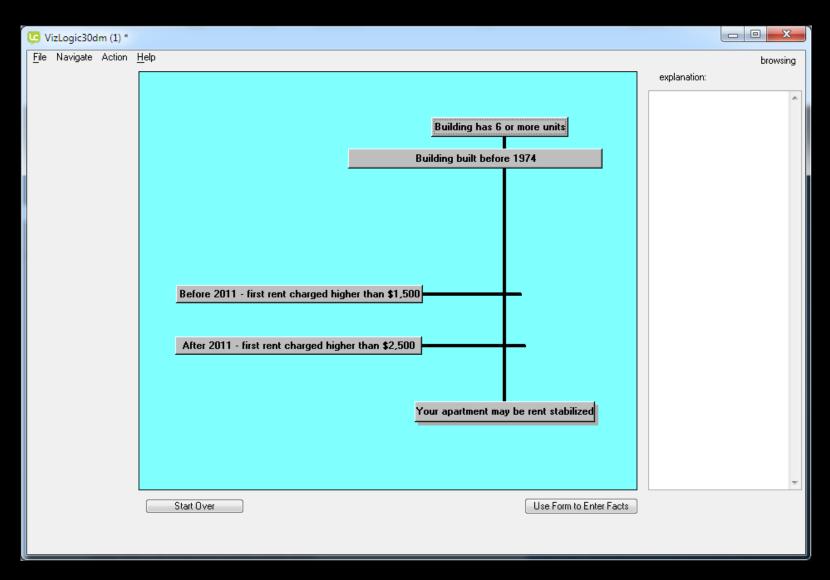
SEC. 202 TOOLS AVAILABLE.

Some work has already been done...



Cole§law by the Sunlight Foundation http://sunlightfoundation.com/blog/2010/06/28/olympics-coleslaw/

SEC. 202 TOOLS AVAILABLE.



Clickable Statutes by DoTank http://dotank.nyls.edu/clickable-statutes/

SEC. 301 CODE MANAGEMENT

- (a) Refine tools to workable state
- (b) Start with pilot project single legal topic/field
- (c) Connect with partners to host "hackathon" events
- (d) Launch
- (e) Grow through crowdsourcing techniques

SEC. 302 DEBUGGING

Bugs:

Seed money

Expertise – legal & programming

Crowdsource structure

Patches:

Legal orgs

Gov3.0 networks

Sandbox/Up Vote model

FEEDBACK?