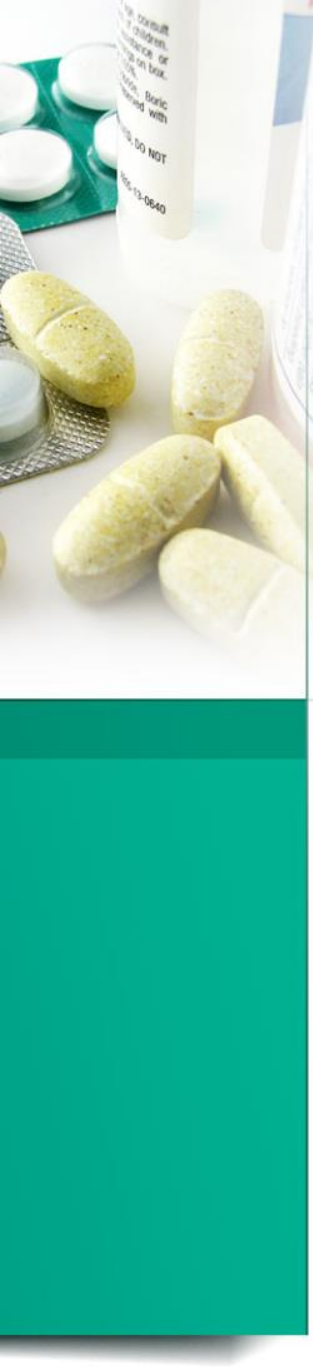
House Bill 43: The Right to Try

Representative Jason Grenn

The Right to Try

"Patients should be free to exercise a basic freedom – attempting to preserve one's own life."

- Christina Corieri, Health Care Policy Analyst



House Bill 43

- **Sec. 1:** Prohibits disciplinary action by the State Medical Board, under specific patient terms. Provides key definitions.
- **Sec. 2:** Physicians, medical team members, manufacturers and distributors acting in good faith are not held liable, with proper informed consent and notification. Also not held liable for choosing not to participate.
- **Sec. 3:** Amends statute limiting the sale and distribution of new drugs to allow for physicians to prescribe and administer under conditions of Sec. 1.
- **Sec. 4:** Precludes hospitals and healthcare facilities from being required to provide increased services.

FDA Drug Review Process

Preclinical Animal Testing & Investigational New Drug (IND) Application

- Drug sponsors conduct preclinical testing in animals
- Upon IND application, results are reviewed
- FDA determines if drug is reasonably safe for human testing

FDA Drug Review Process (cont'd)

PHASE 1 - Safety

- Studies occur after approval of IND application
- Some conducted on healthy volunteers, but not all – depends on purpose of medication
- Determine side effects and toxicity levels

FDA Drug Review Process (cont'd)

PHASE 2 – Efficacy

- Studies begin when drug is determined relatively safe
- Preliminary data on people with specific disease or condition
- Sets stage for scale of Phase 3 studies

FDA Drug Review Process (cont'd)

PHASE 3 – Comprehensive

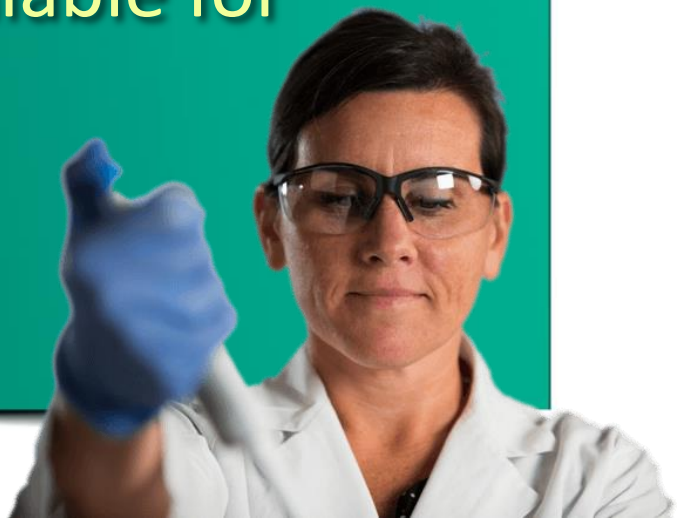
- Studies begin if Phase 2 shows evidence of effectiveness
- Gather more info on safety and effectiveness
- Different dosages, populations and combination with other medications

FDA Drug Review Process (cont'd)

Review Meeting & New Drug Application (NDA)

- Sponsors meet with FDA
- Submit NDA to officially request marketing approval
- FDA has 60 days to decide to file application
- 90% of applications are processed within 10 months of filing

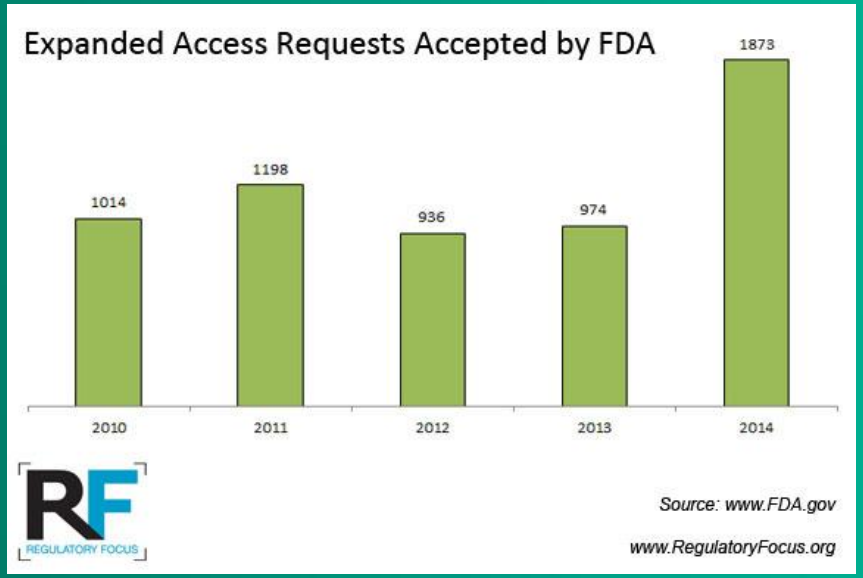
An "*investigational drug, biological product, or device*" in HB 43 has completed Phase 1 and remains in ongoing clinical trials under Phase 2 or 3 or is in the marketing approval process, but is not yet available for general use

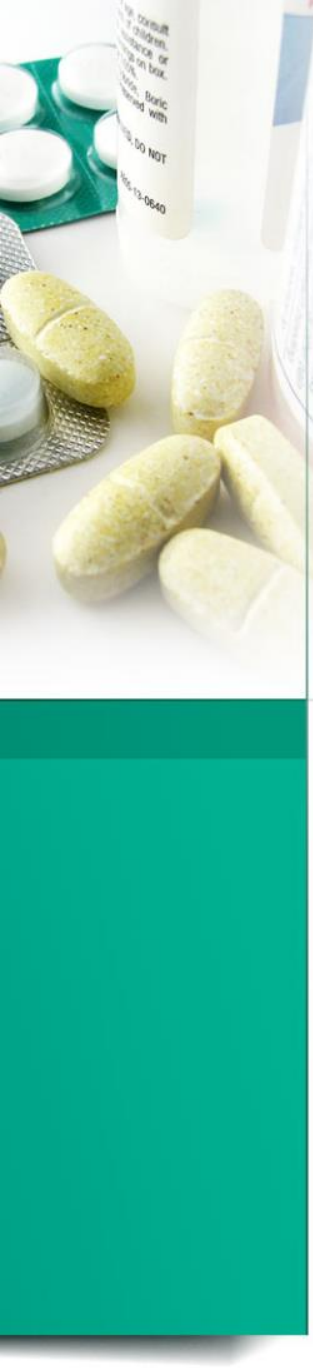


FDA's Expanded Access Program

"Compassionate Use"

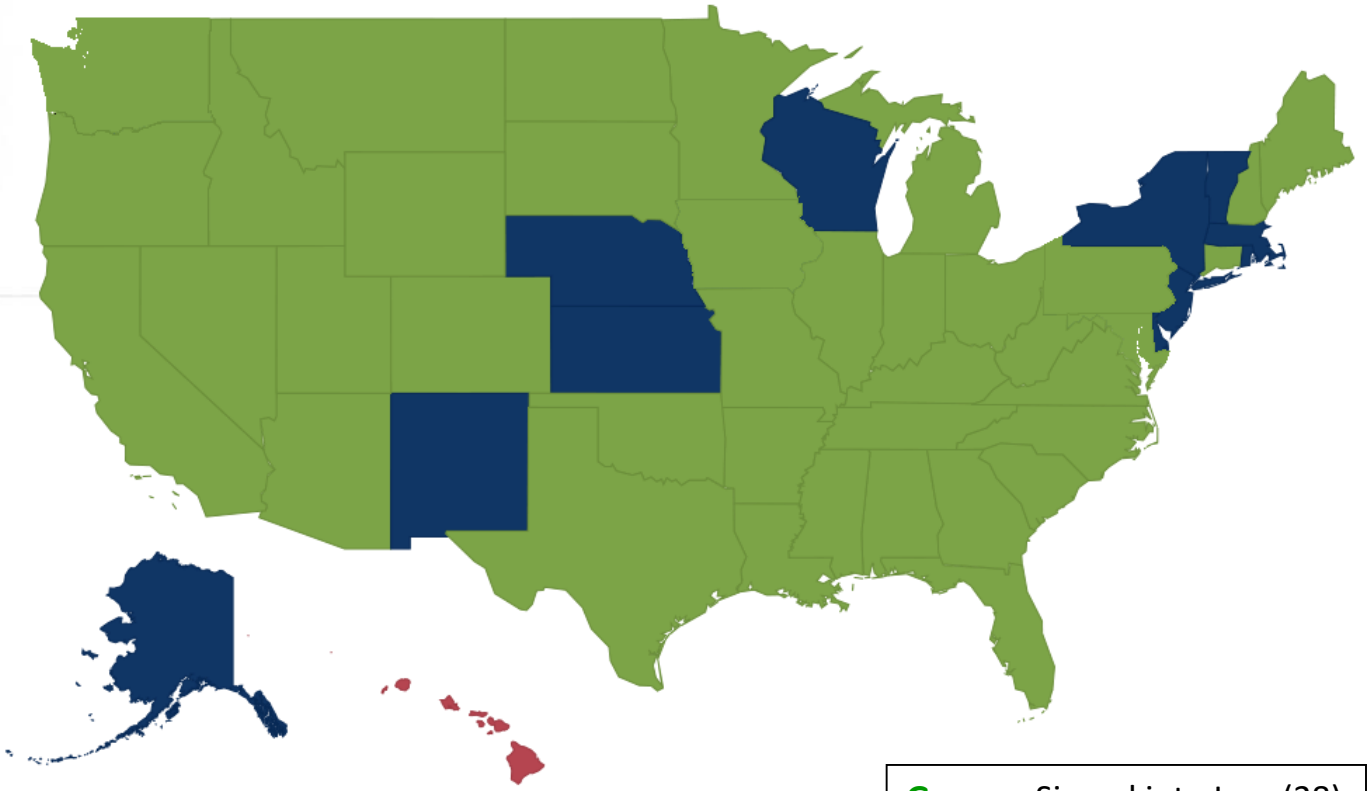
- Approx. 1,200 applicants per year make it through
- Application form has been streamlined, but approval process remains extensive





The Right to Try - A Nationwide Effort

All 50 states have passed or introduced “Right to Try” legislation



Green = Signed into Law (38)
Blue = Introduced (11)
Red = Vetoed (1)

This concludes our presentation for House Bill 43.

Thank you.