



# 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."*

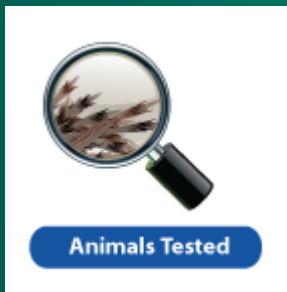
*- Christina Corieri, Health Care Policy Analyst*

A photograph of medical supplies is positioned in the top-left corner of the slide. It includes a blister pack with white and yellow pills, a white plastic bottle with a label that partially reads 'DO NOT', and several loose yellow and white capsules scattered on a white surface.

## 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



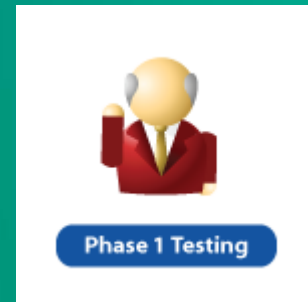
- Drug sponsors conduct preclinical testing in animals
- Upon IND application, results are reviewed
- FDA determines if drug is reasonably safe for human testing



## 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

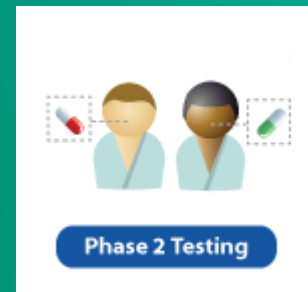




## FDA Drug Review Process (cont'd)

### 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



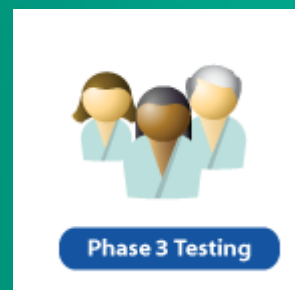




## FDA Drug Review Process (cont'd)

### 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, but is not yet approved for general use by the FDA

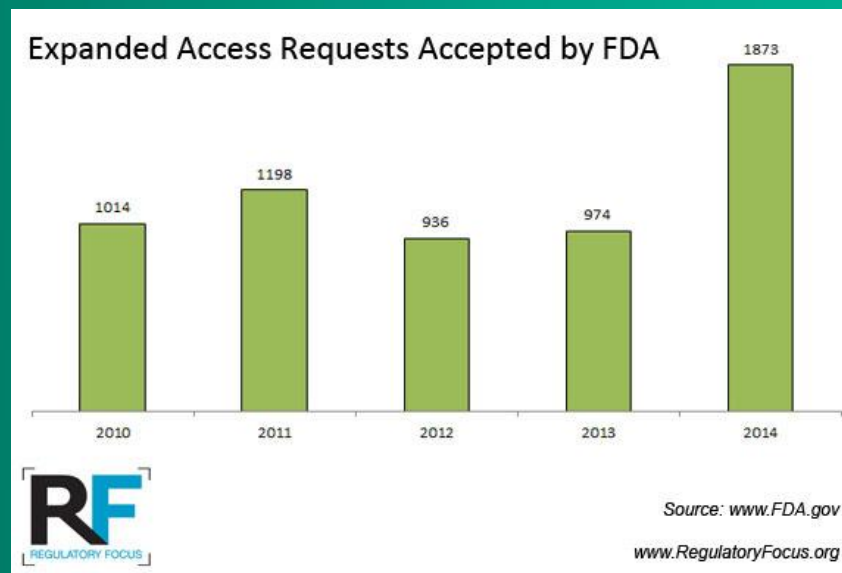




# FDA's Expanded Access Program

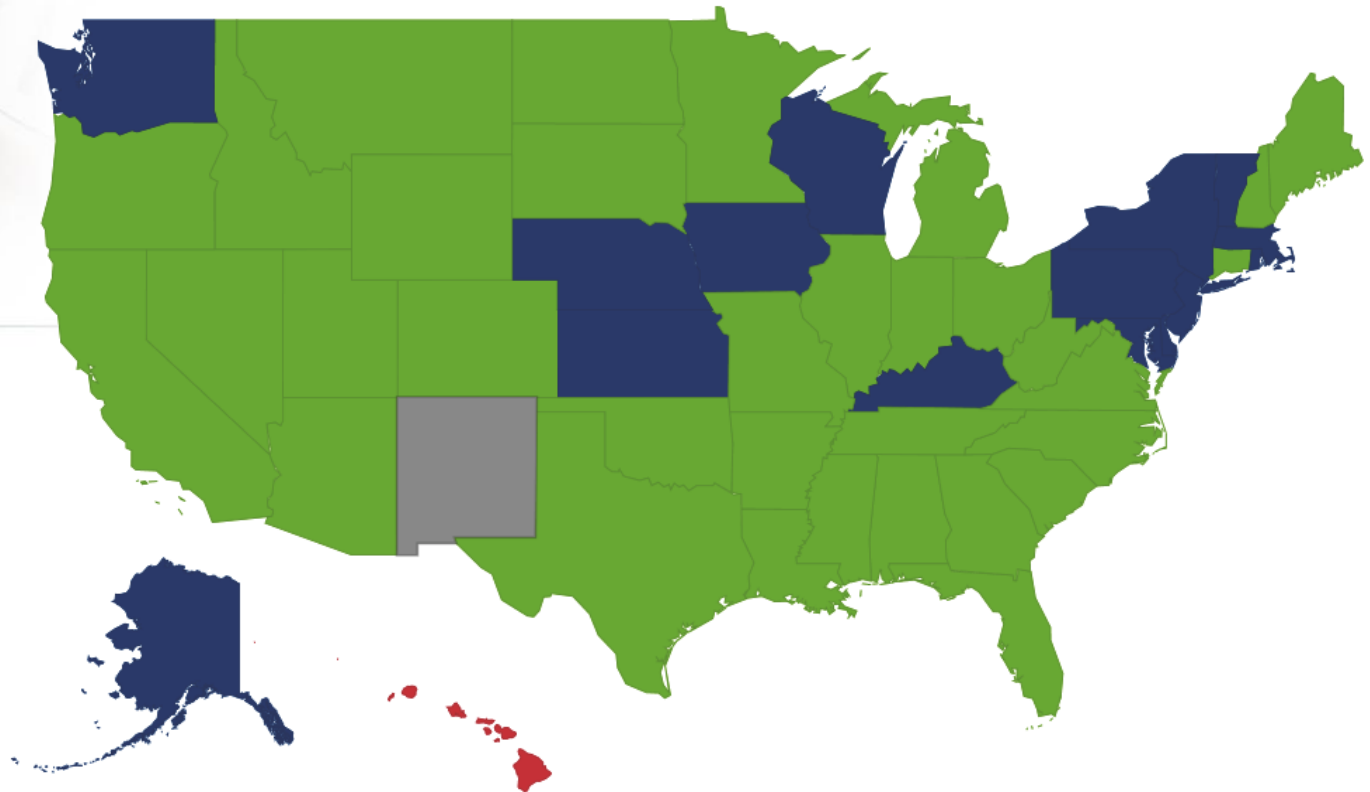
## “Compassionate Use”

- 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

49 states have passed or introduced "Right to Try" legislation



**Green** = Signed into Law  
**Blue** = Introduced  
**Gray** = Not Introduced  
**Red** = Vetoed



This concludes our presentation  
for House Bill 43.

*Thank you.*

