

Compounding Pharmacy

Pharmacy's Past, Present & Future

David G. Miller, RPh

Executive Vice-President & CEO

International Academy of Compounding Pharmacists

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The Basics

- Compounding is defined as the process by which a pharmacist combines or alters drug ingredients according to a doctor's prescription to create a medication to meet the unique needs of an individual human or animal patient.
- A **“triad relationship”** must exist between the pharmacist, the patient and the practitioner.

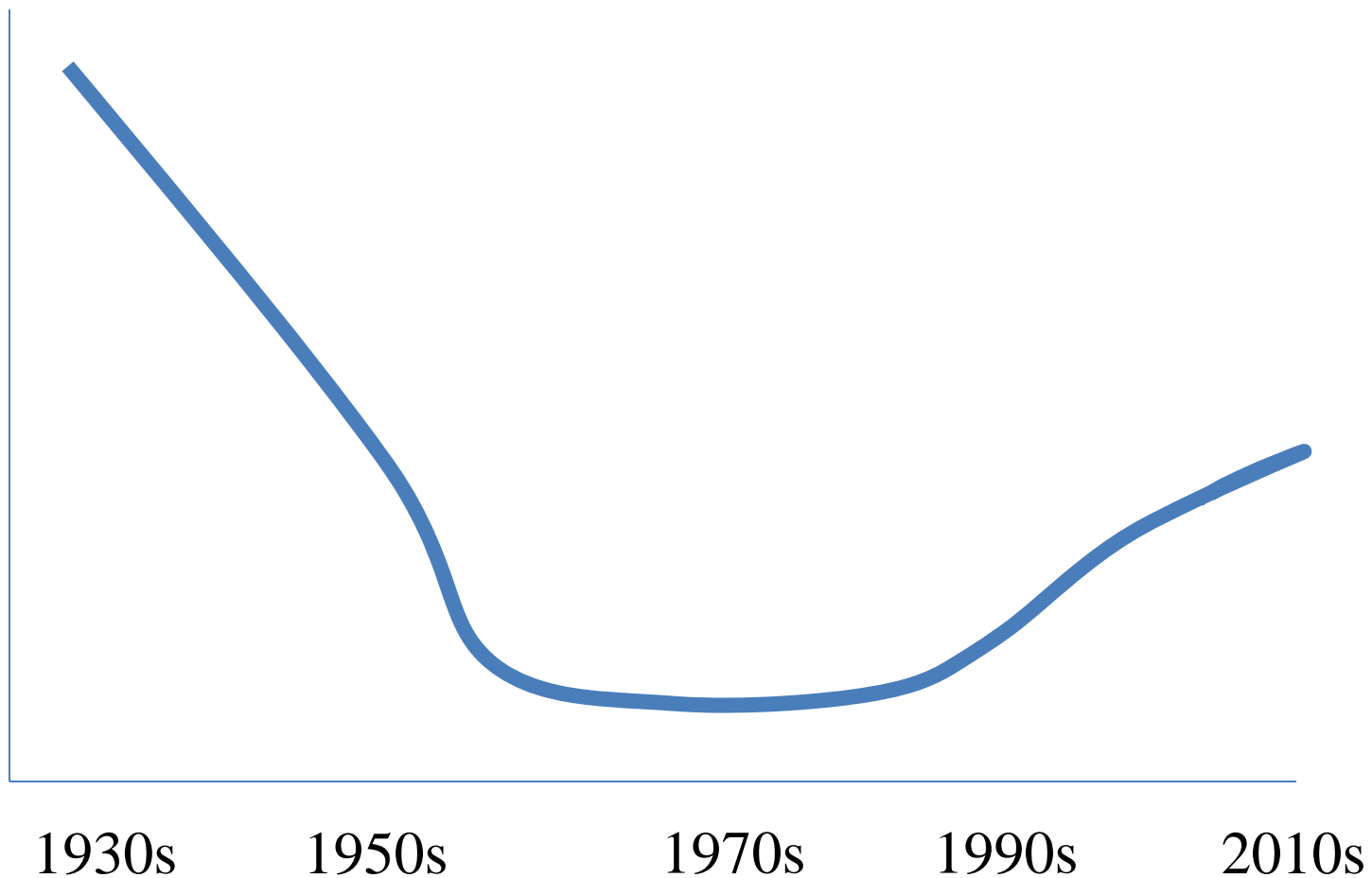


What's Your Perception?

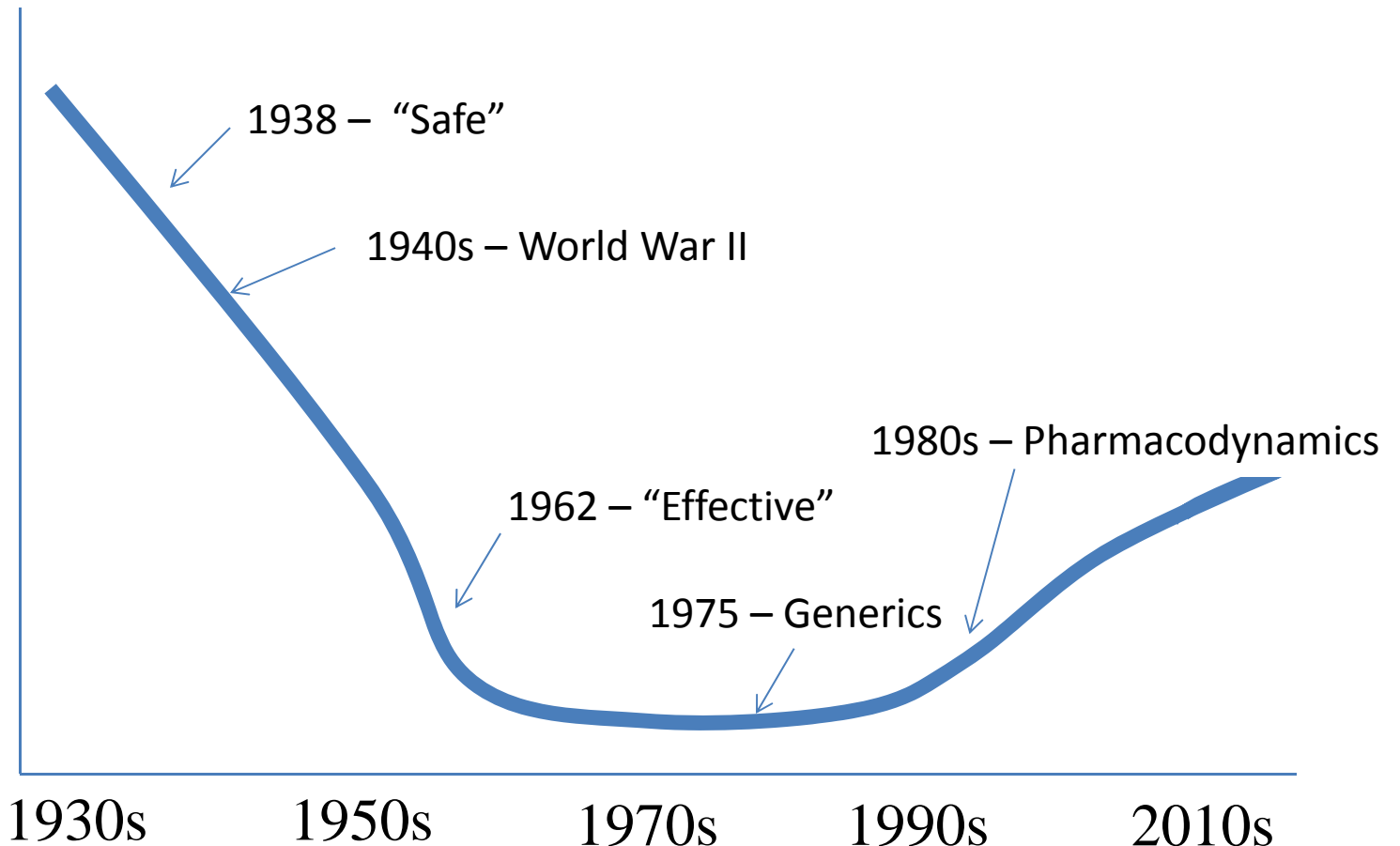
- **Compounded medications:**
 - A) Must be shown to be safe
 - B) Must be shown to be effective
 - C) May be only prepared with FDA-approved drugs
 - D) A & B
 - E) None of the above
 - F) Ummm....



Everything Old is New....



Everything Old is New....



Compounding Resurgence

- Scientific Knowledge
- Consumerism
- Drug Shortages

Compounding Resurgence

Scientific Knowledge

- Aging Population
 - Slowing metabolism
 - Decreased CrCl, hepatic function
 - Dysphagia
 - Pharmacodynamics – decreased body mass, decreased VoD (volume of distribution)
 - CMS mandates for chart reviews in SNFs
 - “Beard’s List”

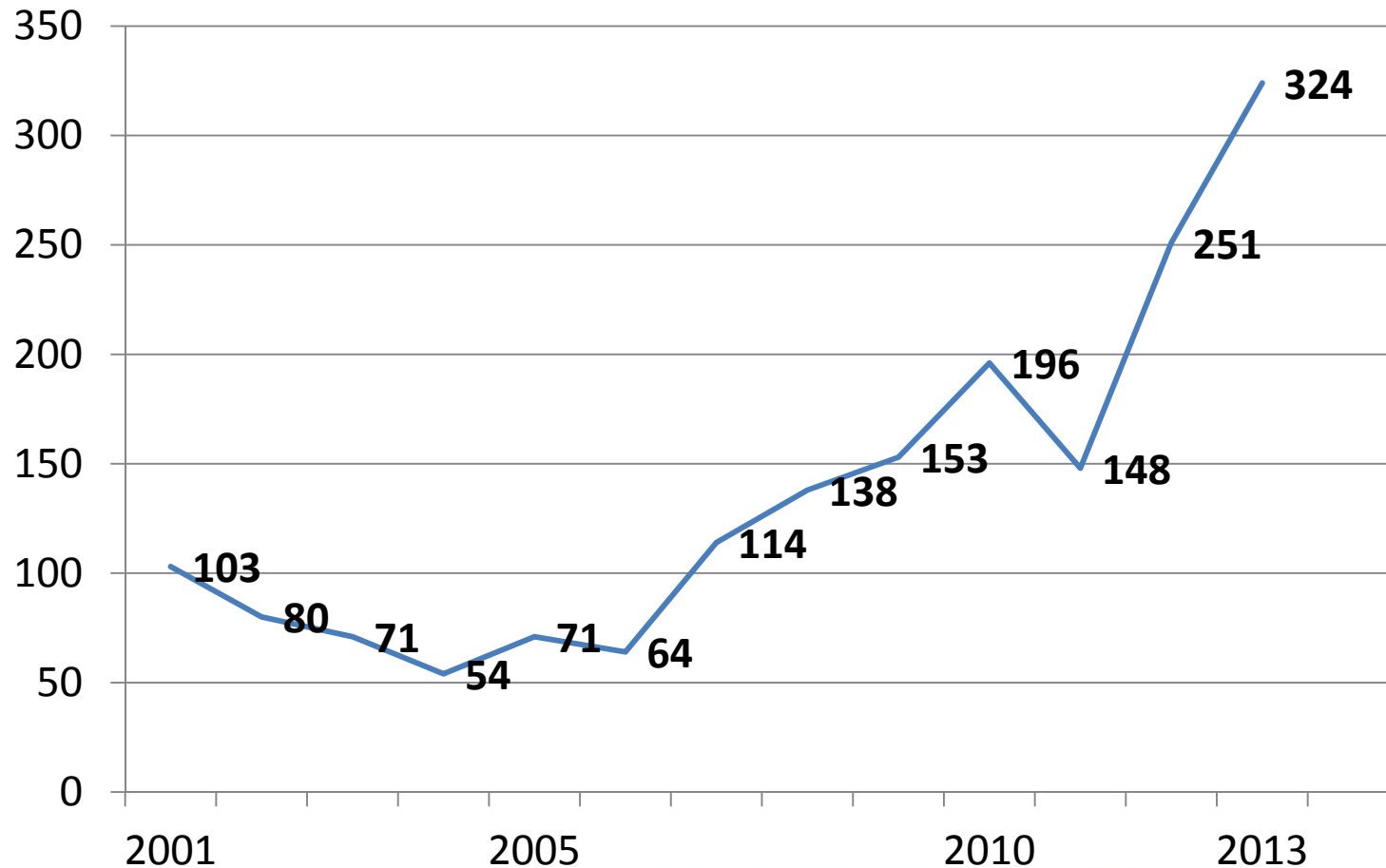
Compounding Resurgence

Consumerism

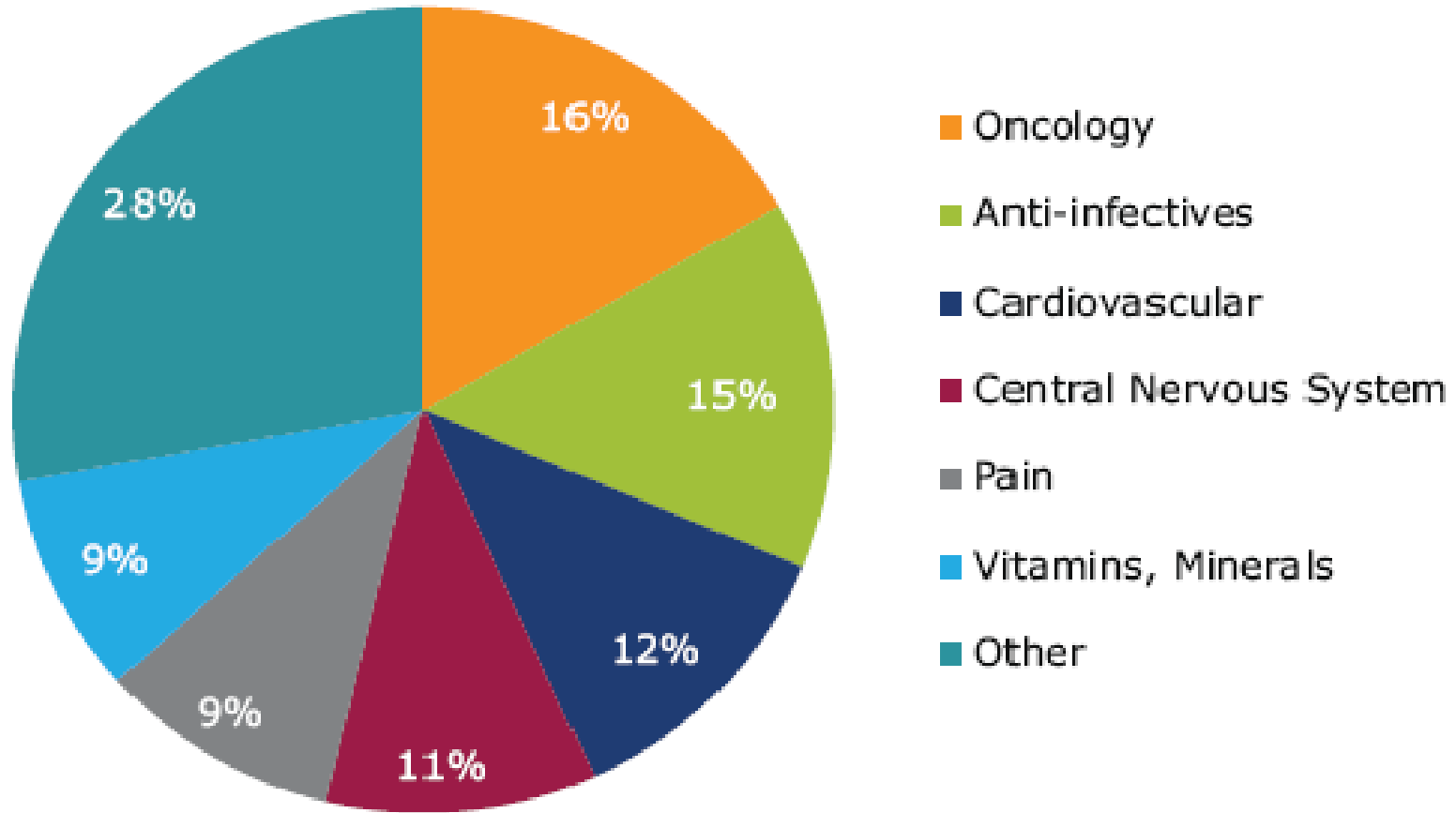
- Access to internet/information
- Interest in non-traditional medicine
- Expectation of “just for me” care and services
- Distrust of pharmaceutical industry
 - Hormone replacement therapy
 - Recalls

Compounding Resurgence

Drug Shortages



Impact on Health Care



Source: IMS National Sales Perspectives, Sep 2006 – Aug 2011

Did You Know?

- Which of the following commonly used nutritional supplements are in **drug shortage**?
 - A) Ascorbic acid for injection*
 - B) Sodium phosphate*
 - C) MVI/MT for adults*
 - D) MVI/MT for infants/children*
 - E) Let me check today...



How Are Compounders Regulated?

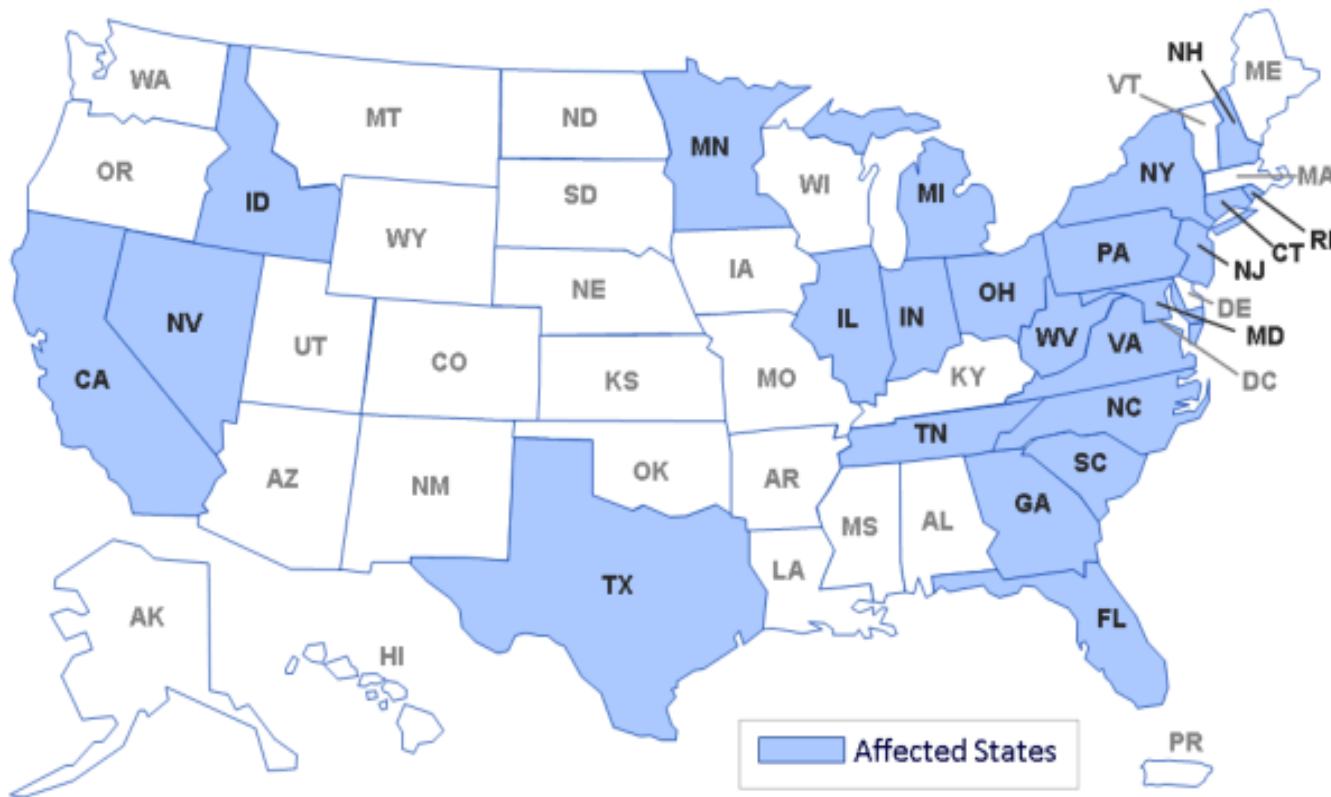
- **State Boards of Pharmacy:** adherence to practice requirements, licensure, permits, USP standard enforcement
- **Food & Drug Administration (FDA):** integrity of the drugs and Active Pharmaceutical Ingredients (APIs) which they order, store and use, cGMP standard enforcement
- **Drug Enforcement Administration (DEA):** handling of controlled substances used in the preparation of compounded medications.



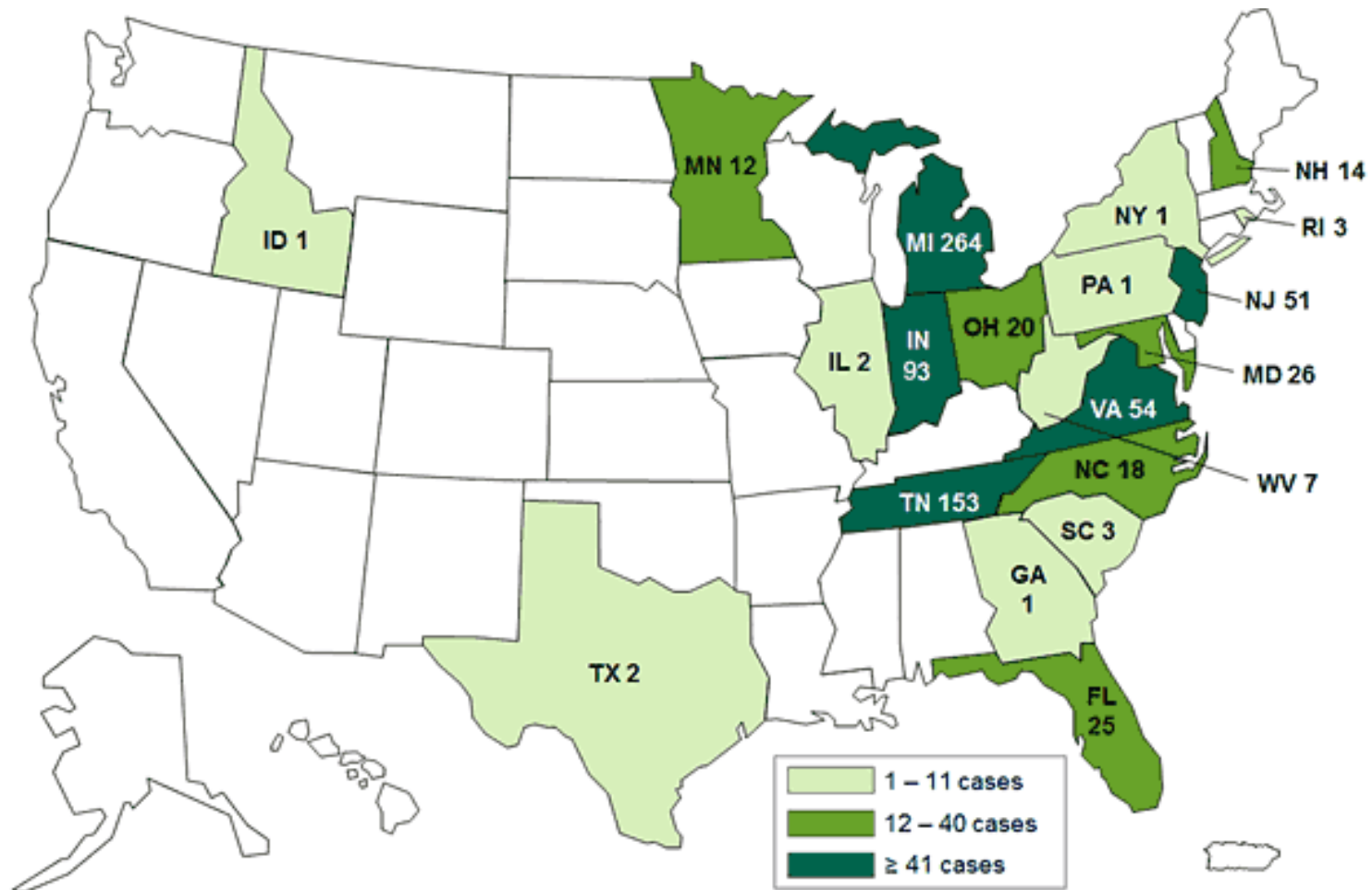
NECC Tragedy



17,676 Doses Shipped



745 Cases, 65 Deaths



Senate 959

- Bipartisan support, combined with T&T
- Creates a new “compounding manufacturer” category
 - Any sterile, non-patient specific drug
 - Interstate shipment
- Extensive new authority for FDA to prohibit certain types of compounding
 - “Difficult”, APIs, commercially available
- Conflicting sections with state law
 - Office-use, anticipatory compounding



House 3089

- Republican driven
- Focus on “cleaning up” FDCA 503(a)
- Initially no expanded authority for FDA
- Creates a new “outsourcing facility” category
 - Sterile, non-patient specific drug
 - Interstate shipment over 5%
- Requires intercommunication between FDA and state Boards of Pharmacy
- Conflicting sections with state law
 - Office-use, anticipatory compounding



House 3204

- Compromise bill dropped 26 September
- Provides for
 - Creation of “outsourcing facility”
 - Sterile non-patient specific (office-use) compounders
 - Does not have to be a pharmacy
 - May fill patient specific prescriptions
 - Voluntary (?)
 - Reaffirmation/re-enactment of 503(a)
 - Patient specific compounded preparations
 - Anticipatory compounding
 - “Do not compound” list
 - New penalties

House 3204 - Scenarios

- Passed House on voice-vote (28 September)
- If enacted...
 - New marketplace competition
 - Questions regarding Boards of Pharmacy authority over “outsourcing facilities”
 - “Office-use” is not recognized in 503(a)
 - Voluntary registration in a environment of so-called enforcement discretion
- Need for...?

States are Changing, Too!

- 63 state bills in 2013
- 27 states overhauling regulations
- Key areas
 - Mandatory USP <795> and <797> compliance
 - Registration of sterile compounders
 - Registration/increased requirements for non-resident pharmacy permit holders
 - Changes to “office-use” dispensing
 - **ACCOUNTABILITY**



Reimbursement – Next Up!

- Public and private plans denying coverage for compounds
 - Non-FDA approved drugs
 - Increasing costs and percentages
 - Upcoming open enrollment
- State Exchanges
 - Will compounds be covered?
 - Will compounders to included as providers?
 - What copay tiers/deductibles?



Questions, Questions

- Makena[®] vs. 17-P
- Medicaid vs. Medicare Part B vs. Part D
- Coverage of APIs (bulk ingredient)
- Increasing % of compound claims
- Increasing \$/Rx compound claims
- What else you got?

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