

Pharmacist opinions on the burden of behind-the-counter pseudoephedrine regulations, New York State 2007

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Background

- **Combat Methamphetamine Epidemic Act 2005**
 - **Federal Act requires documentation of all pseudoephedrine sales**
 - **Moved to Behind-the-Counter**
 - **No prescription is needed (except Oregon)**
- **Rationale: Reduce local methamphetamine production**
 - **Pseudoephedrine is a common chemical used**
- **Previous restrictions on ephedrine and bulk pseudoephedrine purchases**
 - **Effective, however shift to smaller quantities of pseudoephedrine occurred**

Combat Methamphetamine Epidemic Act of 2005

Title VII of Public Law 109-177

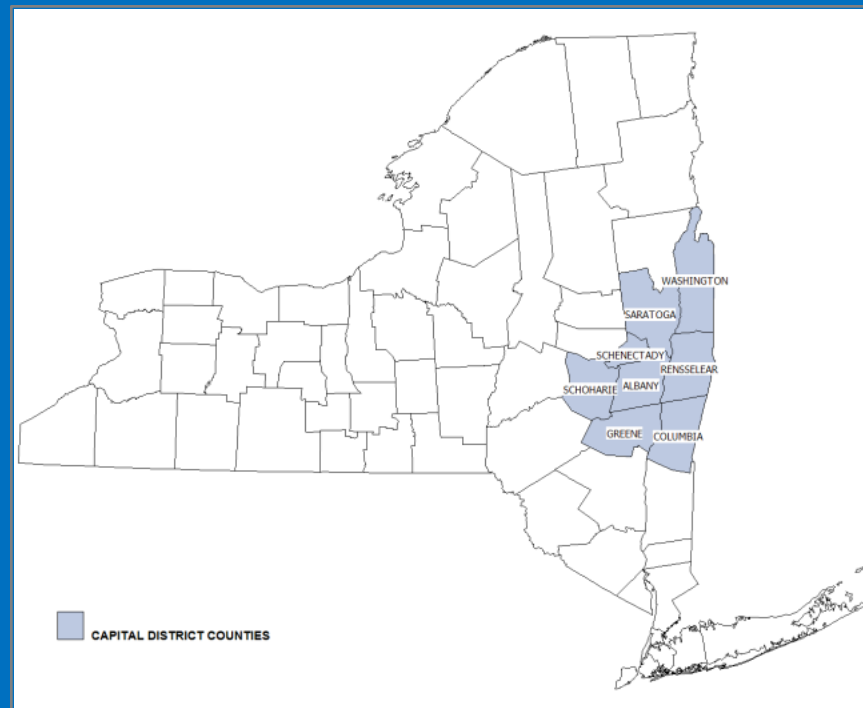
- Pseudoephedrine moves Behind-the-Counter
- Sales restricted to specific amounts per person
 - 3.6 grams per purchase per day
 - 120 30mg tablets
 - 7.5 grams per month
 - 288 30mg tablets
- All sales over 60mg must be recorded
 - Name, Address, Date, Time, Amount
- All employees who sell pseudoephedrine must be trained
- Implemented September 30, 2006

Effects on the Pharmacy Environment

- Does movement of pseudoephedrine behind the counter...
 - Increase pharmacists time burden?
 - Affect sales?
 - Impact the availability of methamphetamine?
 - Impact the production of methamphetamine?

Sampling

- Sampling Frame
 - Eight counties of the Capital Region
 - NYS Licensure database for pharmacies
 - Phonebooks
 - Corporate websites
 - Changes made during visits to pharmacies



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Sampling

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 - Eight counties of the Capital Region
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 - Phonebooks
 - Corporate websites
 - Changes made during visits to pharmacies
- **All pharmacies were sampled**
- **Visits**
 - Grouped into geographic clusters of 4-7
 - Randomized to day of week and time of day

Motivation for Extending Study Region

Corporate FAX to all Capital Region Pharmacies:

“It has been brought to our attention that SUNY Albany students have been visiting our stores and asking employees to take a survey. Please communicate with your staff that per [our] policy any questions should be referred to Corporate Communications ...”

Motivation for FAX

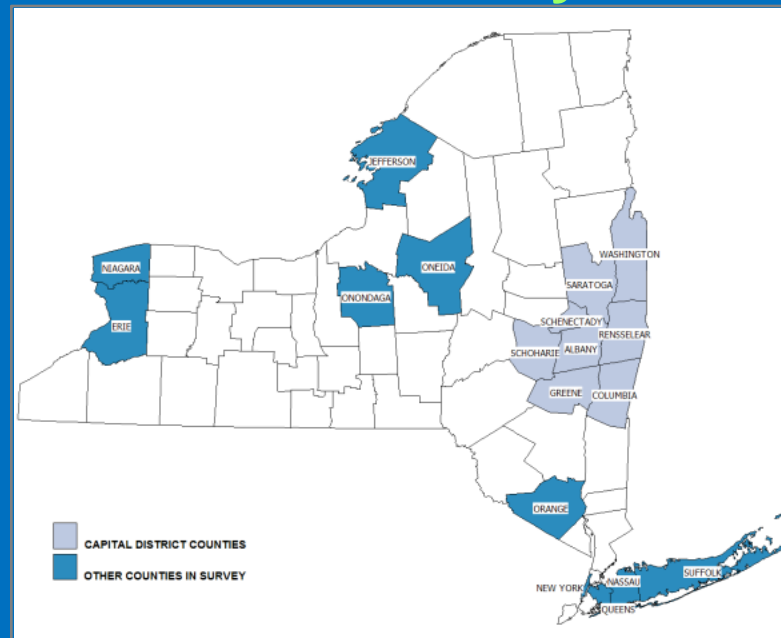
- On April 3, 2007 ABC's News Program 20/20 aired a story about mistakes in the pharmacy

“Who is that person behind the counter, and are you getting the prescription your doctor ordered?”



Other Region Sampling

- Convenience Sampling
 - 9 counties in New York State
 - Selected region
 - Randomly selected pharmacies
- Visits
 - Research assistant availability



Sample Pharmacist

- Pharmacist
 - On duty pharmacists eligible
 - Randomly selected a pharmacist
- Refusals
 - Stated Corporate Policy
 - Not revisited
 - Stated lack of time or disinterest in study
 - Capital Region pharmacies revisited and another on duty pharmacist was selected into study at time of visit

Survey Measurements

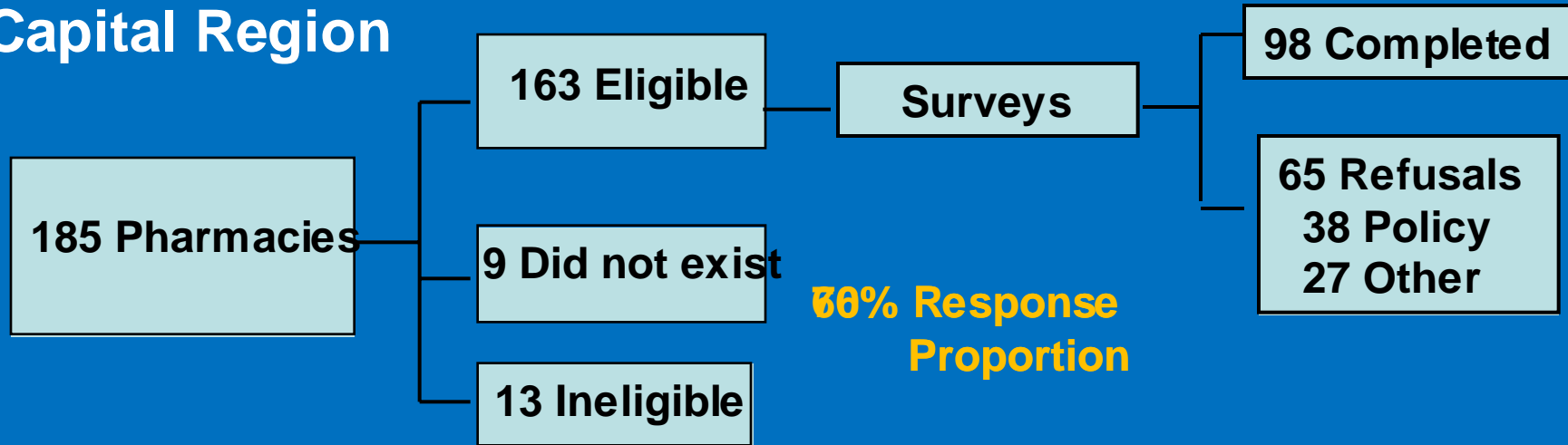
- Domains
 - Perceived time
 - Type of recording system
 - Paper based
 - Computer based
 - Location of sale
 - Pharmacy
 - Other
 - Pharmacists' perceptions of regulation impact
 - Production
 - Availability

Survey Measurements

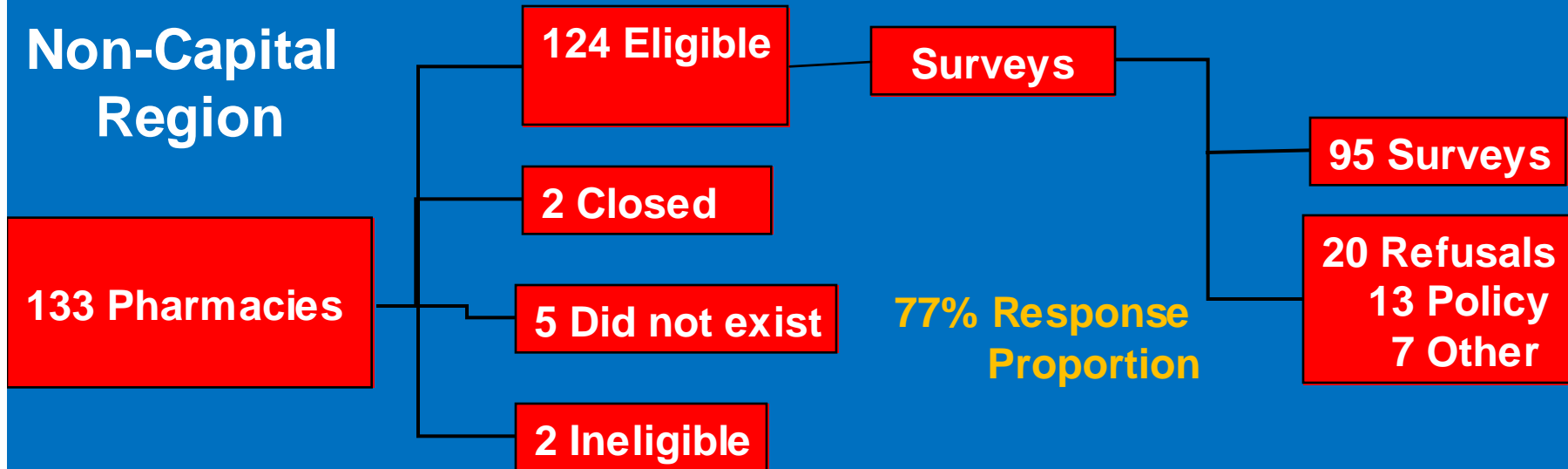
- **Perceived burden**
 - Record keeping is unduly burdensome
- **Perceived impact on sales**
 - Sales of pseudoephedrine products have been reduced
- **Perceived effectiveness**
 - Production of methamphetamine has been reduced
 - Availability of methamphetamine has been reduced
- **Scale: Strongly agree, Agree, No opinion, Disagree, Strongly disagree**

Response

Capital Region



Non-Capital Region



Respondent Characteristics

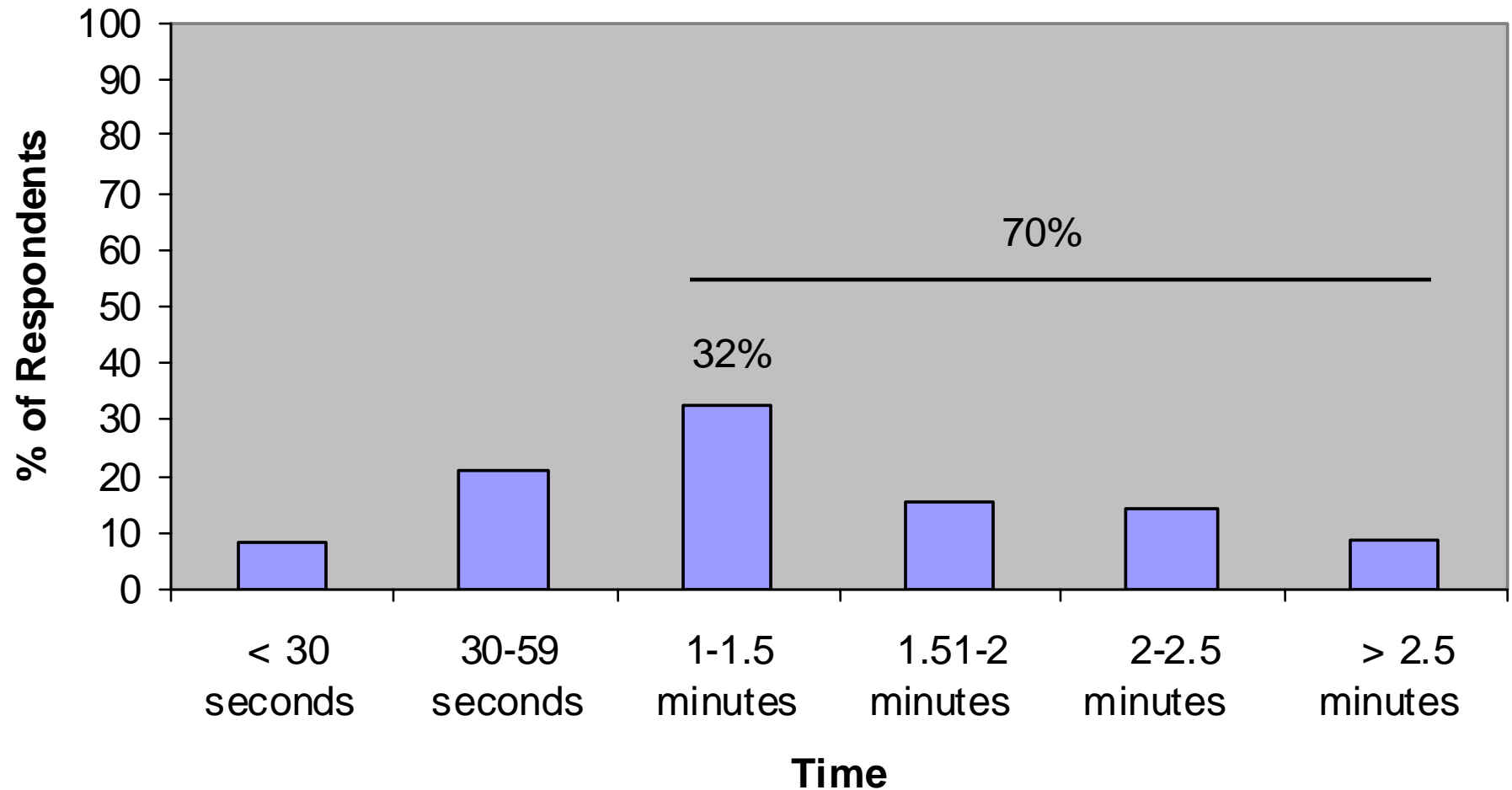
- Respondents

- 52% male
- 64% 31 to 50 years of age
- 86% white
 - Urban regions – approximately half were non-white
- 77% Bachelors of Pharmacy

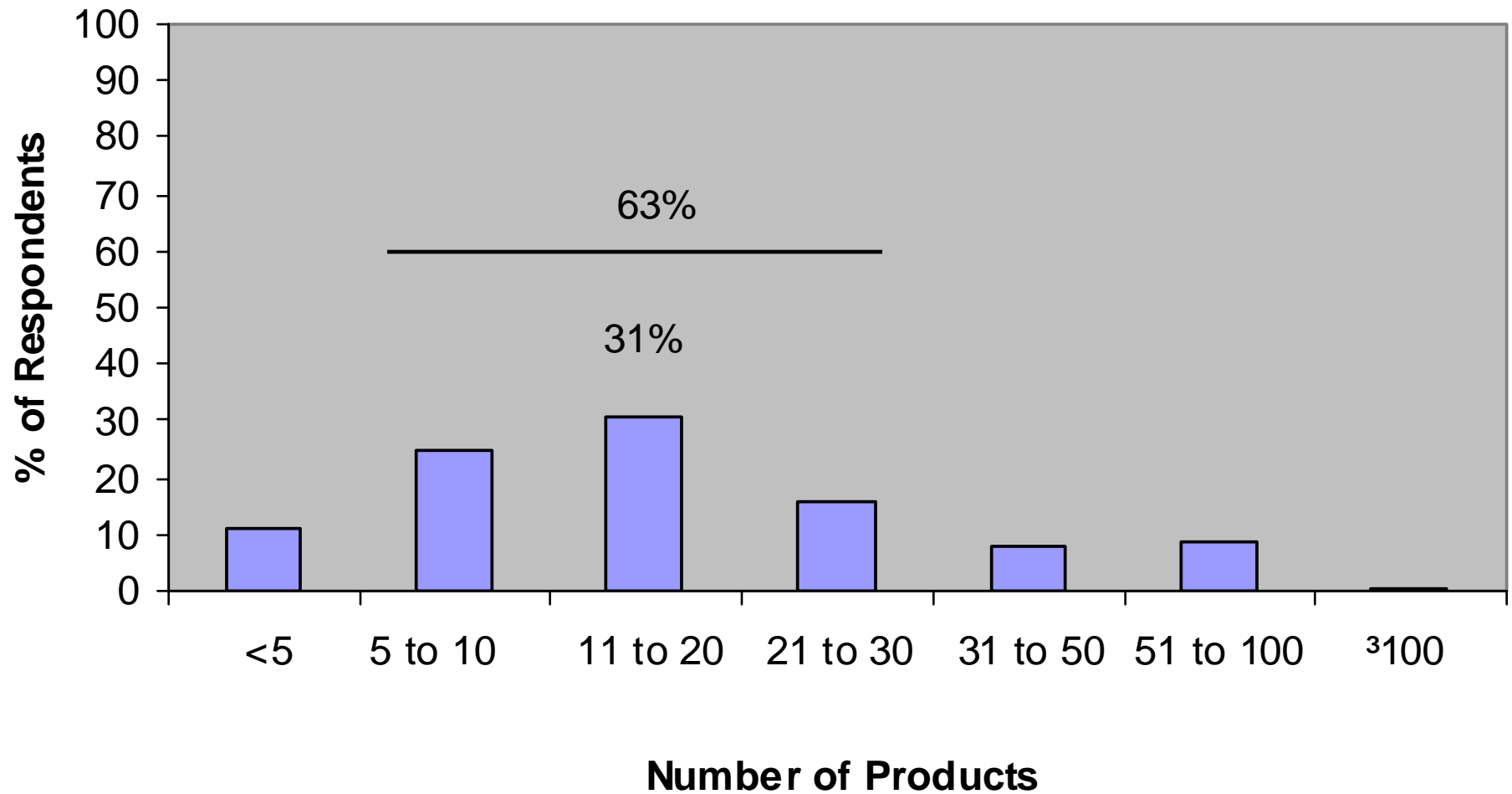
- Pharmacies

- 48% filled more than 1000 Rx per week
- 79% report paper based recording system for Regulation
- 89% report sales only in pharmacy area

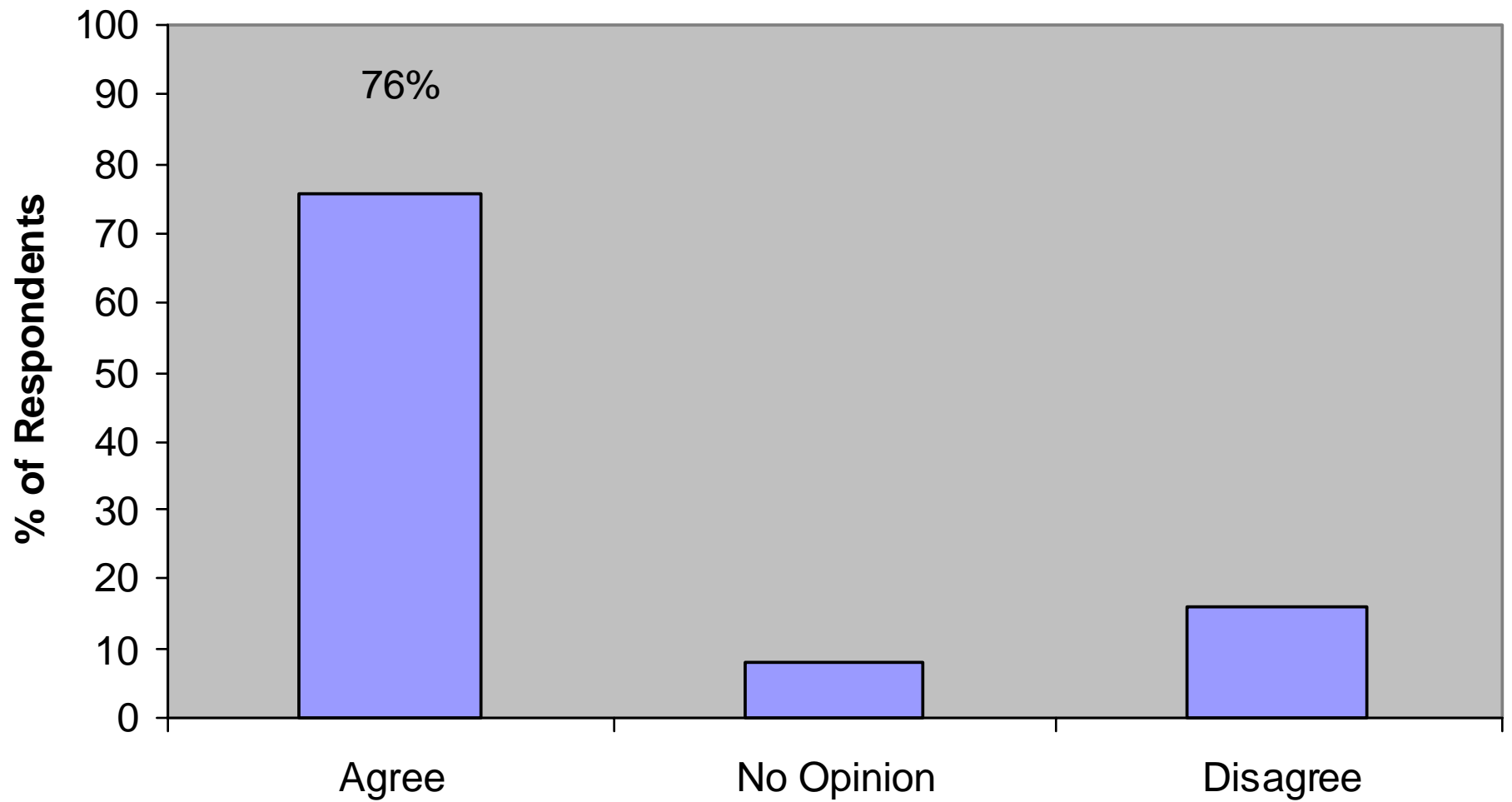
Reported Time Spent Recording Pseudoephedrine Sales



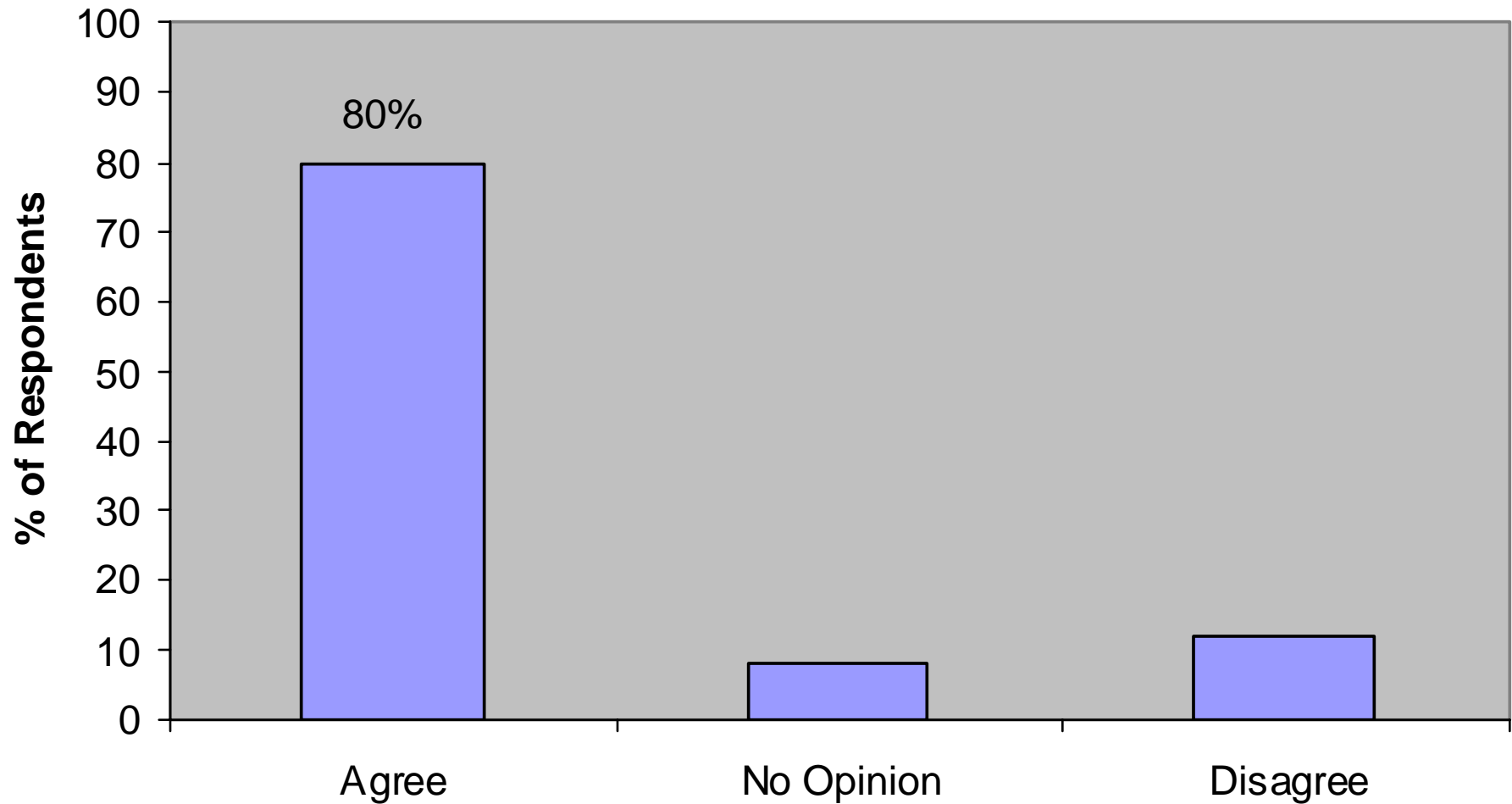
Reported Number of Pseudoephedrine Sales per Week



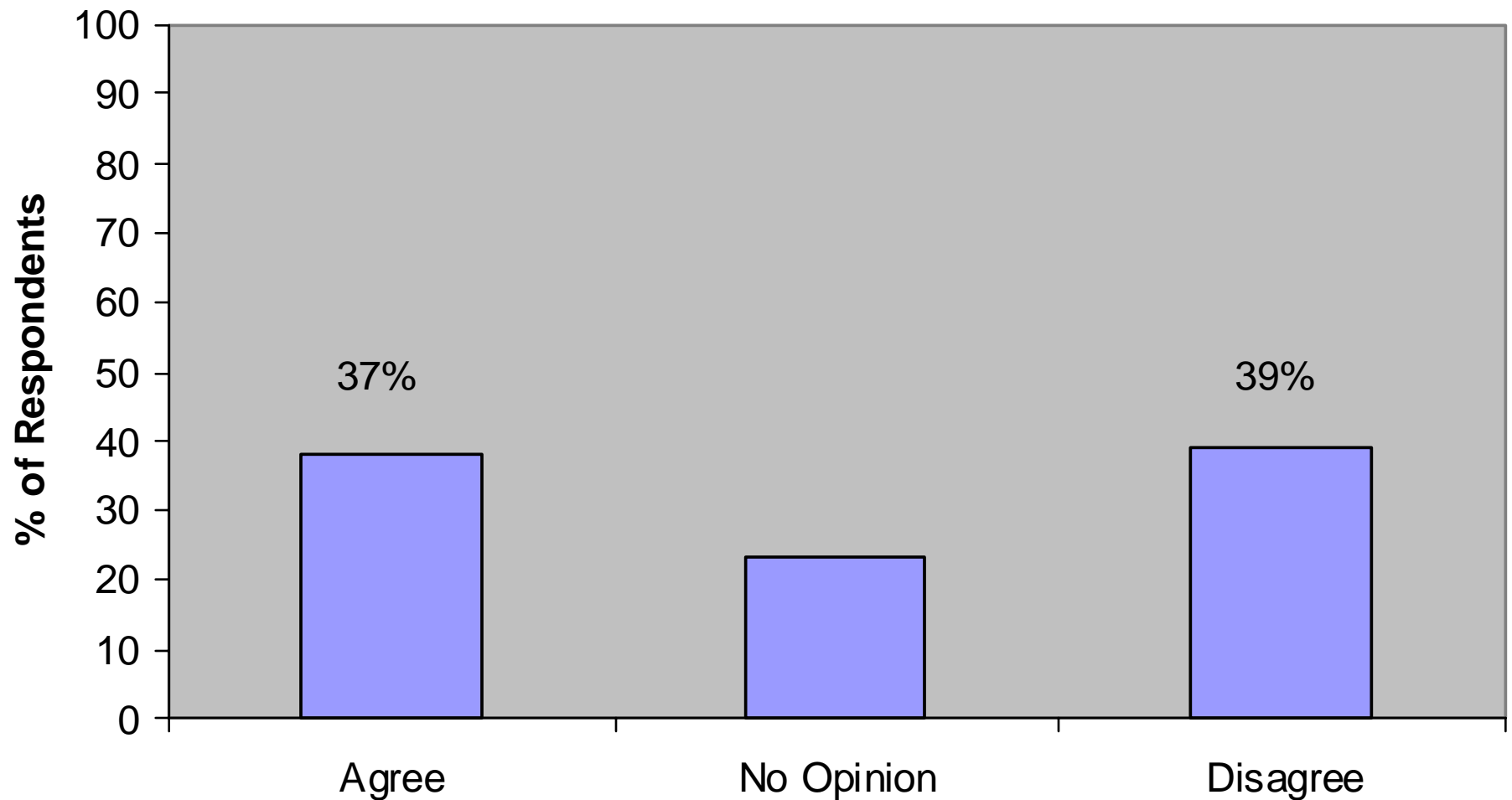
The record-keeping makes this regulation unduly burdensome



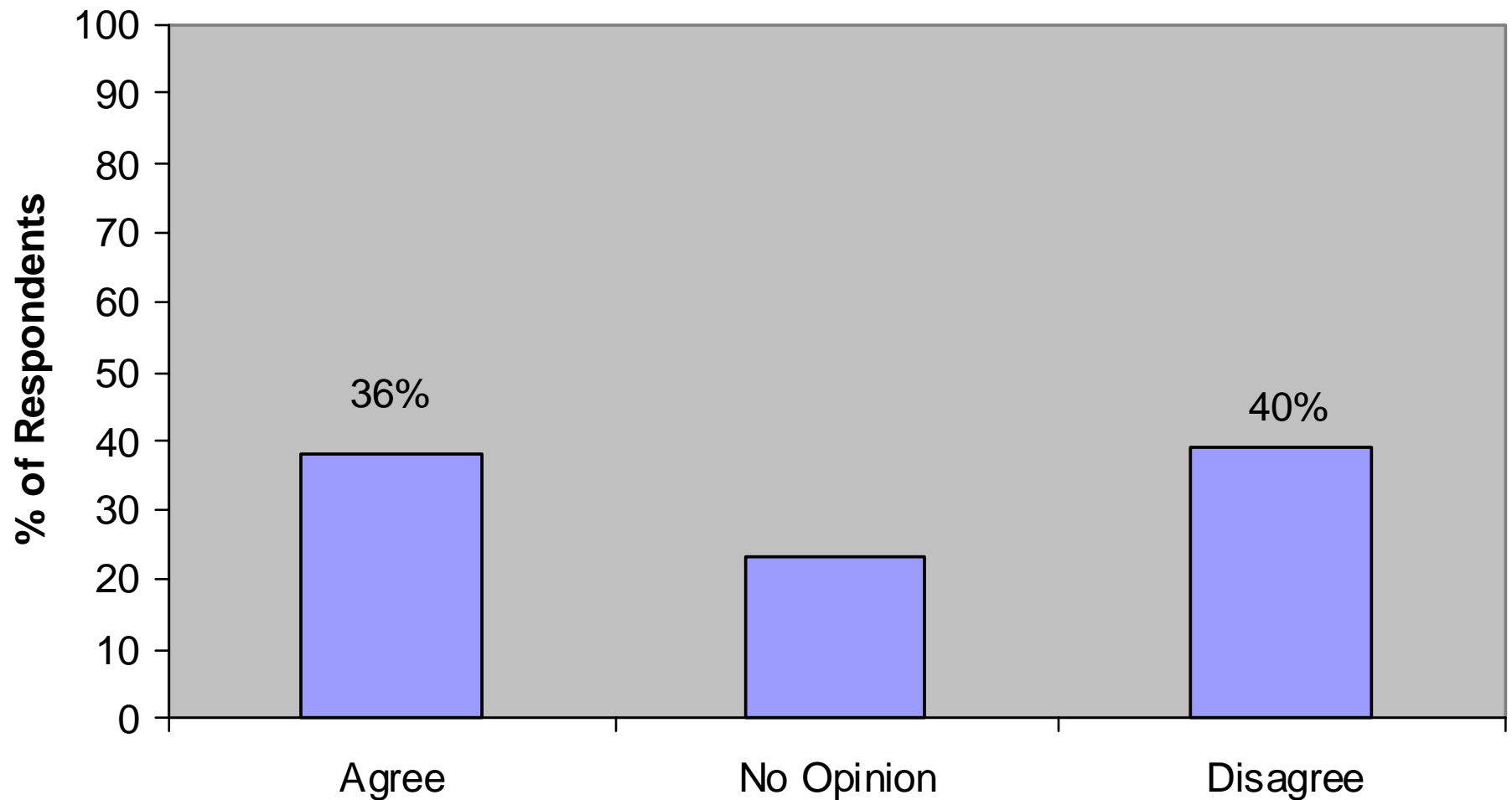
Regulations have resulted in reduced sales of these products



Restrictions make a positive impact on preventing illegal *Production* of methamphetamine



Restrictions make a positive impact on preventing illegal *availability* of methamphetamine



Results

- Perceptions were analyzed among strata of:
 - Age
 - Gender
 - Level of school
 - Census tract income
 - Population density
 - Volume of prescriptions filled per week
- No association between perceptions and these factors were seen

Discussion

- Pharmacists felt that regulations were unduly burdensome
 - However, 80% reported their staff spends less than 1 hour per week
 - Pharmacists may just be too busy
- Pharmacists felt pseudoephedrine sales have been reduced
- Pharmacists question the effectiveness of legislation to control methamphetamine supply in region

Limitations

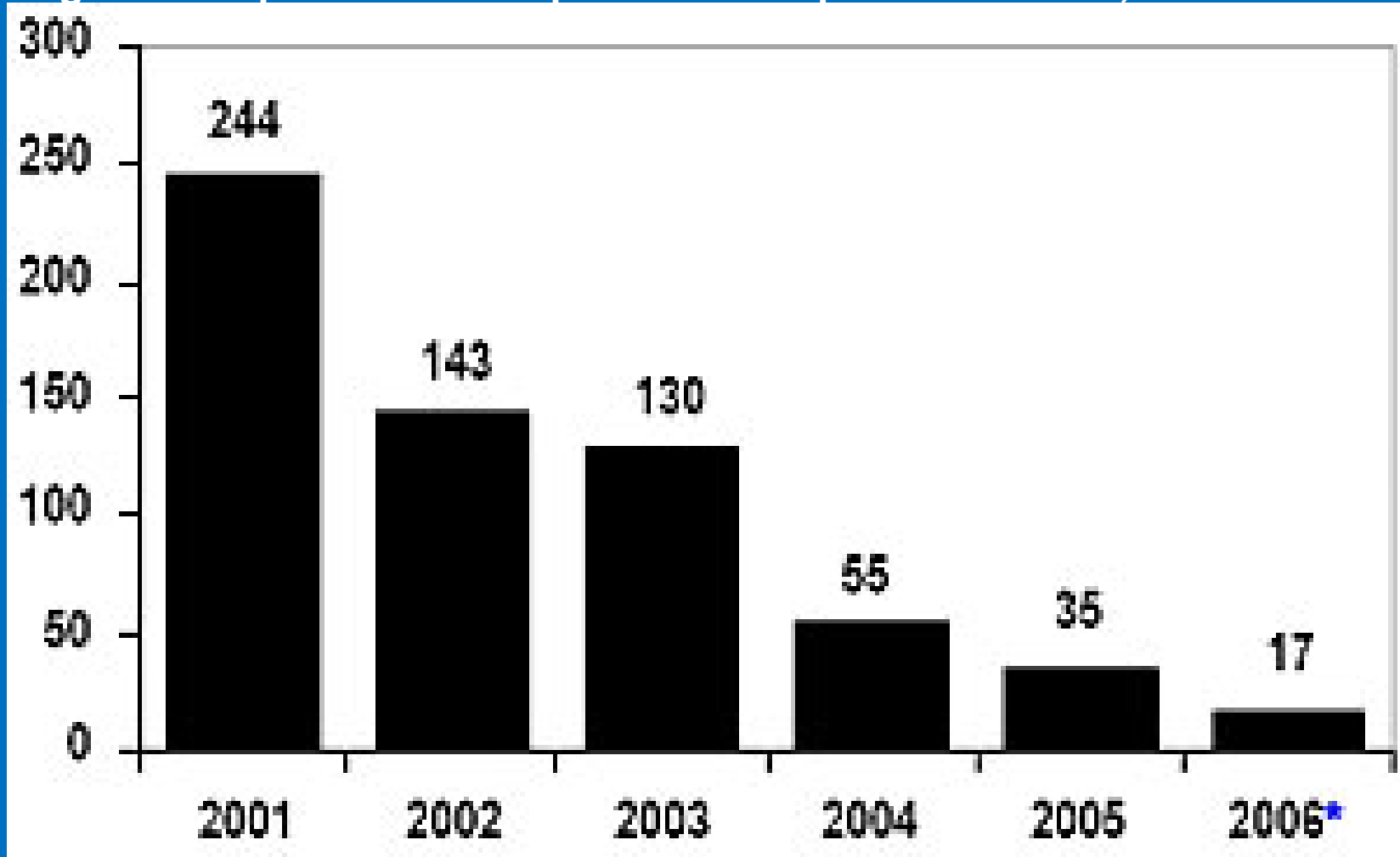
- Pharmacists response due to survey policy
 - Similar responses in both regions after removal of faxed pharmacies
- Difference in sampling between regions
 - Both regions responded similarly to questions
- Inaccurate representation of true time burden
 - Record keeping is not the only time burden associated with sales

Conclusion

- Pharmacists feel new regulation is burdensome and affect sales
 - Computer based systems may:
 - Reduce time burden
 - Change perceptions of effectiveness
- Pharmacists have mixed opinions about the effectiveness of regulations
 - Feedback to pharmacists is needed
- More studies are needed to assess the economic impact
- More studies are needed to assess methamphetamine arrests, hospitalizations, deaths, etc. due to regulation

The Methamphetamine Problem

Figure 1. Reported Methamphetamine Superlab Seizures, 2001-2006.

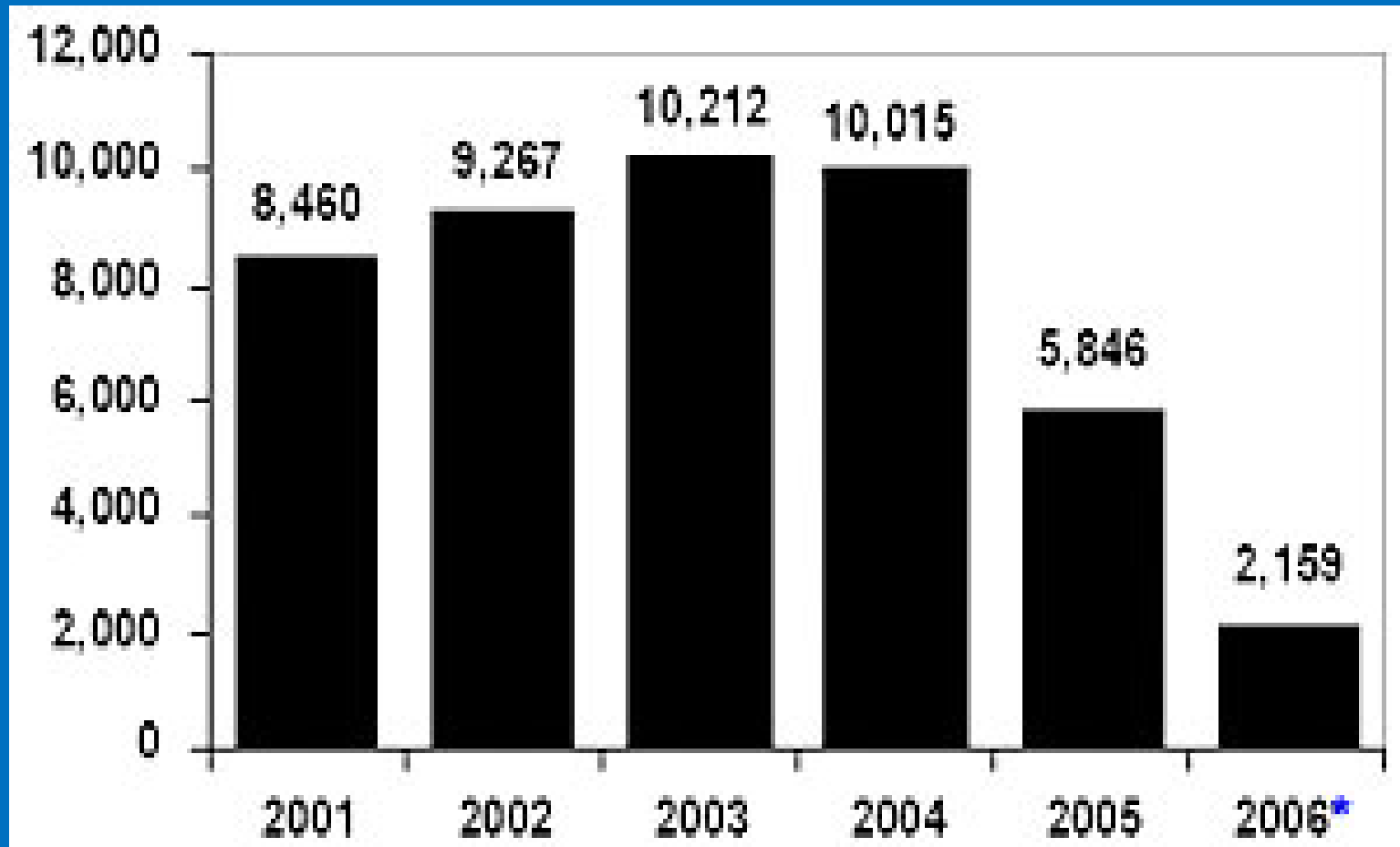


Source: United States Drug Enforcement Agency
National Clandestine Laboratory Seizure System (Run date--September 13, 2006).

*Data for 2006 are incomplete.

The Methamphetamine Problem

Figure 2. Reported Methamphetamine Laboratory Seizures, 2001-2006.



Source: United States Drug Enforcement Agency
National Clandestine Laboratory Seizure System (Run date--September 13, 2006).

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