



**Pharmaceuticals Management Workshop  
Houston-Galveston Area Council  
October 27, 2009**

# ***Unused and Expired Medicines (UEMs): A Public Health Challenge***

***Presenter:***

**Matthew Mireles, Ph.D., M.P.H.**

Community Medical Foundation for Patient Safety  
*[www.communityofcompetence.com](http://www.communityofcompetence.com)*



# Community Medical Foundation for Patient Safety

- Established in 2003, registered in Texas 2004
- Philosophy based on leadership and the *Community of Competence™ (Com.Com)*
- A leader in research and educational programs on *patient safety* and *healthcare quality*
- Goals strongly support humanistic, patient-centered healthcare system and inclusion of the patients and families in all aspect of healthcare



# Community Medical Foundation for Patient Safety--Highlights

- Recognized by U.S. DHHS as Patient Safety Organization #29 (2008)
- Recognized by U.S. EPA (part of funding requirements for drug take back, 2009)
- UEM Project presented at U.S Congressional hearings (2009)
- UEM Project under consideration for the Texas Environmental Excellence Award (2009)
- Faculty members of the National Patient Safety Foundation, Sigma Xi, American Society for Quality Health Care Division



# *Com.Com* as Research Framework for the Unused & Expired Medicines (UEM) Project

- Use framework and methods of *Com.Com* empirically
- Develop, implement, and evaluate models to safely and legally collect and destroy consumers' UEMs from homes
- Develop data repository to systematically characterize and report regional and national trends
- Expand UEM project into a national system



# Timeline and Benchmarks for UEM Project

- 2002** Maine Benzodiazepine Study Group
- 2003** LD1826 (ME) enabling house bill, drug take-back
- 2004** The National Unused and Expired Medicines Registry
- 2006** LD411 (ME) secured funds for drug take-back
- 2007** The Athens Declaration  
First federal guidelines for consumer drug disposal  
Annual Survey of Drug Take-Back Programs launched
- 2008** The National Directory of Drug Take-Back Programs
- 2009** The Istanbul Declaration (final review)  
Maine's 15-day limitation on first prescription  
Second federal guidelines for consumer drug disposal  
Maine Declaration (first draft)

# **Impact on Public Health:** *Childhood Accidental Poisoning and Overdoses*



Almost 40% of  
accidental poisoning  
occurs in grandparents'  
homes

Source: Minnesota Poison Control,  
2004

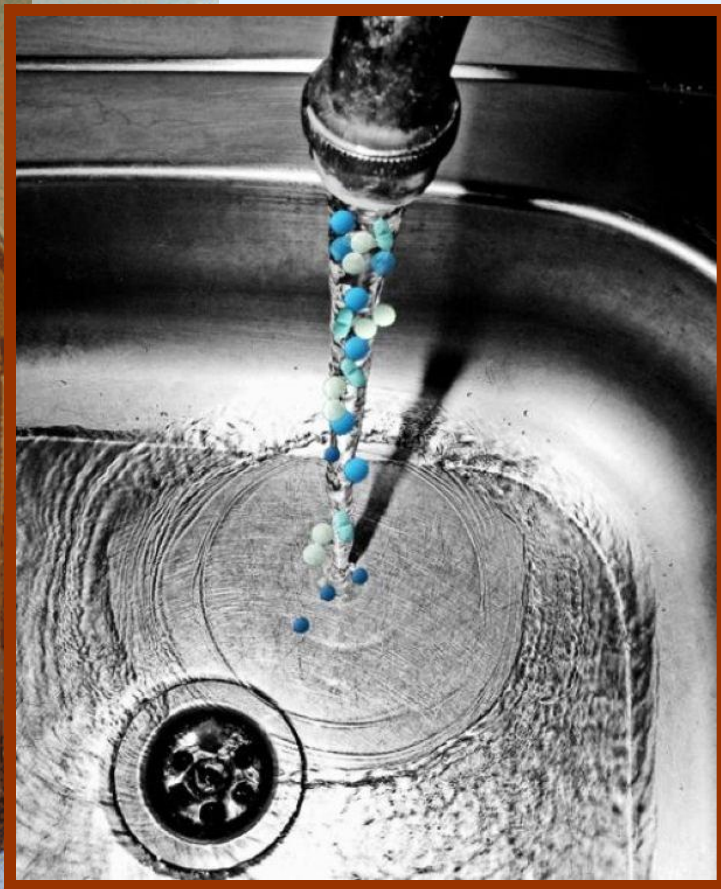
# Impact on Public Health: *Accumulation of Drugs by the Elderly*



Medication errors and overdoses can occur among seniors

Source: CMFPS 2008

## **Impact on All Sectors of Society:** *Contamination of Physical Environment*



80% of streams and waterways have traces of pharmaceuticals

Source: US Geological Survey, 2002

Traces of pharmaceuticals found in drinking water of at least 46 million Americans

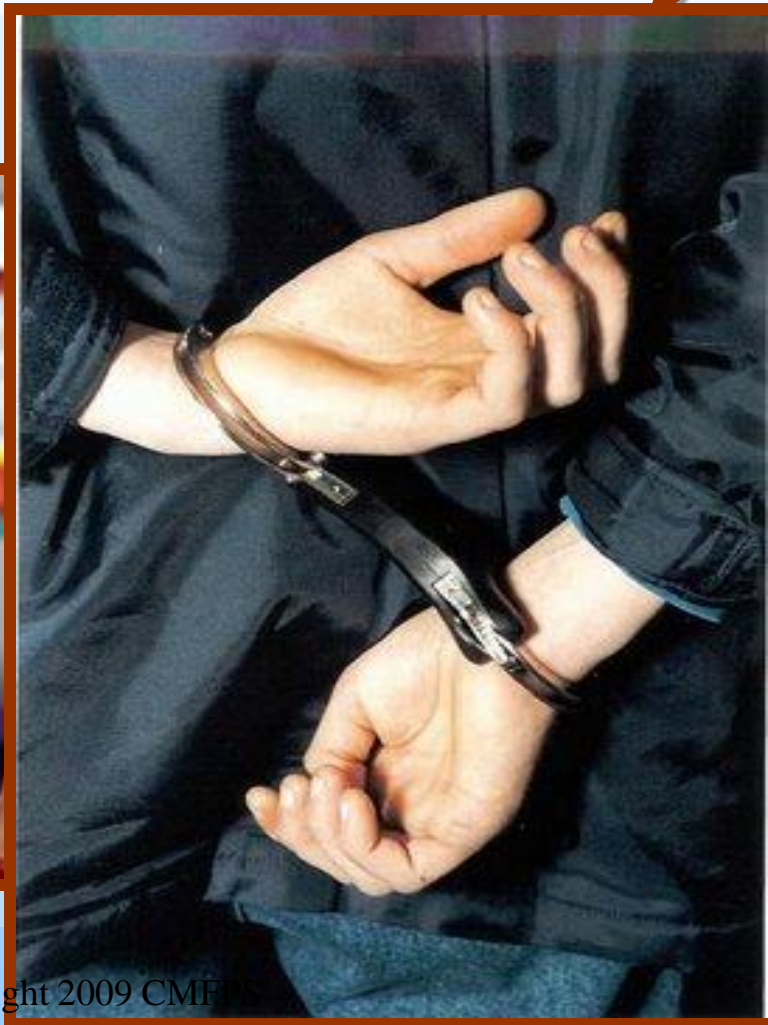
Source: Associated Press, 2008



## **Impact on Public Health:** *Household Drug Theft and Pharming*

Prescription drug arrest is 39% of all arrests; between 2003 and 2008, 250% increase in prescription drug arrests

Source: Maine Drug Enforcement Agency (2008)



## **Impact on Public Health:** *Waste in the Healthcare Systems*

Most unwanted medicines are usually flushed down the sink or toilet, but drug take-back programs are now available to intercept these wasted meds<sup>2</sup>

Source: CMFPS 2008



## **Impact on Public Health:** *Improper International Drug Donation*



600 tons of expired, damaged, or inappropriate medicines were donated post-tsunami, 2004<sup>8</sup>

Source: PSF-CI 2005



## **Framing the Public Health Challenge** *Determining the Magnitude*

- US pop accounts for **5%** of world's pop
- Global production of pharmaceutical products annually is **\$600 billion (US)**<sup>11</sup>
- US consumption of these products is **50%** or about **\$300 billion (US)** worth of drugs<sup>11</sup>
- US consumption growth rate is fastest compared to those of other countries due to more demand (aging population, more prescription, etc.)

## Symptoms and Signs

### *Environmental Impact*

#### Adverse effects on aquatic life

- Continual exposure
- Multi-generational exposures
- High conc in untreated water
- Possible low dose effects

#### Examples

- Salmon—1 ppb to diazinon distrupts olfactory reception
- Calcium-channel blockers inhibit sperm activity
- Flathead minnow—5 ppt of 17 $\alpha$ -ethinylestradiol, feminiz.
- Anti-epileptics are potential human neuroteratogens



## Symptoms and Signs

### *Example of Developmental Defect*



Fungicide carbendazim interferes with cellular differentiation at the earliest stage. 90 % cent of fish larvae spawned at the hatchery from brood stock taken from the Noosa River (Australia) had two heads.

## Symptoms and Signs

### *Example of Developmental Defect*



Ambient exposure to EE2 causes male flathead minnows to develop feminine characteristics (e.g. formation of ovipositor on the ventral side).

## Symptoms and Signs

### *Example of Developmental Defect*



Developmental delay caused by exposure to Prozac. Control (left) shows normal growth; treated specimen (right) failed to develop limbs after 57 days.



## Symptoms and Signs

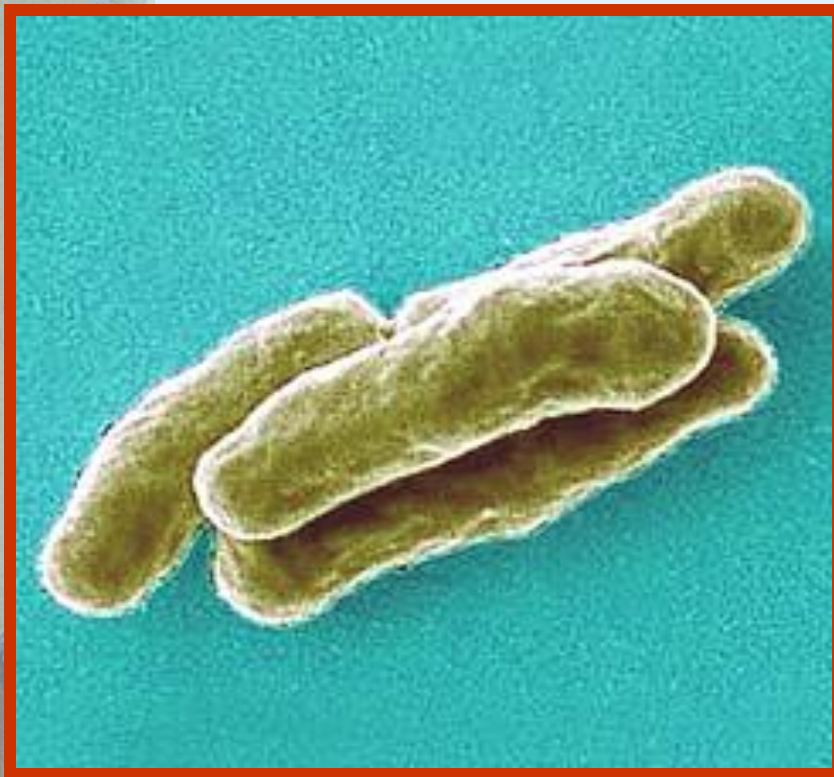
### *Example of Ecological Impact*



NSAID diclofenac found in carcasses and eaten by vultures causes poisoning, renal failure, and death. Vulture population has declined by 95%-97% ; 2-3 species in South Asia are near extinction.

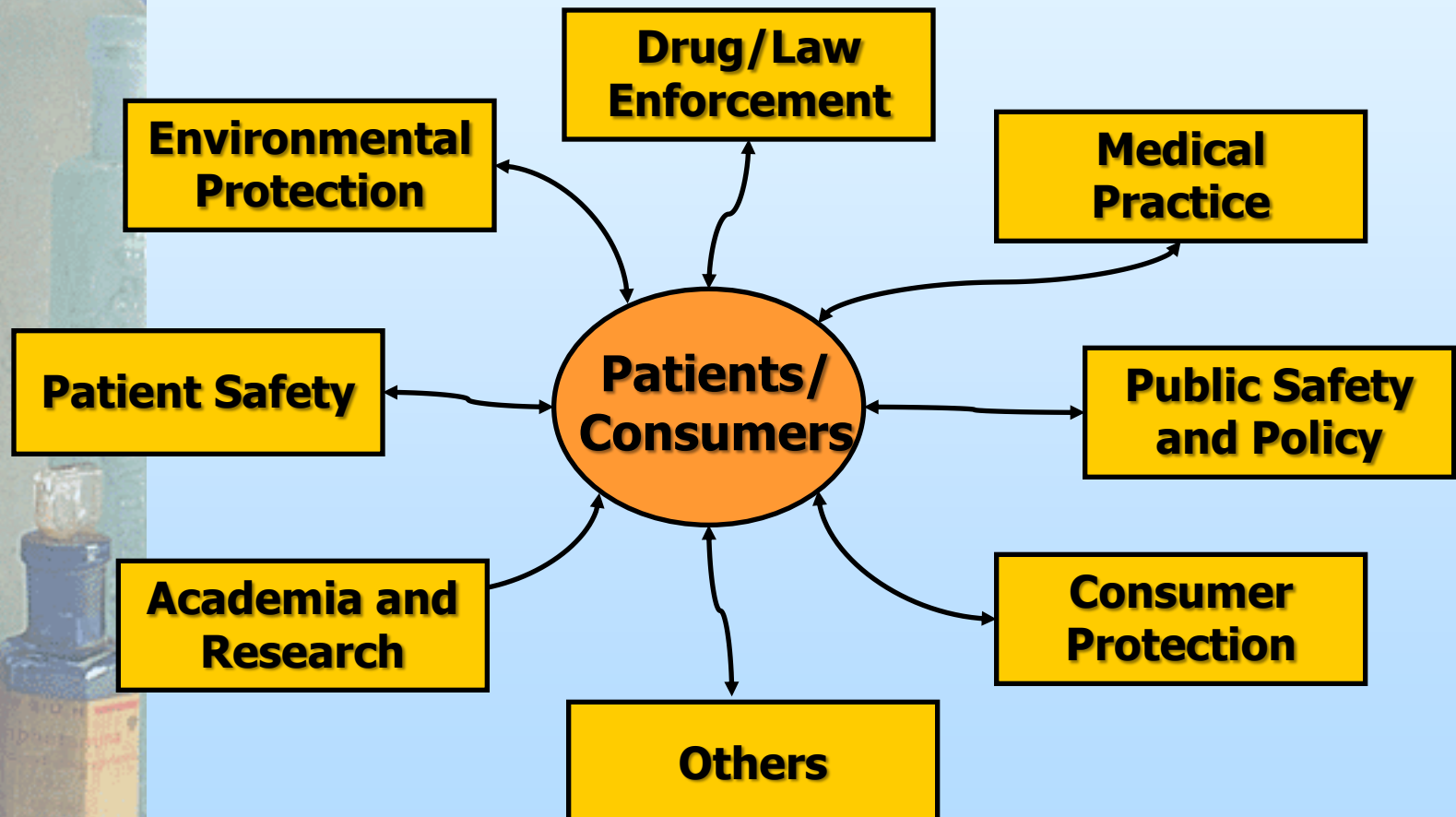
## Symptoms and Signs

### *Example of Probable Mutation*



1.7 million people die from tuberculosis globally each year. A new mutant form XDR-TB, which is immune to all current drugs, has been seen worldwide, including the US, Eastern Europe and Africa.

# Generalized Model Based on Community of Competence™ for UEM Project





# The National Unused & Expired Medicines Registry

- The central component of the *Get Rid of Unused Pharmaceuticals* (GROUP) Campaign
- Classification and coding protocol based on existing systems:
  - Therapeutic class: DAWN (SAMHSA, DHHS)
  - Drug characteristics: FDA NDC Directory
  - Cost (AWP): Red Book
  - Environmental risk/hazard class: JANUS Info
  - Demographic profile: US Census 2000 (zip code)
  - Occupational exposure hazard: OSHA



# Status of National Registry

- More than 36 datasets received (varying sizes)
- More than 24,000 entries (UEMs)
- More than 1.7 million pills, tablets, capsules counted
- Leading categories:
  - CNS agents
  - Psychotherapeutic agents
  - Cardiovascular agents
  - Respiratory agents
  - Gastrointestinal agents
  - Alternative medicines

# Data Collection

DATE

## Get Rid of Unused Pharmaceuticals (GROUP) Medicine Return Form®

Fill out this form by getting the information directly from your prescription labels, pill bottles, or medicine packages. If you need more space, use another form. Write your zip code. 2. Write the date of return. 3. Write the name of each medicine you are returning. 4. Write the strength or dosage of each medicine. 5. Write the number of pills, capsules, tablets, or amount of liquid of each medicine. 6. Check box with "X" for where you got each medicine. 7. Check box with "X" for a reason you are returning the medicine. 8. If the medicine is returned because of a side effect, please write down the side effect or any comment in this space.

1. Your Zip Code:

2. Date of Return:

6. Where did you get this medicine? Check one box below:

7. Why was medicine returned? Check one box below:

Use medicine from pill bottle or package.

Write the strength of the medicine (e.g., 30 mg)

Write approx. number of pills or capsules or amount of liquids you are returning

Doctor's office	Pharmacy	Hospital or clinic	Mail order (please pay)	Emergency	Infernal (online order)	Don't know or other	Expired or outdated	Discontinued by doctor	Used new medicine	Side effects or allergic reaction	Patented or moved away	Did not want to take it	Don't know or other
-----------------	----------	--------------------	-------------------------	-----------	-------------------------	---------------------	---------------------	------------------------	-------------------	-----------------------------------	------------------------	-------------------------	---------------------

If you have had a bad side effect with your medicine and stopped taking it, list the side effect(s) for each medicine.

8. Indicate side effect or other comments

ZIP CODE

(Dosage)

Quantity

SOURCE

REASON

DRUG NAME

DRUG STRENGTH

QUANTITY

SIDE EFFECTS

# Models of Take-Back Programs



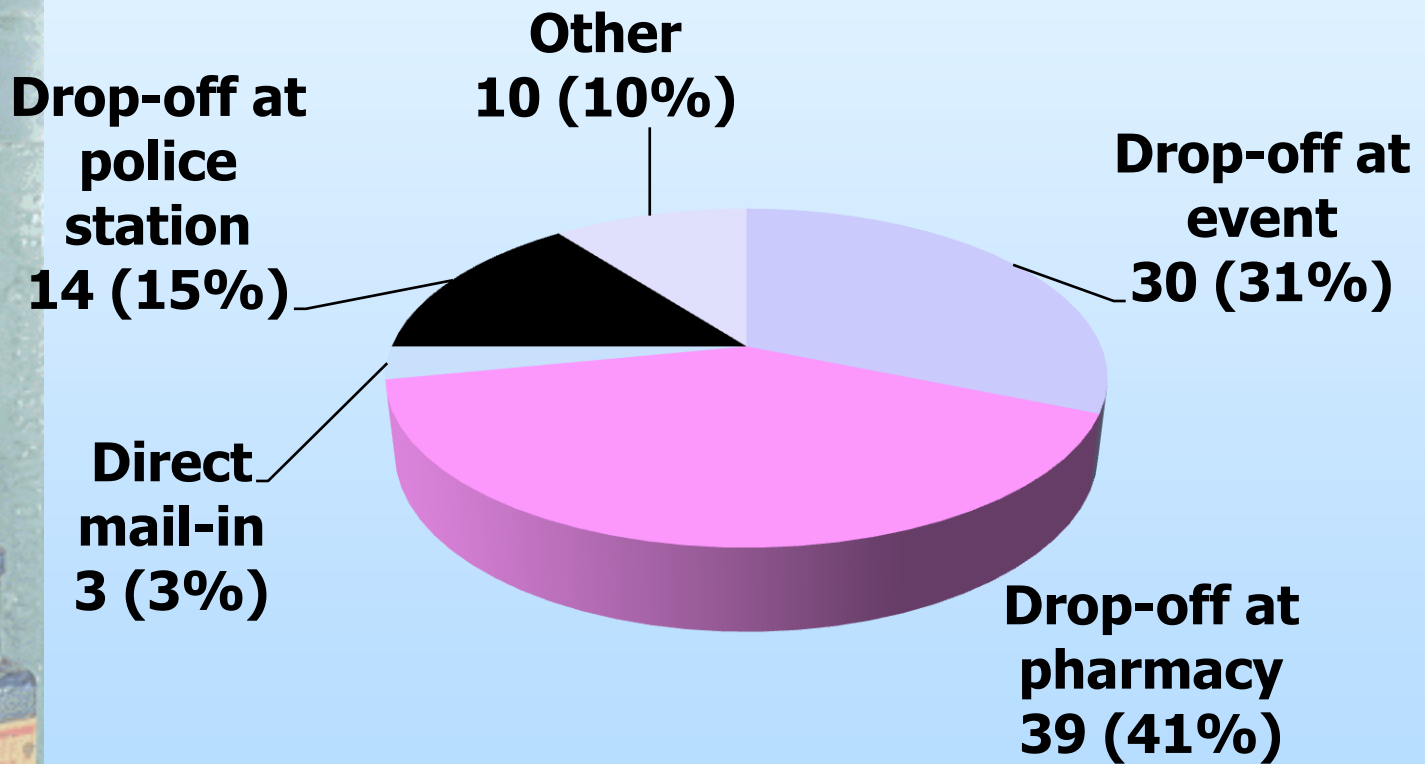
# A Model of Mail-Back Program



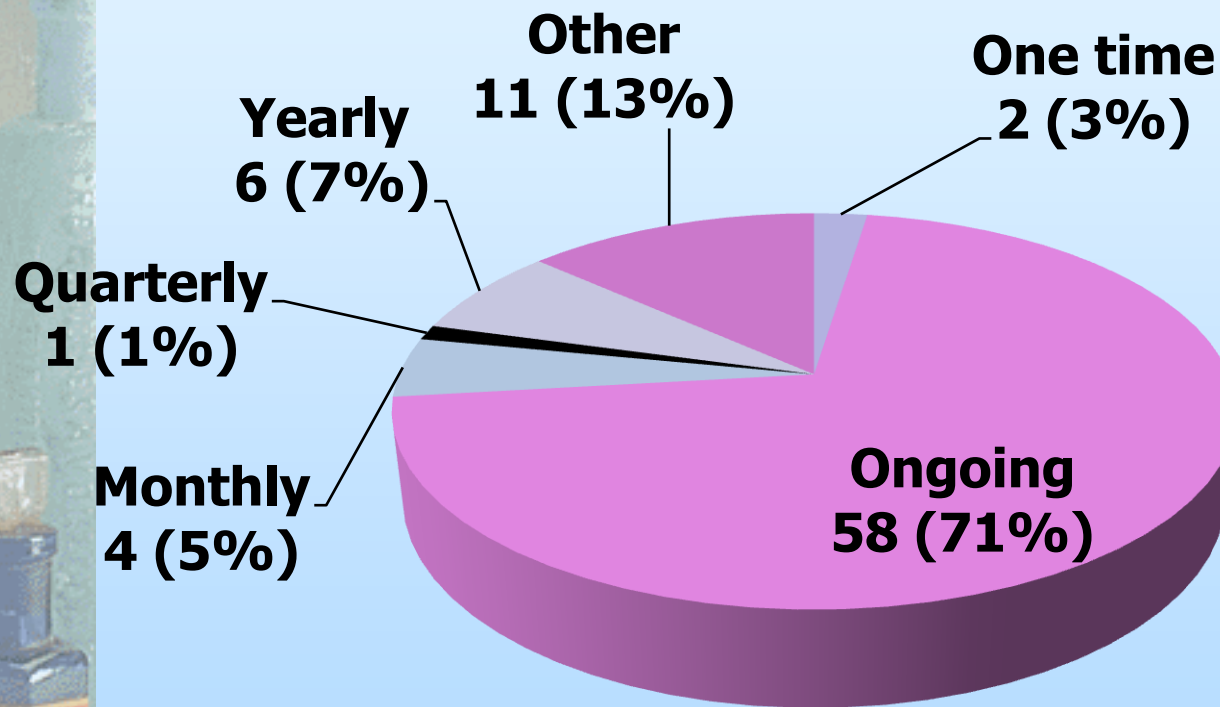




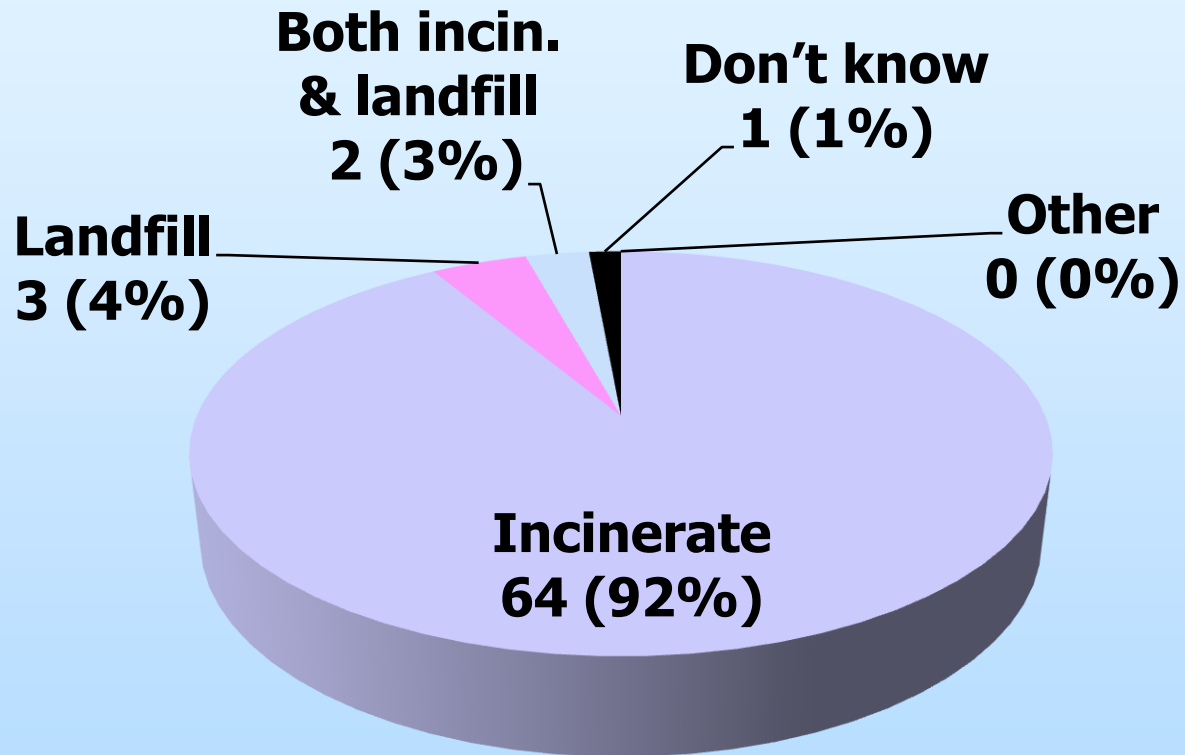
# Method of UEM Collection (n = 96)



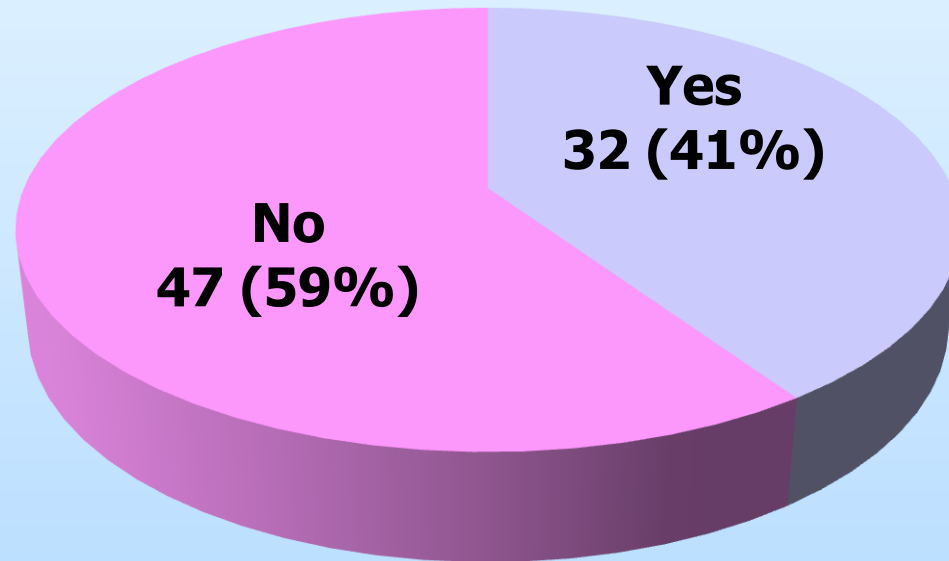
# UEM Collection Schedule (n = 82)



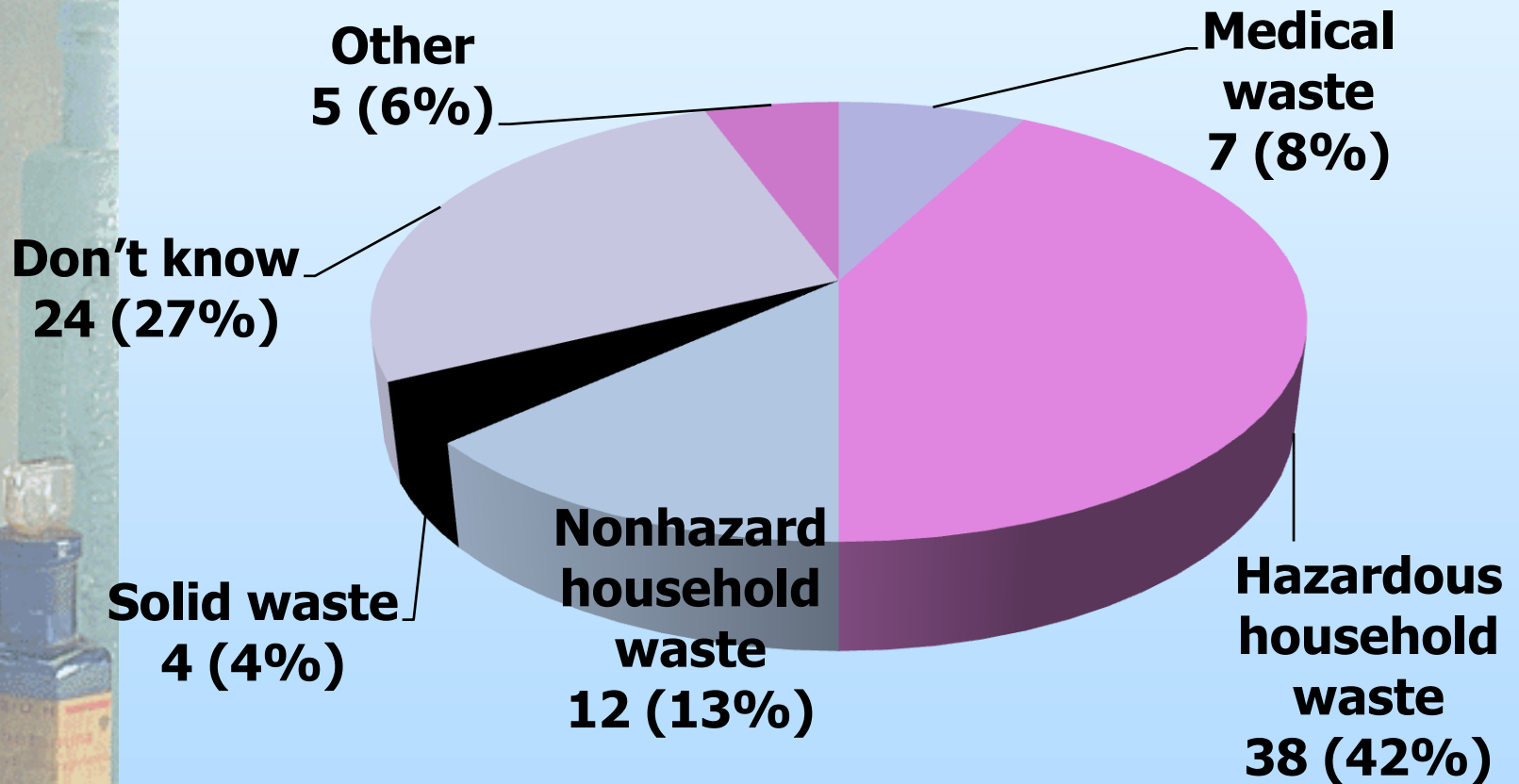
# UEM Destruction Method (n = 70)



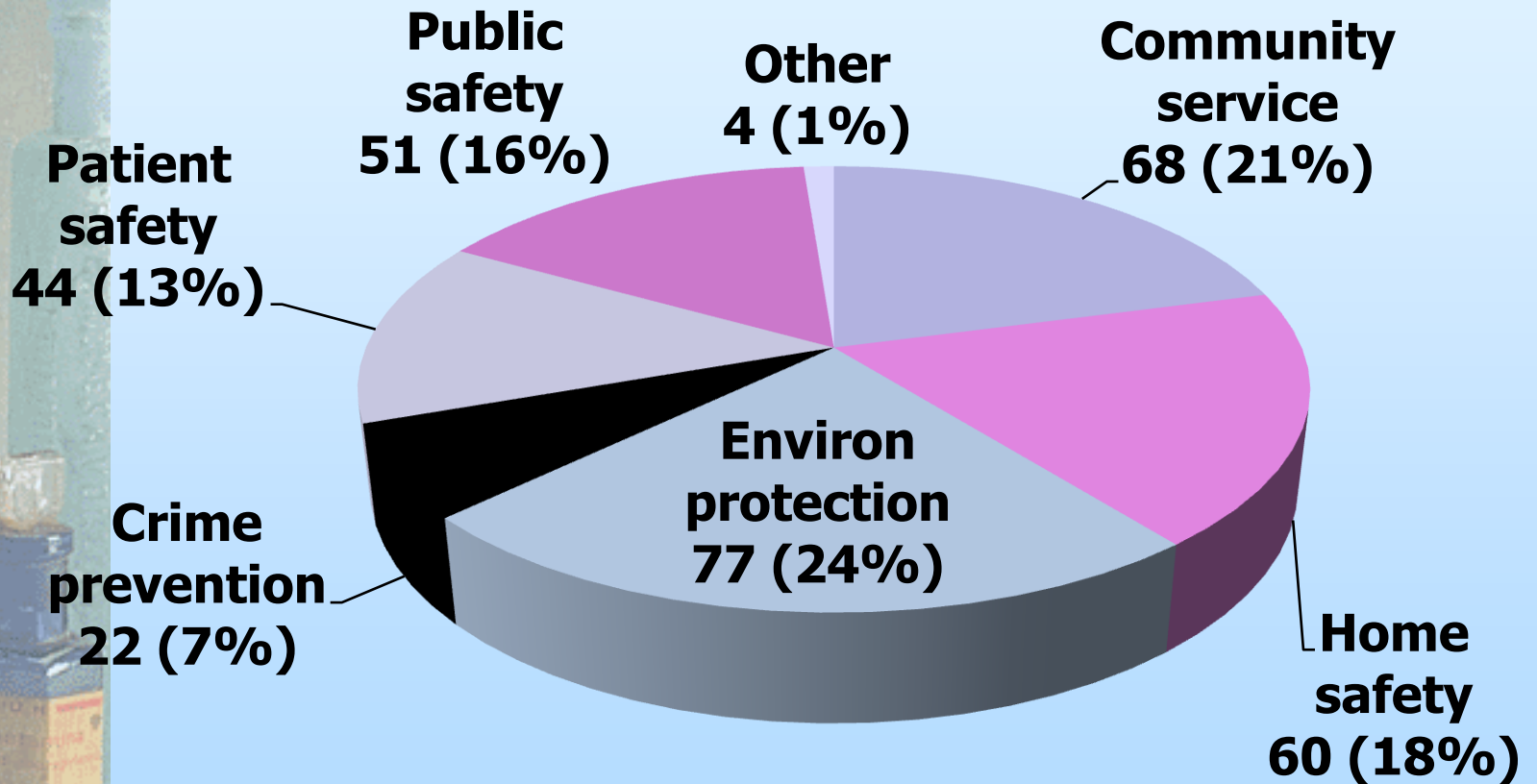
# Law Enforcement Involvement (n = 79)



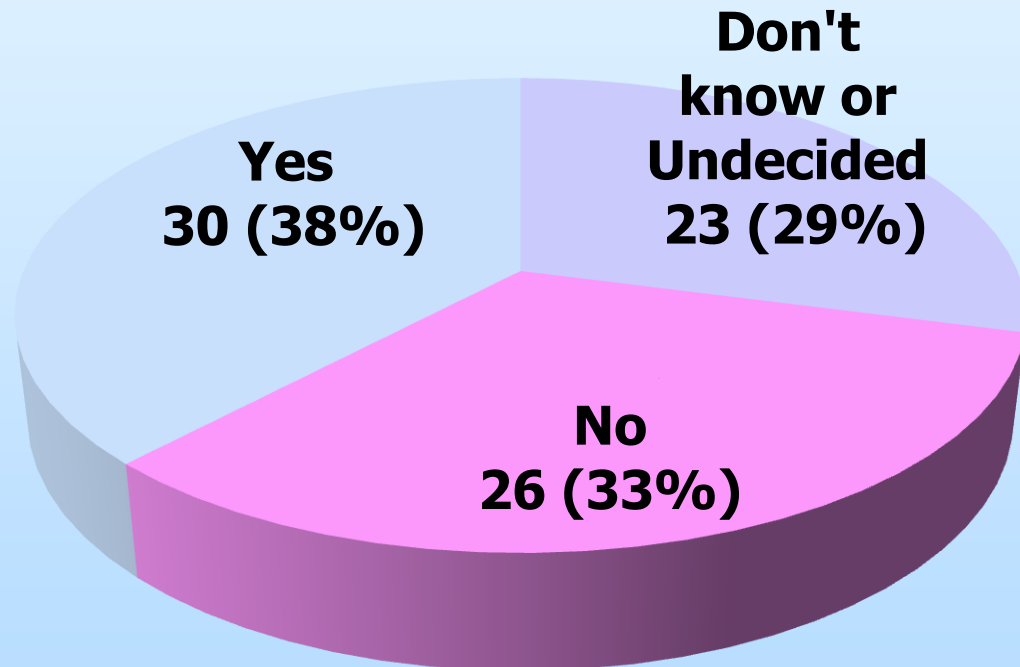
# Classification of UEM (n = 90)



# Purpose of Take-Back Program (n = 326 )



# Participation in the UEM Registry (n = 79)







# Issues of Non-Adherence

- Ref: Variable = REASON; Item 7; Data field 29
- Common Reasons:
  - Medicine expired or outdated\*
  - Doctor discontinued medicine
  - Doctor ordered new medicine
  - Patient “felt” better\*
  - Side effects or allergic reaction\*
  - Patient died or moved away
  - Patient did not want to take medicine\*
  - Don’t know or other\*

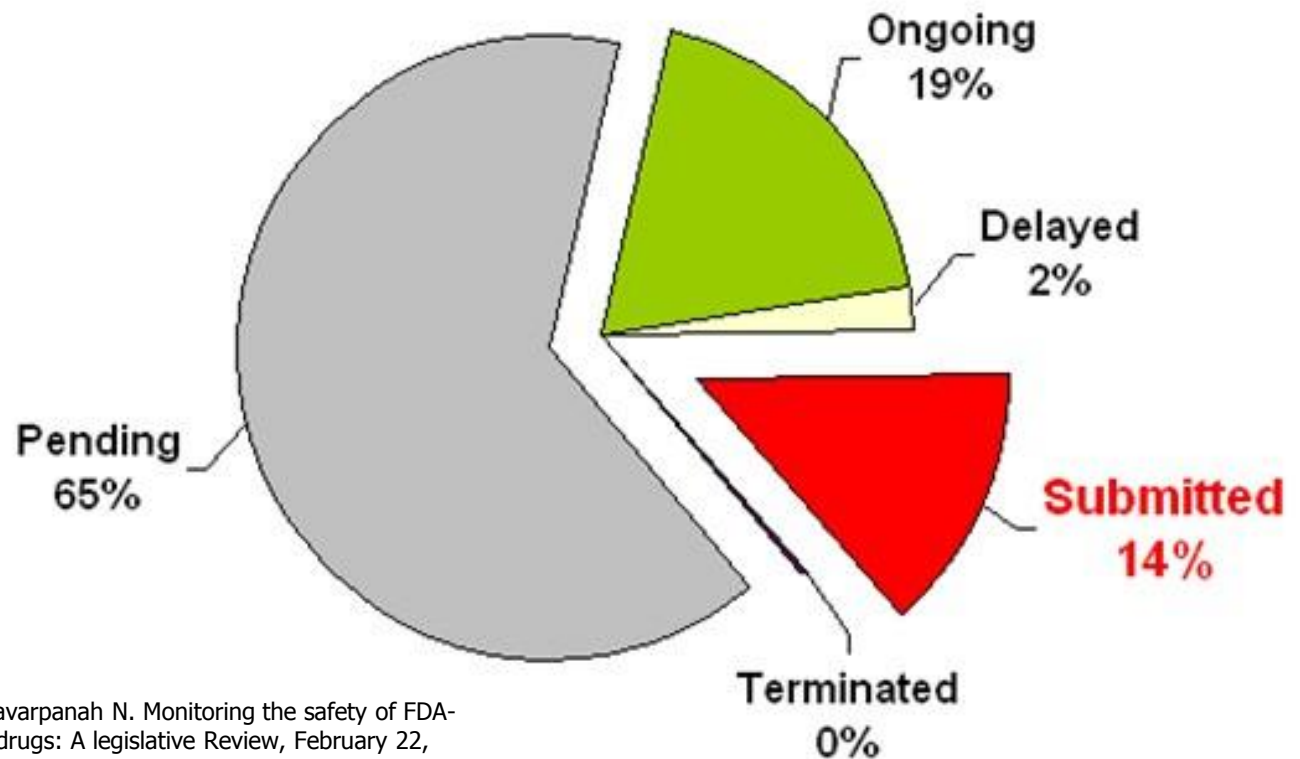


# Issues of Non-Adherence

- What we are learning from the Registry:
  - Patients/consumers often self-medicate
  - They are willing to share their reasons for UEMs
  - They generally are doubtful of benefits of meds
  - They associate new symptoms with new medicines
  - They have low threshold in deciding when to discontinue medicine
  - They seldom communicate concerns about meds with doctors or pharmacists
  - They stockpile discontinued meds
  - Take-back programs as an intervention (?)

# Issues of Non-Adherence: Postmarket Study

## Summary of Postmarketing Study Commitments



Source: Davarpanah N. Monitoring the safety of FDA-approved drugs: A legislative Review, February 22, 2007



# Issues of Non-Adherence: Patient/consumer Behavior

<b>Reason</b>	<b>Freq</b>	<b>(%)</b>
Expired or outdated*	6144	(53)
Didn't want to take it*	2357	(20)
Patient died	1693	(14)
Don't know or other*	836	(7)
Doctor discontinued it	375	(3)
Patient felt better*	103	(1)
Doc ordered new meds	92	(1)
Side effects or interactions*	84	(1)
<b>Grand Total</b>	<b>11684</b>	<b>(100)</b>
<b>Total due to non-adherence</b>	<b>9521</b>	<b>(81)</b>

Source: Northern California, 2007-2008, Teleosis  
Institute



# Issues of Non-Adherence: Patient/consumer's Report of Side Effects

## UEM

## Side Effects

---

**AMBIEN**

**"became suicidal"**

**METHYLPREDNISOLONE**

**"depression"**

**AMOXICILLIN**

**"pill from hell"**

**GABAPETIN**

**"anxiety"**

**GABAPETIN**

**"made me too drowsy"**

**WELCOL**

**"severe muscle pain"**

**ASTELIN**

**"did not work"**

**LIPITOR, LISINOPRIL, etc.**

**"severe fatigue"**

**GLUCOSAMINE**

**"jitteriness"**

---

**Total = 81 (1%)**

Source: Northern California, 2007-2008, Teleosis  
Institute



# Conclusions

- UEMs are a significant, complex problem
- Evidence is still weak concerning effects on human
- Evidence is strong in environmental impact studies
- The National Registry could be used as a public health surveillance system
- The National Registry could support a regional or a national drug take-back system
- The National Registry could become an international system for cross-national comparison and evaluation of programs



# Final Notes

- US pop accounts for **5%** of world's pop
- Global production of pharmaceutical products annually is **\$600 billion**
- US consumption of these products is **50%** or about **\$300 billion** worth of drugs
- US consumption growth rate is fastest compared to those of other countries due to more demand (aging population, more prescription, etc.)
- Imagine waste proportion of 40-50% (from our samples. Are we wasting **\$150 billion** by throwing our meds away?)



***Unused and Expired Medicines (UEMs):  
A Public Health Challenge***

**Thank you!**

For more information, contact

Matthew Mireles, Ph.D., M.P.H.

Community Medical Foundation for Patient Safety

6300 West Loop South, Suite 288

Bellaire, Texas 77401

[www.communityofcompetence.com](http://www.communityofcompetence.com)