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Rationale for a Focus on Reducing Pharmaceuticals In The Environment

SAFE MEDICINE DISPOSAL CONFERENCE October 12, 2011

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What People are Saying

- This is a profoundly stupid proposal. Is there any industry where we hold the manufacturer responsible for what the end user illegally/improperly does? Do we fine the oil companies if some moron dumps his used motor oil down the sewer drain? Do we fine the grocery stores and food makers if someone throws their dinner out on the roadside instead of "properly disposing" of it in the food waste bin? Do we sue Chrysler if someone abandons his LeBaron on 580? Do I blame Sherwin Williams if I'm fined for wrongly dumping paint at the regular waste center? - David



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What People are Saying

- This is another example of another indirect tax on the people who can least afford it. The additional costs on the pharmaceutical companies will be passed on directly to the consumer and it will have the greatest impact on those that can least afford it. It is time that we all vote this type of legislation and the agents of the business interests like Nate Miley out of office.
- If disposal is an issue with the water supply, EBMUD and Oro Loma should provide drop off at their facilities for used pharmaceuticals. They should be directed to do so without cost to rate payers.

»Thomas



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What People are Saying

- Thank heaven for this plan. I had a bottle of morphine hanging around the house for years from taking care of a cancer patient. Finally I learned of a drop off place and was able to get rid of it.
 - It just make sense to have pharmacies take back the drugs that they sell rather than dumping them down the toilet which is what has been happening. Seniors need to be able to dispose of drugs that they no longer use that is convenient, in a safe manner and a safe place.
 - As of now so much of these dangers drugs end up in our water supply and in the food chain and in the bodies of our youth. Opposition to this idea is irresponsible and not well thought out. Please reconsider your position.
 - Someone needs to take on the mega business drug companies. Kudos to Miley!
- Observer



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Impact of Unused Pharmaceuticals

- Childhood poisoning
- Theft, Abuse, Misuse
- Excessive accumulation of unwanted drugs
- Unintended environmental exposure
- Inappropriate international donations



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Childhood Poisoning



- Pharmaceutical poisoning is still a common childhood injury in the United States, as a new study shows that more than 500,000 children are exposed to pharmaceuticals on a yearly basis.
- Researchers of the new study to be published in The Journal of Pediatrics noted that despite years of concerted prevention efforts like improved safe guards on packaging, such type of accidental poisoning is getting worse rather than better.
- September 18, 2011 **IBTimes Staff Reporter**



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Increases in Prescriptions

- Number of prescriptions written for non-controlled drugs
 - **increased 57%**
- Number of prescriptions filled for controlled drugs
 - **increased 154%**
 - National Center on Addiction and Substance Abuse at Columbia University (CASA)
- Overall Population growth in the US between 1992 and 2003
 - **Increased 13%**
 - National Center on Addiction and Substance Abuse at Columbia University (CASA)



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Increased Abuse

- Number of people who admitted to hospitals abusing controlled prescription drugs:
 - Increased 90%
- Among 12 to 17 year olds
 - Increased 203%
- Among those greater than 18-years old
 - Increase 78%
 - National Center on Addiction and Substance Abuse at Columbia University (CASA)



Abuse and Misuse

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- From 1992 and 2003
- Teenage use of Alprazolam, oxycodone, and methylphenidate
 - Increase 212%
- Teenager addicted to opioids, CNS depressants or stimulants
 - Increased 15%--
- Total # of Americans abusing controlled prescription drugs
 - 15.1 million
- Exceeds the combined number abusing
 - cocaine (5.9 million)
 - hallucinogens (4.0 million)
 - inhalants (2.1 million)
 - heroin (.3 million)
- National Center on Addiction and Substance Abuse at Columbia University (CASA)



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County	ME
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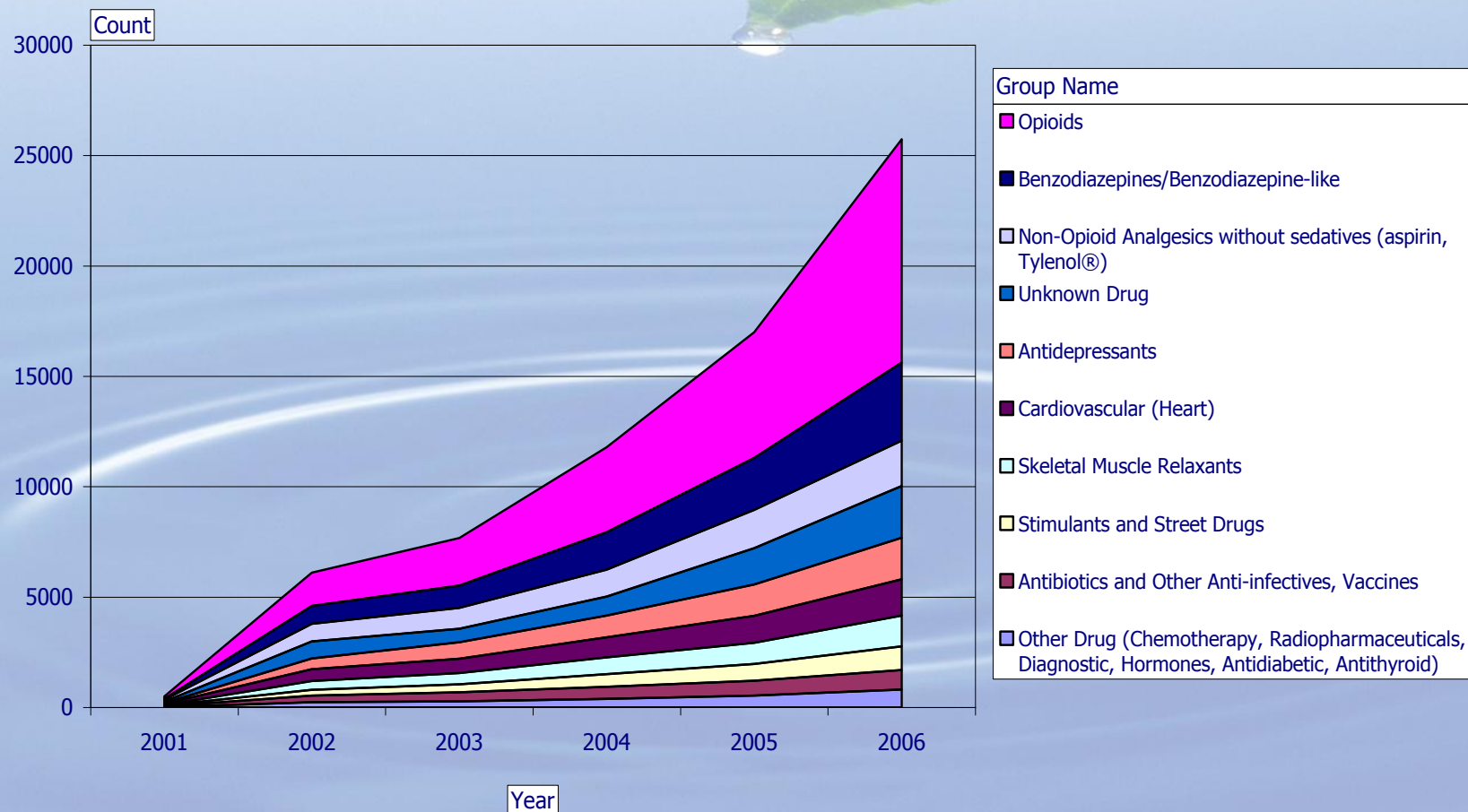
Prescription Drug Abuse

Substances involved in Substance Abuse Questions from 2001 - 2006

Top 10 Categories Only

Northern New England Poison Center's SASRS Database

N = 68,792





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Crime

- Connection between the accumulation of medicines in the home and the potential for diversion and abuse.
 - Hydrocodone and Oxycodone are implicated in 28% of all drug related crime.
 - Methylphenidate and dextromethorphan are implicated in 19% of all drug related crime.





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Excessive Accumulations

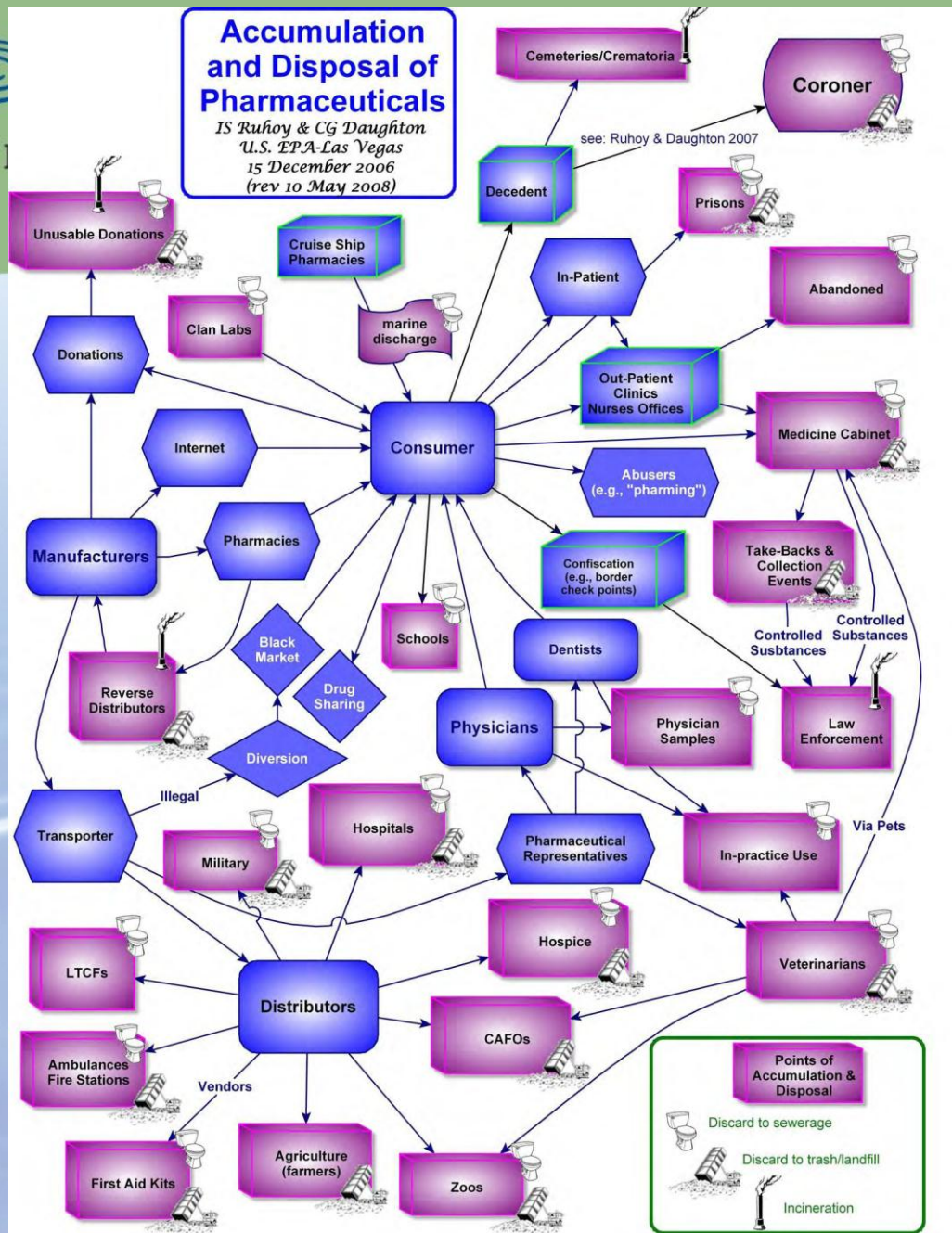
Number of Medications Respondent's Household Contains

<u>Number</u>	<u>Prescription</u>	<u>Nonprescription</u>
• 1	17.1%	11.7%
• 2	19.3%	13.0%
• 3	16.6%	15.6%
• 4	13.2%	12.6%
• 5–7	21.1%	23.8%
• 8+ 12.	8%	23.3%
• Mean	4.4	5.5
• Std. Dev	(3.8)	(4.4)

- Owens & Anand, *Medication Disposal Survey Report* (2009)



IS Ruhoy & CG Daughton
U.S. EPA-Las Vegas
15 December 2006
(rev 10 May 2008)





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Operation Medicine Cabinet

- 3,400 sites join DEA
- Nationwide Effort
- Take-Back Prescription Drugs
 - Sept 25, 2010
- Collected 242,000 lbs





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Environmental Exposures

- Prozac and Luvox induced spawning in bivalves at significantly low concentrations.
 - Nagtegaal M, Ternes TA, Baumann W, Nagel R. Nachweis von UV --Filtersubstanzen in Wasser und Fischen aus dem Meerfelder Maar in der Eifel . Detection of UV --sunscreen agents in water and fish of the Meerfelder maar the Eifel lGermany. *UWSF --Z für Umweltchem Ökotox* . 1997;9(2):79--86
- SSRIs elicit aggressive behavior in lobsters, causing subordinates to engage in fighting against the dominant member, and reducing the propensity to retreat.
 - Huber R, Smith K, Delago A, Isaksson K, Kravitz EA. Serotonin and aggressive motivation in crustaceans: altering the decision to retreat. *Proceedings of the National Academy of Science*; 1997; 94:5939 5939-5942.





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More Ecotoxicity



- Fluoxetine enhances the release of ovary-stimulating hormones in crayfish.
 - Fong PP. Zebra mussel spawning is induced in low concentrations of putative serotonin reuptake inhibitors. *The Biological Bulletin*. 1998;194:143 --149. 143
- Diclofenac has been proven to be toxic to vultures, decimating populations in the Indian subcontinent due to its ubiquitous use in cattle.
 - Kreisberg, J. Ecological healing and the web of life. *Explore: The Journal of Science and Healing* . 2005; 1(2):133 --135. *Healing*. 133



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Inappropriate Humanitarian Drug Donations

- **Armenia, 1988**

5,000 tons of drugs and medical supplies worth US \$55 million were sent.

- It took 50 people six months to gain a clear picture of the drugs that had been received.
 - 8% of the drugs had expired on arrival
 - 4% were destroyed by frost.
 - 88% left
 - only 30% were easy to identify
 - 42% were relevant for an emergency situation.



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Inappropriate Humanitarian Drug Donations

- **France, 1991**

Pharmaciens Sans Frontières collected
4 million kg of unused drugs from
4,000 pharmacies in France.

- **88 centers** sorted
- **20%** used for international aid programs
- **80%** were burnt





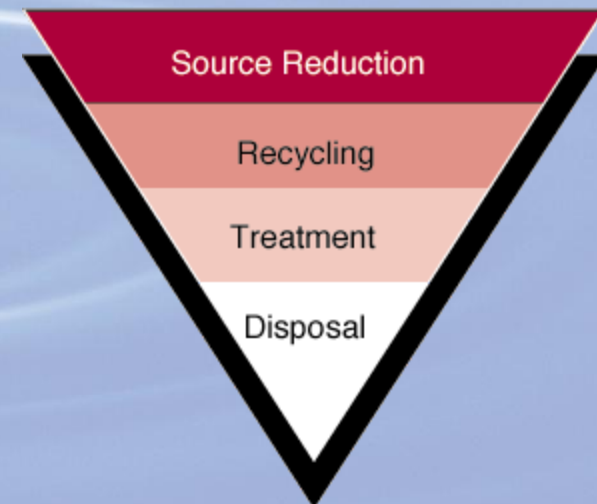
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What can we do?

- Pollution Prevention
 - Control at source
 - Can implement & reduce loading in near term
- Product stewardship



Pollution Prevention Hierarchy





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Flush vs No Flush

- The White House Office of National Drug Control Policy (ONDCP)
 - http://www.whitehousedrugpolicy.gov/publications/pdf/prescrip_disposal.pdf
- The ONDCP website refers to the FDA website for drugs that are approved to be flushed in the toilet or sink.





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Flush vs No Flush

- Single Dose Fatality
 - Certain medicines may be especially harmful and, in some cases, fatal in a single dose if they are used by someone other than the person the medicine was prescribed for.
- These medications should be flushed down the sink or toilet after the medicine is no longer needed.





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Recommended for Flushing

<i>Medicine</i>	<i>Active Ingredient</i>
Actiq , oral transmucosal lozenge *	Fentanyl Citrate
Avinza , capsules (extended release)	Morphine Sulfate
Daytrana , transdermal patch system	Methylphenidate
Demerol , tablets *	Meperidine Hydrochloride
Demerol , oral solution *	Meperidine Hydrochloride
Diastat/Diastat AcuDial , rectal gel	Diazepam
Dilaudid , tablets *	Hydromorphone Hydrochloride
Dilaudid , oral liquid *	Hydromorphone Hydrochloride
Dolophine Hydrochloride , tablets *	Methadone Hydrochloride
Duragesic , patch (extended release) *	Fentanyl
Embeda , capsules (extended release)	Morphine Sulfate; Naltrexone Hydrochloride
Exalgo , tablets (extended release)	Hydromorphone Hydrochloride
Fentora , tablets (buccal)	Fentanyl Citrate



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Recommended for Flushing

<i>Medicine</i>	<i>Active Ingredient</i>
Kadian , capsules (extended release)	Morphine Sulfate
Methadone Hydrochloride , oral solution *	Methadone Hydrochloride
Methadose , tablets *	Methadone Hydrochloride
Morphine Sulfate , tablets (immediate release) *	Morphine Sulfate
Morphine Sulfate , oral solution *	Morphine Sulfate
MS Contin , tablets (extended release) *	Morphine Sulfate
Onsolis , soluble film (buccal)	Fentanyl Citrate
Opana , tablets (immediate release)	Oxymorphone Hydrochloride
Opana ER , tablets (extended release)	Oxymorphone Hydrochloride
Oramorph SR , tablets (sustained release)	Morphine Sulfate
Oxycontin , tablets (extended release) *	Oxycodone Hydrochloride
Percocet , tablets *	Acetaminophen; Oxycodone Hydrochloride
Percodan , tablets *	Aspirin; Oxycodone Hydrochloride
Xyrem , oral solution	Sodium Oxybate

* These medicines have generic versions available or are only available in generic formulations.
List revised: March 2010

Table
Potential Kid Killers:
Medications That Are Lethal in Unintentional Pediatric Exposures^{13,14}

Drug Class and Medication	Pediatric Exposure Fatal Dose, mg/kg	Highest Dosage Available per Tablet, mg	Fatal Outcome, Tablets (No.)	Toxidrome
■ Analgesics <input type="checkbox"/> Opioids – Codeine – Methadone	15 5	60 10 (10 mL)	3 1 tsp	CNS, depression, miosis, respiratory distress CNS, depression, miosis, respiratory distress
■ Anesthetics <input type="checkbox"/> Local/topical – Benzocaine	20	20%	2 mL (20%)	Cyanosis, brown blood, seizure
■ Antidepressants <input type="checkbox"/> Cyclic antidepressants – Imipramine	20	150	1 (150 mg)	Dysrhythmia; electrocardiogram: wide QRS wave; hypotension; seizure
■ Antihistamines <input type="checkbox"/> Diphenhydramine: OTC <input type="checkbox"/> Ethanolamines – Dimenhydrinate	25 25	50 25	5 3	Anticholinergic; dysrhythmias; electrocardiogram: wide QRS wave; seizures Anticholinergic, seizure
■ Antimicrobials <input type="checkbox"/> Antimalarial agents – Chloroquine – Quinine	20 80	500 300	1 (500 mg) 2–3	CNS, depression, dysrhythmias, seizure Blindness, dysrhythmias, seizure
■ Asthma therapies <input type="checkbox"/> Theophylline	50	500	1	Dysrhythmias, seizure
■ Cardiovascular drugs <input type="checkbox"/> β -blocker <input type="checkbox"/> ACE inhibitor with calcium channel blockers <input type="checkbox"/> Antiarrhythmic: other – Quinidine	>4 <40 50	160 240 300	1–2 1–2 1–2	Bradycardia; breath sounds, decreased; CNS; depression; electrocardiogram: normal QRS wave, increased PR interval; hypotension; potassium levels, increased Bradycardia; electrocardiogram: normal QRS wave, increased PR interval; hypotension Dysrhythmias; electrocardiogram: wide QRS wave; seizure
<input type="checkbox"/> Clonidine	0.1	0.3	1 (0.3 mg)	Bradycardia, CNS, depression; hypotension
■ Hormones and hormone antagonists <input type="checkbox"/> Oral hypoglycemics – Sulfonylureas	<1	5	1–2	Hypoglycemia, seizure
■ Sedative/hypnotic/antipsychotics <input type="checkbox"/> Phenothiazines – Phenothiazine – Thioridazine	20 15	200 200	1 (200 mg) 1 (20 mg)	Seizures Dysrhythmias, hypotension
■ Stimulants and street drugs <input type="checkbox"/> Diet aids – Phenylpropanolamine	17	75	1–2	Dysrhythmias, intracranial bleeding
■ Topical preparations <input type="checkbox"/> Camphor <input type="checkbox"/> Methyl salicylate	100 <200	540 (5 mL) 1400 mL	1 tsp 1 tsp (7400 mg)	CNS, seizure Acidosis, cardiovascular collapse, seizure

Abbreviations: ACE indicates angiotensin converting enzyme; CNS, (symptoms present in the) central nervous system; OTC, over-the-counter formulation.



California Board of Pharmacy

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- Advises against flushing
- Why Not?
 - 80 percent of US streams contain small amounts of human medicines.
 - » Kolpin, Dana et al. Pharmaceuticals, hormones and other organic wastewater contaminants in US streams, 1999-2000: a national reconnaissance. *Environmental Science and Technology*. 2002; 26: 1202-1211.
 - Sewage systems cannot remove these medicines from water that is released into lakes, rivers or oceans.
 - Fish and other aquatic animals have shown adverse effects from medicines in the water.
 - And, even very small amounts of medicine have been found in drinking water.
- The California Board of Pharmacy makes several suggestions on how to dispose of unwanted/unused medications in the home.



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California Board of Pharmacy Disposal Advice

- **Home Trash Disposal:**

1. Keep medicine in its original child proof container and mark out all personal identifiable information.
2. Add water to solid medications i.e. pills and capsules followed by adding a non-toxic substance. Some suggestions are kitty litter, coffee grounds, charcoal or powdered spices.
3. Seal lids with packing or duct tape. Use multiple layers of duct tape for blister packs.
4. Place the tape sealed bottles or blister packs in durable packaging that camouflages what is inside.
5. Place in trash close to garbage pick-up time.

- **Pharmacy Take-Back programs:**

- Ask if pharmacy will accept medicines from patients

- **Household Hazardous Waste Collection:**

- Return to local HHW collection site



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Smar_xt Disposal

- Advocates for responsible medication disposal and advises against flushing.
- Smarxt Disposal is a collaboration
 - U.S. Fish and Wildlife Service,
 - American Pharmacists Association
 - Pharmaceutical Research and Manufacturers of America
- <http://www.smarxtdisposal.net/>





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Cradle to Cradle Medicine

- Learning about what is unused will improve the quality of medical care!
 - In theory, waste occurs when the prescription isn't effective.
 - If we get to the point where we have no leftover drugs, will that lead to improved therapeutic outcomes?





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Bay Area Medication Disposal Survey 2009

Kreisberg J, Ruhoy I, Zheng C

***An examination of what is returned to
pharmaceutical take-back sites***



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Take-Back Sites

- Total Sites in the San Francisco Bay Area
 - 126
- Total Population of 9 County Bay Area Region
 - 7.1 Million





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Total Collection and Costs

- Total Pounds Collected in 2009
65,676 lbs
- Total Costs for Disposal
\$119,133
- Average Cost per Pound
\$ 1.99/lbs
- Range of Costs per Pound
\$ 1.13-5.65/lbs



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Location of Sites

TABLE 2. Categories of Take-back Sites

Category of Take-back Sites	Sites	% of Total
Pharmacies	62	49.2%
Law Enforcement Agencies	27	21.4%
Household Hazardous Waste	9	7.1%
Medical Clinics	7	5.5%
Fire Stations*	7	5.5%
Government Offices	7	4.7%
Hospitals	3	2.4%
Other Medical Facilities	2	1.6%
Dental Offices	2	1.6%
Total Take-back Sites	126	

* Fire stations have programs under the supervision of law enforcement



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Collection System

TABLE 5. Style of Collection System Used

Style of Collection System	# of Programs	% of Programs	# of Sites	% of Sites
Front loading single key lock box	6	33.3%	56	44.4%
Open bin behind counter (no public access)	5	27.8%	32	25.4%
Other	3	16.7%	6	4%
Front loading dual key lock box	2	11.1%	4	3.2%
Open bin (with direct public access)	1	5.6%	26	20.6%
Mailer	1	5.6%	2	1.6%
Total	18		126	



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Disposal Bin & Procedures

- Staff should not handle medicines
 - Only provide information, assistance, and answer questions
- Consumers dispose of their medicines directly in the bin
 - Pills acceptable in a zip lock bag (preferred) or original containers
 - Liquids and ointments must remain in original containers
 - Empty bottles go in the trash/recycling after personal information is crossed off
- Staff supervisor checks bin daily
 - Call for pick-up when nearly full
 - Lock the chute if the bin is full





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Percent of Pharmaceuticals

TABLE 8. Percent of Medications by Weight for Palo Alto Sample

	Weight (lbs)	% Packaging by Weight
Medication weight (lbs)	571	85.6%
Plastics lbs	90	13.3%
Paper by lbs	14.5	2.1%
Total Weight	675	100%



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Cost Per Pound

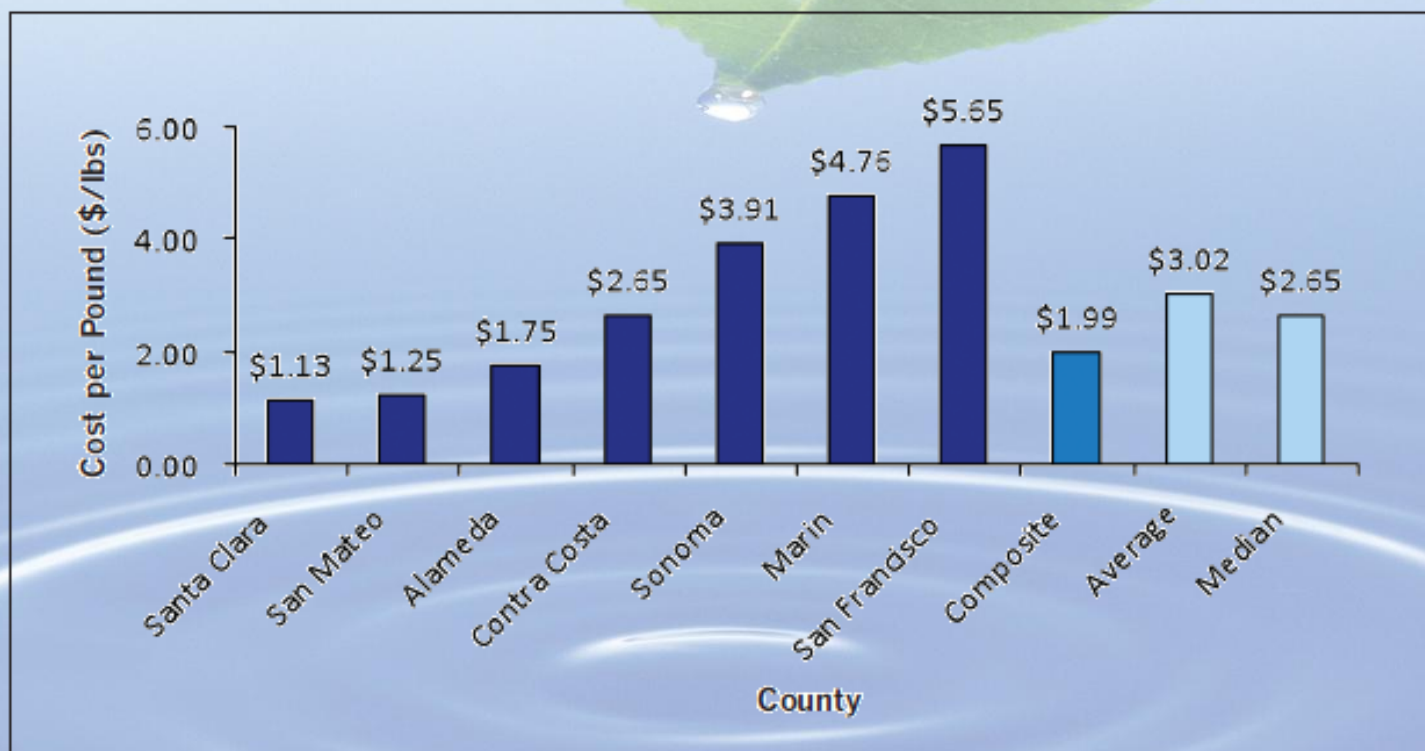


FIGURE 1. Cost per Pound of Medication Disposal



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Dosage Form

TABLE 16. Pharmaceuticals by Dosage Form

Type	Items	%	Continuous % Composite
Pills	5,137	57.2%	57.2%
Liquids	2,382	26.5%	83.7%
Ointments	534	5.9%	89.6%
Injectables	358	4%	93.6%
Powders	278	3.1%	96.1%
Inhalers	166	1.9%	98.6%
Suppositories	76	0.8%	99.4%
Patch	51	0.6%	100%
Total Items	8,982		



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OTC versus RX

TABLE 17. Prescription, OTC, and Supplements

	Items	%
Total Items Returned	8,982	
Total Items Identified as RX/OTC/Supp	8,554	95.2%
Prescription Medication	5,530	64.6%
Over-the-counter Medication	2,172	25.4%
Nutritional Supplement	852	10%



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Expired?

TABLE 18. Expired Medication

	Items	%
Total Items Returned	8,982	
Total Therapeutic Identified	8,174	91%
Items Expired	6,488	79.4%
Items Not Expired	1,686	20.6%



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Most Common Medication

TABLE 15. Most Common Medications Returned

	Items	%	
Total Items Returned	8,982		
Unknown	1,019	11.3%	
Total Generic Medication Identified	7,962	88.6%	
Top 11 Generics	Items	Est. %	Therapeutic Class
Albuterol	512	6.4%	Respiratory Agents
Acetaminophen	440	5.5%	CNS Agents
Ipratropium	417	5.2%	Respiratory Agents
Ibuprofen	151	1.9%	CNS Agents
Aspirin	119	1.5%	CNS Agents
Multi-vitamin*	113	1.4%	Nutritional Products
Naproxen	109	1.4%	CNS Agents
Fluticasone	95	1.2%	Topical Agents
Diphenhydramine	94	1.2%	Psychotherapeutic Agents
Olanzapine	88	1.1%	Psychotherapeutic Agents
Potassium Chloride*	78	1%	Nutritional Products

* Not technically medications



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Samples

TABLE 19. Product Samples

	Items	%
Total Items Returned	8,982	
Unknown	808	9%
Total Product Samples Returned	986	11%



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Packaging

TABLE 20. Percent Packaging

	Items	%
Total Items Returned	8,982	
Items with Packaging Identified	8,441	93.8%
Total Percentage Packaging by Volume		52.2%

Medication Type	Items	Average % Packaging
Inhalers	166	76.9%
Suppositories	74	66.1%
Injectables	328	65.3%
Pills	4,703	56.9%
Ointments	528	56.2%
Patch	35	55.1%
Powders	247	40.6%
Liquids	2,360	39.3%
Product Samples	986	75%



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% Unused

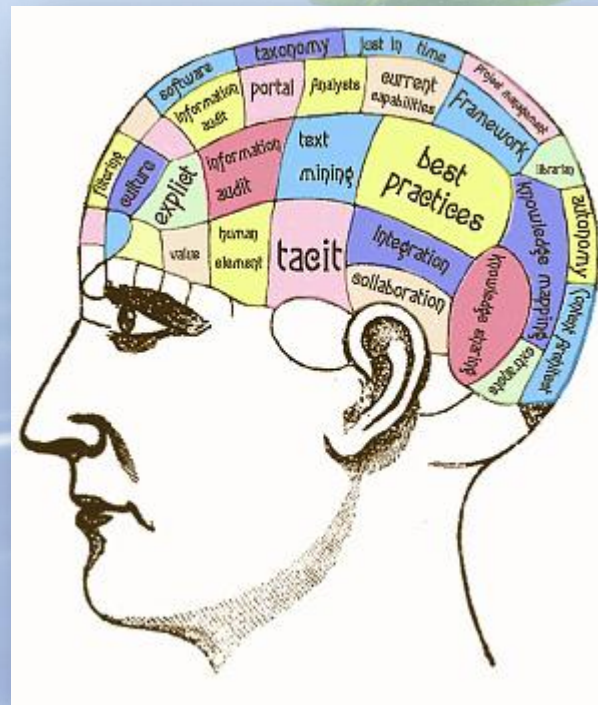
TABLE 21. Amount Unused in Container

	Items	%
Total Items Returned	8,982	
Items Identified as Unused	8,583	95.60%
Medication Type	Items	Average % Unused
Pills	4,757	67.3%
Liquids	2,369	78.2%
Injectables	358	80.8%
Ointments	533	81.6%
Powders	277	63.9%
Suppositories	75	86.6%
Inhalers	161	74.1%
Patch	53	95.6%
Average percentage remaining		73.1%



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Be Knowledgeable!





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Federal regulations - FDA

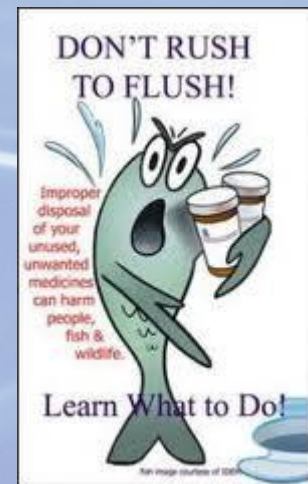
- FDA supports the Federal Guidelines calling for the responsible disposal of medicines from the home.
 - Almost all medicines can be thrown away in the household trash after mixing them with some unpalatable substance
 - Drug take-back programs for disposal can be another good way to remove unwanted or expired medicines from the home.



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Drug Enforcement Agency

- DEA regulations regarding disposal of unused or unwanted medications is intensive and offers very little flexibility.
- Safe Drug Disposal Act of 2010 was signed into law.
- Stay tune for changes





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Best Management Practice

- Destruction by incineration of all discarded drugs is BMP at this time
- Eliminate drain disposal
- Eliminate landfilling





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Hold and Reduce

- Hold medications during the acute hospitalization period of up to 10 days.
- Continue to examine prescribing patterns
 - decrease unexpected changes
 - discontinue medications to help eliminate unused and “wasted” medications



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What everyone can do!

- Commit to a healthy lifestyle
- Focus on prevention
- Dispose unwanted medications at take-back sites
- Purchase drugs in small amounts
- All health providers should know what to do with unused medications
 - Take them back!





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The Benefits of Reducing

- Reducing pharmaceuticals entering the environment at all levels of healthcare delivery will have personal, social and environmental benefits beyond the conventional uses individuals medicines were designed for.



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