



# ***Drug Usage and Disposal: Overview of Environmental Stewardship and Pollution Prevention***

**Christian G. Daughton, Ph.D.**

*Chief, Environmental Chemistry Branch*

Environmental Sciences Division

National Exposure Research Laboratory

Office of Research and Development

Environmental Protection Agency

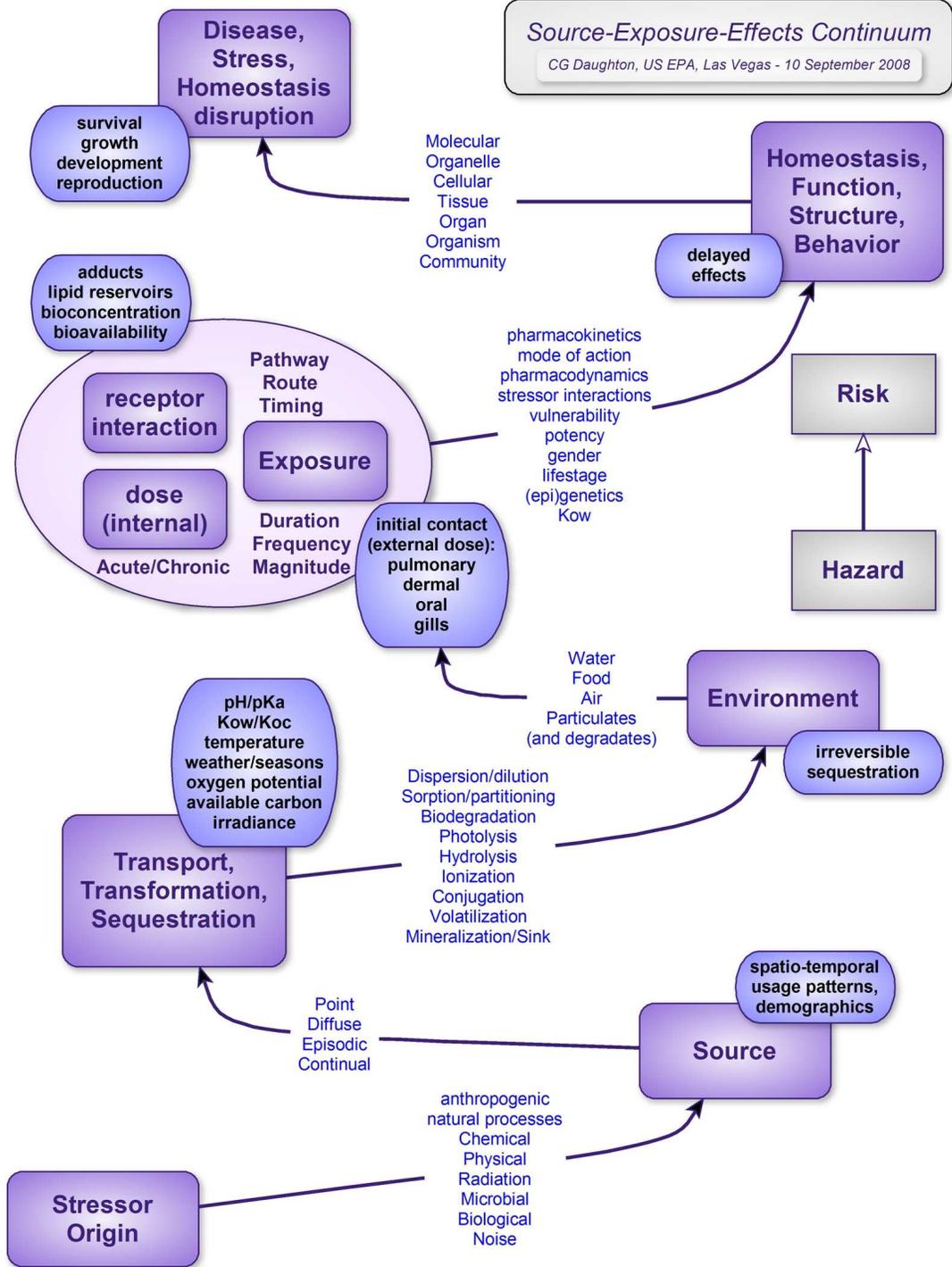
Las Vegas, Nevada 89119

[daughton.christian@epa.gov](mailto:daughton.christian@epa.gov)

Office of Research and Development  
National Exposure Research Laboratory, Environmental Sciences Division, Las Vegas, Nevada



*Source-Exposure-Effects Continuum*  
CG Daughton, US EPA, Las Vegas - 10 September 2008



## *Routes of Entry to the Environment for APIs*

Active pharmaceutical ingredients (APIs) used in the practice of human and veterinary medicine are released to the environment by two primary routes:

### sewerage:

- excretion (as a function of pharmacokinetics)
- bathing (topically applied drugs and API residues excreted via sweat)
- disposal to drains

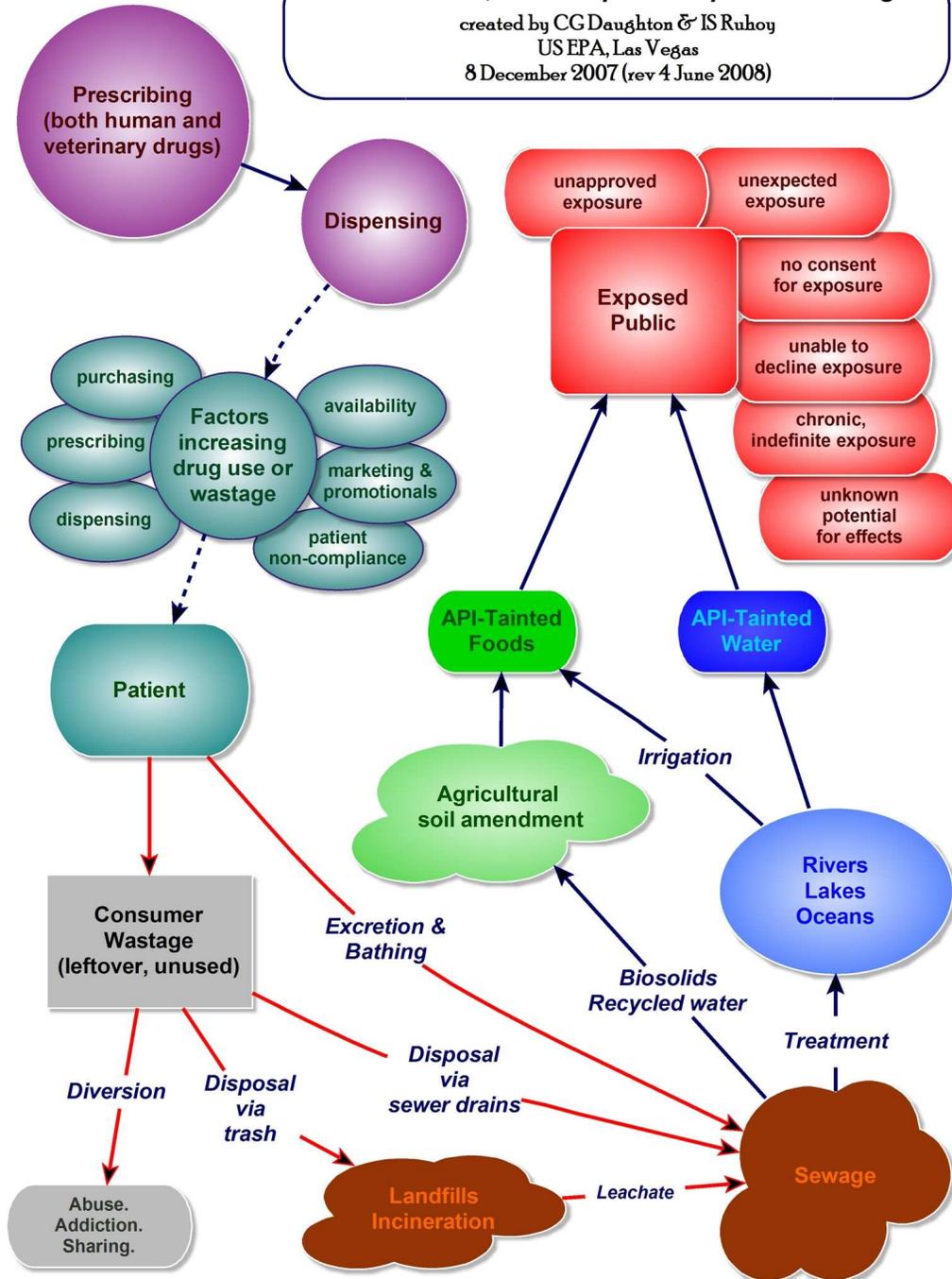
### trash:

- discarding unwanted new medications
- as well as used delivery devices or containers with residual contents



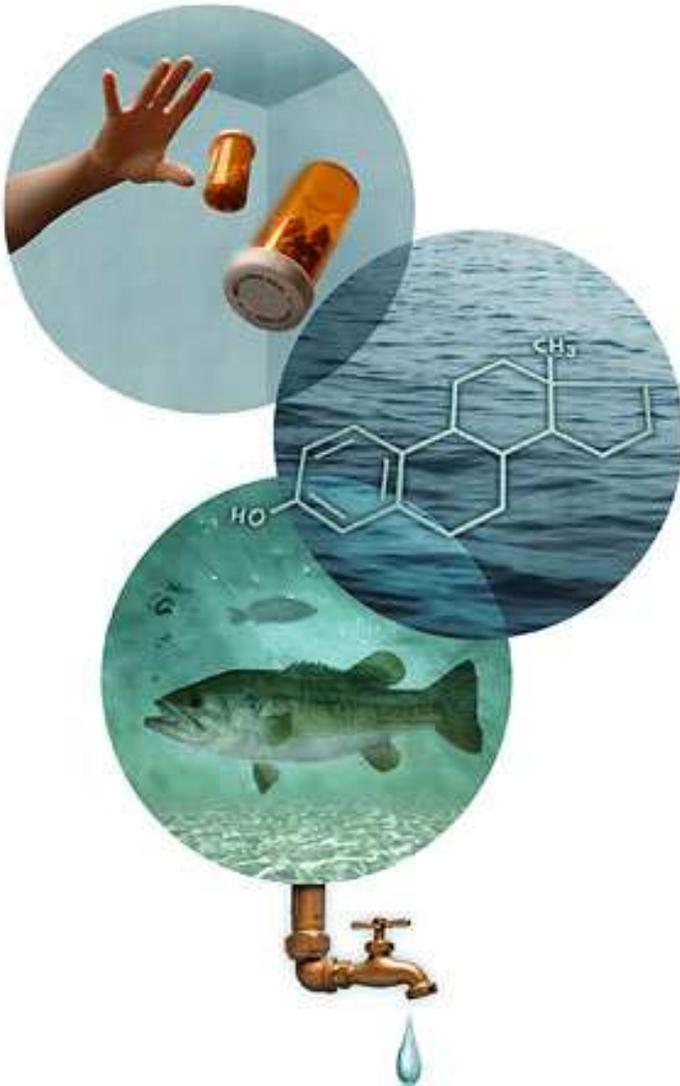
**Unintentional, Unanticipated Exposure to Drugs**

created by CG Daughton & IS Ruhoy  
US EPA, Las Vegas  
8 December 2007 (rev 4 June 2008)





# Stewardship, Pollution Prevention & Source Control



William Duke, New York Times, 3 April 2007



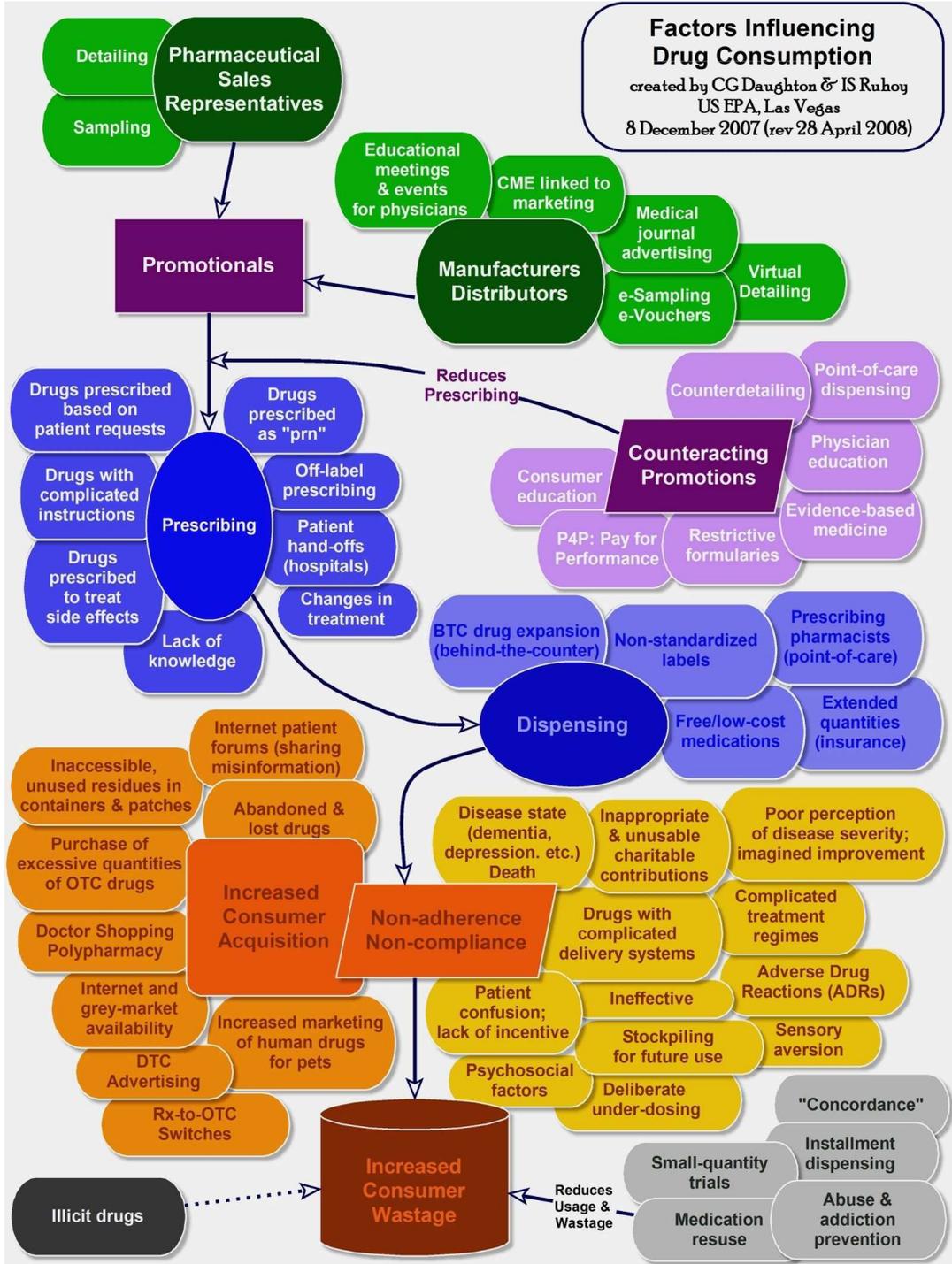
Mike Smith, Las Vegas Sun, 13 March 2008



## *Life-cycle Analysis and Sustainability*

- Life-cycle assessments regarding the various aspects of drug disposal or the numerous approaches to pollution prevention have been largely overlooked.
- For example, a full life-cycle analysis to determine the numerous variables leading to the creation of unused, unwanted, leftover drugs would include the causes of unnecessary prescribing and patient non-compliance/non-adherence.
- Are the current approaches for “prudent” drug disposal sustainable with regard to their environmental footprints or human safety? For example, additional factors to consider include: energy costs (consumer transportation), new forms of pollution (e.g., from incineration, landfilling), and increased hazards associated with possible diversion.

**Factors Influencing  
Drug Consumption**  
created by CG Daughton & IS Ruhoy  
US EPA, Las Vegas  
8 December 2007 (rev 28 April 2008)





## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs***

- How significant is the contribution of APIs to the environment by disposal versus excretion and bathing?
- What portion of APIs (or of individual APIs) in the environment result from disposal?
- Hypothetically, if the need for disposal were completely eliminated, would there be any measurable impact on environmental loadings of APIs?
- Can data on stockpiled unwanted drugs or disposed drugs be more efficiently collected? Such data, coupled with pharmacokinetic data for each API, could be used to assess the potential significance of disposal with respect to overall environmental loadings.





## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs – con't***

➤ Collection events for unused drugs from the public attempt to quantify their success by using **widely different approaches for measuring and reporting the quantities of collected drugs**. Inventories of collected drugs often fail to report measurement units. To enable comparisons between projects, or scientists to use the data for predictive modeling purposes, it is essential that the units of measurement be defined. Measures that have been used include the mass of each API itself, the mass of the formulated medications themselves (e.g., tablets and capsules, including all excipients), the mass of the medications plus their consumer-use packaging, the mass of medications plus packaging and shipping containers, or the volume. **But the only measure having relevance with regard to ecotoxicology and human health is the first: the mass of each individual API.**

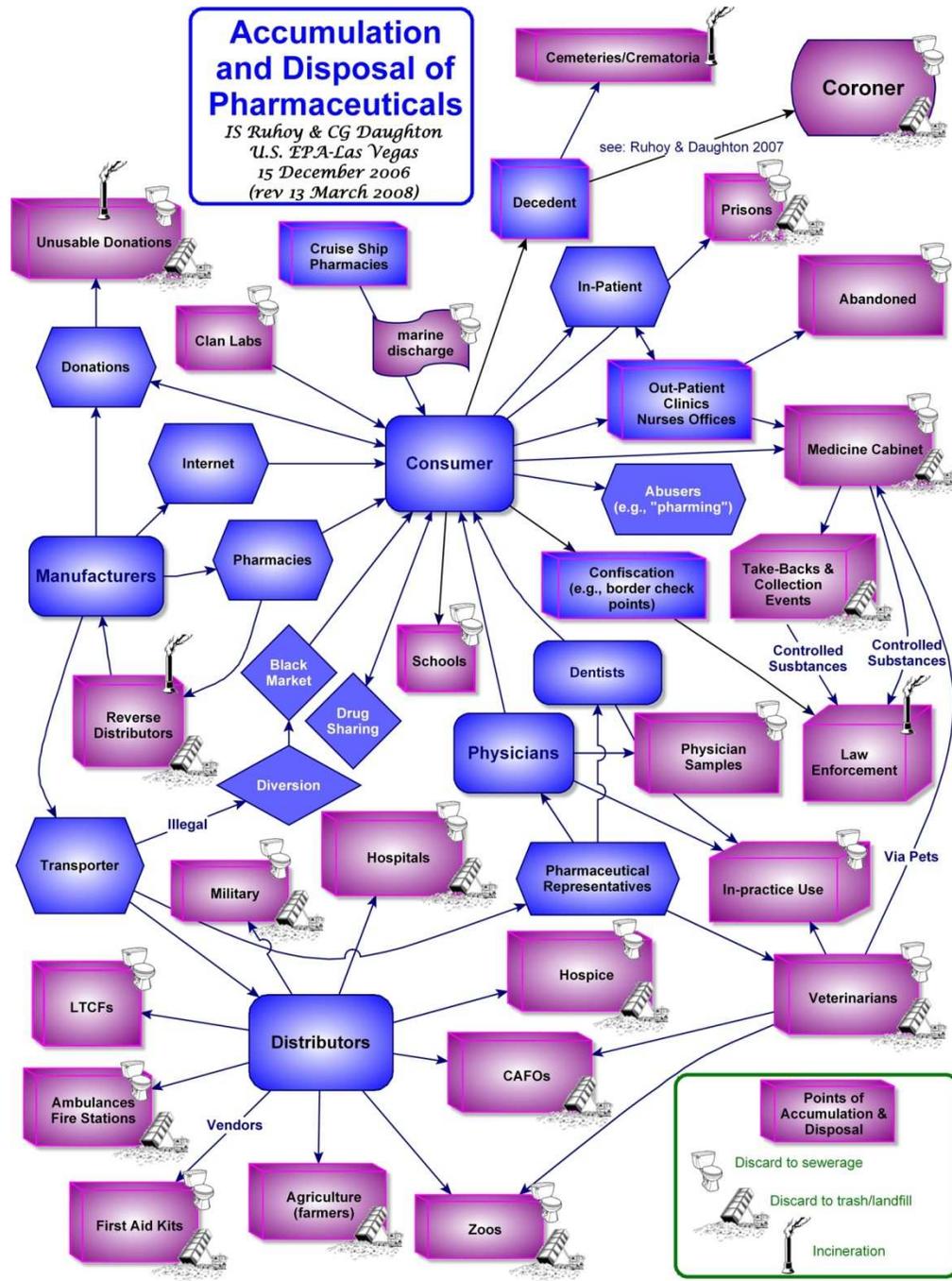
## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs – con't***

- Would collected data be more useful if a standard approach were used for cataloging and grouping APIs? One approach would be to use an international standard for categorizing the APIs according to their action on therapeutic systems, such as the Anatomical Therapeutic Chemical (ATC) Classification System.
- How statistically biased are the data collected from drug take-back events? Are they representative of the population at large? Would they be representative of return rates sustained over longer periods of time? Do drug collection events select for those individuals who are motivated to have stockpiled their unused drugs over long periods of time until they locate an opportunity for disposal?



**Accumulation and Disposal of Pharmaceuticals**

*IS Ruhoy & CG Daughton*  
 U.S. EPA-Las Vegas  
 15 December 2006  
 (rev 13 March 2008)



## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs – con't***

➤ Does drug disposal lead to transient spikes in concentrations of APIs in influents to sewage treatment plants (STPs) or septic systems? If so, how important are these intermittent or episodic, transient surges in concentrations? For example, could the intermittent discharge of large quantities of particular drugs via disposal possibly generate spikes leading to concentrations sufficiently high to have adverse effects on microbiota in STPs?



## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs – con't***

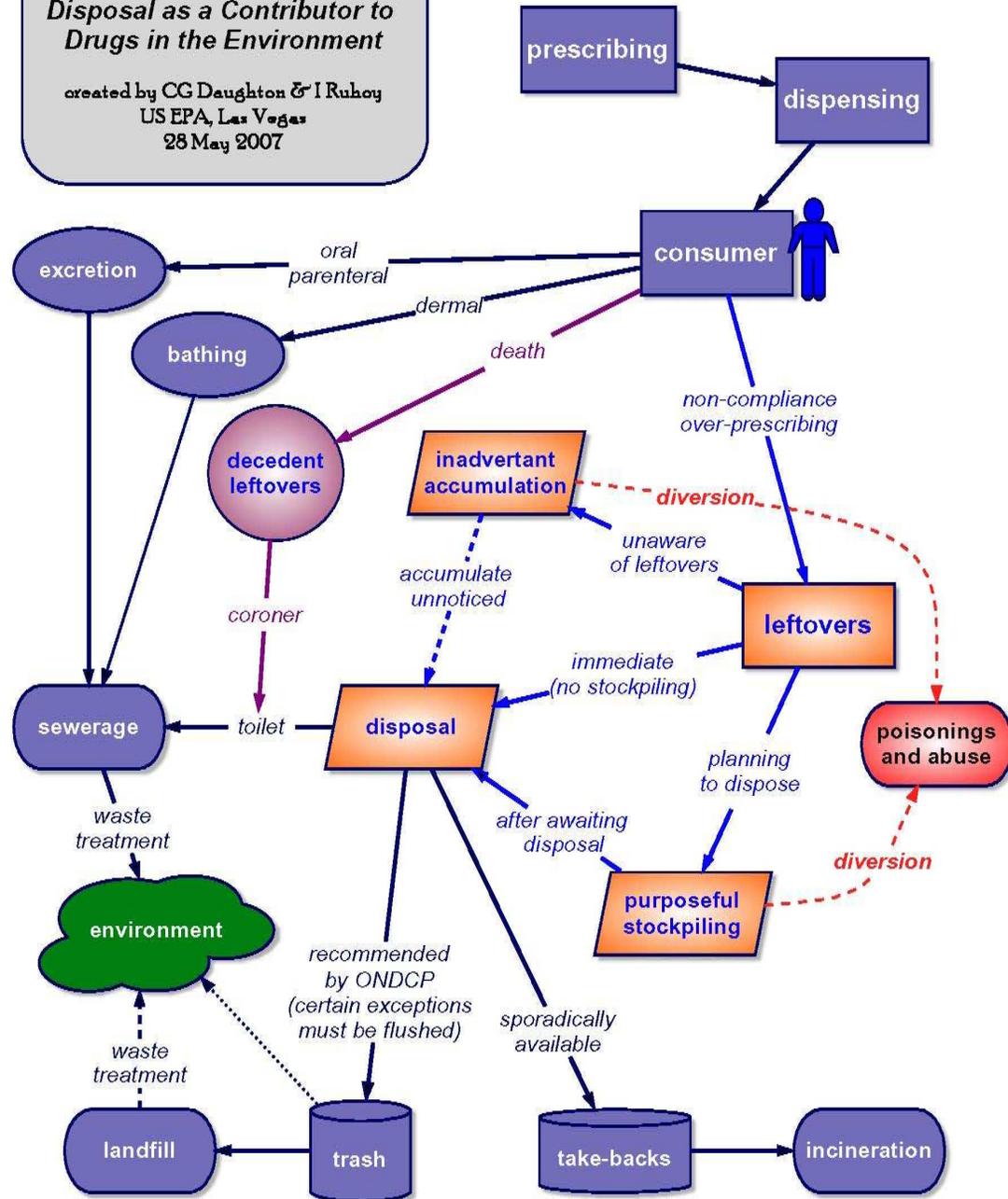
- **The ONDCP disposal guidance for consumers provides a list of “exceptions”** (certain hazardous drugs or those prone to diversion) that are still recommended for disposal by flushing down the sewer. Is this list sufficiently comprehensive as to include all the medications that pose acute risks associated with diversion or poisonings if disposed to trash? Does this list contain drugs that could be better disposed to trash? Does the disposal of these APIs add significantly to the portions that are excreted or released by bathing? Pharmacokinetics can help to address this question.
- **The ONDCP disposal guidance for consumers also recommends making drugs disposed to trash undesirable for reuse.** Does such alteration of drugs really prevent diversion? Does encouraging consumers to physically alter medications prior to disposal in the trash pose health and safety risks (e.g., by causing spillage that wouldn't otherwise occur)? Do these types of health and safety factors need to be re-evaluated in preparing the next generation of disposal guidance?



## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs – con't***

- **To what extent are leftover drugs that accumulate or that are stockpiled in households or trash - - awaiting disposal - - responsible for human morbidity and mortality** from either diversion (purposeful usage by those for whom the medication was not intended; e.g., abuse, addiction, pharming) or accidental/unintended exposure (e.g., ingestion by a toddler or pet)?
- **Do medications disposed to trash and then conveyed to landfills eventually pose a significant source of APIs in the leachates (pollution postponement)?** Do drugs discarded in domestic trash and then to municipal landfills pose not just the potential for future pollution but also risks with regard to re-use by those who actively seek to reclaim them (e.g., human "gleaners" or animal scavengers)?

**Disposal as a Contributor to  
 Drugs in the Environment**  
 created by CG Daughton & I Ruhoy  
 US EPA, Las Vegas  
 28 May 2007





## ***Unanswered Science Questions Regarding the Disposal of Unwanted Drugs – con't***

- Do the packaging materials (especially bottles and dispensers containing concentrated residuals) or the ever-increasing numbers of delivery devices once they have been used (e.g., delivery devices unique to certain drugs such as pumps, dermal patches, inhalers, syringes) pose a significant source of certain APIs?
- Does packaging constitute a significant source of non-API pollutants derived from the packaging itself (e.g., via incineration or weathering/leaching in landfills)?

## ***Stewardship and Pollution Prevention***

### *Disposal control vs. Usage control:*

two basic approaches for reducing the entry of APIs to the environment

- The first approach to pollution prevention (**disposal control**) is environmentally sound practices for disposal of unwanted medications. The second (**usage control**) is the development of practices that reduce the prescribing and dispensing of medications by eliminating unnecessary or imprudent customs. Significantly, **the control of usage is perhaps has greater potential for reducing overall entry of APIs to the environment**, as it can eliminate the need for disposal PLUS also minimize the residues that would otherwise be released by excretion and bathing.
- Control the disposition of APIs to storage or to treatment facilities, where only portions are destroyed (sewage treatment) or sequestered (landfills), where new contaminants are created (incineration, sewage treatment), or where new routes of release are enabled (application of biosolids to arable land).



## ***Stewardship and Pollution Prevention – con't***

- **Actions can be directed at improvements to any part of the life cycle of medications**, such as those spanning the vast, complex chain beginning with design/discovery, manufacturing, packaging, and advertising, and proceeding to prescribing (as also modified by practices of healthcare insurers) and dispensing, and ending with whether the medications are eventually consumed or used by the consumer.
- **Actions can be directed** not just at prudent alternatives for disposal, but **also (and more significantly) to reducing the contributions from excretion and bathing.**
- For guiding the selection of drugs with minimal environmental footprints and the responsible disposal of unwanted medications, would an **"environmental labeling" classification system** (such as the model created in Sweden) be useful for the physician and consumer?

## ***Stewardship and Pollution Prevention – con't***

- **Can "smart" or "intelligent" packaging systems, such as those used in the food industry, be adapted for medications - - with the objective of lengthening shelf life or monitoring and indicating the quality of the medication and whether it is reaching expiry? Examples include more effective oxygen and moisture scavengers and better ways for protecting against heat and light. Knowing the actual shelf life (which is a complex function of storage conditions and time) could prevent the unnecessary, premature discarding of medications.**
  
- Concern has long surrounded the reuse, recycling, or sharing of unused medications so that others do not have to purchase new supplies. Medication recycling is fraught with dangers (such as tampering and self-medication errors); recycling is currently implemented primarily in closed-loop, carefully controlled settings. **Can safe programs be developed for drug reuse or reintroduction into a wider distribution chain?**



## ***Collateral Benefits to Pollution Prevention***

*Reducing environmental pollution might not be the primary driving force or benefit from prudent stewardship.*

Instead, reducing usage of medications might also:

- **lessen healthcare costs** (via more effective treatment, reduced purchase costs, fewer prescribing/dispensing errors)
  
- **improve therapeutic endpoints and healthcare outcomes** (via better patient adherence/compliance)
  
- **reduce morbidity and mortality** caused by poisonings of infants, children, adults, pets, and sometimes wildlife by unused stored drugs or by drugs improperly disposed in trash.

## ***Coordination and Collaboration***

- A wide spectrum of organizations play various roles in drug stewardship and disposal - including city, state, and federal agencies, NGOs, and private companies. **Would an overarching framework be useful in coordinating the many disparate and overlapping activities?** Would such a framework serve to better promulgate what is known, facilitate setting priorities, reduce discrepancies and contradictions, and reduce duplication of effort?
  
- Lack of communication, interaction, and collaboration persists between the environmental sciences and the healthcare/medical communities on issues residing at the interface between the two. Those involved with studying the environmental aspects of drugs as pollutants, for example, generally operate in isolation from those involved with developing environmental stewardship programs. Bridging this gap could benefit both sides of the issue. **Could closer communication and collaboration result in more productive and efficient synergies?**



## ***Coordination and Collaboration – con't***

- No central public database exists that comprehensively compiles the numerous activities nationwide that are relevant to drug disposal (e.g., take back events and programs) and stewardship.
  
- How could the Drug Enforcement Administration best be involved in a dialog to rewrite the Controlled Substances Act (CSA) or provide the requisite waivers, in order to avoid the complications and hurdles that the Act currently imposes on the design, scope, and efficiency of consumer drug take-back programs?

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# Questions

*feel free to contact:*

**Christian Daughton, Ph.D.**

Chief, Environmental Chemistry Branch  
Environmental Sciences Division  
National Exposure Research Laboratory  
U.S. Environmental Protection Agency  
Las Vegas, Nevada 89119  
*daughton.christian@epa.gov*  
*702-798-2207*

<http://www.epa.gov/nerlesd1/bios/daughton.htm>



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**Christian Daughton, Ph.D.**

Chief, Environmental Chemistry Branch  
Environmental Sciences Division  
National Exposure Research Laboratory  
U.S. Environmental Protection Agency  
Las Vegas, NV 89119  
daughton.christian@epa.gov  
702-798-2207

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