

Green Pharmacy

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Presenter Information

- Attorney
- Environmentalist
- Senior Director, Corporate Compliance for a pharmacy
- Service the hospice community
- Wife, mother, friend, non-profit board member
- **Not** a pharmaceutical representative, pharmacist, chemist, or scientific researcher

Why Be Green?

- \$275 billion dollars spent on Rx medications in 2006
- 3.7 billion Rx dispensed
- \$ 1 billion dollars wasted medication in US annually (estimated)
- Heightened awareness of trace medications in nation's water systems

Green Chemistry

- Seeks to eliminate and/or reduce toxic substances from manufacturing processes
- The design of chemical products and processes that reduce or eliminate the use and generation of hazardous substances

Background

- Patient-consumers instructed to flush
- Varying drug concentrations found in US and Canadian waters
- Growing body of evidence indicates affect on aquatic life:
 - Cross-genderization of fish
 - Sterilization
 - aggression

Background

- Active Pharmaceutical Ingredients (API) detected in:
 - surface waters (e.g. rivers, lakes)
 - ground water
 - drinking water
 - Sewage treatment plant effluents

Active Pharmaceutical Ingredients

- API –
 - “a compound responsible for physiological or pharmacological action and used in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans.”

Pharmaceuticals in the Environment (PIE)

- 1999 – USGS national reconnaissance of emerging contaminants
 - 30 states/139 streams sampled for pharmaceutical presence
 - NonRx found most frequently
 - Antibiotics
 - Reproductive hormones
 - Other Rx medications

Pharmaceuticals In The Environment (PIE)

- Pharmaceuticals can enter the environment in several ways:
 - Excretion after therapeutic use
 - Discharge of treated wastewater from manufacturing facilities
 - Disposal of unused medicines by patient-consumers

A Science Based Approach: Evaluating the Significance of PIE

- *PhATE*[™] (Pharmaceutical Assessment and Transport Evaluation)
 - Developed to estimate API in US surface waters that result from patient use of medications
 - Models predicted environmental concentrations (PEC) in select 11 watersheds as representative of most hydrologic regions in US



FIGURE 1. The locations of the 11 watersheds included in the current version of *PhATE* are shown.

PhATE™

- Watersheds represent :
 - 19% (approx.) land area of contiguous US
 - 44,260 km stream length
 - 14% US population
 - 1112 POTW

PhATE™

- Absent:
 - Watersheds containing major Metro areas (e.g. NY, LA, Miami)
 - Drinking water for these provided by sources not affected by POTW discharge
 - Veterinary APIs or septic discharges to groundwater
 - These releases are through pathways other than POTW discharge to surface water

PhACT®

- Pharmaceutical Assessment and Characterization Tool:
 - Database
 - Compilation of all peer-reviewed English language literature on aquatic effects, treatment, and environmental depletion of API
 - Developed by PhRMA
 - Compiles information on specific API (e.g. ibuprofen, naproxen)
 - Identifies data gaps

Green Chemistry Balance & Goals

- Medications must retain efficacy for patient use
- Medication functionality considerations:
 - Sufficient stability to pass through stomach
 - Realistic shelf life
- Continued improvement in understanding metabolism and excretion components results in:
 - Increased specificity
 - Better targeting and delivery
 - Shorter duration therapy

Green Chemistry Goals

- 100% oral absorption- lower emissions from patients
- Reduce/eliminate non-therapeutic effects- no non-target effects
- Maximize efficacy in all patients treated – produces lower overall drug usage

Suggested Goal

- We need to understand what medications are being wasted and why?
 - Mass data collection on wasted medications in:
 - Long-term care facilities
 - Hospice programs
 - Individual patient-consumers (potential to incorporate survey with take back programs)

The Pharmaceutical Industry

- Public commitment to assessing significance of PIE using science-based approaches
- Industry human health assessment models indicate no appreciable risk to human health
- Continued interaction with key stakeholders to understand and resolve:
 - How drugs are removed in wastewater treatment and means of improvement
 - What happens to drugs in the environment and how to predict

Environmental Awareness & Pollution Prevention

- Initiatives
- Awards
- Grants

The Green Chemistry Institute

- 2005 – established Pharmaceutical Roundtable in cooperation with pharmaceutical companies
- **MISSION:** To identify and overcome drug discovery and process chemistry challenges

Green Chemistry Institute Grants

- Professor Jianliang Xiao, University of Liverpool, England
 - Develop a cleaner, more efficient method of reducing amides to amines; uncover high-yield hydrogenation catalysts carried out in H₂O instead of organic solvent
- Professors Robert E. Maleckzka Jr. and Milton R. Smith, III, Michigan State University
 - Work on Suzuki-type C-H activation and C-C coupling of aromatic compounds; avoiding halogenated precursor traditionally needed to make boronic ester intermediate

What Companies Are Doing

- 2006 – Abbott implements four pollution prevention projects at headquarters, receives Illinois Governor's Pollution Prevention Award:
 - Uses more enviro-friendly product to replace volatile organic material in manufacturing process
 - Repairs production lines to reduce CO₂ emissions and energy consumption
 - Lowers the amount of purified H₂O used in production of pharmaceuticals
 - Reduces landfill waste through provision of reusable clothing for employees (v. disposable)

What Companies Are Doing

- 2004 – AstraZeneca's 'SHE Triggers' Model, enabling potential safety, health and environmental issues to be identified and designed out of its manufacturing processes for new active pharmaceutical ingredients at early stage wins the Institution of Chemical Engineers Award.
- Model extended to secondary manufacture processes and pharmaceutical products.

What Companies Are Doing

- 2005 - Glaxo (GSK)
 - Environment, Health and Safety Issues Awards; Green Chemistry/Technology
 - Tonbridge, UK : antiretroviral drug GW873740A
 - no solid waste, 37% less liquid waste, 16% less energy
 - Research Triangle Park, US: mnftr route GW677954X (diabetes drug)
 - Reduced number of synthesis stages required
 - 39% increased yields, 70% reduced waste, avoided use of some hazardous waste materials
- Product Design – incorporating EHS consideration into new product design
- FLASC (Fast Lifecycle Assessment Chemistry) web-based

What Companies Are Doing

- Lily – HSE Strategy Goals
 - 1/3 reduction in energy intensity/corresponding greenhouse gas emission of operations by 2010 (2003 baseline); 2007 progress to date: 19% reduction
 - 1/3 reduction in hazmats purchase by 2010; 2005 progress to date: 37% reduction
 - “0” serious enviro events by 2007; 2006 five events recorded

Green Chemistry v. Green Pharmacy

- Similar objectives, different mechanisms
- Reduced healthcare footprint on environment
- Process change
- Behavioral change
- Source reduction
- Proactive and reactive steps

Pharmacy Trends

- Consumer medication take back programs
 - Washington
 - Maine
 - Wisconsin
 - California

What Other Countries Are Doing

- British Columbia – Medications Return Program (1996)
 - pharmacies accept all Rx, OTC, and herbal products; returns stored in 5 gallon buckets, collected and incinerated
 - European Union – Medication Collections Systems (EU Directive 2001/83)
 - All member states must have collection system
 - Patient-consumers advised to “take back” unused medications

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