Dosed Without Prescription

Mae Wu
Health and Environment Program
Natural Resources Defense Council
mwu@nrdc.org  202-289-6868
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Pipeline

- Design
- Approval FDA — FFDCA, NEPA
- Production EPA — Clean Water Act (NPDES), Clean Air Act (ESHAPs), Safe Drinking Water Act (CCL, UCMR)
- Use FDA
- Disposal/Discharge EPA — RCRA
  DEA — Controlled Substances Act
Use

• Physician Behavior
  – Over-prescription
  – Influence behavior through classification (Swedish example)

• Marketing

• Off-label Use

• Prescription Plans
  – E.g. 90-day, 30-day prescriptions
Disposal/Discharge

- **Intentional Disposal**

- **Unintentional Disposal**
  - Human
  - Animal (CAFOs)

- **Incineration**

- **Wastewater Treatment**
Unanswered Questions

- What is the volume of pharmaceuticals in our tap water and in our waterways?
- Can these amounts cause or contribute to adverse human health effects, considering sensitive populations and their presence as a complex mixture in drinking water?
- Is there a pharmaceutical class or category of biggest concern?
- What proportion of pharmaceutical contaminants come from excretion from humans versus disposal down the toilet?
- What is the relative contribution from animal uses, especially concentrated animal feeding operations for antibiotic and growth hormone drugs?
- Is the disposal in landfills a significant source of contamination? What is the best disposal method to protect the environment?
- How persistent are pharmaceuticals in the environment and how effective is conventional wastewater treatment and drinking water treatment in destroying them?
- What is the magnitude of waste per unit of desired product coming from manufacturing pharmaceuticals and how much of this waste is active ingredient, hazardous chemicals, or biological hazardous waste?