

Things to Consider for the International MRO – The US Perspective

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What is on the mind of the US MRO that are problems / issues?

- New “designer drugs” of abuse
- Escalating synthetic opioid use
- Concern about “identification” v.
“fitness for duty”



Designer Drugs of Abuse

- Bath Salts
- K₂

K2 – What is it?

- Synthetic cannabinoid receptor agonist
- AKA Spice, Spice Gold, Pot-pourri, Serenity and herbal incense
- JWH-018, JWH-073, HU-210, CP 47, 497 (over 100 synthetic cannabinoids)
- Developed for research purposes
 - Pain management
 - Brain research
 - Anti-slip agent
 - Contaminant found in many plastics
- Tetrahydrocannabinol (THC) substitute?
 - But structurally quite different
 - Potentially more potent than THC



K2 – What is it?

- Street drug?
- Marketed as “all natural” to teens and young adults
- Smokeable (pipe, water pipe, rolled papers, inhaled smoke or vapors)
- Internet, tobacco and pipe stores, “head shops,” convenience stores
- Not made for human consumption
- JWH-018 and its chemical cousins have a chemical structure shared with known cancer-causing agents

Los Angeles Times

- Reporting from Sylva, N.C.—
- John W. Huffman is a bearded, elfin man, a professor of organic chemistry who runs model trains in his basement and tinkers with antique cars. At 79, he walks a bit unsteadily after a couple of nasty falls.

Relaxing on his back porch in the Nantahala National Forest, watching hummingbirds flit across his rose beds, Huffman looks every bit the wise, venerable academic in repose.

But this courtly scientist unwittingly contributed to the spread of "designer marijuana" so potent that the Drug Enforcement Administration has declared some of what he created illegal.

Huffman's years of scientific research at [Clemson University](#) on the interaction between drugs and [brain](#) receptors led to so-called fake marijuana with effects far more powerful — and dangerous — than garden-variety marijuana. "[Spice](#)," "K-2," "Skunk" and similar products made using the chemical compounds he formulated have surged in popularity in recent years.



K2 – What is it?

- No published safety data
- No published known effects in humans
- Anecdotal reports of the following:
 - Agitation
 - Anxiety
 - Tachycardia
 - Vomiting
 - Very high blood pressure
 - Seizures
 - Hallucinations
 - Non-responsiveness

Drug Testing for K2

- Remember – K2 or Spice Gold or Spice is **NOT** marijuana (THC)
- Traditional “street drug panel” will not find these synthetic cannabinoids
- Developing a test is complex
- Must first locate and isolate the substance
- Pure metabolite or in an excretion urine
- Human use for research purposes (ethical issues)
- Create the assay and validate the testing methodologies
- Cost prohibitive for most labs
- UCLA Olympic Analytical Lab has developed a screen and confirmation for JWH-018 in urine
- Screen for JWH-073
- Only the metabolites appear in urine
- Short detection window (up to 72 hours?)
- Qualitative test (indicates presence or no presence, no threshold)

“Bath Salts” (Synthetic Cathinones)

- “Bath salts” is a group of synthetic substances that produce effects similar to cocaine, ecstasy, and methamphetamines
- “Bath salts” are not actual salts used for taking a bath. The term is used to market the product legally
- “Bath salts” often contain MPDV Methylendioxypropylone - a psychoactive drug with stimulant properties and reportedly has four times the potency of Ritalin (ADD medicine)
- Although structurally related to MDMA (Ecstasy), MPDV has purely stimulant effects, such as Cocaine, and no empathogen and entactogen effects (distinctive emotional and social effects, like ecstasy)

“Bath Salts”

- Common Names
 - Ivory Wave
 - Vanilla Sky
 - Pure Ivory, Purple Wave
 - Charge+
 - Ocean Burst, Sextacy
- Available online and in head shops
- Effects are reported to last six to eight hours,
- Overdoses and death related to use have been reported in Europe and Australia



Table 1. “Bath-Salt”-Related Calls Reported to U.S. Poison Control Centers

| Year | Number of Calls |
|-------------|------------------------|
| 2009 | 0 |
| 2010 | 302 |
| 2011* | 2,237 |

Source: American Association of Poison Control Centers, data run by AAPCC on May 12, 2011.

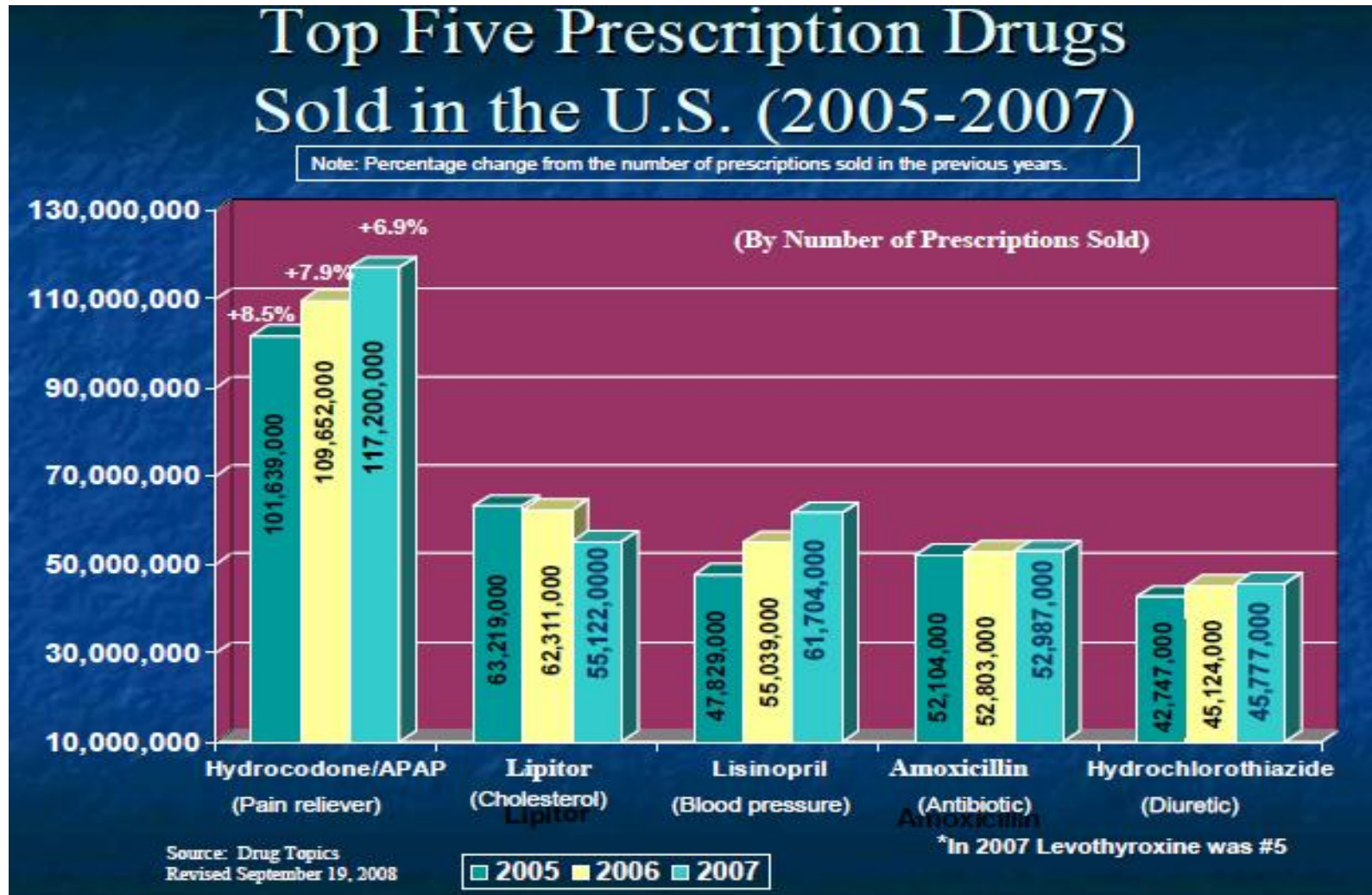
*Data reflect calls received and reported from January 1, 2011, through May 12, 2011.



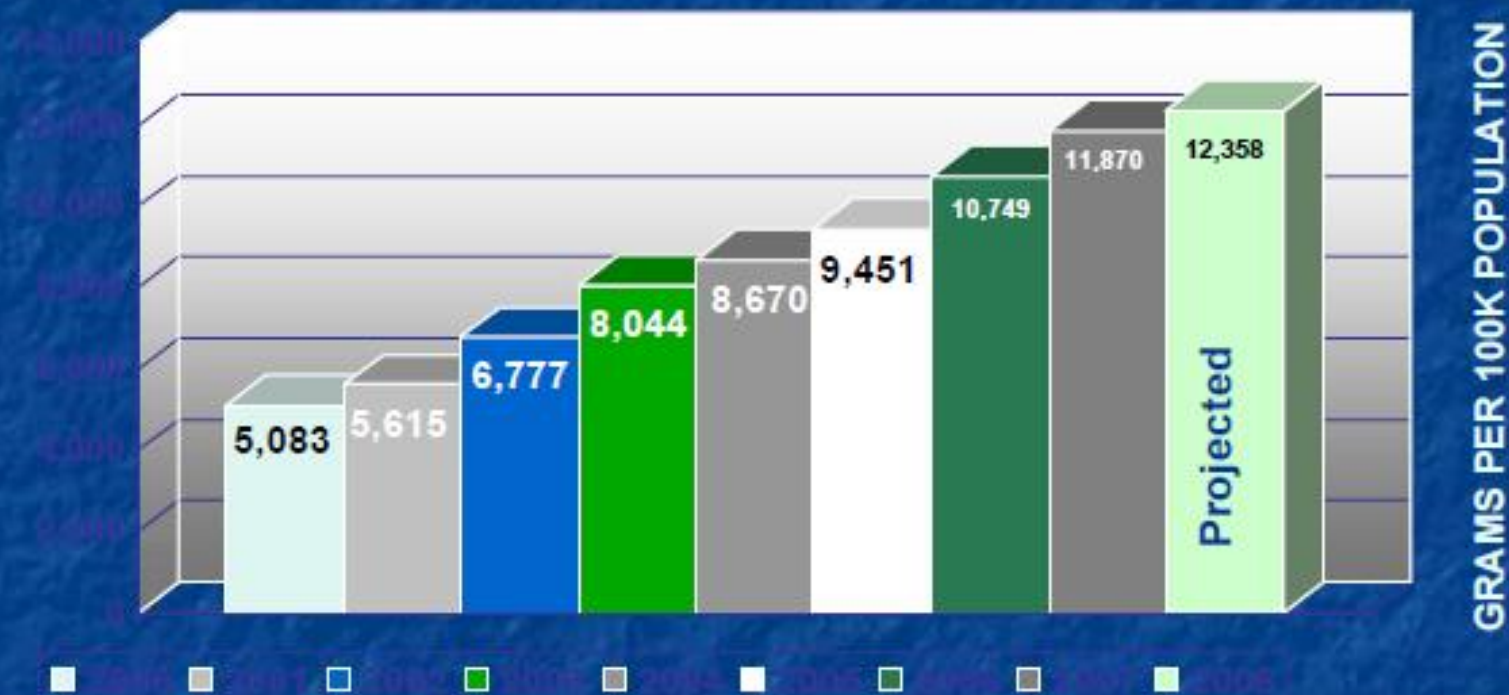
Bath Salt Drug Testing

- Few labs currently test
- Testing (if available) usually focused on three chemicals
 - Mephedrone
 - 3,4 methylenedioxypropylamphetamine (MDPV)
 - Methylone
- A few labs offer expanded 11 panel testing

Escalating Synthetic Opioid Misuse / Abuse



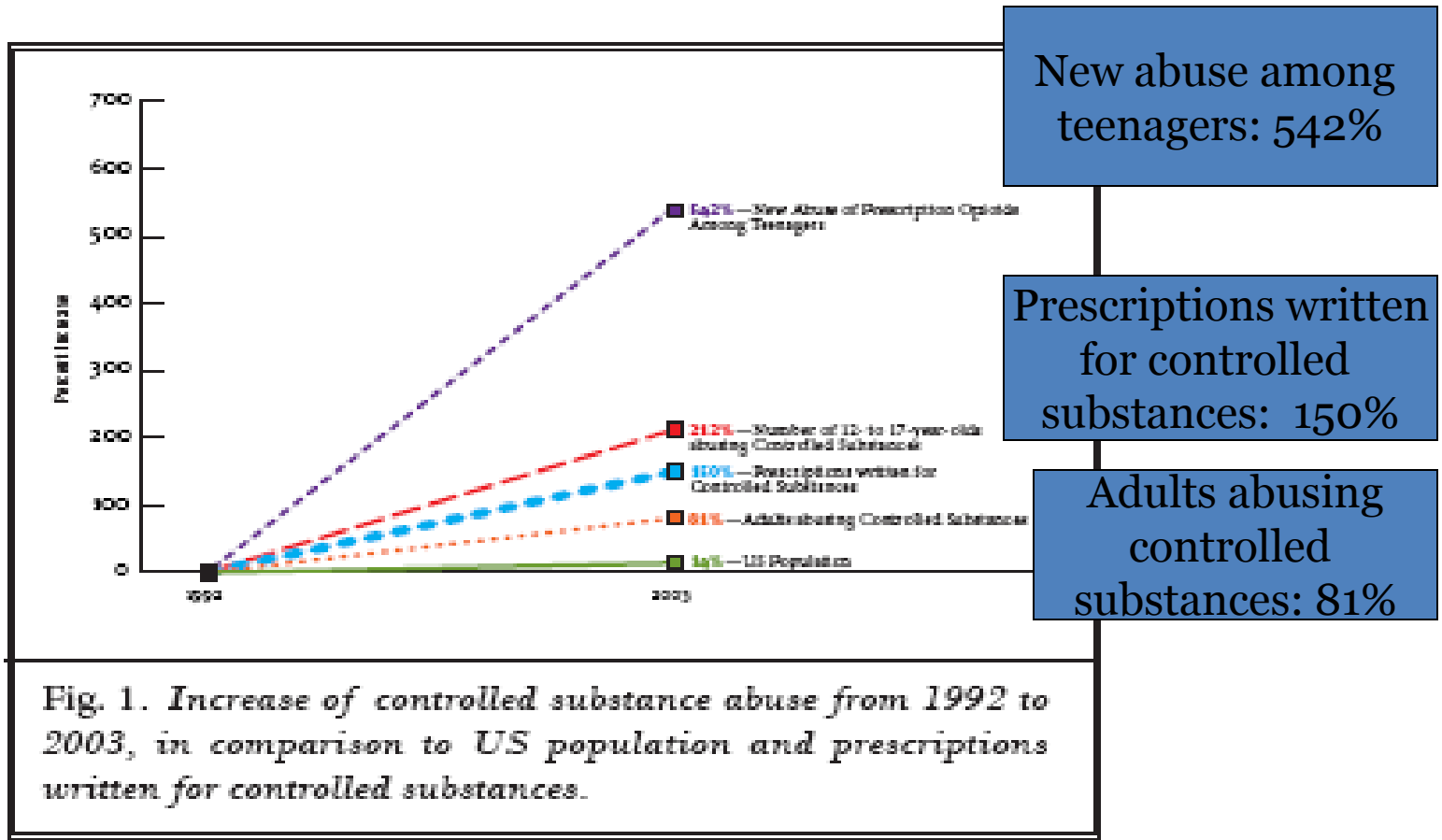
Hydrocodone Distribution* CY2000-2008 U.S. Average



* Includes sales to Retail Registrants, i.e. pharmacies, hospitals, practitioners, teaching institutions, and mid level practitioners

01/01/2008-06/30/2008

Abuse statistics outpace rate of increased Rx's





What Has Changed?

- Dramatic increase in past decade in use of medications for:
 - chronic pain
 - anxiety
 - sleep disorders
 - attention deficit disorders.

Current Issues

- Hundreds of new drugs on the market every year that have potential “impairing” effects
- Medication interactions are often unknown and not monitored because people get multiple medications from several physicians
- Aging population being prescribed more and more drugs
- Painkillers, tranquilizers, sleep aides readily available via the internet and “walk-in” clinics

What Is the Issue?

- Abuse and misuse of prescribed meds takes several forms:
 - Use for longer than medically indicated
 - Use in dosages higher than recommended
 - Use in combination with other drugs & OTC medications
 - Use when performing tasks that are contraindicated

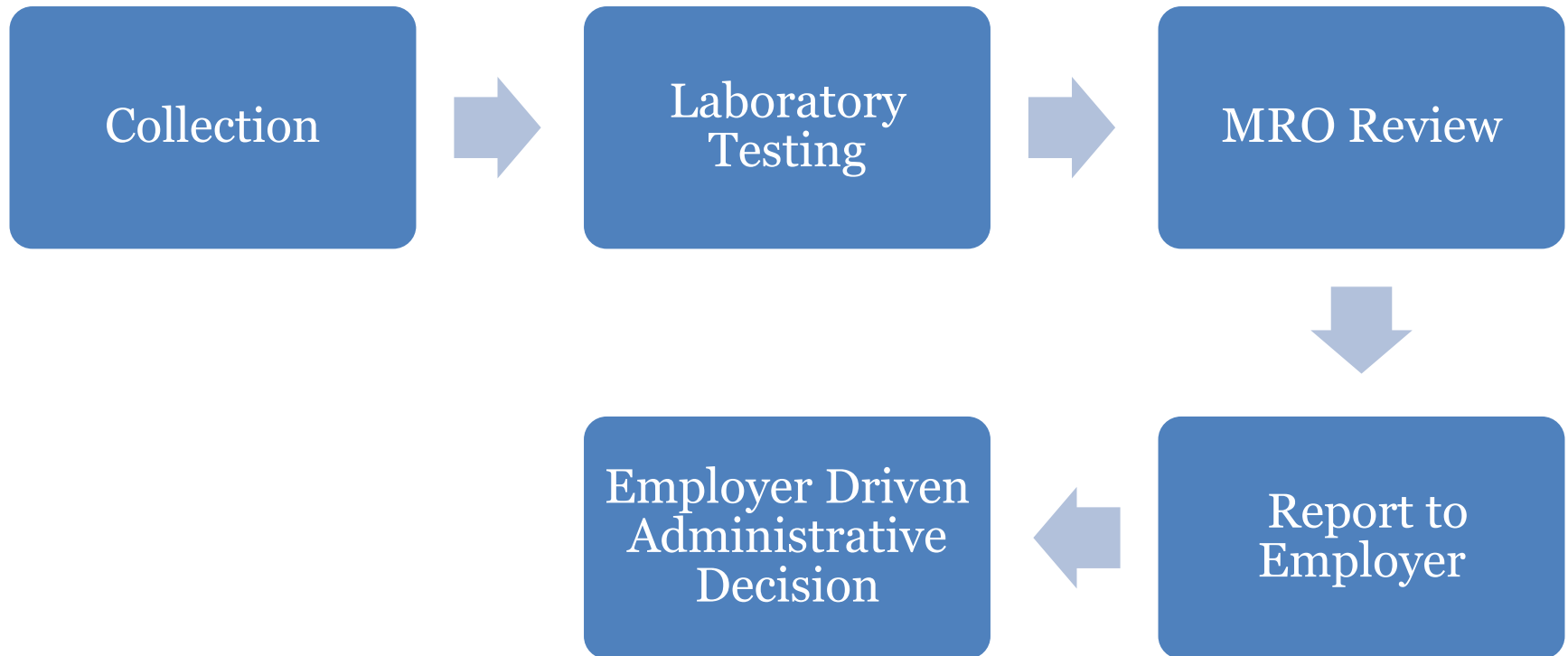


What is the Current Data?

- Americans consume 80% of the global supply of opioids
- This includes 99% of the world's hydrocodone and 2/3s of the world's illegal drugs
- They constitute 4% of the world's population

Manchikanti L. National drug control policy and prescription drug abuse: facts and fallacies. *Pain Physician*. 2007;10:399-424.

Traditional MRO Role – US Model



Integrated MRO Model



THANK YOU
FOR YOUR INVITATION
AND ATTENTION



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