Policy, Advocacy, Legislative Agenda

Why?

Protect public health

- Reduce abuse and diversion
- Improve patient access to effective medication
- Require post-marketing surveillance
- Provide incentives for the development of new formulations
    - Remove older, more abused compounds from the market (post-marketing)
    - Create a duty to utilize abuse-deterrent formulations (avoid litigation)

Who?

- PhRMA scientific group
- Pain Policy and Studies Group
- American Pain Foundation
- National Pain Foundation
- Anti-drug organizations
    - Partnership for a Drug Free America
    - CADCA
- NIDA
- SAMHSA
- Companies' lobbyists
- Congressional hearing
- Friends of NIDA
- CPDD
- Prescribing physician advocacy groups
    - APS
    - AAPM
    - ASAM
    - AGS
    - ASIPP

What?

- Nosology group to develop agreed-upon definitions of terms
- Collaboration among concerned parties to approach Congress
    - Which entity?
    - What actions?
    - Further refine recommendations over the next month

Congress

- Authorize incentives
- Guaranteed reimbursement (incremental increase in price over non-deterrent products), tax benefits
- Provisional Scheduling (based on phase IV commitments)
- PDUFA for guidance documents

FDA

- Guidance
- Fast Track
- Priority Review
- Implicit Claims
- Explicit Claims (post-market)

DEA

- Differential scheduling (post-market)