Citizen's Petition

- Content
  - Request FDA produce a guidance document on abuse-deterrent formulations
  - ADFs receive fast track status and priority review
  - Meaningful labeling fostered
  - Ask FDA to develop a credible legislative remedy to provide greater incentives for development of ADFs
    - Excluivity, reimbursement, tax credits
  - Resources be allocated to accomplish above
  - Accompany with "scientific background paper"

Citizen's Petition

- Process
  - THCI to produce draft CP
  - Circulate to those present today for feedback
  - Obtain feedback on other potential signatories
  - Circulate revised draft to larger THCI group and additional potential signatories
  - Submit final CP
- CP itself unlikely to produce fast results
  - Need to consider legislative initiatives

Scientific Background Paper

- Identify key issues that must be addressed in the ADF guidance
- Provide general recommendations in 6 key areas:
  - CMC (tampering/extractability)
  - Preclinical studies
  - Human clinical pharmacology (alcohol)
  - Human abuse liability studies
  - Clinical trials (efficacy, safety, abuse)
  - Epidemiology and surveillance
- Provide scientific evidence underlying these recommendations
- Indicate potential labeling claims and supporting evidence required