

The Controlled Substances Act A New Frontier



Jay Campbell

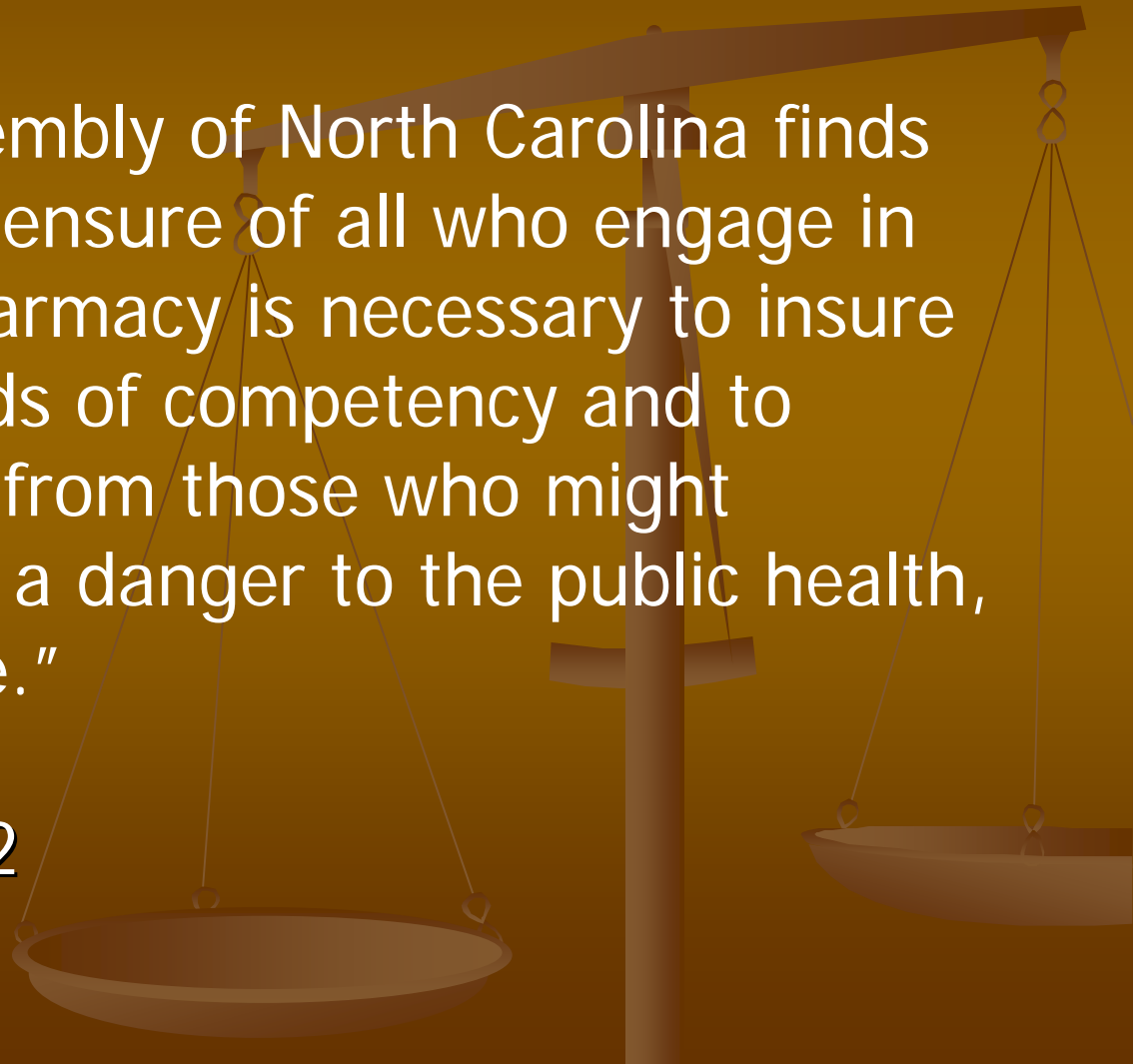
Executive Director

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy

"The General Assembly of North Carolina finds that mandatory licensure of all who engage in the practice of pharmacy is necessary to insure minimum standards of competency and to protect the public from those who might otherwise present a danger to the public health, safety and welfare."

N.C.G.S. § 90-85.2



Mission Variance

- Boards of Pharmacy are, with some exceptions, “law enforcement agencies” in the traditional sense.
- Pharmacists are, of course, health care providers, not deputized law enforcement agents.
- Nonetheless, as long as the law provides pharmacists with a legally created “monopoly” on dispensing of controlled substances, the law will continue to impose a set of monitoring and reporting responsibilities on pharmacists.

Plus ça change . . .



"[I]f the druggists of the United States do not resolutely take hold of the regulation of the sale of narcotic drugs . . . they will merely be turning it over to the care of people who are less competent to deal with it than themselves."

James H. Beal
American Pharmaceutical Association
1903

Striking the “Balance”

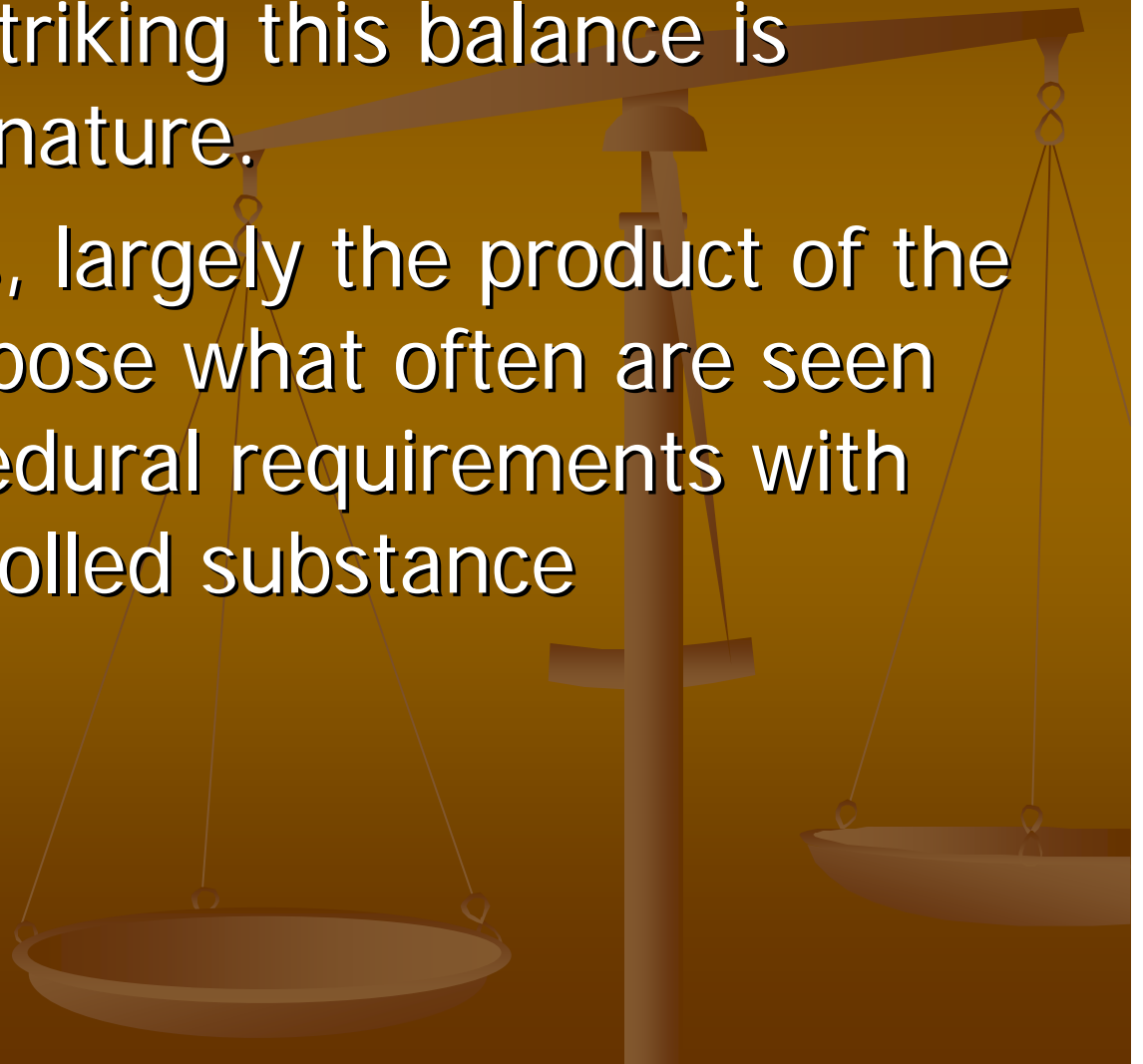


“Both healthcare professionals, and law enforcement and regulatory personnel, share a responsibility for ensuring that prescription pain medications are available to the patients who need them and for preventing these drugs from becoming a source of harm or abuse. We all must ensure that accurate information about both the legitimate use and the abuse of prescription pain medications is made available. The roles of both health professionals and law enforcement personnel in maintaining this essential balance between patient care and diversion prevention are critical.”

“Promotion Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act,” A Joint Statement from 21 Health Organizations and the Drug Enforcement Administration

Striking the “Balance”

- One means of striking this balance is “procedural” in nature.
- DEA regulations, largely the product of the early 1970s, impose what often are seen as archaic procedural requirements with respect to controlled substance prescriptions.



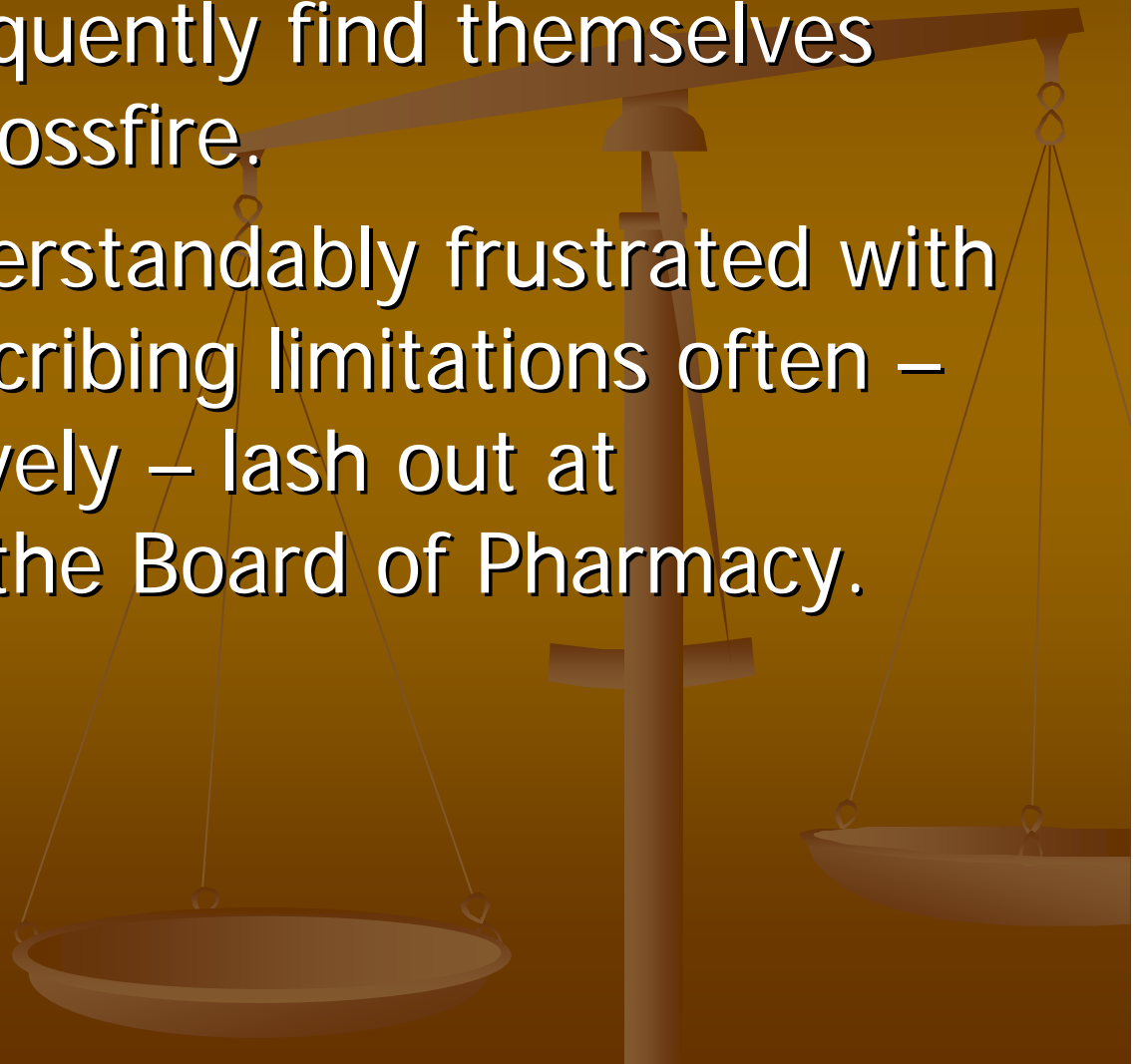
Procedural Frustrations



- Examples:
 - Prohibition on refills for Schedule II controlled substances (although some used for chronic conditions)
 - DEA's marked reluctance to green light electronic controlled substance prescriptions (new rule now out – after nine years of “study”!)
 - DEA's recent, and narrow, interpretation of who an “agent” of a prescriber may be for transmitting controlled substance prescriptions, particularly in the long-term care setting

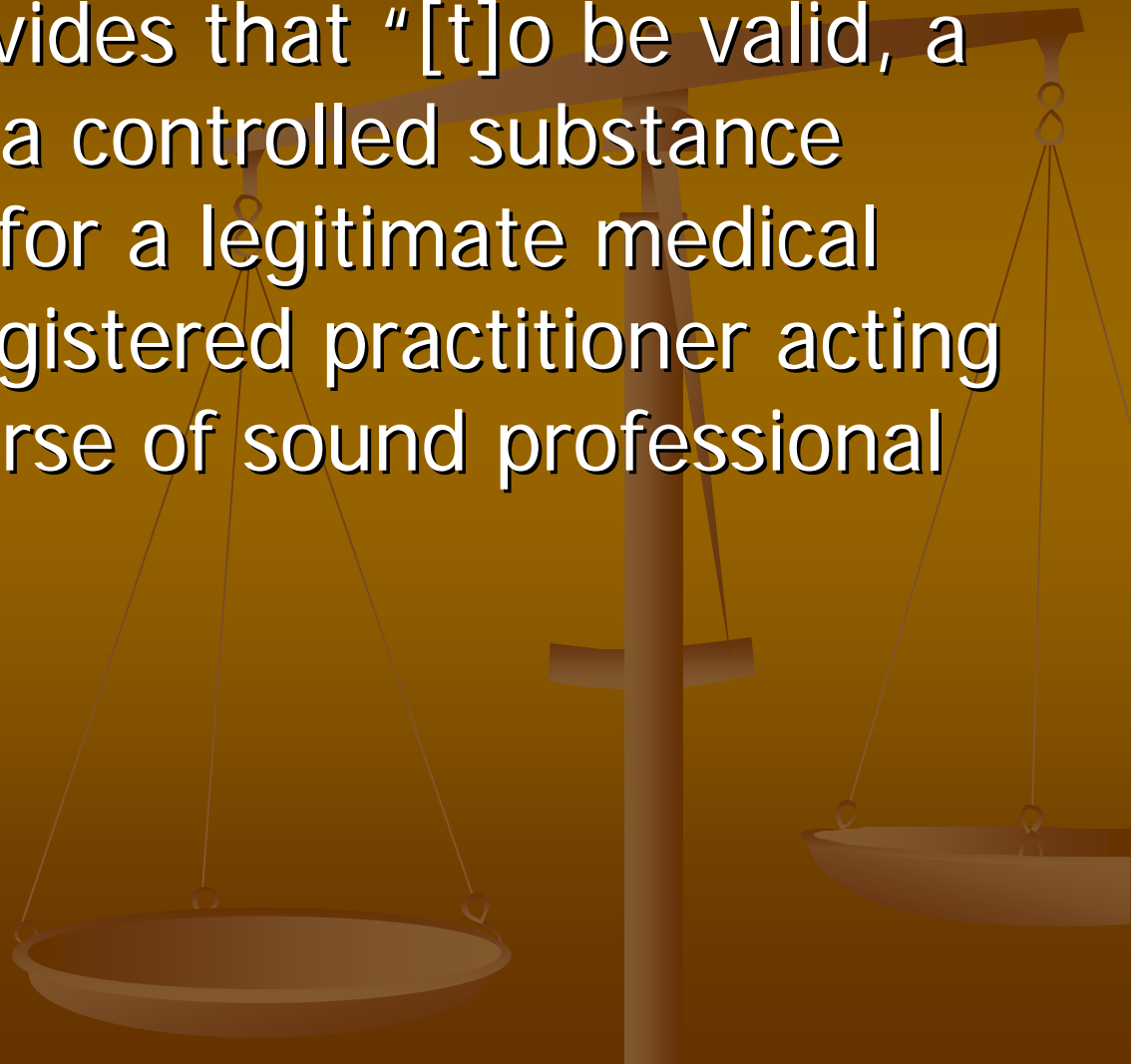
Pharmacists in the Crossfire

- Pharmacists frequently find themselves caught in the crossfire.
- Prescribers understandably frustrated with procedural prescribing limitations often – and unproductively – lash out at pharmacists or the Board of Pharmacy.



“Substantive” Balance Striking

Federal law provides that “[t]o be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a registered practitioner acting in the usual course of sound professional practice.”



Pharmacy Practice Act Regulations

21 NCAC 46 .1801 RIGHT TO REFUSE A PRESCRIPTION

(a) A pharmacist or device and medical equipment dispenser may refuse to fill or refill a prescription order, if, in his professional judgment, it would be harmful to the recipient, is not in the recipient's best interest or if there is a question as to its validity.

(b) A pharmacist shall not fill or refill a prescription order if the pharmacist actually knows or reasonably should know that the order was issued without a physical examination of the patient and in the absence of a prior prescriber-patient relationship

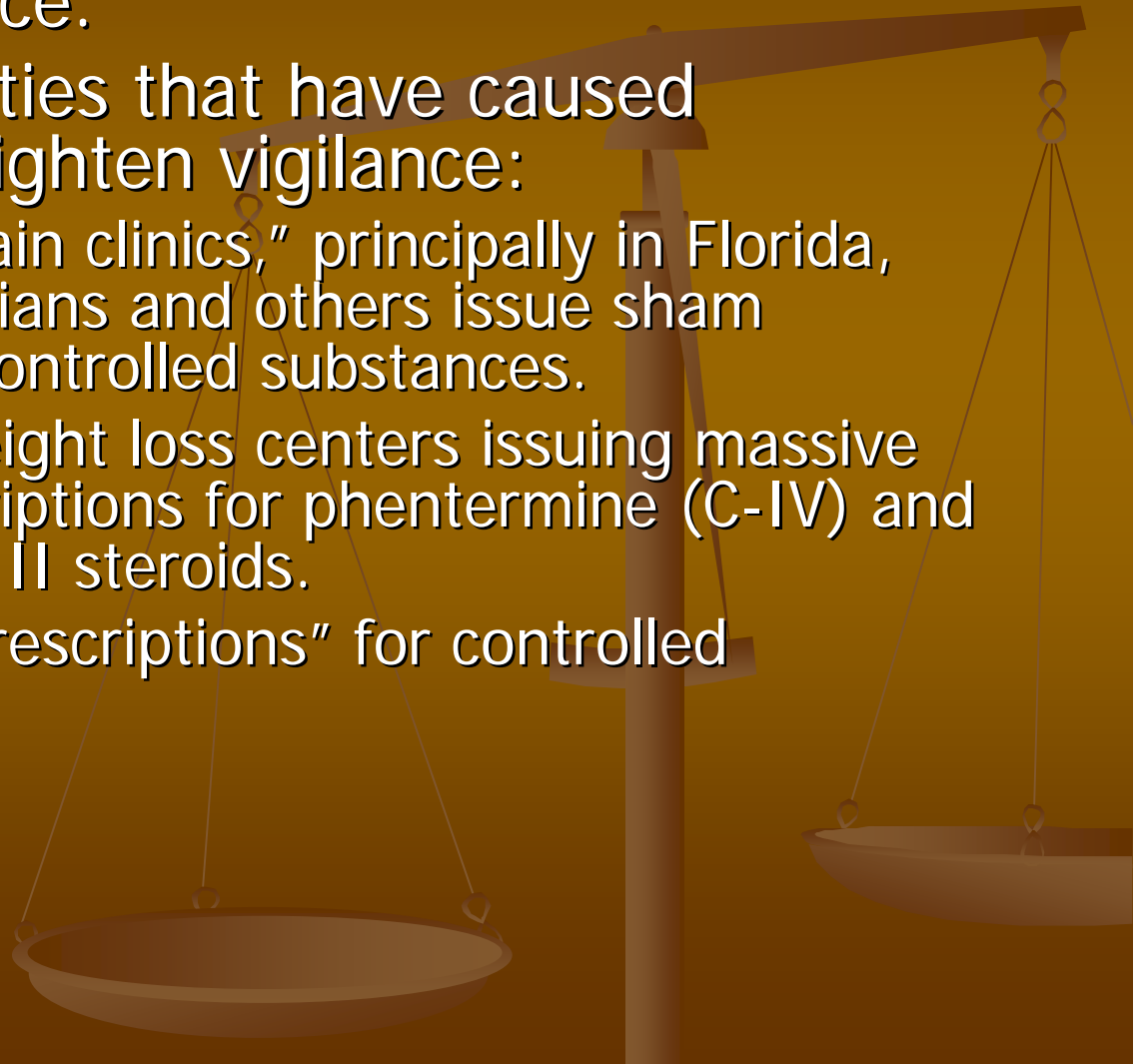
Monitoring “Legitimate Medical Purpose” and Legitimate “Patient-Prescriber Relationships”

- Pharmacists are not encouraged by the Board of Pharmacy to act as deputized law enforcement agents or otherwise be inherently suspicious of all controlled substance prescriptions.
- Neither federal nor state law “mandate[s] or even authorize[s] a pharmacist to question every prescription or to conduct an investigation to determine whether an otherwise facially valid prescription has been issued other than in the ‘usual course’ of a doctor’s practice.” *Ryan v. Dan’s Food Stores, Inc.*, 972 P.2d 395 (Utah 1998)



Reasonable Diligence

- Pharmacists do, nonetheless, have duties of reasonable diligence.
- Examples of activities that have caused pharmacists to heighten vigilance:
 - Proliferation of “pain clinics,” principally in Florida, from which physicians and others issue sham prescriptions for controlled substances.
 - Proliferation of weight loss centers issuing massive numbers of prescriptions for phentermine (C-IV) and various Schedule III steroids.
 - Internet-based “prescriptions” for controlled substances.

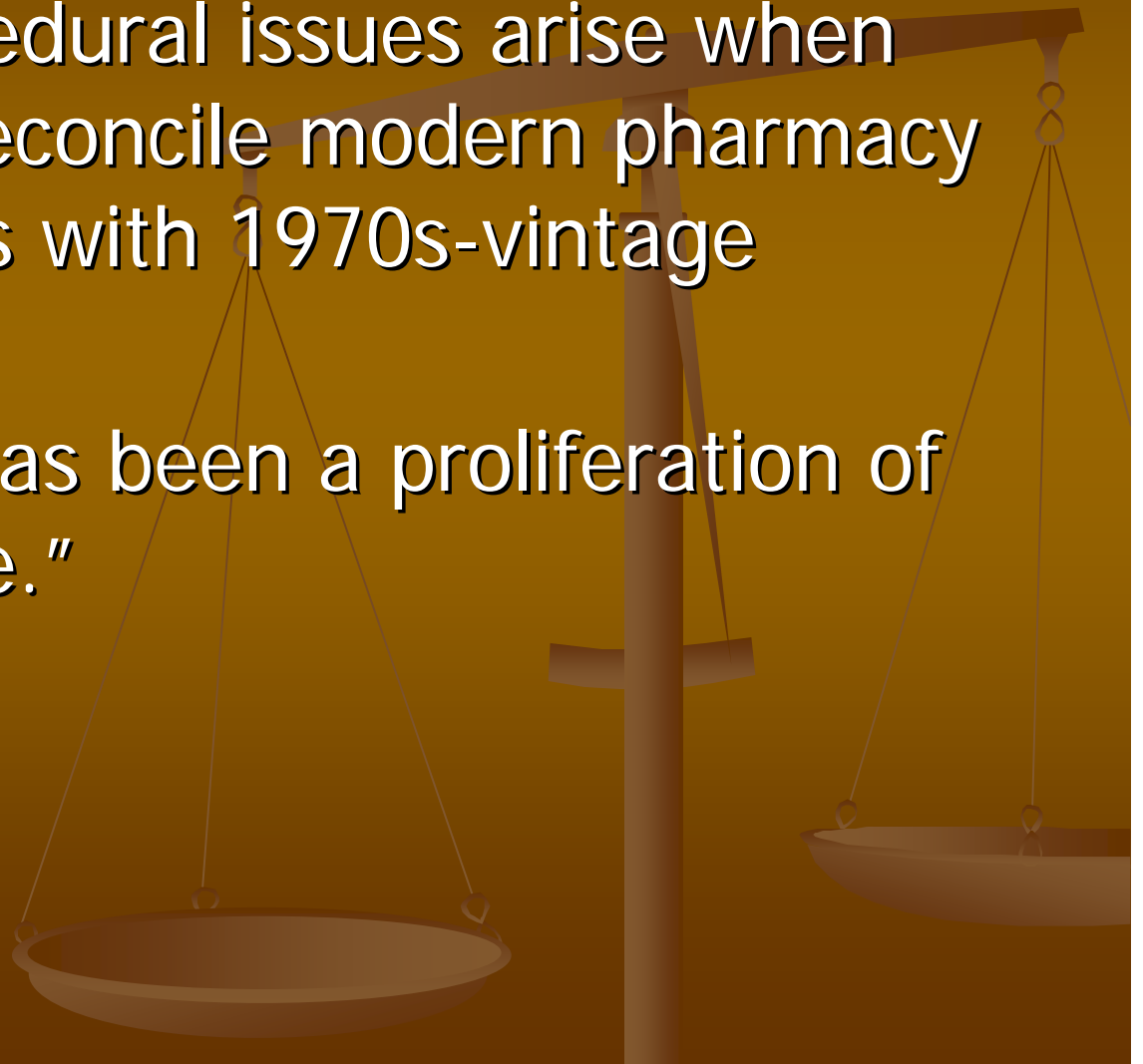


Means of Regulation

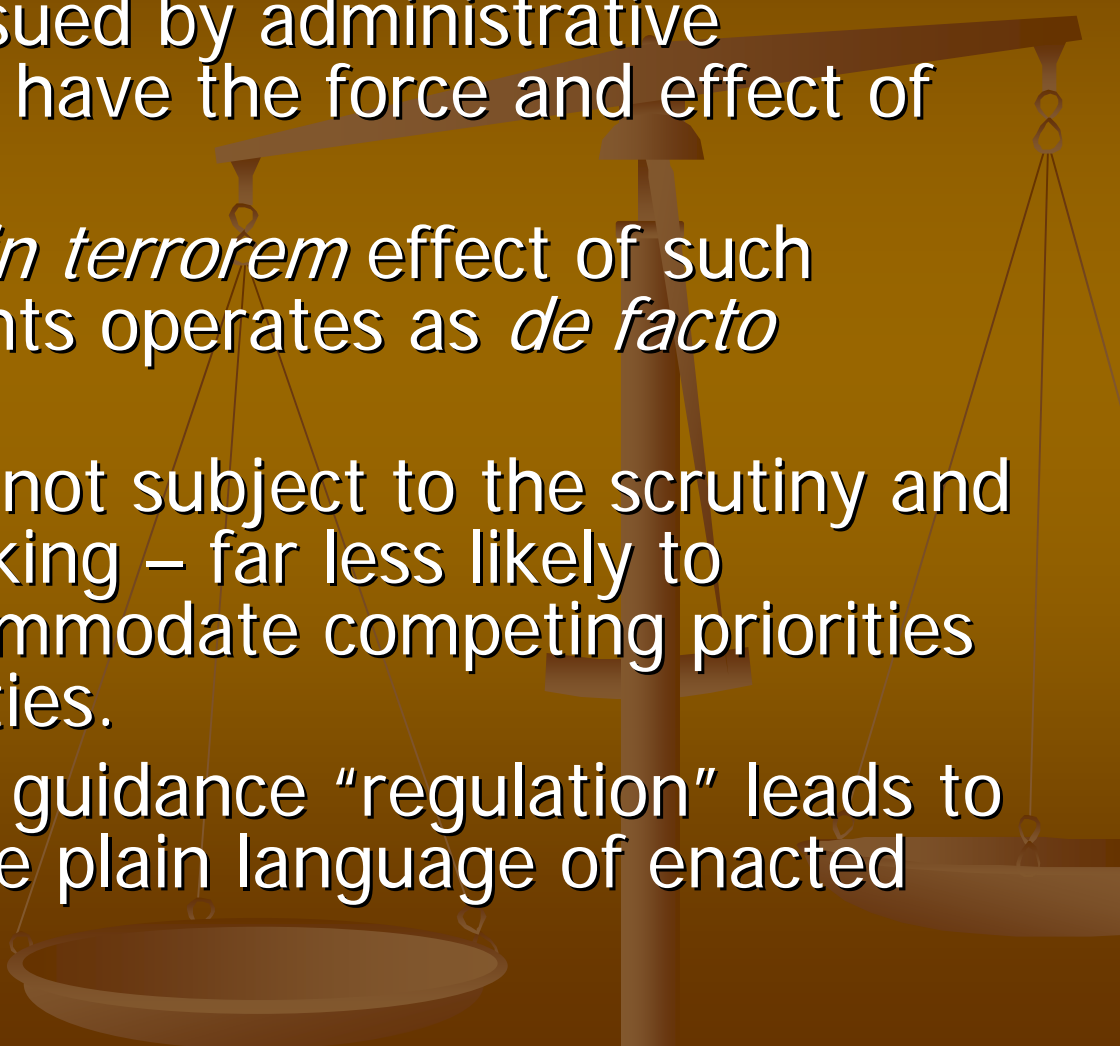


Policy “Guidance” as a Substitute for Clear Rules

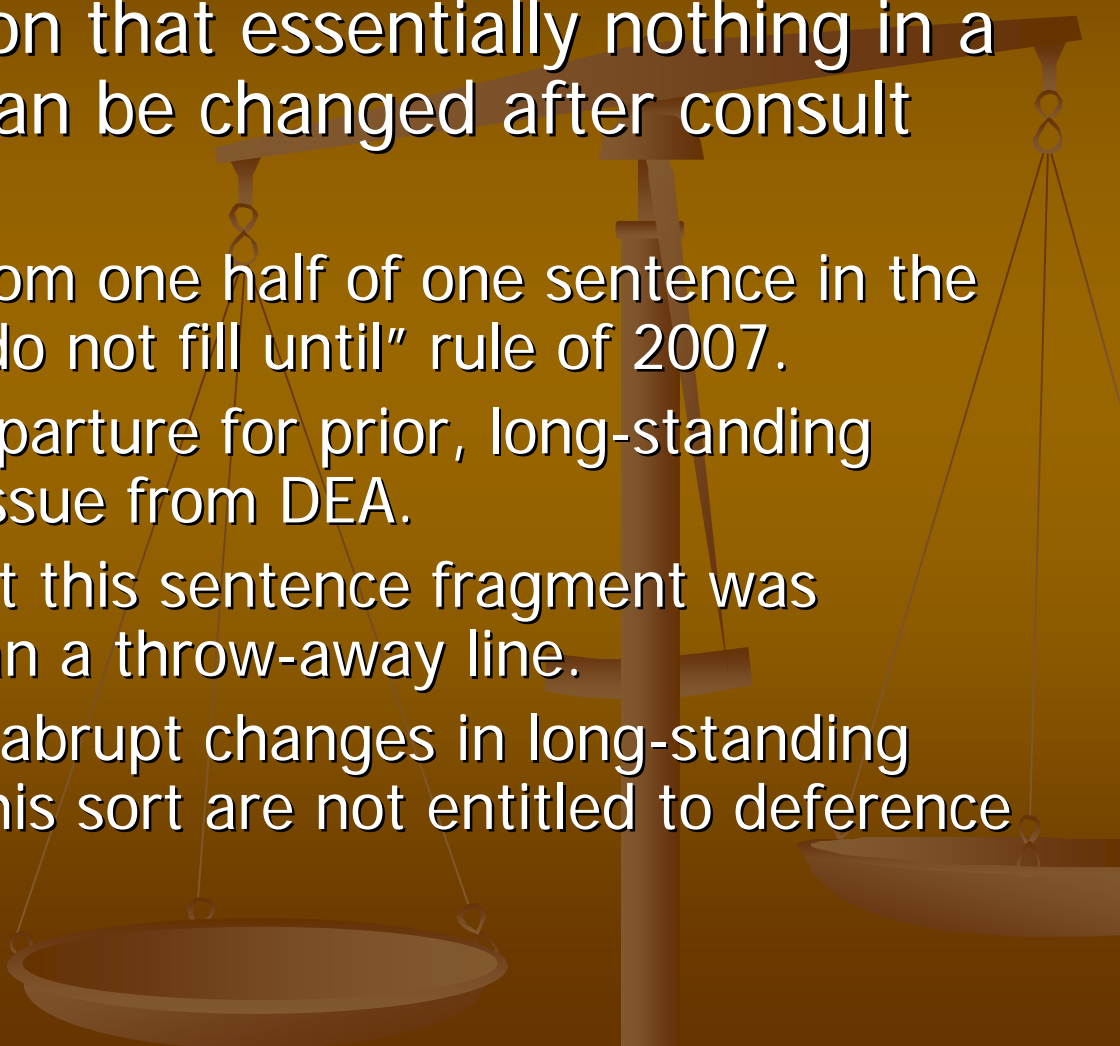
- Numerous procedural issues arise when attempting to reconcile modern pharmacy practice realities with 1970s-vintage regulations.
- DEA response has been a proliferation of “policy guidance.”



Weakness of Policy-Guidance Driven Regulation

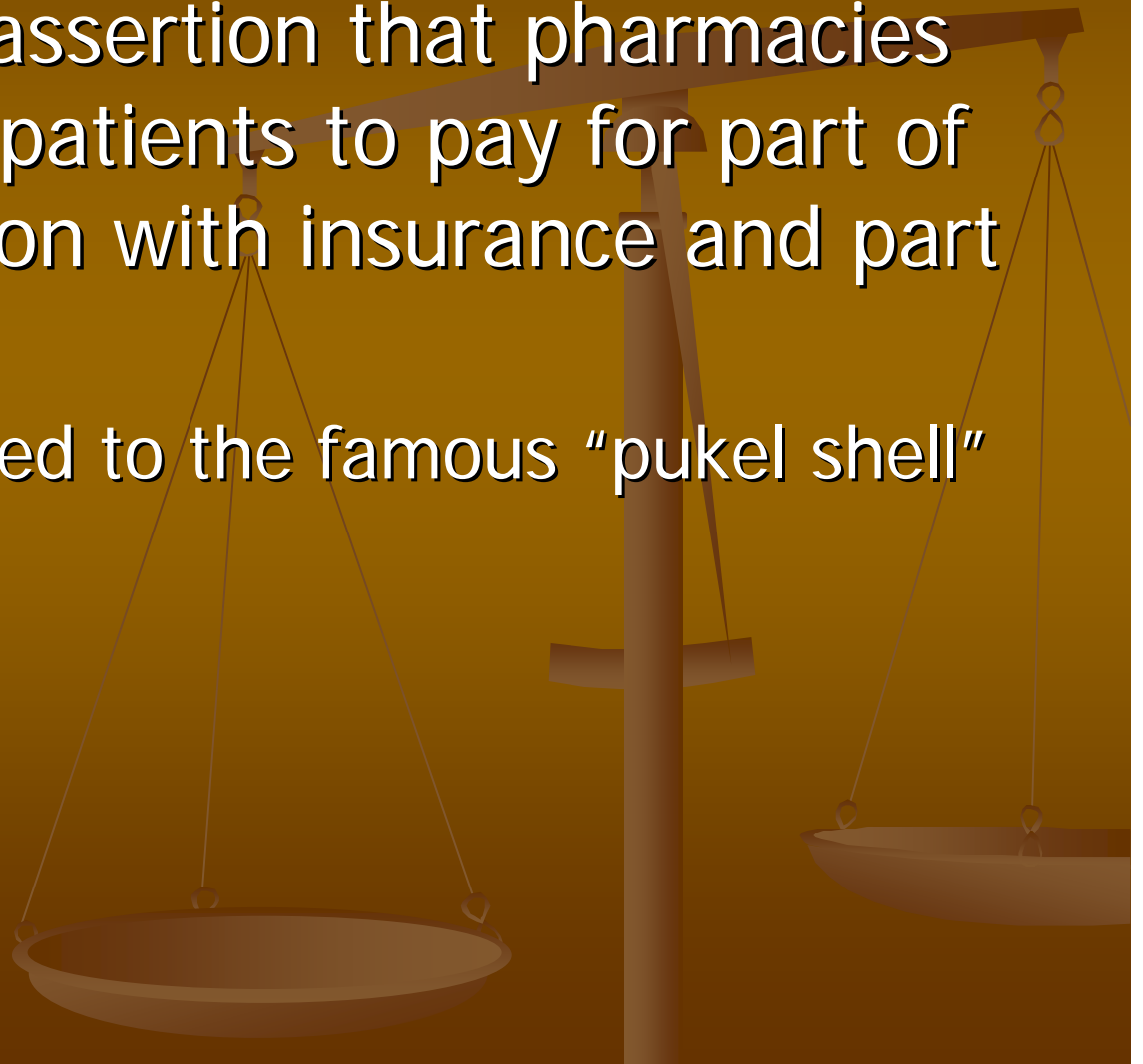
- Policy guidance issued by administrative agencies does not have the force and effect of law.
 - Nonetheless, the *in terrorem* effect of such guidance documents operates as *de facto* regulation.
 - Policy guidance is not subject to the scrutiny and process of rulemaking – far less likely to consider and accommodate competing priorities and practical realities.
 - Reliance on policy guidance “regulation” leads to drift away from the plain language of enacted regulations.
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Examples

- DEA's new assertion that essentially nothing in a C-II prescription can be changed after consult with a prescriber.
 - Assertion stems from one half of one sentence in the preamble to the "do not fill until" rule of 2007.
 - Marks a radical departure for prior, long-standing guidance on this issue from DEA.
 - Little evidence that this sentence fragment was anything other than a throw-away line.
 - As a legal matter, abrupt changes in long-standing agency policy of this sort are not entitled to deference by courts.
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Examples

- DEA's seeming assertion that pharmacies could not allow patients to pay for part of a C-II prescription with insurance and part with cash.
 - That assertion led to the famous "pukel shell" response letter.



Examples

- DEA's recent assertion that nurses at long-term care facilities may not act as agents of prescribers for purposes of transmitting prescription orders.
- DEA says that "agent" means only "employee."
- This, despite the fact that DEA's own rules state "[a] prescription issued by an individual practitioner may be communicated to a pharmacist by an employee or agent of the individual practitioner." 21 CFR 1306.03(b)
- Under the plain text of DEA's own rule, an agent is not limited to an employee.

Examples



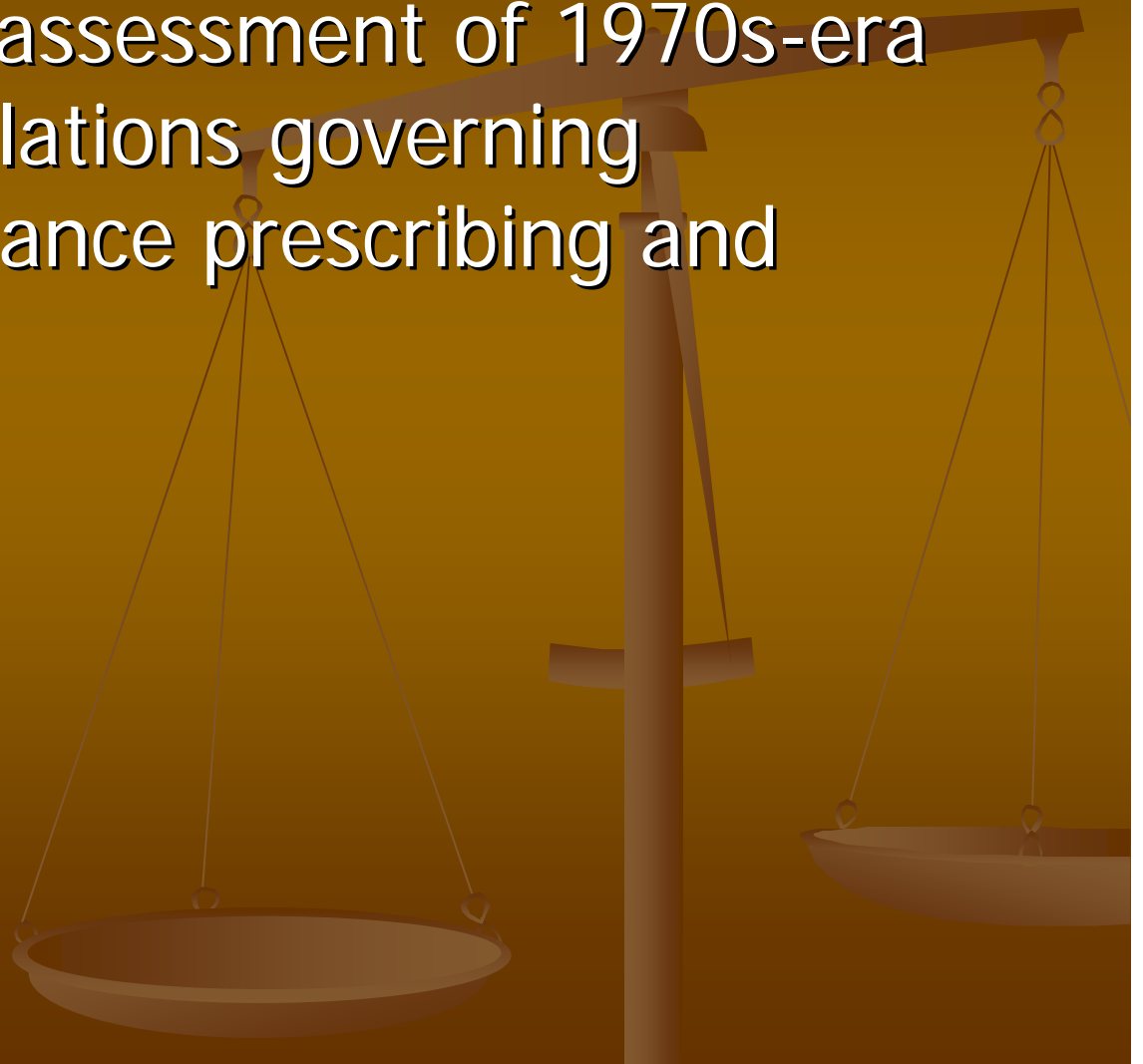
- Recent assertions by some DEA field staff that disposal of controlled substance waste by DEA registrants in compliance with state-mandated procedures violates federal law.
- This despite the fact that DEA's own rule on disposal states "This section shall not be construed as affecting or altering in any way the disposal of controlled substances through procedures provided in laws and regulations adopted by any state." 21 CFR 1307.21(d)

To a New Frontier



Needs

- Fundamental reassessment of 1970s-era procedural regulations governing controlled substance prescribing and dispensing.



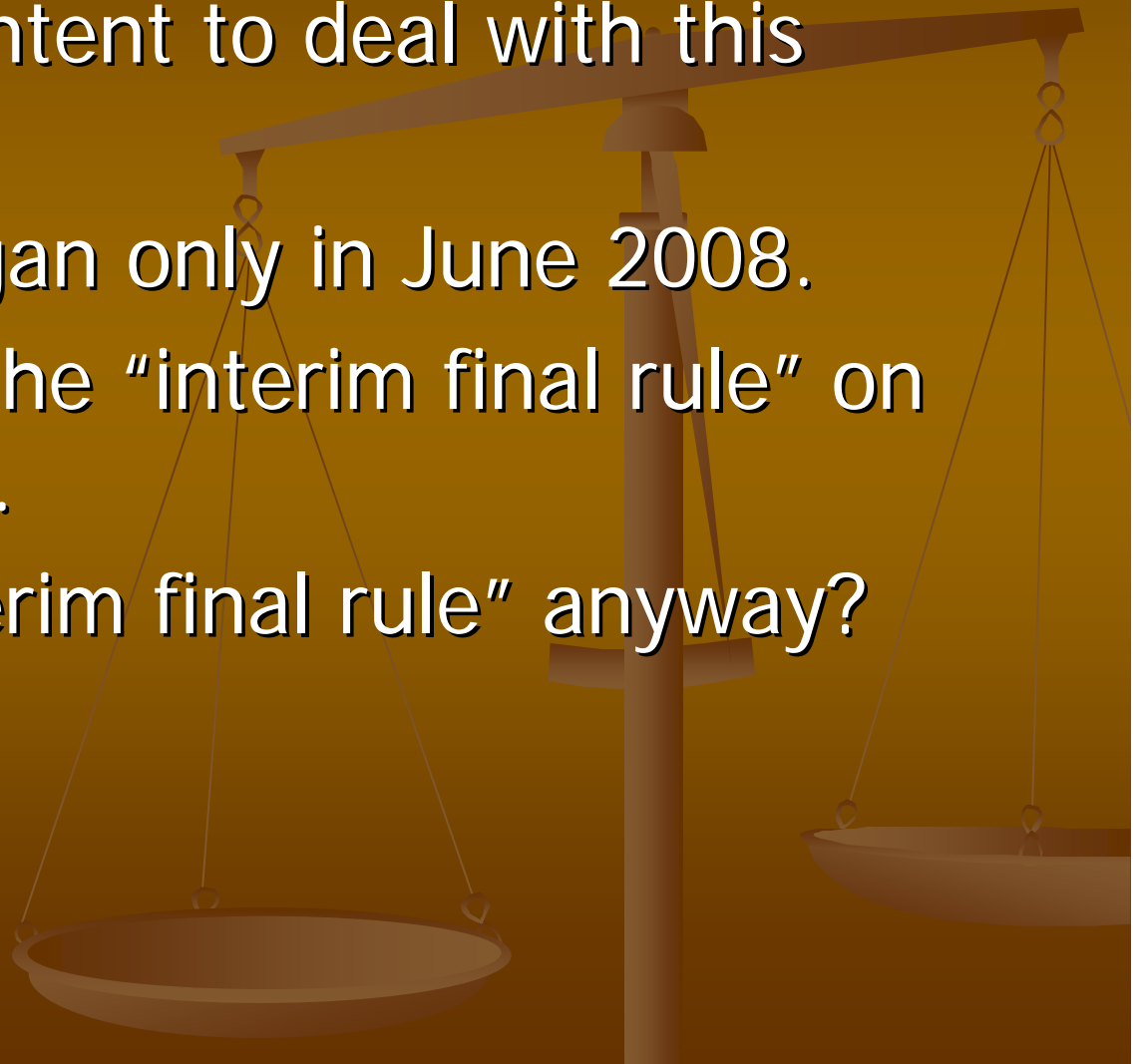
Is the New CSERx Rule a Step in that Direction?

- Yes and no.
- Baby steps.



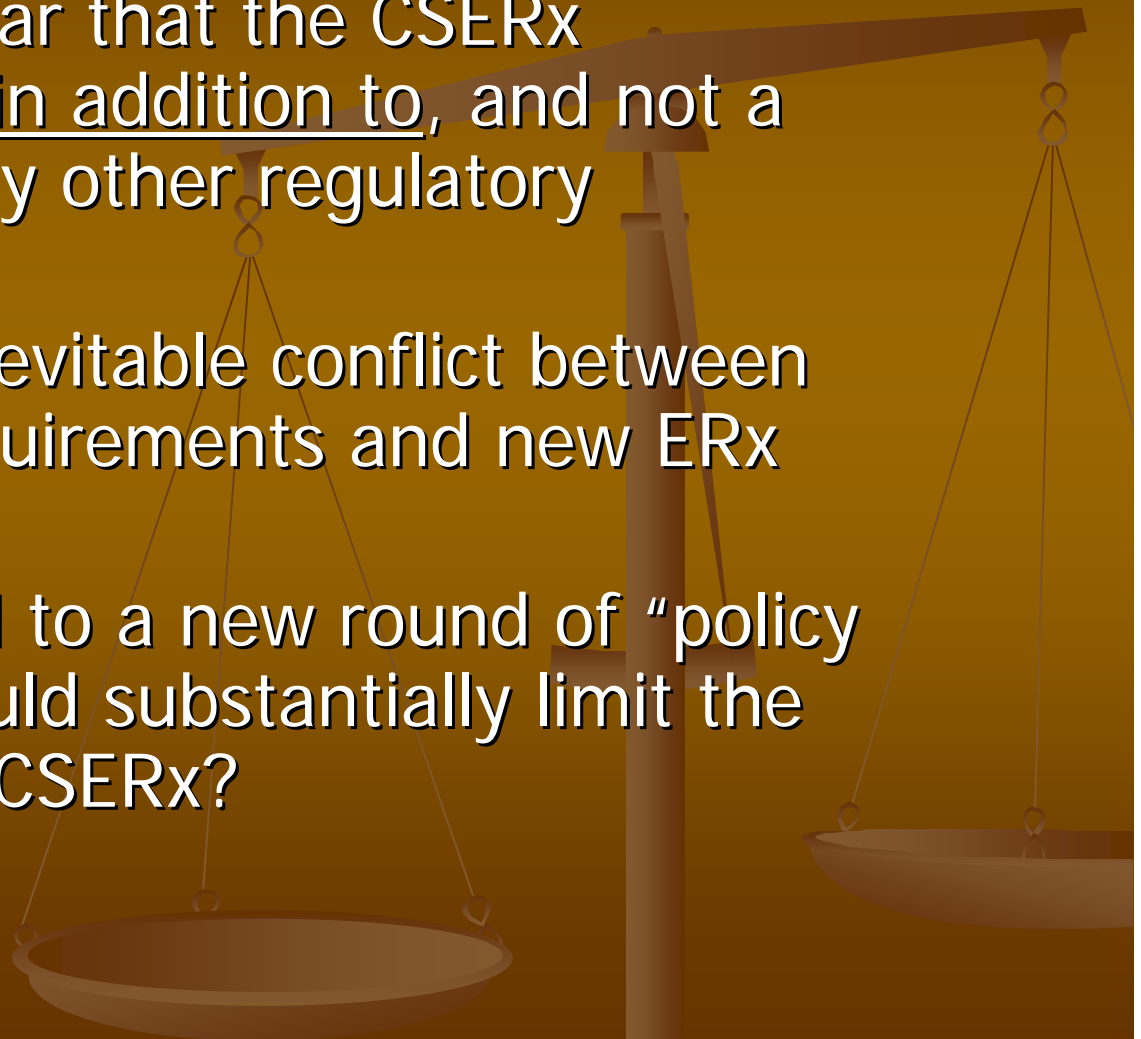
Timeline

- DEA stated its intent to deal with this issue in 2001.
- Rulemaking began only in June 2008.
- DEA published the “interim final rule” on March 24, 2010.
- What is an “interim final rule” anyway?



Incrementalism

- DEA has made clear that the CSERx requirements are in addition to, and not a replacement of any other regulatory requirements.
- Will this lead to inevitable conflict between “paper based” requirements and new ERx requirements?
- If so, will this lead to a new round of “policy guidance” that could substantially limit the practical utility of CSERx?



Enlightened Policy Guidance



- If a fundamental revisiting of DEA procedural rules is not in the offing . . .
 - Policy guidance should reflect input from practitioners, awareness of practical realities (including technological changes), and frank consideration of prior DEA statements on a given issue.
- “Be careful what you ask for.” Pharmacists (and pharmacy organizations) can also be their own worst enemies by attempting to box DEA into taking a very specific stand when common sense and good judgment has – and can continue to – govern a particular practice.