Federal-State Meeting to Discuss Pharmacy Compounding

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Memorandum of Understanding

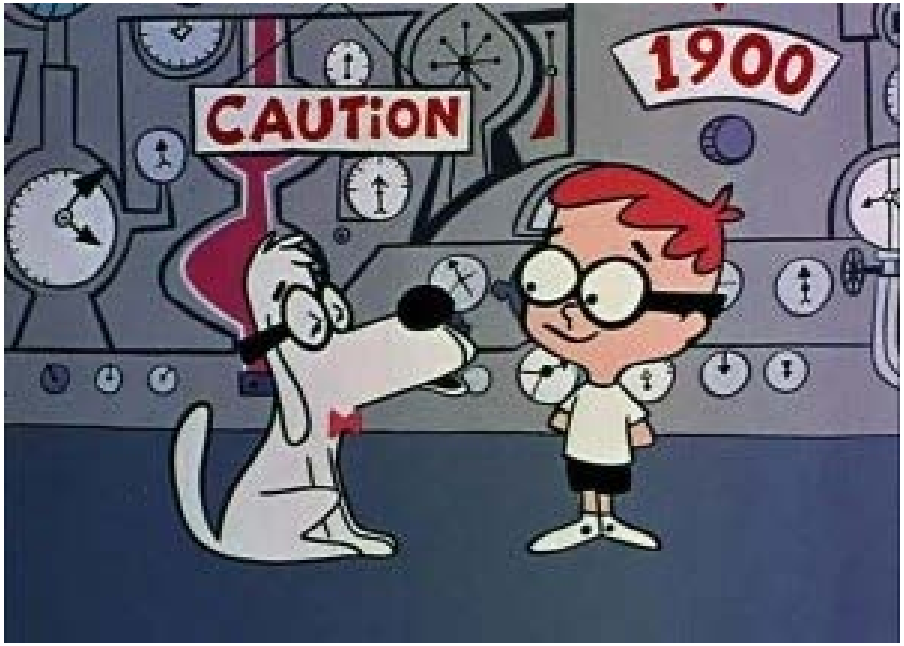
NABP Perspective – MOU

To qualify for the exemptions under Section 503A, a compounding pharmacy cannot ship compounded drugs interstate that exceed 5% of the total prescription drugs dispensed or distributed unless the state in which it is located has signed a memorandum of understanding (MOU) with Food and Drug Administration (FDA).

NABP Perspective – MOU

The MOU must address the distribution of inordinate amounts of compounded drug products interstate and provide for appropriate investigation by a state agency of complaints relating to compounded drug products distributed outside the state.


DANGER


CAUTION
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Guidance for Industry

Enforcement Policy During Implementation of Section 503A of the Federal Food, Drug, and Cosmetic Act. United States Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), November 1998.

MOU – 1999

In consultation with the NABP, the agency is currently developing a draft standard MOU on pharmacy compounding that would establish a cooperative program between FDA and state agencies that choose to enter into the MOU, regarding the regulation of interstate distribution of compounded drug products.

MOU – 1999

- The Guide listed examples of activities that the FDA believed raised concerns and would be considered in determining whether to bring an enforcement action.
- The Guide further warned that pharmacies could not dispense drugs to third parties for resale to individual patients without losing their status as retail entities.

Considerations and Substance of the MOU

- Define “inordinate amount”
- Measurable metrics to define and determine “5%”
- Not a bypass for “office use” or “stock” compounding
- Communication and enforcement collaboration with the states