

School of Dental Medicine  
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## Diet Dr. Pepper® vs. SLEP

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## Diet Dr. Pepper®

- Obvious drink of choice for doctors
- FDA: "...ensures that carbonated soft drinks are safe, sanitary, and honestly labeled. In fact, FDA has established Current Good Manufacturing Practices (CGMPs) for carbonated soft drinks, which describe the basic steps manufacturers and distributors must follow to make sure carbonated soft drinks are safe."



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## Diet Dr. Pepper®: Labeling

- Nutrition
- Manufacturer contact information
- Net quantity
- Ingredients
  - Via decreasing order per weight
- Chemical preservatives
  - Including function
- Phenylalanine statement
  - For those with phenylketonuria



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## Diet Dr. Pepper®: Labeling 2

- What is missing?
- Expiration date?
  - The FDA does not preclude the sale of food that is past the expiration date. This information is entirely at the discretion of the manufacturer.
  - A product that is dangerous to consumers would be subject to potential action by the FDA to remove it from commerce regardless of any date printed on a label.

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## 1979: "We're here to help..."

- FDA mandated that all drugs have expiration dates.




"The nine most terrifying words in the English language are: 'I'm from the government and I'm here to help.'"  
-Ronald Reagan

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## What about Pharmaceuticals?

- Do drugs become dangerous or ineffective after the exp. date?
  - Frimpter GW, Timanelli AC, et al, Reversible "Fanconi Syndrome" Caused by Degraded Tetracycline, *J Am Med Assn*, 184:2, 111-113, April 1963
  - Cohen LP, "Many Medicines Are Potent Years Past Expiration Date", *Wall Street Journal*, 28 March 2000.

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## Relatively rare exceptions:

- NTG: 
- Insulin: 
- Water-purification tablets
- Sodium nitroprusside: 

**DRUGS FOR HYPERTENSIVE CRISIS**

**SODIUM NITROPRUSSIDE**

- inactivated by light – wrap in aluminum foil
- Blue or brown discoloration – means drug is degraded
- prolonged use – can lead to cyanide poisoning

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## FDA mandated date:

- Indicates that the drug's quality is maintained for *whatever period of time the manufacturer wants to warrant*
- “Manufacturers put expiration dates on for marketing, rather than scientific, reasons. It's not profitable for them to have products on a shelf for 10 years. They want turnover.”
  - Kramer TAM, “Do Medicines Really Expire?”, *Medscape General Medicine*, 2003; 5(3)

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## Myrmidon response to selves:

- Exemption
- Shelf-Life Extension Program (SLEP)
  - In place since the 1980's
  - Stale dated pharmaceuticals are stockpiled for later government (i.e. military) use.
  - Drugs are spot tested for quality and in many cases have been retained for decades after expiration date.

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## Petitions to benefit the public:

- Non-federal entities have been advised that such use is: “...not feasible at this time.”
  - National Strategy for Pandemic Influenza Implementation Plan 2006, <http://www.flu.gov/planning-preparedness/federal/pandemic-influenza-implementation.pdf>, Accessed 02 DEC 2015

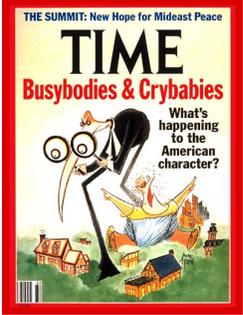
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## Apparatchik response to public:

- Malum prohibitum enforcement
  - (vs. Malum in se conduct)
- Consequence:
  - Promotion of drug sale quantities by increasing patient drug costs without any therapeutic benefit whatsoever to patients.

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## TIME: Societal Trends...



12 August 1991