

# Qui Tam Activity in Drug Pricing & Reporting

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# Limiting Factors in “Garden Variety” Kickback Cases

- **Overload** – the “Centers of Excellence” are getting swamped.
- **Resource Starvation** – What DOJ isn’t allowed to tell the public – or Congress.
- **Part D-ification** -- Gearing up for the next new thing

# Why Pricing Cases Are Attractive

## ■ TYPE OF FRAUD

- Kickbacks
- Off-Label
- GMP
- Pricing

## ■ DEGREE OF EFFORT

- High Intensity – Proof “on the ground”
- High Intensity – Proof “on the ground”
- Moderate Intensity
- Prove it once – build damages model

# Current Trends

## ■ **AWP**

- – The Move to Off-Invoice Discounts
- -- Biologics ... *WHICH* Class of Trade Applies?

## ■ **BEST PRICE**

- -- Nominal price as discounts as kickbacks
- -- Nominal price discounts as marketing
- -- Off – invoice discounts
  - (Schering, Bayer, Nevada Litigation, MCOs)

# Enforcement Dynamics

- Markedly increased state activity
- Markedly increased state coordination
- Increased state – federal cooperation
  - Old model ... “We’ve done the case. Give us your numbers.”
  - *New Model ...*
    - *Closer collaboration on theories and evidence*