Hot Topics in Retail Pharmacy Compliance

2019 Healthcare Enforcement Compliance Conference

November 5, 2019

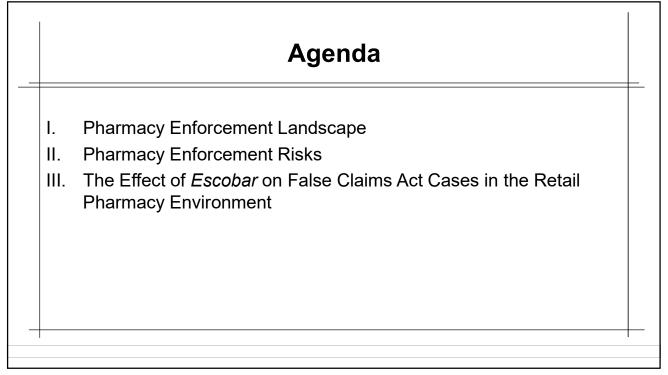
Daniel Fitzgerald

Commercial Litigation Department, Walgreen Co.

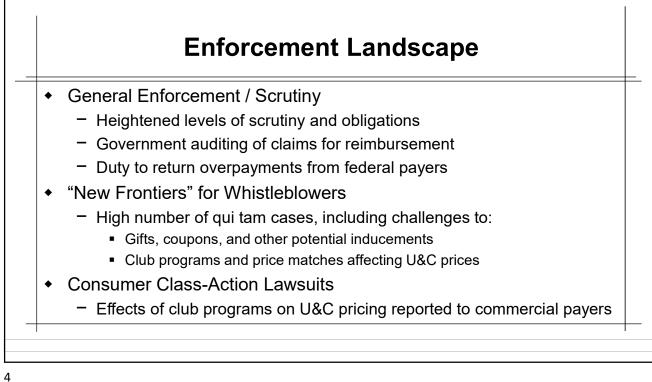
Selina Coleman

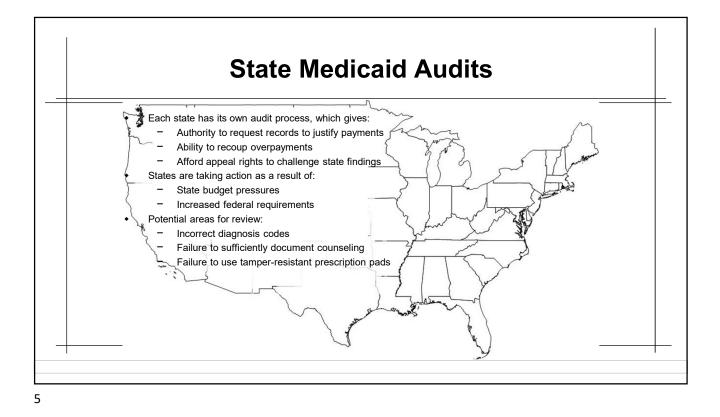
Reed Smith LLP

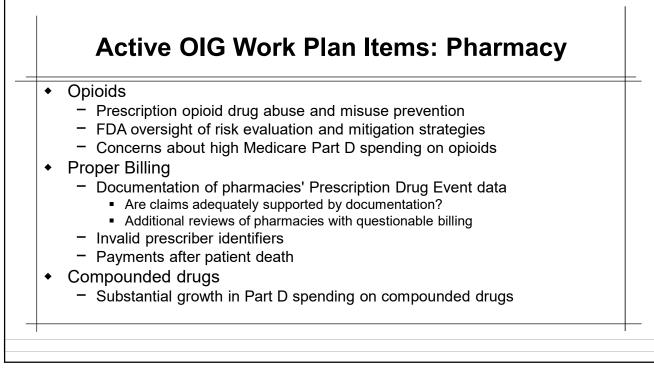
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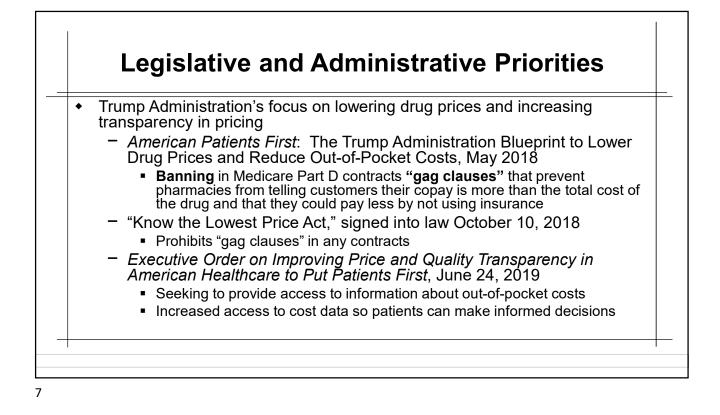


I. Pharmacy Enforcement Landscape

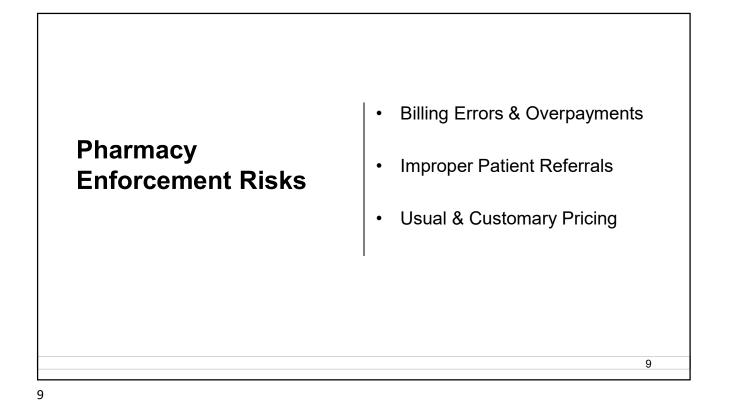




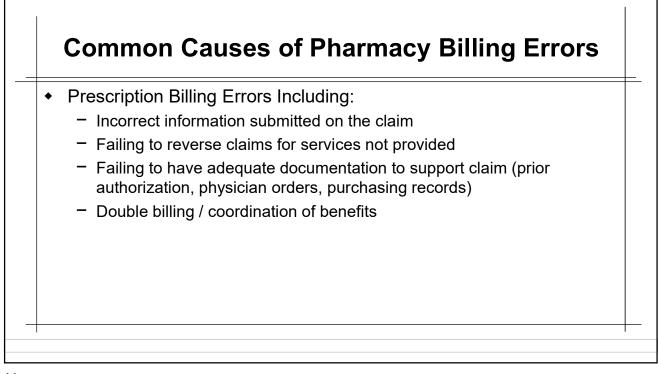




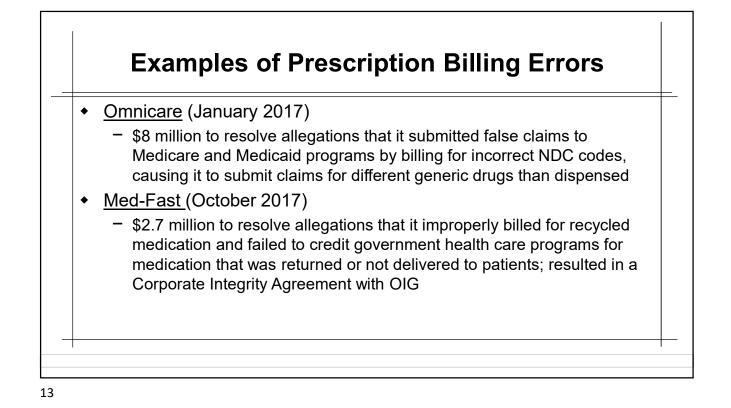


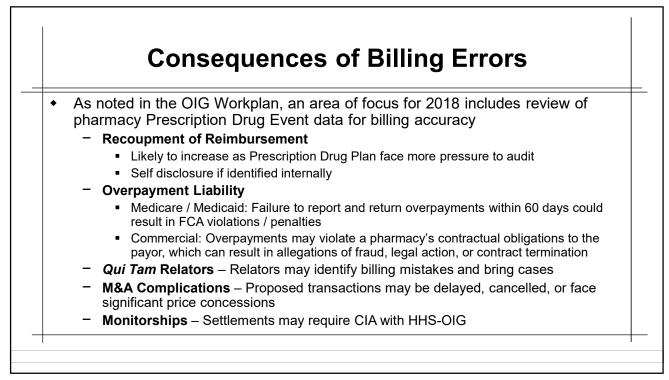




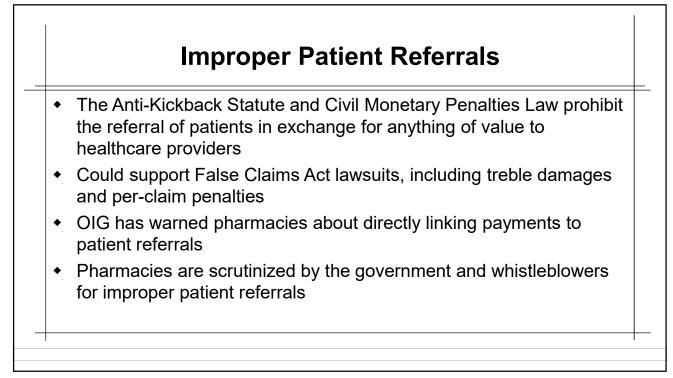


	Examples of Prescription Billing Errors
•	Target (December 2018)
	 \$3 million to resolve allegations that it improperly billed Massachusetts' state Medicaid program by automatically refilling prescriptions that were not explicitly requested by a MassHealth patient or caregiver, in violation of state regulations
	 Massachusetts' Attorney General had previously settled similar allegations with PharmaHealth, Neighborhood Diabetes, and AllCare Pharmacy
٠	<u>Nashville Pharmacy (</u> January 2016)
	 \$7.8 million to resolve billing errors, including automatically refilling medication against contractual requirements, billing for medications after the date of the beneficiary's death, and billing for prescriptions from unlicensed prescribers
٠	<u>Rhine Drug Company (</u> June 2017)
	 \$2.2 million to resolve allegations that it violated the FCA by billing for medication not provided and failing to follow Controlled Substance Act requirements; resulted in a Corporate Integrity Agreement with the OIG





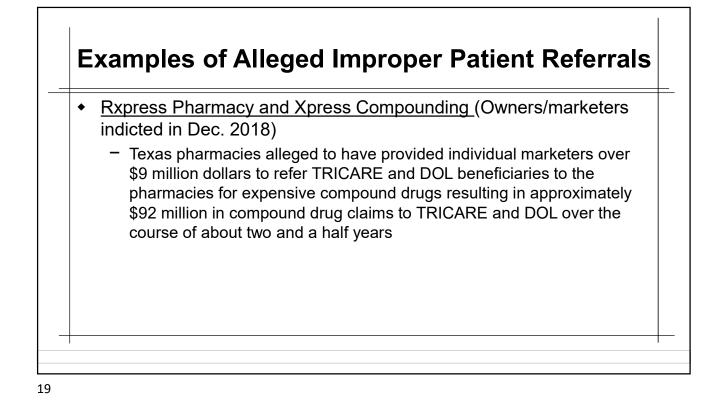
Improper Patient Referrals

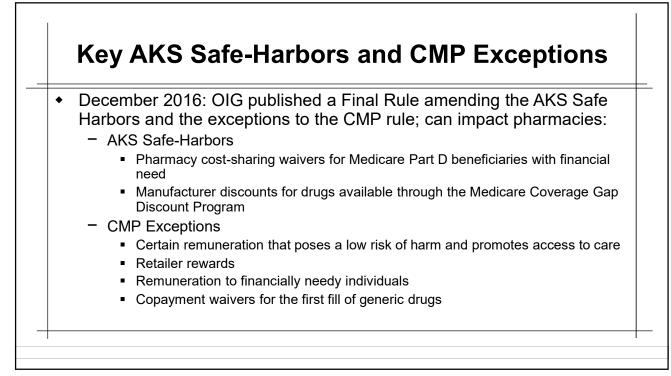


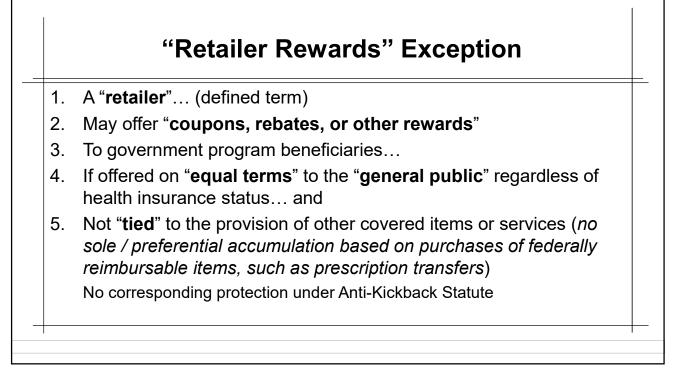


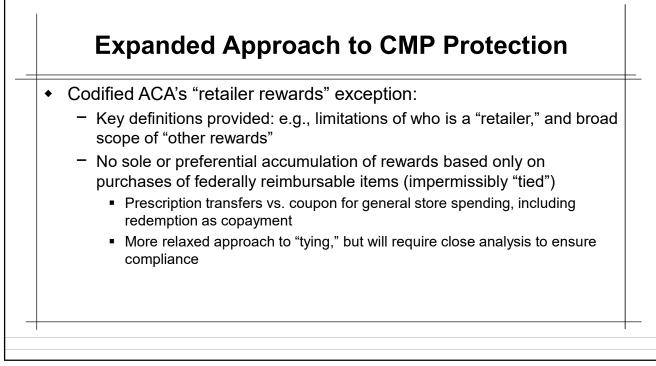
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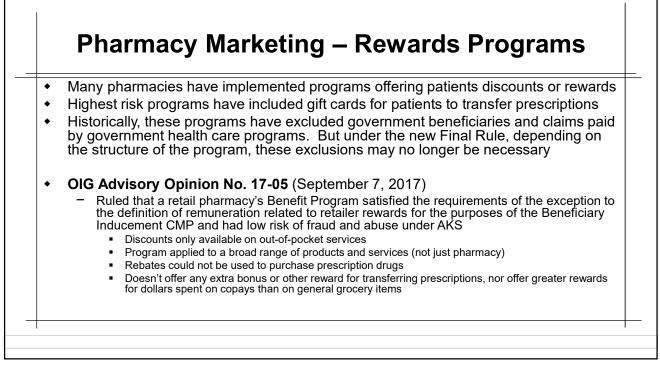
•	Florida Pharmacy Solutions (Owner/employee convicted in Sept. 2017)
	 Alleged to have provided a marketing firm over \$12 million dollars to steer TRICARE beneficiaries to the pharmacy resulting in over \$30 million in TRICARE reimbursement in 6 months (up from about \$4 million annually) Many similar cases have been pursued in Florida against compounding pharmacies
•	 <u>NY Pharmacy Inc.</u> (Owner and companies pled guilty in Feb. 2019) Alleged to have provided kickbacks to patients to fill their HIV prescriptions and then used an auto-refill program to continue to bill for those prescriptions, even when the medication was not delivered Sentenced on March 15, 2019 to 2-6 years in state prison and forfeiture of over \$3.6 million



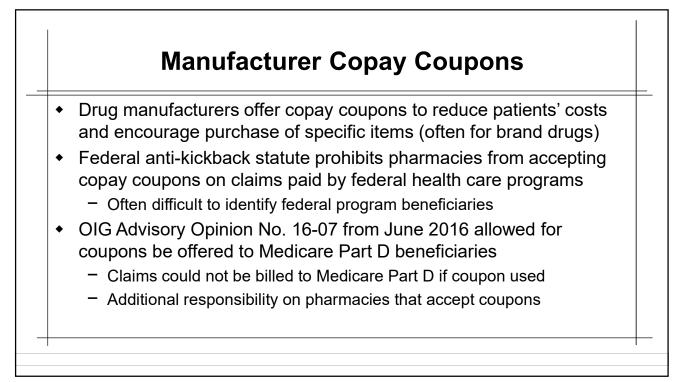




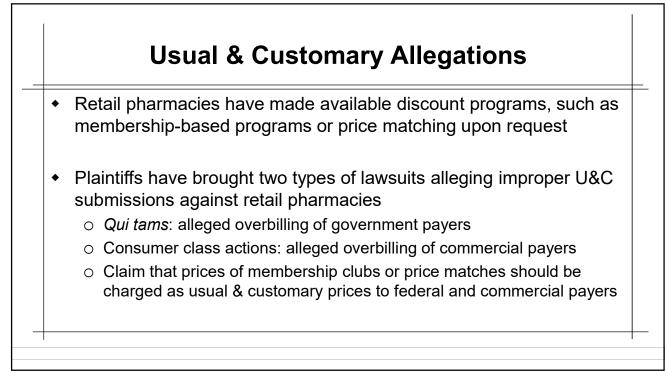


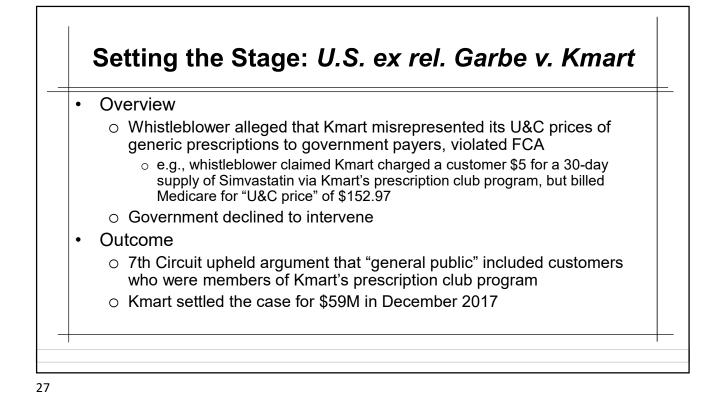


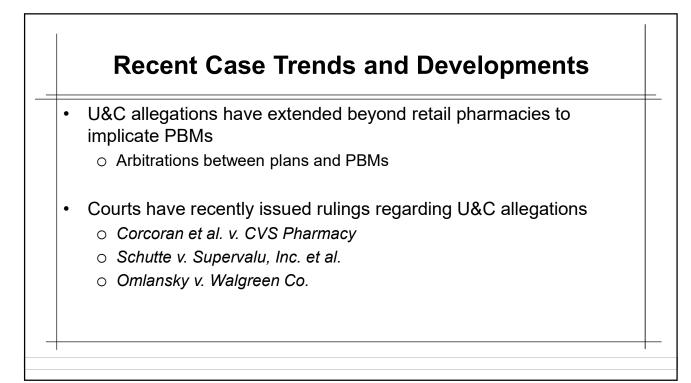


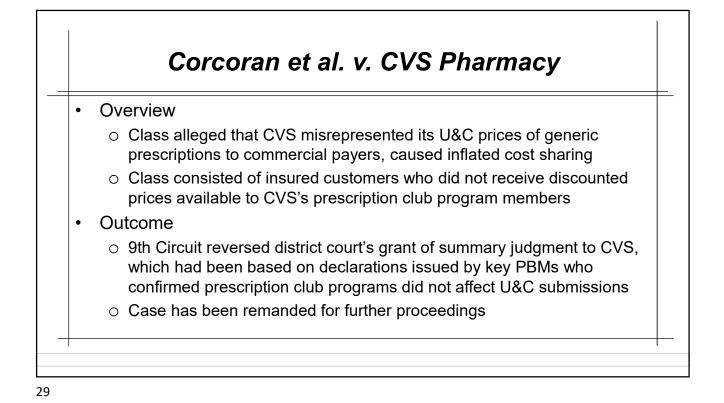


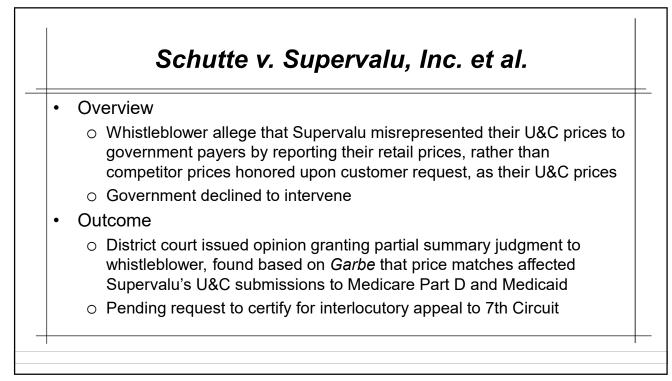
Usual & Customary Pricing

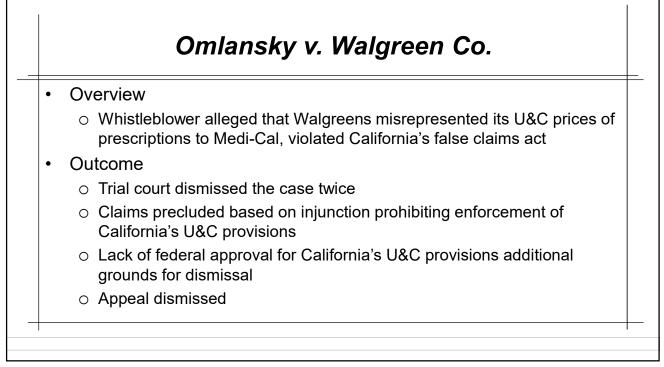




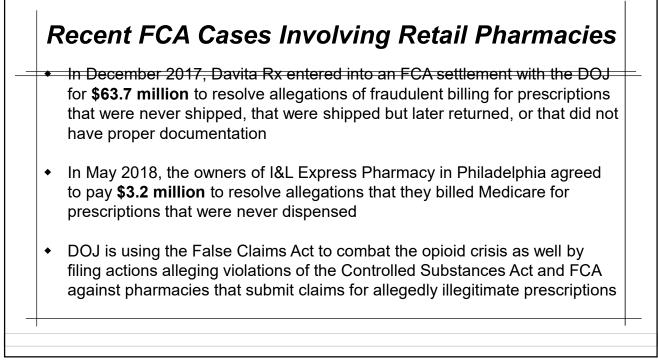




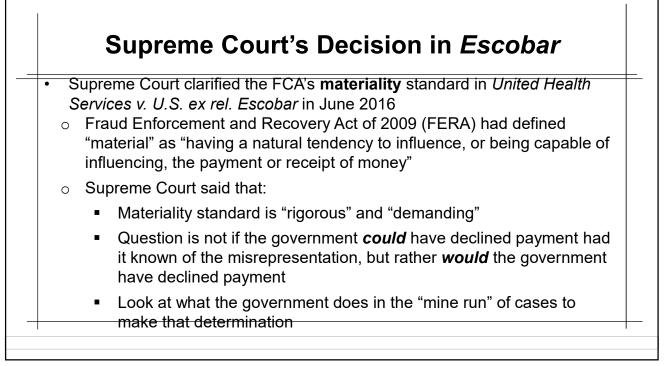


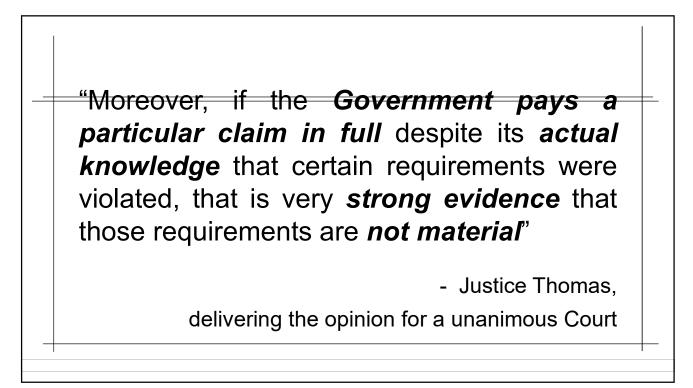


III. The Effect of *Escobar* on False Claims Act Cases in the Retail Pharmacy Environment



Supreme Court's landmark decision in *Escobar*



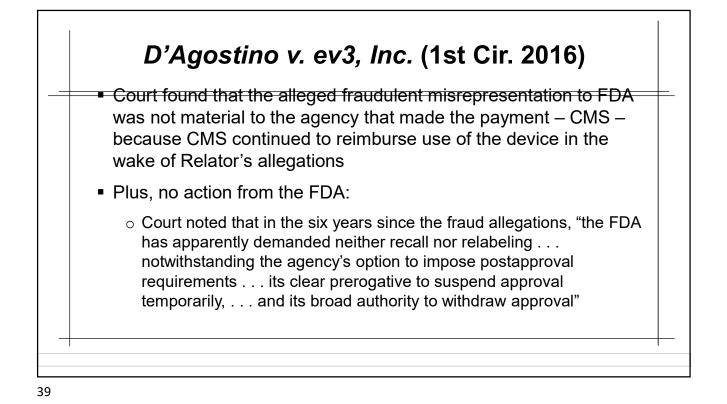


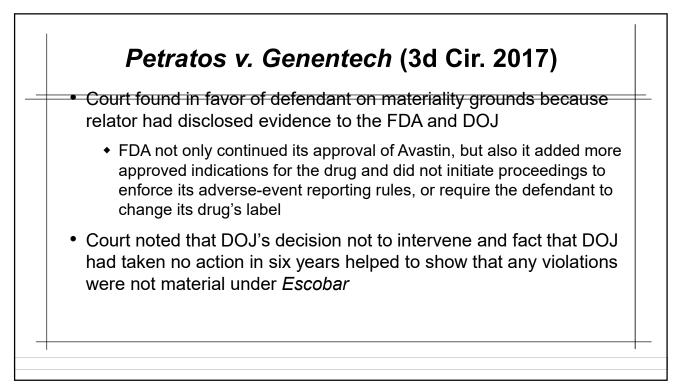
Key Interpretations of Escobar

United States ex rel. Spay v. CVS Caremark (3d Cir. 2017)

 CVS Caremark discovered that its claim submissions to CMS for thousands of prescriptions triggered errors involving prescription IDs, and CVS Caremark created "dummy IDs" for the affected prescriptions to facilitate processing

- Court affirmed District Court's summary judgment decision that the dummy IDs were not material because CMS continued payment of the pharmacy claims in full despite actual knowledge that the dummy IDs were in use
- Court also noted that the case's circumstances were "precisely the situation" alluded to in *Escobar*





Practical Implications for the Pharmacy Industry

