

Defense Perspectives

- Legal issues
 - Statutory limits
 - Causation
 - “Before-tax” profit
 - Scope of civil releases

Defense Perspectives

- Factual Issues Driving Settlement
 - Off-label sales percentage
 - Causation/background rate
 - Cost credit
 - Multipliers
 - Government-reimbursed sales

Defense Perspectives

- **Strategic issues**
 - Global settlement
 - Factual admissions
 - Parallel consumer protection settlements
 - Ancillary relator claims
 - NAMFCU process
 - Restitution

Defense Perspectives

- Lessons learned
 - Negotiating based on both the specific facts of the case and the complicated legal background governing off-label promotional claims is critical
 - The Government rewards candor—acknowledgement of bad facts, cooperation in individual investigations
 - Government may have mutual interest in resolving several together without a full-blown investigation
 - Coordination of all of the moving pieces of the negotiation is critical
 - In a multiparty negotiation such as this, numerous parties may seek to assert "holdup" leverage
 - A cooperative relationship with the NAMFCU and/or CP leadership teams is extremely helpful in achieving state settlements