

Getting Management Buy-In

Soft Sell

Tie compliance to “Core Values” “Corporate Mantra”

Competitive differentiation: Sell relationship safety to employees and customers (e.g., insurance: the “good hands people” theme)

Rational Sell

Give them numbers: Dollars and Sense Issues for Govt.

Cost Avoidance: share price, investigations and outside lawyers, damage to brand, recruiting and retention

Scare Sell

Government warnings for device makers: Quote the DOJ and OIG

Cases and consequences for companies: chance of exclusion

Cases against sales execs and officers: Serono and TAP execs

Steroids Analogy: competitive edge, get caught, get banned

Rational Sell: Govt. Health Spending Soaring

Year	All Healthcare Expenditures	Percentage of US GDP	Medicare	Medicaid (Poor)	Total Federal
1960	23.6	4.5	*	*	2.1
1970	63.8	6.2	7.3	*	*
1980	217	7.8	36.4	14.5	50
1999	1,200	13.0	213.6	107.7	400
2002	1,400	14.0	385.0	240	625

2006-16 Medicare Part D +\$500,000,000,000+

Scare Sell: Healthcare Enforcement Statistics

2002

1.49 Billion in criminal and civil fines

Civil sanctions against doctors from \$20,000 to \$611,000

2003

531 criminal defendants charged, 437 convicted

96-03: criminal cases up 47% per year

Scare Sell: Learning Compliance the Hard Way

Pfizer– Guilty Plea and Settlement – \$420 million (May 2004)

TAP Pharmaceuticals – Settlement – \$875 million (2001)

Schering-Plough – Settlement – \$345 Million

Abbot Laboratories – Settlement – \$614 Million

Really Scary Sell: Serano Labs – Adam Stupak

(According to press reports citing indictment)

Serano sold *Serostim*, AIDs wasting drug: 12 week courses at \$21,168. 75% cases covered by Medicaid funded programs

Allegation: 3-1-99 VPs of Marketing and Sales call six RSDs to Boston to “dig their way out” of a shortfall in company’s sales goal. Launched “\$6m-6 Day Plan” – offering key physicians deemed “thought leaders” free trips with guest to healthcare conference in Cannes, France, if they agreed to Rx *Serostim*.

RSDs executed: Some doctors rejected, but 10 accepted, wrote Rx, took trip with guest. Serano paid “thousands” for the trips, and announced the 10 doctors in a press statement.

Doctors referred to in the indictment only by their initials.

Really Scary Sell: Don't be a Stupak

Adam Stupak—Regional Sales Director —

Guilty Plea on 12-21-04; Sentencing Spring 05

5 years federal prison

3 years post-release supervision

\$25,000 fine per count

Criminal fines not dischargeable in bankruptcy

What about Company? Execs? Other RSDs? Doctors?

11 TAP execs on trial Spring 2004

Really Scary Sell: More Serano Labs

Headline April 15, 2005

execs charged with luring physicians with trips

Indicted: John Bruens, 48, VP of Marketing, 7 counts

Indicted: Mary Stewart, 44, VP of Sales, 7 counts

Indicted: Melissa Vaughn, 43, Regional Sales Director, 2 counts

Indicted: Marc Sirockman, 41, Regional Sales Director, 2 counts

Charges: conspiracy to violate the Anti-Kickback Statute

Jeopardy: 5 years prison; up to \$250,000 fine per count

April 23, 2005: Serono reserves \$725 Million for possible settlement

Government Target: Device Industry

“The detection and elimination of health care fraud and abuse is a top priority of Federal law enforcement”

United States Department of Health and Human Services and the Department of Justice
Health Care Fraud and Abuse Control
Program Annual Report for FY 2001

The Department of Health and Human Services plans to accelerate its investigations of alleged fraud and abuse by medical device companies. . .

The inquiries will likely center on kickbacks and other improper sales and marketing deals between doctors and companies in the fast-growing industry. . .

Executives in the medical device industry can expect even more actions within a year to 18 months as the workload from pharmaceutical investigations winds down. . . .

Cases against other device makers are going to be coming into the pipeline. . . . The medical device salespeople are engaged in the same fraud [as the Pharmaceutical companies].

Recent comments of Lewis Morris, Chief Counsel to the Health and Human Service's Department of the Inspector General: