James P. Gallatin, Jr.

Partner, Reed Smith

Context

- Your company has just acquired another company or a pharmaceutical product line
- You have been asked to conduct a compliance review
- This is what you need to know about government contract compliance

- Why Government Contract Compliance Is Important (I)
 - The U.S. Government is a significant purchaser (and developer) of pharmaceuticals
 - The Veterans Health Care Act effectively requires non-generics to be sold to the U.S. Government under Federal Supply Schedule contracts

- Why Government Contract Compliance Is Important (II)
 - The principal enforcement authorities are very aggressive
 - The penalties are just as draconian as elsewhere in the field
 - The plaintiffs' bar is just as eager, too

- How Noncompliance Happens (I)
 - Government contracts are relative stepchildren
 - Government contract administration is a relative dead-end
 - Compliance is cumbersome and unpopular with everyone else

- How Noncompliance Happens (II)
 - Compliance requires trained personnel and training
 - Compliance requires good systems and procedures
 - The Contracts are badly drafted
 - There are many different types of contracts

- What Are The Principal Government Contracts Compliance Issues?
 - Pricing
 - Sourcing
 - Subcontracting
 - Grant costs