Purpose: To educate spine surgeons how the FDA has impacted innovation and its detrimental impact to our patients.

Methods: Metanalysis of discussions with Spine company CEO's, venture capitalists, and product managers.

Venture Capitalists typically invest in a start up spine company with a 5 to 7 year exit strategy either through an IPO or an acquisition. They expect a 2.5 to 3 time return. If $100 million is invested, an acquisition would require $250-300 million as a sale price. The numbers do not work anymore. An FDA IDE study to obtain a PMA costs $30-40 million. Because of the current climate at the FDA, approval for an IDE is more than a 5-7 year timeframe. The numbers for VC money into an IDE simply no longer exist. There is no VC funding for new technologies for start-up companies and a big exit of VC money is expected for any medical or surgical device company. Another FDA detriment to VC investment is FDA unpredictability. It costs $2 million and two years to enter the E.U. while it costs $70 million and 7 years to enter the US market.

The 510(k) approval process has a long history. The vast majority of US products are predicate devices. The FDA has a database of all device complications for the last 10 years. The 510(k) process has resulted in very few device complications. 510(k) allows innovation without harm. Despite this the FDA has made the 510(k) process difficult if not impossible. Companies which typically received 15 to 25 510(k)'s a year and within an average 44 days now get 2 per year averaging 210 days. Products 510(k)'d 8 to 10 years ago are being challenged. Companies are being required to conduct IDE type studies for a 510(k). In the last year, there has been 1/3 less 510(k) approvals, all requiring three times longer. The Menaflex story will be presented.

Explanations for the change in the FDA include the new administration, new people at FDA and directions from congress to audit everything.

Conclusion: Many CEO's do not anticipate any new FDA IDE spine studies secondary to cost and FDA unpredictability of ever receiving approval.

Venture Capitalists cannot deal with this environment of unpredictability. The first question asked to any company is whether this is a 510(k) product, a 510(k) product requiring data or an IDE and what are the possibilities of the product ever being reimbursed. In the current environment, ideas are not getting funded. There is a major shift of investment capital and jobs to outside the U.S. The current FDA does not have our patients' best interest as a priority. Future innovative spine surgery will be performed only outside the U.S.