Southern New England Entrepreneurs Forum

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Fall River, MA

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Major Issues

- Shutting out industry participation in regulation and guidance development…
  - Device premarket 510(k) program
    - Senator Franken (D-MN)
    - Senator Kerry (D-MA)
  - "Letter to Industry" preempts guidance development process – no public participation.

Congressional Oversight

- July 20, 2011: Energy and Commerce Subcommittee on Oversight and Investigations. Chairman Stearns (R-FL)
- Burdensome approval process delays innovative patient care and costs jobs.
- FDA approval process makes it too risky for venture capital.

510(k) Premarket Program

- Institute of Medicine review, an outside policy group, to evaluate FDA's proposed changes to the 510(k) program. (When and so what?)
- Criticism: CDRH is slow and unpredictable
- CDRH: The quality of 510k submissions vs. change in CDRH review criteria (a moving target)
  - (The same finding of the 1995 the congressional Energy and Commerce Oversight subcommittee.)

Regulating more products

- Mobile applications for health care
- Computerized systems used in hospitals
- Laboratory developed test

Contact Information

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