Information Sharing Issues: FDA and Colorado example

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Sunshine Laws

- Regulations requiring openness in government
- Make meetings, records, votes, deliberations, investigations and other official actions available to public
- Specifics are often state-dependent
Colorado Open Records Act (CORA)

- Requires that most public records be available to the public.

- Unless specifically outlined in Colorado statute, all documents are open to the public and can be requested at any time.

Special exceptions:
- Individually identified health information not subject to CORA
- “Draft” documents or unfinished investigations are not released
CORA and sharing with FDA

- Potential conflicts, particularly if something is no longer considered “draft”

- Tension for FDA commissioned individuals – subject to both federal and state requirements

- May cause barriers to information sharing
Issues noted at state level

- Strict restrictions on information sharing can lead to timeliness issues
- Commercially confidential information – state staff sometimes unclear on what this means
- FDA Commissioned personnel
  - Limited in ability to share information
  - May affect ability to respond to health and safety issues
- Duplication of efforts can occur due to information sharing difficulties (i.e. repeat inspections, lab testing, etc)