Sharing Non-Public Information

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Agenda

- 20.88 Agreements and non-FOIA Sharing
- Overview of the FOIA
- Relevant FOIA Exemptions and Examples
- Sunshine Law/Public Records Overview

Information Sharing with Federal, State and Local Agencies

FDA Info Disclosure Policy

- If applicable legal requirements are met, FDA may share non-public information (NPI) on own initiative or upon request regarding:

- Confidential commercial information (CCI)
- Trade secret information (TSI)
- Pre-decisional, deliberative process
- Personal (Privacy Act)
- Open investigatory law enforcement materials

What Can or Cannot Be Shared Under a 20.88 agreement?

Trade Secret	Confidential Commercial
The FDA cannot disclose Trade Secret Information (TSI) to the States pursuant to §20.88 without the express written authorization from the owner or submitter.	Confidential Commercial Information (CCI) can be disclosed without the owner's authorization pursuant to §20.88, but the state must agree to protect the information against further disclosure and it must be in the interests of public health for FDA to share the information.

Sharing w/ State Agencies

21 CFR § 20.88

- Discretionary sharing
- Of certain NPI, according to law and procedures
- With a state or local government agency
- Having counterpart functions to FDA:
  - Regulatory law enforcement (LE)
  - Health oversight
  - Public health function
- Case-Specific and Long-Term Options

Commissioned Officials

20.88 Does NOT Apply

- Qualified state regulatory official
- Commissioned to "receive and review official FDA documents"
- May receive FDA's NPI, including CCI and TSI

20.88 Long Term Information Sharing Agreements

Drug Compounding

- AZ
- CA
- DE
- MD
- NY
- OR
- TX
- UT
- WI
- MN

Drug Supply Chain Security (DSCSA)

- New August 2016
- Posted on 50 State Meeting Website

5 Year Single-Signature Long-Term Drug Compounding Information Sharing Agreements (ISA)

- In the past, the FDA required a signature on a 20.88 agreement from every State and local government official who needed access to the information.
- This sometimes resulted in delays in sharing of the information. To prevent recurrence of such delays, individual signatures will no longer be required for the Food Information Sharing 20.88 Agreements. Only agency head will need to sign.
- Agreements will cover a period of five (5) years, beginning July 1, 2014.

Long-Term Drug Compounding ISA

- The single signature Drug Compounding Information Sharing 20.88 Agreement covers the sharing of certain NPI related to Pharmacy Compounding.
  - One official authorized to sign for the agency will sign.
  - This typically should be the top executive of the relevant agency; e.g. Commissioner, Director, etc.
  - Allows for FDA to share certain NPI proactively, or on receiving a written request.
  - The state agency may then provide NPI to its officials and employees who need the information to perform their official duties for the uses authorized in the agreement

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Pre-Disclosure Assurances

In signing the Single-Signature Long-Term Information Sharing Agreement for the agency, a State official:

Certifies that the agency has legal authority to protect NPI received from FDA from public disclosure

AND

Provides the agency's written commitment not to make unauthorized disclosure of FDA's NPI.

State's Responsibilities

The State agency will adopt safeguards to prevent unauthorized disclosures, including:

- Procedures and policies for handling NPI
- Providing training (drafted by the FDA) to employees or officials who may have access to FDA's NPI.

State's Responsibilities

- All persons who receive NPI under the agreement are responsible for protecting the NPI they receive from FDA from unauthorized disclosure.

- Unauthorized disclosure of NPI may carry adverse consequences.
  - May jeopardize future cooperative relationships between FDA and the State agency.
  - Potential administrative, civil or criminal penalties under applicable Federal laws for persons making unauthorized disclosures.

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Additional State Responsibilities

- State government agencies commit to inform FDA if the following situations should arise:
  - An attempt is made to obtain NPI that FDA provided to the state agency by a court process such as subpoena or court order.
  - The Agency has received a request for NPI pursuant to the State's FOI statutes or regulations.
  - There are any changes to the State's FOI statutes or regulations which may impact the Agency's ability to keep its commitment.
  - There is actual or suspected unauthorized disclosure of any information shared pursuant to the agreement

Permission to Further Disclose

Any request to the FDA to further disclose NPI must be in WRITING

Request can be an email or physical letter

AND

must be sent to OPRM

Freedom of Information Act
5 USC 552

- Provides for the sharing of agency records with the public.
- FOIA is a disclosure statute, but has 9 exemptions for non-public information.
  - FDA has regulations in 21 CFR Part 20 that implement the exemptions.
- Sharing with states, local governments, and other federal agencies occurs outside of the FOIA, but has the same concepts of non-public information.

Exemption 4 of the FOIA

- Exemption 4 exempts confidential commercial and trade secret information from disclosure under FOIA. This protects the financial interests of the information owner and prevents competitive harm.
- Other statutes, and FDA's regulations, prohibit the agency from disclosing information covered by this exemption except in limited circumstances.

Examples – Confidential Commercial Information

- Customer lists
- Suppliers
- Contractual relationships
- Lot size
- Units sold
- Future business plans
- SOP details

Examples – Trade Secret Information

- Formulas
- Manufacturing process
- Sterilization methods

Exemption 5 of the FOIA

- Exemption 5 protects certain intra-agency and inter-agency records from disclosure:
  - Internal, pre-decisional deliberations
  - Records within the attorney/client privilege
  - Attorney work product (records prepared in anticipation of litigation)

Exemption 5 - Examples

- Internal discussion regarding potential violations
- Internal discussion regarding possible enforcement actions
- Communications with agency attorneys regarding violations, enforcement, etc.

Exemption 6 of the FOIA

- Exemption 6 exempts from disclosure information that would constitute an unwarranted invasion of personal privacy.
- Balance of the public's right to know against the individual's right to privacy.
- Other statutes and FDA's regulations prohibit FDA from disclosing information protected by this exemption except in limited circumstances.

Exemption 6 - Examples

- Patient name, address, etc
- Medical staff name, location, etc
- Photographs of faces
- Names of complainants or confidential sources
- Names of non-management staff at firms

FOIA Exemption 7

- Exemption 7 protects from disclosure certain types of law enforcement records, including:
  - Records that could reasonably be expected to interfere with enforcement proceedings
  - Records that could reasonably be expected to constitute an unwarranted invasion of personal privacy (similar to Exemption 6);
  - Records that could reasonably be expected to disclose the identity of a confidential source;
  - Records that would disclose techniques and procedures for law enforcement investigations

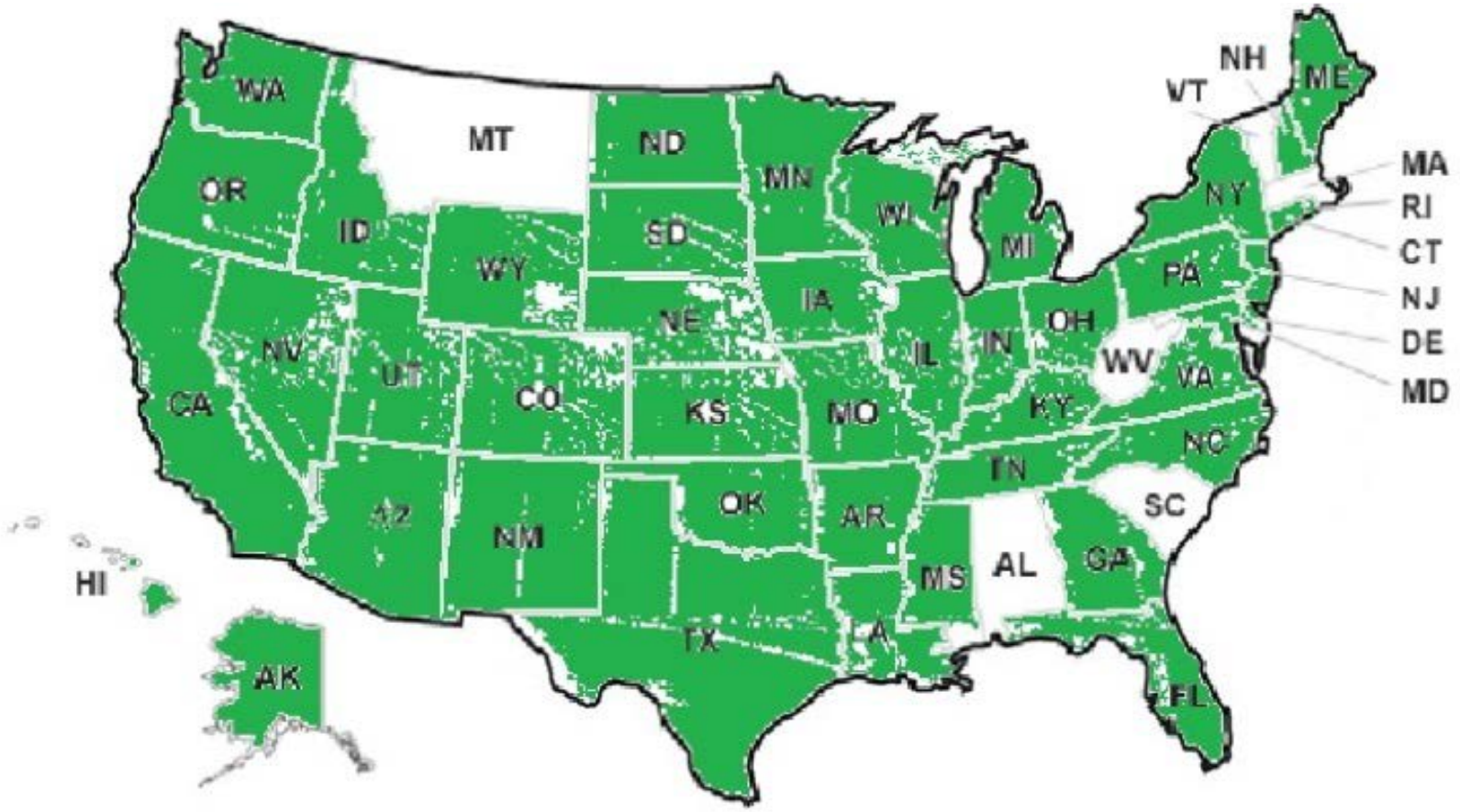
Exemption 7 - Examples

- Establishment Inspection Report if case is open (7A)
- Internal memo if case is open (7A)
- Records that would identify a confidential source (7D)
- Patient name, address, etc (7C)
- Methods used for investigating or prosecuting cases (7E)

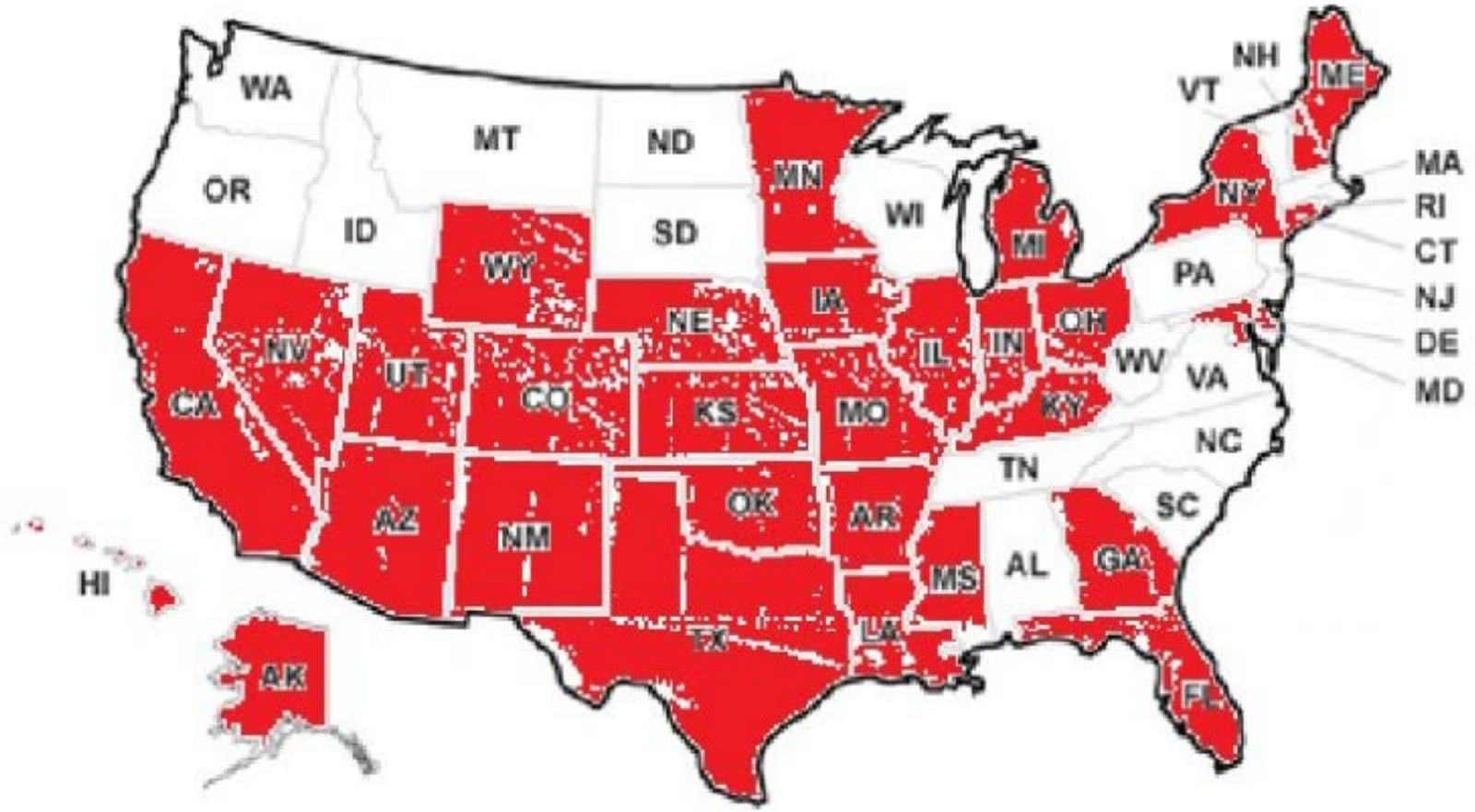
Sunshine Law/Public Records

- What is a Sunshine Law?
- Purpose of this research project
- 20.88 Interplay

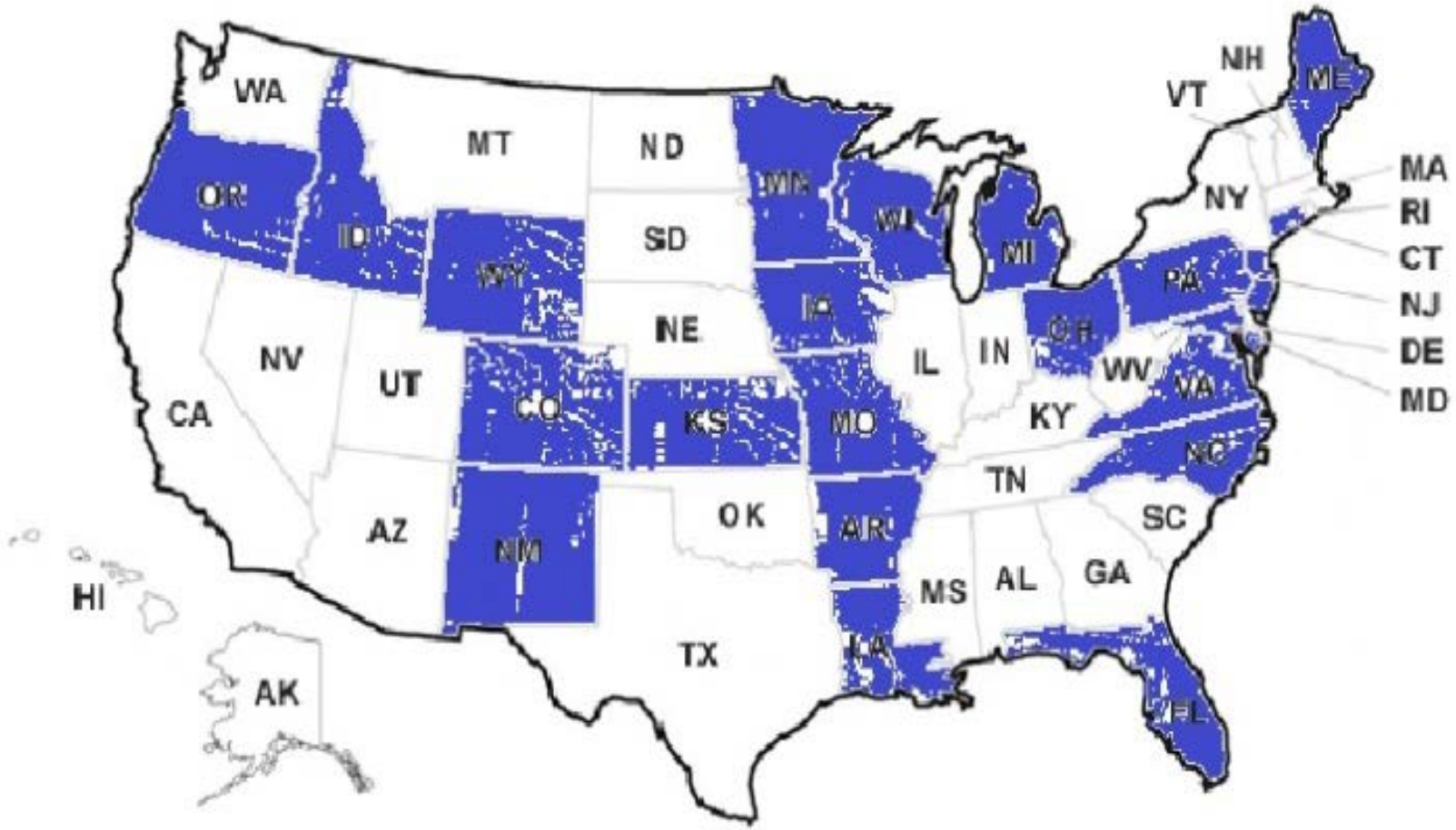
All States that currently have a LT 20.88 with the FDA



Department of Health 20.88's



Department of Agriculture 20.88's



Drug Compounding 20.88's