

ADVANCING PUBLIC HEALTH THROUGH INFORMATION SHARING

Division of Information Disclosure Programs

Office of Partnerships

Office of Regulatory Affairs

Information Disclosure Touchpoints*

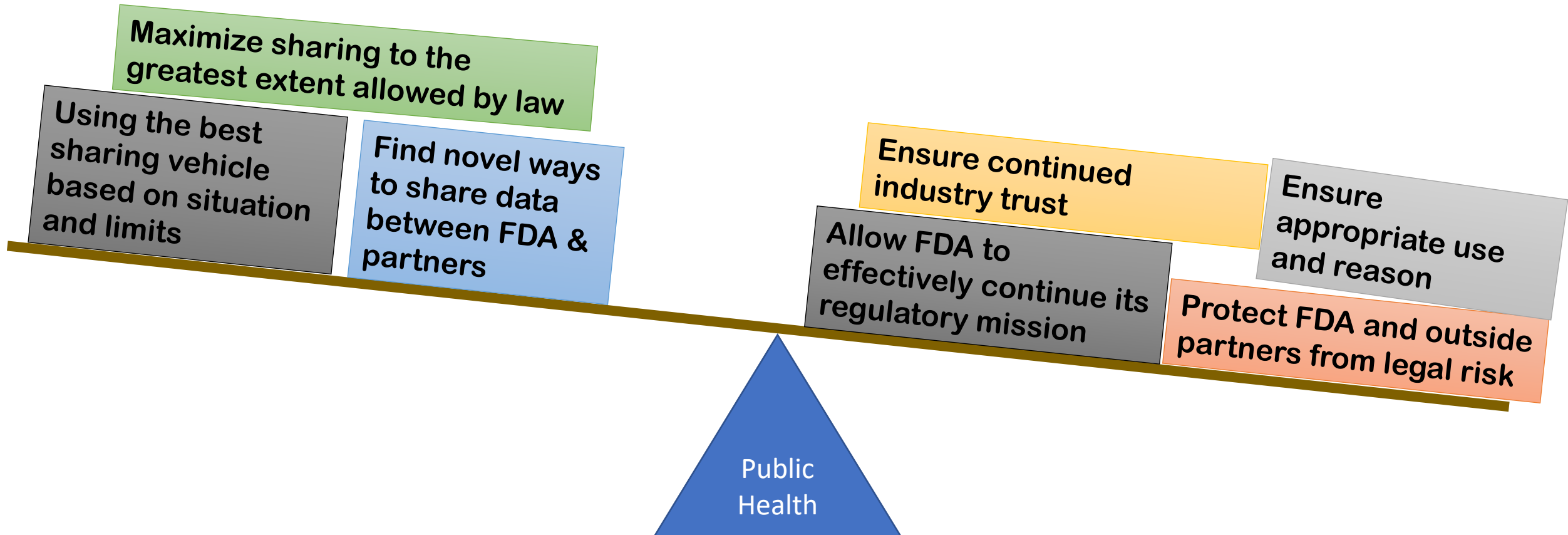
Freedom of Information (FOIA)	Contracts	Cooperative Agreements	Rapid Response Teams
Emergency Response	Memoranda of Understanding (MOUs)	Confidentiality Commitments (Foreign)	Federal Partnership (20.85)
State Partnership (20.88)	Litigation	Press Releases	State/Federal Government Inquiries

*Not all inclusive

BALANCING INFORMATION SHARING

SHARING

PROTECTION



NON-PUBLIC INFORMATION CATEGORIES

CATEGORIES	EXAMPLES	LEGAL CONSIDERATIONS
TRADE SECRET (TSI)	☞ Specific brands of equipment used ☞ Unique equipment or processes equipment ☞ Quality control procedures ☞ Internal Sampling methods ☞ Formulations	➤ Cannot disclose TSI to States or federal outside HHS pursuant to 21 CFR §20.88/20.85 without the express written authorization from the owner or submitter ➤ Cannot be shared with industry/public per the Trade Secrets Act and 301(j) of the FD&C Act ➤ Can be shared with commissioned officer
CONFIDENTIAL COMMERCIAL (CCI)	☞ Customer names ☞ Number of employees ☞ Product failure rates ☞ Distribution/consignee lists ☞ Production volume ☞ Financial information ☞ Traceforward/traceback information	➤ CCI can be disclosed to states and other federal agencies if they commit to keeping it confidential per 21 CFR Part 20 ➤ FDA cannot disclose certain CCI information relating to Devices and Tobacco products pursuant to 21 U.S.C. § 360j(c) and 21 U.S.C. § 387f(c) ➤ Cannot be shared with industry/public per the Trade Secrets Act
PERSONAL PRIVACY (PPI)	☞ Certain Consumer Complaint information ☞ Individual's identifiable information ☞ Complainant's name ☞ SSN ☞ Hospital name ☞ Whistleblower	➤ Shared only personal information pertinent for the state to conduct investigation shared ➤ Whistleblower information is not shared outside FDA ➤ Cannot be shared with industry/public per the Privacy Act and 21 CFR Parts 20 and 21
PRE-DECISIONAL OR DELIBERATIVE PROCESS	☞ Samples prior to final results ☞ Trying to figure out the distribution chain in a recall ☞ Draft documents (e.g., guidance documents)	➤ Protected from disclosure under FOIA; discretionary disclosure to industry/public requires approval from information owner and triggers uniform access
OPEN INVESTIGATORY LAW ENFORCEMENT	☞ Background for compliance actions (e.g., warning letter, reg. meeting) ☞ Unredacted copies of the warning letter and responses	➤ Protected from disclosure under FOIA; discretionary disclosure to industry/public requires approval from information owner and triggers uniform access

VEHICLES FOR INFORMATION SHARING

Allows FDA to disclose communications and non-public information (NPI) with federal, state & local government counterparts as part of cooperative law enforcement or regulatory efforts

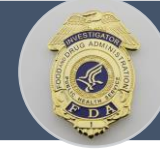
20.88 (STATES)

20.85 (non-HHS)



Authorizes state employees to conduct examinations and investigations as FDA employees

COMMISSION



Allows FDA to share information as outlined in contract

CONTRACT/

CONTRACTOR



Commodities Types	Can combine commodities into one agreement	Commodity specific	Specific to contract
Applies to	Anyone who signs confidentiality form accompanied by request letter	Individual only	Covers all working under contract
FDA’s Requirement to Share	Discretionary sharing		
NPI Access	Share all NPI <u>EXCEPT TSI</u> ² Discretionary for PPI/whistleblower	Able to share all NPI (including TSI) Discretionary for PPI/whistleblower	
Further Use of Information	For further State/Federal action	Only for work directly for FDA	
Ability to Protect Information	Must agree to protect and not further disclosure outside of group/agency ¹		
Regulatory Citations	21 CFR 20.88	21 U.S.C. §372(a) , 21 U.S.C. §331(j) , 18 U.S.C. §1905 , 5 U.S.C. §552a , 21 CFR §20.88(a)	21 U.S.C. §331(j) , 21 U.S.C. §360j(c) , 18 U.S.C. §1905 , 21 CFR §20.88(b) , 21 CFR §20.90

¹Commissioned individuals can only share with same agency office with same commodity endorsement

²Device and tobacco CCI is considered TSI and can't be shared under 20.88/20.85 agreements

20.88 Agreements

Long Term Agreements

- Umbrella agreement—coverage of those under signatory
- Must be in place before information is released to agency
- Request processed directly through Division of Information Disclosure Programs (DIDP)
- Current agreements
 - Food, Feed, and Cosmetics
 - Drug Compounding/Security Act
 - Human/Animal Drug & Biologics
 - Imports Cross Commodity

Case Specific Agreements

- Used by agencies that DO NOT have a Long-Term Agreement
- Processed by DIDP
- Agreements valid for the duration of the issue for which the request was made
- Information shared only with those who signed the agreement

Limited Scope/Extension 20.88 Agreement

- Uses an addendum to limit the scope of information sharing to an agreed upon set of records.
- May authorize further sharing as defined by the addendum.
- Example - MDARD has the Extension LT 20.88 agreement with an addendum to authorize sharing to counties that have a Limited Scope 20.88



20.88 Agreement Certifying Information

- Under this confidentiality agreement, you are certifying, on behalf of your agency, that the agency has the legal authority to protect all non-public food information that FDA shares with individuals in your agency and committing not to disclose such information. The reference to “non-public information” covered by this agreement includes information subject to limitations on public disclosure under federal law and regulations. For FDA documents shared under this agreement, this may include: confidential commercial information, personal privacy information, pre-decisional information, deliberative information, and law enforcement records. Trade secrets may not be shared under this agreement. Any request to share non-public information outside of your agency must be approved in advance by FDA.

COVERSHEET

**MAINTAIN ON EVERY
ATTACHMENT FROM FDA**

Non-public Information Coversheet

**DOCUMENTS ENCLOSED
Contain
Non-Public Information**



The enclosed document(s) may contain information prohibited from public disclosure by law. Unauthorized disclosure of non-public information could be a civil or criminal violation and carry consequences for the disclosing official. If you are not the intended recipient or believe that you have received document(s) in error, do not copy, disseminate or otherwise use the information and contact FDA regarding the handling of these document(s). Any request to share this information outside of the intended recipients must be approved in advance by FDA. Contact orainfoshare@fda.hhs.gov.

Why do we guard information?



IT'S THE LAW



PROTECT PUBLIC TRUST

Publicly Available FDA Regulatory and Inspection Resources



Inspections

- [Inspection Classification Database](#): view the classification of inspection outcomes
- [Database FAQ](#)



Compliance

- [Warning Letters](#): view redacted FDA warning letters
- [Recalls, Market Withdrawals, & Safety Alerts](#): view public information on recalls



Outbreaks

- [Outbreaks of Foodborne Illness](#): view outbreak investigations reports, and prevention information



Imports

- [Voluntary Qualified Importer Program \(VQIP\)](#): helps expedite review and import entry of foods
- [Accredited Third-Party Certification Program \(TPP\)](#): helps establish eligibility for participation in VQIP
- [Import Alerts](#)

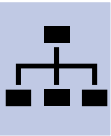


Datasets

- The [FDA Data Dashboard](#) provides interactive data visualizations and downloadable datasets on inspections, compliance, and imports.

Contact Information

FDA/ORA/OFFICE OF PARTNERSHIPS DIVISION OF INFORMATION DISCLOSURE PROGRAMS



DIRECTOR

- Lisa Bellows



POLICY

- Melissa Pickworth



TESTIMONY SPECIALISTS

- Jessica Whiting
- Tobi Erskine
- Whitney White



FOIA

- Lisa Elrand
- Tamara Coley



MOU/OTHER AGREEMENTS

- LaTiffany Parker



SPECIAL PROJECTS/STATE CONSULTS

- Jason Schilling
- Christa Kiggundu

Information Sharing Questions: ORAINFOSHARE@FDA.HHS.GOV
FOI Questions: ORAOSPOPFOIAInfodiscpolicydivmgmt@fda.hhs.gov
[ORA Information Disclosure Sharepoint](#)