

**Disclosure Fact Sheet**  
Extracted from:  
<http://www.fda.gov/cber/summaries/binkleytrg.ppt>  
**FDA workshop on Disclosure**  
**August 29, 2001**  
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**Disclosure:**

1. The act or process of revealing or uncovering.
2. Something uncovered; a revelation.

**Drug development:**

The sponsor of the drug (company) is the only entity allowed to disclose information about the drug to the public.

**Statutes that may affect disclosure include:**

- The Freedom of Information Act (FOIA) 5 U.S.C. 552
- Trade Secrets Act 18 U.S.C. 1905
- Privacy Act
- Health Insurance Portability and Accountability Act of 1996

**Freedom of Information Act (FOIA): 5 U.S.C. 552**

- First enacted September 6, 1966 as part of the Administrative Procedure Act, effective on 7/4/67
  - Amended, several times, once in 1974 by overriding a presidential veto
  - Other amendments made in 1967, 1976, 1978, 1984, 1986 and 1996
- To **ensure that the government's operations are apparent**
- Except where disclosure would harm an individual, corporate entity or national security

FOIA provides that any person has a right, enforceable in court, of access to Federal agency records except to the extent that such records are protected from disclosure by one of nine exemptions.

**Nine exemptions to FOIA:**

- Classified documents
- Internal personnel rules and practices
- Information exempt under other laws
- **Confidential business information**
- **Internal government communications**
- **Personal privacy**
- Law enforcement

- Financial institutions
- Geological information

### **Trade Secret or Confidential Commercial Information**

- Trade secrets and commercial or financial information obtained from a person and privileged or confidential.

### **Internal government communications**

- Inter-agency or intra-agency memoranda or letters which would not be available by law to a party other than an agency in litigation with the agency.

### **Personal Privacy**

- Personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

### **Evaluate using “Foreseeable Harm Standard”**

October 4, 1993 memo from the Attorney General Janet Reno States:

It shall be the policy of the Department of Justice to defend the assertion of a FOIA exemption only in those cases where the agency reasonably foresees that disclosure would be harmful to an interest protected by that exemption.

### **Disclosure outside of FOIA**

- Discretionary disclosure by Commissioner
  - Extreme public hazard: Burzynski
- Court orders
- Congress
- State and local government officials
- Other Federal government departments and agencies
- Foreign Government officials

### **Disclosure regulations**

- General Disclosure Regulations: 21 CFR Part 20
- Regulations specific to biologic products:
- 21 CFR 601.50, 601.51, 601.70(e), (also see 601.8, and 640.120)
- Regulations specific to INDs: 312.130
- Regulations specific to devices: 803.9, 806.40, 807.95, 809.4, 812.38, 814.9, 814.122, 821.55, 860.5

What is disclosure?

Definition

What is disclosure at FDA?

Definition / examples (use imclone)

What’s the background of this issue?

FOIA, exemptions, king/

How disclosure can serve patients and advocates

Incentive for developing new drugs

How disclosure might harm patients and advocates