

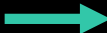
# THE FDA WEBSITE IMPROVING TRANSPARENCY AND EFFECTIVENESS

Stephen A. Weitzman, J.D., LL.M.



# GOAL

- My goal today is to recruit you in an effort to get FDA to devote more resources to meet your information needs
- FOIA Efficiency -- Proactive Disclosure
- Enterprise Control Over Information
  - Cataloging Documents – LIBRARY FUNCTION
  - Inserting Document Properties – Standard Metadata
- A Cooperative Means of Fostering Disclosure
  - Interim Steps
  - An MOU



File name:	rl34045.pdf
File size:	219 KB (224,192 bytes)
Title:	untitled
Author:	-
Subject:	-
Keywords:	-
Creation Date:	4/27/2010, 1:35:22 PM
Modification Date:	11/16/2015, 1:54:28 PM
Creator:	-
PDF Producer:	Acrobat Distiller 8.1.0 (Windows)
PDF Version:	1.4
Page Count:	18
Close	



## TRANSPARENCY IN THIS CONTEXT

- translucency, limpidity, clearness, clarity "the transparency of the glass"
- openness, accountability, straightforwardness, candor
  - "government aims for better transparency"

# INITIATIVES: DECISION MAKING PROCESS

- **The FDA Transparency Initiative**

(<https://www.fda.gov/AboutFDA/Transparency/TransparencyInitiative/default.htm>)

- 2009, FDA launched an initiative
- Aimed to make more **regulatory decisions and analyses available** to the public
- Although FDA moved some of these proposals forward, others were never implemented.
- A lot was statistics
- OPEN FDA – Adverse Events and Other Databases (2014)

- **Sharfstein: Enhancing Transparency at the US Food and Drug Administration (JAMA, March 13, 2017, <http://jamanetwork.com/journals/jama/fullarticle/2612200>)**

- 18 Recommendations
- More open process
- Release of all correspondence on substance of decisions and recommendation to sponsors
- Clinical Information

# DISCLOSURE OF CLINICAL TRIAL DATA - SHARFSTEIN

- Clinical Trial Data – EMA policy (Only 6 drugs so far)
- Several pharmaceutical and device companies now release data files in partnership with academic centers to permit independent analysis.
  - USA: Voluntary Access to data led by GSK and SAS – <https://clinicalstudydatarequest.com/>
  - **Astellas, Bayer, Boehringer Ingelheim, Daiichi Sankyo, Eisai, GSK, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and ViiV Healthcare.**
  - J & J (<http://www.clinicaltrialstudytransparency.com/>)
- FDA should disclose reasons for rejecting applications
  - What if it was for a new use for an approved drug – (Will doctors continue to prescribe it for off-label use)



# ADEQUATE DIRECTIONS FOR USE

- What Sharfstein misses is that what he seeks in part for doctors really is the statutory mandate for **ADEQUATE DIRECTIONS FOR USE**
- A point our IBM Watson colleague raised (I assume he did) was that in the age of Precision Medicine the best way for a practitioner to prescribe a drug is to first compare his patient based on phenotype and genomics to patients in clinical trials as well as post market medical record data and patient observational data on the use of that treatment.

# TRANSPARENCY - WHY IRAI

[www.iraionline.org](http://www.iraionline.org)

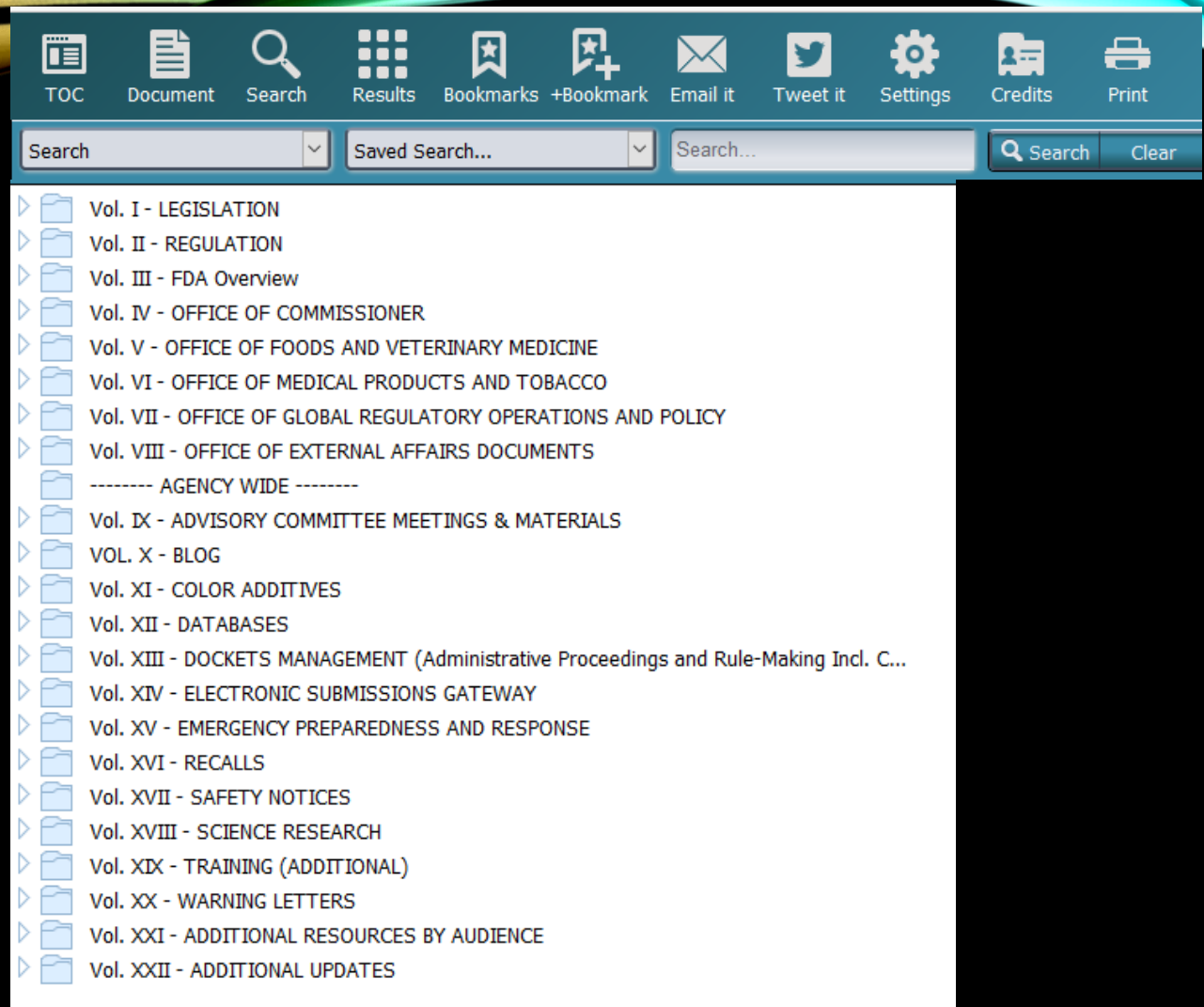
- Improved Search and Retrieval Tools
  - We all search by keywords – but there is no thesaurus
  - More Help – Boolean template – Advanced search (implements complex Boolean searches in a simple template)
  - Search Results – The numbers of documents with hits in all categories
- Content
  - Those regulated by FDA need more than is on the FDA website
  - They need:
    - Legislation
    - Case Law & Briefs (We need to add this)
    - Federal Register and Comments
      - ON FDA website until 2009
      - After 2009 on GPO site – Comments on the GPO site are not indexed
    - Narrative Explanation of FDA Law and Regulation – FDA Ends in 1998 – We Add CRS Reports
  - Organization: We organize like a textbook

# INFORMATION RESPOSITORY FOR ACADEMIC INSTITUTIONS FEATURES





# STRUCTURED TABLE OF CONTENTS



The screenshot displays a web application interface with a dark blue header bar containing various icons and labels. Below the header is a search bar with a dropdown menu for 'Saved Search...' and a 'Search...' input field. The main content area is a white box with a list of folders, each preceded by a blue folder icon and a right-pointing triangle. The folders are organized into a structured table of contents.

Folder Name
Vol. I - LEGISLATION
Vol. II - REGULATION
Vol. III - FDA Overview
Vol. IV - OFFICE OF COMMISSIONER
Vol. V - OFFICE OF FOODS AND VETERINARY MEDICINE
Vol. VI - OFFICE OF MEDICAL PRODUCTS AND TOBACCO
Vol. VII - OFFICE OF GLOBAL REGULATORY OPERATIONS AND POLICY
Vol. VIII - OFFICE OF EXTERNAL AFFAIRS DOCUMENTS
----- AGENCY WIDE -----
Vol. IX - ADVISORY COMMITTEE MEETINGS & MATERIALS
VOL. X - BLOG
Vol. XI - COLOR ADDITIVES
Vol. XII - DATABASES
Vol. XIII - DOCKETS MANAGEMENT (Administrative Proceedings and Rule-Making Incl. C...
Vol. XIV - ELECTRONIC SUBMISSIONS GATEWAY
Vol. XV - EMERGENCY PREPAREDNESS AND RESPONSE
Vol. XVI - RECALLS
Vol. XVII - SAFETY NOTICES
Vol. XVIII - SCIENCE RESEARCH
Vol. XIX - TRAINING (ADDITIONAL)
Vol. XX - WARNING LETTERS
Vol. XXI - ADDITIONAL RESOURCES BY AUDIENCE
Vol. XXII - ADDITIONAL UPDATES

# THREE WAYS TO SEARCH

The screenshot shows a toolbar with icons for TOC, Document, Search, Results, Bookmarks, +Bookmark, Email it, Tweet it, Settings, Credits, and Print. Below the toolbar, a search dropdown menu is open, showing options: Search, Boolean Search, and Advanced Search. The 'Search' option is highlighted.

## Advanced Search

You can **search a subset** of the site by choosing sections in the table of contents (in the frame on the left).

### Search for documents...

containing **all** these words:

and **not** containing any of these words:

and containing **one or more** of these words:

and containing this **exact phrase**:

and containing these words **near** each other:

☒ YES ☐ Find alternate word forms (stemming)

☐ NO ☒ Find synonyms (thesaurus)

Show document excerpts in the results list

Off Short ☒ Medium Long

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Off Short ☒ Medium Long



RESULTS  
WINDOW  
Key Word  
In  
CONTEXT  
NOW  
CLICK ON  
FIRST  
RESULT

TOC Document Search Results Bookmarks +Bookmark Email it Tweet it Settings Credits Print Save Email Help i-ONLINE Digital Repository BETA

Search Saved Search... Search... Search Clear

1 - 20 of 544 results

Document Excerpts: Medium

**Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs**  
Vol. VI - OFFICE OF MEDICAL PRODUCTS AND TOBACCO / Vol. VI.C - CDER - CENTER FOR DRUG EVALUATION AND RESEARCH / CDER GUIDANCES / Guidances (Drugs by Category) / Guidance Compliance Regulatory Information / Guidances (Drugs) / Advertising  
... Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Human...  
... Drugs Guidance for Industry Guidance for Industry Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs Guidance for Industry...  
... Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Human...  
... Research (CDER) February 2015 Advertising Revision 1...  
... Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Human...

**Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs Guidance for Industry**  
Vol. VI - OFFICE OF MEDICAL PRODUCTS AND TOBACCO / Vol. VI.C - CDER - CENTER FOR DRUG EVALUATION AND RESEARCH / Associated PDFs and Office Documents / Drugs / Guidance Compliance Regulatory Information / Guidances  
... Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription...  
... Guidance for Industry Microsoft Word - CDER08032015 draft.doc Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs Guidance for Industry...  
... Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription...  
... Medicine (CVM) August 2015 Advertising Revision 2...  
... Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs...

**FDA Reissuing Draft Guidance for Human and Animal Drug Manufacturers on Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription Drugs**  
Vol. V - OFFICE OF FOODS AND VETERINARY MEDICINE / Vol. V.B - CVM (CENTER FOR VETERINARY MEDICINE) / News & Events / CVM Updates / By Subject / Minor Use  
... a reissued revised draft guidance for industry, "Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription...  
... the full FDA-approved package insert (PI) to fulfill the [adequate directions](#) for use requirement for consumer-directed print promotional labeling for...  
... Notice of Availability of Draft Guidance for Industry: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription...  
... Drugs Brief Summary and [Adequate Directions](#) for Use: Disclosing Risk [Information](#) in Consumer-Directed Print Advertisements and Promotional Labeling for Prescription...

**Advertising/Labeling Definitions**  
Vol. VI - OFFICE OF MEDICAL PRODUCTS AND TOBACCO / Vol. VI.C - CDER - CENTER FOR DRUG EVALUATION AND RESEARCH / THE CDER HANDBOOK - [Ed. A guide to CDER's Processes and Activities] / NEW DRUG DEVELOPMENT AND REVIEW PROCESS / Post Drug Approval Activities / Advertising  
... Labeling must include the established name, proprietary name (if any), [adequate directions](#) for use, and [adequate](#) warnings. The agency considers the approved product labeling, sometimes called...  
... the full prescribing [information](#), to be [adequate directions](#) for use and [adequate](#) warning. Q. Are there exceptions to the requirements for labeling...  
... Yes. Reminder labeling is exempt from the requirements for [adequate directions](#) for use and adequate warnings. Reminder labeling, as defined in...

**\$801.109 Prescription devices.**  
Vol. II - REGULATION / 21 C.F.R. (Code of Federal Regulations) 2016 / Volume 8 800-1299 MEDICAL DEVICES AND RADIOLOGICAL HEALTH / PART 801-LABELING / Subpart D-Exemptions From Adequate Directions for Use

FIRST RESULT  
DOCUMENT  
APPEARS  
WITH  
LOCATION  
IN THE TOC

TOC Document Search Results Bookmarks +Bookmark Email it Tweet it Settings Credits Print Save Email Help iFDA-ONLINE iFDA DIGITAL REPOSITORY BETA

Search Saved Search... Search... Clear

Sync Prev Doc Next Doc Prev Match Next Match Highlights Prev Hit Doc Next Hit Doc

Page: 1 of 15 Automatic Zoom

**Brief Summary and Adequate Directions for Use: Disclosing Risk Information in Consumer-Directed Print Advertisements and Promotional Labeling for Human Prescription Drugs**

**Guidance for Industry**

**REVISED DRAFT GUIDANCE**

**This guidance document is being distributed for comment purposes only.**

Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Julie Chronis 301.796.1200 or [Vol ... TOBACCO > > Brief ... Drugs](#)





# IMPROVING ACCESS TO FOIA RELEASABLE DOCUMENTS

- Start with the FOIA Log and Post all released documents
- Release all releasable documents as generated
  - Issue – Resources to redact every releasable document for distribution
  - Issue – Converting all Office Documents to PDF and adding properties
    - Taking advantages of PDF display and functions – search within document
  - Issue - FDA has no structured file system that allows for easy searching and locating documents as generated
  - FOI Office has no real archive of released documents



# OTHER WAYS TO IMPROVE TRANSPARENCY AND EFFICIENCY

- ONE STOP AND SHOP of
  - All Government-Related information Relevant to meeting FDA Requirements
  - Other International Agency public domain information
  - Publications and Webinars of other Professional Organizations
- Developing an FDA information cataloging system that could be used by FDA and all professional organizations (RAPS, DIA, etc., Publishers) to catalog documents, books, and webinars to enable easy access to these resources.

# IMMEDIATE APPROACHES

- **INTERIM**

- FDA Must Publish the FOIA Log
- MedDATA will request every released document and post them on IRAI
- Anyone desiring a document not on the website can ask MedDATA to make the FOIA request (at a small fee to cover handling)
- When a document is received, it goes to the requestor and is also added to IRAI
- The regulated industry can submit to IRAI documents they have and/or previously requested under FOIA which will be metadated and published on IRAI

- **PROPOSED MOU**

- MedDATA is proposing an MOU with FDA to jointly work to improve access through improvements in the FDA website and IRAI (IRAI Report at <http://www.meddatafoundation.org/irai-report.html>) and draft MOU <http://www.meddatafoundation.org/draft-mou.html>
- Major Suggestion – Public Private Partnership with Expert Editorial Board from Stakeholders to work with the FDA Office of External Affairs, The Centers, and the Office of Global Regulatory Operations (International and Domestic)



# WHOM TO CONTACT AT FDA ABOUT CONCERNS

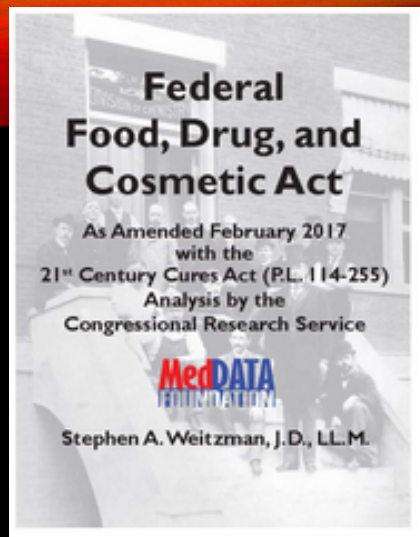
- Last name Kalavritinos
- First name John
- Middle name C
- Agency FDA
- Organization DHHS/FDA/OC/OEXA
- Job title ASSOC COMM FOR EXTERNAL AFF
- Building
- Room
- Duty station Silver Spring MD 20993-0002
- Phone 301-796-8913
- Internet e-mail Jack.Kalavritinos@fda.hhs.gov



# ARE YOU INTERESTED?

- Will YOU support this Disclosure Effort and Write FDA?
- Should our SLA committees organize to address these issues and lobby our corporate regulatory affairs and policy offices to work with our professional and trade associations to get these recommendations implemented?
- Would YOU be interested in being a Subject Editor to improve IRAI TOC organization?
- Would YOU be interested in working on a Cataloging system?

IF YES, Contact Stephen Weitzman at [saw5198@earthlink.net](mailto:saw5198@earthlink.net)



- Food, Drug, And Cosmetic Act (2017) With 21st Century Cures Amendments and Analysis by the Congressional Research Service.
- Single Copy - Softbound - \$95.00 including Shipping within the United States
- SLALIFE – Coupon Code \$20.00 Discount April 3 to April 17