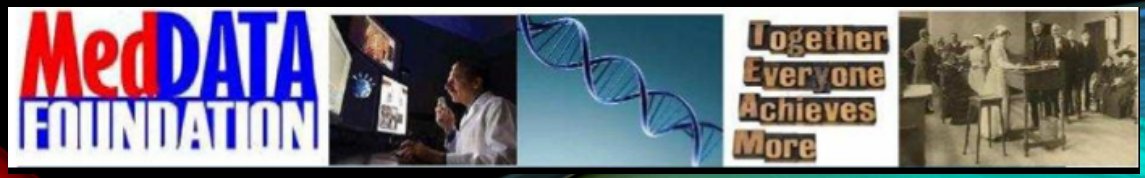
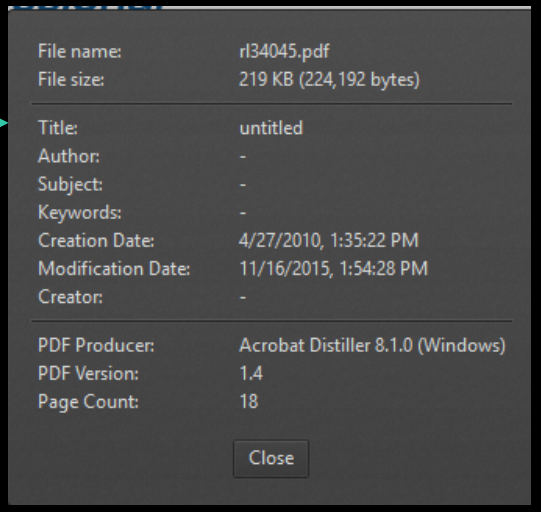
THE FDA WEBSITE IMPROVING **TRANSPARENCY** AND EFFECTIVENESS

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



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.

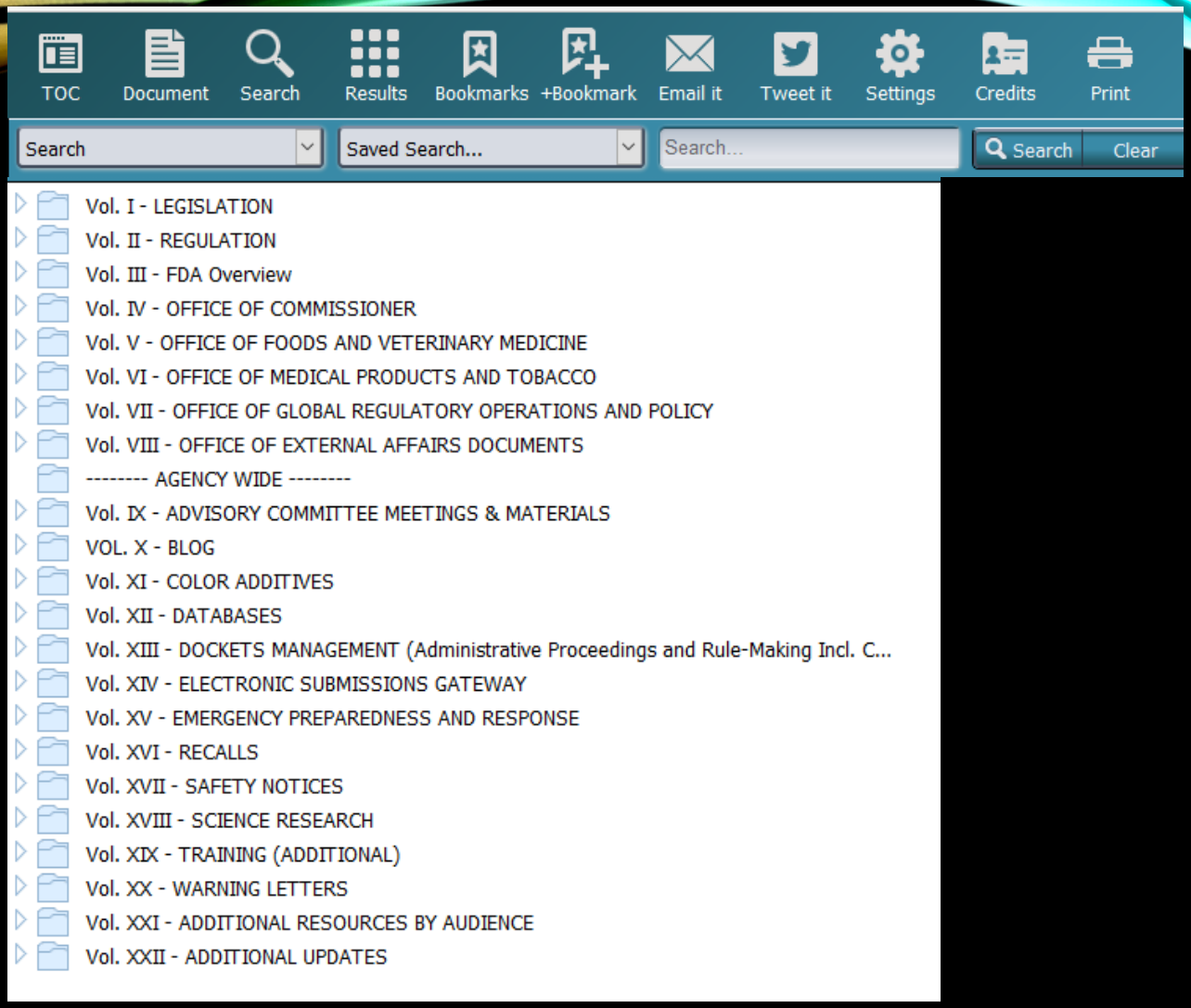
TRANSPARENCY - WHY IRAI

www.iraionline.org

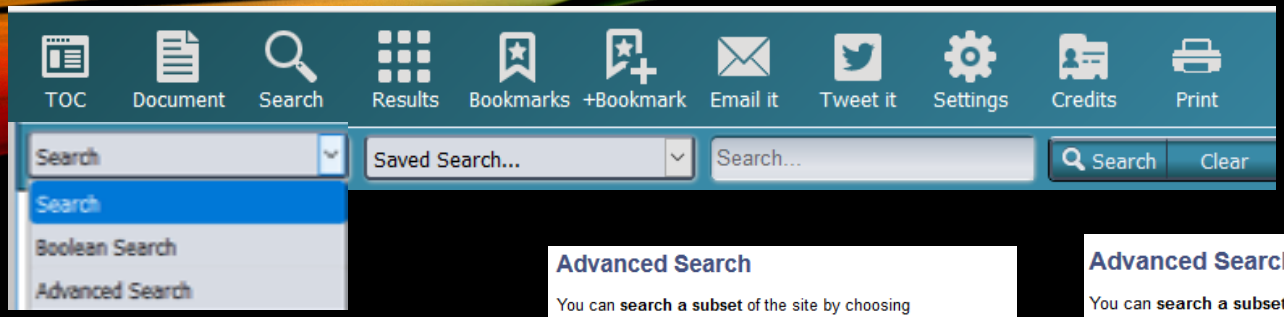
- Improved Search and Retrieval Tools
  - We all search by keywords – but there is no thesaurus
  - More Help – Boolean template – Advanced search (implements complex Boolean searches in a simple template)
  - Search Results – The numbers of documents with hits in all categories
- Content
  - Those regulated 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

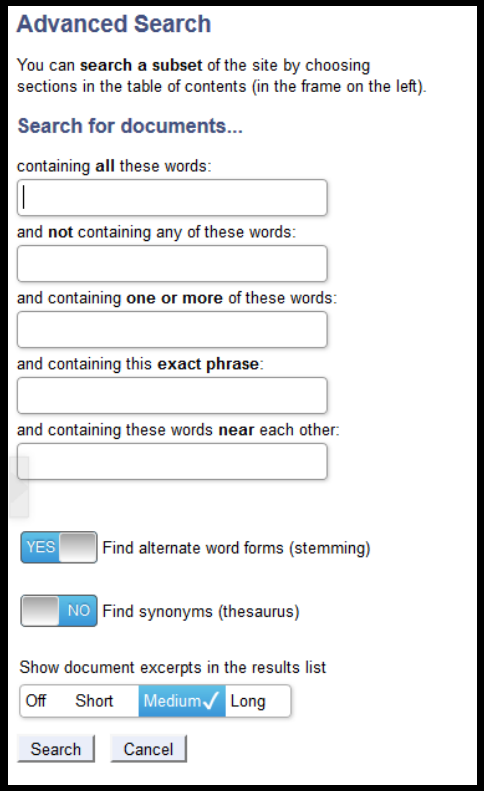
INFORMATION RESPOSITORY FOR ACADEMIC INSTITUTIONS FEATURES

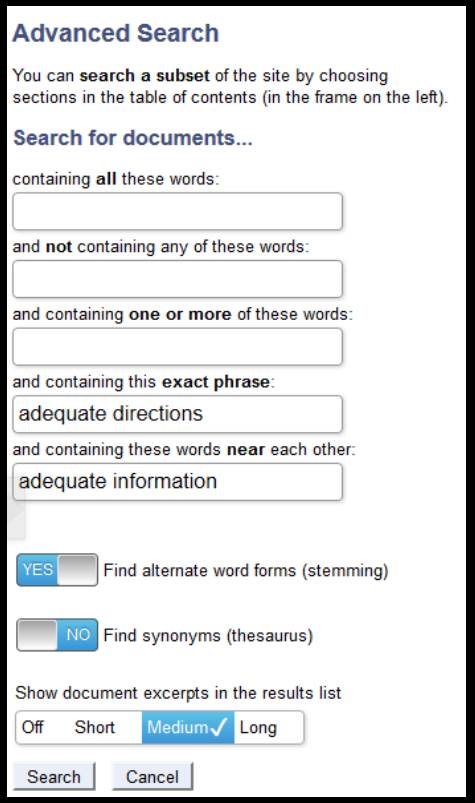
STRUCTURED TABLE OF CONTENTS



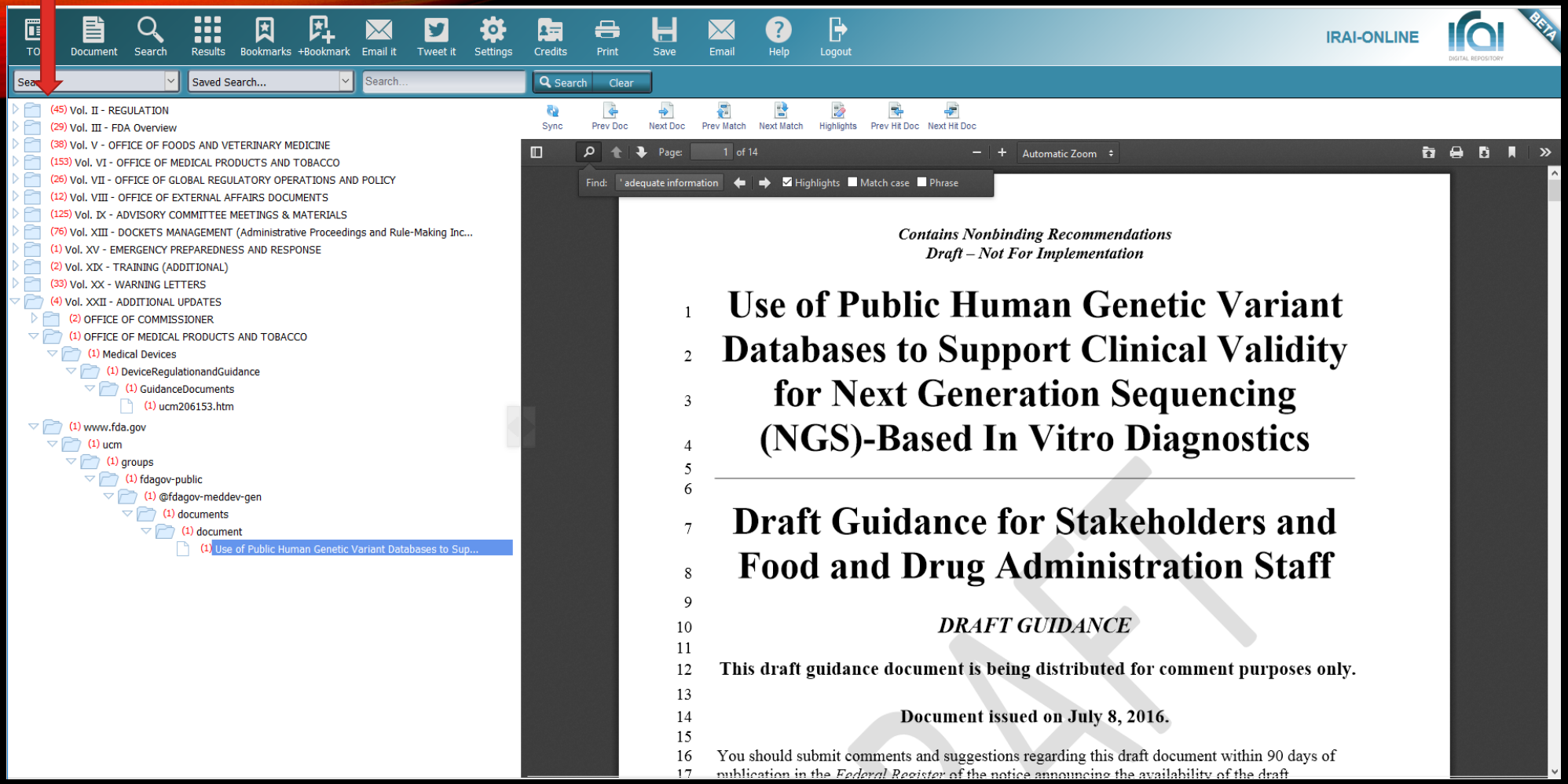
THREE WAYS TO SEARCH







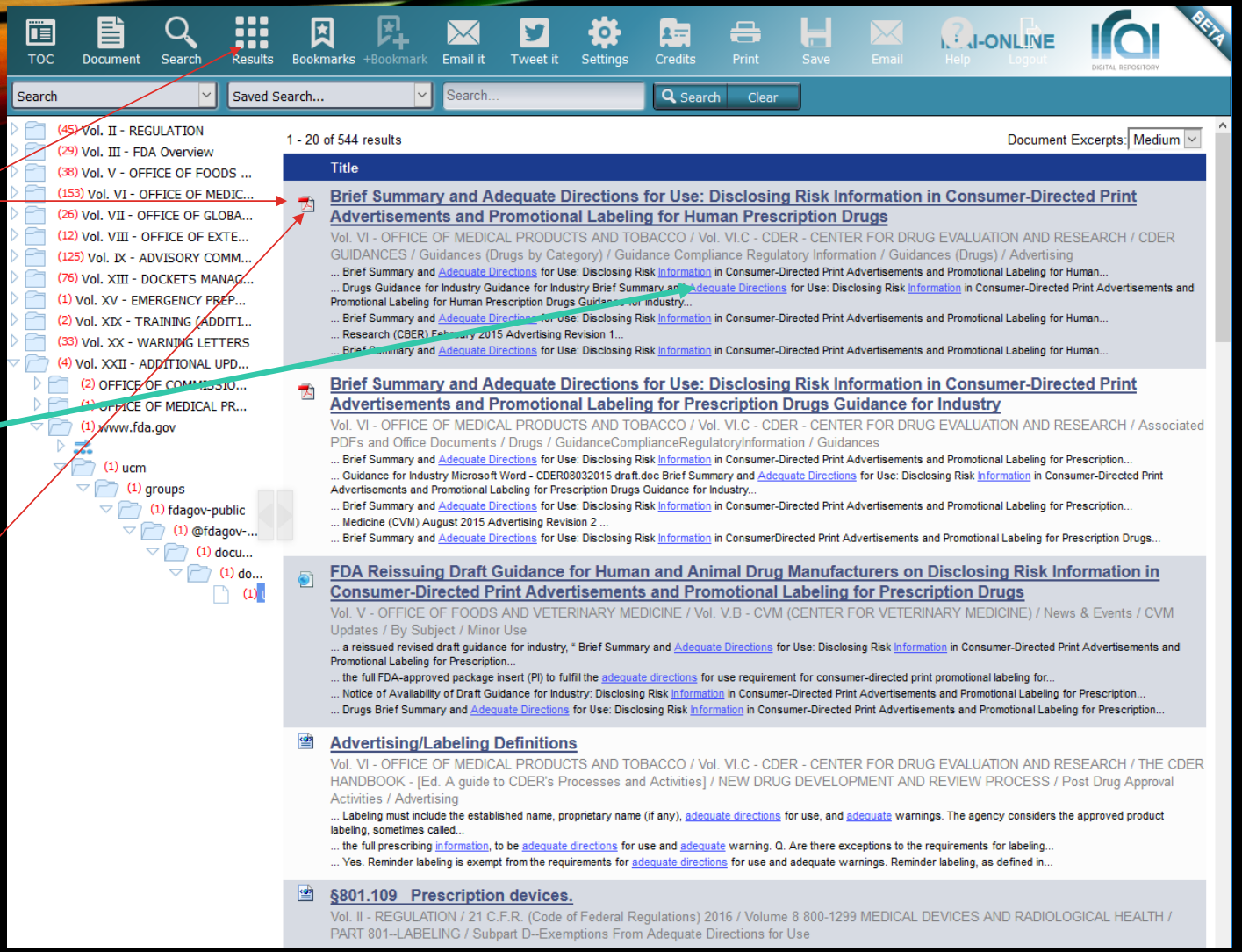
A 35,000 FOOT VIEW OF EVERY HIT ON THE SITE - DRILL DOWN



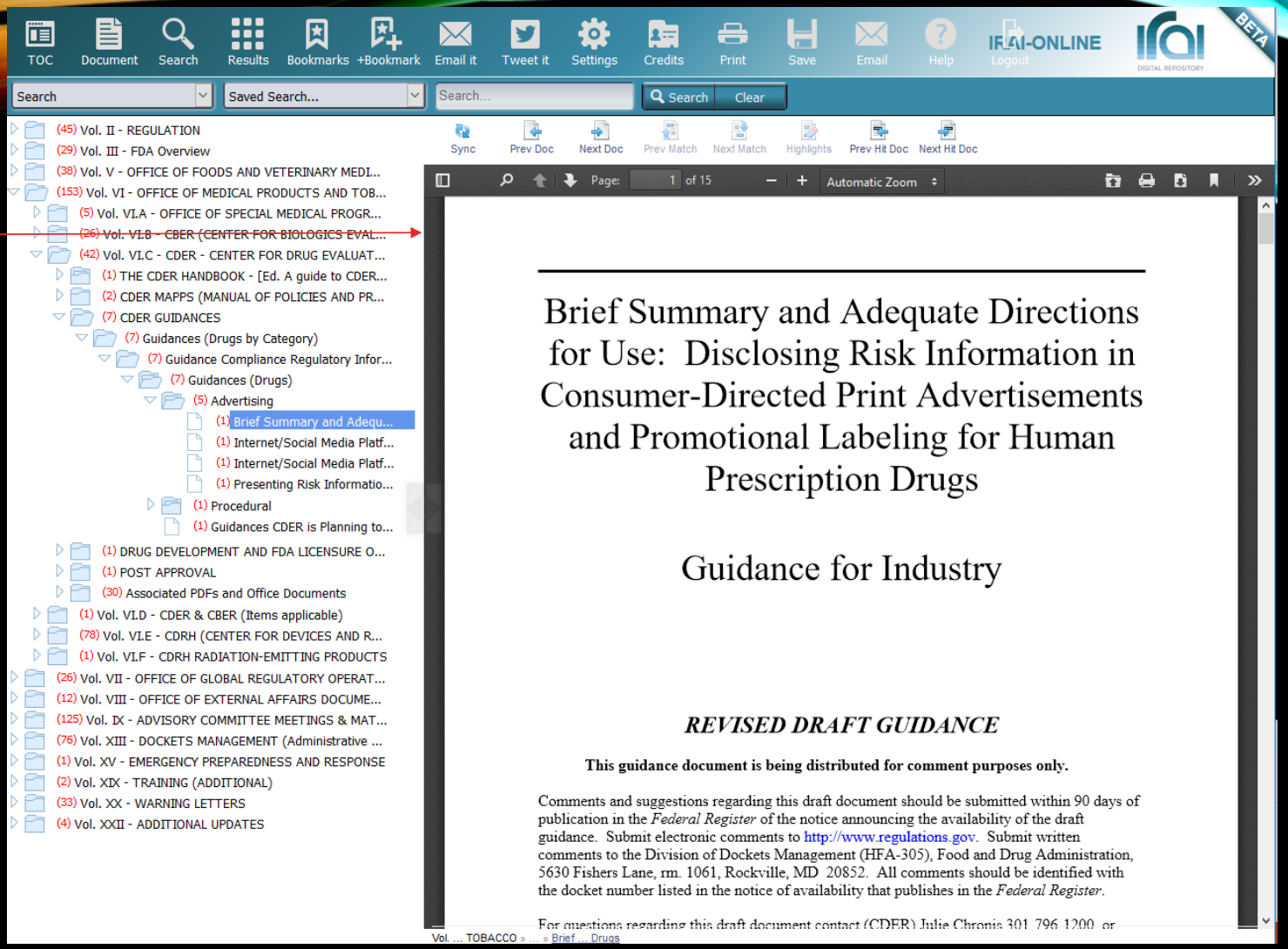
RESULTS WINDOW

Key Word In CONTEXT

NOW CLICK ON FIRST RESULT



FIRST RESULT - DOCUMENT APPEARS WITH LOCATION IN THE TOC



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
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- Duty station Silver Spring MD 20993-0002
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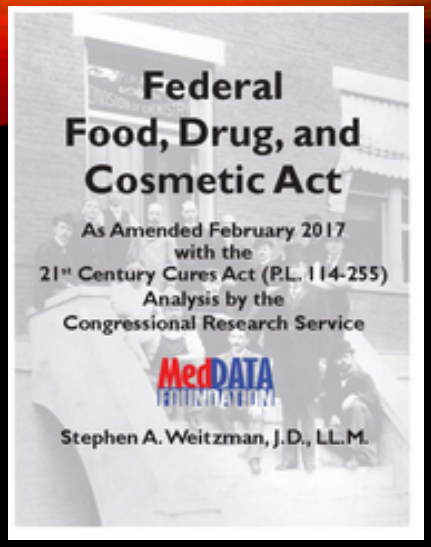
ARE YOU INTERESTED?

- 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



- Food, Drug, And Cosmetic Act (2017) With 21st Century Cures Amendments and Analysis by the Congressional Research Service.
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