THE FDA WEBSITE
IMPROVING
TRANSPARENCY
AND EFFECTIVENESS

Stephen A. Weitzman, J.D., LL.M.
• 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)

  • 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, Daichichi 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
| 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
Use of Public Human Genetic Variant Databases to Support Clinical Validity for Next Generation Sequencing (NGS)-Based In Vitro Diagnostics

Draft Guidance for Stakeholders and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

Document issued on July 8, 2016.

You should submit comments and suggestions regarding this draft document within 90 days of publication in the Federal Register of the notice announcing the availability of the draft.
Now click on first result.
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) Julia Chronis 401-786-1250 or
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 metadataled 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

• Single Copy - Softbound - $95.00 including Shipping within the United States

• SLALIFE – Coupon Code $20.00 Discount April 3 to April 17