

Exhibit A: Selected Bibliography

FDA Documents:¹

- FDA/CDER. New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval. *Notice of Proposed Rulemaking*, 57 Fed. Reg. 13234 (April 15, 1992)(“*Subpart H Proposed Rule*”).
- New Drug, Antibiotic, and Biological Drug Product Regulations; Accelerated Approval. *Final Rule*, 57 Fed. Reg. 58942 (Dec. 11, 1992)(“*Subpart H Final Rule*”).²
- Statistical Review and Evaluation (May 21, 1996) (“Statistical Review”).³
- Center for Drug Evaluation and Research, Reproductive Health Drugs Advisory Committee. *Hearings on New Drug Application for the Use of Mifepristone for Interruption of Early Pregnancy* (July 19, 1996)(“*FDA Hearings Transcript*”)[FDA FOIA Release: MIF 005200-90].
- Letter, FDA/CDER to Ann Robbins, Population Council (Sept. 18, 1996)(“1996 Mifepristone Approvable Letter”).⁴
- *Guidance for Industry: Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products* (May 1998)(“*FDA Effectiveness Guidance*”).⁵
- “Medical Officer’s Review of Amendments 024 and 033: Final Reports for the U.S. Clinical Trials Inducing Abortion up to 63 Days Gestational Age and Complete Responses Regarding Distribution System and Phase 4 Commitments,”(Jan. 27, 2000) (“Medical Officer’s Review”).⁶
- Letter, FDA/CDER to Sandra P. Arnold, Population Council (Feb. 18, 2000)(“2000 Mifepristone Approvable Letter”).⁷
- Letter, FDA/CDER to Sandra P. Arnold, Population Council (Sept. 28, 2000) (“Mifeprex Approval Letter”).⁸
- Memorandum to NDA 20-687 MIFEPREX (mifepristone) Population Council (Sept. 28, 2000) (“Mifeprex Approval Memo”).⁹
- “Mifepristone Questions and Answers 4/17/2002.” (Apr. 17, 2002)(“FDA Q & As”).¹⁰
- “NDAs Approved under Subpart H,” FDA webpage;¹¹ and, “NDA Supplements Approved under Subpart H,” FDA webpage.¹²

¹ The FDA documents are listed chronologically.

² Available at: <<http://www.fda.gov/cder/fedreg/fr19921211.txt>>.

³ Available at: <http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_statr.pdf>.

⁴ Available at: <http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_approvableltr.pdf>.

⁵ Available at: <<http://www.fda.gov/cder/guidance/1397fnl.pdf>>.

⁶ Available at: <http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P1.pdf> and <http://www.fda.gov/cder/foi/nda/2000/20687_Mifepristone_medr_P2.pdf>.

⁷ Available at: <<http://www.fda.gov/cder/foi/appletter/2000/20687approvable00.pdf>>.

⁸ Available at: <<http://www.fda.gov/cder/foi/appletter/2000/20687appltr.pdf>>.

⁹ Available at: <<http://www.fda.gov/cder/drug/infopage/mifepristone/memo.pdf>>.

¹⁰ Available at: <http://www.fda.gov/cder/drug/infopage/mifepristone/mifepristone-qa_4_17_02.htm>.

¹¹ Available at: <<http://www.fda.gov/cder/rdmt/accapp.htm>>. The most recently available version of the chart is reproduced in Appendix C.

¹² Available at: <<http://www.fda.gov/cder/rdmt/accappr1.htm>>.

Danco or Population Council Documents:

Population Council. Responses to “FDA Letter, [redacted] to Arnold, Sandra (Febr. 18, 2000)”(Mar. 2000)[FDA FOIA Release: MIF 000523-24](“March 2000 Response”).

Danco Laboratories. Open Letter to Health Care Providers (Apr. 19, 2002)(“Dear Doctor Letter”).¹³

Searle/Pharmacia Document:

Cullen, Michael, M.D. Open Letter to Health Care Providers (Aug. 23, 2000) [FDA FOIA Release: MIF 008022].

International Conference on Harmonisation (ICH)¹⁴ Documents and FDA Republications:¹⁵

ICH E8:

FDA. “International Conference on Harmonisation; Guidance on General Considerations for Clinical Trials.” *Notice*, 62 Fed. Reg. 66113 (Dec. 17, 1997)(*FDA Guidance (ICH: E8): General Considerations*).¹⁶

ICH E9:

FDA. “International Conference on Harmonisation; Guidance on Statistical Principles for Clinical Trials; Availability.” *Notice*, 63 Fed. Reg. 49583 (Sept. 16, 1998)(*FDA Guidance (ICH:E9): Statistical Principles*).¹⁷

ICH E10:

FDA. “Guidance for Industry: E 10 Choice of Control Group and Related Issues in Clinical Trials.” Rockville, Md.: May 2001 (“*FDA Guidance (ICH:E10): Choice of Control Group*”).¹⁸

ICH E11:

FDA. “Guidance for Industry: E11 Clinical Investigation of Medicinal Products in the Pediatric Population.” Rockville, Md.: Dec. 2000 (“*FDA Guidance: E11 Clinical Testing for Pediatric Uses*”).¹⁹

Books, Articles, and Other Publications:

American College of Obstetricians and Gynecologists. “Medical Management of Abortion.” *ACOG Practice Bulletin: Clinical Management Guidelines for Obstetrician Gynecologists* (April 2001), No. 26 (“ACOG Practice Bulletin”).

¹³ Available at: <http://www.fda.gov/medwatch/SAFETY/2002/mifeprex_deardoc.pdf>.

¹⁴ “ICH” is an abbreviation for: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. ICH efficacy documents are posted at: <<http://www.ifpma.org/ich5e.html>>.

¹⁵ FDA’s version of ICH documents may be found at: <<http://www.fda.gov/cder/guidance/index.htm>> under “ICH” (left-hand column), then “Efficacy.”

¹⁶ FDA’s posting of “E8” (Fed. Reg. version) is available at: <<http://www.fda.gov/cder/guidance/1857fml.pdf>>.

¹⁷ FDA’s publication of “E9” is available at: <http://www.fda.gov/cder/guidance/ICH_E9-fnl.PDF>.

¹⁸ FDA’s publication of “E10” is available at: <<http://www.fda.gov/cder/guidance/4155fml.pdf>>.

¹⁹ FDA’s publication of “E11” is available at: <<http://www.fda.gov/cder/guidance/4099FNL.PDF>>.

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- Miller, Henry. "Failed FDA Reform." *Regulation* 21:3 (Summer 1998): 24-30.²⁸

²⁰ Available at: <<http://www.nyu.edu/pages/lawreview/75/6/monas.html>>.

²¹ Available at: <http://www.fdli.org/pubs/Journal%20Online/53_1/art9.pdf>.

²² Available at: <<http://www.nyu.edu/pubs/jlpp/articles/vol3num2/greenberg.pdf>>.

²³ Available at: <http://www.jamwa.org/vol55/pdf/55_3_10.pdf>.

²⁴ Available at: <<http://www.kff.org/content/2001/3130/MifepristoneIssueUpdate.pdf>>.

²⁵ Available at: <http://pdf.thelancet.com/pdfdownload?uid=llan.357.9268.editorial_and_review.16344.1&x=x.pdf>.

²⁶ Available at: <http://www.fdli.org/pubs/Journal%20Online/54_1/art12.pdf>.

²⁷ Available at: <http://obgyn.pdr.net/be_core/g/sections/c_past_issues/index.jsp?navtype=g&showPoll=no&filename=<filename/>>.

²⁸ Available at: <<http://www.cato.org/pubs/regulation/regv21n3/v21n3-ftp2.pdf>>.

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- Zimmerman, Rachel. "Clash Between Pharmacia and FDA May Hinder the Use of RU-486." *Wall Street Journal* (Oct. 18, 2000): B1.

²⁹ Available at: <http://www.fdpi.org/pubs/Journal%20Online/50_4/art4.pdf>.

³⁰ Available at: <<http://www.nytimes.com/library/magazine/home/19990711mag-abortion-pill.html>>.

³¹ Available at: <http://www.jamwa.org/vol55/pdf/55_3_3.pdf>.

³² Available at: <http://www.jamwa.org/vol55/pdf/55_3_5.pdf>.

³³ Available at: <http://www.fdpi.org/pubs/Journal%20Online/54_4/art10.pdf>.

³⁴ Available at: <<http://www.newscientist.com/news/news.jsp?id=ns99991212>>.