

Off-Label Pharmaceutical Marketing Resource Handout

October 2015

This resource handout contains a list of sources that health care professionals, State Medicaid program integrity personnel, and pharmaceutical sales representatives and employees may find useful with regard to off-label promotion of prescription drugs. This is not intended to be a complete list.

U.S. Department of Health and Human Services

Agency for Healthcare Research and Quality

- Off-Label Use of Atypical Antipsychotics: An Update. (2011, September). http://www.effectivehealthcare.ahrq.gov/ehc/products/150/778/CER43_Off-LabelAntipsychotics_20110928.pdf
- Off-Label Use of Atypical Antipsychotics: an update [September 2011 update]: AHRQ Comparative Effectiveness Review Surveillance Report. (2014, August). <http://www.effectivehealthcare.ahrq.gov/ehc/products/150/2061/atypical-antipsychotics-off-label-update-surveillance-150407.pdf>

Centers for Medicare & Medicaid Services

- How to Report Fraud and Suspected Fraud. (2014, December 16). https://www.cms.gov/medicare-medicare-coordination/fraud-prevention/fraudabuseforconsumers/report_fraud_and_suspected_fraud.html

U.S. Food and Drug Administration

- Bad Ad Program: 2011–2012 Year End Report. (2012, July 13). <http://www.fda.gov/drugs/guidancecomplianceregulatoryinformation/surveillance/drugmarketingadvertisingandcommunications/ucm258719.htm>
- Bad Ad Program: FDA Aims to Keep Drug Promotion Truthful. Promotional Settings. (2015, April 29). <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm211791.htm>
- The Bad Ad Program and Prescription Drug Promotion. (2013, October 15). <http://fdabadad.sigmatech.com>
- Overview of Bad Ad Program: How to Recognize and Report Misleading Promotion. (2013, April 16). <http://www.fda.gov/downloads/aboutfda/workingatfda/fellowshipinternshipgraduatefacultyprograms/pharmacystudentexperientialprogramcder/ucm347817.pdf>



- Division of Drug Marketing, Advertising, and Communications Enforcement Webinar. (2011, August 25). <http://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/UCM270811.pdf>
- Educational Case Studies. (2013, October 28). <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm368438.htm>
- Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices. (2009, January). <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125126.htm>
- Office of Prescription Drug Promotion. Prescription Drug Marketing Regulatory Primer. (2012). <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM312608.pdf>
- OPDP Update on Oversight of Prescription Drug Promotion. (2012, October 1). <http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/UCM330855.pdf>
- Promotion of Unapproved Drugs and Medical Devices. Statement Before the Senate Committee on Labor and Human Resources. (1996, February 22). (Statement of William B. Shultz, Deputy Commissioner for Policy, Food and Drug Administration). <http://www.fda.gov/newsevents/testimony/ucm115098.htm>
- Truthful Prescription Drug Advertising and Promotion. (2014, October 10). <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/DrugMarketingAdvertisingandCommunications/ucm209384.htm>

Office of Inspector General

- Hearing Before the Subcommittee on Labor, Health and Human Services, Education, and Related Agencies of the House Committee on Appropriations Agencies. (2010, March 4). (Testimony of Daniel R. Levinson, Inspector General of the Department of Health and Human Services). <http://oig.hhs.gov/testimony/docs/2010/3-4-10LevinsonHAppropsSub.pdf>
- Management Issue 8: Protecting Consumers of Food, Drugs, and Medical Devices. (n.d.). <http://oig.hhs.gov/reports-and-publications/top-challenges/2012/issue08.asp>
- Overprescribed: The Human and Taxpayers' Costs of Antipsychotics in Nursing Homes. Hearing Before the Senate Special Committee on Aging. (2011, November 30). (Testimony of Daniel R. Levinson, Inspector General of the Department of Health and Human Services). http://oig.hhs.gov/testimony/docs/2011/levinson_testimony_11302011.pdf

Social Security Act

- Payment for Covered Outpatient Drugs. Social Security Act § 1927. http://www.ssa.gov/OP_Home/ssact/title19/1927.htm

United States Code

- False Claims, 31 U.S.C. § 3729. <http://www.gpo.gov/fdsys/pkg/USCODE-2013-title31/pdf/USCODE-2013-title31-subtitleIII-chap37-subchapIII-sec3729.pdf>
- False, Fictitious or Fraudulent Claims, 18 U.S.C. § 287. <http://www.gpo.gov/fdsys/pkg/USCODE-2013-title18/pdf/USCODE-2013-title18-partI-chap15-sec287.pdf>
- Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301–399. <http://www.gpo.gov/fdsys/pkg/USCODE-2013-title21/pdf/USCODE-2013-title21-chap9.pdf>

- Sentence of Fine, 18 U.S.C. § 3571. <http://www.gpo.gov/fdsys/pkg/USCODE-2013-title18/pdf/USCODE-2013-title18-partII-chap227-subchapC-sec3571.pdf>

Other Statutes

- Food and Drug Administration Safety and Innovation Act. Pub. L. 112–144, 121 Stat. 993. (2012, July 9). <http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf>

Code of Federal Regulations

- Investigational New Drug Application (IND), 21 C.F.R. § 312.20–312.38. (2013). <http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=1&SID=e0f74104bdd6eecb6a4491aa96f13451&ty=HTML&h=L&n=21y5.0.1.1.3&r=PART#21:5.0.1.1.3.1.1.1>

Law Review Articles

- Ausness, R. (2008, January 1). “There’s Danger Here, Cherie!”: Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses. 73 Brooklyn Law Review 1253. http://uknowledge.uky.edu/cgi/viewcontent.cgi?article=1045&context=law_facpub

Other Sources

- American Cancer Society. (2013, April 3). Off-Label Drug Use. <http://www.cancer.org/treatment/treatmentsandsideeffects/treatmenttypes/chemotherapy/off-label-drug-use>
- Letter from Sandra Dennis, Deputy General Counsel, Health Care, Biotechnology Industry Organization, to the FDA re: Draft Guidance for Industry on Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices. (2012, March 27). http://www.bio.org/sites/default/files/BIO%20Comments%20to%20FDA%20on%20Unsolicited%20Requests%203.27.12_0.pdf
- Mello, M., Studdert, D., & Brennan, T. (2009, April 9). Shifting Terrain in the Regulation of Off-Label Promotion of Pharmaceuticals. 360 New England Journal of Medicine 1557, 1564. http://cdn1.sph.harvard.edu/wp-content/uploads/sites/487/2012/09/Off-label_PDF.pdf
- National Association of Insurance Commissioners. (2013, October). Off-Label Drug Use Model Act (ST-148-3–ST-148-6). <http://www.naic.org/store/free/MDL-148.pdf>
- Schneider, A. (n.d.). The Role of the False Claims Act in Combatting Medicare & Medicaid Fraud by Drug Manufacturers: An Update. http://www.taf.org/public/drupal/publications/reports/schneider07drugreport_0.pdf
- U.S. Probes Use of Antipsychotic Drugs on Children. FoxNews.com. (2013, August 12). <http://www.foxnews.com/health/2013/08/12/us-probes-use-antipsychotic-drugs-on-children/>

Cases

- In re: W. Scott Harkonen, Department of Health and Human Services. Departmental Appeals Board, Appellate Division. No. 2485 (Final Decision, Nov. 9, 2012). <https://www.hhs.gov/dab/decisions/dabdecisions/f-2133-dab2485.pdf>
- United States ex rel. Matthew Cestra, et al. v. Cephalon, Inc., et al., No. 10 Civ. 6457 (SHS), Statement of Interest of the United States of America (p. 2). (2013, Nov. 7). <http://www.jonesday.com/files/upload/Statement%20of%20Interest%20-11-7-13.pdf>
- Morrison v. B. Braun Medical Incorporated, No. 10-1548, slip op. (6th Cir. December 8, 2011). <http://www.ca6.uscourts.gov/opinions.pdf/11a0306p-06.pdf>

- United States v. Caputo, 517 F.3d 935 (7th Cir. 2007), cert. denied, 555 U.S. 819 (2008). <http://media.ca7.uscourts.gov/cgi-bin/rssExec.pl?Submit=Display&Path=Y2008/D02-27/C:06-3612:J:Easterbrook:aut:T:op:N:0:S:0>
- United States v. Caronia, No. 09-5006-cr., slip op. (2nd Cir. December 3, 2012). http://www.ca2.uscourts.gov/decisions/isysquery/56c688e9-dc1e-4c8f-b231-4df212cc49d7/2/doc/09-5006-complete_opn.pdf
- United States ex rel. David Franklin v. Parke-Davis, No. 96-11651-PBS, slip op. (D. Mass. August 22, 2003). <http://dida.library.ucsf.edu/pdf/pza00a10>
- United States v. Harkonen, Nos. 11-10209, 11-10242, slip op. (9th Cir. March 4, 2013), (not for publication), cert. denied 571 U.S. [not yet published], 134 S. Ct. 824 (2013). <http://cdn.ca9.uscourts.gov/datastore/memoranda/2013/03/04/11-10209.pdf> and http://www.supremecourt.gov/orders/courtorders/121613zor_p861.pdf

Settlements: U.S. Department of Justice

- Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox®. (2010, September 1). <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>
- Forest Pharmaceuticals Sentenced to Pay \$164 Million for Criminal Violations. (2011, March 2). <http://www.justice.gov/opa/pr/2011/March/11-civ-270.html>
- Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-Label Drug Marketing. (2010, April 27). <http://www.justice.gov/opa/pr/2010/April/10-civ-487.html>
- U.S. Pharmaceutical Company Merck Sharp & Dohme Sentenced in Connection With Unlawful Promotion of Vioxx. (2012, April 19). <http://www.justice.gov/opa/pr/2012/April/12-civ-497.html>
- U.S. Subsidiary of Belgian Pharmaceutical Manufacturer Pleads Guilty to Off-Label Promotion; Company to Pay More Than \$34 Million. (2011, June 9). <http://www.justice.gov/opa/pr/2011/June/11-civ-751.html>
- Wyeth Pharmaceuticals Agrees to Pay \$490.9 Million for Marketing the Prescription Drug Rapamune for Unapproved Uses. (2013, July 30). <http://www.justice.gov/opa/pr/2013/July/13-civ-860.html>

To see the electronic version of this resource handout and the other products included in the “Off-Label Pharmaceutical Marketing” Toolkit, visit the Medicaid Program Integrity Education page at <https://www.cms.gov/Medicare-Medicaid-Coordination/Fraud-Prevention/Medicaid-Integrity-Education/edmic-landing.html> on the CMS website.

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