



**ATTACHMENT 1: Reference Documents**  
(in alphabetical order)

**Only includes reference documents for footnotes  
not previously cited in McNeil's Petition, nor by Bayer**

1. American College of Gastroenterology. Letter to the FDA Docket 2005P-0048, May 4, 2005.
2. American Diabetes Association. Aspirin therapy in diabetes. *Diabetes Care*. 2004;27(1):S72-73.
3. Antman EM, Anbe DT, Armstrong PW, et al. *ACC/AHA Practice Guidelines*. ACC/AHA Guidelines for the Management of Patients With ST-Elevation Myocardial Infarction. A report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee to Revise the 1999 Guidelines for the Management of Patients with Acute Myocardial Infarction). Developed in Collaboration With the Canadian Cardiovascular Society. ACC Foundation and the AHA, Inc. 2004; e1-e212.
4. Berlin JA, Graham A, Colditz A. The role of meta-analysis in the regulatory process for foods, drugs and devices. *JAMA*. 1999;281:830-834.
5. Berlin JA. The use of meta-analysis in pharmacoepidemiology. In: Strom BL, ed. *Pharmacoepidemiology*. 3<sup>rd</sup> ed. West Sussex, England, UK: John Wiley & Sons, Ltd; 2000:633-659.
6. Cook DJ, Guyatt GH, Laupacis A, Sackett DL, Goldberg RJ. Clinical recommendations using levels of evidence for antithrombotic agents. *Chest*. 1995;108:227-230.
7. Eikelboom JW, Hirsh J, Weitz JI, et al. Aspirin-resistant thromboxane biosynthesis and risk of myocardial infarction, stroke, or cardiovascular death in patients at high risk for cardiovascular events. *Circulation*. 2002;105:1650-1655.
8. Guyatt GH. et al., Users's guides to the medical literature - IX. A method for grading health care recommendations. *JAMA*. 1995;274:1800-1804.
9. Michelson AD, Cattaneo M, Eikelboom JW, et al. Aspirin resistance: position paper of the *working group on aspirin resistance*, Platelet Physiology Subcommittee of the Scientific and Standardization Committee of the International Society of Thrombosis and Haemostasis. *J Thrombosis & Haemostasis*. 2005;3:1-3.
10. National Stroke Association. Letter to FDA Docket 2005P-0048, May 23, 2005.
11. PLAVIX (clopidogrel bisulfate) Prescribing Information, issued November 2004.
12. Serebruany VL, Steinhubl SR, Berger PB, et al. The risk of bleeding after different doses of aspirin: A post-hoc analysis of 192,036 patients enrolled in 31 randomized controlled trials. *Am J Card*. 2005; 95:1218-1222.
13. Temple RJ. Meta-analysis and epidemiologic studies in drug development and postmarketing surveillance. *JAMA*. 1999;281(9):841-844.
14. Temple RJ. The regulatory evolution of the integrated safety summary. *Drug Information Journal*. 1991;25:485-492.