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## FDA Announces In November 2007 That It Will Investigate Possible Link Between Maxipime And Increased Risk Of Death

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FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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### A Medical Journal Article Published In May 2007 Suggested This Emerging Drug Safety Issue; Why Was There A Six-Month Delay In Starting This FDA Investigation?

In mid-November 2007 the FDA sent an MedWatch Email Alert to inform the public about an emerging drug safety issue involving Maxipime (Cefepime), an injectable antibiotic that was approved by the FDA in 1996. In summary, the FDA announced the start of its investigation into a possible increased risk of death associated with Maxipime use, and said that their safety evaluation should take about four months to complete. Maxipime is manufactured by Bristol-Myers Squibb Co. (BMY). Maxipime is marketed in the U.S. by Elan Corp. PLC (ELN).

More detail is set forth in the FDA's "[Early Communication About an Ongoing Safety Review Cefepime \(marketed as Maxipime\)](#)", which the agency issued in November 2007:

An article in a recent issue of *The Lancet Infectious Diseases* has raised the question about increased mortality with the use of cefepime (Yahav D, Paul M, Fraser A et al. Efficacy and safety of cefepime: a systematic review and meta-analysis. *Lancet Infect Dis* 2007; 7: 338–48). FDA is currently reviewing some safety data and has requested additional data to further evaluate the risk of death in patients treated with cefepime. Cefepime is a broad spectrum cephalosporin antibiotic currently approved for the treatment of a variety of infections due to susceptible strains of microorganisms. It is a member of the class of antibiotics known as  $\beta$ -lactams.

The article in the May 2007 issue of *The Lancet Infectious Diseases* describes a higher all-cause mortality in patients treated with cefepime compared to other  $\beta$ -lactams. Overall, the all-cause mortality was higher with cefepime than other  $\beta$ -lactams (risk ratio [RR] 1.26 [95% CI 1.08–1.49]) and for the subgroup of patients with febrile neutropenia

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(RR 1.42 [95% CI 1.09–1.84]).

As an aside, this additional information raises the issue of why did it take six months for the FDA to start its safety review of Maxipime. Perhaps more will be learned about this delay in the months to come (especially if the timing of this Maxipime safety review comes to the attention of some of our more inquisitive members of Congress who have had their eyes on the FDA, recently).

A November 14, 2007 article by *Bloomberg* reporter Beth Jinks, "[Bristol-Myers, Elan's Maxipime Will Get U.S. Review](#)", presented some information from BMS spokesmen relevant to this new FDA safety investigation:

- "Bristol-Myers Squibb has conducted a detailed review of cefepime data from BMY-sponsored trials as well as data from post-marketing safety databases and a review of the literature," said Tony Plohoros, a company spokesman. "The review of the totality of data indicates that the safety profile of cefepime is unchanged from that previously described in regulator submissions."
- The drug is approved in the U.S. to treat lower respiratory, urinary, gynecological and skin infections as well as bacteria in the blood and febrile neutropenia, a fever and reduction in white blood cells usually resulting from chemotherapy, according to Bristol-Myers spokesman Jeffrey Macdonald.

As with all serious side effects involving prescription drugs, in their November 2007 announcement about this Maxipime safety review, the FDA urged both healthcare professionals and patients to report side effects from the use of Maxipime to the FDA's MedWatch Adverse Event Reporting program by one of the following means:

1. online at [www.fda.gov/medwatch/report.htm](http://www.fda.gov/medwatch/report.htm);
2. by returning the postage-paid FDA form 3500 available in PDF format at [www.fda.gov/medwatch/getforms.htm](http://www.fda.gov/medwatch/getforms.htm) to 5600 Fishers Lane, Rockville, MD 20852-9787;
3. faxing the form to 1-800-FDA-0178; or,
4. by phone at 1-800-332-1088.

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