



Bayer Emails on Yaz Seem to Flout the Law

By [Patrick A. Malone](#)

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Another chapter in the book of “Big Pharma Behaving Badly” is being written, courtesy of a story by [Bloomberg News](#). The news service obtained Bayer company emails reportedly showing executives discussing ways to illegally promote a long-controversial drug.

The suspect drug, Yaz, is a member of the family of birth control pills known as Yasmin, which several studies suggest carry elevated risks for blood clots, and, possibly, pulmonary embolism, deep vein thrombosis and other life-threatening injuries. As noted on [AboutLawsuits.com](#), an FDA advisory committee is supposed to review the data about the risks of Yaz and Yasmin next month.

The Bloomberg report charges that Bayer may have sought to market the birth-control pills for unapproved—or “off-label”—uses, misleading women about the health risks the drug posed. Specifically, Bayer is alleged to have discussed promoting the contraceptive Yaz to treat several types of premenstrual syndrome (PMS). The FDA has approved Yaz only for the most severe form of PMS.

Doctors are not prohibited from prescribing drugs for off-label uses, but manufacturers are not allowed to promote their drugs for any use other than what the FDA has approved. Earlier this month, we wrote about a [large legal settlement](#) paid by GlaxoSmithKline over its off-label marketing of a diabetes drug.

Patrick A. Malone
Patrick Malone & Associates, P.C.
1331 H Street N.W.
Suite 902
Washington, DC 20005

pmalone@patrickmalonelaw.com
www.patrickmalonelaw.com
202-742-1500
202-742-1515 (fax)

In the Bayer emails, a consultant allegedly suggested how the company's sales representatives could converse with doctors in a way that invites them to conclude that Yaz is suitable for off-label use: asking doctors, for example, what percentage of their patients had common PMS symptoms, then asking what effect they thought Yaz might have on those situations.

An even bolder, in-your-face repudiation of federal law reflected in another email supposedly came from an executive promising that a doctor under contract to a Bayer unit would promote off-label use of Yasmin on the "Today" show.

According to AboutLawsuits.com, the FDA has warned Bayer at least three times in recent years about problems with Yasmin or Yaz advertisements. Bayer has been busted for its misleading ads overstating the efficacy and benefits, and minimizing the risks of Yaz and Yasmin.

"In 2009, Bayer was forced to run a \$20 million corrective advertising campaign to address problems with Yaz advertisements that stressed the potential benefits in treating acne and symptoms of PMS, while minimizing the potential risk of blood clots and other side effects of Yaz," the website reports.

As additional punishment for its loathsome marketing behavior, Bayer must get any U.S. advertisements for Yaz approved in advance by the FDA.

The legal process of suing someone or some organization involves "discovery," in which both sides look for evidence from each other supporting their arguments. The Bayer emails were unearthed during the discovery process in numerous lawsuits involving Yaz and Yasmin filed against Bayer by women who took the medicine and suffered blood clots, strokes and gallbladder problems.

If a product is so great, why does its manufacturer have to bypass law and common decency to spread the word?

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