Seeing Both Sides

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By MIKE AUERBACH, Editor, *Pharmaceutical Processing*

The late, great Yankees player and coach Billy Martin was not known for holding his tongue. Through many seasons as the Yankees skipper, Martin had more than his fair share of arguments, ejections and fights with umpires and, of course, Yankees owner George Steinbrenner.

He had his opinions and always made them known. In fact, I remember him in a late ‘70s Miller Lite beer commercial. At the time, the company was really playing up its "Tastes great. Less filling” slogan. In the commercial, two of his friends are arguing whether the “tastes great” or “less filling” is more important, and turn to Martin for his opinion.

“I feel very strongly both ways,” Martin deadpans, completely contrary to his outspoken personality.

I now know how he felt.

Back in December, the 2nd Circuit U.S. Court of Appeals issued its long-awaited decision in the United States vs. Caronia case and ruled that a pharmaceutical sales representative's conversations with a physician about the off-label use of a drug is protected by the First Amendment.

I have no problem with the free speech aspect of the case. I believe an educated pharmaceutical sales rep should be able to talk to a physician about anything relating to the drug in question.

What concerns me, and here is where I can see both sides, is whether the needs of the patient outweigh safety. In other words, is it OK for a doctor to prescribe a drug for an off-label use because the doctor has seen it work for other conditions?

Doctors (hopefully) become doctors to help people, and at times, when indicated drugs don’t work, they must feel a great deal of angst prescribing an alternative that is not indicated for treatment. While the FDA does not specifically ban off-label use, these drugs have not been tested by the FDA for their off-label usage and their safety for that use cannot be ensured.

Safety or treatment? I feel very strongly both ways.

What's your take? Please feel free to comment below or email mike.auerbach@advantagemedia.com *[1].*

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