

Business Europe: A German Conspiracy Theory With No 'Legs'

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By Richard Miniter

Bayer AG's sagging fortunes -- a high-profile drug recall on three continents, a profit warning that sent its stock tumbling almost 25% off its peak, lawsuits in France and four U.S. states, a delay in its listing on the New York Stock Exchange -- recently took a very odd turn.

The venerable old man of the German press, the Frankfurter Allgemeine Zeitung, published a bizarre conspiracy theory involving Bayer, the German drug maker, and its American rival, Pfizer. Inc, last week.

No one doubts that Bayer is in trouble. Baycol, also known as Lipobay, raised concerns with U.S., European and Japanese drug regulators who began to suspect a connection between a rare muscle-wasting disorder and the Bayer anticholesterol product. Some research suggests that the drug may be linked to 52 deaths out of the more than 700,000 people estimated to be using the drug -- and that belief is also the basis for both American and European lawsuits recently filed against the drug maker.

All but ignoring these facts, the FAZ article was long on suspicious "coincidences" and short on actual evidence. (In all cases, I am working from English translations pulled from German newspaper Web sites.) Udo Ulfkotte, one of the FAZ's editors, wrote that a Pfizer drug will "probably fill in part of the market gap" left by the recall of Bayer's drug. "Another reason why Bayer's image loss comes in handy for Pfizer: In a few months, Bayer will launch a potency drug called Vardenafil" which, the author says, has "far fewer side effects than Pfizer's unique Viagra."

Next, the author cited U.S. Food and Drug Administration records that, the author suggests, show 983 deaths are attributed to Viagra -- which, if true, would be more deaths than the 52 tentatively linked to Bayer's recalled drug.

This is unusual for the buttoned-down daily, one of Germany's largest. It is as if the New York Times raised questions based on Pierre Salinger's conspiracy theory about the U.S. military downing a commercial airliner. Oh wait, that happened in 1997. And that is what the FAZ article amounts to -- a departure from otherwise sober news judgment. Other German publications and European outlets soon followed. Die Welt, another large, center-right German daily, which noted that "the timing and the intensity of the attacks against Bayer are suspicious" and wondered: "Has Bayer's U.S. competition supplied the FDA and the lawyers with information on the side effects of Baycol?"

These conspiracy theories are nuts. They indicate a lack of understanding of America's sometimes-perverse political economy and a failure to examine the deeper causes of Bayer's distress.

Like its EU counterpart, the U.S. FDA concentrates on the hard science of drug safety and is maddeningly risk averse. Former FDA commissioner David Kessler told me a decade ago that aspirin probably wouldn't be approved under the agency's stringent new-drug approval process.

Suspecting bias at the FDA, Die Welt suggested that Europeans are "not particularly popular" because of the denial of the GE-Honeywell merger. Well, maybe that's true on Capitol Hill. But the FDA is a 45-minute subway ride away and the bureaucrats have very little contact with Congress and even less with antitrust regulators. Besides, the EU itself is raising the same health concerns, as are the Japanese. Just how big is this conspiracy anyway?

As for the FDA records on Viagra, please. The FAZ author is referring to something called the "Adverse Event Reporting System," which is an all-inclusive list of virtually any bad thing that happened to a patient while on a drug. One pharmaceutical executive told me that, several years ago, his company reported a car accident to the FDA because a passenger was on its medication. "When in doubt, put it in" seems to be the motto of play-it-safe managers in this highly regulated business. As a result, most of those 983 deaths relate to pre-existing conditions, old age, accidents and other causes -- not Viagra. Indeed, none may have been caused by Viagra.

The FDA itself notes: "An accumulation of adverse events does not necessarily indicate that the adverse event was caused by the drug; rather the event may be due to an underlying disease or some other factors." Or, as they say in freshman philosophy: "Correlation doesn't equal causation."

Viagra has been prescribed for more than 15 million men world-wide and approved by more than 100 countries -- if it had lethal side effects, we'd have seen them by now. "There is not a single case of a single death connected to Viagra," Hugh O'Connor, President of Pfizer's European division, told me Friday, "when the drug is used as prescribed."

If Pfizer had worked with regulators to stifle a competitor, it would be breaking U.S. law. Nor is there much reason for its managers to risk a jail term. Pfizer is No. 1 in terms of global sales and No. 4 in Europe. By contrast, Bayer is not even in the top 10 in Europe, let alone around the world. Bottom line: These two companies probably don't spend a lot of time thinking about each other.

Finally, let's consider motives. Pfizer actually has a lot to lose by the Bayer drug recall. Why? Because the recalled Bayer drug is part of class of drugs called "statins," which lower cholesterol. Pfizer holds 50.3% of the U.S. market for statins, compared to Bayer's 4.6%, as calculated by IMS Health, a market-research firm. Any problem with any statin is likely to draw the interest of regulators to all statins. That's exactly what happened. The EU, U.S., Germany and others are taking a hard look at statins. There are good reasons to believe that the flaw in Bayer's drug doesn't apply to other statins -- but regulators like to be safe, not sorry. What business wants a regulatory cloud over their top products?

Finally, there is the idea that American drug makers might have whipped up the trial lawyers to sue Bayer. Hardly. The sad fact is that trial lawyers are sharks that infest American waters, looking for any ship in distress.

Let's quash the counterconspiracy before it starts. No, Bayer didn't plant these stories. "These articles have thrown together rumors and speculations on which the company has no comment," Guenter Forneck, the Bayer spokesman in Leverkusen, Germany told me Friday. Is there any financial relationship between Bayer and the FAZ's Mr. Ulfkotte?

"Definitely not," said Mr. Forneck.

Forget conspiracies. What Bayer needs is a sound business plan to recover from the loss of its blockbuster product. Focusing on that would make both the company and its shareholders a lot healthier.

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