

BUSINESS & FINANCE

■ STEVEN MILLOY

Merck's Costly Withdrawal

Now that a Food and Drug Administration advisory panel has rehabilitated Vioxx, Celebrex, and the other arthritis medications known as Cox-2 inhibitors, it's time to consider the wisdom of Merck's panicky withdrawal of Vioxx from the market last September.

Merck pulled the drug because new data from a clinical trial indicated that Vioxx users had twice as many heart attacks as placebo users (15 events per 1,000 Vioxx users versus 7.5 per 1,000 placebo users over an 18-month period).

"Although we believe it would have been possible to continue to market Vioxx with labeling that would incorporate these new data, given the availability of alternative therapies and the questions raised by the data, we concluded that a voluntary withdrawal is the responsible course to take," Merck CEO Raymond Gilmartin said.

"Responsible," may be the new watchword in corporate public relations, but which meaning of the word — "reliable" or "liable" — best characterizes Merck's actions?

When Merck announced it was forgoing Vioxx sales worth \$700 million to \$750 million per quarter, its

The company should have defended its products vigorously,

market capitalization fell 27% or about \$25 billion. Merck lost another \$15 billion by the time its stock bottomed out in mid-November.

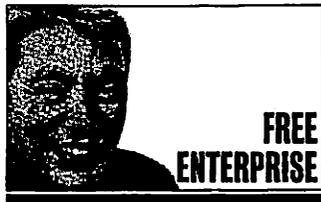
Merck's announcement launched a trial lawyer feeding frenzy. Many lawsuits have been filed and the company's liability has been estimated as high as \$30 billion — a sum that dwarfs the \$675 million Merck has reserved for Vioxx litigation.

One thing is for certain, based on today's trends in personal injury litigation involving medical devices and pharmaceuticals: Merck will be fortunate to survive the Vioxx mess.

In the litigation involving silicone breast implants and the diet drug combination known as "fen-phen," few, if any, deaths were alleged, yet the settlements were in the multi-billion dollar range. In contrast, recently published studies allege — though not necessarily credibly — that tens of thousands of deaths may be attributable to Vioxx.

Merck's potential liability could reach asbestos-like proportions.

What should Merck have done?



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remained on the market but been re-labeled so it wouldn't be prescribed, for example, to patients at high risk of cardiovascular events. It's important to remember that the vast majority of Vioxx patients — more than 99% according to the clinical trial launching the controversy — didn't suffer cardiac events. Merck should also have defended Vioxx's safety more vigorously. The clinical trial triggering the panic is contradicted by many earlier studies not reporting any increased risk of heart attack or stroke. Nor is the new trial particularly statistically impressive. The reported risk correlations are small and may, in fact, be byproducts of inappropriate study design. The clinical trial giving rise to the Vioxx controversy wasn't, after all, specifically designed to test whether the drug posed a heart attack risk. The data came from a study of Vioxx's potential gastrointestinal effects. Better-designed scientific study will be needed to flesh out whether Vioxx actually harmed anyone.

In contrast to Merck, Celebrex manufacturer Pfizer didn't panic when caught up in the frenzy and pull its drug from the market. Pfizer will nevertheless be targeted by trial lawyers — in part thanks to Merck's capitulation — but no lawyer will be able to point to Pfizer in front of a jury and say that "the manufacturer was uncertain of its product's safety." Moreover, Pfizer's fate doesn't now lie with a federal agency under a political microscope. Despite the FDA advisory committee ruling, Merck's withdrawal of Vioxx means the FDA will now have to decide whether Vioxx can be marketed again. The FDA may very well decide — and not necessarily for scientific reasons — against Merck. As in the case of silicone breast implants, an adverse FDA decision would certainly be exploited by trial lawyers and could help seal Merck's fate — that is, bankruptcy and, ultimately, a takeover. Merck's misguided notions of "responsibility" may prove a real liability to itself and others.

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NEW YORK PORTFOLIO

Fostering U.S.-German Relationship

Sostarich-Barsamian's Quest in Manhattan

By PRANAY GUPTA

Special to the Sun

Hélène Sostarich-Barsamian is the executive director of the Friends of Freie Universität Berlin, Inc. which was founded in January 2003 with the support of the Freie Universität Berlin in Germany. In her highly exuberant fashion, she reminded The New York Sun yesterday that the Free University was founded in 1948 to espouse ideas of political freedom and intellectual independence in Germany after World War II, largely with support from America, to preserve a politically unencumbered educational environment during the time of West Berlin's geographical and political isolation.

She spoke to a reporter in English, but the Romania-born Ms. Sostarich-Barsamian — who holds degrees in French and German languages and literatures from Rice University in Houston, Université Catholique de Louvain, Belgium, and New York University — could just have easily spoken in French, German, Romanian, Armenian, and Italian, languages in which she's fluent.

"For more than five decades, the Freie Universität Berlin has built upon its passionate history, continuing its dedication to the founding principles contained in its motto: 'Truth, Justice and Liberty,'" Ms. Sostarich-Barsamian said from her office on First Avenue near the United Nations.

This evening, FFUB will honor Klaus Schwab, founder and executive chairman of the Geneva-based World Economic Forum, with the 2005 Transatlantic Bridge Award at its annual gala the Pierre Hotel in Manhattan. John Costas, chairman and CEO of UBS Investment will serve as chairman of the event. More than 300 of the

city's elite will attend, thanks to Ms. Sostarich-Barsamian's extensive network of corporate, academic, and cultural contacts.

She began building that network as project manager for the real-estate investments arm of Prudential Financial, and thereafter as assistant dean for administrative affairs at the John C. Whitehead School of Diplomacy and International Relations at Seton Hall University. "I have always pursued an agenda of incorporating a grasp of cultural and social diversity for the benefit of the institutions that I've been associated with," Ms. Sostarich-Barsamian said.

She said that the Free University — which has nearly 40,000 students on its Berlin campus — has some 3,500 alumni in America. Ms. Sostarich-Barsamian wants to track down all of them in order to build "lasting intellectual and cultural alliances" between America and Germany. She expects that her organization will open offices in California and the Midwest, working in tandem with major U.S. companies.

Ms. Sostarich-Barsamian has long been active on the New York social and cultural scene with her support of the New York City Ballet, the New York Philharmonic, the New Jersey Shakespeare Festival, and the Smithsonian Institution in Washington, D.C. She sits on the board of trustees of the Morris Museum, where she recently bequeathed in the name of her father, Carol Sostarich, a collection of African tribal masks and figurines that she collected over a period of 30 years.

How does she manage to find time for all this activity? "Let's just say that I don't like to sit still," Ms. Sostarich-Barsamian said.



SOSTARICH-BARSAMIAN Intellectual capital exchanged across the Atlantic.

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