

Devil or Angel: Will the Real Merck Please Stand Up?

By ACSH Staff — November 4, 2004

It's been quite a rollercoaster six weeks for old-line pharmaceutical company Merck, based in New Jersey. As September ended, the company announced the voluntary withdrawal of its blockbuster anti-arthritis COX-2 inhibitor drug, Vioxx, due to cardiovascular toxicity. Subsequently, Merck has been embroiled in charges of a cover-up involving what they knew about Vioxx's side effects and when they knew it. The company faces legions of litigants led by tort-lawyer centurions, while TV and newspaper ads implore those "injured by Vioxx" to call for a free consultation. If internal memos are found to support charges of intentional malfeasance, it will merely add punitive damages to the billions that may soon be paid (mainly to attorneys).

But the bad news about Vioxx comes at the same time as a medical breakthrough -- an effective cancer vaccine -- and it's also a Merck product. It is to be hoped that the pending litigation about Vioxx doesn't threaten the development of this new product.

The vaccine is protective against infection with the Human Papillomavirus, or HPV, which causes almost all cases of cervical cancer. HPV is spread by sexual contact and is much more common among women who engage in unprotected sex with multiple partners.

In the U.S., about 13,000 new cases of cervical cancer are diagnosed and about 4,000 die each year, despite the fact that the disease is easily diagnosed using the simple Pap test, and treatment is almost always curative in its early stages. Worldwide, the cancer annually kills 250,000 women, making it one of the deadliest cancers in less-developed regions. About half of these cancers are caused by HPV-16, the sub-type that is effectively blocked by immunization with the new Merck vaccine.

The original study involved almost 2,400 women aged sixteen to twenty-three, half of whom received the active vaccine while a control group got inactive placebo, in three doses. The current report (presented at the American Society for Microbiology) is a forty-eight-month follow-up and confirms that the vaccine was 100% effective in preventing cancerous and pre-cancerous lesions of the cervix. One hundred eleven out of 750 women who received the dummy shot developed persistent HPV infection, twelve of whom developed pre-cancerous lesions. The 755 women who received the active vaccine had only seven HPV infections and zero cancerous or pre-cancerous lesions.

Merck plans to try to get FDA approval to market this cervical cancer vaccine in 2005 or 2006. The approach would be to immunize young women in their early teens, before they become sexually active and thus exposed to the virus. Merck is also testing a vaccine active against all four types of HPV known to be associated with cervical growths (including types 16 and 18). The vaccine would

also be protective against viral types that cause genital and anal warts. Boys might also be vaccinated, for two reasons: preventing boys from contracting HPV would help protect their female partners, and it would simultaneously protect boys from other HPV diseases: genital and anal warts.

U.K.-based GlaxoSmithKline, another large drug company, is working on a similar vaccine but is in an earlier stage of research.

This new vaccine, if the early promise proves true, will be among the greatest medical discoveries of modern times and may be a harbinger of more such anti-cancer approaches (the vaccine against hepatitis B has had significant effect against liver cancer since its introduction almost twenty years ago). This assumes, of course, that regulatory obstacles and threats of litigation don't delay or thwart entirely the promise of this anti-cancer vaccine, and that drug importation and its attendant price controls don't stifle such pharmaceutical innovation, as government intervention has in Europe and in the foreign and domestic vaccine industry.

Those of us devoted to the cause of public health should be rooting for Merck to get past the issues roiling around its Vioxx debacle and hoping that they keep their focus on finishing research and production of the HPV vaccine -- as well as other lifesaving drugs now in their developmental pipeline.

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