

## BILLIONS IN LEGAL COSTS AND SETTLEMENTS, PAINKILLER BRINGS GREAT PAIN TO MERCK



A unit of Merck & Co, the second largest Pharma Company in the US, pleaded guilty to a criminal transgression of violating US Federal law in connection with the marketing of its former painkiller Vioxx. The charge against Merck was that it had promoted Vioxx as a treatment for rheumatoid arthritis before the FDA had approved it for the purpose in 2002, exposing users to potential heart attacks and strokes. In 2004, Merck had voluntarily withdrawn the drug from the market after research showed that its consumption could lead to a higher risk of heart attacks and strokes. It is estimated that before Merck withdrew the drug more than 25 million Americans had used it. The painkiller was among the biggest revenue earning drugs for the company, generating \$2.5 billion each year in sales. US District court judge Patti Saris in Boston accepted the plea, as part of Merck's acceptance to pay a \$321.6 million criminal fine and \$628.3 million to resolve claims that it sold the drug for non-proven uses and had incorrectly advertised that it was safe to use. The judge said she accepting the guilty plea, "because I think it's in the public interest at this point." "I hope the size of this settlement and the fact that all these cases are being pressed by the federal and state governments -- the 44 states' attorneys general -- will be a signal that this isn't acceptable conduct," she added. In a statement Merck said, "The government recognized Merck's full cooperation with its investigation and by putting this long-standing investigation to rest, we can more fully focus on discovering, developing and providing innovative medicines and vaccines that save and improve lives around the world." A part of the \$950 million settlement also was to settle parallel civil allegations, that Merck's deceptive and false claims of the drug safety, caused government's health programs to pay for the drug use. Merck had denied the civil allegations. In 2007, Merck had agreed to pay \$4.85 billion to settle 27,000 lawsuits, claiming injury or death caused by use of Vioxx. Stuart F. Delery, a U.S. Justice Department lawyer, said in an e-mailed statement, "The United States will not tolerate unlawful conduct by pharmaceutical companies. Those who put profits before patient safety by promoting their products for unapproved uses will be prosecuted and held accountable." Merck said that there was no basis to assume that Merck's management was involved in the violations and no individuals were held responsible for the company's wrongful activities. Moreover, the settlement did not constitute an admission of any liability or wrongdoing. However, Merck said, they would accept federal monitoring as part of the agreement. The criminal case is U.S. v. Merck, Sharp & Dohme Corp., 11-CR-10384-PBS, U.S. District Court, District of Massachusetts (Boston).