

California and National News

Senate Approves More Policing of Drugs: The U.S. Senate has passed a bill to give the FDA new power to police drug safety, order changes in drug labels, regulate advertising, and restrict the use and distribution of medicines that prove to have serious risks. This bill basically is a new philosophy and operational policy that requires the FDA to focus on the entire life cycle of a drug, not only the initial approval of the drug. The federal government would establish a surveillance system to track the adverse effects of approved drugs. The FDA has lost significant credibility over the past few years, the Vioxx fiasco being the turning point. The bill also renews authority for the federal government to collect fees from drug companies to speed reviews of their products. At the same time, the pharmaceutical giants succeeded in blocking a proposal to legalize imports of lower-priced drugs from Canada. The Senate also side-stepped the question as to how to give consumers access to lower-cost copies of biotechnology drugs, although there is a general sentiment to create a procedure for approval of such copycat drugs (generic biologics). On the other hand, the Senate bill would increase collaboration between the FDA and the drug industry by increasing the FDA's reliance on user fees to finance drug reviews. *(Summarized from article by Robert Pear, New York Times, May 10, 2007.)*

Physicians Collect Huge Sums For Anti-Anemia Drugs: Amgen (Aranesp and Epogen) and Johnson and Johnson (Procrit), two of the world's largest drug companies, have been rewarding physicians (mainly nephrologists and oncologists) hundreds of millions of dollars each year for prescribing their anti-anemia drugs. Beyond the ethical implications, there also may be inappropriate and unsafe use of these drugs. The payments are considered legal! The FDA is investigating prescribing patterns as there is not any enhanced quality of life or extension of survival. Moreover, higher-than-needed doses (encouraged by the manufacturers) may lead to heart attacks and strokes. The two companies had combined sales of over \$10 billion for these drugs last year. They represent the single largest drug expense for Medicare. Federal law bars drug companies from paying physicians to prescribe medicines in pill form that are purchased by patients from pharmacies. However, these companies can rebate part of the price that physicians pay for these drugs, which they then dispense in their offices. These RBC production stimulators are parenterally administered, and rebates are given to physicians after they purchase the drugs. These physicians also receive reimbursement from Medicare and private insurers, often marked up from the purchase price. The rebates are related to the amount of drugs the physician buys. Since their introduction, the average dose of these drugs has nearly tripled, enough to raise hematocrits into levels considered risky from a cardiovascular point of view. *(Summarized from article by Alex Berenson and Andrew Pollack, New York Times, May 9, 2007.)*

Substance Abusing, Immoral Spanish Anesthesiologist Infects 275

with Hepatitis C: A 60-year-old Spanish anesthesiologist with hepatitis C was sentenced to 1,993 years in prison for infecting 275 people with hepatitis C by injecting them with morphine from the same needle and syringe that he used to inject morphine he diverted into himself. He first would give himself a portion of the morphine he had drawn for the patient, and then inject the remainder into the patient without changing needle or syringe! The Valencia physician was sentenced after a trial that began in 2005, although the most he can serve under Spanish law is only 20 years! Four of the patients that he infected between 1988-1997 have died, although many more may succumb from the usually smoldering damage to the liver. Then we only are left to guess as to how many more fortunate patients never became infected from the contaminated needles. The court ordered him to pay \$200,000 to each of the families of the four dead patients, but the grand total of fines for all of the victims was \$27 million, still a pittance by American standards. The court dismissed Juan Maeso's argument that he had acted because he was hopeless from his drug addiction, saying that Maeso could have used the drugs in such a way as to not pass on any infection.

New Finance Committee Report Focuses on Drug Company Grants for Medical Education:

U.S. Senate Finance Committee Chairman Max Baucus and Ranking Republican Chuck Grassley released results of a Committee inquiry into drug company grants to fund continuing education for medical providers. They launched their probe following allegations that drug companies were using education grants for improper purposes, such as rewarding physicians for prescribing their drugs, influencing clinical practice guidelines and Medicaid formularies, or *promoting* drugs for "off-label" use (an illegal practice). Guidance on keeping education programs independent of drug company influence has been issued by numerous organizations, including the ACCME whose oversight of accredited CME providers appears insufficient to guarantee the required independence. "American taxpayers spend billions of dollars every year on drug treatments for Medicare and Medicaid patients, and those scarce dollars need to be spent wisely. Medical education funded by drug companies have to be real education, not a soft sell designed to sway treatment decisions," said Baucus. "As long as drug companies' medical education efforts can influence Medicare and Medicaid spending, the Finance Committee has to insist that there be more improvement." Grassley said, "What drugs doctors prescribe for patients and what drugs federal health care dollars buy should be made based on accurate scientific information and what is best for that particular patient, not on improper influence from any drug maker."