

RE-EMPOWER THE FDA AND PERMIT CITIZEN LAWSUITS AGAINST DRUG COMPANIES WHICH FALSIFY DATA

WHEREAS pharmaceutical companies are responsible for presenting accurate information to the public and to the Food and Drug Administration (FDA) regarding possible harmful side effects of their products; and

WHEREAS Johnson and Johnson obscured evidence that its Ortho Evra birth control patch delivered substantially more estrogen than standard birth control pills, to a level exceeding that allowed in pills; and

WHEREAS increased levels of estrogen are known to be associated with higher risks of blood clots;

WHEREAS more than 3000 women and their families have sued Johnson and Johnson, asserting that users of the patch experienced heart attacks, strokes, lung clots, and in 40 cases, death; and

WHEREAS Johnson and Johnson is claiming in court that it cannot be sued by these plaintiffs on the basis of “pre-emption,” arguing the company is not liable because the FDA approved the patch; and

WHEREAS the FDA no longer has the funding or the manpower to adequately regulate drug companies; and

WHEREAS lawsuits have provided oversight of drug safety when the FDA has not, including suits over the now-withdrawn pain pill Vioxx, the diabetes medication Rezulin, and several antidepressants, among others;

THEREFORE BE IT RESOLVED that the federal government must reinstate the regulatory powers of the FDA by increasing their funding and expertise to levels needed to perform their duties; and

THEREFORE BE IT FURTHER RESOLVED that said duties should include the ability to critically analyze data and to penalize companies which fail to follow agency rules without fear of reprisal;

THEREFORE BE IT FURTHER RESOLVED that drug companies that hide or distort negative data relating to their products should be liable in a court of law, regardless of prior FDA approval. The doctrine of pre-emption does not permit misrepresentation of facts; and

THEREFORE BE IT FINALLY RESOLVED that we request that our Congressional Delegation do everything in their power to help enact legislation to support this resolution.

Adopted 11 June 2008 by the 34th District Democrats of King County, Washington