

Comparing Medicine Regulation The Vioxx Crisis and its Effects in the UK and the US

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Abstract:

The withdrawal by the pharmaceutical company Merck, on September 30th 2004, of their anti-inflammatory drug Vioxx placed drug safety and the role of pharmaceutical companies firmly on the political agenda. Vioxx became a landmark case in the new focus on poor risk communication, diminished trust and regulatory failings in the area of drug safety. Moreover, the case clearly shows the limitations of adopting a risk elimination approach in risk studies, due to the nature of drug safety in general, where any side effects must be considered in the light of the usefulness of the drug.

The paper examines how the regulatory systems in the UK and the US dealt with a crisis where drug safety came under public and political scrutiny and how the Vioxx case, furthermore, caused certain fundamental changes in risk regulation regimes in the pharmaceutical area. On a theoretical level, the paper examines how current approaches to regulation can further the understanding of a regulatory crisis, particularly evaluating the core assumption of regime theory and network theory in this light. When comparing the regulatory regimes in the US and the UK and the challenges they are facing, the general insight that regulation is failing is discussed in the light of the implications for the health authorities. This, furthermore, brings forward considerations on the relations between the authorities, the stakeholders and the political actors and the degree of co-operation and conflict existing between them. The changes in the risk regulation regimes are particularly considered in relation to a situation where risk is controversial and political in the light of a high level of public debate.