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this provision is preempting the existing legal and regulatory frameworks under which liability for drugs rests, which are still operating at their current status and reflecting a reliance on well established guidelines. a failure to adopt tasma (and possibly other alternative approaches) undermines the premise of the viox drug litigation. therefore, the adoption of tasma and a dramatic shift to a more precautionary approach would lead to a fundamental re-think of liability and fda regulation in relation to the entire spectrum of therapeutics, including drugs, medical devices, and biologics. the 2001 supreme court decision in *Pliva, Inc. v. Mensing* threw down the regulatory gauntlet on the question of directed liability at the fda. if the fda were to adopt tasma with a complete ban on non-precautionary drugs, or a ban on new drug approval of any drug that has no proven efficacy in reducing patient suffering or mortality, it would make the fda's mission to protect public health an afterthought to the legal responsibility of manufacturers, health-care providers, consumers, and patients. third, most surveillance systems for potential adverse drug effects rely heavily on the individual health-care providers or the pharmaceutical industry to identify drugs that are under surveillance. this is important as it helps reduce the effect of reporter bias, but the results of those studies are often susceptible to self-report bias, and may only look at drugs of interest that are marketed by the same manufacturers as those that are known to cause adverse events. alternatively, most surveillance systems create large, expensive databases with advanced analytic tools or large prospective pharmaco-epidemiological studies that suffer from large sample sizes and are subject to selection bias and lack of external validation. one example of this first issue is the recently released vigibase, which collects information on potential adrs from health-care providers, and now drug manufacturers, in the european union.

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