BIG DATA AND PHARMAVOIGILANCE: USING HEALTH INFORMATION EXCHANGES TO REVOLUTIONIZE DRUG SAFETY

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ABSTRACT

Data on individual patients collected through state and federal health information exchanges has the potential to usher in a new era of drug regulation. These exchanges, produced by recent health care reform legislation, will amass an unprecedented amount of clinical information on drug usage, demographic variables, and patient outcomes. This information could aid the Food and Drug Administration with post-market drug surveillance because it more accurately reflects clinical practice outcomes than the trials relied upon for drug approval. However, even with this data available, there is a weak market-driven impetus to use it to police drugs. This is fixable; the post-market drug regulatory process needs new incentives to boost third party participation. While this could be achieved with a variety of mechanisms, the best option for generating robust results may be an administrative bounty proceeding that will allow third parties to submit evidence to the Food and Drug Administration to contest the claimed safety and efficacy profiles of drugs already on the market. The case study of Merck’s former blockbuster drug Vioxx demonstrates how this system might work. In creating a new incentive that counters the powerful financial motivation of drug manufacturers to obscure or misrepresent safety profiles, this regime could lead to an improved balance of the risks and benefits of drugs used by the American public. More broadly, this article illustrates how the private sector can be incentivized to supplement regulatory activity in a complex field.

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