



Ethics of Pharmacovigilance: Balancing Patient Protection and Industry Interestscha

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ABOUT THE STUDY

A vital component of the healthcare sector is pharmacovigilance, the science of monitoring and assessing the safety and efficacy of medications. Pharmacovigilance's main goal is to safeguard patients against negative drug responses, ultimately enhancing public health. Pharmaceutical vigilance is not without ethical issues, though. Healthcare professionals, regulators, and lawmakers have been debating how to strike a balance between patient protection and business interests.

On the one hand, pharmacovigilance is essential for ensuring patient safety. By monitoring and assessing the risks and benefits of drugs, healthcare professionals can identify and manage adverse drug reactions promptly. This helps to reduce the morbidity and mortality associated with the use of drugs. For example, the discovery of the link between thalidomide and birth defects in the 1960s led to the establishment of pharmacovigilance systems, which have since prevented similar tragedies.

On the other hand, pharmacovigilance can also impact the interests of pharmaceutical companies. Drug development is a costly and time-consuming process that involves significant investment in research and development. Pharmaceutical companies have a legitimate interest in recouping their investment and generating profits from their products. As such, they may resist reporting adverse drug reactions or downplay the risks associated with their drugs to protect their bottom line.

The tension between patient protection and industry interests is a significant ethical challenge in pharmacovigilance. The pharmaceutical industry has a responsibility to put patient safety first, but they are also accountable to their shareholders. Regulators and policymakers must balance the interests of all stakeholders while ensuring that patient safety remains paramount.

One way to address this ethical dilemma is through transparency. Pharmaceutical companies should be transparent

about the risks and benefits of their drugs, including adverse drug reactions. This transparency can build trust with patients, healthcare professionals, and regulators, leading to a more collaborative and effective pharmacovigilance system. Additionally, regulators and policymakers should ensure that the incentives for pharmaceutical companies are aligned with patient safety. This can be achieved through appropriate regulations and policies that promote transparency and accountability in the pharmaceutical industry.

Another ethical issue in pharmacovigilance is the use of patient data. Patient data is essential for monitoring the safety and effectiveness of drugs. However, the use of patient data raises concerns about privacy and confidentiality. Patients must be informed about the use of their data and should have control over how their data is used. Additionally, healthcare professionals and researchers should follow ethical guidelines when collecting and using patient data to ensure that patients are not harmed or exploited.

The use of patient data for pharmacovigilance can also raise issues of justice. Certain populations, such as racial and ethnic minorities, may be underrepresented in clinical trials, which can lead to a lack of data on the safety and effectiveness of drugs in these populations. This can lead to health disparities, where certain populations may be at greater risk of adverse drug reactions or may not have access to drugs that are effective for their condition. Healthcare professionals and policymakers must ensure that pharmacovigilance systems are inclusive and equitable and that all patients have access to safe and effective drugs.

Finally, conflicts of interest can arise in pharmacovigilance. Healthcare professionals and researchers may have financial or professional ties to pharmaceutical companies, which can influence their reporting of adverse drug reactions or their interpretation of data. Additionally, regulators and policymakers may have conflicts of interest if they have ties to the pharmaceutical industry. Conflicts of interest can undermine the integrity of pharmacovigilance systems and erode public

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trust. Healthcare professionals, researchers, regulators, and policymakers must disclose their conflicts of interest and take steps to mitigate them to ensure that pharmacovigilance systems are transparent and trustworthy.

In conclusion, pharmacovigilance is essential for protecting patient safety and improving public health. However, balancing patient protection and industry interests poses significant ethical challenges. Transparency, privacy, justice, and conflicts of

interest are all ethical considerations that must be addressed in pharmacovigilance. Regulators, policymakers, healthcare professionals, and pharmaceutical companies must work together to ensure that pharmacovigilance systems are transparent, inclusive, and focused on patient safety. By doing so, we can ensure that the benefits of drugs outweigh the risks and that patients receive safe and effective treatments.