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New Regulations Proposed for Off-Label Uses of Drugs

Researchers from the David Geffen School of Medicine at University of California, Los Angeles (UCLA) have proposed a system that combines reporting, testing and enforcement regulations and allowing interim periods of off-label use for off-label drug prescriptions.

The off-label use of drugs and medical devices in unapproved ways has long been a part of medicine. Healthcare providers often make their own decisions about using drugs off-label since the FDA couldn't approve each off-label use as the burden of approval would be too high. While there may be benefits of using off-label drugs, there are also some risks that should be kept in mind since such use may not be supported by clinical evidence.

That is why the UCLA team of researchers have proposed their recommendations which have been published in the Duke Law Journal. These recommendations give patients more treatment options but at the same time provide regulators with evidence of the drugs' safety and efficacy.

According to Dr. Ryan Abbott, visiting assistant professor of medicine in UCLA's division of general internal medicine and health services research, "Even though a drug or device has been approved for one indication, physicians can prescribe them for other uses as well -- it's been part of medical practice for a long time. Our proposals are important because there is a tension between providing access to the drugs and devices that could benefit patients in untested ways and the need to prevent harmful uses."

The proposal comprises of three key elements:

- Improved reporting of off-label use through disclosure of diagnostic codes in reports to the FDA, when providing data related to physicians' prescribing habits as well as information regarding Medicare/Medicaid reimbursement requests.
- Expansion of post-market testing requirements for off-label use of drugs and medical devices.
- A tiered labelling system for drugs consisting of red box warnings that prohibit certain off-label uses.

The authors believe that the improved reporting, testing and enforcement regulations would produce a more layered range of regulatory responses and can provide the FDA with better information about the extent of off-label use and any adverse effects associated with such use.

Source: University of California, Los Angeles (UCLA), Health Sciences

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