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On Site: FDA and PatientsLikeMe Collaborate to Test Social Media Adverse Event Reporting

To gain a better understanding of patients who share their drug-use experiences, symptoms and hospitalizations through social media communities, the FDA has turned to PatientsLikeMe, a large patient-networking site. The agency's goal is to see how social media-reported adverse event (AE) experiences complement existing voluntary spontaneous reporting systems.

To date, industry and agency use of social media in clinical research and for pharmacovigilance has been extremely limited. The industry has been concerned about how to validate AEs as reported by patients and how to weigh different and often conflicting reports from multiple stakeholders. Insights from this collaboration will ultimately help the agency determine whether to use, and how to use, social media as a reliable AE reporting system.

Typically, healthcare professionals and patient groups file reports to biopharmaceutical companies, which are required to send these reports to the FDA. The agency also collects AE reports on the Sentinel system in partnership with health insurers and electronic medical records, and the MedWatch system, a voluntary reporting system largely used by health providers.

"The real-world data, such as those from PatientsLikeMe, when appropriately collected, measured, aggregated and analyzed, may be beneficial to supplementing surveillance data the FDA analyzes," said Gerald J. Dal Pan, MD, FDA director of the Office of Surveillance and Epidemiology. "The FDA is interested in the patient's voice."

The three-year program between the FDA and PatientsLikeMe will tap into PatientsLikeMe's 350,000 social media community members, providing more than 110,000 AE reports on 1,000 different medications. The PatientsLikeMe data dates back to 2008.

Under the new collaboration with the agency, a minor AE that may appear harmless to a regulatory official could reveal information on symptoms patients were experiencing in the days leading up to the event and the detrimental impact an AE may have on a patient's quality of life.

"Our data are different in that the information is generated by patients themselves who provide real-time insights about what it's like to use medical products over time, like tolerability of the drug and factors that may influence taking the drug as prescribed," said Sally Okun, PatientsLikeMe vice president of advocacy, policy and patient safety. "We will help the FDA understand our data, along with some of the analyses we typically use in data sets, and along with the analytics to help them."

Okun said the FDA is partnering with PatientsLikeMe to work directly with deidentified patient data so they have a collective voice as part of the FDA's safety surveillance system.

"In the real world, nausea, sexual dysfunction, and constipation could be much more important and influence people's ability to adhere to a prescribed drug regimen," Okun said. "Along with comorbidities, these side effects, which don't appear in the clinical trial data, provide real-world information and a deeper understanding of how some people might react to a particular drug."

Another AE example is weight gain from a particular drug that users often are reticent to discuss and may have underestimated during the clinical trial. Okun also cited how some

patients may experience drowsiness from a medication taken over a period of time, which was not apparent during clinical trials.

"We are undertaking this research collaboration to determine whether these types of data may be beneficial to supplementing our existing data safety surveillance data," Dal Pan said. "By design, this research collaboration agreement is intended to be exploratory. We have very little, if any, experience with data of this type, and we would like to see if these data are useful for post-marketing safety surveillance."

"This is the first time FDA's Center for Drug Evaluation and Research has explored the use of a real-time source of patient-generated data for pharmacovigilance," Dal Pan added.

— Ronald Rosenberg

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