FDA Leverages Patient-Reported Information to Monitor Drug Safety

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FDA has recently partnered with PatientsLikeMe, an online patient networking forum, to leverage patient-reported information to bolster its drug safety monitoring efforts. PatientsLikeMe, with its 350,000 members representing over 2,500 health conditions, has collected more than 110,000 adverse event reports on 1,000 different drugs. This partnership, which is in the form of a research collaboration agreement, will provide FDA with access to “real-world” data about patients’ drug and disease experiences (the information provided to FDA is anonymous; so it does not appear, at least at this time, that FDA would be able to follow up with patients who post on the forum). More broadly, this partnership is evidence of increasing interest, among both regulators and pharmaceutical manufacturers, in the value of social media as a tool to identify potential adverse drug reactions and safety issues.

Postmarketing surveillance focuses on tracking the safety of drugs once they’ve reached the market. Such surveillance plays a critical role in ensuring drug safety as premarket clinical trials, which are designed to capture safety issues on the front end, have certain inherent limitations. For example, because clinical trials are conducted under controlled and standardized conditions, they are unable to adequately capture data that reflects “real world” use. That’s where postmarketing surveillance comes in. But FDA’s current postmarketing surveillance system has clear shortcomings.

To monitor potential safety concerns surrounding approved drugs, FDA collects drug adverse event reports and compiles them into its FDA Adverse Event Reporting System (FAERS) database. Such reports are submitted to FDA by patients, healthcare professionals (doctors, nurses, pharmacists, etc.) and pharmaceutical manufacturers. However, only pharmaceutical manufacturers are required to submit such reports; reporting for all others is voluntary. Not surprisingly, the largely passive nature of this system results in significant underreporting. Head of global safety at Novartis, David Lewis, has noted, “Adverse drug reactions (ADRs) are grossly under reported by everyone, including healthcare professionals, but particularly so by patients (emphasis added).” Underreporting by patients is one limitation of FDA’s postmarketing surveillance system that a partnership with PatientsLikeMe may help to address. Yet, another major limitation of the FAERS data arises from uncertainty about whether the reported adverse event was actually caused by the drug (FDA does not require reports to prove a causal relationship and reports often lack sufficient detail for FDA to assess the adverse event). It’s unclear whether access to patient-reported information from forums like PatientsLikeMe will help address this limitation and provide FDA with the robust data it needs to make decisions about drug safety.

Mining data from social media sources, such as PatientsLikeMe, Twitter and Facebook, is undoubtedly picking up traction as a way to help address some of the current limitations in FDA’s postmarketing surveillance efforts. U.S. company, Epidemico, is breaking ground in this space. The company is working to develop algorithms to identify side effects from social media sources. Specifically, it utilizes its “Med-WatcherSocial platform” to find adverse drug reports in social media posts for 1,400 drugs.
Ultimately, obtaining information from social media sources may improve the chances of capturing adverse events that a patient may not complain about to their own physician (or to regulatory agencies). According to Lewis, “Physicians are great at diagnosing illnesses and noting objective signs, but patients are great at reporting subjective reactions and feelings.” And they often take to social media to do so.

Still, many open questions remain surrounding the use of information posted on social media for postmarket surveillance purposes. How can patient-generated information from social media sources be distilled and used? Can (and should) regulators and pharmaceutical companies reach out to patients posting on social media for follow up? What are the legal and ethical considerations? How will FDA and companies manage the sheer volume of data using the current systems without becoming overwhelmed? Should “social-media”-specific regulations be developed to account for differences from traditional passive reporting systems? And, finally, is there a point where collecting more information actually does more harm than good by obscuring true safety signals? Despite these open questions, interest in this area continues to grow, as regulators, pharmaceutical companies and industry partners work to harness the power of social media to improve drug safety monitoring.

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