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Drug Safety Business: Start-Up With AERS Filter Eyes Bisphosphonate Events

Brenda Sandburg b.sandburg@elsevier.com

A small start-up company has developed a technique to filter the data in FDA's Adverse Events Reporting System (AERS) database, which it says provides a more accurate analysis of adverse event reports.

AdverseEvents Inc. used its system, dubbed RxFilter, to analyze AERS data on adverse events reported with four bisphosphonates.

The company said it found twice as many medication-related adverse events as FDA identified. It also found differences in side effect risks between the drugs, with Merck & Co. Inc.'s Fosamax (alendronate) appearing to be linked to higher adverse event risks than Warner Chilcott's Actonel (risedronate) and Roche's Boniva (ibandronate).

AEI co-founder Brian Overstreet said he and his co-founding partner developed their searching tool to overcome the flaws in AERS, which he claims is corrupted and unstandardized.

AEI's business model is a commercial example of a trend that pharma companies have seen in recent years, mostly from academic and government circles: efforts to discuss the safety and performance of drug products using data beyond the control of sponsors.

Specifically, he said AERS is rife with misspellings – he stated that Sanofi's Ambien has 440 different spellings – and that brand name drugs are recorded as generics and non-U.S. brand names, and extra data are included in database fields.

The RxFilter consists of a 17-step process to cleanse the data so it is standardized, normalized and aggregated. AEI had it in beta testing for 18 months and officially launched it at the Health 2.0 conference in San Francisco in mid-September.

Bisphosphonates May Differ In Side Effects

The company used the system to do an analysis of adverse events related to bisphosphonates. It focused on that drug class when FDA called a meeting of two of its advisory panels to discuss the benefits and risks of long-term use of the drugs to prevent and treat osteoporosis.

The Reproductive Health Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee met jointly in September and concluded that the drug labels should be clearer in discussing long-term use but did not recommend limiting the duration of use ("Bisphosphonates Labels Should Discuss Duration Of Use, Advisory Panels Conclude," "The Pink Sheet" DAILY, Sept. 9, 2011).

In its analysis, AEI evaluated bisphosphonate-related adverse event reports in the AERS database that were reported to FDA from Jan. 1, 2004 to Dec. 31, 2010. It examined reports on Fosamax, Actonel, Reclast and Boniva, and included generic equivalents and foreign designations.

"What we found most compelling in these results are the apparent differences in side effect risks between the four distinct bisphosphonate drugs," AEI wrote in an unpublished paper on its analysis.

"Of the 21 separate adverse event categories we searched, Reclast (injectable) had the highest percentage risk in 13 categories while Fosamax had the highest risk in the remaining eight."

"Interestingly, Fosamax appeared to be consistently linked to higher adverse event risks than the other two oral bisphosphonates (Actonel and Boniva), neither of which showed the highest risk in any of the 21 adverse event categories we analyzed," the paper stated.

AEI calculated the percentage risk based on the number of prescriptions filled for a given drug using IMS data.

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Overstreet said AEI submitted its paper to FDA but has not heard back from the agency.

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FDA Seeks To Improve Its Safety Tracking

AEI's business model is a commercial example of a trend that pharma companies have seen in recent years, mostly from academic and government circles: efforts to discuss the safety and performance of drug products using data beyond the control of sponsors. If AEI becomes successful, it could spur other firms to try to sell services that shape a product's use.

Meanwhile, FDA itself has been developing a new system to replace AERS. The FDA Adverse Event Reporting System (FAERS) is expected to improve the timeliness, accuracy and usability of FDA's product safety surveillance data, although how exactly the structure will differ from the current system is unclear.

FDA's Sentinel Initiative is also intended to improve FDA's ability to track the safety of drugs and devices. Mandated under the Food and Drug Administration Amendments Act of 2007, the initiative will enable FDA to query automated health care data holders, such as electronic health record systems and insurance claims databases.

A subcommittee of FDA's Science Board recently told FDA that it needed to articulate a clear plan for Sentinel and how it will co-exist with other tools ("Sentinel Initiative Needs Better Defined Goals, Outside Review Concludes," "The Pink Sheet" DAILY, May 18, 2011).

2AEI hopes to get pharmaceutical and insurance companies to buy its analysis of AERS data. Overstreet said subscribers to its service would be able to access AEI's basic reporting and run queries on a specific drug with specific parameters, such as age of users or time period of use.

AEI is selling the service as providing data that could be used to create competitive intelligence, to assess a licensing situation or to pursue a particular market. As for the cost, Overstreet said how the data are used will determine how they price it.

The company also has an interactive site for patients to conduct research. They will have free access if they submit their side effects to the database.

Asked how pharma companies have responded to its system, Overstreet said they have been concerned that this is "throwing covers off of what is going on in the marketplace" with their drugs and those of their competitors. Nevertheless, he noted that some large firms are doing demos of the database.

Overstreet said he expects RxFilter to influence prescribing, drug development and which drugs insurance companies cover.

But it is uncertain if it will take off. The company is trying to get recognition and to that end has sought to work with academia. The firm also submitted its bisphosphonates paper to several medical journals for peer review.

AEI is a seven-person shop, with half its employees based in San Diego and half in Healdsburg, Calif. The company received angel funding in the spring from unspecified sources and plans a venture capital round this year. Overstreet was previously co-founder and CEO of Sagient Research, which produces and sells research and data to pharmaceutical companies and others.

AEI is continuing to demonstrate its RxFilter. The company will be releasing a paper this month that evaluates the adverse event reports for all the statins.

"There is a clear winner and loser," Overstreet said.