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Having achieved positive results from an initial market test, Pharmaceutical Research and Manufacturers of America (PhRMA; Washington, DC) is about to launch a full-scale nationwide trial of its paperless labeling initiative. The trade group will kick off the test of technology solutions sometime this summer.

The PhRMA program allows pharmacists to electronically receive current versions of all drug labeling each day. The initial proof-of-concept testing was recently completed at 10 pharmacies in Washington, DC. This field trial, however, is much larger in scope. Across the country, 265 pharmacies will take part in the test, which is expected to last between 12 and 16 weeks.

Alan Goldhammer, PhRMA's associate vice president of domestic regulatory affairs, is clear about what the organization wants to do with the project. "Our long-term goal is the full electronic dissemination of labeling information," he says. "This test is important for us because it will have many more drugs in the database. It will also allow us to do real-time updates."

Goldhammer explains that pharmacists will use either a Web-based solution that allows them to obtain labeling information on-line or a stand-alone database system with labeling information on its hard drive. Depending on the results, commercial rollout to all drug-dispensing sites in the country could happen in 2005, he says.

The system is the brainchild of PhRMA's Paperless Labeling Task Force, formed in 2000. It would provide PDF versions of the labeling that would be updated as soon as they were changed, with a pharmacist being alerted to all changes since he or she last logged on. In theory, such a system would appear to address some of the perceived problems of paper inserts. One concern is that information can be static, even though labeling information constantly changes.

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However, not everyone agrees that it would be for the best. Peter Mayberry, executive director of the Pharmaceutical Printed Literature Association (Falls Church, VA), suggests that electronic labeling could be an enhancement to the current system, rather than a complete alternative. "Printed literature is critical for proper dispensing," he says. "Also, calling this paperless labeling is a misnomer. We prefer to think of it as an electronic update system."

Though he calls the technology 'promising,' Mayberry also has some questions. "This could allow for instant reporting on the pertinent information pharmacists and physicians need. But these machines could break down, and FDA would have no oversight. Those are things that are important to think about," he says. In addition, he adds, a switchover to such a system might be too quick. "If this works, we could reasonably expect pharmaceutical companies to seek a change of FDA regulations regarding labeling," he says. "That would be a big mistake. The bottom line is that this test involves a much bigger audience. We'll wait to see how it really works."

Whatever your stance on the matter, it is important to wait and see, as Mayberry suggests. Drug makers don't throw their drugs onto the market without months or even years of exhaustive clinical trials. Similarly, there shouldn't be a rush to get this system installed.

Wisely, exhaustive testing looks as if it is PhRMA's tactic, and they're going about it in the right manner. That way, if and when it becomes federally mandated, you can rest assured that it's proven to work.

The National Association of Chain Drug Stores (NACDS), one of the organizations participating in the test, promises to release the final study results by the end of the year. Like many others in the industry who will be tracking the development of this technology, we look forward to the final results.

Ben Van Houten