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PSI Project to Enhance FDA's Drug Safety Surveillance

Using the Power of Technology to Improve Patient Safety

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The Patient Safety Institute announced today that it will be working with the U.S. Food and Drug Administration (FDA) to streamline and enhance FDA's post-marketing adverse event reporting system, known as MedWatch. MedWatch allows healthcare professional and consumers to report serious problems that they suspect are associated with the medical products they prescribe, dispense, or use. MedWatch also provides important and timely information about safety issues involving medical products to the medical community and the general public.

PSI's efforts to enhance the FDA MedWatch web-based reporting system will initially focus on:

- Making the MedWatch web site more user-friendly;
- Developing software to export all adverse event reports using the Health Level Seven Individual Case Safety Report (HL7 ICSR) standard XML messages from the web site to FDA; and
- Developing software that integrates FDA standard vocabulary and automated coding systems.

"The culmination of the PSI efforts will be the creation of a streamlined approach that facilitates a more efficient and easier-to-use post-marketing adverse event reporting process through the FDA MedWatch system," said Jack Lewin, CEO of the California Medical Association and Chairman of the PSI Board of Directors. "This project also lays the foundation for integrating MedWatch reporting into electronic medical record-keeping and making the process easier for both providers and patients to use."

The current mechanism for submitting post-marketing adverse event reports to MedWatch can be time-consuming for both reporters and FDA. Reports are filed using either paper forms or web pages, neither of which are user-friendly.

"We appreciate the opportunity to work with the FDA on drug safety surveillance carrying out our shared goal of protecting and enhancing patient and consumer safety," said Johnny Walker, CEO of the Patient Safety Institute. "We anticipate additional alliances with government agencies to transform how information flows through all segments of the healthcare system, with the common mission of improving the health and health care of every American."

About PSI
Patient Safety Institute is a national, nonprofit, patient-centric 501(c)(3) open membership organization that is dedicated to supporting communities across the nation in their development of clinical information sharing networks.

PSI is governed by leading consumer, physician and hospital advocates. It was formed to provide the healthcare community with a commonly owned, inclusive, multi-stakeholder network utility to improve patient safety, quality of care and lower costs.

PSI is not a vendor and does not promote a proprietary technology or product. PSI offers national connectivity of clinical information through a representative, collaborative organization, like VISA, that allows communities and organizations to achieve success together, that they could only dream of individually.

For more information on PSI, please visit www.ptsafety.org.