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## Preventing Medication Errors – A National Priority

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In his first prime-time press conference, President Obama provided the world with the groundwork for his administration's *Economic Recovery and Reinvestment Plan*. Rebutting claims that the plan was largely comprised of "wasteful government spending," Obama argued that the plan included, "direct investment in areas like health care...investments that will save jobs, create new jobs and new businesses and help our economy grow again..." Later in his speech, the president provided some insight into how his plan will improve health care, specifically with regards to information technologies, stating "We're still using paper -- we're still filing things in triplicate. Nurses can't read the prescriptions that doctors have written out. Why wouldn't we want to put that on an electronic medical record that will reduce error rates, reduce our long-term cost of health care, and create jobs right now?" In a speech with few specifics, Obama's mention of reducing medication errors as an opportunity to reinvest in America's future should put everyone involved in the development of pharmaceutical nomenclature on alert. Change is coming.

The idea of updating the nation's hospitals with computerized prescription and electronic medical record systems is not new. According to a 2007 article in *Science Daily* titled 'Computerized Doctor's Orders Reduce Medication Errors,' transcription errors and illegible handwriting account for about 61 percent of medication errors in hospitals - and only about 9 percent of hospitals have computerized prescription systems. A study from the University of Minnesota on the subject concluded that American hospitals already using computerized systems witnessed a 66 percent decline in prescription errors. What *is* new is the recent alignment of political conviction and public capital, a combination that has the potential to significantly change how the pharmaceutical and health care industries operate and how prescription drug names are reviewed and subsequently approved or rejected. As prescription technologies evolve, the methodology used to test pharmaceutical nomenclature for potential medication errors related to look-alike and sound-alike proprietary names, unclear label abbreviations, acronyms, dose designations, and error-prone label and packaging designs must also evolve. Before this opportunity for *national reinvestment* gained political momentum and was brought into the public spotlight, the Food and Drug Administration was well

aware of the overdue changes needed within this industry. It had already started taking steps to assess how America might reduce prescription errors due to pharmaceutical nomenclature, packaging and labeling.

President Bush signed the Food and Drug Administration Amendments Act of 2007 into law in September of 2007. The bill included the reauthorization and expansion of the Prescription Drug User Fee Act, which according to the FDA's website "will significantly broaden and upgrade the agency's drug safety program...and facilitate more efficient development of safe and effective new medications for the American public." The expansion of PDUFA also includes a pilot program aimed at finding the best way of assessing pharmaceutical nomenclature, packaging and labeling safety. Under the program, participating pharmaceutical firms are empowered to utilize their own *best practices*. Using FDA-proposed methodologies as guidelines, companies will evaluate the safety of proposed proprietary names and submit the resulting data to the agency for review. There are several goals for the program according to the project's concept paper: "minimize the use of names that are misleading or that are likely to lead to medication errors, to make FDA's application review more efficient, and make regulatory decisions more transparent." After the pilot, the results will be evaluated to determine whether industry-conducted reviews and submissions are superior to having the agency conduct "de novo" reviews of proprietary names.

So what does this all mean? The institution of computerized prescription technologies throughout America's hospitals means that proposed pharmaceutical nomenclature must be assessed for safety within the context of this new computerized environment. While computerized prescription systems promise to significantly reduce errors by simply eliminating many of the variables associated with interpreting handwritten prescriptions, the methodology and mechanics of assessing the safety of proposed pharmaceutical nomenclature within this electronic environment is still in its infancy stage. Pharmaceutical manufacturers should partner with agencies that have implemented prescription simulation studies, computerized orthographic & phonological analysis and computerized physician order entry (CPOE) systems to ensure nomenclature safety within the context of this new prescribing environment. Proposed nomenclature should still be tested from a handwritten and call-in perspective, because the *old* way of prescribing medicines will still exist, albeit to a lesser extent. As such, pharmaceutical

manufacturers should still insist that their names are rigorously tested in the context of the standard (handwritten & call-in) prescribing environment. Some of these safety evaluation *best practices* include orthographic & phonological testing, failure modes & effect analysis (FMEA) and the utilization of historical medication error data.

If the PDUFA pilot program is adopted as law, much of the name, packaging and labeling safety review responsibilities will be transferred from the government to the pharmaceutical industry. This could happen as early as 2012. This transfer of responsibilities will likely bring an increased level of scrutiny from the FDA regarding the industry's adherence to the methodologies put forth in the guidance document. The ability to test drug names using the FDA's proposed guidelines is a task for which few pharmaceutical companies or their branding partners are prepared. The complexity of the prescribing scenarios proposed within the guidance document and the ability to accurately test name candidates via computerized physician order entry systems requires a dynamic shift in how industry currently assesses the safety of pharmaceutical nomenclature. Accordingly, companies and their brands will be best positioned for name approval if they solicit the assistance of a naming partner that has the means and methodologies to accurately and efficiently test names using standards that are in line with the government's guidelines. The methodologies proposed in the reauthorization and expansion of the Prescription Drug User Fee Act were conceived to provide more consistency and clarity regarding what the FDA expects from the pharmaceutical industry when testing the safety of proposed drug names. These processes have the potential to reduce medication errors, improve patient safety and even save lives. It is likely that many of the newly proposed methodologies will become standard operating procedure at the FDA (and potentially other global regulatory agencies), even if the pilot program is not adopted as law.

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