FDA Wants Companies to Simplify Drug Packaging, Naming, and Labeling To Reduce Medication Errors

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Medication errors continue to be a hot topic in Washington, because their reduction has been linked to lower health care costs, not to mention improved patient safety. Ensuring that patients receive the correct drug in the correct dosage has now become doubly important for hospitals because the Patient Protection and Affordable Care Act—the health care reform bill—makes some incipient efforts to restructure hospital payments from Medicare and Medicaid based on “episodes” of care. This means hospitals, in effect, will be penalized if a patient’s stay is unnecessarily prolonged by a mistake that the hospital inadvertently made. For example, a patient might be given the wrong medication, such as an injection of the anti-histamine hydroxyzine pamoate (Vistaril, Pfizer) instead of the vasodilator hydralazine (Apresoline, Novartis).

Drugs with similar names are a major cause of medication errors. The problem generally became a cause célèbre of sorts in late 1999, when an Institute of Medicine (IOM) committee released a pathbreaking report called To Err Is Human: Building a Safer Health System. The report cited two major studies stating that from almost 44,000 patients to perhaps as many as 98,000 die in hospitals each year as a result of preventable medical errors. It has taken a decade for that seed to germinate real policy solutions in Washington—but a seedling is clearly visible, and a couple of branches have sprouted very recently.

One of the leaders of the committee that wrote the 1999 IOM report was Donald Berwick, MD, MPP, whom President Obama has nominated to be administrator of the Centers for Medicare and Medicaid Services (CMS). Dr. Berwick is a well-known patient safety advocate and was plucked by Mr. Obama from the Institute for Healthcare Improvement (IHI), which he started in 1989 after a career at the Harvard Community Health Plan. The Senate initially balked at confirming Dr. Berwick because of some statements he made praising Great Britain’s health system. These statements were interpreted to suggest that he had some sympathy for rationing health care. To get around the Senate impediment temporarily, the President gave Dr. Berwick a recess appointment at the CMS this past summer. It is highly likely the Senate will eventually confirm him this fall.

Dr. Berwick’s influence will be most strongly felt at Medicare and Medicaid, but given his expertise on medication errors, he will probably be called on by Health and Human Services (DHHS) Secretary Kathleen Sebelius to help out on issues beyond CMS. One obvious target would be the FDA’s development of guidance on simplifying naming, labeling, and packaging of drugs. The concern over confusing drug names and hard-to-read packaging has gone back to the 1999 IOM report Dr. Berwick helped to write. However, the change to the FDA to actually do something about that problem came from Congress in 2007 in the form of a provision in the FDA Amendments Act of 2007. That law instructed the FDA to implement various measures to reduce medication errors. As that bill was being finalized, the FDA agreed that by the end of fiscal year 2010—on September 30, 2010—after public consultation with academia, industry, and others from the general public, it would publish a draft guidance describing practices for naming, labeling, and packaging drugs and biologics to reduce errors.

That deadline is now upon the agency. As has been its wont, the FDA has been a bit slow getting things off the ground. The agency held a two-day workshop in late June to get thoughts from drug companies, hospital administrators, pharmacists, and others on what the upcoming draft guidance should look like. Guidance, of course, has no legal standing. Pharmaceutical companies can ignore it, although they often take it to heart. So it was worth noting that Carol Holquist, RPh, Director of the FDA’s Division of Medication Error Prevention and Analysis, emphasized that after any draft guidance was made final, the FDA would move on to a “more stringent requirement, which is regulation.”

On the one hand, the prospect of new medication labeling and packaging guidance is great news for hospitals and their pharmacists, who are often in the unenviable position of trying to decipher a confusing drug label, whether because of its colors, the name of the drug, the lack of clarity in dosing information on the label, or one of many other problems. Joanne Kowiatek, RPh, MPM, FASHP, Pharmacy Manager at the University of Pittsburgh Medical Center Presbyterian Shadyside, explains: “One pet peeve of mine is epinephrine, which is a very dangerous drug that still continues to have ratios on the vials that really don’t mean a lot to providers.”

Yet the FDA to date has no guidance, much less regulations, on the naming of drugs. Typically, when a drug company applies for approval of a new product, the FDA uses techniques such as human factors development and failure modes and effects analysis to determine whether the name is acceptable. There is FDA guidance on labeling, as to size of type, and what needs to be included, and where, on the label.

One would think that providing drug manufacturers with some simple guidelines on naming drugs and label etiquette is the kind of “low-hanging fruit” that ought to be harvested from the seedling planted 10 years ago by Dr. Berwick, among others.