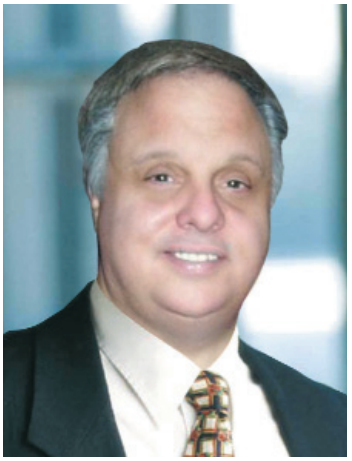
ADVERTISING or Patient Safety?

Contributed by Frederick J. Balboni Jr., Executive Director, Consortium for the Advancement of Patient Safety (CAPS)

What if all label instructions and warnings **suddenly disappeared?**



Limiting the type of information that can be printed or otherwise displayed on drug packaging could ultimately compromise patient safety and supply-chain security, and thwart efforts to combat drug counterfeiting.

ISSUE OVERVIEW

In May 2010, the pharmaceutical manufacturing industry may be faced with a daunting change. The United States Pharmacopoeia (USP) — an official public standards-setting authority for all medications and other healthcare products manufactured or sold in the United States — has revised General Chapter 1 Injections, Labeling on Ferrules and Cap Overseals, to limit printing and other types of messaging on drug packaging.

The changes included in this revision would limit printing to only cautionary statements on the top surface of the ferrule or cap overseal of an injectable drug product. The USP defines a cautionary statement as "one intended to prevent an imminent life-threatening situation if the injectable drug is used inappropriately."

The revision to USP 1 would require pharmaceutical manufacturers to abandon the use of technologies used to improve patient safety and help combat the growing threat of drug counterfeiting. Limiting the type of information that can be printed or otherwise displayed on drug packaging could ultimately compromise patient safety and supply-chain security, and thwart efforts to combat drug counterfeiting.

CAPS' POSITION

The Consortium for the Advancement of Patient Safety (CAPS) was formed in response to USP 1. Members of CAPS feel strongly that pharmaceutical manufacturers should have access to all available technologies and processes to reduce the risk of medication errors and protect against drug counterfeiting. Pharma manufacturers use the ferrule and cap overseal as a platform for anticounterfeiting technology and to display information on dosage, cold-chain management, and point-of-use administration instructions as a means of preserving patient safety. USP 1 is germane to pharmaceutical manufacturers based outside of the United States because they must meet the standard for products imported into the United States. CAPS members believe that the USP should permit printing and embossing of instructional information intended to prevent medication errors and allow printing and embossing that help combat drug counterfeiting.

INDUSTRY BACKGROUND

Patient safety is of the utmost importance in the healthcare and pharmaceutical industries. Companies go to considerable lengths to help ensure that the products they develop and manufacture are effective and safe for patients and healthcare providers alike.

Drug packaging plays a critical role in this process. The elastomeric stoppers used for drug vials are manufactured from clean formulations and incorporate films and coatings to protect the packaged drug against leachables. Drug vials are manufactured from inert materials that help protect drug purity against similar effects as well as particles.

The stopper and vial are secured by a secondary seal that consists of an aluminum shell (ferrule) and plastic button (cap). Crimping the seal to the vial keeps contaminants from getting into the vial, helping to maintain drug purity.

The seal plays another vital role in patient safety.

Instructions printed on the plastic buttons and aluminum shells provide those who give injectable drugs valuable information at the point of administration to enhance patient safety. This information often serves as a final check for healthcare providers to help ensure that the correct drug in the correct strength is being administered. Further, it is common industry practice to print or emboss unique product identifiers on caps and shells that can help identify products as genuine at the point of use. These measures are increasingly important as more and more counterfeit drugs make their way into the supply chain. These technologically sophisticated markings can be torturous for counterfeiters to copy.

Medication errors still occur despite the efforts to prevent them, and the results can often be disastrous and, in some cases, even fatal. In 2007, six infants were mistakenly given adult doses of the drug Heparin in an Indianapolis hospital; three of the babies sub-

WARNING LIMITS

PHARMACEUTICAL COMPANIES CURRENTLY PRINT AND EMBOSS A VARIETY OF MESSAGES ON PLASTIC BUTTONS AND SEALS THAT WOULD BE PROHIBITED BY THE REVISED USP 1. SEVERAL EXAMPLES INCLUDE:

- Dosing information such as "Multi-dose" provides a final check at the point of administration.
- Drug administration instructions such as "Dilute with 100 mL" help assure that the patient receives the correct dose.
- Pharmaceutical companies sometimes have their corporate or drug product logo molded into the plastic button. Such applications are difficult for drug counterfeiters to replicate and help identify the drug as genuine.
- Storage instructions such as "Store Frozen" and "Refrigerate" can help prevent mishandling of drugs in pharmacies and can support cold-chain management.

sequently died as a result of the overdose. In a separate incident, the media has widely reported the adult doses of Heparin administered to the infant twins of the actor Dennis Quaid and his wife Kimberly.

Heparin is commonly used in hospitals and there is little difference between the packaging used for the 10-unit pediatric dose and the 10,000-unit adult dose. The vials are identical in size and shape. The only difference is the shade of the blue plastic button, which may not be sufficient to clearly differentiate the two if they are not seen together. A safety solution for Heparin could encompass printing dosage strength on the plastic button and aluminum shell, a solution that would be proscribed by revised USP 1.

The aluminum shell also provides a platform for important messages. Printing on the shell can be concealed until the plastic button is removed, providing covert protection against drug counterfeiting. Some pharmaceutical companies use a clear plastic button so the message printed on the seal is visible before the button is removed. Such applications provide valuable point-of-administration information and can be an effective anticounterfeiting measure because the plastic button cannot be reattached after it is removed.

The revised USP 1 would allow cautionary statements to be printed on the plastic cap and seal. A cautionary statement might be: "Warning: Paralyzing Agent" and "Must Be Diluted." Such warnings are currently printed on plastic buttons and seals for a number of drugs.

The Consortium for the Advancement of Patient Safety (CAPS) was formed by global pharmaceutical and biopharmaceutical manufacturers. The mission of the educational consortium is to address the growing issue of medication errors and the need for anticounterfeiting measures and to promote awareness of the benefits of printing on drug packaging, specifically secondary closures, to improve patient safety. For more information, visit caps-edu.org or e-mail joint.chairs@caps-edu.com.

Editor's note: Since this article was written, CAPS and the USP have engaged in a collaborative dialogue for the purpose of ensuring that patient safety concerns are addressed as related to printing on ferrules and cap overseals on injectable drug products. Based on this discussion, CAPS is optimistic that the USP will evaluate its position on General Chapter 1. The USP has stated that it intends to come to a final resolution quickly so industry has clear direction for planning product development initiatives. Further, the FDA has accepted an invitation to meet with CAPS to discuss this important issue. ✦

CALL TO ACTION

The USP welcomes comments on potential, proposed, or official standards. Please communicate your views to the USP on how the revised USP 1 could be detrimental to the safe and intended use of injectable drug products.

Send your comments to: Roger L. Williams, M.D., Executive VP, CEO, Chair, Council of Experts, United States Pharmacopeia, 12601 Twinbrook Parkway, Rockville, Md., 20852–1790.

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.