

Institute for Safe Medication Practices
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**ISMP Urges Greater Examination and
Improvement of Drug Recall Policing Process**

California Experience Highlights Need for Continued Collaboration

Horsham, Pa.— The California Board of Pharmacy (CBOP) and California Department of Public Health (CDPH) recently took decisive action to ensure that the state’s hospitals had responded to life threatening drug recalls; fines and citations for “unprofessional conduct” were levied against some individual pharmacists and hospitals that were inspected and still found to have the recalled products. The Institute for Safe Medication Practices (ISMP) supports compelling the removal of recalled drugs and other threats to patient safety, but has identified some concerns with the punitive nature of the process.

The cover article of the October 9, 2008 issue of ISMP’s Medication Safety Alert! newsletter is devoted to analysis and recommendations arising from California’s experience in enforcing drug recalls.

Fines and Citations

The fines and citations were in some cases levied on hospitals where staff had gone to great lengths to remove the recalled products only to find supplies in unlikely places or from uncontrollable sources. Several cases of accidental non-removal of a recalled drug were recently reported to ISMP, including an incident where heparin vials in hospital-prepared treatment kits had been overlooked, and another where pharmacy staff thought they had removed all recalled heparin from the facility, but had not realized that their syringe manufacturer’s name had changed and was no longer the same as the company on the recall list. In both of these cases, as well as others, the hospital and pharmacists in charge were cited.

ISMP hopes that the conditions under which hospitals and pharmacies are found noncompliant will be evaluated to best support patient safety as well as fairness to healthcare professionals and hospital leaders who have otherwise demonstrated a sustained commitment to patient safety, even if that requires changes in regulation.

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Public Reprimands

Public reprimands of “unprofessional conduct” for individual pharmacists may have been unnecessarily harsh for those cases that were due to human error in overlooking products not within typical distribution avenues instead of intentional disregard of product recalls. In addition, about a quarter of California hospitals were found during the initial inspections to have recalled heparin products in their facilities, which suggests that the problem is larger than any individual pharmacist’s performance, and most likely a large-scale systems issue.

ISMP urges the CDPH, BOP, and US hospitals to learn from California’s experience and address aspects of the current processes for removing recalled products that need improvement. ISMP also encourages the BOP and CDPH to include key healthcare workers in its efforts to create a more robust framework for recalls that does not punish human error but sets standards to make it more difficult to err. Convening biannual safety forums with California hospitals to help identify priority safety issues and suggest reasonable and reliable solutions could also help provide guidance on focused safety initiatives that CDPH, BOP, and California hospitals can work on collaboratively.

For a copy of the full *ISMP Medication Safety Alert!* cover article on this issue, which includes additional recommendations and analysis, visit <http://www.ismp.org/newsletters/acutecare/articles/20081009.asp>.

For more information or interviews, contact Renee Brehio at 704-831-8822 or rbrehio@ismp.org.

About ISMP: The Institute for Safe Medication Practices (ISMP) is a 501c(3) nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. For more information on ISMP, or its medication safety alert newsletters and other tools for healthcare professionals and consumers, visit www.ismp.org.

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