August 23, 2012

Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20903

Dear Commissioner Hamburg:

I am writing to discuss a serious patient safety issue that can be significantly lessened by more timely and direct disclosure by the FDA of crucial, emerging information about medication errors and risks to the Institute for Safe Medication Practices (ISMP) and other Patient Safety Organizations (PSOs).

Mix-ups between methylergonovine injection and hepatitis B vaccine provide an example regarding the need for more timely and direct communication. In a letter dated July 2012 but received by hospitals this month, Novartis told healthcare professionals about newborn infants who had accidentally received methylergonovine instead of the intended vaccine. The letter mentioned that the mix-ups had been reported to both the company and the FDA. However, ISMP was unaware of the problem until a health professional forwarded the letter to us; the letter was not sent directly to ISMP or any other PSOs to our knowledge. A brief FDA listserv notice in June did not provide enough information about the problem for ISMP to give healthcare professionals specific recommendations for effective prevention strategies. Had ISMP been notified of the problem, we could have issued a national alert right away, thus notifying the healthcare community to the risk long before the manufacturer sent a letter to healthcare professionals.

ISMP is listed by the Agency for Healthcare Research and Quality as a PSO. Providing notification to ISMP and other PSOs of error reports and ongoing safety issues that merit an alert to the healthcare community would allow additional information to move through distribution channels in a more timely fashion. Unfortunately, patients are unnecessarily exposed to a risk of medication errors during the time it takes for the FDA and the company to react publicly. In this case it has been case several months since the company and the FDA became aware of the problem. A National Alert Network (NAN) operated by ISMP with the American Society of Health-System Pharmacists and the National Coordinating Council on Medication Error Reporting and Prevention can be used for this purpose. Previously issued alerts have reached millions of health professionals just days after notification of a serious event (hwww.ismp.org/Newsletters/acutecare/hazardalerts.asp). In addition, ISMP and PSOs would be able to give healthcare professionals additional clinical perspective and advice on error prevention beyond what the FDA and manufacturers could offer.

Novartis actually stopped marketing its methylergonovine product earlier this year, and there is currently a severe shortage, which contributed to at least one of the errors recently reported to ISMP. We have also confirmed with two hospitals that contacted us after receiving the letter that the actual product involved in their events was manufactured by American Regent (AR), not Novartis, the original manufacturer. This was not disclosed in any communication by FDA or the company. Such information is important, as healthcare professionals in both hospitals reported that look-alike containers of AR methylergonovine and GlaxoSmithKline Engerix-B (hepatitis B vaccine) played a prominent role in the mix-ups. None of the public communications

surrounding the drug to date have mentioned the shortage and implications for stopping future mix-ups in perinatal settings where both drugs are likely to be present.

The intent of the Patient Safety Act and Quality Improvement Act of 2005 was to get information out through PSOs in order to prevent harm to patients. ISMP hopes that the FDA will develop a process for more direct involvement of the PSOs in alerting all segments of the healthcare community to safety risks and problems identified through FDA monitoring.

Sincerely,

Michael R. Cohen
President

MRC/ls

cc:

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