Congress of the United States
Washington, DC 20515

October 16, 2006

Andrew C. von Eschenbach, M.D.
Acting Commissioner
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Dear Acting Commissioner von Eschenbach:

We are writing to urge you to strengthen FDA's regulations regarding the packaging and labeling of prescription drugs. A tragic accident recently occurred at Methodist Hospital in Indianapolis, Indiana. A pharmacy technician mistakenly stored adult doses of heparin in the neonatal unit's drug cabinet. The heparin was labeled correctly, but infant and adult doses of this drug come in the same size vial and have labels of similar color. Unfortunately, six infants received adult doses of heparin, and three subsequently died.

Preventable medical errors occur too often in our nation's hospitals. We are very concerned that the Institute of Medicine's July 2006 report concluded there are "at least 1.5 million preventable adverse drug events that occur in the U.S. each year." This is unacceptable.

The heartbreaking accidents that have occurred in Methodist Hospital and in hospitals all over the country certainly warrant our attention. In light of these tragedies, we would be remiss if we did not take action.

In 2004, you passed a rule requiring the use of bar coding technology on prescription drugs. Please comment on the status of the implementation of that rule. Has full compliance been achieved? In order for the technology to be fully effective, do you believe that hospitals will need to implement bar coding technology on machines that dispense medicine and on patient bracelets, as well?

In your July 20th press release, you stated that you are partnering with the Institute on Safe Medication Practices (ISMP) to refine your review of drug names and labeling. Over two months have passed since you issued this statement, and you have not yet met with ISMP. We urge you to work with ISMP to determine labeling recommendations and move quickly to publish guidance on this topic. We also request that you report to Congress on your timetable for developing this guidance.

Moreover, we highly recommend that you issue guidance to the pharmaceutical industry regarding failure mode and effects analysis for labeling and packaging of new drugs. As you know, many companies currently engage in failure mode and effects analysis when

naming prescription drugs. A similar process for the packaging and labeling of prescription drugs could be very useful in reducing medical errors, as well.

Too many medical errors have occurred under our watch, and it is time for FDA to take decisive action in response to these tragic events.

Thank you for your consideration. We look forward to your prompt reply.

Sincerely,

JULIA CARSON
Member of Congress

DAN BURTON
Member of Congress

RICHARD G. LUGAR
U.S. Senate

EVAN BAYH
U.S. Senate

PETER J. VISCLOSKY
Member of Congress

DONALD M. PAYNE
Member of Congress

CAROLYN MCCARTHY
Member of Congress

SHEILA JACKSON LEE
Member of Congress

SILVESTRE REYES
Member of Congress