

MICHAEL F. BENNET
COLORADO

COMMITTEES:
AGRICULTURE, NUTRITION, AND FORESTRY

BANKING, HOUSING, AND
URBAN AFFAIRS

HEALTH, EDUCATION, LABOR,
AND PENSIONS

SPECIAL COMMITTEE ON AGING

United States Senate

WASHINGTON, DC 20510-0609

September 6, 2011

WASHINGTON, DC:
458 RUSSELL SENATE OFFICE BUILDING
WASHINGTON, DC 20510
(202) 224-5852

COLORADO:
2300 15TH STREET
SUITE 450
DENVER, CO 80202
(303) 455-7600

<http://www.bennet.senate.gov>

Dr. Margaret Hamburg
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Dr. Hamburg:

I am writing to express my concerns about the critical drug shortages our nation is currently facing. Specifically, many life-saving antibiotics and cancer treatments are in short supply nationwide, forcing doctors to choose between prescribing prohibitively expensive drugs or drugs from nontraditional sources that may supply less effective and potentially unsafe products. As an example, in Colorado Springs, drug shortages have forced doctors at Penrose-St. Francis Hospital to delay therapy for some leukemia patients, and to substitute less effective antibiotic medications for those that are in short supply. And this does not seem to be an exclusive case.

I am particularly concerned about its effect on the safety of the drug supply chain. As you know, I am committed to working with the Food and Drug Administration (FDA) and my colleagues here in Congress to ensure your Agency has adequate authority and resources to safeguard our globalized drug supply chain from the start of the drug manufacturing process to the pathways an approved drug can take to reach patients.

Recently, Premier healthcare alliance found that when there is a massive drug shortage, providers are faced with price gouging attempts by "gray market" vendors of offered markups of drugs on average 6.5 times - and as much as 45 times - their normal market price. The gray market includes the selling of drugs through unofficial or unauthorized supply channels where providers cannot always verify the source of a drug. The Premier report included data on 1,745 unsolicited gray market offers with the highest mark-ups seen for critical care sedation and surgery; emergency care; chemotherapy; and fighting infectious disease.

In light of these findings, I encourage you to consider the benefits of a uniform pedigree standard as a component of a comprehensive solution to our country's drug shortage problems. A uniform pedigree standard would allow the FDA to efficiently monitor individual drugs as they move through the supply and distribution chain, thereby ensuring that all drugs are manufactured, stored and distributed safely, and that they enter distribution channels legally. Also, a uniform standard would better serve patients and providers by making it easier for supply chain partners to have a shared understanding when working across state lines rather than struggling to follow the current patchwork of state regulations. Potential drug shortages would be easier to identify and avoid with a uniform pedigree standard because the FDA would be able to verify the amount of each drug currently available or in the manufacturing process. And providers purchasing

products in short supply would be in a much better position to verify the safety and authenticity of a product.

We have a collective responsibility to ensure that the United States' drug supply is both safe and readily available to patients. I recognize that the supply chain involves a range of important stakeholders and that any proposed change will require careful analysis. However, I strongly encourage FDA to consider the many values of a uniform federal pedigree that accomplishes the goals of being able to find a drug product wherever it is in the supply chain at that moment, and to know where it has already been.

Thank you again and I look forward to your response. If you have any questions regarding the foregoing, please do not hesitate to contact me or my staff, Rohini Kosoglu, at 202-224-5852.

Sincerely,



United States Senator
Michael F. Bennet