

U.S. SENATOR MICHAEL BENNET

*Member: Agriculture, HELP, Banking and Aging Committees*

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CONTACT: [Michael Amodeo](#) – 303-249-5286

[Alex Obregon](#) – 303-455-1359

## Bennet Renews Call for System to Avoid Critical Drug Shortages, Increase Prescription Drug Safety

### *Uniform Pedigree Standard Would Monitor Drugs Through Supply and Distribution Chain*

Washington, DC – In light of ongoing critical drug shortages in Colorado and around the country, Colorado U.S. Senator Michael Bennet today urged the Food and Drug Administration (FDA) to consider a uniform system as a component of a comprehensive solution to drug safety and drug shortage problems.

In a letter to FDA Commissioner Margaret Hamburg, Bennet pushed for a uniform pedigree standard that 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.

“We have a collective responsibility to ensure that the United States’ drug supply is both safe and readily available to patients,” Bennet wrote in the letter. “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.”

Bennet also explained the benefits of a uniform pedigree standard to help ensure we never experience the kinds of critical drug shortages we are currently experiencing.

“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,” Bennet wrote in the letter. “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.”

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. Drug shortages can also lead to price gouging and prescription drug offers

from the “gray market,” where doctors and hospitals cannot be sure of the safety, origin and handling of drugs through the supply chain.

*Full text of the letter is included below.*

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.

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