

March 22, 2021

Dr. Janet Woodcock
Acting FDA Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20903

Re: Request for Meeting – White Bagging and DSCSA

Dear Commissioner Woodcock,

The undersigned healthcare organizations are writing to express concern that the payer-mandated drug distribution model, known as “white bagging” is jeopardizing patient safety and exacerbating supply chain security challenges that the Drug Supply Chain Security Act (DSCSA) sought to address.

Payers are using white bagging to circumvent hospital supply chain controls by requiring patient medications be distributed through a narrow network of specialty pharmacies that are often directly affiliated with the payer, thereby disregarding DSCSA’s requirements for wholesale distribution of drugs. Hospitals and providers are then forced to further manipulate and dispense these medications before they can be safely administered to patients.

White bagging has surged in frequency over the past decade, creating what amounts to a shadow inventory that hospitals and health systems do not legally own and which exists largely outside of the DSCSA’s track and trace requirements. A Drug Channels report found that in 2019, nearly a third of infusion drugs (both oncologic and non-oncologic) provided in hospital outpatient departments were distributed via white bagging.¹ Given the growing ubiquity of payer-mandated white bagging, we are concerned that this practice threatens DSCSA’s underlying goals. Further, because hospitals do not have legal title to white bagged medications and the drugs are delivered outside of hospital-established supply chains, white bagging can raise additional patient safety risks by enabling diversion and heightening the possibility of drug spoilage/wastage. In addition, as white bagged drugs bypass established supply chain channels it also disrupts and significantly complicates the ability to respond to FDA drug recalls.

We strongly encourage FDA to consider the patient safety and supply chain security risks of white bagging, and take appropriate enforcement action to protect patients. We would welcome the opportunity to meet with your team to discuss our hospital and health system compliance concerns in greater detail. We are deeply appreciative of the work FDA staff has put into implementing DSCSA to date, and we recognize the challenge white bagging presents to the overall goals of DSCSA. We hope to work collaboratively with the Agency to protect against the creation of payer-mandated distribution models that could undermine patient safety. Please contact Tom Kraus at tkraus@ashp.org if you have any questions or if we can provide any additional assistance.

¹ <https://www.drugchannels.net/2020/09/specialty-pharmacy-keeps-disrupting-buy.html>

Sincerely,

ASHP (American Society of Health-System Pharmacists)

Allina Health

Ascension

Atrium Health

Baptist Health - Jacksonville

Baptist Health - South Florida

Bay Care Health System

Baystate Health

Bon Secours Mercy Health

Bryan Health

Cincinnati Children's Hospital Medical Center

Citizens Memorial Hospital

City of Hope National Medical Center

Cleveland Clinic

Common Spirit Health

Dana-Farber Cancer Institute

Dartmouth-Hitchcock Health

Deaconess Health System

Ephraim McDowell Regional Medical Center

Eskenazi Health

Essentia Health

Freeman Health System

Froedtert & the Medical College of Wisconsin

Glens Falls Hospital

Harris Health System

Indiana University Health

Inova Health System

Lee Health

Lifespan

Mass General Brigham

Memorial Healthcare System

Memorial Care-Long Beach Medical Center

Mercy Health

Methodist Health System

Moffitt Cancer Center

Murray-Calloway County Hospital

Nebraska Medicine/the Nebraska Medical Center

North Oaks Health System

Novant Health New Hanover Regional Medical Center

OSF Healthcare

Premier Healthcare Alliance

Providence

Renown Health

Saint Luke's Health System
Sanford Health
Sutter Health
The University of Illinois Hospital and Clinics
Truman Medical Centers / University Health
Tufts Medical Center
UC Health
UNC Health
Union Hospital
Unity Point Health
University Hospitals Health System
University of California San Francisco Health
University of Chicago
University of Illinois at Chicago, College of Pharmacy
University of Missouri Health Care
University of Tennessee Medical Center
Virginia Mason Franciscan health
Vizient, Inc.
Yale New Haven Health

CC:

Dr. Patrizia Cavazzoni
Andi Lipstein Fristedt