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Brownstein Hyatt Farber Schreck Spearheads Effort to Pass Safe Doses Act

Today, October 5, 2012, the President of the United States signed into law H.R. 4223, the "SAFE DOSES Act," which will modernize the U.S. criminal code to increase criminal penalties for medical product cargo theft and provide law enforcement tools in order to deter this criminal behavior and take down the offenders. Current federal criminal laws do not distinguish between stealing a load of insulin and stealing a truck full of radios – even though the potential harm is vastly greater when medical products are involved. Through this new law, higher possible sentences will not only make people think twice before acting, but also will provide law enforcement agencies with the tools they need to obtain cooperation in bringing down criminal organizations. The SAFE DOSES Act will apply well-proven law enforcement tools to go after the multi-dimensional enterprises carrying out these crimes and prevent the health risks created by the improper care and handling of sensitive medical products.

Brownstein Hyatt Farber Schreck's Washington, DC office represented the Coalition for Patient Safety and Medicine Integrity, a diverse group of pharmaceutical, medical device and medical products companies committed to protecting patients from the risks posed by stolen and inappropriately handled medical products re-entering the legitimate supply chain. The Coalition was created with the single mission of passing important legislation to protect the public during a challenging time in Congress. Members include: Abbott Laboratories, Eli Lilly, GlaxoSmithKline, Johnson & Johnson, Novartis, Novo Nordisk, Sanofi, the Pharmaceutical Research and Manufacturers of America, and the Healthcare Distribution Management Association.

Today in the U.S., large-scale medical product theft is a significant problem. Sophisticated criminal organizations are stealing large quantities of medical products, not properly handling them, and re-introducing them into the legitimate supply chain, including into pharmacies and hospitals. When this occurs, patient safety is at risk because improperly cared for medical products – which can be ineffective or harmful – are being used by unsuspecting patients and health care professionals. All types of pharmaceuticals, medical devices and specialty nutrition products including infant formula are being stolen. High-value pharmaceuticals, including treatments for serious diseases, are frequent targets. Unfortunately, these high-value items are sensitive products that need careful handling and temperature control as many medical products can become ineffective if stored at the wrong temperature, even for a brief time. Medical cargo theft has drawn the attention and scrutiny of the Food and Drug Administration. Pharmaceutical, medical device and medical products companies have adopted sophisticated security systems and practices. Although these efforts are making it more difficult for the criminals to get what they want, only the genuine threat of significant criminal penalties can provide effective deterrence.

As a result of the Coalition's strategic vision and disciplined execution, the SAFE DOSES Act enjoyed broad bipartisan support. The House of Representatives passed H.R. 4223, sponsored by Rep. James F. Sensenbrenner, Rep. Pedro R. Pierluisi and Rep. Linda T. Sanchez, on June 26, 2012, following the House Judiciary Committee's unanimous approval on June 6, 2012. In the Senate, S. 1002, which is sponsored by Sen. Charles E. Schumer and Sen. Jon Kyl and cosponsored by 32 other senators, was unanimously approved by the Senate on September 22 after unanimous approval by the Senate Judiciary Committee on March 8th.

The Coalition's efforts were supported by:

- Food and Drug Administration (FDA)
- Pharmaceutical Security Institute
- National Insurance Crime Bureau (NICB)
- Biotechnology Industry Organization (BIO)
- National Community Pharmacists Association (NCPA)
- Alliance for Patient Access
- Global Healthy Living Foundation
- Men's Health Network
- National Council for Community Behavioral Healthcare
- Prostate Health Education Network (PHEN)

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Brownstein has a proven track record helping clients navigate successfully the maze of politics and policy in Washington DC, and at the state and local level. We possess the creativity, know-how and tenacity required to overcome virtually any public policy challenge. Our results speak for themselves. Our team is bipartisan, and has served at the highest levels of government. It includes: veteran political strategists, campaign operatives and communicators, a former Cabinet Secretary; former senior Congressional staff and committee counsels, former senior executive branch officials, and a bevy of experienced lobbyists with dozens of successes to their name. We are supported by some of the most respected legal minds in the profession. This expertise allows us to communicate effectively the needs of our clients to decision makers in Congress, the White House, federal agencies and regulatory bodies. But communicating alone is not enough. We relish developing and executing winning strategies on behalf of our clients.

This document is intended to provide you with general information about the passage of the SAFE DOSES Act. The contents of this document are not intended to provide specific legal advice. If you have any questions about the contents of this document or if you need legal advice as to an issue, please contact the attorney listed below or your regular Brownstein Hyatt Farber Schreck, LLP attorney. This communication may be considered advertising in some jurisdictions.

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