The Partnership for **SAFEMEDICINES**[®]

May 23, 2024

The Honorable Darrell Issa 2108 Rayburn House Office Building Washington, D.C. 20515 The Honorable Jerrold Nadler 2132 Rayburn House Office Building Washington, D.C. 20515

RE: Letter of Support for the SHOP SAFE Act

Dear Chairman Issa and Ranking Member Nadler:

Thank you for your continued leadership in protecting American consumers from dangerous and substandard counterfeit products flooding the U.S. supply chain. On behalf of the members of the Partnership for Safe Medicines (PSM), we appreciate the opportunity to provide comments for the record for the House Judiciary Subcommittee on Courts, Intellectual Property and the Internet's hearing, "Intellectual Property: Enforcement Activities by the Executive Branch," from March 7, 2024

PSM is proud to support the SHOP SAFE Act (S.2934) and urge you to reintroduce a House companion to combat the influx of counterfeit medicines sold through online marketplaces, which jeopardize the health and safety of American patients.

PSM is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. Comprised of more than 45 non-profit organizations, PSM studies counterfeit drug crime, threats to American patients, and educates the public, policymakers, and health care professionals about threats to the safety of the U.S. drug supply.

The most counterfeited medicines often are protected by trademark law. Online marketplaces need to comply with the elements of the SHOP SAFE Act so brand protection teams can track and trace counterfeiters who sell fake, illicit and dangerous counterfeit medicines to the public and the legitimate supply chain. A recent example is the discovery by Gilead Sciences Inc. of a broad, national criminal ring that sold counterfeit versions of their trademarked HIV medicines. To date, over US \$240mm of counterfeit medicines have been found and some of the counterfeit medicines reached patients who had medical adverse events. The perpetrators are being prosecuted for trademark infringements under the Lanham Act.

Unfortunately, this counterfeit HIV medicines case is just one of too many examples of criminals taking advantage of American consumers in order to make a buck. Business to consumer (B2C) marketplaces, like Amazon Marketplace and etsy.com, host listings for third party vendors that sell counterfeit versions of trademarked medical products. In 2010 counterfeit versions of the weight loss product Alli appeared in many places online including online marketplaces such as eBay. In 2023, we have seen an explosion of counterfeit Ozempic for sale online, with consumers able to easily find compounded semaglutide for sale on etsy.com. The FDA is also investigating reports of hospitalizations after patients were exposed to suspected counterfeit semaglutide.

Much of the enforcement of counterfeit medicines is done today through pharmaceutical manufacturer brand protection teams. These teams do not have the power of law enforcement, and sometimes cannot

The Partnership for SAFEMEDICINES®

even see the listings of B2C online marketplaces. The SHOP SAFE Act would provide them with the access and authority necessary to monitor for counterfeit listings and give them additional rights to enforce their trademarks, which would help protect patients and reduce the plethora of counterfeit medicines available on these online marketplaces.

We commend the subcommittee for acknowledging that platforms must do more to prohibit the sales of counterfeit products, bringing reprieve for U.S. enforcement agencies and helping to keep dangerous medicines from harming patients. We especially thank Ranking Member Nadler for his continued commitment with Chairman Issa to reintroduce the SHOP SAFE Act to further reduce the number of dangerous counterfeits online before reaching consumers. The SHOP SAFE Act will go a long way to protecting the health of the American public from counterfeit medical products, and we support its reintroduction in the House and ultimate passage through Congress.

Please do not hesitate to contact us for more information on recent counterfeit medicines within the U.S. supply chain. We look forward to working with the Committee to protect consumers from dangerous counterfeit medicines.

Sincerely,

S. Salder

Shabbir Imber Safdar, Executive Director Partnership for Safe Medicines