House FY26 FDA Appropriations Report Language

503A Pharmacy and 503B Outsourcing Facility Inspections.—The Committee is concerned about FDA inspection delays for pharmacies and outsourcing facilities, citing staffing and resource shortages as contributing factors. The Committee requests a report with in 180 days of enactment of this Act detailing inspections and ad dressing resolution timelines for observation and warning letters.

Access to Compounded Hormones.—As the FDA reviews recommendations from the National Academies of Sciences, Engineering, and Medicine (NASEM) report on the Clinical Utility of Compounded Hormones, the Committee urges FDA to engage with compounders and other stakeholders to help ensure access to compounded drugs for patients who need them.

Animal Drug Compounding.—As the agency continues to implement Guidance for Industry #256, Compounding Animal Drugs from Bulk Drug Substances, the Committee encourages the FDA to continue collaborating with stakeholder organizations, including State boards of pharmacy, pharmacy organizations, and accreditation bodies, to develop inspectional guidelines that are shared with the inspected pharmacies and allow for consistent application. Furthermore, the Committee encourages FDA to consult with practicing veterinarians and to adequately consider their concerns when evaluating nominations and making decisions for the List of Bulk Drug Substances for Compounding Office Stock Drugs for Use in Nonfood-Producing Animals.

Compounding.—The Committee is concerned about recent drug shortages and considers patient access to critical medications a patient safety issue. The Committee recognizes the important role 503A state-licensed compounding pharmacies and 503B outsourcing facilities have played during shortages of drugs needed to treat COVID patients and subsequent shortages of children's suspension drugs. The Committee urges the FDA to continue to utilize the regulatory flexibility provided by Congress to quickly respond to drug shortages in the short term by allowing pharmacies and outsourcing facilities to safely compound those drugs and protect patient access until manufacturers are able to stabilize the supply chain and meet patient needs. Counterfeit Medicines.—The Committee is concerned about the production of counterfeit and untested GLP–1 and GIP/GLP–1 medications, posing a serious risk to public health and patient safe ty. The Committee encourages the FDA to exercise its existing authority to combat the illegal distribution of counterfeit and inappropriately labeled or manufactured GIP/GLP–1 medications to ensure patients' safety. The Committee directs the FDA to provide to the Committee a briefing, no later than 60 days after enactment of this act followed by a report within 120 days, outlining

the FDA's plan to stop the entrance of counterfeit GIP/GLP–1 medications in the supply chain to avoid harm to patient safety.

Illegal Imports of Unapproved New Drugs.—The Committee expresses deep concern over the health risks posed by illegal importation of unapproved and misbranded drugs, particularly through third-party brokers facilitating access via employer-sponsored health plans. These unapproved drugs lack FDA oversight, potentially containing incorrect dosages, unknown ingredients, or contaminants, which can lead to serious health consequences, especially for vulnerable populations with conditions like HIV, cancer, or hepatitis. The substitution of FDA-approved medications with unapproved versions can cause patient confusion, medication errors, and negatively impact treatment outcomes, as healthcare providers may unknowingly base decisions on patients' responses to these unregulated drugs. Furthermore, sourcing from uninspected and unregulated supply chains increases the risk of receiving adulterated or improperly stored medications. Given these significant dangers, the Committee directs the FDA to provide a comprehensive report within 180 days of enactment of this Act addressing this issue, including safety risks, verification challenges, enforcement actions, and recommendations for strengthening oversight. This action is critical to protect U.S. consumers from the potential harm of unapproved and misbranded drugs circumventing regulatory safeguards.

Pharmacy Compounding Advisory Committee (PCAC).—The Committee recognizes that the PCAC established under the Drug Quality and Security Act provides recommendations to FDA on scientific, technical, and medical issues concerning drug compounding under sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act. It is therefore vital that voting members of PCAC have a thorough understanding of compounding to appropriately advise FDA. The Committee encourages FDA to appoint qualified voting members with actual and diverse experience in the preparation, prescribing, and use of compounded medications.

Senate FY26 FDA Appropriations Report Language:

Animal Drug Compounding.—The Committee urges the FDA to provide public clarification on the role of Animal Drug Compounding in outsourcing facilities registered under section 503B of the Federal Food, Drug, and Cosmetic Act. While both CVM and CDER have stated in guidance documents that 503B pro visions do not apply to animal drugs, many 503B facilities continue to advertise an ability to compound any needed animal preparation in their 503B facility. The FDA should publicly clarify the use of these outsourcing facilities to produce compounded preparations for animals.

Counterfeit Drugs.—The Committee is concerned by the increased presence of counterfeit drugs in the U.S. pharmaceutical distribution supply chain. The Committee directs the FDA to provide a report that outlines the challenges that the FDA faces with preventing counterfeit drugs from entering the U.S. pharmaceutical distribution supply chain and reaching patients. The report should include recommendations for funding or authorities needed to address this problem to protect public health and should be provided to the Committee within 120 days of the enactment of this act.

Drug Shortages.—The Committee is concerned by ongoing drug shortages in the United States, including for drugs that have been on the shortage list for many years, without solutions to remove them from the list. The Committee directs the FDA to provide a briefing that outlines how it is working with industry to facilitate the resolution of drug shortages and discuss potential recommendations for improving supply chain resilience to reduce the potential for such drugs to return to list in the future. The briefing should be held within 120 days of the enactment of this act and should also include the methodology used by the FDA to determine whether a drug meets the statutory standard for addition to or removal from the drug shortage list.

Illegal Import of Unapproved New Drugs.—The Committee expresses deep concern over the health risks posed by illegal importation of unapproved and misbranded drugs, particularly through third-party brokers facilitating access via employer-sponsored health plans. These unapproved drugs lack the FDA's oversight, potentially containing incorrect dosages, unknown ingredients, or contaminants, which can lead to serious health consequences, especially for vulnerable populations with conditions like HIV, cancer, or hepatitis. The substitution of an FDA-approved medications with unapproved versions can cause patient confusion, medication errors, and negatively impact treatment outcomes, as healthcare providers may unknowingly base decisions on patients' responses to these unregulated drugs. Furthermore, sourcing from uninspected and unregulated supply chains increases the risk of receiving adulterated or improperly stored medications. Given these significant dangers, the Committee directs the FDA to provide a comprehensive report within 180 days, addressing various aspects of this issue, including safety risks, verification challenges, enforcement actions, and recommendations for strengthening oversight. This action is critical to protect U.S. consumers from the potential harm of unapproved and misbranded drugs circumventing regulatory safeguards.

Menopause and Mid-Life Women's Health.—The Committee encourages the FDA to continue outreach and engagement activities with healthcare providers and researchers on perimenopause, menopause, post-menopause and mid-life women's health, and to facilitate the development and testing of new pharmacological (hormonal and non-

hormonal) treatments for menopausal symptoms, as well as oversight and consumer protection efforts to assess the safety and effectiveness of new diagnostic tools for menopausal 148 symptoms, including devices that use artificial intelligence. Within 180 days of enactment of this act, the FDA is directed to provide a report on its activities, including specific information on research, staffing, outreach and engagement activities, and coordination with Federal agencies.

Safe and Effective Products.—The Committee recognizes the FDA's continued efforts to ensure the safety and effectiveness of products for U.S. patients. The Committee strongly supports FDA's ongoing adherence to the statutory limits on compounded copies of medicines once an FDA approved safe and effective medicine is otherwise available. The demand for certain products, including incretin medications, should be addressed with FDA-approved safe and effective treatments, as required by law, unless the FDA has declared a shortage and authorized a temporary, alternative source to meet individual needs. At the same time, the Committee understands the need for continued access to compounded medications when commercially available drugs cannot meet a patient's specific needs; including in circumstances where a prescriber has determined that an individual patient requires a formulation change that makes a medically significant difference in line with section 503A of the Food, Drug & Cosmetic Act. The Committee remains concerned that unapproved and misbranded drugs are being imported illegally and directs the FDA to coordinate closely with U.S. 157 Customs and Border Protection and other partners to prevent unapproved and misbranded drugs from entering the market, thereby upholding regulatory standards and safeguarding the drug supply chain to protect patient health. The Committee directs the FDA to provide to the Committee a briefing, no later than 60 days after the enactment of this act highlighting the FDA's comprehensive approach to prevent the distribution of unapproved and misbranded incretin medications into the supply chain to avoid harm to patient safety.

Supply Shortages for Critical Medications.—The Committee is concerned about continued reports of supply shortages for critical medications and devices, including diabetes, cancer, antibiotic, ADHD, and other drug shortages, which continue to pose a significant challenge and affect patients access to vital treatments and care. Within 90 days of enactment, the Committee requests a report from the FDA regarding its implementation of shortage-related authorities, and the status of shortage related guidance documents.