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Division of Dockets Management (HFA-305)  
Food and Drug Administration  
Department of Health and Human Services  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

## **CITIZEN PETITION**

Covington & Burling LLP, on behalf of the Pharmaceutical Research and Manufacturers of America (“PhRMA”), Ballard Spahr LLP, on behalf of the Partnership for Safe Medicines (“PSM”), and Sidley Austin LLP, on behalf of the Council for Affordable Health Coverage (“CAHC”), respectfully submit this citizen petition pursuant to 21 C.F.R. § 10.30 to request that the Commissioner of Food and Drugs take the actions set forth below with respect to the State of Florida’s Section 804 Importation Program Proposal for the Importation of Prescription Drugs from Canada (hereinafter the “Proposal”).

### **Actions Requested**

Through this petition, PhRMA, PSM, and CAHC respectfully request that the U.S. Food and Drug Administration (“FDA”) refrain from authorizing the Proposal and disclose the identities of Foreign Sellers for public comment.

### **Statement of Grounds**

#### **I. Executive Summary**

On September 24, 2020, the Secretary of the Department of Health and Human Services (“HHS”) purported to certify to Congress that implementation of the commercial importation provisions of section 804 of the Federal Food, Drug, and Cosmetic Act (“FDCA”) will not pose any additional risk to the public’s health and safety and will result in a significant reduction in the cost of covered products to the American consumer (the “Certification”). That same day, HHS and FDA issued a final rule (the “Final Rule”) permitting the commercial importation of certain prescription drugs from Canada without the manufacturer’s authorization. The Final Rule provides for commercial importation through Section 804 Importation Programs (“SIPs”), which will be authorized by FDA and managed by states or tribes.

On November 23, 2020, PhRMA, PSM, CAHC filed suit challenging the Certification and the Final Rule. The complaint alleges that the Certification is invalid for multiple reasons. For instance, section 804 does not permit a conditional certification that assumes states or tribes will submit SIPs in the future that will meet the safety and cost criteria, and contrary to section 804, the Final Rule would allow SIPs to be approved based on potential cost savings that do not reflect a significant reduction in the cost of the covered products to the American consumer. The complaint further alleges that the Final Rule is unlawful because, for example, the SIP

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scheme exposes patients to the risks associated with imports of unapproved, misbranded, and adulterated drugs.

Also on November 23, 2020, Florida became the first state to submit a SIP Proposal to FDA for review. FDA is not authorized to approve the Proposal because the Certification is invalid and the Final Rule is unlawful for the reasons described in the litigation. As for the Proposal itself, it does not include the name of the Canadian wholesaler, which the Final Rule refers to as the “Foreign Seller,” and FDA cannot approve a SIP unless and until a Foreign Seller is identified who meets all the requirements of the statute and the Final Rule.

In addition, FDA should not authorize the Proposal because it would jeopardize patient safety. The Proposal delegates significant responsibilities to a private sector vendor, which undermines FDA’s emphasis on state supervision, and adds a new vulnerability not contemplated by the statute or Final Rule. The Proposal also fails to sufficiently incorporate guardrails FDA has identified as critical to ensuring that commercial importation does not increase the risk to the public’s health and safety. The Proposal lacks assurances that imported drugs will be transported, stored, repackaged, and relabeled appropriately; exempts imported drugs from the testing requirements in the statute that help to ensure that the imported drugs are authentic and not degraded; and lacks robust supply chain security measures that are necessary to protect patients from counterfeits and other substandard medicines. Furthermore, the pharmacovigilance, recall and return, and compliance plans in the Proposal are inadequate to respond to adverse events, products that need to be removed from distribution, and noncompliance. And the Proposal omits any discussion of whether the SIP participants have the requisite funding and capacity to ensure that imported drugs would be safe.

Moreover, the Proposal does not demonstrate that the SIP will result in any reduction to the cost of covered products for consumers—much less the “significant reduction in the cost *to the American consumer*” required by statute. The Proposal instead focuses on savings to the State, without demonstrating that consumers would see a benefit. And the State’s estimates lack adequate factual support and ignore significant costs associated with establishing and administering an importation program. Accordingly, the Proposal fails to satisfy either of the primary criteria for authorization.

The Proposal also suffers from additional flaws and deficiencies. The Proposal does not provide sufficient evidence that manufacturer trade secrets and confidential commercial information (“CCI”) will be protected. Additionally, the Proposal’s labeling provisions are insufficient to protect the manufacturer’s reputational interests. The Proposal also omits relevant data points necessary for FDA to conduct a thorough evaluation, including basic information about the manufacturers and the commercial availability of the drugs.

Finally, we request that FDA publicly disclose Foreign Sellers as soon as they are identified, as doing so is important for promoting transparency, due process, and international coordination.

## **II. Legal and Regulatory Background**

### **A. Commercial Importation under the FDCA**

To ensure the safety of the U.S. drug supply, the FDCA prohibits entities other than a drug’s manufacturer (or entities authorized by that manufacturer) from importing into the U.S. a drug that was originally manufactured and labeled for another country, with narrow

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exceptions.<sup>1</sup> One such exception is section 804 of the FDCA. Section 804 provides two pathways for HHS to authorize the importation of certain prescription drugs by wholesalers or pharmacists (“commercial importation”) or by individuals for personal use (“personal importation”). However, Congress conditioned the implementation of section 804 on an initial certification by the Secretary. Section 804(l) provides that the section shall become effective only if implementation will—(A) pose no additional risk to the public’s health and safety; and (B) result in a significant reduction in the cost of covered products to the American consumer.<sup>2</sup>

Section 804(b) of the FDCA, the provision that concerns commercial importation and is cited as the source of statutory authority for Florida’s proposed importation program, directs the Secretary to promulgate regulations “permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States.”<sup>3</sup> The FDCA imposes a number of conditions and limitations on commercial importation in sections 804(c) through (h). Regulations must include safeguards to ensure that imported product complies with section 505 (including with respect to being safe and effective for the intended use of the prescription drug), with sections 501 and 502, and with other applicable requirements of the FDCA, as well as other “appropriate” safeguards determined by the Secretary.<sup>4</sup> Additionally, section 804 imposes a number of conditions and limitations on commercial importation, including labeling conditions, reporting and recordkeeping responsibilities, and laboratory testing requirements aimed at assuring authenticity and degradation.<sup>5</sup>

Section 804 does not exempt imported prescription drugs from the premarket approval, misbranding, or adulteration provisions of the FDCA. Section 801 of the FDCA explicitly directs that any drugs “being imported or offered for import into the United States” that appear to be unapproved, misbranded, or adulterated “shall be refused admission” to this country.<sup>6</sup> This provision is mandatory, and FDA has “no discretion to make an exception” by allowing the importation of drugs that appear to violate this prohibition.<sup>7</sup>

### **B. The Certification and Final Rule**

Until now, every HHS Secretary has declined to authorize importation of prescription drugs under section 804 due to safety risks and the inability to show the required cost savings. A 2004 HHS Task Force Report (“Task Force Report”) made numerous factual findings about the problems of importation, including that it would increase the risk that counterfeit drugs

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<sup>1</sup> FDCA § 801(d).

<sup>2</sup> *Id.* § 804(l)(1).

<sup>3</sup> *Id.* § 804(b).

<sup>4</sup> *Id.* § 804(c). Sections 501 and 502 of the FDCA define, respectively, adulterated and misbranded drugs. Section 505 prohibits the introduction into interstate commerce of unapproved drugs.

<sup>5</sup> *Id.* § 804(d)–(h).

<sup>6</sup> *Id.* § 801(a)(3).

<sup>7</sup> *Cook v. FDA*, 733 F.3d 1, 8–9, 12 (D.C. Cir. 2013).

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would enter the drug supply chain and have little impact on drug prices.<sup>8</sup> The Task Force was chaired by the Surgeon General and included representatives from HHS (including then-General Counsel Alex Azar and then-Administrator of the Centers for Medicare & Medicaid Services Mark B. McClellan), FDA, and other agencies. As recently as May 2018, current HHS Secretary Azar derided importation as a “gimmick” that would have “no meaningful effect” on drug prices and could not “be safely achieved.”<sup>9</sup>

On December 18, 2019, the Agencies issued a notice of proposed rulemaking (the “NPRM”) soliciting comments on a proposal to authorize commercial—but not personal—importation of certain prescription drugs from Canada under section 804.<sup>10</sup> On September 24, 2020, the Secretary wrote to Congress purporting to certify that implementation of the commercial importation provisions in subsections (b) through (h) of section 804 “poses no additional risk to the public’s health and safety and will result in a significant reduction in the cost of covered products to the American consumer.”<sup>11</sup> Immediately after the Secretary signed the letter to Congress, FDA and HHS jointly issued the Final Rule allowing for the commercial importation of certain drugs from Canada.<sup>12</sup>

The Final Rule authorizes the importation into the U.S. of certain drugs that are approved for sale in Canada. Such drugs could be imported from Canada under SIPs, which would be sponsored by states or tribes. The SIPs must identify Foreign Sellers, which would buy drugs from manufacturers and resell them to U.S. wholesalers or pharmacists (“Importers”), which in turn would arrange for the drugs to be imported and tested for authenticity and degradation (among other things). The Final Rule contains a nonseverability provision stating that if any provision of the Rule is invalidated, the entire rule will cease to be effective. In addition to the entire rule becoming invalid, the Certification also would become “null and void.”<sup>13</sup>

A potential SIP Sponsor must submit an application (a “SIP Proposal”) that identifies the SIP Sponsor and any co-sponsors, the eligible prescription drugs to be imported, the Foreign Seller in Canada that will purchase the eligible prescription drug directly from the manufacturer,

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<sup>8</sup> HHS Task Force on Drug Importation, Report on Prescription Drug Importation, at x–xi (Dec. 2004) (“Task Force Report”), <http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf>.

<sup>9</sup> Alex M. Azar II, Remarks on Drug Pricing Blueprint (May 14, 2018), <https://www.hhs.gov/about/leadership/secretary/speeches/2018-speeches/remarks-on-drug-pricing-blueprint.html>.

<sup>10</sup> The NPRM was published in the Federal Register on December 23, 2019. See Importation of Prescription Drugs, 84 Fed. Reg. 70,796 (Dec. 23, 2019), <https://www.govinfo.gov/content/pkg/FR-2019-12-23/pdf/2019-27474.pdf>.

<sup>11</sup> Letter to Kevin McCarthy, Minority Leader, U.S. House of Representatives (Sept. 23, 2020) (the “Certification”), <https://www.safemedicines.org/2020/09/hhs-secretary-sent-congress-the-certification-to-allow-canadian-drug-importation.html>.

<sup>12</sup> The Final Rule was published in the Federal Register on October 1, 2020. See Final Rule, Importation of Prescription Drugs, 85 Fed. Reg. 62,094 (Oct. 1, 2020), <https://www.govinfo.gov/content/pkg/FR-2020-10-01/pdf/2020-21522.pdf>.

<sup>13</sup> 85 Fed. Reg. at 62,111.

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the Importer in the U.S. that will buy the drug directly from the Foreign Seller, the FDA-registered repackager or relabeler (if different from the Importer), and the laboratory in the U.S. which will conduct the testing required under section 804 (if the Importer will be responsible for conducting the statutorily-required testing).<sup>14</sup> A SIP Proposal must also explain how the SIP Sponsor will ensure, among other things, that:

- imported drugs meet applicable testing requirements;
- the supply chain is secure;
- the labeling requirements of the FDCA and the Final Rule are met;
- the post-importation pharmacovigilance and other FDCA requirements are met; and
- the SIP will result in a significant reduction in the cost to the American consumer.<sup>15</sup>

FDA must decline to authorize the SIP Proposal for failure to meet the Final Rule's requirements.<sup>16</sup> Furthermore, even if a SIP Proposal does meet the relevant requirements, FDA may nonetheless decide not to authorize the SIP Proposal for a wide array of reasons, including because of potential safety concerns, uncertainty that the SIP Proposal would adequately ensure the protection of public health, or the relative likelihood that the SIP Proposal would not result in significant cost savings to the American consumer.<sup>17</sup>

Neither the Certification nor the Final Rule analyzed the safety or cost savings implications of Section 804 implementation. Instead, the Secretary determined that implementation of Section 804 as contemplated by the Final Rule would satisfy the requisite safety and savings standards because the Agencies would approve only those SIPs that demonstrated the ability to achieve those standards.

### C. Ongoing Litigation

On November 23, 2020, PhRMA, PSM, and CAHC filed a complaint in the U.S. District Court for the District of Columbia challenging the Certification and the Final Rule.<sup>18</sup> Among other allegations concerning the Certification, the complaint alleges that the Certification fails to satisfy section 804(D)(1) of the FDCA because that provision does not permit the Secretary to make a certification that is conditioned on future events or information, i.e., information

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<sup>14</sup> 21 C.F.R. § 251.3(d)–(e). The Final Rule provides for the possibility of a phased review process to evaluate a SIP Proposal that does not identify a Foreign Seller but otherwise meets the relevant requirements, provided the Foreign Seller is identified within six months of the initial submission date. *Id.* § 251.4.

<sup>15</sup> *Id.* § 251.3(d)–(e).

<sup>16</sup> *Id.* § 251.4(a).

<sup>17</sup> *Id.*

<sup>18</sup> Compl., PhRMA v. U.S. Dep't of Health & Human Servs., No. 1:20-cv-03402 (D.D.C. Nov. 23, 2020).

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contained in future SIP Proposals.<sup>19</sup> The complaint also alleges that section 804(D)(1) requires the Secretary to certify that implementation of Section 804 would reduce the *cost of covered products to American consumers* (whereas the Final Rule indicates that HHS and FDA may approve SIPs that demonstrate cost savings in ways not contemplated by the statute).<sup>20</sup> Additionally, the complaint challenges the Final Rule as unlawful on multiple grounds, including because it threatens patient safety.<sup>21</sup> Based on these claims, among others, the plaintiffs seek an order holding unlawful, setting aside, and declaring invalid both the Certification and the Final Rule, as well as enjoining FDA and HHS from implementing the Certification or Rule.

### D. Florida's SIP Proposal

On June 11, 2019, Governor Ron DeSantis signed into law a bill establishing the Canadian Prescription Drug Importation Program within Florida's Agency for Health Care Administration ("AHCA").<sup>22</sup> The bill required AHCA to submit a request for federal approval of the program by July 1, 2020, and to begin operating the program within six months of receiving federal approval.<sup>23</sup>

Subsequently, on August 20, 2019, Florida submitted a concept paper to HHS "to demonstrate the ability of a state to safely and effectively import prescription drugs into the U.S." and to provide information on the State's proposed commercial prescription drug importation program design.<sup>24</sup> The concept paper provided a sample list of qualifying drugs to be imported through bulk orders and shipments. Florida anticipated that it would seek federal approval based on purported savings to State government agencies such as the Department of Corrections, rather than to consumers directly.<sup>25</sup>

On November 23, 2020, following the issuance of the Final Rule, Florida became the first state to submit a SIP Proposal to FDA.<sup>26</sup> According to the Proposal, Florida's SIP will be sponsored by the AHCA ("Sponsor") and the Florida Department of Business and Professional Regulation ("DBPR") ("Co-Sponsor"). The Florida Department of Health ("DOH") Central Pharmacy will be the Importer for the SIP. AHCA and the Importer will designate a third-party

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<sup>19</sup> *Id.* ¶ 103.

<sup>20</sup> *Id.* ¶ 106.

<sup>21</sup> *Id.* ¶¶ 125, 135; *see also id.* ¶¶ 61–71.

<sup>22</sup> 2019 Fla. Sess. Law Serv. 2019-99 (C.S.H.B. 19) (West), *codified at* Fla. Stat. § 381.02035.

<sup>23</sup> Fla. Stat. § 381.02035(9).

<sup>24</sup> Florida's Canadian Prescription Drug Importation Concept Paper (Aug. 20, 2019), [https://www.safemedicines.org/wp-content/uploads/2019/08/Florida\\_Canadian\\_Prescription\\_Drug\\_Importation\\_Concept\\_Paper.pdf](https://www.safemedicines.org/wp-content/uploads/2019/08/Florida_Canadian_Prescription_Drug_Importation_Concept_Paper.pdf).

<sup>25</sup> *Id.* at 16.

<sup>26</sup> The State of Florida's Preliminary Section 804 Importation Program (SIP) Proposal for the Importation of Prescription Drugs from Canada ("Proposal") (Nov. 2020), <https://www.safemedicines.org/wp-content/uploads/2019/09/SIP-Proposal-to-HHS-11-23-2020.pdf>.

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logistics firm, LifeScience Logistics, LLC (“LSL”), to assist with the operation and management of the SIP and to conduct relabeling. The Proposal indicates that the State is still in the process of identifying a Foreign Seller and will update the application within the six-month timeframe permitted by the Final Rule.

The Proposal provides a list of prescription drugs that Florida will initially attempt to import from Canada, mainly in therapeutic areas such as HIV/AIDS, asthma, chronic obstructive pulmonary disease, and diabetes.<sup>27</sup> The Proposal asserts that these drugs will yield “the highest potential savings.”<sup>28</sup>

### III. FDA cannot authorize the Proposal for the reasons set forth in the litigation.

FDA cannot authorize the Proposal because it was submitted pursuant to an invalid Certification and unlawful Final Rule. No SIPs can be authorized until the Secretary makes a valid Certification and FDA and HHS promulgate a valid rule pursuant to section 804.

#### A. Secretary Azar’s purported certification is invalid because it violates the FDCA and the Administrative Procedure Act (“APA”).

The Certification is contrary to section 804(l)(1) in several respects. For example, the Certification is conditioned on assumptions that States will submit SIPs in the future that will meet the safety and cost criteria. Yet, the statute requires the Secretary to certify “that the implementation of [section 804] *will*” produce significant savings for American consumers at no additional risk to public health and safety<sup>29</sup>—leaving no room for the Secretary to defer this determination until sometime into the future. Additionally, Secretary Azar did not certify “implementation of this section,” as required by statute,<sup>30</sup> but instead certified only commercial importation under subsections (b) through (h). The Certification also implements section 804 through discrete SIPs sponsored by individual states or tribes, even though the statute requires the Secretary to certify that implementation will pose “no additional risk to the *public’s* health and safety” and will “result in a significant reduction in the cost of covered products to *the American consumer.*”<sup>31</sup> Furthermore, section 804(l)(1) requires the Secretary to certify that implementation of Section 804 will lead to a “significant reduction *in the cost of covered products* to the American consumer,”<sup>32</sup> but the Final Rule permits SIPs to be approved on the basis of “cost savings that are passed on to consumers in other ways, such as increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program.”<sup>33</sup>

The Certification also does not satisfy the APA’s requirement of reasoned decisionmaking. The Secretary inadequately considered both the potential health risks and the consumer savings associated with importation. He also entirely failed to consider, or failed to

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<sup>27</sup> *Id.* at 8–14.

<sup>28</sup> *Id.* at 8.

<sup>29</sup> FDCA § 804(l)(1) (emphasis added).

<sup>30</sup> *Id.*

<sup>31</sup> *Id.* (emphasis added).

<sup>32</sup> *Id.* (emphasis added).

<sup>33</sup> 85 Fed. Reg. at 62,101.

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adequately consider, important aspects of the problem before him and failed to acknowledge or adequately explain HHS and FDA's departure from long-held prior positions and factual findings related to importation. Furthermore, the Secretary's stated rationale is internally inconsistent and fails to support his decision to authorize commercial importation under the Final Rule.

Finally, the Certification was procedurally improper. HHS lacked authority to promulgate the NPRM before the Certification was issued. By failing to disclose facts or analyses supporting the Certification during the notice-and-comment process, the Secretary also deprived parties of the opportunity to comment meaningfully on the Certification.

### **B. The Final Rule violates the APA, the FDCA, and the U.S. Constitution.**

The Final Rule conflicts with the FDCA in key respects. Drugs imported under the Final Rule would necessarily be unapproved new drugs and misbranded drugs, neither of which can legally be imported into the U.S. Under the FDA's rigorous approval process, FDA scrutinizes everything about the drug, including its composition, the method of its manufacture, its packaging, and its labeling.<sup>34</sup> Drugs imported under the Proposal, however, would differ from drugs approved in the respective applications, e.g., because the parties responsible for relabeling and repackaging a drug imported under a SIP and the relabeling and repackaging processes would not be identified in the New Drug Application ("NDA") or Abbreviated New Drug Application ("ANDA") of the comparable FDA-approved drug. For similar reasons, drugs imported under the Final Rule would also be misbranded.<sup>35</sup> Unapproved drugs cannot be labeled as approved, and since drugs imported under a SIP would be unapproved, they also would be misbranded. Even if imported drugs were approved, the labeling mandated by regulation would mislead consumers that the drugs have been approved by FDA (which they have not) and have the assurances associated with FDA-approved drugs (which they do not).

Additionally, the Final Rule is unlawful because FDA lacks the authority to (1) require a manufacturer to attest that a drug meets the conditions in an approved NDA or ANDA but for the fact that the drug bears Canadian labeling, or to notify FDA and explain with specificity why it cannot provide that attestation; (2) disclose the trade secret and confidential information that the U.S.-approved product and foreign-approved product are the same; and (3) require manufacturers to disclose trade secrets and other confidential information and provide samples of analytical reference standards and the FDA-approved drug to Importers for free. Apart from the absence of statutory authority, these provisions of the Final Rule raise serious constitutional questions under the Fifth Amendment to the U.S. Constitution, which prohibits the Government from taking property without providing just compensation.

The Final Rule is also arbitrary and capricious. Nowhere does the Final Rule explain why HHS is deviating from its longstanding policy that "Canadian versions" of FDA-approved drugs are unapproved and misbranded drugs that are not eligible for importation, and its prior repeated determinations that section 804 importation would not significantly reduce consumer drug costs. Additionally, the Final Rule fails to adequately consider how commercial importation under SIPs will necessarily increase the likelihood that U.S. patients will receive

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<sup>34</sup> See FDCA § 505(b)(1).

<sup>35</sup> See *id.* § 502(a) (stating that a drug is misbranded if its labeling is false or misleading).



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adulterated drugs and otherwise compromise U.S. public health and safety.<sup>36</sup> That is because the Final Rule, among other things, shifts relabeling and repackaging from FDA-inspected facilities that are identified in an application to other facilities that FDA has not necessarily inspected and refuses to commit to inspect prior to SIP authorization; loosens restrictions on the drug supply chain by exempting supply chain members from DSCSA requirements; and increases the number of entities that are in the supply chain and which test product. The Final Rule asserts that States will be able to protect public health and safety because FDA will approve a SIP Proposal only upon a demonstration that the public health and safety will be protected—but that is a tautology, not the reasoned explanation required by law. Moreover, the Final Rule is arbitrary and capricious insofar as it fails to offer a reasoned explanation for why manufacturers cannot charge Importers reasonable, market-based prices for the costs of conducting the statutory testing or provision of trade secrets and CCI, analytical reference standards, and FDA-approved drugs.

Furthermore, the Final Rule compromises manufacturers' constitutional speech rights. As promulgated, the Final Rule compels manufacturers to allow Importers to use, at no cost, the manufacturers' FDA-approved labeling, which includes the manufacturers' speech. This compelled use of manufacturers' labels, which often include the manufacturer's name and other trademarks, would imply that the manufacturers vouch for the quality of the imported drugs and the accuracy of their labeling and are associated with the Importer and the SIP, notwithstanding the statement that drugs were being imported without manufacturers' authorization. The compelled attestation, use-of-labeling, and testing provisions also amount to a compelled subsidy of Importers, and a knowing failure to comply with the testing provisions is a crime punishable by up to 10 years' imprisonment.<sup>37</sup> Furthermore, in addition to forcing manufacturers to associate themselves with imported drugs, the Final Rule deprives them of the opportunity to add to the labels any disclaimers or other language to indicate, for instance, that they do not stand behind such products. In addition, because the Final Rule does not establish a process for solving disputes over attestations, manufacturers may feel compelled to make attestations with which they disagree, in violation of the First Amendment.

Finally, the Final Rule raises serious questions under the Fifth Amendment Takings Clause. The Fifth Amendment to the U.S. Constitution prohibits the Government from taking property without providing just compensation. The Final Rule would work an uncompensated taking by expropriating manufacturers' intellectual property in their drug labeling, testing protocols (or testing services), and in the similarity (or lack thereof) of U.S. and Canadian drugs, and giving it to Importers without providing any compensation.

#### **IV. FDA cannot approve the Proposal unless and until a Foreign Seller is identified that meets the statutory and regulatory requirements.**

The Proposal does not identify a Foreign Seller,<sup>38</sup> a key supply chain participant whose ability to distribute drugs that meet the safety and cost criteria must be heavily scrutinized. The Final Rule emphasizes the importance of a short supply chain limited to just three entities—one manufacturer, one Foreign Seller, and one Importer—and the central role that the Foreign Seller

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<sup>36</sup> See *id.* § 501(a)(2)(B) (stating that a drug is adulterated if it is not manufactured and held in conformance with FDA's current and good manufacturing practice ("CGMP") requirements).

<sup>37</sup> FDCA § 303(b)(6).

<sup>38</sup> Proposal at 5.

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plays in purchasing the drugs from the manufacturer and selling them to the Importer.<sup>39</sup> While the Final Rule allows SIP Proposals to be submitted without even naming the Foreign Seller, it does not allow them to be approved until the Foreign Seller is named (which must occur within six months of submission of the SIP) and FDA concludes that it meets the statutory and regulatory requirements.<sup>40</sup> As the Final Rule explains, FDA will conduct a “phased review” where the Foreign Seller is not identified in the initial SIP, and “[a] Foreign Seller will still need to be identified and registered with FDA, and FDA will still review information about the Foreign Seller, before FDA will authorize a SIP.”<sup>41</sup>

This is logical, as FDA cannot fully assess whether the safety or cost criteria can plausibly be met without knowing the identity of this pivotal supply chain participant. If and when Florida names the Foreign Seller, FDA must evaluate, among other things, whether the Foreign Seller is licensed to wholesale drugs by Health Canada and registered with FDA as a Foreign Seller, has been the subject of disciplinary actions, and has demonstrated the capability of meeting current good manufacturing practice (“CGMP”) requirements and supply chain security requirements, including serialization, maintaining traceability records, and monitoring for counterfeit drugs. Closely inspecting the Foreign Seller is also essential to evaluating the risks posed by transshipments and counterfeits and the jurisdictional and enforcement challenges posed by the Foreign Seller being an ex-U.S. entity. In addition, the Foreign Seller’s sales arrangements with the Importer must be examined to meaningfully assess whether importation will result in cost savings to the American consumer. The Agency cannot approve the Proposal unless and until a Foreign Seller is identified who meets all the requirements of the statute and the Final Rule, including the safety and cost savings criteria.

### **V. The Proposal diverges from the requirements in the FDCA and the Final Rule in ways that undermine public health and safety.**

Section 804(I)(1) of the FDCA requires the Secretary to certify that importation will “pose no additional risk to the public’s health and safety.”<sup>42</sup> Florida’s Proposal could have a devastating impact on patient safety, because it impermissibly delegates responsibilities to a private third-party entity, fails to satisfy guardrails in the statute and Final Rule pertaining to the safety of the drug supply, and omits any discussion of whether the SIP participants have the requisite resources and capacity to ensure that imported drugs would be safe.

#### **A. The Proposal impermissibly delegates significant State and Importer responsibilities to LSL, without providing a justification.**

With no explanation, the Proposal provides that a private “licensed wholesale distributor,” LSL, will “assist the state and importer” with the following tasks: (1) identifying a foreign seller and manufacturer(s) capable of participating in the SIP; (2) negotiating drug prices from the foreign seller/manufacturer that will yield savings under the program; (3) relabeling and repackaging the product; (4) providing logistics support in transporting the

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<sup>39</sup> 85 Fed. Reg. at 62,094.

<sup>40</sup> 21 C.F.R. § 251.4.

<sup>41</sup> 85 Fed. Reg. at 62,099; *see also* 21 C.F.R. § 251.3(d) (“The proposal must include . . . (7) [t]he name and address of the Foreign Seller.”).

<sup>42</sup> FDCA § 804(I)(1)(A).

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eligible drugs into the U.S. (including customs clearance, ensuring all laboratory testing is complete, and that the product is trackable and traceable throughout the supply chain); and (5) distributing the imported eligible drugs to the end user (pharmacies dispensing on behalf of the State programs).<sup>43</sup> Such a delegation conflicts with FDA’s position in the Final Rule regarding state supervision over commercial importation. Florida’s SIP Proposal also creates a role for LSL as an additional supply chain participant, increasing the entities that the State must oversee and the opportunity for supply chain security problems. Furthermore, LSL’s dual role as both a stand-in for the State and a supply chain participant creates potential conflicts of interest.

This delegation is inconsistent with both the statute and the Final Rule. Notably, the FDCA does not provide for a role for states in determining whether commercial importation will pose no additional risk to safety and will lead to significant savings for consumers. Instead, the *Secretary of HHS* must certify that imported drugs pose no additional risk to public safety and will lead to significant savings for the American consumer.<sup>44</sup> The Final Rule provides for SIPs to be operated by states and tribes, and punts the responsibility for demonstrating safety and cost savings to state and tribal governments, under the theory that “these entities, which oversee pharmacies and wholesale distribution and have tools to protect public health, are uniquely positioned to provide independent oversight of importation activities.”<sup>45</sup> Without any justification other than a need for “logistics support,”<sup>46</sup> the Proposal then further punts key state responsibilities to a private entity. Under the proposed scheme, LSL will be at least partly responsible for identifying the Foreign Seller and manufacturers and negotiating prices with such parties that will yield savings, tasks assigned to the SIP Sponsor, i.e., the State, under the Final Rule.<sup>47</sup> Such a delegation defeats the purpose of state involvement in importation as articulated in the Final Rule and undermines the very safety assurances that state supervision purportedly provides.

LSL is also tasked with supply chain member functions that the State is supposed to oversee, such as relabeling and repackaging, providing logistics support, and distributing imported drugs to the end user. Although the Final Rule permits a SIP Proposal to include the name of an FDA-registered repackager or relabeler (other than the Importer),<sup>48</sup> the delegation of the remaining tasks from the Importer to LSL is inconsistent with the Final Rule, which limits each SIP’s supply chain to three entities, i.e., one manufacturer, one Foreign Seller, and one

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<sup>43</sup> Proposal at 6; *see also id.* at 35 (providing that LSL “will be performing many duties on behalf of the importer and State”). Elsewhere, the Proposal claims that LSL simply is serving as the Importer’s “designee for certain functions.” *Id.* at 5. However, the wide array of tasks State-specific tasks assigned to LSL undermine this assertion.

<sup>44</sup> FDCA § 804(l)(1).

<sup>45</sup> 85 Fed. Reg. at 62,098.

<sup>46</sup> Proposal at 6.

<sup>47</sup> 21 C.F.R. §§ 251.3(b) (requiring the State to designate one Foreign Seller), 251.3(e)(9) (requiring the State to demonstrate how it will ensure that the SIP will result in a significant reduction in the cost to the American consumer of the eligible prescription drugs that the State seeks to import).

<sup>48</sup> *Id.* § 251.3(d)(10).

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Importer.<sup>49</sup> In the Preamble, FDA justifies this restriction on the importation supply chain as a necessary guardrail in light of the novel nature of commercial importation:

Based on FDA's experience with drug importation and implementation of new programs, we believe that an increase in the number of entities a SIP must oversee and, potentially, a corresponding increase in the volume of product, could multiply the opportunity for supply chain security problems. Absent a demonstrated track record of oversight capability and compliance, initially limiting a SIP to one Foreign Seller and one Importer is an important safeguard.<sup>50</sup>

Adding a fourth entity to the supply chain necessarily makes the supply chain more vulnerable by introducing additional complexity in the operationalization of the SIP. Such added complexity also increases Florida's oversight responsibilities and makes it easier for security problems to arise.

LSL's dual role as a stand-in for the State and a supply chain member which the State must supervise presents a potential conflict of interest. For example, the Proposal specifically provides that LSL is responsible for negotiating drug prices that yield cost savings.<sup>51</sup> Yet, cost considerations may vary depending on whether the analysis is conducted by a given supply chain participant or by the State which must evaluate cost savings across the supply chain. Additional conflicts could arise to the extent that LSL is in a position to supervise itself or to use its strategic position to influence the State's supervision of LSL. The State may also be inclined to rubber stamp LSL's compliance with statutory and regulatory standards, given that LSL also plays a supervisory role in the SIP scheme. Moreover, the State provides no information on how LSL will be compensated. LSL's compensation could pose a conflict to the extent that it incentivizes LSL to take steps that might compromise safety or decrease consumer savings.

### **B. The Proposal's Storage, Handling, Supply Chain, and Reporting Guidelines are Insufficient to Protect Patient Safety.**

The preamble to the Final Rule emphasizes that commercial importation can be implemented consistently with the section 804(l)(1) certification criteria because "[t]he final rule includes requirements relating to the types of drugs eligible for importation, the distribution channels and methods used for product traceability, and the testing of eligible prescription drugs for authenticity and degradation" and because "[t]he SIP Sponsor must demonstrate, among other things, how it will ensure that the supply chain in the SIP is secure."<sup>52</sup> The Proposal fails to satisfy these guardrails, thereby posing significant safety risks that require FDA to reject the Proposal.

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<sup>49</sup> *Id.* § 251.3(b); 85 Fed. Reg. at 62,094. FDA may authorize a supplemental proposal to add additional Foreign Sellers or Importers at a future date, only if the SIP Sponsor can demonstrate that the SIP has consistently remained in accordance with section 804 and the Final Rule. 21 C.F.R. § 251.8(c).

<sup>50</sup> 85 Fed. Reg. at 62,100.

<sup>51</sup> Proposal at 6.

<sup>52</sup> 85 Fed. Reg. at 62,106.

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### 1. **The Proposal fails to provide assurances that imported drugs will be transported, stored, repackaged, and relabeled in compliance with CGMP requirements.**

A drug is adulterated if it is not manufactured and held in conformance with FDA's CGMP requirements.<sup>53</sup> Florida's SIP Proposal fails to provide adequate assurances that imported drugs will be transported, stored, repackaged, and relabeled in compliance with CGMP requirements.

The inclusion of HIV/AIDS drugs in the proposed list of drugs to be imported raises significant adulteration concerns. Under the Final Rule, FDA will determine whether drugs requiring conditions such as temperature controls can be imported safely in the context of a specific SIP Proposal on a product-by-product basis.<sup>54</sup> Twenty-five drugs listed in the Proposal are HIV/AIDS drugs, which must be stored at a temperature that does not exceed 20 to 25 degrees Centigrade. Yet, beyond noting the importance of "controlling temperature" in Florida's tropical climate,<sup>55</sup> the Proposal provides no guidelines for ensuring that each supply chain participant complies with the storage instructions included in each drug's labeling. Adverse consequences resulting from improper storage, testing, or processing would present material risk to consumers, particularly among vulnerable populations such as patients with HIV/AIDS.

Moreover, the Proposal also does not indicate how Florida plans to ensure that the drug supply chain participants screen the eligible prescription drugs for adulterated, counterfeit, damaged, tampered with, expired, suspect, or illegitimate foreign product. The Proposal provides that LSL will "physically inspect each drug shipment received from the foreign seller against shipping paperwork and a set of specifications developed for each drug imported."<sup>56</sup> The Proposal further states that LSL "has developed a CGMP compliant set of standard operating procedures (SOPs) that ensure each product is handled, stored, and distributed in accordance with applicable FDA, Drug Enforcement Agency and State of Florida guidelines," and that the State "will maintain SOPs governing all processes associated with products inbound, inventory management, order management, returns, and preventive/corrective maintenance."<sup>57</sup> Yet, without evaluating the specifications and SOPs themselves, FDA has no way to ensure that drugs will be manufactured and held in a CGMP compliant manner. Even if delegating responsibilities to LSL is permissible (it is not), such a conclusory statement does not adequately establish that LSL is equipped to ensure that each drug is what it purports to be.

Repackaging and relabeling activities are also not described in adequate detail. As discussed in the litigation and addressed above, commercial importation necessarily increases the risk that the drugs will not conform with CGMP requirements, since it shifts repackaging and relabeling from FDA-inspected facilities that are identified in an application (manufacturers) to other facilities that FDA has not necessarily inspected and refuses to commit to inspect (repackagers and relabelers) before they can participate in this importation

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<sup>53</sup> FDCA § 501(a)(2)(B).

<sup>54</sup> 85 Fed. Reg. at 62,097.

<sup>55</sup> Proposal at 25.

<sup>56</sup> Proposal at 26.

<sup>57</sup> *Id.*

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program.<sup>58</sup> The Proposal provides no information on repackaging and relabeling processes to assuage such a concern, including only a conclusory statement that the State “will ensure that these products are relabeled appropriately.”<sup>59</sup>

The fact that LSL is a licensed wholesale distributor does not mitigate the risk of adulteration, since manufacturers still would no longer possess oversight to confirm CGMP compliance. Moreover, for NDA products, FDA’s inspection oversight of manufacturing and packaging facilities goes well beyond general facility, personnel and procedural controls. It also includes evidence that the facility is capable of manufacturing or packaging the specific product submitted in the NDA, which generally requires a product-specific validation study. Therefore, the mere use of FDA-registered facilities for repackaging and relabeling activities without disclosure of such a facility in the NDA and the safeguard of a potential inspection to assure product-specific capability would undermine important regulatory protections.

### **2. The Proposal does not satisfy requirements related to testing, supply chain security, and post-importation pharmacovigilance.**

The Proposal fails to satisfy standards in section 804 and the Final Rule related to testing, supply chain security, and post-importation pharmacovigilance.

#### **a) Statutory Testing**

Although “no testing scheme is foolproof,”<sup>60</sup> testing helps ensure that imported product will pose no additional risk to the public’s health and safety. Accordingly, section 804 of the FDCA and the Final Rule mandate that the Importer or the manufacturer test imported drugs for authenticity, degradation, and compliance with established specifications and standards of the FDA-approved drug (“Statutory Testing”).<sup>61</sup> The Final Rule further requires that a SIP Proposal include a summary of how the SIP Sponsor will ensure that “[t]he imported eligible prescription drugs meet the Statutory Testing requirements.”<sup>62</sup> Florida’s testing provisions violate the Final Rule and are insufficient to secure the safety and efficacy of the drug supply.

Florida proposes to exempt imported drugs from Statutory Testing altogether. The Proposal posits that, because the “Canadian products are fully compliant with FDA-approved New Drug Applications (NDA) (except for labeling), *it will not be necessary* to perform statutory

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<sup>58</sup> 85 Fed. Reg. at 62,101 (“[W]e decline to add a pre-authorization inspection requirement . . .”).

<sup>59</sup> Proposal at 18.

<sup>60</sup> HHS Task Force Report at 30.

<sup>61</sup> FDCA § 804(e), (d)(1)(J), (L); 21 C.F.R. § 251.16(a). “Statutory Testing” is defined to mean “the testing of an eligible prescription drug as required by section 804(d)(1)(J) and (L) and section 804(e) of the [FDCA], including for authenticity, for degradation, and to ensure that the prescription drug is in compliance with established specifications and standards.” 21 C.F.R. § 251.2.

<sup>62</sup> 21 C.F.R. § 251.3(d)(11)(i).

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testing on these products.”<sup>63</sup> Instead, the State suggests that it will simply provide to FDA “evidence to establish that these products are manufactured according to the specifications in the FDA-approved NDAs,” thereby “avoid[ing] duplicative testing efforts and reduc[ing] overall costs.”<sup>64</sup> Only if it is not possible to avoid “duplicative testing efforts” will the State, through its contracted entities, ensure that a qualifying laboratory tests statistically valid sample batches or shipments of imported prescription drugs in accordance with CGMP guidelines.<sup>65</sup>

Neither the FDCA nor the Final Rule provides for such an exemption to avoid conducting Statutory Testing. In fact, in the preamble to the Final Rule, FDA explicitly rejected an approach where a state would provide the manufacturer’s batch release or conformance testing in lieu of statutory testing.<sup>66</sup> Moreover, the Proposal does not specify what kind of evidence other than testing results it expects the State to submit to support a finding that Statutory Testing is unnecessary. Establishing that the products are manufactured according to the specifications in the FDA-approved NDAs would require access to confidential information within the NDA or confidential records from upstream manufacturing or testing facilities. As a result, the SIP does not provide adequate assurances that imported drugs would be tested to ensure that they meet the relevant established specifications and standards of FDA-approved counterpart drugs.

### **b) Supply Chain Security**

A SIP Proposal must include the procedures a SIP Sponsor will use and the steps it will take to ensure that “(i) storage, handling, and distribution practices of supply chain participants, including transportation providers, meet the requirements of part 205 of this chapter [providing guidelines for state licensing of wholesale prescription drug distributors] and do not affect the quality or impinge on the security of the eligible prescription drugs; and (ii) [the] supply chain is secure.”<sup>67</sup> The Final Rule assigns SIP Sponsors responsibility for administering SIPs. But States play no role in implementing the DSCSA.<sup>68</sup> Moreover, states will often lack jurisdiction to take action against non-compliant Foreign Sellers and out-of-state entities.<sup>69</sup>

The Proposal contains only vague assurances that drugs will be stored, handled, and distributed in a compliant manner on foreign soil. Although the Proposal generally states that facilities and vehicles located in Canada will need to meet “specific state and federal guidelines,”<sup>70</sup> the uncertainty regarding FDA’s ability (much less Florida’s ability) to enforce compliance by entities located outside the U.S. will pose additional risk to the public health and

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<sup>63</sup> Proposal at 18 (emphasis added).

<sup>64</sup> *Id.*

<sup>65</sup> *Id.*

<sup>66</sup> 85 Fed. Reg. at 62,110.

<sup>67</sup> 21 C.F.R. § 251.3(e)(11)(i)–(ii); *see also id.* § 251.3(d)(11) (stating that the overview of the SIP Proposal must include a summary of how the SIP Sponsor will ensure that the supply chain is secure).

<sup>68</sup> *See generally* FDCA § 581 *et seq.*

<sup>69</sup> Partnership for Safe Medicines, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 3 (Feb. 11, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-0055>.

<sup>70</sup> Proposal at 24–25.

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safety. As Innovative Medicines Canada noted in its comment to the NPRM, certain companies involved in commercial importation may not have a nexus to the U.S. and may therefore “fall outside FDA’s regulatory ambit,” thereby impeding FDA’s ability to ensure compliance and to fully investigate and redress violations.<sup>71</sup> The Proposal does not explain how the SIP program will address FDA’s limited reach overseas, much less how the State of Florida can exercise jurisdiction over entities with no connection to the State. Nor does it address the practical limitations of Federal and State enforcement abilities.

Additionally, the Proposal fails to adequately address how the State will ensure that the supply chain is secure and that SIP participants will comply with the Final Rule and the DSCSA. The relevant section of the Proposal is brief and focuses exclusively on the transmission and review of transaction documentation, which is merely one aspect of DSCSA compliance:

As the SIP sponsor, the State will require the importer or its designee to verify at receipt, maintain, and submit all transaction histories, information, and statements. When monitoring for compliance, the Agency and DBPR will review the transaction documents and verify their accuracy as well as confirm that all prescription drugs being imported meet Health Canada and FDA guidelines.<sup>72</sup>

Yet, the Proposal does not address how the State will ensure SIP participants are taking appropriate steps to confirm the accuracy of transaction documentation that is exchanged, such as by requiring the Importer to cross-reference documentation received from the Foreign Seller against information received from the manufacturer.<sup>73</sup> And, because transaction histories, information, and statements are not required for products marketed outside of the U.S., the Importer will not be reviewing the entire supply chain. This missing information may lead to confusion from entities downstream from the Importer about whether imported drugs are suspect or illegitimate.

Moreover, the Proposal does not indicate how the State plans to ensure that the Foreign Seller and Importer are taking appropriate steps with regard to handling, investigating, and reporting suspect and illegitimate product, as required under both the DSCSA and the Final Rule.<sup>74</sup> The DSCSA includes detailed requirements regarding how supply chain entities identify suspect and illegitimate products, notify other members when such products are identified, and ultimately arrive at a determination. These provisions are especially important for imported drugs, given the complexity of the supply chain. Yet, the Proposal does not address these requirements, nor does it identify what steps the State will take if it determines that the Foreign Seller or Importer is not in compliance with the Final Rule or the DSCSA.

The delegation of data capture and physical inspection responsibilities to LSL poses additional concerns, as the State does not demonstrate that LSL has the expertise necessary to

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<sup>71</sup> Innovative Medicines Canada, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 6 (Mar. 6, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1145>.

<sup>72</sup> Proposal at 25.

<sup>73</sup> 21 C.F.R. § 251.14(d)(5).

<sup>74</sup> FDCA § 582; 21 C.F.R. § 251.14(c)–(d).



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comply with its delegated duties. Florida asserts that LSL “fully complies with the DSCSA (including the components that are not yet enforced by the FDA – i.e., serialization).”<sup>75</sup> However, Florida does not provide any support for such a statement.<sup>76</sup> Florida also fails to explain how the State will oversee LSL’s compliance with the DSCSA.

Moreover, the proposed reporting requirements related to supply chain security fail to capture key metrics that would help FDA evaluate the SIP’s operations. Florida only proposes to include in its quarterly reports “[p]roof that the eligible prescription drug was received by the foreign seller from the manufacturer and subsequently shipped by the foreign seller to the importer.”<sup>77</sup>

### c) Post-Importation Pharmacovigilance

The Final Rule requires a SIP Sponsor to demonstrate that post-importation pharmacovigilance and other requirements of the FDCA and the Final Rule are met.<sup>78</sup> Relatedly, the SIP Sponsor must explain the steps that will be taken to ensure that the “Importer fulfills its responsibilities to submit adverse event, field alert, and other reports.”<sup>79</sup> Florida’s delegation of pharmacovigilance responsibilities from the Importer to LSL is impermissible, and, furthermore, LSL does not have the expertise necessary to assume such a role. In addition, the SIP Proposal as a whole indicates that the State lacks a comprehensive understanding of what pharmacovigilance entails and requires.

Longstanding FDA regulations impose adverse event and field alert reporting requirements on NDA/ANDA applicants, i.e., *manufacturers* of prescription drugs,<sup>80</sup> and the Final Rule requires the *Importer* to submit adverse events, field alerts and other reports.<sup>81</sup> In its Proposal, Florida punts pharmacovigilance responsibilities to LSL, stating that “[AHCA] and DBPR will require the *importer or its designee* to conduct adverse incident reporting and issue field alerts to state and federal agencies.”<sup>82</sup> Furthermore, LSL will be required to file field alerts *independently* within 72 hours of becoming informed of patient injury or death; labeling problems that can cause the prescription drug to be identified as another product; biological contamination; changes in the chemical or physical composition of the prescription drug that

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<sup>75</sup> Proposal at 25.

<sup>76</sup> In fact, LSL is not listed in the FDA database showing wholesale distributors and third-party logistics providers that have registered with FDA. *See* FDA, *Wholesale Distributor and Third-Party Logistics Providers Reporting*, <https://www.accessdata.fda.gov/scripts/cder/wdd3plreporting/index.cfm>.

<sup>77</sup> Proposal at 28.

<sup>78</sup> 21 C.F.R. § 251.3(d)(11)(iv).

<sup>79</sup> *Id.* § 251.3(e)(11)(iv).

<sup>80</sup> 21 C.F.R. §§ 314.80, 314.81, 314.98.

<sup>81</sup> *Id.* §§ 251.3(e)(11)(iv), 251.12(a)(7).

<sup>82</sup> Proposal at 27. Additionally, the Importer or designee must inform Health Canada and Health Canada’s Health Products and Food Branch (“HPFB”) of any defect, contamination, or adulteration of a prescription drug. *Id.*

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leads to deterioration, degradation, or toxicity; and/or any failure of a shipment or batch of prescription drugs to meet the specifications in its NDA or ANDA.<sup>83</sup>

Such a delegation is inconsistent with the Final Rule, which explicitly vests responsibilities for pharmacovigilance with the Importer, not a third-party entity. It also is troubling in light of the significant expertise and operational capacity necessary to carry out pharmacovigilance responsibilities. The submission of adverse event reports is merely one aspect of pharmacovigilance. Pharmacovigilance involves a number of complex steps in which entities take in adverse event information and make assessments that require medical and scientific expertise as to whether the event is serious and unexpected, and is, in fact, caused by the drug. Manufacturers have complex pharmacovigilance systems and processes in place to detect, assess, and understand any adverse effects and drug-related problems. The Proposal provides no evidence that either DOH Central Pharmacy or LSL has such systems and processes in place to assume this role. To highlight just one example, it is unclear whether either of these entities employs medical professionals who can make determinations regarding causation. Importers and wholesalers also have no experience with or infrastructure for reporting adverse events to FDA or following up on adverse event reports to receive more information.

Moreover, the State's apparent confusion regarding applicable pharmacovigilance and other requirements undermines its credibility and suggests that it is not equipped to oversee such activities. For example, the Proposal conflates adverse event reporting, which addresses reporting and recordkeeping requirements related to adverse patient drug experiences, with field alerts, a CGMP requirement to ensure product quality.<sup>84</sup> The Proposal states that “[w]hen an imported prescription drug fails testing, becomes compromised, has a recall issued, or results in patient injury, [AHCA] and DBPR will require the importer or its designee to conduct adverse incident reporting and issue field alerts to state and federal agencies.”<sup>85</sup> Such a provision ignores the fact that these are two separate requirements and that, for instance, patient injury would likely trigger the adverse event reporting requirement, and not the field alert requirement.

Additionally, the Proposal indicates that Florida plans to submit field alerts for only a subset of contamination events identified in FDA's regulations. FDA regulations provide that a field alert is required for “any bacteriological contamination.”<sup>86</sup> FDA has interpreted bacteriological broadly “to mean *microbiological*, which includes any kind of microbial contamination, such as bacteria, yeast, fungus, or virus.”<sup>87</sup> The Proposal, by contrast, suggests

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<sup>83</sup> *Id.*

<sup>84</sup> Compare 21 C.F.R. § 318.80 with *id.* § 314.81; see also *id.* § 314.98 (providing that ANDA applicants must meet these two discrete requirements).

<sup>85</sup> Proposal at 27.

<sup>86</sup> 21 C.F.R. §§ 314.81(b)(1)(ii) (NDAs), 314.98 (ANDAs).

<sup>87</sup> FDA, Draft Guidance for Industry, Field Alert Report Submission Questions and Answers, at 1 n.3 (July 2018), <https://www.fda.gov/media/114549/download>. Additionally “[t]he contamination of distributed drug product by yeast, fungus, or virus would also be reportable as a *change or deterioration in the distributed drug product, or as a failure of one or more distributed batches of the drug product to meet the specification established for it in the application.*” *Id.* (citing 21 C.F.R. § 314.81(b)(1)(ii)).

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that the State plans to submit reports only for “biological contamination,” which it refers to as harmful bacteria—a subset of bacteriological contaminants that excludes yeast, fungus, and viruses.<sup>88</sup> This oversight further demonstrates that the State lacks the knowledge and expertise necessary to carry out the manufacturers’ oversight functions.

Lastly, and notably, the Proposal does not include any contract terms between Florida and LSL. Such an agreement likely would address questions essential to FDA’s evaluation of the SIP, including LSL’s role as an agent of the State and whether LSL owes a fiduciary duty to the State. Additionally, the agreement likely would address insurance requirements, allocation of risk, rights and remedies, and the applicability of state ethics and consumer protection laws.

### **3. The Proposal’s recall, return, and compliance plans leave critical questions unanswered.**

Under the Final Rule, FDA must approve the SIP Sponsor’s recall, return, and compliance plans. The plans outlined in the Proposal lack essential elements required under the Final Rule.

#### **a) Recall and Return Plans**

The Final Rule requires that a SIP Proposal include the SIP’s recall plan, including an explanation of how the SIP Sponsor will obtain recall or withdrawal information and how it will ensure such information is shared among the SIP Sponsor, the Foreign Seller, the Importer, FDA, and the manufacturer.<sup>89</sup> In language added following public comment, the Final Rule also requires the SIP Proposal to include the SIP’s return plan, including an explanation of how the SIP Sponsor will ensure that non-saleable returned product is properly dispositioned in the U.S. and how the SIP Sponsor will prevent the non-saleable returned drugs from being exported from the U.S.<sup>90</sup>

The Proposal’s recall and return plans are insufficient to ensure that dangerous products will be taken out of distribution. The fact that the Proposal assigns recall-related responsibilities to four different entities raises a red flag, particularly because the division of duties is not clearly articulated. The Proposal provides that AHCA and DBPR will be responsible for monitoring recalls or market withdrawals by FDA and Health Canada and for handling the communications with stakeholders, while the DOH Central Pharmacy and its designee (LSL) will be responsible for working with relevant stakeholders to collect the recalled drugs.<sup>91</sup> However, the “Agency and DBPR Communication Plan” does not differentiate between AHCA- and DBPR-specific tasks, and the “Importer Recall Plan” does not differentiate between Importer- and LSL- specific tasks. The failure to assign discrete roles to each entity adds redundancy and impedes the State’s ability to effectively oversee the recall process. Meanwhile, the recall plan leaves entirely unanswered how AHCA and DBPR will ensure that recall or market withdrawal information is

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<sup>88</sup> Proposal at 27.

<sup>89</sup> 21 C.F.R. § 251.3(e)(13).

<sup>90</sup> *Id.* § 251.3(e)(14).

<sup>91</sup> Proposal at 31–33.

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shared with the Foreign Seller and FDA and provided to the manufacturer, as required under the Final Rule.<sup>92</sup>

Furthermore, the Proposal does not address how any one entity will make the critical determination of whether a recall is warranted. Traditionally, the decision to institute a recall falls under the purview of the manufacturer in close consultation with FDA, but the Final Rule requires the SIP Sponsor to assume the role of effectuating a recall if mandated or requested by FDA, or if initiated by the SIP Sponsor itself, the Foreign Seller, the Importer, or the manufacturer.<sup>93</sup> The Proposal does not discuss how AHCA, DBPR, DOH Central Pharmacy, or LSL will determine whether a recall is necessary. It provides that AHCA and DBPR “will immediately halt the importation of affected prescription drugs under the SIP in accordance with the FDA’s Importation of Prescription Drugs final rule.”<sup>94</sup> Subsequently, it states that AHCA and DBPR “are granting” the Importer and its designee the ability to issue a recall if either party “determines that a recall is necessary.”<sup>95</sup> The “grant” to the Importer is unnecessary, since the Final Rule already permits the Importer to initiate a recall.<sup>96</sup> Delegating the ability to initiate a recall to the designee, i.e., LSL, is troubling for the reasons discussed above—the Final Rule is intended to be limited to three supply chain participants, and lengthening the supply chain adds risks that the Final Rule explicitly sought to avoid. Moreover, the lack of robust discussion on exactly how SIP participants will come to the conclusion that a recall is “necessary” indicates that the State’s recall plan is insufficient.

FDA states that “a drug recall is the most effective way to protect the public from a defective or potentially harmful product.”<sup>97</sup> Under Florida’s SIP, the plan is so unclear that an inability to successfully carry out a recall may cause patient harm.

The return plan suffers from similar flaws, identifying a chain of reporting but failing to specify who in the supply chain will determine that a recalled prescription drug can be returned to market, or what criteria will be utilized to make that determination.<sup>98</sup>

### **b) Compliance Plan**

In the Final Rule, FDA added a requirement for the SIP Proposal to include the SIP’s compliance plan for FDA’s authorization.<sup>99</sup> Manufacturer compliance plans typically include the

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<sup>92</sup> 21 C.F.R. § 251.3(e)(13).

<sup>93</sup> *Id.* § 251.18(e).

<sup>94</sup> Proposal at 31.

<sup>95</sup> *Id.* at 33.

<sup>96</sup> 21 C.F.R. § 251.18(e)(2).

<sup>97</sup> FDA, *Drug Recalls*, <https://www.fda.gov/drugs/drug-safety-and-availability/drug-recalls>.

<sup>98</sup> Proposal at 33–34.

<sup>99</sup> 21 C.F.R. § 251.3(e)(15). The compliance plan must include (i) a description of the division of responsibilities among co-sponsors, if any, which includes a plan for timely communications of any compliance issues to the SIP Sponsor; (ii) identification of responsible individual(s) and a description of the respective area(s) of the SIP, the FDCA, or Part 251 that will be under each responsible individual’s oversight; (iii) the creation of written compliance policies, procedures,

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development of a compliance committee, a program for internal monitoring and auditing of compliance, and well-established processes for disciplinary actions for noncompliance. Florida's compliance plan is insufficient and lacks multiple elements required under the Final Rule.

The Proposal fails to provide adequate assurances that AHCA and DBPR will oversee an independent review and consistently conduct monitoring and performance. Instead, it provides unsupported, conclusory statements that AHCA and DBPR will monitor performance and ensure compliance, that other SIP participants and their designees and subcontractors will submit "detailed reports" on their performance, and that AHCA and DBPR will conduct on-site visits.<sup>100</sup> What is missing is a set of objective criteria for the SIP Sponsor to utilize to ensure that all requirements are met.

Additionally, the division of compliance responsibilities among supply chain entities remains unclear. The Final Rule requires the SIP Proposal to include "a description of the division of responsibilities among co-sponsors," but the Proposal includes only two sentences stating that AHCA, "acting as the importation program sponsor, will manage the contract with the importer or its designee and monitor its performance. As the importation program co-sponsor, DBPR will collaborate with the Agency to ensure that the importer or its designee and subcontractors comply with state and federal prescription drug wholesale and distribution regulations."<sup>101</sup> The Proposal provides even less clarity on the division of labor among parties that will operationalize the SIP, simply stating that the contract between AHCA and LSL will "outline delegated duties."<sup>102</sup>

Furthermore, the Proposal does not include specific forward-looking written compliance policies, procedures and protocols. The Proposal states that the AHCA "will maintain policies that govern how this program will operate" and "approve the standard operating procedures that are developed by [LSL] in the operation of the program, on the State's behalf."<sup>103</sup> Additional rules specific to prescription drug importation will be provided in the contract between AHCA and LSL, and potentially in multiple contracts or agreements with additional third parties. Without evaluating the specific policies, procedures, and protocols themselves, FDA cannot determine whether they are sufficient. Nor can FDA simply rely on Florida's assurance that AHCA can ensure compliance by imposing a corrective plan, assessing liquidated damages, or terminating the agreement if the Importer or subcontractors do not adhere to the contract's terms and conditions.<sup>104</sup> As stated in the Final Rule, the State must develop policies

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and protocols; (iv) the provision of education and training to ensure that Foreign Sellers, Importers, qualifying laboratories, and their employees understand their compliance-related obligations; (v) the creation and maintenance of effective lines of communication, including a process to protect the anonymity of complaints and to protect whistleblowers; and (vi) the adoption of processes and procedures for uncovering and addressing noncompliance, misconduct, or conflicts of interest. *Id.*

<sup>100</sup> Proposal at 35.

<sup>101</sup> *Id.*

<sup>102</sup> *Id.* at 37.

<sup>103</sup> *Id.*

<sup>104</sup> *Id.* at 38.

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and procedures to uncover and address noncompliance, misconduct, and conflicts of interest *before* the SIP is approved.

**C. The Proposal does not demonstrate that the SIP entities have the fiscal resources and capacity necessary to ensure that drugs imported under the SIP would be safe.**

The Final Rule assigns SIP Sponsors responsibility for administering SIPs. But states lack the know-how to ensure that drug supply chain participants are compliant with CGMP and good distribution practices; do not have the systems in place to inspect drug supply chain participants; play no role in implementing the DSCSA; lack expertise with pharmacovigilance;<sup>105</sup> and do not effectuate product recalls and returns. States seeking to pursue commercial importation will need to budget appropriate resources to fulfill these responsibilities. However, Florida's Proposal provides no explanation of how the importation program will be funded. State regulators already are strapped for resources, and failure to budget adequate funds could impede the State's efforts to secure the safety of the drug supply.<sup>106</sup>

Additionally, the Final Rule vests Importers with new responsibilities that greatly exceed those of typical state-licensed wholesale distributors or pharmacies,<sup>107</sup> such as tracing imported drugs throughout the supply chain to ensure CGMP compliance and carrying out pharmacovigilance responsibilities. It also imposes new responsibilities on Foreign Sellers, such as serialization.<sup>108</sup> The Proposal does not address whether DOH Central Pharmacy has the requisite expertise or operational capacity. Assigning such tasks to an underfunded and capacity-constrained entity would inevitably increase safety risks (as well as require substantial investments, the recoupment of which would greatly reduce, if not eliminate, any purported cost savings from importation).

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<sup>105</sup> PhRMA, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 22 (Mar. 9, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1236>.

<sup>106</sup> Nat'l Ass'n of Boards of Pharmacy, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 4 (Mar. 4, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-1082> ("This Proposal comes at a time when boards of pharmacy around the country are feeling pressure to do more with less. It is vital that the very expertise the Proposal contemplates utilizing within the state government is sufficiently resourced to handle the incredibly important safety obligations this Proposal would place on Sponsors."); Partnership for Safe Medicines, Comment Letter on NPRM, Docket No. FDA-2019-N-5711, at 3-4 (Feb. 11, 2020), <https://www.regulations.gov/document?D=FDA-2019-N-5711-0055> ("Law enforcement and regulators are already struggling to inspect large volumes of pharmaceuticals coming over the U.S. border, including deadly fentanyl and other drugs masquerading as legitimate medicine. These resource-strapped regulators will not have the ability to oversee an importation program under the proposed rule and would not be able to protect the public health. Moreover, a state importation program would stretch resources even more, exacerbating risks already posed by counterfeit medicines.").

<sup>107</sup> PhRMA Comment Letter at 3.

<sup>108</sup> 21 C.F.R. § 251.14(c).

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### **VI. The Proposal fails to demonstrate how the SIP will result in a significant reduction in the cost to the American consumers as required by the statute and the Final Rule.**

As discussed above in Section III, Section 804 requires a demonstration that importation will lead to a “significant reduction in the *cost of covered products to the American consumer*.”<sup>109</sup> The Final Rule purports to allow for consumer cost savings to be demonstrated in other ways, such as by increasing the number of people covered by a State program, or increasing the availability of drugs covered by the program.<sup>110</sup> Even if that were permitted by the statute (and it is not), the Proposal provides no indication that the SIP program will lead to any—let alone significant—reduction in cost to consumers. The Proposal estimates only that, for the first year, the SIP will save the *State* “approximately \$80 to \$150 million.”<sup>111</sup> This provides no indication that the Proposal will reduce costs to *consumers*. Moreover, the Proposal lacks factual support to justify its wide-ranging estimates. Lastly, the Proposal ignores substantial start-up and administrative costs which will limit the State’s cost savings or eliminate any savings entirely.

#### **A. The Proposal focuses on purported savings to the State, without demonstrating that consumers would see a benefit.**

Both the FDCA and the Final Rule require a demonstration of “significant” cost savings to consumers.<sup>112</sup> Indeed, FDA states in the preamble to the Final Rule that a SIP Proposal should “clearly articulate the mechanism by which the proposal will reduce costs to consumers” and “provide relevant information given that context.”<sup>113</sup> By contrast, Florida seeks approval based on purported savings to the State itself. Florida’s SIP is limited to patients who receive medications through State agencies and government programs, namely the Department of Health, the Department of Corrections, the Department of Children and Families, the Agency for Persons with Disabilities, and the AHCA.<sup>114</sup> Through importation, the Proposal argues, the State will “be able to reap significant savings” by obtaining lower prices on government-purchased drugs.<sup>115</sup>

Whereas savings to the State are discussed in relative detail,<sup>116</sup> the Proposal devotes a single paragraph to potential consumer savings, proposing several ways in which consumers *might* see a benefit. For example, the Proposal states that, since some government programs are

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<sup>109</sup> FDCA § 804(l)(1)(B).

<sup>110</sup> 85 Fed. Reg. at 62,101; *see also* 21 C.F.R. § 251.3(d)(11)(v), (e)(9).

<sup>111</sup> Proposal at 7. The Proposal further states projects “over \$150 million” in annual savings upon full implementation. *Id.* at 22.

<sup>112</sup> FDCA § 804(l)(1)(B); 21 C.F.R. § 251.3(d)(11)(v), (e)(9).

<sup>113</sup> 85 Fed. Reg. at 62,101.

<sup>114</sup> Proposal at 3.

<sup>115</sup> *Id.*

<sup>116</sup> In support of its estimates, the Proposal includes a table listing six HIV/AIDS drugs and presenting the estimated difference between the total spend in the first quarter of 2018 and the potential spend (based on Canadian unit costs). *Id.* at 22.

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funded with both State and Federal dollars, “any savings derived will benefit all American taxpayers.”<sup>117</sup> It also provides that State savings can be reinvested in other programs/services that support Floridians.”<sup>118</sup> However, these savings mechanisms are purely speculative and wholly unrelated to the cost of prescription drugs for consumers, which is the statutory requirement.

Additionally, the Proposal concludes that state savings can be used to offset copayment amounts “[t]o the extent consumers pay co-payments on the imported drugs.”<sup>119</sup> This savings mechanism is inconsistent with the statutory requirement that cost savings be calculated based on a patient’s out-of-pocket costs for the covered product. Moreover, the Proposal offers no estimates for these indirect cost savings, nor does it provide a methodology for how such savings could be calculated.

### **B. The Proposal lacks factual support to justify its wide-ranging cost savings estimates.**

Under the Final Rule, the SIP Sponsor must provide a “sufficiently detailed” explanation of the purported cost savings that includes “any assumptions and uncertainty,” in order to “allow for a meaningful evaluation.”<sup>120</sup> Florida estimates that the State will recognize \$80 to \$150 million in savings for the State in the first year, and over \$150 million in annual savings once the program is fully implemented. However, the Proposal does not explain how these figures were calculated, nor provide an adequate explanation for the enormous range.

The sole evidence provided to support Florida’s purported cost savings is a table listing six HIV/AIDS drugs and presenting the estimated difference between the total spend in the first quarter of 2018 and the potential spend (based on Canadian unit costs).<sup>121</sup> The final row of the table indicates a total estimated difference of approximately \$20 million for this subset of drugs. This corresponds to \$80 million in annual savings, the lower limit of the State’s estimates, but Florida does not explain how it arrived at the \$150 million figure for the whole program. The lack of factual support, as well as the \$70 million range in potential savings undermine any meaningful review by FDA.

### **C. The Proposal ignores significant costs associated with establishing and administering an importation program.**

Florida’s purported cost savings estimates are further clouded by the fact that the State fails to account for significant costs associated with importation. The Proposal provides that the State has included a markup on the Canadian price to account for costs potentially imposed by the Foreign Seller. We assume that this markup will be provided in a subsequent submission once the Foreign Seller is identified. However, costs imposed by the Foreign Seller represent only a small fraction of the total cost of establishing and administering an importation program. The creation and operation of the SIP will require substantial investments across the supply chain, since, as provided above, AHCA, DBPR, and LSL will need to undertake responsibilities

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<sup>117</sup> *Id.*

<sup>118</sup> *Id.*

<sup>119</sup> *Id.* at 22–23.

<sup>120</sup> 21 C.F.R. § 251.3(e)(9).

<sup>121</sup> Proposal at 22.



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traditionally handled by manufacturers. Florida also would incur costs related to Statutory Testing, repackaging and relabeling, and entering into relationships with LSL and other contracted agencies.

A SIP Sponsor cannot obtain approval by noting the price differential between FDA-approved drugs and their so-called “Canadian equivalents,” because such figures do not account for the actual costs associated with importation. Without transparency regarding start-up and administrative costs, FDA cannot determine whether the SIP Proposal meets statutory and regulatory requirements.

### **VII. The Proposal Suffers From Additional Flaws.**

The Proposal suffers from additional legal flaws. Florida’s importation plan lacks sufficient protection of trade secrets and confidential commercial information (“CCI”), leaving manufacturers vulnerable to significant damage if such information is released to the public. The failure of the proposed labeling to adequately distinguish between SIP drugs and drugs under the control of the manufacturer raise additional risk of reputational harm. Furthermore, the Proposal omits data points necessary for FDA to provide a thorough evaluation of the SIP.

#### **A. The Proposal lacks strong protection of trade secrets and CCI.**

The Final Rule requires manufacturers either to conduct Statutory Testing themselves or to divulge highly confidential trade secrets and CCI to Importers to facilitate the authentication of drugs and their labeling.<sup>122</sup> In apparent recognition of manufacturers’ significant intellectual property rights in their drugs and trade secrets, the Final Rule requires a SIP Proposal to explain how the SIP Sponsor will ensure that trade secrets and CCI “are kept in strict confidence and used only for the purposes of testing or otherwise complying” with the FDCA and Part 251.<sup>123</sup>

The Proposal pays scant attention to how this valuable and highly confidential information will be protected. For example, while the Proposal provides that the trade secrets or CCI in documents submitted to DBPR or obtained during an inspection will not be disclosed “if sought through a public records request,” it does not provide appropriate safeguards against any theft or misuses.<sup>124</sup> Manufacturers invest in security systems with multiple layers of protections to ensure that trade secrets and CCI are kept confidential, yet no such systems are identified in the Florida Proposal. Even with their sophisticated security systems, pharmaceutical companies are targeted by cybercriminals, and Importers and laboratories are even easier targets, as many have not invested in sophisticated security systems. Manufacturers could suffer significant economic effects if such information became public.

#### **B. Failure to adequately incorporate SIP-specific language in the labeling could lead to reputational harm for manufacturers.**

The Final Rule requires that a SIP Proposal include copies of the FDA-approved drug labeling for the FDA-approved counterpart of the eligible prescription drug, a copy of the proposed labeling that will be used for the eligible prescription drug, and a side-by-side

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<sup>122</sup> 21 C.F.R. § 251.16(b).

<sup>123</sup> *Id.* § 251.3(e)(16).

<sup>124</sup> Proposal at 40.

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comparison of the FDA-approved labeling and the proposed labeling, including the Prescribing Information, carton and container labeling, and patient labeling, with all differences annotated and explained.<sup>125</sup> By contrast, the Proposal includes only a comparison of the carton and container labeling and basic information of a sample drug—efavirenz, emtricitabine and tenofovir disoproxil fumarate tablets.<sup>126</sup> The sample drug labeling does not include any prescribing information or patient labeling for that sample drug.

Drug labeling must distinguish between a SIP drug, distributed by an Importer, and other drugs under the control of the manufacturer. Improper repackaging and relabeling can adversely impact the manufacturer's reputation and good will in the market by associating its brand with products that manufacturers cannot vouch for or control. For example, failure to incorporate or poor incorporation of SIP-specific language in the labeling can lead consumers to believe that the imported drug was sponsored or approved by the manufacturer, even though it was not. Additionally, adverse events inappropriately linked to the manufacturer through unclear labeling will cause negative financial and reputational repercussions, which could extend to the manufacturer's other products.

### **C. The Proposal lacks requisite information required for FDA to evaluate the SIP.**

There are several other deficiencies associated with the Proposal with respect to information about the NDA/ANDA holders and manufacturers of the eligible drugs and the commercial availability of FDA-approved counterparts. The Final Rule requires SIP Sponsors to include such information in their SIP Proposals, and Florida's failure to do so militates against approval.

First, the Proposal fails to include the name and address of the applicant that holds the NDA or ANDA for each eligible prescription drug's FDA-approved counterpart.<sup>127</sup> The Proposal also does not include the name and address of the manufacturer of the finished dosage form, active ingredient, and ingredients of the eligible prescription drug, without providing an explanation for why that information is not known or reasonably known.<sup>128</sup> Instead, the Proposal simply claims that the State has not secured agreements from manufacturers.<sup>129</sup>

Second, the Proposal indicates that the State has verified that each drug proposed for importation has an FDA-approved counterpart that is "readily available in the U.S. market."<sup>130</sup> However, the Proposal does not include any evidence to support such a statement, much less "adequate evidence that each [Health Products and Food Branch]-approved drug's FDA-approved counterpart drug is currently commercially marketed in the United States."<sup>131</sup>

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<sup>125</sup> 21 C.F.R. § 251.3(d)(11)(iii), (e)(8). The SIP Proposal must also include a copy of the HPFB-approved labeling. *Id.* § 251.3(e)(8).

<sup>126</sup> Proposal 111–13. The Proposal states that additional labeling will be included "in a forthcoming submission." *Id.* at 21.

<sup>127</sup> 21 C.F.R. §§ 251.3(d)(4), 251.3(e)(1).

<sup>128</sup> *Id.* §§ 251.3(d)(5)–(6), 251.3(e)(1).

<sup>129</sup> Proposal at 8.

<sup>130</sup> *Id.* at 17.

<sup>131</sup> 21 C.F.R. § 251.3(e)(6).

**VIII. FDA should publicly disclose Foreign Sellers to promote transparency, due process, and international coordination.**

Petitioner requests that FDA disclose the name of Foreign Sellers in SIPs, and in particular, the name of the Foreign Seller added to Florida's Proposal as soon as the State provides the relevant information to FDA.

The public interest undoubtedly weighs in favor of disclosure here because, as argued above, the SIP must meet the statutory criteria for safety and cost savings to the American consumer and the identity of the Foreign Seller is critical to assessing whether those criteria can plausibly be met. Furthermore, disclosing the identity of the Foreign Seller is critical for promoting transparency and due process, particularly in the context of a novel and untested program. It is impossible for a petitioner to fully comment on a SIP Proposal without information on the Foreign Seller. The responsibilities of the Foreign Seller, like those of the Importer, are new and much greater than the responsibilities of a typical state-licensed wholesale director or pharmacy, and the public should have the opportunity to comment on whether the SIP Sponsor has demonstrated that the Foreign Seller is capable of fulfilling such functions. Disclosure of the Foreign Seller also is important for promoting international harmonization. Under a recently released interim order, the Canadian government may take action with respect to the Foreign Seller if its plans to export drugs would cause or exacerbate a drug shortage in Canada.<sup>132</sup> Public identification of the Foreign Seller would allow relevant federal and state regulatory bodies to coordinate with their Canadian counterparts.

The identity of the Foreign Seller is not confidential business information that FDA must protect from disclosure. FDA asserts in the preamble to the Final Rule that it “do[es] not intend to publicly disclose information from the SIP Proposal or authorization that is confidential business information where such disclosure is restricted by law, *potentially* including information about Foreign Sellers or the eligible prescription drugs that might be imported.”<sup>133</sup> Commercial or financial information is considered confidential within the meaning of the Freedom of Information Act (“FOIA”) under Exemption 4 where it is both customarily and actually treated as private by its owner and is provided to the government under an assurance of privacy.<sup>134</sup>

However, it is far from clear whether States would treat the identity of the Foreign Seller as confidential. As the preamble to the Final Rule recognizes, the information may become public through disclosure of state open records laws.<sup>135</sup> State open records laws may require public dissemination of the identity of the Foreign Seller if, for example, the State does not

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<sup>132</sup> Specifically, the Interim Order prohibits Canadian “establishment licence” holders from distributing drugs “for consumption or use outside Canada unless the [licence holder] has reasonable grounds to believe that the distribution will not cause or exacerbate a shortage of the drug.” Interim Order Respecting Drug Shortages (Safeguarding the Drug Supply) § 2 (Nov. 27, 2020), <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/importation-exportation/interim-order-drug-shortages-protecting-supply.html>.

<sup>133</sup> 85 Fed. Reg. at 62,100 (emphasis added).

<sup>134</sup> *Food Marketing Inst. v. Argus Leader Media*, 139 S. Ct. 2,356, 2,366 (2019).

<sup>135</sup> 85 Fed. Reg. at 62,100.

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consider the identity of the Foreign Seller to be confidential business information, the information is voluntarily provided to a state agency without a promise of confidentiality, the information is submitted to the agency as required by law or conditioned on receipt of a governmental contract or other benefit, or the public's interest in disclosure weighs in favor of disclosure. The Florida Constitution creates a right of access to public records unless the records in question have been exempted or specifically made confidential,<sup>136</sup> and the State has not indicated in its SIP Proposal that the Foreign Seller's identity would be confidential. FDA has the burden of demonstrating that FOIA Exemption 4 properly applies to the identity of the Foreign Seller,<sup>137</sup> and so may not decline to disclose the identity of the Foreign Seller unless it has received information from the State sufficient to demonstrate that the relevant state's law would provide for confidential treatment and all other requirements of Exemption 4 are met.

Additionally, the identity of the Foreign Seller will have to be disclosed to the manufacturer, who has no obligation to keep the Foreign Seller's identity confidential. The regulations require that "the manufacturer must provide to the Importer, within 30 calendar days of receiving the Importer's request, a copy of all transaction documents that were provided from the manufacturer to the Foreign Seller."<sup>138</sup> Obviously, a manufacturer cannot provide copies of these documents without knowing the identity of the Foreign Seller. Moreover, nothing in the regulations requires manufacturers to keep the identity of the Foreign Seller confidential. Thus, by definition FDA cannot claim that the identity of a Foreign Seller is provided with an express or implied assurance of confidentiality.

### **IX. Conclusion**

For the reasons explained above, FDA should refrain from authorizing the Proposal. The Proposal was submitted pursuant to an invalid Certification and an unlawful Final Rule, and cannot be approved for the reasons described in the litigation. In addition, the Proposal fails to satisfy either of the primary criteria for authorization. Florida does not adequately demonstrate that importation will pose no additional risk to public health and safety, and it fails to show that importation will lead to any reduction—let alone a significant reduction—in the cost of prescription drugs for consumers. Other deficiencies in the Final Rule raise issues of reputational harm for manufacturers and inhibit FDA from conducting a thorough review. Moreover, the failure to submit the identity of the Foreign Seller for public comment interferes with the public's ability to provide a thorough assessment of the proposed importation scheme and should be rectified by FDA making the identity of the Foreign Seller publicly available.

### **X. Environmental Impact**

Petitioner claims a categorical exclusion under 21 C.F.R. § 25.30.

### **XI. Economic Impact**

Petitioner will submit economic information upon request of the Commissioner.

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<sup>136</sup> Fla. Const. art. 1, § 24(a); Fla. Stat. § 119.07(1).

<sup>137</sup> *Citizens for Responsibility & Ethics in Wash. v. U.S. Dep't of Justice*, 746 F.3d 1,082, 1,088 (D.C. Cir. 2014).

<sup>138</sup> 21 C.F.R. § 251.14(b).

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**XII. Certification**

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

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