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

CITIZEN PETITION

Covington & Burling, LLP respectfully submits this Citizen Petition on behalf of its client, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), pursuant to 21 C.F.R. § 10.30. This Petition requests that the Secretary of Health and Human Services and the Commissioner of Food and Drugs take the actions set forth below with respect to the grant of case-by-case waivers of the prohibition on importation set forth in section 804(j)(2) of the Federal Food, Drug, and Cosmetic Act ("FDCA").

A. Actions Requested

Through this petition, and for the reasons explained in more detail below, PhRMA respectfully requests that the U.S. Food and Drug Administration ("FDA" or "Agency") and the U.S. Department of Health and Human Services ("HHS"):

1) Discontinue section 804(j) implementation efforts, including withdraw HHS and FDA's "Request for Proposals Regarding Waivers for Individual Drug Importation Plans"[1] and refrain from approving any Individual Waiver Importation Plans; or

2) Refrain from granting waivers to authorize personal importation pursuant to section 804(j)(2) unless and until HHS:

    a. Certifies to Congress, after an appropriate notice-and-comment proceeding, that the implementation of section 804 of the FDCA, including section 804(j), poses no additional risk to the public's health and safety and results in a significant reduction in the cost of covered products to the American consumer;

    b. Publishes a final guidance document in accordance with FDA's Good Guidance Practices that describes the circumstances under which the Secretary will grant case-by-case waivers prior to issuing any waiver pursuant to section 804(j)(2);

[1] HHS and FDA, *Request for Proposals Regarding Waivers for Individual Prescription Drug Importation Plans* (Sept. 24, 2020), https://www.hhs.gov/sites/default/files/individual-prescription-drug-importation-programs.pdf.

c. Grants case-by-case waivers to individuals solely in compliance with statutory requirements applicable to personal importation under the FDCA;

d. Follows the appropriate due process procedures for informal adjudications under the Administrative Procedure Act ("APA"); and

e. Publishes notice of any approvals of any individual drug importation plans or grants of case-by-case waivers immediately upon issuance.

B. Statement of Grounds

I. Executive Summary

On July 24, 2020, President Trump announced an Executive Order directing the HHS Secretary to facilitate grants of waivers of the prohibition on importation of prescription drugs, provided that such importation poses no additional risk to public safety and results in a lowering of costs to prescription drugs.[2] The Executive Order cites section 804(j)(2), a provision of the FDCA governing certain aspects of personal importation.

HHS has sought to implement the President's directive by announcing a novel program to authorize Individual Waiver Importation Plans ("IWIPs"). HHS's "Request for Proposals Regarding Waivers for Individual Drug Importation Plans" ("RFP") describes a mechanism by which pharmacies, distributors, and wholesalers ("sponsors") can seek approval of an IWIP to import certain allowable drugs from specified countries.

HHS's IWIP program constitutes a significant departure from requirements of both the FDCA and the APA. First, HHS is proceeding to implement section 804(j)(2) without having met the threshold requirements of section 804, including certification that implementation of that section will pose no additional risk to the public's health and safety and result in a significant reduction in the cost of covered products to the American consumer.[3] To the contrary, HHS has expressly declined to certify the personal importation provisions, and it lacks any factual basis to do so. For decades, seven HHS Secretaries in four Administrations, across political parties, have refused to certify section 804 and implement the personal importation provisions because of serious concerns about the potential for this pathway to result in patients receiving unapproved, adulterated, and misbranded drugs.

Second, the IWIP program impermissibly conflates personal importation with commercial importation. The personal importation provisions of section 804 contemplate importation by *individuals*, while the commercial importation provisions contemplate importation by *entities*, including pharmacies and wholesalers. The waiver from the prohibition of importation that may be available to individuals under section 804(j) does not apply to commercial entities. Because commercial importation is likely to occur on a larger scale than individualized personal importation, the FDCA imposes additional conditions and limitations on the former that do not apply to the latter. By developing a system for commercial entities to engage in "personal" importation, the RFP makes an impermissible end-run around the safeguards that Congress imposed to reduce the risks associated with commercial importation.

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[2] Exec. Order No. 13,938, § 2(a), 85 Fed. Reg. 45,757 (July 29, 2020).

[3] FDCA § 804(l).

In addition, interpreting the personal importation provisions as applicable to commercial entities without a reasoned explanation is arbitrary and capricious in light of HHS's past statements that these provisions apply to importation by individuals.

Third, the drugs that would be subject to an IWIP would be unapproved, misbranded, and likely adulterated and thus cannot be imported into the U.S. It is also likely that the IWIP drugs would violate drug supply chain security requirements under the FDCA, a prohibited act.

Fourth, HHS has failed to issue the required guidance describing the circumstances in which it intends to grant such waivers.

Fifth, HHS and FDA have, for many decades, described significant safety and cost concerns associated with personal importation. To date, HHS has not explained how the IWIP program will resolve those concerns or why those concerns, which continue to appear on FDA's website, are no longer valid. In the absence of such explanations, approval of any IWIP will be arbitrary and capricious. In addition, the IWIP program departs from statutory requirements to effectuate and implement the personal importation provisions of the FDCA, causing it to be contrary to law under the APA.

Finally, each approval of an IWIP or other grant of a case-by-case waiver is an informal adjudication under the APA. Interested persons, including manufacturers of the FDA-approved "counterparts" of the foreign-made IWIP drugs must be given notice and have an opportunity to provide input.

HHS must not grant any case-by-case waivers of the prohibition of importation pursuant to section 804(j)(2), unless and until the program comports with certification requirements and personal importation provisions of the FDCA, as well as requirements of the APA.

II. Legal and Regulatory Background

A. Importation Under Section 804 of the FDCA

Section 804 of the FDCA sets forth statutory requirements for importation of drugs into the United States. It describes two pathways for HHS to authorize the importation of certain prescription drugs from abroad, either as "commercial importation" or "personal importation." For these provisions to take effect, the Secretary of HHS must certify to Congress that the implementation of section 804, in its entirety, 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.[4]

Section 804(b) of the FDCA directs the Secretary to promulgate regulations "permitting pharmacists and wholesalers to import prescription drugs from Canada into the United States."[5] This is known as "commercial importation." The FDCA imposes a number of conditions and limitations on commercial importation in sections 804(b) through (h), including labeling conditions, reporting and recordkeeping, and laboratory testing requirements aimed at assuring authenticity.

[4] *Id.*

[5] FDCA § 804(b).

Section 804(j) of the FDCA concerns personal importation. Section 804(j)(2), the subject of HHS's IWIP program, authorizes the Secretary of HHS to grant waivers of the prohibition on importation "to *individuals*, by regulation or on a case-by-case basis . . . under such conditions as the Secretary determines to be appropriate."[6] The FDCA goes on to require the HHS Secretary to

> publish, and update as necessary, guidance that accurately describes the circumstances in which the Secretary will consistently grant waivers on a case-by-case basis . . . , so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.[7]

The statutory framework thus makes clear that Congress intended pharmacists and wholesalers to engage in commercial importation and individuals to engage in personal importation. Congress' intent to distinguish between personal and commercial importation is evident in the legislative history of section 804. The Medicine Equity and Drug Safety Act of 2000 ("MEDS Act"), which established the predecessor text to the current section 804, authorized the Secretary to "promulgate regulations permitting pharmacists and wholesalers to import into the United States covered products," subject to limitations designed to help assure safety and efficacy.[8] The MEDS Act limited importation under these new provisions to pharmacies and wholesalers. It did not authorize personal importation. In the debates leading up to enactment of the MEDS Act, Congress considered and affirmatively rejected a personal importation provision. One Senator observed that an amendment then under consideration "dropp[ed] a provision in [the] original bill that would have allowed personal imports" in order to "answer concerns that some raised about safety."[9]

Instead, the MEDS Act established the circumstances under which FDA may send a "warning notice" to an individual who is not in the business of importing drugs into the United States.[10] Among other things, the legislation provided that

> [f]or purposes for this section, the term "warning notice," with respect to the importation of a drug, means a communication from the Secretary (written or otherwise) notifying a person, or clearly suggesting to the person, that importing the drug for personal use is, or appears to be, a violation of this Act.[11]

Congress's express rejection of personal importation in the very legislation that created a potential commercial importation pathway, taken together with that same legislation's

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[6] FDCA § 804(j)(2)(A) (emphasis added).

[7] FDCA § 804(j)(2)(B).

[8] Pub. L. No. 106-387, § 745, 114 Stat. 1549, 1549A-35, 1549A-36 (2000).

[9] 146 Cong. Rec. 15,411 (2000) (statement of Sen. Jeffords).

[10] Pub. L. No. 106-387, § 746, 114 Stat. 1549, 1549A-40 - 1549A-41 (2000); FDCA § 801(g)(1).

[11] *Id*. at 114 Stat. 1549A-41.

description of individuals importing drugs for personal use in the context of a warning notice, demonstrated a clear and intentional distinction between commercial and personal importation.

Congress preserved this distinction when it enacted the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), which reflects the current text of section 804 of the FDCA.[12] There, Congress created a potential personal importation pathway, following section 804(l) certification, provided certain requirements are met, including a requirement that the importation be limited to individuals. Congress continued to provide a pathway for pharmacies and wholesalers to engage in commercial importation of drugs from Canada.[13]

Separate and apart from legislation, FDA has, for decades, maintained an enforcement discretion policy that provides for individuals to engage in personal importation of prescription drugs notwithstanding any statutory prohibition, provided certain conditions are met. Circumstances in which FDA does not object to an individual bringing an unapproved prescription drug into the country include: [14]

1. when the intended use is appropriately identified, such use is not for treatment of a serious condition, and the product is not known to present a significant health risk; and

2. when: (a) the intended use is unapproved and for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means; (b) there is no known commercialization or promotion to persons residing in the U.S. by those involved in the distribution of the product at issue; (c) the product is considered not to represent an unreasonable risk; *and* (d) the individual seeking to import the product affirms in writing that it is for the patient's own use (generally not more than 3 month supply) and provides the name and address of the doctor licensed in the U.S. responsible for his or her treatment with the product, or provides evidence that the product is for the continuation of a treatment begun in a foreign country.

B. Regulatory History of Personal Importation

Until this RFP, HHS and FDA have maintained a consistent and longstanding position that personal importation is not a viable pathway to import drugs under section 804 because of dangers in the supply chain. In 2004, pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, an HHS task force published a report to Congress ("Task Force Report") detailing its findings regarding safety and cost of various forms of importation, including personal importation. 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. Findings in the report include:

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[12] Pub. L. No. 108-173, 117 Stat. 2066, 2464-69(2003).

[13] *Id*. at § 1121, 117 Stat. 2464(providing that under Sec. 804(a)(1), "[t]he term 'importer' means a pharmacist or wholesaler"); FDCA § 804(a).

[14] *See* FDA, *Regulatory Procedures Manual*, Chapter 9: Import Operations and Actions 9-2-5 (Oct. 2020), https://www.fda.gov/media/71776/download.

- "It would be extraordinarily difficult and costly for 'personal' importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs."[15]

- "Personal importation creates numerous vulnerabilities in the drug distribution system, making it extraordinarily difficult to ensure that imported drugs are safety and effective, and putting patients at risk."[16]

- "Personal shipments of imported drugs may not contain the U.S.-approved formulations or include the U.S.-approved label and required patient information."[17]

- "Legalizing personal importation in the U.S. could lead to the proliferation of [rogue] internet pharmacies. Because of the ease with which such websites can be established and obscure their physical location, it would be nearly impossible to monitor, find, or inspect all of these pharmacies. Furthermore, the volume of packages entering the U.S. today has been increasing at a steady rate. Under a personal importation program, it would be very difficult to distinguish which of these millions of packages are from 'permitted' internet pharmacies and which are from rogue websites, increasing the potential safety risks associated with imported drugs."[18]

As recently as February 2020, FDA issued a press release describing concerns about shipments through international mail. FDA Commissioner Stephen Hahn stated that

> [w]ith standards and regulations varying in each country, U.S. consumers face hazards when they order drugs and other FDA-regulated products from unauthorized foreign sources and receive them through the international mail system. Consumers and physicians purchasing medicines cannot be assured the products they are receiving are legitimate, safe or effective if they are obtained from outside of the FDA-regulated pharmaceutical supply chain.[19]

FDA also sent a warning letter in February 2019 to CanaRx for violating the FDCA by "facilitating the distribution of unapproved new drugs and misbranded drugs to U.S. consumers," noting that "[t]hese drugs are potentially dangerous to U.S. consumers." FDA's press release announcing the warning letter states that

> [w]hen a consumer goes online to buy medicines purportedly from Canada, they may get a medicine sourced from elsewhere that could

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[15] HHS, *HHS Task Force Report on Drug Importation* XIII (Dec. 2004), http://www.safemedicines.org/wp-content/uploads/2018/03/HHS-Report1220.pdf.

[16] *Id*. at 44.

[17] *Id*. at 54.

[18] *Id*. at 19.

[19] Press Release, FDA, *FDA Takes Action with Indian Government to Protect Consumers From Illicit Medical Products* (Feb. 18, 2020), https://www.fda.gov/news-events/press-announcements/fda-takes-action-indian-government-protect-consumers-illicit-medical-products.

> be counterfeit, expired or misbranded. While operations or illegal online pharmacies may state on their websites that its medicines are coming from Canada, the United Kingdom, Australia, etc., this is not necessarily always the case. Such operations and illegal online pharmacies take advantage of unsuspecting Americans by purporting to distribute safe and effective imported drugs, at least some of which are instead expired, mislabeled, subject to recalls or potentially counterfeit and that are provided outside of the closed American distribution system meant to protect patient safety. Such schemes are particularly egregious, as they deceive patients and their employers who provide prescription drug coverage. Operations like CanaRx use their names to imply that patients are receiving medicines approved in Canada, when it's likely that patients are receiving medicines from other countries, and which may be sub-potent, super-potent or counterfeit.[20]

Citing safety concerns, FDA expressly excluded personal importation from its 2019 proposed rule and 2020 final rule to implement provisions of section 804. FDA explained its concerns with consumers' instant access to prescription medicines online:

> Medications that are purchased online and imported through international mail, express couriers, and other means pose significant challenges for FDA and its ability to adequately safeguard the quality and safety of drugs taken by U.S. consumers. . . . [T]here are many rogue online pharmacies that sell medicines at deeply discounted prices, often without requiring a prescription or adhering to other safeguards followed by pharmacies licensed by a State in the United States. These rogue online pharmacies are often run by sophisticated criminal networks that knowingly and unlawfully cause the importation of adulterated, counterfeit, misbranded and unapproved drugs into the United States. These criminals frequently use sophisticated technologies and are backed by larger enterprises intent on profiting from illegal drugs at the expense of American patients. Consumers go to these websites believing they are buying safe and effective medications, but often they are being deceived and put at risk by individuals who put financial gain above patient safety.[21]

The Agency provided an example regarding Canada Drugs Ltd., an internet-based pharmacy located in Canada, that purchased drugs "from questionable sources that were outside FDA's closed supply chain" and "put the public health at risk through widespread sales of misbranded and unapproved drugs to U.S. consumers at discounted prices."[22] In two instances,

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[20] Press Release, FDA, *FDA Warns CanaRx for Selling Unapproved, Misbranded, and Unsafe Imported Drugs to Unsuspecting Americans* (Feb. 28, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-canarx-selling-unapproved-misbranded-and-unsafe-imported-drugs-unsuspecting-americans.

[21] 84 Fed. Reg. 70,796, 70,800 (Dec. 23, 2019) (citations omitted).

[22] *Id.*

Canada Drugs, through a subsidiary, distributed counterfeit versions of cancer drugs Avastin and Altuzan, which contained no active ingredient, to U.S. healthcare providers, tried to conceal the problem, and never notified FDA or other U.S. authorities.[23] FDA further noted that in many instances drugs are promoted as being from Canada or approved by Canadian authorities when they are neither from Canada nor approved. To illustrate that "these drugs are obtained from ever-evolving illicit sources of supply," FDA cited a 2005 FDA analysis of drugs imported through International Mail Facilities revealing that "while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of those drugs originated elsewhere and were fraudulently represented as Canadian."[24] The Agency warned that these drugs typically "are smuggled into the United States after being transshipped to third party countries, such as Canada, in an effort to avoid detection and create a more trustworthy appearance."[25]

C. Implementation of 21 U.S.C. § 804(j)(2), Individual Waiver Importation Plans

On September 24, 2020, the Trump Administration took action to implement the July 2020 Executive Order in the form of a new program to solicit proposals for IWIPs. Under this program, which purports to implement section 804(j)(2), individuals can obtain waivers from the Secretary of HHS to receive drugs imported from an "Acceptable Foreign Source."[26]

Although the RFP states that individuals may receive waivers to import IWIP drugs, it is actually the plan's sponsor, which can be a distributor, wholesaler, or pharmacy, that would submit the IWIP.[27] And even though a commercial entity, rather than an individual, would import drugs under the IWIP program, HHS has not limited the Acceptable Foreign Source to Canada, as Congress did for commercial importation under sections 804(b)-(h). Instead, importation under an IWIP program extends broadly to Australia, Canada, the European Union or a country in the European Economic Area, Israel, Japan, New Zealand, Switzerland, South Africa, and the United Kingdom.[28]

HHS and FDA purportedly will evaluate the adequacy of the controls described in the submission to assure "that the IWIP will pose no additional risk to the public's health and safety and would result in a significant reduction in the cost of the covered products to the American consumer" and approve or deny the IWIP on that basis.[29] If approved, the sponsor would import the drug. The RFP states that the IWIP "pathway would not authorize individuals in the United States to purchase prescription drugs through the Internet, directly from a foreign pharmacy, or from any other foreign seller."[30] Instead, the patient would need to present a

[23] *Id.*

[24] *Id.*

[25] *Id.*

[26] RFP, *supra* note 1, at 1.

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

prescription to a domestic pharmacy after the sponsor has already imported it to the United States.[31]

III. HHS may not grant a waiver for personal importation unless and until it certifies section 804 of the FDCA.

Section 804, including the personal importation provisions, is ineffective unless and until the Secretary certifies to Congress that implementation of section 804 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."[32] The HHS Secretary has not made this certification with respect to personal importation and lacks a factual basis to do so. In addition, HHS cannot rely on the contents of an IWIP as the basis for certification.

A. HHS has expressly excluded personal importation from any attempted certification of section 804.

HHS has not certified section 804 with respect to personal importation.[33] As recently as the October 2020 final rule to implement the commercial importation provisions of section 804, HHS expressly excluded personal importation from its purported certification of section 804. The final rule states that HHS and FDA "are not implementing the personal importation provisions in section 804(j) of the FD&C Act through this rulemaking"[34] and that "[t]he Secretary is making [the section 804(l)] certification with regard to section 804(b) through (h) to Congress concurrent with the issuance of this final rule."[35] The final rule also acknowledges that section 804(j) would need to be certified for it to take effect.[36]

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[31] *Id.* We note, however, that as discussed further below, preventing individuals from importing drugs directly from a foreign entity does not address the safety concerns that HHS and FDA have long expressed.

[32] FDCA § 804(l).

[33] PhRMA submitted a comment to the docket for FDA's December 2019 proposed rule on commercial importation. Among other things, PhRMA disagreed with the Agency's interpretation of section 804(l) to allow HHS to certify section 804 piecemeal, i.e., to certify commercial importation provisions while excluding personal importation provisions. *See* PhRMA, Comments to Importation of Prescription Drugs; Proposed Rule, Dkt. No. FDA-2019-N-5711 (March. 9, 2020). PhRMA continues to disagree with HHS's position that it can certify the commercial importation provisions of section 804 in isolation and maintains that section 804(l) requires certification of section 804 in its entirety or not at all. HHS cannot certify for the additional reason that it cannot make the requisite findings of safety and cost reduction with regard to either personal importation or commercial importation. However, certification and implementation of the commercial importation provisions are not the subject of this Citizen Petition.

[34] 85 Fed. Reg. 62,094, 62,097 (Oct. 1, 2020).

[35] *Id.* at 62,095.

[36] *Id.* at 62,112.

B. HHS lacks a factual basis to make a section 804(l) certification with regard to personal importation.

1. HHS lacks a factual basis to conclude that personal importation under the IWIP program will pose no additional risk to the public's health and safety.

As discussed in section II.A., HHS and FDA have a long and consistent history, continuing into 2020, of concerns about the safety and cost of personal importation. For example, FDA currently maintains on its website "5 Tips for Traveling to the U.S. With Medications" stating that the Agency

> does not permit personal importation of unapproved versions of FDA-approved drugs from foreign countries. FDA cannot assure that foreign-made versions of FDA-approved drugs have been properly manufactured, are safe and effective, and are the same formulation as the FDA-approved versions.[37]

The IWIP RFP does not disavow those concerns or supply a new factual basis to reach the conclusion regarding safety and cost savings that would be required for a section 804(l) certification. For example, the 2004 Task Force was concerned that shipments obtained through personal importation "may not contain the U.S.-approved formulations."[38] The RFP and accompanying Frequently Asked Questions state that the IWIP drug must be "FDA-approved."[39] However, HHS has failed to explain how sponsors will attempt to ensure that the IWIP drug is in fact the same formulation as the drug product manufactured in the United States.

FDA has also expressed concern that patients may have the impression that they are receiving drug products from Canada when in fact the drugs were manufactured elsewhere. In 2019, FDA issued a warning letter to CanaRx, an online pharmacy, advising that "[w]hen a consumer goes online to buy medicines purportedly from Canada, they may get a medicine sourced from elsewhere that could be counterfeit, expired, or misbranded."[40] These concerns were also described in the proposed rule on importation of prescription drugs, which reported that a 2005 FDA analysis of drugs imported through International Mail Facilities revealed that

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[37] FDA, Consumer Update: *5 Tips for Traveling to the U.S. With Medications* (last visited Nov. 23, 2020), https://www.fda.gov/consumers/consumer-updates/5-tips-traveling-us-medications.

[38] Task Force Report, *supra* note 15, at 54.

[39] RFP, *supra* note 1, at 1-2; FDA and HHS, *Fulfilling President Trump's Executive Order on Facilitating Drug Importation to Lower Prices for American Patients Request for Industry Proposals for Personal Importation of Prescription Drugs*, *Frequently Asked Questions* 3 (Sept. 24, 2020), https://www.hhs.gov/sites/default/files/individual-prescription-drug-importation-faq.pdf.

[40] Press Release, FDA, FDA Warns CanaRx for Selling Unapproved, Misbranded and Unsafe Imported Drugs to Unsuspecting Americans (Feb. 28, 2019), https://www.fda.gov/news-events/press-announcements/fda-warns-canarx-selling-unapproved-misbranded-and-unsafe-imported-drugs-unsuspecting-americans.

"while nearly half of imported drugs claimed to be Canadian or from Canadian pharmacies, 85 percent of those drugs originated elsewhere and were fraudulently represented as Canadian."[41] These concerns would apply equally to drugs purportedly sourced from an "Acceptable Foreign Source."

For many years, rogue online pharmacies and other foreign actors seeking to corrupt the supply chain have been a focal point of safety and quality concerns related to personal importation. HHS evidently has sought to address that concern by preventing individuals from obtaining IWIP drugs "through the Internet, directly from a foreign pharmacy, or from any other foreign seller."[42]

HHS may claim that these safety risks have spurred it to create the IWIP program, and may argue that those risks are mitigated by the IWIP structure. This argument fails for two reasons. First, in seeking to address this safety risk, HHS created a program that unlawfully conflates personal importation and the commercial importation provisions of section 804, effectively expanding the scope of commercial importation from Canada to other countries and disregarding other statutory limitations on commercial importation. Section 804(j)(2) does not accommodate importation by commercial entities for subsequent dispensing to domestic patients. Instead, it contemplates importation by individuals who may, if section 804 is appropriately certified, receive a waiver from HHS to import drugs from abroad.[43] If HHS decides to grant case-by-case waivers for personal importation, it must do so in compliance with the FDCA, i.e., to individuals, rather than to commercial entities, to import drugs from abroad. The concerns about rogue online pharmacies and other criminal actors thus remain and, as has been the case for decades, represent a substantial factor preventing implementation of section 804(j) from meeting the safety prong of the certification requirement.

Second, even if HHS could properly eliminate internet pharmacies as a threat via the IWIP structure, this limitation would not resolve concerns about counterfeit, expired, or misbranded drug products entering the supply chain, for a number of reasons. For example, the IWIP program does not impose guardrails to ensure that drug products purportedly imported from an Acceptable Foreign Source were not originally manufactured in and transshipped from another country that is not authorized. Nor does it explain how sponsors can effectively detect and avoid bad actors who intentionally introduce counterfeit, adulterated, or misbranded drugs into the supply chain.

HHS has cited a "recent study" that "concluded that 'difficult-to-make prescription pharmaceuticals marketed in the US consistently meet quality standards even when manufactured outside the US."[44] Researchers studied "difficult-to-make" prescription solid oral dosage form drug products for dosage unit uniformity and dissolution. However, they did not evaluate other dosage forms that may be eligible for personal importation under an IWIP or examine other important quality attributes like identity or purity. Nor did the study address the

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[41] 84 Fed. Reg. at 70,800.

[42] RFP, *supra* note 1, at 1.

[43] *See* Section IV.A.1, *infra*.

[44] *See Frequently Asked Questions*, *supra* note 39, at 3 (citing Adam C. Fisher, Alex Viehmann, Melika Ashtiani, et al., *Quality Testing of Difficult-to-Make Prescription Pharmaceutical Products Marketed in the US*, JAMA Netw Open. 2020 Aug 3;3(8):e2013920).

well-documented problem of intentional introduction of counterfeit or otherwise adulterated or misbranded drugs into the supply chain.[45]

Finally, consumers may not rely on regulators to ensure that IWIP drugs are safe and not counterfeit or otherwise adulterated and misbranded. The 2004 Task Force advised that "[t]here is no realistic level of resources that could ensure that personally imported drugs are adequately inspected to assure their safety since visual inspection, testing and oversight of all personally imported prescription drugs are not feasible or practical at this time."[46] The Task Force also stated that most of the drugs imported into the United States via personal importation did not meet all of the factors set forth in FDA's enforcement discretion policy including, as described in Section II.B., that any drug intended to treat a serious condition be for the individual's personal use and generally not to exceed a three months' supply.[47] However, the Task Force noted that despite this failure, "given the high demand and limits on available resources it is difficult to effectively police this practice."[48] This enforcement concern remains true today. In Fiscal Year 2020 alone, FDA examined and sampled only 80,121 lines and 9,779 lines, respectively, of the 43,680,981 lines of FDA-regulated commodities imported into the United States.[49]

2. HHS lacks a factual basis to conclude that the IWIP program will result in a significant reduction in cost of IWIP drugs to the American consumer.

With respect to the "significant reduction in cost" prong of the section 804(l) certification, FDA stated that "[i]t would be extraordinarily difficult and costly for 'personal' importation to be implemented in a way that ensures the safety and effectiveness of the imported drugs."[50] The 2004 Task Force advised that implementing a personal importation program that even attempts to ensure that the necessary standards for a safety certification are met would require substantial additional resources, which could increase the cost of imported drugs for American consumers.[51] HHS has not sought to disclaim its past characterization of personal importation as costly to implement or to otherwise assert a factual basis to conclude that this prong of the certification requirement can be met under the IWIP program.

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[45] Fisher et al., *supra* note 44.

[46] Task Force Report, *supra* note 15, at 51.

[47] *Id.* at 5.

[48] *Id.*

[49] *See* FDA, Compliance Dashboards, *Imports Summary*, https://datadashboard.fda.gov/ora/cd/impsummary.htm (last visited Nov. 22, 2020). Import "lines" are " portions of import shipments listed separately on an entry document, often consisting of several items of the same product." Brief for Appellants at 7, *Cook v. FDA*, 733 F.3d 1 (D.C. Cir. 2013) (Nos. 12-5176, 12-5266).

[50] Task Force Report, *supra* note 15, at X.

[51] *Id.* (stating that substantial additional resources for a commercial importation program could increase the cost of imported drugs).

Even if an IWIP sponsor were capable of establishing and implementing adequate controls to secure the supply chain from the foreign manufacture of an IWIP drug through its importation and ultimate dispensing to a U.S. consumer, the cost would be prohibitive. HHS has, in fact, been hesitant to guarantee cost savings. In the Frequently Asked Questions, HHS says only that savings "would *likely* . . . be substantial," which is not the same thing as the required certification that the importation will result in a significant reduction in the cost of covered products to the American consumer.[52]

C. Even if there were a factual basis for certification, it cannot be conditioned on the contents of an IWIP.

It appears that HHS may seek to fulfill the section 804(l) certification requirement by approving IWIPs that contain controls that HHS believes will meet that standard. This approach is both procedurally and substantively flawed. First, as a procedural matter, the plain language of the FDCA requires HHS to certify that implementation of section 804 will meet the safety and cost savings criteria to Congress. Second, as a substantive matter, it is not plausible that individual IWIPs could contain the required information to meet the section 804(l) standard.

1. Relying on controls described in individual IWIPs departs from the plain language of the section 804 certification requirement.

The RFP states that the sponsor of an IWIP submission should "outline a program with controls sufficient to ensure that the IWIP will pose no additional risk to the public's health and safety and would result in a significant reduction in the cost of the covered products to the American consumer."[53] Hence, the RFP improperly delegates to private entities the responsibility to meet the standard for certification—a showing that HHS has, to this day, been unable and unwilling to make.

Seeking to effectively delegate HHS's certification obligation to private entities departs from the plain language of the FDCA in two significant respects. First, the plain text states that the *section*, meaning section 804, must be certified for section 804 to take effect. Section 804(l) of the FDCA is titled "effectiveness of this section," referring to section 804. Subsection (1), "commencement of program," provides that "[t]his section shall become effective only if the Secretary certifies to the Congress that the implementation of *this section* will" meet the required threshold for safety and cost reduction.[54] Individual sponsors addressing the safety and cost reductions associated with their IWIPs are not equipped to make such representations regarding the personal importation provisions in section 804(j), and much less 804 in its entirety.

Second, section 804(l) requires that the HHS Secretary certify to Congress that implementation of section 804, including the personal importation provisions, meets the standard described above. This requirement cannot be satisfied by IWIP sponsors making representations in support of individual certifications to HHS with each application.

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[52] *Frequently Asked Questions*, *supra* note 39, at 2.

[53] RFP, *supra* note 1, at 1.

[54] FDCA § 804(l) (emphasis added).

2. Individual IWIPs could not plausibly supply the substantive assurances required for certification.

Lacking a factual basis to sustain a section 804(l) certification, HHS has shifted its statutory certification responsibility to individual private entities, which are ill-equipped to provide the necessary assurances. Not only does this depart from the plain text of the FDCA, but it also is not plausible that individual IWIPs could reach the conclusions required for certification under section 804(l). Section III.B. of this Petition, above, establishes that HHS lacks a factual basis to certify the personal importation provisions of the FDCA and shows that HHS has expressly declined to do so. Neither HHS nor FDA has provided a basis to abandon that view.

Nor does HHS's RFP provide sufficient information for a sponsor to submit a plan with meaningful patient safety and cost reduction controls. The vague guidance and omissions raise concerns that FDA and HHS may approve IWIP proposals without adequate assurances. First, HHS has stated in broad terms issues that sponsors should address in their proposal. However, the enumerated issues are far too vague to be useful. For example, HHS and FDA direct applicants to address the issue of "[m]aintain[ing] supply chain security and safety to help protect consumers from exposure to products that may be counterfeit, stolen, contaminated, or otherwise harmful."[55] Given that the federal government has not been able to make such assurances, it is unclear how a private entity could do so. Importing drugs from countries that do not have supply chain security laws comparable to the U.S. Drug Supply Chain Security Act presents supply chain challenges, particularly when HHS has authorized importation from such a wide variety of countries. Sponsors would benefit from far more specific direction, if section 804(j)(2) were implemented.

Second, HHS has omitted any guidance regarding the "cost" prong. The IWIP RFP states that the sponsor's submission should have sufficient controls to "ensure that the IWIP . . . would result in a significant reduction in cost of the covered products to the American consumer."[56] However, all of the issues that the sponsor must address in the IWIP proposal pertain to safety. HHS has neglected to offer even the most basic guidance as to what constitutes a "significant reduction" in cost; whether those costs can be passed down to the American consumer through lower insurance premiums; and the role, if any, of rebates.

HHS and FDA presents a question and answer in their Frequently Asked Questions, "How significant of price reductions can patients expect?"[57] This question is directly relevant to the cost reduction prong of the section 804(l) certification requirement. The response, however, merely restates the text of President Trump's Executive Order that the cost of prescription drugs in the United States is too high, followed by the statement that "[t]he amount of the price reductions will depend," which cannot meet the actual requirements imposed by section 804.[58]

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[55] RFP, *supra* note 1, at 1.

[56] *See*RFP, *supra* note 1 at 1.

[57] *Frequently Asked Questions*, *supra* note 39, at 2.

[58] *Id*.

D. Certification of section 804, including section 804(j), of the FDCA would be arbitrary and capricious and contrary to law under the APA.

Under the APA, courts must hold unlawful and set aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law."[59] An agency action is arbitrary and capricious if, among other things, it: (1) is not adequately explained, (2) fails to consider relevant factors, (3) fails to consider an important aspect of the problem, or (4) runs counter to the evidence before the agency.[60] The APA also requires a court to hold unlawful and set aside agency action, findings, and conclusions found to be not in accordance with law and in excess of statutory authority or short of statutory right.[61]

To overcome a challenge that its certification of section 804 is arbitrary and capricious, and to approve an IWIP if section 804 is eventually certified, HHS would need to supply an adequate explanation for its decision, present an administrative record that adequately supports the decision, and show that it considered important evidence and arguments that point to a different decision.[62] Sections III.A through III.C of this Petition show that HHS lacks a factual basis for a decision that implementation of section 804(j) would meet the safety and cost reduction standard required for certification. In fact, many of the longstanding warnings about the dangers and cost of personal importation originated with HHS and FDA and have been echoed by those Agencies over the course of four Administrations representing both political parties. These very agencies are now seeking to effectuate it without a meaningful explanation for the sudden reversal.

Further, any decision to certify section 804, including section 804(j), would be contrary to law in violation of the APA. Section 804 cannot take effect until the section 804(l) standard has been met with respect to section 804 in its entirety, that is, including the personal importation provisions. As noted above, HHS lacks a factual basis to certify section 804. Any action to effectuate section 804 without meeting the section 804(l) standard would violate the FDCA and thus be contrary to law under the APA. Similarly, Section IV of this Petition shows that implementation of section 804(j)(2) pursuant to the IWIP program deviates from requirements for personal importation under the FDCA. Should HHS and FDA approve an IWIP in the program's current form, therefore, such implementation would violate the APA.

IV. The IWIP program departs from statutory requirements for personal importation under the FDCA.

HHS's IWIP program fails to comply with the personal importation provisions of the FDCA. As discussed below, the program conflates statutory provisions governing personal and commercial importation, two distinct operations, and it signals an intent to proceed without first publishing statutorily mandated guidance. Because entities that import drugs pursuant to an IWIP are ineligible for the waiver of the prohibition on importation in section 804(j), drugs imported under an IWIP must be refused admission to the United States and the IWIP program should not be implemented.

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[59] 5 U.S.C. § 706(2)(A).

[60] *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29 (1983).

[61] 5 U.S.C. §§ 706(2)(A), (C).

[62] *See generally State Farm*, 463 U.S. 29.

A. HHS's IWIP program comports with neither the regulation nor case-by-case waiver pathway under the FDCA.

The FDCA provides two pathways for HHS to grant to individuals waivers for personal importation: by regulation or on a case-by-case basis. HHS has embraced the latter pathway, which requires it to issue guidance prior to granting any waivers to individuals. However, the IWIP program departs from the FDCA by providing for commercial entities, rather than individuals, to import drugs, and to do so from countries other than Canada. It also departs from the FDCA by providing for HHS to grant waivers without first issuing guidance.

1. The personal importation provisions apply only to individuals, not commercial entities.

The personal importation provisions of section 804 contemplate importation of drugs by individuals, not by private commercial entities. Section 804(j) of the FDCA is titled "Waiver Authority For Importation By Individuals." Section 804(j)(2)(A) of the FDCA states that "[t]he Secretary may grant to *individuals*, by regulation or on a case-by-case basis, a waiver of the prohibition of importation of a prescription drug . . . or class of prescription drugs . . . , under such conditions as the Secretary determines to be appropriate." An "individual," by definition, is a "single human being,"[63] and does not encompass corporate entities.[64]

Section 804(j)(1) confirms that individual importation is limited to importation by individual people. Most notably, section 804(j)(1) directs the Secretary to exercise discretion to permit individuals to engage in personal importation where the personal importation is both "clearly for personal use" and the imported drug "does not appear to present an unreasonable risk to the individual."[65] Likewise, the provision "refers to enforcement against individuals of the importation prohibition," and it directs the Secretary to "focus enforcement on cases in which the importation by an individual poses a significant threat to public health."[66]

Accordingly, section 804(j) contemplates *individuals* receiving a waiver of the prohibition on importation, because the *individual* would be the one actually importing the drug.

The IWIP program departs from this basic requirement of the FDCA by providing for commercial entities, including pharmacies, distributors, and wholesalers, to sponsor the IWIP and import the drug. The only involvement by individuals proposed by FDA is for individuals to apply for a waiver, which they would then present to the pharmacy when picking up the drug—*after* it has already been imported.[67] Individuals would not be the ones actually importing the drug. Nor would specific individuals appear to have any involvement in the IWIP approval

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[63] *See* Oxford English Dictionary, definition of "individual," https://www.oed.com/view/Entry/94633?redirectedFrom=individual#eid (last visited Nov. 22, 2020).

[64] *See* 1 U.S.C. § 1 ("person" includes "corporations" and various other entities, "as well as individuals").

[65] *See* FDCA § 804(j)(1)(B).

[66] *See* FDCA § 804(j)(1)(A).

[67] *Frequently Asked Questions*, *supra* note 39, at 1.

process. Thus, as a matter of the plain statutory text, the IWIP program exceeds FDA's authority.

The legislative history discussed in section II.A. of this Petition further supports the proposition that Congress was intentional in its language distinguishing commercial importation by pharmacies and wholesalers under sections 804(b) through (h) of the FDCA from personal importation by individuals under section 804(j). In the MEDS Act of 2000, Congress affirmatively decided to refrain from authorizing personal importation, instead solely providing for pharmacies and wholesalers to import drugs under certain circumstances.[68] Within the same legislation, Congress described the circumstances under which HHS could issue "warning notices" to *individuals* who import drugs for *personal use*.[69] The MMA of 2003 then added provisions to section 804 for HHS to authorize personal importation. In the MMA, Congress continued to distinguish importation by individuals under the personal importation provisions from importation by pharmacies and wholesalers under the commercial importation provisions, and to limit the latter to importation from Canada.[70]

This has also been the longstanding interpretation of HHS and FDA. For example, the 2004 Task Force observed that "under a personal importation scheme, each *individual consumer* becomes an importer who has limited knowledge and resources to ensure the legitimacy of entities that offer drugs for sale, particularly over the internet."[71] Yet HHS's IWIP program adopts the contrary view, without explanation, that commercial entities can engage in personal importation. Any approval of an IWIP proposal that omits an explanation for this consequential change in position would be arbitrary and capricious in violation of the APA. Because the FDCA limits personal importation to individuals, this would also be contrary to law under the APA.

Moreover, Congress had good reason to distinguish individual from commercial importation. While personal importation is limited to individuals, private entities including pharmacies and wholesalers can import drugs in compliance with the "commercial importation" statutory provisions of sections 804(b) through (h), assuming section 804 is properly certified and those sections are in effect. Recognizing that commercial importation presents particular risks, Congress imposed a number of conditions and limitations for pharmacies and wholesalers to engage in this practice. These statutory constraints do not apply to personal importation, which occurs on a smaller, individualized scale. For example, under the *commercial* importation provisions:

- The drugs may only be imported from Canada.[72]

[68] Pub. L. No. 106-387, § 745(c), 114 Stat. at 1549A-36.

[69] *Id.*, § 746(c), 114 Stat. at 1549A-40; *see also* FDCA § 801(g)(1).

[70] Pub. L. No. 108-173, 117 Stat. at 2,464-68.

[71] Task Force Report, *supra* note 15, at 41 (emphasis added).

[72] FDCA § 804(b).

- The importer must submit certain information and documentation to the Secretary related to the attributes of the drug, price, and shipment.[73]

- The importer must submit documentation regarding sampling and testing of the drug for authenticity and degradation.[74]

- The importer must submit "[l]aboratory records, including complete data derived from all tests necessary to ensure that the prescription drug is in compliance with established specifications and standards."[75]

Importantly, the IWIP program would appear to enable sponsors to import drugs on a large scale, consistent with commercial importation. HHS has not limited the volume or variety of prescription drugs that a single pharmacy, distributor, or wholesaler can include in a particular IWIP. Nor has HHS limited the number of IWIPs that a sponsor can manage. By conflating personal importation with commercial importation, the IWIP program facilitates an end-run around the statutory provisions intended to reduce the risk of commercial importation to American consumers. For example, commercial entities can import IWIP drugs not just from Canada, but from eight countries as well as the European Union and countries within the European Economic Area.[76] The IWIP program also specifies no requirement for specific documentation to the Secretary regarding the drug, quantity, and price of IWIP drugs, or for sampling and laboratory analysis.

2. HHS must issue guidance required for waivers "on a case-by-case basis" before it could approve any IWIPs.

Section 804(j)(2)(B) of the FDCA requires the Secretary to issue guidance concerning the standard for case-by-case waivers under paragraph (j)(2)(A). It states that

> [t]he Secretary shall publish, and update as necessary, guidance that accurately describes circumstances in which the Secretary will consistently grant waivers on a case-by-case basis under subparagraph (A), so that individuals may know with the greatest practicable degree of certainty whether a particular importation for personal use will be permitted.

Under the plain language of section 804(j)(2), the section 804(j)(2)(B) guidance is a pre-requisite to granting waivers. First, the text of the statute directs the Secretary to publish guidance describing the "circumstances in which the Secretary *will* consistently grant waivers."[77] Congress drafted this provision in the future tense to establish chronology. Only after the Secretary issues guidance can it grant a case-by-case waiver consistent with the policy set forth therein.

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[73] FDCA § 804(d).

[74] FDCA § 804(d)(1)(J).

[75] FDCA § 804(d)(1)(L).

[76] RFP, *supra* note 1, at 1.

[77] FDCA § 804(j)(2)(B) (emphasis added).

Second, in section 804(j)(2)(B), Congress sought to ensure that "individuals will know with the greatest practicable degree of certainty" whether a case-by-case waiver request will be granted. Congress chose to express its intention not just in committee reports or floor statements, but in the codified text of the statute itself. Failure to issue the guidance prior to approving or disapproving case-by-case waiver applications would frustrate Congress' express goal of transparency. The guidance would have, at best, minimal value if HHS could approve or deny waivers using criteria hidden from public view, only to issue guidance at some point in the future at the Secretary's discretion. This would deprive the public of the opportunity to receive notice of the criteria and provide feedback by submitting comments, as required by section 701(h)(1)(C)(i) of the FDCA and FDA's Good Guidance Practices at 21 C.F.R. § 10.115.

Pursuant to Good Guidance Practices, FDA is required to publish a Level 1 Guidance. A Level 1 Guidance, among other things, sets forth initial interpretations of statutory or regulatory requirements; sets forth changes in interpretation or policy that are of more than a minor nature; or covers highly controversial issues.[78] To issue a Level 1 guidance, FDA must publish a draft for public comment prior to issuing the final guidance setting forth Agency policy.[79]

The RFP, issued jointly by HHS and FDA, does not satisfy the requirement for guidance under section 804(j)(2)(B). It meets the general definition of a "guidance document" because it is a "document[ ] that relate[s] to . . . the processing, content, and evaluation or approval of submissions."[80] However, rather than describe, pursuant to section 804(j)(2)(B), the "circumstances in which the Secretary will consistently grant waivers on a case-by-case basis," the RFP solicits proposals from private entities describing how *they* would design a personal importation program.[81] Further, because the RFP "set[s] forth initial interpretations of statutory . . . requirements" and "covers highly controversial issues," it is a Level 1 Guidance that must first be published in draft for public comment before it can take effect.[82] HHS and FDA have made the IWIP program immediately effective without first soliciting public comments.

B. Drug products offered for importation pursuant to an IWIP must be refused admission to the United States because they are unapproved, misbranded, and likely adulterated.

Section 801(a) of the FDCA, which applies to drugs imported under section 804, requires FDA to refuse admission to drugs that appear to be unapproved, misbranded, or adulterated.[83] The drugs that would be offered for import by a wholesaler, distributor, or pharmacy pursuant to an IWIP would be unapproved, misbranded, and likely adulterated. FDA would therefore be required to refuse admission to the drugs imported under the IWIP.

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[78] 21 C.F.R. § 10.115(c), (g).

[79] 21 C.F.R. § 10.115(g).

[80] 21 C.F.R. § 10.115(b)(2).

[81] RFP, *supra* note 1, at 1-2.

[82] 21 C.F.R. § 10.115.

[83] *See Cook v. FDA*, 733 F.3d 1,7 (D.C. Cir. 2013) (finding that "the ordinary meaning of 'shall' is 'must'").

The RFP misleadingly directs sponsors to "[e]nsure that each IWIP drug is FDA-approved."[84] Similarly, the Frequently Asked Questions states that "[o]nly drugs that have already been approved by the FDA and that are manufactured in FDA-registered facilities will qualify for the personal importation program."[85] HHS also directs sponsors to "[e]nsure that the labeling for each IWIP drug comports with the labeling of its U.S.-approved counterpart."[86]

Contrary to the statements made in the RFP, the drugs that would be imported under an IWIP are unapproved. IWIP drugs are not FDA-approved, but rather foreign "counterparts" of FDA-approved drug products. IWIP drugs may differ in important respects from FDA-approved drug products. For example, an IWIP drug may be manufactured in or subsequently handled (e.g., repackaged or relabeled) by facilities and pursuant to processes that are not identified in an approved new drug or abbreviated new drug application.

The drugs would also be misbranded. Under section 502(f)(1) of the FDCA, a drug is misbranded if is not labeled with "adequate directions for use."[87] To satisfy this requirement, a drug's labeling must include "directions under which the layman can use a drug safely and for the purposes for which it is intended."[88] IWIP drugs are prescription drugs. Because prescription drugs by definition are unsafe unless used under the supervision of a doctor, it is not possible to provide adequate directions for use by a layman; thus, prescription drugs are "presumptively misbranded."[89] However, prescription drugs are exempted from the requirement for adequate directions for use if they are either being distributed to patients through a prescription by a licensed physician, or if they are labeled with FDA-approved labeling pursuant to a new drug application.[90]

Drugs imported under the IWIP program qualify for neither exception to section 502(f)(1)'s "adequate directions for use" requirement.[91] At the time of importation, IWIP drugs are not distributed to a patient, and thus do not qualify for the statutory exception under section 503(b)(2) of the FDCA. Nor does an IWIP drug qualify for the exception for drugs labeled pursuant to an approved new drug application.[92] The RFP specifies that "the labeling for each IWIP drug comports with the labeling of its U.S.-approved counterpart except to identify the product as having been imported subject to an authorized IWIP."[93] As discussed above, IWIP drugs will fail to meet the requirements of section 505 and therefore will be an unapproved new drug, outside the scope of the marketing application for the product manufactured for the U.S.

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[84] RFP, *supra* note 1, at 2.

[85] *Frequently Asked Questions*, *supra* note 39, at 3.

[86] RFP, *supra* note 1, at 2.

[87] FDCA § 502(f)(1).

[88] 21 C.F.R. § 201.5.

[89] *United States v. Regenerative Sciences, LLC*, 741 F.3d 1314, 1324 (D.C. Cir. 2014) (citation omitted).

[90] FDCA § 503(b)(2); 21 C.F.R. § 201.100.

[91] FDCA § 502(f)(1).

[92] 21 C.F.R. § 201.100.

[93] RFP, *supra* note 1, at 2.

market. As a result, the IWIP drug cannot be labeled with FDA-approved labeling pursuant to an approved marketing application and thus cannot qualify for the exception under 21 C.F.R. § 201.100. Because the IWIP drug will qualify for neither exception to section 502(f)(1)'s "adequate directions for use" requirement, it is misbranded.

In addition, an imported IWIP drug would be misbranded because it would not satisfy the requirements of the Drug Supply Chain Security Act.[94] A drug is misbranded if "it fails to bear the product identifier as required by section [582 of the FDCA]."[95] Because an imported IWIP drug will have been manufactured overseas or domestically for overseas markets, it will not bear an identifier as it would if it were intended for the U.S. market.

IWIP drugs will also fail to meet other requirements of DSCSA. For instance, the importer of an IWIP drug would not have received the transaction history, transaction information, and a transaction statement for the product.[96] To acquire the IWIP drug, the importer would likely have to conduct business with an entity that is not an authorized trading partner.[97] And, the importer would not be able to comply with the requirement to verify that a product in the importer's possession or control contains a "standardized numerical identifier" at the package level.[98] Importation of drugs that fail to comply with the requirements of the DSCSA is a prohibited act under section 301(t) of the FDCA.[99]

Further, the drugs are likely to be adulterated. For instance, there are no assurances that the drugs will be handled in conformance with current good manufacturing practice requirements. Establishment registration with FDA, which the RFP does mention, does not mean that the Agency has inspected or otherwise evaluated that facility to verify that it has the necessary conditions and controls to manufacture a high quality drug product.

Because a drug imported under an IWIP program would be an unapproved new drug, a misbranded drug, and potentially an adulterated drug, as well as a drug that violates drug supply chain security requirements, it cannot be lawfully imported into the United States.[100]

V. HHS cannot approve an IWIP or grant a case-by-case waiver without affording all interested parties notice and an opportunity to participate.

Section 804(j)(2) of the FDCA authorizes the Secretary to grant waivers to individuals by regulation or on a case-by-case basis. Through its IWIP program, HHS has opted to implement the latter pathway, albeit unlawfully by authorizing importation by commercial entities rather than individuals. Accordingly, even if the IWIP program were lawful under section 804(j)(2), approval of an IWIP proposal would constitute an adjudication subject to requirements under the APA. Granting a case-by-case waiver to an individual would similarly be an adjudication

[94] FDCA § 581 et seq.

[95] FDCA § 502(cc).

[96] *See* FDCA § 582(c)(1)(A).

[97] FDCA § 582(c)(3).

[98] FDCA § 582(c)(4)(A)(i).

[99] FDCA § 301(t).

[100] FDCA § 801(a).

subject to APA requirements.[101] HHS's IWIP RFP does not indicate that HHS and FDA intend to adhere to constitutional or statutory obligations associated with the adjudication of an IWIP proposal or case-by-case waiver application.

Holders of approved new drug or abbreviated new drug applications for FDA-approved "counterparts" of the drug products that may become eligible for importation must be able to participate in the adjudication of an IWIP. By the Administration's own admission, imports of the foreign-made versions of an FDA-approved drug product are intended to compete with the sale of the FDA-approved drug product to decrease prices. Such importation could interfere with the patent protections and exclusivities that allow a new drug manufacturer to recoup their investments for a limited duration of time. It also would reduce incentives for new drug application holders, going forward, to engage in research and development and to obtain new drug approvals.

In addition, the approval of an IWIP or grant of a case-by-case waiver will hurt the goodwill that new drug application holders establish in their name, product name, and trademarks. HHS has not adequately explained whether or how the longstanding safety concerns surrounding personal importation no longer apply; counterfeit and substandard drugs may be imported under this program. New drug application holders will need to invest in pharmacovigilance and consumer education to address the increased adverse events, medication errors, and consumer confusion associated with this personal importation scheme. When patients are harmed by counterfeit or otherwise substandard versions of an FDA-approved drug product, the application holders will suffer reputational harm.

As such, application holders have a Due Process right under the Fifth Amendment to participate in IWIP approval proceedings and to receive notice of the outcome of an adjudication of an IWIP application or case-by-case waiver request.[102] This will, for example, enable an interested party to take action, as appropriate, to protect its property rights in its products and trademarks. HHS and FDA should explain how they intend for interested parties to receive notice of the adjudication as required by the APA and the Due Process Clause. Otherwise, the adjudication would be "without observance of procedure required by law" in violation of the APA.[103]

VI. Conclusion

For the reasons explained above, HHS's implementation of section 804(j)(2) fails to conform to the FDCA and the APA. Because HHS has not, and cannot, certify to Congress that its implementation of the personal importation provisions meets the section 804(l) standard for safety and cost reduction, the provision has not taken effect under law. But even if that threshold requirement were met, the IWIP program departs from requirements for personal importation under the FDCA, and any approval of an IWIP proposal in its current form would be both arbitrary and capricious and contrary to law under the APA. If HHS seeks to effectuate the case-by-case waiver provisions of section 804(j), it must properly certify section 804, including section 804(j), to Congress; implement section 804(j)(2) in a manner that comports

[101] 5 U.S.C. § 551(7). The APA defines an "order" as "the whole or a part of a final disposition, whether affirmative, negative, injunctive, or declaratory in form, of an agency in a matter other than rulemaking but including licensing." 5 U.S.C. § 551(6).

[102] 5 U.S.C § 555(b).

[103] 5 U.S.C. § 706(2)(D).

with the FDCA; and adjudicate applications, with adequate explanation, in conformance with the APA. We urge HHS and FDA to discontinue efforts to implement section 804(j), including withdraw the RFP and refrain from approving any IWIPs, or refrain from issuing any case-by-case waivers under section 804(j)(2) unless and until it has taken the aforementioned steps.

C. Environmental Impact

Petitioners claim a categorical exclusion under 21 C.F.R. § 25.30(h).

D. Economic Impact

Information on the economic impact of this petition will be provided on request.

E. Certification

Pursuant to 21 C.F.R. § 10.30(b), the undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petitioner relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

Julie Dohm

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cc:

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