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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 respectfully submits this citizen petition on behalf of the Pharmaceutical Research and Manufacturers of America ("PhRMA") 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 reimportation of insulin.

Actions Requested

Through this petition, and for the reasons explained in more detail below, PhRMA requests that FDA take the following actions:

1. Withdraw the Request for Proposals Regarding Insulin Reimportation Programs ("RFP") issued on September 24, 2020.

2. Refrain from authorizing reimportation of insulin under section 801(d)(2) unless insulin is in shortage as a result of a medical emergency.

3. Establish a process by which the drug manufacturer has notice and an opportunity to participate in the decision-making process with respect to an application for reimportation of its drug product under section 801(d)(2).

4. Provide the public with notice whenever an application for drug reimportation under section 801(d)(2) has been approved.

Statement of Grounds

I. Executive Summary

FDA's RFP issued on September 24, 2020, announced FDA's novel finding that, due to "widespread rationing" of insulin as result of the price of the drug, reimported insulin is "required for emergency medical care" under section 801(d)(2) of the FDCA and therefore should be made available to the public through reimportation programs. [1]

FDA should withdraw this RFP, which ignores significant risks to patient safety posed by reimported insulin and failed to consider the factors FDA itself has identified as relevant to determining whether a drug is "required for emergency medical care." The RFP also relies on an improper reading of section 801(d)(2)'s "required for emergency medical care" provision, which should be limited to reimportation necessary to address drug shortages caused by medical emergencies. The RFP's interpretation of section 801(d)(2) contradicts the plain text of the

[1] FDA Request for Proposals Regarding Insulin Importation Programs (Sept. 24, 2020) ("RFP") at 1.

statute and is inconsistent with how Congress has used "emergency" throughout the FDCA, FDA's past interpretation of section 801(d)(2), and FDA's drug shortage policy. Limiting reimportation under section 801(d)(2) to drugs in shortage as a result of a medical emergency would respect the overall structure of the statutory provisions that Congress has crafted to govern drug importation and affordability, as well as the purpose of the reimportation prohibition in section 801(d)(1). FDA should therefore refrain from authorizing reimportation of insulin under section 801(d)(2) unless insulin is in shortage as a result of a medical emergency.

The RFP is also plagued by additional legal flaws. As an initial matter, the RFP constitutes a rule setting forth new criteria under the statute and binding factual findings under section 801(d)(2) and therefore should not have been issued without notice-and-comment procedures. In addition, insulin reimported under the RFP would be out of compliance with the Drug Supply Chain Security Act. Compelled use of the FDA-approved labeling would also violate the First Amendment rights of insulin manufacturers and constitute a taking without just compensation under the Fifth Amendment Takings Clause. For each of these additional reasons, FDA should withdraw the RFP and refrain from approving any Reimportation Applications submitted under it.

Finally, FDA should establish a process whereby manufacturers may participate in FDA's consideration of any request by another entity under section 801(d)(2) to reimport that manufacturer's specific drugs. Manufacturers can bring relevant information to bear and have a procedural right to participate in these proceedings under the Fifth Amendment's Due Process Clause and the Administrative Procedure Act ("APA"). Consistent with the FDA's past practices and the principles set forth in the RFP, the public should also be made aware of any reimportation authorized under section 801(d).

II. Background on Insulin Pricing and Affordability

Net prices of brand diabetes medicines—the prices actually paid to the manufacturer after rebates, discounts, and wholesaler fees—have fallen in recent years. Since 2014, net prices for the most commonly used classes of insulins have fallen between 40-50% and are lower today than in 2007.[2] This is due in part to pharmacy benefit managers leveraging robust competition among the broad range of long-acting and rapid-acting insulins to negotiate deep discounts from manufacturers in exchange for preferred formulary placement.[3] These dynamics lowered the net price of insulins, on average, by 83% in 2019.[4]

Despite these decreases in net prices, the amount that health plans ask patients to pay out-of-pocket for these medicines has been on the rise in recent years. That is because health plans' benefit designs increasingly subject medicines to deductibles and/or coinsurance,

[2] PhRMA analysis of SSR Health net price data, https://www.ssrhealth.com/dataset (October 2020). This analysis includes long-acting insulin analogs (50% decline in class average annual net price between 2014 and 2020) and rapid-acting insulin analogs/mixed insulins (40% decline in class average annual net price between 2014 and 2020). These classes align with how these data are reported in SSR Health reports. These calculations do not adjust for inflation.

[3] Drug Channels, "The 2020 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers" (March 2020), available at: https://drugchannelsinstitute.com/products/industry_report/pharmacy/.

[4] PhRMA analysis of SSR Health net price data (October 2020).

resulting in more patients paying their cost-sharing based on the undiscounted list price of medicines. This practice has exposed certain patients to significant out-of-pocket costs.[5]

In light of these challenges, every biopharmaceutical company that produces insulin offers patient-assistance and cost-sharing assistance programs to help with the costs of insulin and other diabetes medicines, which help to ensure that patients have access to the medications they need.[6] Many companies have taken additional steps in recent months to expand their assistance programs to help patients maintain access to therapy.[7]

PhRMA is committed to supporting policy solutions that will make insulin more affordable for patients and realign and strengthen the incentives in the system that have led to the high cost sharing for insulin that some patients experience today. More of the significant discounts, rebates, and other price concessions paid by biopharmaceutical companies should be shared with patients to lower costs at the pharmacy counter. However, as reimportation does not address the underlying drivers of patient affordability it is likewise ill-suited to address these challenges.

III. Legal Background

A. Reimportation Under the FDCA

The FDCA establishes a closed system in which drug imports are tightly monitored and controlled. Section 801 of the FDCA governs this closed system. Section 801(a) provides that a drug offered for import that appears unapproved, misbranded, or adulterated "shall be refused admission."[8] Section 801(d) provides, in full, the following:

> (d) **Reimportation**
>
> (1)
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> (A) Except as provided in paragraph (2) and section 384 of this title, no drug subject to section 353(b) of this title or composed wholly or partly of insulin which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the manufacturer of the drug.

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[5] IQVIA, *Patient Affordability Part One: The Implications of Changing Benefit Designs and High Cost-Sharing* (May 2018), available at: https://www.iqvia.com/locations/united-states/library/case-studies/patient-affordability-part-one; IQVIA, *Diabetes Costs and Affordability in the United States* (June 2020), available at https://www.iqvia.com/insights/the-iqvia-institute/reports/diabetes-costs-and-affordability-in-the-united-states.

[6] *See* PhRMA, Medicine Assistance Tool, https://medicineassistancetool.org (providing database of available affordability programs).

[7] *See, e.g.*, Press Release, Eli Lilly & Co., Lilly Commits Insulin Value Program, Featuring $35 Copay Card, to Suite of Affordability Solutions for People with Diabetes (Sept. 10, 2020), available at: http://lilly.mediaroom.com/index.php?s=9042&item=138086.

[8] 21 U.S.C. § 381(a).

> (B) Except as authorized by the Secretary in the case of a drug that appears on the drug shortage list under section 356e of this title or in the case of importation pursuant to section 384 of this title, no drug that is subject to section 353(b)(1) of this title may be imported into the United States for commercial use if such drug is manufactured outside the United States, unless the manufacturer has authorized the drug to be marketed in the United States and has caused the drug to be labeled to be marketed in the United States.
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> (2)
> The Secretary may authorize the importation of a drug the importation of which is prohibited by paragraph (1) if the drug is required for emergency medical care.[9]

Section 801(d)(1)(A)'s broad prohibition on importation applies to drugs subject to section 503(b)—i.e., prescription drugs—and to insulin-containing drugs. The exception incorporates section 801(d)(2), which narrowly limits the Secretary's authority to approve re-importation to situations when "the drug is required for emergency medical care."[10]

In 1999, FDA issued regulations implementing section 801(d)(2). The regulations provide:

> No prescription drug or drug composed wholly or partly of insulin that was manufactured in a State and exported from the United States may be reimported by anyone other than its manufacturer, except that FDA may grant permission to a person other than the manufacturer to reimport a prescription drug or insulin-containing drug if it determines that such reimportation is required for emergency medical care.[11]

The regulations advise that applications for reimportation should be submitted to the FDA District Office in the district in which the reimportation would take place and establish a process for appeals from an adverse decision.[12]

Since at least 2011, FDA has had in place an Import Alert authorizing detention without physical examination of insulin products imported by a party other than the manufacturer outside of an authorization by the Secretary for emergency medical use.[13]

In 2014, FDA issued another Import Alert that listed factors relevant to determining whether a drug is "required for emergency medical care" such that the section 801(d)(2) exception applies.[14] These factors include:

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[9] 21 U.S.C. § 381(d).

[10] 21 U.S.C. § 381(d)(2).

[11] Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures, 64 Fed. Reg. 67720, 67757; 21 C.F.R. § 203.10.

[12] 21 C.F.R. §§ 203.11–203.12.

[13] FDA, Import Alert 66-65: *Detention Without Physical Examination of Reimportation of Insulin* (Oct. 12, 2011), https://www.accessdata.fda.gov/cms_ia/importalert_201.html.

[14] FDA, Import Alert 66-14: *Reimportation of All Prescription Drugs for Human Use* (Sept. 17, 2014), https://www.accessdata.fda.gov/cms_ia/importalert_177.html.

(1) the reason this situation should be considered an emergency
(2) availability, during the relevant treatment period, of the product and of alternative products on the domestic market
(3) data supporting the expected duration of the emergency situation and the number of expected users of the reimported drug
(4) accountability for product that may not be consumed during the emergency, including a plan for disposition of any remaining product at the end of the emergency situation.[15]

Nowhere in the statute, regulation, or Import Alerts is there any indication that the price of a drug is relevant to FDA's determination of whether that drug is "required for emergency medical care" under section 801(d)(2).

B. Recent Administration Actions on Insulin Reimportation

On July 24, 2020, President Trump signed an executive order ("EO") directing the Secretary of HHS to increase "drug importation to lower prices for American patients."[16] This EO includes three substantive provisions "to expand safe access to lower-cost imported prescription drugs."[17] One EO provision directed the HHS Secretary to authorize the "re-importation of insulin upon a finding that it is required for emergency medical care" pursuant to 21 U.S.C. § 381(d)(2).

Without engaging in any notice-and-comment procedures or other process involving public input, on September 24, 2020, the Secretary followed the President's directive by unilaterally issuing the RFP. The RFP asserts that "HHS and FDA are aware of an emerging body of evidence that American patients are rationing insulin due to cost," and posits that "widespread rationing of insulin" exists.[18] Without considering or addressing whether there is an actual emergency relating to insulin or an actual shortage of domestically manufactured insulin, the RFP announces that "the Secretary has concluded that the widespread rationing of insulin constitutes an emergency, that insulin is required for emergency medical care, and that insulin should be available to the American people through authorized reimportation programs."[19]

Through the RFP, FDA "invites persons to submit Insulin Reimportation Program proposals (each a 'Reimportation Application'), pursuant to which insulin could be reimported in a manner that meets applicable legal requirements."[20] The RFP indicates that FDA will begin accepting applications immediately.[21] The RFP does not provide a process by which an insulin manufacturer can participate in the decision-making about reimportation of its own product or make clear whether approval of a Reimportation Application will be announced publicly.

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[15] *Id.*

[16] *See* Exec. Order No. 13,938.

[17] *Id.*

[18] RFP at 1.

[19] *Id.*

[20] *Id.*

[21] *Id* at 4.

II. The RFP Ignores Significant Risks to Patient Safety Posed By Reimportation and the Factors FDA Has Identified as Relevant under Section 801(d)(2).

A. Reimportation of Insulin Under the RFP Would Threaten Patient Safety.

Reimportation of insulin under the RFP would introduce significant risks to patient safety. The RFP seeks proposals that would open the "closed" U.S. drug distribution system by creating programs whereby insulin can be reimported into the U.S. by entities other than the manufacturer. Under the FDCA, a single entity, the manufacturer, is held accountable for ensuring that the drug is manufactured and stored in compliance with current good manufacturing practice (CGMP), distributed according to good distribution practices and drug supply chain requirements, appropriately labeled, and monitored through pharmacovigilance systems. For drugs reimported under the RFP, the manufacturer will not be in a position to ensure these responsibilities are met. Introducing programs where the manufacturer lacks visibility into reimportation of its own drugs undermines the critical regulatory protections provided by manufacturer oversight and accountability.

Entities other than the manufacturer will not be able to fill the shoes of the manufacturer because they lack the experience and know-how necessary to carry out the manufacturer's responsibilities. Reimporters will not have the requisite experience and knowledge to implement the CGMP, supply chain, labeling, and pharmacoviligance requirements normally carried out by the manufacturer for its own products. Such entities cannot provide the same assurances of safety, efficacy, and quality as the manufacturer can for drugs distributed under its control.[22] Consequently, there will be increased risks that any insulin reimported under the RFP would not be adequately handled and stored, tracked and traced, labeled, and monitored for adverse events.

The heightened risks associated with reimportation by entities other than the manufacturer under the RFP are particularly acute for biological products like insulin, which are especially sensitive to their storage and handling conditions.[23] Biologics manufacturers tightly control the manufacture and handling of their products to help ensure that patients receive safe and effective medications. Even slight differences in equipment, facilities, or handling can result in changes in the biological product itself that can cause the drug to be unsafe or ineffective. Administration of unsafe or ineffective insulin can lead to serious injury or even death.[24] Patients should not be unnecessarily exposed to such risks, especially when domestically available FDA-approved insulin can meet their medical needs.

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[22] FDA, Proposed Rule, Importation of Prescription Drugs, 84 Fed. Reg. 70,796, 70,814 (Dec. 23, 2019) ("We acknowledge that there are certain assurances regarding authenticity and quality when a manufacturer manufactures drugs intended for sale in the United States.").

[23] *See* FDA, *Guidance or Industry: Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application* (Jan. 2018) ("[M]any biological products are particularly sensitive to changes to storage and handling conditions and can break down or aggregate if exposed to heat or light, if dropped, or if shaken during storage and handling.").

[24] FDA, FDA Warns Against the Use of Unauthorized Devices for Diabetes Management (May 17, 2019) ("[U]nsafe insulin dosing . . . can lead to injury requiring medical intervention or even death.").

Reimportation also will increase the risk that adulterated drugs will enter the country. Reimportation lengthens the supply chain, which in itself introduces the risk for adulterated drugs to enter the country.[25] It also requires relabeling and likely repackaging, which introduces additional risk of adulteration and fraud.[26] In addition, the RFP does not state that FDA will inspect the repackager or the relabeler before authorizing these entities to reimport insulin products and regularly thereafter, which increases the risk that insulin would be repackaged and relabeled in uninspected facilities. As HHS's Task Force on Importation acknowledged, "[l]egalized importation of drugs in such a way that creates an opening in the 'closed' system will likely result in some increase in risk, as the evidence shows that weaknesses in the oversight of drug regulation and the distribution system have been exploited."[27]

What is more, the RFP appears to contemplate that individual applicants will each devise their own systems for ensuring the products are safe. The RFP instructs that applications "should describe the controls applicants will use to ensure the integrity and quality of the drug supply chain."[28] This will create a patchwork of unrelated and inconsistent supply chain security measures and handling practices. Reimportation alone increases the likelihood that unapproved and counterfeit insulin will infiltrate the U.S. supply chain, and the makeshift supply chain security system envisioned by the RFP would multiply this risk.[29] And, in addition to the serious breaches that could occur under a Reimportation Program, making reimported insulin widely available could give unscrupulous actors, including rogue online pharmacies, an opportunity to introduce counterfeit insulin by misleading consumers to believe the insulin is part of an authorized Reimportation Program. The likely result of these increased risks will be that patients are harmed by illegitimate and otherwise substandard insulin.

While the RFP states that FDA will "evaluate whether the Reimportation Application adequately addresses the public health concerns and insulin product considerations" described in the RFP,[30] it is not clear that FDA has fully considered the safety implications of allowing third-party insulin reimportation. Nor is it clear what standards the Agency will apply in evaluating whether the safety protocols set forth in applications are satisfactory. The grave safety risks associated with insulin that would be reimported under these programs have not been sufficiently addressed by the RFP.

B. The RFP Ignores the Factors FDA Itself Has Identified as Relevant to Section 801(d)(2) Reimportation.

The RFP fails to cite FDA's own import alert on reimportation of prescription drugs under section 801(d)(2), which identifies the factors FDA has identified as relevant to determining whether reimportation of a drug is "required for emergency medical care."[31] Three

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[25] HHS, Task Force on Drug Importation, Report on Drug Importation (Dec. 2004) ("HHS Task Force Report") at 30.

[26] 84 Fed. Reg. at 70,819.

[27] HHS Task Force Report at 35.

[28] RFP at 3.

[29] *See* HHS Task Force Report at x, 35

[30] RFP at 4.

[31] FDA, Import Alert 66-14: *Reimportation of All Prescription Drugs for Human Use* (Sept. 17, 2014), https://www.accessdata.fda.gov/cms_ia/importalert_177.html.

of the four factors—concerning availability of the product on the domestic market, the expected duration of the emergency and number of expected users of the reimported drug, and accountability for any product remaining at the end of the emergency—are not addressed at all in the RFP.[32] Nor do the facts relating to these factors support a determination that there is an "emergency" with regard to insulin. Insulin is widely available on the domestic market, and the RFP gives no indication that FDA intends for insulin reimportation programs to be limited in time or scale.

The sole factor that is discussed in the RFP—"the reason this situation should be considered an emergency"—is inadequately explained and factually unsupported. The RFP makes a finding that insulin pricing is causing an "emergency." For reasons discussed below, insulin pricing is not a valid reason to find an "emergency" exists, but even if it were, the finding lacks factual support and ignores information that undermines it. For instance, FDA failed to consider the complex set of factors affecting insulin prices paid by patients, including increased use of co-insurance and deductibles as well as fees charged by distributors, and whether reimportation would effectively decrease insulin costs in light of these factors. Moreover, multiple manufacturers offer affordability programs, including programs that allow patients to purchase insulin for as low as $35 per month, and to receive free insulin in the case of an emergency.[33] While insulin is primarily a treatment for a chronic condition and is not indicated for emergency medical care,[34] these programs help patients to avoid emergency medical situations related to lack of access to insulin. FDA has not even attempted to examine the effect of these programs or other factors on patient access to insulin. Thus, even under the RFP's expansive interpretation of section 801(d)(2), FDA's conclusion that reimported insulin is "required for emergency medical care" lacks adequate explanation and factual support.

III. The RFP Adopts an Improper Definition of "Required for Emergency Medical Care."

The RFP adopts a vastly overbroad definition of section 801(d)(2)'s "required for emergency medical care" provision, which is properly interpreted to allow reimportation of a drug only when a shortage of that drug arises as the result of a medical emergency. Since the "required for emergency medical care" provision at section 801(d)(2) was added to the FDCA in 1988, FDA has never issued a rule or guidance document pursuant to notice and comment procedures interpreting this language. Now, FDA, through the RFP, has set forth a novel interpretation of "required for emergency medical care" that allows reimportation based upon a purported finding that a medicine is not affordable. But the text, structure and purpose of section 801(d)(2) and the FDCA more broadly make clear that section 801(d)(2) is intended to address drug shortages caused by medical emergencies, not drug pricing. Because the RFP's

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[32] *See generally* RFP.

[33] *See* Eli Lilly, Helping People With Diabetes Get the Medicine They Need, https://www.insulinaffordability.com/; Novo Nordisk, Novo Nordisk's new insulin affordability offerings now available in the US, https://www.novonordisk-us.com/media/news-releases.html?122978; Sanofi, Sanofi provides unprecedented access to its insulins for one set monthly price, http://www.news.sanofi.us/2019-04-10-Sanofi-provides-unprecedented-access-to-its-insulins-for-one-set-monthly-price.

[34] *See, e.g.*, Eli Lilly and Company, Prescribing Information for HUMALOG (insulin lispro injection), https://pi.lilly.com/us/humalog-pen-pi.pdf. Thus, requirements of insulin for its intended patient population are foreseeable rather than unlooked for, sudden or accidental.

interpretation of section 801(d)(2) is improper, FDA should withdraw the RFP and refrain from authorizing reimportation of insulin under section 801(d)(2) unless insulin is in shortage as a result of a medical emergency.

A. The RFP Departs From The Language of Section 801(d)(2).

Section 801(d)(2) creates a narrow exception to section 801(d)(1)(A)'s general prohibition on reimportation that applies only when a drug is "required for emergency medical care."[35] The RFP interprets section 801(d)(2) in a way that disregards the plain and ordinary meaning of the text. By its plain language, section 801(d)(2) is applicable when reimportation of a drug is necessary to address an urgent, unforeseen, and temporary set of circumstances involving imminent danger to patients. Based on its statutory language, 801(d)(2) should be applied only to drugs in shortage as a result of a medical emergency, such as a declared public health emergency or other urgent, unforeseen, and temporary set of circumstances affecting domestic supply of a drug. Two key aspects of the statutory text lead to this conclusion.

First, section 801(d)(2) specifies that the drug must be "required" for emergency medical care. A drug is "required" if it is *necessary* to address the emergency, i.e., if there is no viable alternative.[36] A reimported drug is "required" only when the demand or projected demand for the drug within the United States exceeds the supply of the drug.[37] As long as supply of the FDA-approved drug meets demand, it provides a safer alternative for patients than a foreign version of the drug reimported by a third party. Thus, a reimported drug is required only when that drug is in shortage.[38]

Second, an "emergency" is "an unforeseen combination of circumstances or the resulting state that calls for immediate action."[39] For reimportation of a drug to be required to address an

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[35] 21 U.S.C. § 381(d)(2).

[36] *See* Merriam Webster, Inc., Merriam Webster Online, https://www.merriam-webster.com/dictionary/required (defining "required" as "stipulated as necessary to be done, made, or provided").

[37] *See* 21. C.F.R. § 314.81(f) ("Drug shortage or shortage means a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.").

[38] A drug is in shortage when it appears on FDA's drug shortage list under section 506E of the FDCA. *See* 21 U.S.C. § 356e*; see also* FDA, Drug Shortages, https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

[39] Merriam Webster, Inc., Merriam Webster Online, https://www.merriam-webster.com/dictionary/emergency (emphasis added). *See also, e.g.*, *Acuity Ins. Co. v. McDonald's Towing & Rescue, Inc.*, 747 F. App'x 377, 381 (6th Cir. 2018) ("Because the statute does not otherwise define 'emergency,' we give the word its ordinary meaning, as found in these dictionary definitions. Thus, an 'emergency towing' is one that happens in response to unforeseen circumstances requiring immediate attention." (citation omitted); *Int'l Bh'd of Teamsters v. Local Union No. 810*, 19 F.3d 786, 793 (2d Cir. 1994) ("Emergency is defined as 'an unforeseen combination of circumstances or the resulting state that calls for immediate action.'"); *Sowell's Estate v. Commissioner*, 708 F.2d 1564, 1567 (10th Cir. 1983) (citing dictionary definition that an "emergency" is "an unforeseen combination of circumstances or the resulting state that calls for immediate action," and noting "[j]udged by the definitions given, it

"emergency," that reimportation must be necessary to address an urgent, unforeseen and temporary set of circumstances that affects a drug's supply, making alternatives to reimported drugs unavailable.

Accordingly, under its plain language, section 801(d)(2) should apply only to drugs in shortage as a result of a medical emergency, such as a public health emergency or other unforeseen, temporary set of circumstances affecting a drug's supply. This interpretation is consistent with the legislative history, which makes clear that Congress created only "[a] *limited* exception … to authorize reimportations, on a case-by-case basis, of pharmaceuticals needed for emergency medical care."[40]

Such an interpretation is also consistent with other provisions in the FDCA that create "emergency" exceptions, all of which are designed to address temporary drug shortages. For example, the Prescription Drug Marketing Act of 1987 (PDMA), the same statute that created the section 801(d)(2) exception, created an exception for "emergency medical reasons" to a prohibition on the sale or transfer of drugs purchased by hospitals or healthcare entities or donated or supplied at a reduced price to charitable organizations.[41] Congress defined "emergency medical reasons" to include "transfers of a drug between health care entities or from a health care entity to a retail pharmacy undertaken to alleviate *temporary shortages* of the drug arising from delays in or interruptions of regular distribution schedules."[42] Thus, even an emergency exception for the domestic sale or transfer of a drug by a hospital or healthcare entity applies only in the case of a temporary shortage.

Section 503 of the FDCA also includes an exception for "emergency medical reasons" to restrictions on the distribution of drug samples.[43] Excluded from these restrictions is "the distribution of a drug or an offer to distribute a drug for emergency medical reasons, including a public health emergency declaration pursuant to section 319 of the Public Health Service Act."[44] This provision states that "a drug shortage not caused by a public health emergency shall not constitute an emergency medical reason."[45] The phrase "required for emergency medical care" should similarly be limited to shortages caused by medical emergencies.

The Drug Supply Chain Security Act (DSCSA)[46] exempts from the definition of a transaction covered by the statute "the distribution of a product for emergency medical reasons including a public health emergency declaration pursuant to section 247d of title 42[.]" Like section 801(d), the DSCSA regulates the drugs that may enter U.S. distribution channels. In this context, Congress used "emergency" to refer to a public health emergency. Like the exception for drug sample distribution, the DSCSA exception specifies that, "a drug shortage not caused by

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is an event which is special; also, it is sudden; moreover, it calls for immediate action, or it is pressing.").

[40] S. Rep. 100-303 at 3 (emphasis added).

[41] *See* Pub. L. 100-293, 102 Stat. 97, § 4 (April 22, 1988).

[42] *Id.* (emphasis added).

[43] *See* 21 U.S.C § 353(d)(1).

[44] 21 U.S.C. § 353(e)(4)(C).

[45] *Id.*

[46] *See* 21 U.S.C. § 360eee *et seq.*

a public health emergency shall *not* constitute an emergency medical reason[.]"[47] Again, the language of the exception suggests that the "emergency medical reasons" refers to a drug shortage caused by a medical emergency.

Each of these provisions creates an "emergency" exception to the safeguards Congress has put in place throughout the FDCA to protect the safety of the U.S. drug supply. Each exception provides a workaround for a temporary drug shortage. None of these provisions mentions affordability or pricing or contemplates the RFP's interpretation of "required for emergency medical care." To ensure consistency with Congress's use of "emergency" throughout the FDCA, FDA should limit reimportation under section 801(d)(2) to that necessary to address drug shortages caused by medical emergencies.[48] Because the scope of reimportation envisioned by the RFP dramatically expands section 801(d)(2) beyond any permissible interpretation of the text, it is improper.

B. Limiting Section 801(d)(2) Reimportation to Drug Shortages Caused by Medical Emergencies Would Be Consistent With FDA's Previous Interpretation of Section 801(d)(2).

FDA's own previous interpretation of the section 801(d)(2) "required for emergency medical care" provision demonstrates that FDA has in the past correctly reserved this exception for temporary emergencies during which drug shortages exist. All four factors listed in FDA's 2014 Import Alert show that FDA considers the temporary unavailability of medically-necessary drugs when assessing whether a drug is "required for emergency medical care."[49] These factors include:

- "the reason this situation should be considered an emergency"
- "availability, during the relevant treatment period, of the product and of alternative products on the domestic market"
- "data supporting the expected duration of the emergency situation and the number of expected users of the reimported drug"
- "accountability for product that may not be consumed during the emergency, including a plan for disposition of any remaining product at the end of the emergency situation."[50]

Each of these factors contemplates a temporary drug shortage caused by an emergency medical situation. The factors also make clear that any reimportation would take place only for the duration of the emergency, and that patients should access drugs through the normal distribution channels when the emergency has passed.

Conversely, none of these factors supports the RFP's characterization of reimported insulin as required for emergency medical care. The price of the drug is not a valid reason to

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[47] 21 U.S.C. § 360eee(24)(B)(iii).

[48] *See, e.g.*, *Grace v. Barr*, 965 F.3d 883, 908 (D.C. Cir. 2020) ("[I]dentical words and phrases within the same statute should normally be given the same meaning[.]").

[49] *See* FDA, Import Alert 66-14, *Reimportation of All Prescription Drugs for Human Use* (Sept. 17, 2014), https://www.accessdata.fda.gov/cms_ia/importalert_177.html.

[50] *Id.*

find that an emergency exists. Insulin does not appear on FDA's drug shortage list.[51] The RFP makes no reference to a time limit on reimportation or to an end to the "emergency" that the Secretary claims is created by insulin pricing purportedly associated with "widespread rationing." The RFP does not call for a plan to account for remaining product at the end of the emergency. Based on the factors that FDA previously announced were relevant, it is clear that FDA has never contemplated that reimportation of a drug not in shortage, with no time limit on such reimportation, outside an existing emergency, would be permitted for the sole purpose of reducing the cost of the drug.

FDA's statements made in the connection with issuing the regulation under section 801(d)(2) further demonstrate that FDA has intended this exception to be applied narrowly. In the regulatory impact analysis published with the regulation, FDA explained that the Agency expected emergency importation under the 801(d)(2) to be rare: "As few requests for emergency reimportation are expected, the annual paperwork costs for all reimporters to fill out the emergency reimportation application total only $144."[52] FDA's analysis also indicated that it expected only twelve applications a year for reimportation.[53] These statements further underscore that FDA has never anticipated permitting the breadth of reimportation under 801(d)(2) contemplated by the RFP. Limiting reimportation under section 801(d)(2) to drug shortages caused by medical emergencies would be consistent with the factors that FDA district offices are currently advised to consider, as well as with FDA's previous statements indicating the narrow effect of this provision.

Finally, limiting section 801(d)(2) to drug shortages caused by medical emergencies would be consistent with FDA's drug shortage policy. FDA allows temporary importation of foreign-sold drugs only when other avenues for addressing a shortage have been exhausted or are unavailable. These other avenues include working with manufacturers to expedite approval of additional production lines or new raw material sources or allowing an extension of an expiration date for available inventory when supported by data.[54] FDA looks to redirect drug products not manufactured for the U.S. market only "[w]hen the US manufacturers are not able to resolve a shortage immediately and the shortage involves a critical drug needed for US patients[.]"[55] "FDA's preferred solution to a shortage is a supply of approved drugs sufficient to meet patient demand."[56] FDA's approach to drug shortages reflects the increased safety risks of redirecting drugs manufactured for foreign markets. Applying section 801(d)(2) for the narrow purpose of addressing drug shortages caused by medical emergencies would be consistent with this policy.

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[51] FDA, FDA Drug Shortages (search "insulin"), https://www.accessdata.fda.gov/scripts/drugshortages/dsp_SearchResults.cfm.

[52] 64 Fed. Reg. 67,720, 67,752 (Dec. 3, 1999).

[53] 59 Fed. Reg. 11,842, 11,861 (Mar. 14, 1994).

[54] *See* FDA, Frequently Asked Questions About Drug Shortages, https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#q5.

[55] *Id.*

[56] FDA, Strategic Plan for Preventing and Mitigating Drug Shortages, 14 (Oct. 2013).

C. The RFP's Interpretation of Section 801(d)(2) Is Contrary to the Statutory Structure, Including Section 804 and Statutory Provisions Addressing Insulin Affordability.

The Agency's interpretation of section 801(d)(2) also disregards the limited role of that provision in the context of the larger statutory structure. That structure includes section 804, which is incorporated into the exception in section 801(d)(1)(A) and creates a separate pathway for importing drugs to address affordability concerns.

Section 804 was enacted after a prolonged debate over the balance of the potential cost savings and safety risks of drug importation. The balance that Congress struck in section 804 requires that, before wholesalers and pharmacists can import drugs for the purpose of reducing their costs, the Secretary must certify to Congress that such importation will pose no additional risk to the public health and safety and will result in significant cost reductions of the covered product to the American consumer.[57] It requires the Secretary to issue regulations setting forth requirements for entities involved in importation governing recordkeeping, labeling, and testing of imported drugs.[58] And it excludes biological products, such as insulin, which are particularly sensitive to storage and handling conditions.[59] Because section 804 addresses in great detail the circumstances in which entities other than the manufacturer may import drugs to address cost concerns, and the requirements that should be imposed on such importation, importation for the purpose of reducing drug prices should be limited to that permitted under the section of the FDCA created for this very purpose.

The RFP effectively circumvents section 804 by allowing drugs intended for foreign markets to enter the U.S. supply chain without satisfying the demanding requirements of that section. The RFP even goes a step further, stating that Insulin Reimportation Programs should offer a pathway to provide "potentially lower-cost insulin products" to patients, suggesting that the Reimportation Programs may *not* reduce actually insulin costs at all. Further, the RFP states that "FDA intends to evaluate whether the Reimportation Application adequately addresses the public health concerns," suggesting that FDA is free to apply a less stringent safety standard than that set out in section 804(l). Reimporting insulin under section 801(d)(2) would also expand the scope of importation to address pricing beyond the extent permitted by section 804 to include biologics such as insulin. This would bypass important safety constraints adopted in section 804. As Congress has legislated a careful balancing of priorities in the realm of drug importation for the purpose of cost reduction, FDA should not attempt to circumvent that balance by operating an importation program through a different statutory provision, section 801(d)(2), that was not intended to address cost concerns.

Moreover, Congress specifically addressed insulin affordability in the Biologics Price Competition and Innovation Act of 2009 (BPCI Act).[60] Congress passed the BPCI Act to create an abbreviated biosimilars pathway for biological products, similar to the previously-existing pathway available for generics of small molecule drugs.[61] This legislation paved the way for less expensive, follow-on versions of biologics like insulin. In 2020, Congress further expanded the definition of biological product such that chemically-synthesized insulin is now also included

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[57] 21 U.S.C. § 384(l).

[58] 21 U.S.C. § 384(b).

[59] *See* 32 U.S.C. 384(a)(3)(b).

[60] Pub. L. 111-148, 124 Stat. 119, Title VII, (March 23, 2010).

[61] *See id.*

and eligible for the pathway created by the BPCI Act.[62] Thus, Congress has chosen to manage pricing of biologics like insulin by facilitating approvals of biosimilars, while excluding them from the section 804 importation scheme.

Congress's legislation in this area also involved a careful balance of the need to incentivize and reward manufacturers' investments in research and development with the goal of fostering competition.[63] Allowing expansive importation under section 801(d)(2) would upend this balance by effectively abrogating the exclusivity protections granted to innovator companies. This would make it more difficult for drug sponsors to recoup research and development costs. The result would be reduced incentives to engage in research development activities and therefore fewer new drugs. And because of the complexity and expense of developing manufacturing methods for biological products, such reduced incentives may disproportionately hinder development of biosimiliars[64]—the very avenue through which Congress has chosen to address insulin affordability. As the 2004 HHS Task Force on Importation reported in the context of commercial importation, importation would "adversely affect R&D of new drugs, causing future drug consumers to forego the health benefits associated with innovation."[65] Where Congress has made specific choices regarding the appropriate measures for reducing prices of biologics like insulin, FDA should not attempt to make different choices by setting forth an expansive interpretation of a separate section of the FDCA intended for emergency situations. Restraint in this area is particularly appropriate in light of the fact that FDA does not have jurisdiction over drug pricing. As the agency has stated publicly, "FDA has no authority to investigate or control the prices set by manufacturers, distributors and retailers."[66] Even in the context of drug shortages, FDA has made clear that "[p]ricing issues are not within the purview of FDA."[67]

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[62] Pub. L. No. 116-94 § 605 (Dec. 20, 2019).

[63] *See, e.g.*, Biologics and Biosimilars: Balancing Incentives for Innovation, Hearing before the Subcommittee on Courts and Competition Policy, Committee on the Judiciary, Serial No. 111-73 (July 14, 2009), Statement of Subcommittee Chairman Rep. Henry C. Johnson ("The question before us today is how to frame the intellectual property protections in a pathway for biosimilars that incentivizes the extraordinary investment required to develop new biologics but does not discourage biosimilar introduction.").

[64] *See* Blackstone & Fuhr, *The Economics of Biosimilars*, 6 AM. HEALTH DRUG BENEFITS 469, 470–471 (Sept./Oct. 2013) ("The investment needed to develop and market a biosimilar is considerably higher than the $1 million to $4 million that is required in the generic market. It takes 7 to 8 years to develop a biosimilar, at a cost of between $100 million and $250 million).

[65] *See* HHS Task Force Report at 82.

[66] FDA, Frequently Asked Questions about CDER, https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/frequently-asked-questions-about-cder.

[67] FDA, *Frequently Asked Questions about Drug Shortages*, https://www.fda.gov/drugs/drug-shortages/frequently-asked-questions-about-drug-shortages#q2.

D. Limiting Reimportation Under Section 801(d)(2) to Drugs In Shortage As a Result of a Medical Emergency Would Be Consistent With Section 801(d)(1)'s Purpose to Guard Against Unsafe Reimported Drugs.

Limiting reimportation under section 801(d)(2) to drugs in shortage as a result of a medical emergency is consistent with the legislative purpose of 801(d)(1), which was to protect the public from unapproved, misbranded, and adulterated drugs entering the country as American goods returned. Current sections 801(d)(1)(A) and (d)(2) of the FDCA were originally enacted as part of the PDMA.[68] Congress enacted section 801(d)(1) to address the increased potential for reimported drugs to "become subpotent or adulterated during foreign handling and shipping" and for the commission of fraud against U.S. manufacturers.[69] Indeed, the text of the PDMA includes Congressional findings that make plain the purpose of the statute:

- "Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping."

- "The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs."

- "The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, mis-branded, subpotent, or expired drugs will be sold to American consumers."[70]

In instituting the prohibition in 801(d)(1), Congress made clear its intentions to protect the American public from reimportation of substandard drugs, as well as from counterfeit drugs that enter the supply chain as part of that process. As FDA stated in connection with its issuance of regulations under PDMA, "[i]t was intended that PDMA would protect the public against the threat of subpotent, adulterated, counterfeit, and misbranded drugs posed by the existence of drug diversion schemes and a drug diversion submarket, and the absence of appropriate controls over and creation and maintenance of appropriate records regarding the distribution of prescription drugs."[71] In light of this purpose, the "required for emergency medical care" provision of section 801(d)(2) should be construed narrowly to preserve the protections that Congress put in place to reduce the danger of exposure to substandard drugs. The interpretation proposed in the RFP would effectively eliminate the section 801(d) prohibition by allowing any drug that can be characterized as unaffordable to some patients to bypass this provision, thereby undermining the purpose of the statute.

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[68] Pub. L. 100-293, 102 Stat. 97 at § 2 (April 22, 1988).

[69] *Id.*

[70] *Id.*

[71] 59 Fed. Reg. 11,843 (March 14, 1994).

IV. The RFP Suffers From Additional Legal Flaws.

The RFP also suffers from additional legal flaws. In issuing the RFP, FDA failed to comply with procedural requirements giving manufacturers and other interested parties an opportunity to participate in formulating the criteria for reimportation. The RFP would also allow for reimportation of insulin that would fail to meet statutory standards for supply chain security. Finally, compelled use of the FDA-approved labeling would violate manufacturers' constitutional rights. Each of these reasons warrants withdrawal of the RFP.

A. FDA Failed to Comply With Procedural Requirements.

The RFP announces that insulin is "required for emergency medical care" for purposes of section 801(d)(2). The Agency provided no prior notice or opportunity to comment on this determination, which was both unlawful and unwise as a matter of policy.

Under the APA, a "rule" is "an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law[.]"[72] In the RFP, FDA not only adopted a new and untenable interpretation of section 801(d)(2)'s "required for emergency medical care" provision, but also announced that "the widespread rationing of insulin constitutes an emergency, that insulin is required for emergency medical care, and that insulin should be available to the American people through authorized reimportation programs."[73] These determinations will apply to all future applications to reimport insulin, thus eliminating the requirements that applicants must demonstrate the existence of an "emergency," and that the drugs they propose to import satisfy the statute, FDA's regulations, and its Import Alert.[74] The blanket determination that insulin reimportation is required for emergency medical care is a statement of general applicability and future effect that is binding on regulated entities, as well as HHS and FDA. As such, it was required to undergo the notice and comment procedures of section 553 of the APA.[75]

Separate and apart from the requirements of the APA, the Agency should have treated the announcement of this new interpretation as a Level I Guidance under the Agency's Good Guidance Practices. FDA has never issued a rule or guidance document pursuant to notice and comment procedures setting forth criteria for the satisfaction of section 801(d)(2), and therefore the RFP, which was issued jointly by HHS and FDA, is an "initial interpretation[] of statutory or regulatory requirements."[76] The interpretation of "required for emergency medical care" also amounts to a vast expansion of the statutory provision and a change in the criteria set forth in the Agency's 2014 Import Alert. It thus qualifies as a "change[] in interpretation or policy . . . of

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[72] 5 U.S.C. § 551(4).

[73] *See* RFP at 1

[74] 21 C.F.R. § 203.10; Import Alert 66-14.

[75] The FDA did not determine that there is "good cause" to waive the notice and comment requirements, *see* 5 U.S.C. §§ 553(b)(3)(B), (d), and there is no apparent basis for such a determination.

[76] 21 U.S.C. § 371(h)(1)(C); 21 C.F.R. § 10.115(c)(i).

more than a minor nature," as well as "highly controversial."[77] FDA therefore was required, but failed, to make a draft guidance available and give the public an opportunity to comment.[78]

Even if public notice and an opportunity to comment were not required, the Agency should have provided an opportunity for notice and comment as a matter of wise public policy. The Agency's determination raises, among other issues, questions about the extent to which U.S. patients are rationing their use of insulin due to its cost, the health effects of any such rationing, the extent to which reimportation would eliminate any such health effects, and the adverse health effects that might result from reimportation of insulin. These are precisely the type of complex factual issues that could benefit from public comment. Rather than considering input from the public, including insulin manufacturers, providers, patients, and others, the Agency has relied on a wholly inadequate factual record, consisting of only a few items of published literature. As a result, the Agency lacks an administrative record sufficient to survive judicial review.

In sum, if FDA wishes to institute the radical new approach set forth in the RFP, it must do so through a notice-and-comment process. Apart from the legal requirement that it do so, the Agency should provide an opportunity for notice and comment as a matter of good administrative policy.

B. Insulin Reimported Under the RFP Would Fail To Meet the Requirements of the DSCSA.

Reimported insulin would violate the FDCA in that it would fail to satisfy the requirements of the Drug Supply Chain Security Act.[79] For instance, the DSCSA requires that products manufactured for the U.S. market bear a product identifier to facilitate tracing of the product through the pharmaceutical supply chain.[80] Insulin imported under a Reimportation Program will have been manufactured for overseas markets, and thus it will not bear an identifier as it would if it were intended for the U.S. market. Reimportation programs will also violate the DSCSA in other ways. The importer of insulin under a Reimportation Application would not have received the transaction history, transaction information, and a transaction statement for the product.[81] To acquire the insulin, the importer would have to conduct business with an entity that is not an authorized trading partner.[82] 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.[83] Failure to comply with the requirements of the DSCSA is a prohibited act under section 301(t) of the FDCA.[84] The RFP has not addressed these significant violations.

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[77] 21 U.S.C. § 371(h)(1)(C); 21 C.F.R. § 10.115(c).

[78] *See id.*

[79] 21 U.S.C. § 360eee et. seq.

[80] *See* 21 U.S.C. § 360eee-1(b).

[81] *See* 21 U.S.C. § 360eee-1(c)(1)(A).

[82] *See id.*

[83] *See id.* at § 360eee-1(c)(4)(A)(i).

[84] *See* 21 U.S.C. § 331(t).

C. Reimportation Under the RFP Would Exceed FDA's Authority and Lead to Violations of Manufacturers' Constitutional Rights.

Allowing insulin reimporters to use a manufacturer's labeling, as contemplated by the RFP, would be unlawful and would infringe upon manufacturer's constitutional rights. At the outset, the FDCA does not grant the Secretary authority to allow a third party to use a manufacturer's FDA-approved labeling without the manufacturer's permission. The RFP specifies that reimported insulin must include the FDA-approved labeling for the product.[85] Such an authorization therefore would be in excess of the Secretary's statutory authority.[86]

Approval of a Reimportation Application under the RFP would also violate insulin manufacturer's First and Fifth Amendment rights.

First, the compelled use of manufacturers' labels, which often include the manufacturer's name and potentially other trademarks, would imply that the manufacturers vouch for the quality of the imported insulin products and the accuracy of their labeling, and are associated with the importer of the drugs. These insulin products will have traveled outside of the control of the manufacturer, and the manufacturer will not be able to oversee the supply chain to ensure their quality. This is particularly true in light of insulin's sensitivity to storage and handling conditions. Nor will the manufacturer have any contractual relationship with the importer to ensure proper handling and safety procedures. The result will be that manufacturers' names and trademarks will be associated, against the manufacturer's will, with products with a lesser assurance of safety, effectiveness, and quality than the FDA-approved products that the manufacturer intends for the U.S. market. The First Amendment prohibits the government from requiring manufacturers to be unwillingly associated with products whose, safety, effectiveness, and quality they cannot control and importers with whom they have no relationship.

In addition, the compelled use of manufacturers' labeling amounts to a compelled subsidy of importers. The First Amendment prohibits the government from requiring manufacturers to support other private parties unless the subsidy "serve[s] a compelling state interest that cannot be achieved through means significantly less restrictive of associational freedoms."[87] Given that insulin is not in shortage, this subsidy of importers in support of reimportation does not meet a compelling government interest, and insulin demand can be met without infringing on manufacturers associational freedoms. The system set forth in the RFP nevertheless allows importers to appropriate the goodwill associated with name-brand insulin and to free-ride on manufacturers' substantial investments in developing, testing, manufacturing, and securing FDA approval for their insulin products.

Reimportation under the RFP would unlawfully restrict manufacturers' speech, because it would deprive them of the opportunity to add to the labels of imported insulin any disclaimers or other language explaining that, for example, they cannot stand behind the quality of the products. The insulin reimportation authorization thus injures manufacturers by restricting them from speaking their opinion about those products, a classic speech restraint. This restriction exacerbates the forced association between the manufacturers, the importers, and the re-imported insulin products.

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[85] RFP at 3.

[86] *See* 5 U.S.C. § 706(2)(C).

[87] *Janus v. AFSCME Council 31,* 138 S.Ct. 2448, 2465 (2018).

Finally, FDA providing authorization to a third party to use a manufacturer's FDA-approved labeling and trademarks at no cost would be an unlawful taking under the Fifth Amendment. Manufacturers devote significant resources toward developing their FDA-approved labeling and building their brands and trademarks. Under the reimportation programs contemplated by the RFP, FDA would authorize importers to use manufacturers' labeling and trademarks without compensating the manufacturer. This amounts to a taking without just compensation. In addition, a taking must be for "public use"[88]; the government may not transfer private property from one private party to another. The FDA's transfer of property from the insulin manufacturer to the importer thus further violates the manufacturer's Fifth Amendment rights.[89]

V. FDA Should Give Manufacturers An Opportunity To Participate in Reimportation Application Evaluations and Make Reimportation Decisions Public.

Under any implementation of section 801(d)(2), FDA should create a process that gives manufacturers an opportunity to participate in decision-making regarding reimportation of their products. Manufacturers have unique expertise regarding their products and thus can bring to bear information relevant to the determination of whether a reimportation program is warranted or whether the controls set forth would adequately preserve the quality of the product. Further, manufacturers should be afforded an opportunity to participate because an approval of a Reimportation Application "constitutes formation of an order" and is thus an "adjudication" within the meaning of the APA.[90] Approval of an application to reimport a manufacturer's products has potential to cause financial and reputational harm to the manufacturer and thus will have a significant impact on the property interests of the manufacturers. As such, manufacturers have a right under the Due Process clause of the Fifth Amendment and section 555(b) of the APA to participate in an adjudication affecting such interests.[91] Providing an avenue for manufacturer participation will ensure that any reimportation under section 801(d)(2) satisfies the procedural requirements of the U.S. Constitution and the APA.

FDA should also make public any decision to allow reimportation under section 801(d)(2). FDA acknowledges through the RFP that the public should have a right to know whether or not their drugs were manufactured for the U.S. market. The RFP specifies that insulin reimported under a Reimportation Application must bear a disclosure that it was reimported and that reimported insulin must not be commingled with insulin manufactured for the domestic market.[92] Making importation decisions public would be consistent with these requirements, as well as with FDA's approach to imported drugs in the past. For instance, FDA notifies the public when it exercises enforcement discretion to allow temporary importation of

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[88] U.S. Const. amend. X.

[89] *See Calder v. Bull*, 3 U.S. 386, 388 (1798).

[90] 5 U.S.C. § 551(7).

[91] *See id.* at § 555(b).

[92] RFP at 3–4.

drugs in shortage.[93] These alerts explain why the drug is being imported and by whom.[94] The public should similarly be provided with information regarding the process through which drugs reimported under section 801(d)(2) might reach their pharmacies.

VI. Conclusion

For the reasons explained herein, FDA should withdraw the RFP, which is flawed both factually and legally, and refrain from authorizing reimportation of insulin under section 801(d)(2) unless insulin is in shortage as a result of a medical emergency. Further, FDA should establish a process for facilitating manufacturer participation in the process for approval of any request to reimport under section 801(d) and notify the public when a request is approved.

VII. Environmental Impact

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

VIII. Economic Impact

Petitioner will submit economic information upon request of the Commissioner.

IX. 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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[93] *See, e.g.*, FDA, Frequently Asked Questions Temporary Importation of Lipodox, https://www.fda.gov/media/83117/download.

[94] *See id.*