MEMORANDUM

TO: Food & Drug Administration

FROM: Express Delivery & Logistics Association

DATE: April 25, 2005

RE: FDA's authority to impose Prior Notice requirements on transshipments
FDA Docket No. 2002N-0278

Issue

At a recent meeting between Express Delivery & Logistics Association (XLA) members and Food & Drug Administration (FDA) officials, there was a discussion regarding XLA's filed comments in response to FDA's Interim Final Rule Prior Notice (PN) requirements in which XLA members requested exemption of transshipments from PN requirements under the Final Rule, scheduled to be published in June 2005. Specifically, the issue discussed was whether there existed a *legal* basis from exempting transshipments from PN requirements pursuant to the provisions of the Bioterrorism Act of 2002 (BTA). As detailed below, it is XLA's position that there is a legal basis from exempting lab samples from such PN requirements.

Questions Presented: (1) Whether FDA has authority under the Bioterrorism Act ("BTA") to impose prior notice requirements on transshipments through the United States? (2) And, alternatively, if it is determined that the term "import" is ambiguous, as FDA has argued, was FDA justified in concluding that Congress circumscribed its ability to narrow the scope of Prior Notice to exclude transshipments when it pegged Registration to food consumed in the United States but did not similarly limit Prior Notice?

Short Answer:

With respect to the first question, we conclude that FDA does not have authority under the Bioterrorism Act to impose a Prior Notice Requirement on transshipments.[1] Over the course of nearly 100 years, Congress has manifested a consistent policy with respect to the term "import." If in enacting a statute Congress intended to regulate or prohibit only those goods that were brought into the country for the purpose of entering the stream of commerce, Congress used the term "import" standing alone. This is known as the narrower, tariff sense of the term because this is the definition generally used in tariff statutes. If, however, Congress intended to reach more broadly and regulate goods transshipped or simply entering the territory of the United States even if those goods were not intended to enter the stream of commerce, Congress has

[1] While this conclusion is not without weaknesses, we have concluded that we have a solid answer to those weaknesses that we have identified. We have noted a number of the weaknesses below.

made it a practice of using additional language such as "to bring in" or "to possess" or has opted to directly address transshipments, or has opted to specifically define out the tariff sense of the word. This conclusion is bolstered by the fact that the Attorney General of the United States early on concluded that the term "import" standing alone does not encompass transshipments.

With respect to the second question, we conclude that under this circumstance FDA's discretion to exclude transshipments from the Prior Notice requirement would not be circumscribed. Having taken the position that it has discretion by virtue of an ambiguity in the use of the word import, FDA may not now rely on tools of statutory construction to avoid the policy judgments they are called upon to make. Moreover, reliance on the particular maxim referenced by FDA is insufficient to conclude that Congress in fact intended to impose a prior notice requirement on transshipments.

Analysis:

Background

FDA has taken the position that they have the authority and/or are required to impose prior notice requirements on transshipments[2] in order to give effect to the intent of Congress and as such they have published a regulation imposing a prior notice requirement on transshipments. FDA's justification for the proposed rule was, for purposes of the rulemaking, rooted in the case of *Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 843-44 (1984), which stands for the proposition that an administrative agency's construction of a statutory provision it is entrusted to administer shall be given substantial deference.

Although the Prior Notice provision only affirmatively authorizes FDA to impose prior notice requirements on food that is "imported or offered for import," FDA has concluded that transshipped goods, which are neither imported nor offered for import, should nevertheless be subject to prior notice. After concluding that the phrase "imported or offered for import" is ambiguous, in part because numerous courts have defined the words in various ways,[3] FDA reasoned that nevertheless regulating transshipments was necessary to achieve Congress' goal of enhancing FDA's ability to inspect and detain food that may threaten U.S. citizens. In particular, FDA explained that if prior notice requirements were not imposed on transshipments, existing Customs rules were such that food could enter the U.S. under a Transportation & Exportation Permit (T&E Permit) and once inside could enter the stream of commerce either lawfully or unlawfully. In either instance, FDA would be without prior notice. And, in the case of unlawful entry, FDA would have no ability, not even an after-the-fact ability to evaluate the risk of the food shipment.[4] Thus, because of holes in Customs' rules relating to T&E permits, FDA concluded that it was reasonable and proper under *Chevron* to regulate transshipments.

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[2] "In transit" and "transshipment" are used interchangeably to describe shipments that enter the U.S. and travel through the U.S. for export. For FDA's purposes, these shipments transiting through the country are in contrast with the scenario where goods enter a U.S. port but which are not allowed (by customs rules) to leave the port of arrival except for export. FDA has specifically exempted the latter scenario from Prior Notice Requirements. 21 CFR § 1.277.

[3] It is not defined in the BTA or the underlying statute that the BTA Prior Notice Provision amends, which is 21 U.S.C. § 381, which is part of the Federal Food, Drug, and Cosmetic Act.

[4] Although FDA would not have prior notice of transshipments, FDA would not be devoid of all authority over a rogue transshipment of the sort contemplated by FDA in the rulemaking document. If by means other than prior

FDA has also advanced the argument that because the food section of BTA contains a Registration Requirement for food facilities involved with food "intended for consumption in the United States," the Prior Notice Requirement, which does not say that it is limited to food "intended for consumption in the United States," must necessarily apply to any and all food shipments entering the United States, even if such shipments are only being transshipped through the United States. Prior Notice of Imported Food, Interim Final Rule, 68 *Fed. Reg*. 58974, 58990-58991 (October 10, 2003).

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notice FDA determined that transshipped food was adulterated, FDA would still have authority over the food pursuant to 21 U.S.C. § 331 (a) – (c) (prohibiting adulterated food in interstate commerce).

Part I – FDA Lacks Authority To Impose A Prior Notice Requirement On Transshipments

FDA Wrongly Concluded That The Term Import Was Ambiguous

Although the Supreme Court case of *Chevron v. Natural Resources Defense Council*, 467 U.S. 837, 843-44 (1984), stands for the proposition that an administrative agency's construction of a statutory provision it is entrusted to administer shall be given substantial deference, the Supreme Court in that case, and in a number of cases since, has also made clear that courts remain the arbiters of what a statute means. As such traditional rules of statutory construction should be applied to ascertain Congress' intent before giving deference to an agency's interpretation of the statute:

> The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent. [citations omitted.] If a court, employing traditional tools of statutory construction, ascertains that Congress had an intention on the precise question at issue, that intention is the law and must be given effect.

467 U.S. at 843, n. 9. In our case, traditional rules of statutory construction contradict FDA's conclusion that there is ambiguity over the scope of the term "import."

Although, as FDA has indicated, there are varying definitions of the term import, this does not create an ambiguity. It is true that with respect to tariff statutes the term has generally been defined to mean *to bring into the U.S. with intent to unlade*[5] or *the time when goods leave the Customs warehouse and enter the commerce of the country. Proctor & Gamble Mfg. v. United States*, 19 C.C.P.A. 415, 422 (1932). While, with respect to prohibitory statutes, such as the National Prohibition Act and the 18th Amendment (discussed in *Cunard v. Mellon*, 262 U.S. 100 (1923)), the Reenactment of the Opium Exclusion Act (discussed in Reenactment of the Opium-Exclusion Act, H.R. Rep. No. 24 [To accompany H.R. 1966] at 3-4 (Jun. 24, 1913)), and the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. § 951), the term has been defined more broadly to mean *to bring into the territory of the United States*, thus leaving entry into commerce or consumption out of the equation. The significant nuance that FDA has overlooked in concluding that these differing uses of the term create an ambiguity is that these varying definitions are more like two alternative definitions and they have come about because the term has become a technical term that is specific to the purpose and language of the various statutes *as conveyed or adopted by Congress*.

Although courts, including the Supreme Court, have at times construed the term "import" in the broadest sense, they generally have done so only when there has been additional language in the statute or an unmistakably clear statement of intent by the legislature to regulate any and all shipments entering the United States without regard to whether the goods were actually going

[5] If this case were going to court, we would want to flesh out the meaning of "unlade" a bit more. There was some indication that unloading from one plane to another might cause a transshipment to fall under the definition of import, but given Congress' later and fairly regular attempts to define "import" in prohibitory statutes more broadly than "import" in tariff statutes, we feel comfortable putting forth this argument to FDA.

to end up in the United States. In the absence of such additional language, the narrower sense of the term has been the default.

Thus, the case law, and the statutes being construed there under, demonstrate that rather than being ambiguous the term import when used by itself is narrowly defined to comport with the meaning within the tariff statutes and does not ensnare shipments merely passing through the United States or its territories. When Congress has regularly defined a term in a consistent manner, courts may presume that Congress intended to retain the long-established definition. This is consistent with the general view that if Congress has a demonstrated practice of defining terms a certain way, and it does not take measures to change or opt out of that practice by remaining silent and not defining the term another way, then Congress is deemed to have followed the established policy. *Halverson v. Slater*, 129 F.3d 180, 186, n.9 (D.C. Cir. 1997) (suggesting that analogies that are made to several statutes or a general course of legislation may be relied on to construe meaning).

Congress knows how to and has a history of using additional language when it wishes to regulate beyond the tariff definition of import

In some cases, Congress has ensnared shipments passing through the United States or its territories by extending the definition of the term import using additional language that Congress included in the underlying statute.[6] In *Cunard v. Mellon*[7], for example, the Supreme Court defined import in the broadest sense stating "[i]mportation, in a like sense, consists in bringing an article into a country from the outside. If there be an actual bringing in it is importation regardless of the mode in which it is effected." 262 U.S. 100, 122 (1923). However, this definition is neither binding on FDA nor creates a basis for saying that the term import is ambiguous in the absence of a definition. A review of the Court's analysis, which lead to this conclusion convincingly demonstrates that the Court reached this conclusion based on the express language used in the 18th Amendment as well as the Act itself. *Id.* at 121, 127. In both cases, words such as manufacture, sale, or *transportation of intoxicating liquors within*, *possess*, the importation thereof into, or the exportation thereof from the United States and territory, were used to define the scope of the prohibition against intoxicating liquors. Thus, it was additional language from Congress itself, both in its legislative history (*i.e.*, the 18th Amendment) and in the Act itself, which led to the Court's construction. In the absence of such additional language, there is no basis for concluding that the Supreme Court would have similarly construed the term. *See also Palmero v. U.S.*, 112 F.2d 922 (1st Cir. 1940) (where additional language akin to the language present in the Prohibition Act, including language such as "bringing in," caused the

[6] There is a potential weakness in this argument because one might counter that generally each word in a statute is presumed to have its own meaning. However, our reading of these cases suggests that the words were read together as modifiers or amplifiers.

[7] The Supreme Court was confronted with a question of whether alcohol for ship board use that was on a passenger ship passing through a U.S. port was illegal under the Prohibition Act, which was adopted to enforce the 18th Amendment of the Constitution. The Court concluded that this did in fact constitute a violation of the Act. Although the Supreme Court stated that "the alcoholic beverages therein involved, which had not been unladed, had been imported when they were brought into the territorial waters of the United States," that statement was based on the Court's conclusion that additional language such as, **"**transportation within" (*Id.* at 132), was intended to ensure that alcohol would not be present in the United States. In particular, the Court concluded that [i]t is obvious that those whose wishes and opinions are embodied in the Amendment meant to stop the whole business. They did not want intoxicating liquor in the United States…." *Id.* at 132.

court to construe the statute in the broadest sense so that the court concluded that possession of drugs on a ship passing through the New York harbor, but not yet at its destination in the U.S. violated the Narcotic Drugs Import and Export Act).

Congress knows that the term import standing alone does not encompass transshipments and has demonstrated an ability and willingness to directly address the issue when it wishes to regulate transshipments

In other cases, instead of just expanding the scope of the term import with additional language such as transport, possess, or bring in, Congress has chosen to adopt a specific provision addressing transshipments.

Thus, for example, Congress twice amended the Opium Exclusion Act in 1913 and 1922 to directly address the legal status of opium transshipments. An Act To Amend An Act Entitled An Act To Prohibit Importation and Use of Opium for Other Than Medicinal Purposes, H. Rep. No. 852 [To accompany H.R. 2193] at 4 (Mar. 27, 1922).

The amendment in 1913 is of particular application here. In order to expand the Act so that Customs could enforce the Act against transshipments of opium, Congress concluded that it could not rely on the provision relating to imports and instead adopted additional language in the import provision to expand the scope therein and a parallel a provision directed at transshipments specifically. Reenactment of the Opium-Exclusion Act, H. Rep. No. 24 [To accompany H.R. 1966] at 3-4 (Jun. 24, 1913).

Congress did this largely in response to an opinion by the United States Attorney General which had concluded that transshipments could not be regulated under existing provision addressed to imports alone. In particular, the Committee Report explained the Attorney General's Opinion as follows:

> In short, the opinion of the Attorney General was that since under the February act opium prepared for smoking was no longer subject to the payment of duties – it being a prohibited article – and as the bringing of opium into port by one vessel for immediate exportation by another did not constitute an importation in the meaning of the February act, its transfer from one vessel to another in port could be lawfully made.

Reenactment of the Opium-Exclusion Act, H. Rep. No. 24 at 3-4 [To accompany H.R. 1966] (Jun. 24, 1913). As a result of the Attorney General's Opinion, opium being transshipped in the U.S. was permitted to be in the territory for up to 15 days. *Id.* This gave a lot of leeway to opium smugglers and ultimately caused Congress to conclude that it had to amend the statute to do away with transshipments. *Id.*

In short, the fact that Congress responded the Attorney General's Opinion by choosing to specifically address transshipments is an indication that Congress has adopted the view that if it wishes to address transshipments, Congress simply cannot do so by relying on the term import alone.

Congress recognizes that the term import without more will be construed in the tariff sense

The unmistakable conclusion from these cases is that Congress knows that when it wishes to regulate or prohibit the shipments of goods through the United States, such as transshipments, it must say so because it simply is not enough to use the term "import" without more. That Congress has adopted this view is further reinforced by the language Congress used in the Comprehensive Drug Abuse Prevention and Control Act of 1970 (P.L. 91-513, 84 Stat. 1236, *codified as amended*, 21 U.S.C. §§801-971 (1988)). Specifically, section 951(a) of the Act defines the term "import" as "any bringing in or introduction of [an] article into any area (*whether or not such bringing in or introduction constitutes and importation within the meaning of the tariff laws of the United States*)." 21 U.S.C. § 951(a) (2004) (*emphasis added*). Importantly, the language in the parenthetical signals in the clearest of ways that Congress recognizes that if it chooses to use the word "import" without more, it will undoubtedly be taken to mean import in the narrower tariff sense of the word meaning to bring into the U.S. with intent to unlade or the time when goods leave the Customs warehouse and enter the commerce of the country. *Proctor & Gamble*, 19 C.C.P.A. at 422.

Thus, in the absence of broad statutory language reaching beyond "imports" to "transportation" or "bringing in" or "possession," or in the absence of clear language addressing transshipments directly, or in the absence of language indicating that the term "import" should not be limited to the narrower tariff sense of the word, a court would be hard pressed to agree with FDA that Congress has created an ambiguity or intentionally left the question to FDA to answer with respect to whether transshipments should be subject to prior notice by only referencing food that is "imported or offered for import." In the absence of any such ambiguity, no court should defer to FDA's interpretation of the BTA's Prior Notice Provision.

Part II – Under A *Chevron* Discretion Analysis, FDA's Reliance on The Expriessio Unius Maxim Is Misplaced and Such A Maxim Cannot Serve To Overturn A Decision By FDA To Exclude Transshipments From The Prior Notice Requirement

Even if a court agrees with FDA's argument that there is ambiguity sufficient to allow FDA to regulate all imports, including transshipments, FDA must still confront the issue of whether or not it possesses the discretion to exclude transshipments. FDA seems to conclude it lacks this authority, even after it found that the statute was ambiguous. FDA notes that Congress limited Registration to food consumed in the United States while not providing a parallel limitation for Prior Notice. In other words, after erroneously concluding that it has the discretion to interpret imports regardless of the long-standing use of that term, FDA then attempts to say Congress has tied its hands by directing that all imports are covered by Prior Notice.

The argument that FDA has set forth is an application of the expriessio unius maxim. The weight of the authority demands that FDA need not and should not be constrained by the application of the expriessio unius maxim, which means that "when people say one thing, they do not mean something else." 2A Norman J. Singer, *Sutherland Stat. Const.* §47.24 (2000).

If, as FDA asserts, Congress' ambiguous definition of imports provides the agency with the discretion to interpret the statute, then it should employ its policy judgment and not rely on

maxims to discern legislative intent. After all, the two-part test of *Chevron* is premised upon the constitutional roles of the judicial and executive branches. The first part of the test, grounded in statutory construction, is a role for the courts, and an agency's view of the clarity of the statute is afforded no deference. Once that hurdle is cleared and the statute is determined to be ambiguous, then an agency may employ its policy judgment, which is afforded deference. In this case, FDA attempts to cloak a policy judgment – to require notice for all imports – in the guise of legislative intent. In such a case, deference to an agency's statutory interpretation is inappropriate because it is not exercising its own judgment. *Arizona v. Thompson*, 281 F.3d 248, 254 (D.C. Cir. 2002) (HHS was wrong to conclude it lacked discretion based on its reading of the statute).

In addition, the expriessio unius maxim on which FDA relies is simply insufficient to determine that Congress spoke with the clarity necessary to preclude a reasonable interpretation by an agency. The maxim – that Congress' explicit direction in one statutory provision and its absence in a parallel provision suggests Congress' intent – is based on a logical assumption of congressional intent and not any actual evidence. Regardless of its application in other contexts, the maxim does not provide the unambiguous statement demanded by *Chevron*. In *Cheney Railroad v. ICC*, 902 F.2d 66 (D.C. Cir. 1990), the plaintiff claimed that the absence of procedures in found in one part of the Staggers Acts but not another tied the hands of the agency. The D.C. Circuit disagreed and declared that this principle of construction is "an especially feeble helper in an administrative setting." *Id*. at 69. *See also Mobile Communications Corp. v. FCC*, 77 F.3d 1399, 1405 (D.C. Cir. 1996) (maxim is "too thin a reed" to support conclusion that Congress clearly resolved the issue); *TRT Telecommunication v. FCC*, 876 F.2d 134, 146 (D.C. Cir. 1989) (use of rule of maxim insufficient to provide unambiguously expressed intent of Congress). Simply put, the maxim of statutory construction is insufficient to meet the *Chevron* standard necessary to strip an administrative agency of its discretion.

What is more, the maxim cited by FDA does not apply when Congress addresses different tasks; the inherent comparison demands that the items be of a parallel nature. *Barnhart v. Peabody Coal Co*., 537 U.S. 149, 168 (2003) (maxim does not apply to every statutory listing, only when items are members of an associated group). On registration, Congress had to somehow limit the universe of facilities that must register with the federal government. Congress sought to cover foreign facilities, but only those with a connection to this country. To solve this dilemma, Congress chose "consumption in the United States" as the test by which to judge whether or not a facility must register. By this one phrase, Congress included relevant foreign facilities and excluded domestic facilities that do not supply food for the U.S. Congress faced no comparable issue with regard to prior notice for food entering the country. Congress was not asked to engage in the line-drawing demanded by the registration requirement and nothing in the legislative history suggests any consideration regarding whether or not prior notice should apply to food not consumed in the U.S.

Finally, the interpretation of the statute that permits FDA to focus notification on food consumed in this country is consistent with the intent of Congress. Rep. Billy Tauzin, the floor manager and chair of the House-Senate conference on the bill, described the purpose of the bill a as: "The conference report also helps to protect the safety of America's food supply." *Cong. Rec*. H2845 (May 22, 2002). Rather than unambiguously preventing FDA from focusing on the U.S. food supply, Congress would applaud such efforts as consistent with the legislative intent.

In sum, if a court finds that the Prior Notice provision is ambiguous such that FDA *may* impose a prior notice requirement on transshipments, the BTA would still permit FDA to exercise its discretion to limit prior notice requirements to imports that become part of the U.S. food supply.

Conclusion

For the reasons detailed herein, XLA concludes that there is a legal rationale for FDA to exempt transshipments from its prior notice requirements. For further information, please contact Sue Presti at 703-998-7121 or spresti@cox.net.