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Is the Incorporation of the United States Pharmacopeia into the Food, Drug, and Cosmetic Act an Unconstitutional Delegation of Legislative Power?

ANNE STARK*

ABSTRACT

When Congress incorporated the United States Pharmacopeia (USP) into key provisions of the 1906 Pure Food and Drug Law (and subsequently, the 1938 Food, Drug, and Cosmetic Act), it impermissibly conferred legislative authority on a private trade organization in two different ways. First, Congress defined "drug" for the purposes of the statute as any article listed in the USP. In doing this, Congress enabled the United States Pharmacopeial Convention (USPC) to shape the reach of the Food, Drug, and Cosmetic Act (FDCA) and the jurisdiction of the Food and Drug Administration (FDA). Secondly, it defined "adulteration" and "misbranding" in the statute by incorporating drug standards published in the USP. This empowered the USPC to create legally binding requirements, the violation of which is punishable by criminal penalty. Although this broad delegation of authority to a private organization has been defended on the grounds of practical necessity and legal precedent, these arguments fail to justify its constitutionality. Even if legislative delegations to private parties like the USPC are permissible, this delegation is impermissible because Congress failed to provide any intelligible principle to guide or constrain the discretion of the USPC. This paper outlines how the FDCA's incorporation of the USP violates the nondelegation doctrine and analyzes how this invalid statutory arrangement has survived for more than one hundred and ten years.

INTRODUCTION

In 2012, the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) began investigating a multistate outbreak of fungal meningitis which was eventually traced back to contaminated steroid injections from the New England Compounding Center (NECC) in Framingham, Massachusetts.[1] Altogether, more than 60 people died, and another 700 were sickened, after receiving

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[1] CENTERS FOR DISEASE CONTROL AND PREVENTION, MULTISTATE OUTBREAK OF FUNGAL MENINGITIS AND OTHER INFECTIONS (2015), https://www.cdc.gov/hai/outbreaks/meningitis.html.

fungus-contaminated drugs.[2] In the largest criminal case resulting from contaminated drugs in the United States, federal prosecutors brought charges against Barry Cadden, co-founder of NECC, and thirteen of his employees, alleging racketeering, fraud, and the interstate sale of adulterated drugs.[3]

Prior to trial, Cadden and his co-defendants submitted a motion to dismiss several counts of the indictment against them.[4] While this kind of motion is typical, what was unusual were the grounds on which the defendants justified their request. The defendants asserted that they were being prosecuted for failing to adhere to the drug compounding standards published in the United States Pharmacopeia (USP), a compendium published by the United States Pharmacopeial Convention (USPC), a nonprofit trade organization founded in 1820.[5] A provision of the Food, Drug, and Cosmetic Act (FDCA) incorporates the standards of the USP by defining drug "adulteration" as a departure from USP standards.[6] Cadden and his co-defendants argued that by letting the USPC create legally binding rules, Congress had unconstitutionally delegated a legislative function to a private trade organization.[7] One hundred and ten years after the Pure Food and Drug Act of 1906 first incorporated USP standards into law, Cadden called into question the constitutionality of this arrangement.

Cadden's motion invoked the nondelegation doctrine, an old and (outside of legal circles), somewhat obscure constitutional principle. While this invocation may look like a "Hail Mary" strategy of a desperate defendant, on closer examination, the FDCA's incorporation of the USP raises a real constitutional problem. The nondelegation doctrine, which is rooted in the idea of separation of powers, allows Congress to delegate its legislative authority to another entity only when it provides an "intelligible principle" to guide and constrain how the delegate exercises that authority.[8] Moreover, typically such Congressional delegations are made to the President, or to government agencies, rather than to private organizations.[9] And yet the Pure Food and Drug Act of 1906 (1906 Act), and its 1938 successor, the FDCA, not only authorize a private organization to generate legally binding standards, but they place no limitations on the exercise of that power. Under the FDCA, neither FDA nor any other government agency can modify or veto the standards the USPC creates or revises. Any standards it publishes automatically become part of the law. Furthermore, the FDCA's definition of "drug" also incorporates the USP, which empowers the USPC to fundamentally alter what items qualify as drugs under the

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2 Milton J. Valencia*, Pharmacist's Greed Led to 25 Deaths, Prosecutors Say*, THE BOSTON GLOBE (Jan. 9, 2017), http://www.bostonglobe.com/metro/2017/01/09/opening-statements-due-fatal-meningitis-trial/VX6R3nroUD5RuxSkQ0QMSK/story.html?event=event12.

3 Denise Lavoie, *14 Charged for Roles in Meningitis Outbreak*, WBUR (Dec. 17, 2014), http://www.wbur.org/news/2014/12/17/framingham-meningitis-outbreak-arrests.

4 United States v. Cadden, WL 1948832 at *1 (D. Mass. 2016).

5 *Id.* at *2.

6 The provision defines a drug as adulterated if "it purports to be or is represented as a drug the name of which is recognized in an official compendium and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium." 21 U.S.C. §351(b).

7 *Cadden*, WL 1948832 at *2.

8 J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 409 (1928).

9 Section II(A)(3) outlines contrasting views on the constitutional permissibility of delegation to private parties.

statute. In sum, these delegations of power to the USPC appear to blatantly violate the nondelegation doctrine.

But if the FDCA's delegation of authority to the USPC violates the nondelegation doctrine in such an obvious way, how has this statutory arrangement lasted for more than one hundred and ten years without being invalidated by a court? One potential answer to this question is that this delegation only appears to violate the nondelegation doctrine, and that, on closer inspection, it is actually permissible. Alternatively, the FDCA's incorporation of the USP may be unconstitutional, but for one or more reasons, courts have avoided or resisted invalidating it.

This paper evaluates the constitutionality of the FDCA's incorporation of the USP. The first section evaluates its incorporation into the statutory definition of "drug" and the second section addresses the incorporation of USP standards into how the statute defines "adulteration" and "misbranding." Both sections analyze the various arguments that have been made to justify the constitutionality of these delegations and describe how courts have grappled with this issue. Over the last one hundred years courts have tried to reconcile this delegation with the nondelegation doctrine by avoiding the nondelegation issue altogether, engaging in creative statutory interpretation, and attempting to situate this delegation within the categories of permissible delegation. Ultimately, this paper concludes that the arguments justifying this delegation are unconvincing and that the provisions of the FDCA that delegate authority to the USPC are unconstitutional. In the conclusion, it reflects on what the survival of this delegation over the last one hundred and ten years might signal about the place and importance of the nondelegation doctrine more generally.

I. BACKGROUND

A. The Nondelegation Doctrine

1. A Brief Introduction to the Nondelegation Doctrine

The nondelegation doctrine is rooted in the principle of separation of powers. Its textual basis is Article I, Section 1 of the Constitution, which vests "all legislative Powers" in Congress.[10] The nondelegation doctrine forbids Congress from transferring its legislative power to another branch, helping to preserve the integrity of the tripartite system of the government ordained by the Constitution.[11] The heart of this doctrine has often been described with the maxim, *delegate potestas non potest delegari* ("no delegated powers can be further delegated").[12] In a democracy, the voters have conferred legislative authority on their representatives and this power to legislate is something the representatives cannot give away. The late Justice Scalia summarized the nondelegation doctrine by observing that, "it has always been assumed that these powers are non-delegable- or as John Locke put it, that legislative power consists of the power to 'make laws . . . not legislators.'"[13]

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[10] U.S. Const. art. I, §1.

[11] Marshall Field & Co. v. Clark, 143 U.S. 649, 692 (1892).

[12] Patrick W. Duff & Horace E. Whiteside, *Delegata Potestas Non Potest Delegari: A Maxim of American Constitutional Law*, 14 CORNELL L. REV. 168, 175 (1929).

[13] Bank One Chicago, N.A. v. Midwest Bank & Trust Co., 516 U.S. 264, 280 (1996)(Scalia, J., concurring).

Although the Constitutional text granted legislative power exclusively to Congress, the practical implications of this limitation were not immediately clear. Over the next century, the Supreme Court gradually articulated the outlines of the modern nondelegation doctrine.[14] In 1813, the Court made it clear that although Congress could not delegate its legislative power to another entity, it could make the operation of a law contingent on a factual determination made by the President.[15] The Court further fleshed out the nondelegation doctrine in 1825, writing that "the legislature makes, the executive executes, and the judiciary construes the law," but that "the maker of the law may commit something to the discretion of the other departments."[16] Unhelpfully, the Court observed that "the precise boundary of this power is a subject of delicate and difficult inquiry, into which a Court will not enter unnecessarily,"[17] but did not provide guidance about how courts were to distinguish between lawful and unlawful delegations. This lack of clarity has led some scholars to assert the Supreme Court did not adopt the nondelegation as a workable legal doctrine until 1892.[18] In that year, in *Field v. Clark*, the Supreme Court quoted an Ohio Supreme Court decision when it summarized the nondelegation doctrine: a legislature "cannot delegate its power to make a law," but "can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend."[19]

The distinction was straightforward conceptually, but determining whether a particular delegation was permissible could be challenging. The Supreme Court had long recognized that when Congress makes laws, it must often confer some degree of discretion on the person or agency authorized to execute the law because its execution sometimes depends on factual contingencies,[20] or because it is administratively impossible for Congress to determine the many numerous details[21] contemplated by a particular statute. In 1928, the Supreme Court finally articulated a

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[14] As a general restriction on legislative bodies, the nondelegation doctrine applies not just to Congress, but also to state legislatures. Although Supreme Court nondelegation cases receive the most scholarly attention, historically, state courts have heard more nondelegation challenges. Out of the 2,506 nondelegation cases heard in federal courts or state supreme courts between 1789 and 1940, more than 85 percent were decided in the state supreme courts. Keith E. Whittington & Jason Iuliano, *The Myth of the Nondelegation Doctrine*, 165 U. Pa. L. Rev., 379, 418 (2017).

[15] The Aurora, 11 U.S. 382, 388-89 (1813). The plaintiff in Aurora had argued that the Non-Intercourse Act violated the nondelegation doctrine by making an embargo contingent on the President's evaluation of whether Great Britain and France had met certain preconditions. *Id.* at 386.

[16] Wayman v. Southard, 23 U.S. 1, 46 (1825).

[17] *Id.*

[18] *E.g.,* Andrew J. Ziaja, *Hot Oil and Hot Air: The Development of the Nondelegation Doctrine Through the New Deal, A History, 1813-1944*, 35 HASTINGS CONST. L.Q. 921, 931 (2008).

[19] *Marshall Field*, 143 U.S. at 694.

[20] *E.g., Marshall Field*, 143 U.S. at 681-94 (upholding the Tariff Act of 1890 which authorized the President to suspend provisions of the Act when foreign governments imposed duties on certain products that were "reciprocally unequal and unreasonable"); Union Bridge Co. v. United States, 204 U.S. 364, 386 (1907)(upholding a statute in which Congress declared a general rule and directed the Secretary of War to determine which cases came within the rule).

[21] *E.g.*, Panama Ref. Co. v. Ryan, 293 U.S. 388, 421 (1935)("Undoubtedly legislation must often be adapted to complex conditions involving a host of details with which the national Legislature cannot deal directly"); J.W. Hampton, Jr., & Co. v. United States, 276 U.S. 394, 407 (1928) (acknowledging the impossibility of Congress fixing the "myriad" rates of interstate carriers itself and concluding that "common sense" required that Congress be able to delegate this administrative burden to a commission).

test to distinguish between permissible and impermissible delegations. What separates a lawful and unlawful delegation of authority is whether Congress laid down an "intelligible principle" to constrain the discretion of the entity receiving the delegation.[22]

The most famous example of Congressional failure to provide an "intelligible principle" occurred in 1935. In *A.L.A. Schechter Poultry Corp. v. United States*, the Supreme Court invalidated a provision of the National Industrial Recovery Act (NIRA) which authorized the President to approve or prescribe industry codes, affecting broad sectors of the national economy, but which supplied no standards or constraints for the exercise of his discretion other than the goal of assuring "fair competition."[23] Earlier the same year, the Court found another provision of NIRA deficient under the intelligible principle test. In *Panama Refining Company v. Ryan*, it struck down another NIRA provision which gave the President the authority over the interstate transportation of petroleum, but which completely failed to qualify or limit this Presidential authority.[24]

Since 1935, the Supreme Court has not invalidated a single statute on nondelegation grounds, leading Cass Sunstein to observe that the doctrine has had "one good year, and two hundred and two bad years."[25] The conventional explanation for the waning of the nondelegation doctrine after 1935 is that this decline was a necessary part of the reconstruction of the constitutional order that was accomplished during the New Deal Era.[26] The complex, interventionist economic legislation of the New Deal made Congress increasingly reliant on administrative agencies to "fill in the details" of the statutes it passed.[27] Since the New Deal, the Court has repeatedly upheld statutes in the face of nondelegation challenges, even statutes which delegate fairly broad powers with relatively minimal Congressional guidance.[28] One recent decision, *Whitman v. American Trucking Associations*, highlights the leniency with which the Supreme Court has applied the intelligible principle test. In *Whitman*, the Court affirmed the constitutionality of the Clean Air Act, which gave the Environmental Protection Agency the authority to set national ambient air quality standards at a level "requisite to protect public health."[29] In concluding that even this relatively vague language provided an adequate intelligible

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[22] *J.W. Hampton*, 276 U.S. at 409.

[23] A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 541–42 (1935).

[24] *Panama Ref. Co.,* 293 U.S. at 415.

[25] Cass R. Sunstein, *Is the Clean Air Act Unconstitutional?*, 98 MICH. L. REV. 303, 330 (1999).

[26] Whittington & Iuliano, *supra* note 14, at 386.

[27] *E.g.*, Sunshine Anthracite Coal Co. v. Adkins, 310 U.S. 381, 398 (1940) ("the effectiveness of both the legislative and administrative processes would become endangered if Congress were under the constitutional compulsion of filling in the details beyond the liberal prescription here").

[28] *See e.g.*, Yakus v. United States, 321 U.S. 414, 427 (1944)(Congressional instructions that prices be "fair and equitable" provided sufficient standards to constrain the discretion to constrain authority of Price Administrator); Am. Power & Light Co. v. Sec. & Exch. Comm'n, 329 U.S. 90, 105 (1946)(charge to Securities and Exchange Commission to prevent unfair or inequitable distribution of voting power among security holders provided sufficient guidance); Touby v. United States, 500 U.S. 160, 160 (1991)(limiting Attorney General's power to schedule a controlled substance on a temporary basis when doing so is "necessary to avoid an imminent hazard to public safety" was an adequate intelligible principle).

[29] Whitman v. Am. Trucking Associations, 531 U.S. 457, 473 (2001).

principle, Scalia summarized the Court's past nondelegation cases by noting that "we have almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law."[30]

2. Is the Nondelegation Doctrine Still Relevant?

The uneven enforcement of the nondelegation doctrine has led some to conclude that the nondelegation doctrine is a paper tiger.[31] But there are reasons to believe that the nondelegation doctrine remains relevant. First, while the Supreme Court has been lenient in applying the intelligible principle standard, it has signaled that there are clear nondelegation limits they are willing to enforce. Second, as some commentators have argued, the nondelegation doctrine may be alive and well as a group of canons of statutory construction.[32] Finally, the democratic values the doctrine serves continue to be relevant, prompting several scholars to advocate for its formal rehabilitation.

The Supreme Court's relatively recent jurisprudence suggests that some members of the Court are willing to enforce real limits on Congress' delegation of power. Justice Scalia's opinion in *Whitman*, although a very liberal application of the intelligible principle test, described one such limit. The degree of agency discretion that is acceptable, Justice Scalia wrote, "varies according to the scope of the power congressionally conferred."[33] Congress need not provide direction to the EPA about a relatively unimportant detail such as the definition of grain elevators, he observed, but it must provide "substantial guidance" when directing the EPA to set air standards affecting the entire national economy.[34] This suggests the Court might invalidate a statute which confers very broad power without substantial guidance. Other members of the court have also shown a readiness to invalidate a law on nondelegation grounds. In *Department of Transportation v. Association of American Railroads* (the *Amtrak* Case), Justice Alito would have found the statute in question unconstitutional on the grounds that it conferred lawmaking power on a private arbitrator, a kind of delegation for which he asserted that "there is not even a fig leaf of constitutional justification."[35] Finally, Justice Thomas has also demonstrated a strong commitment to the nondelegation doctrine, although he has articulated dissatisfaction with the intelligible principle test.[36]

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[30] *Id.* at 474–75.

[31] *E.g.*, Bernard W. Bell, *Dead Again: The Nondelegation Doctrine, the Rules/Standards Dilemma and the Line Item Veto,* 44 VILL. L. REV. 189 (1999).

[32] *See* Cass R. Sunstein, *Nondelegation Canons*, 67 U. CHI. L. REV. 315, 315-16 (2000).

[33] *Whitman v. Am. Trucking Associations*, 531 U.S. at 475.

[34] *Id.*

[35] Dep't of Transp. v. Ass'n of Am. Railroads, 135 S. Ct. 1225, 1238 (2015). The permissibility of delegations to private parties is discussed in the following section.

[36] *See* Whitman v. Am. Trucking Associations, 531 U.S. 457, 487 (2001)(Thomas, J., concurring)("I am not convinced that the intelligible principle doctrine serves to prevent all cessions of legislative power") and Dep't of Transp. v. Ass'n of Am. Railroads, 135 S. Ct. 1225, 1251-52 (2015)(Thomas, J., concurring)("It may never be possible perfectly to distinguish between legislative and executive power, but that does not mean we may look the other way when the Government asks us to apply a legally binding rule that is not enacted by Congress pursuant to Article I. We should return to the original meaning of the Constitution: The Government may create generally applicable rules of private conduct only through the proper exercise of legislative power").

A second reason the nondelegation doctrine may still be relevant is that, despite the Supreme Court's reluctance to use the nondelegation doctrine to strike down statutes, the doctrine is, as Sunstein argues, "alive and well" and "relocated rather than abandoned."[37] According to Sunstein, the nondelegation doctrine now appears as a set of canons of statutory construction, which prevent federal agencies from taking certain actions unless Congress has authorized them unequivocally.[38] The practical effect of these tools is that they are accountability-fostering, allowing the courts to force Congress to make certain decisions explicitly, instead of allowing agencies to make them.[39]

One of the best examples of the nondelegation doctrine at work in the guise of a tool of statutory construction is *Industrial Union Department, AFL-CIO v. American Petroleum Institute* (also known as the *Benzene* Case). At issue in the case was how to interpret provisions of the Occupational Safety and Health Act of 1970 (OSH Act). The OSH Act charged the Secretary of Labor with promulgating health and safety standards that were "reasonably necessary or appropriate to provide safe or healthful employment and places of employment."[40] And more specifically, in the context of regulating toxic substances, the Act provided that the Secretary "shall set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity."[41] OSHA had interpreted this provision to mean that, for carcinogens like benzene, if a minimum safe exposure level could not be determined, it must set an exposure limit at the lowest technologically feasible level that would not impair the economic viability of the regulated industries.[42] This line of reasoning led OSHA to abandon the previous limit on benzene (ten parts benzene per million parts of air) in favor of a more stringent standard (one part benzene per million parts of air).[43] The Court summarized the new standard as "an expensive way of providing some additional protection for a relatively small number of employees."[44] OSHA estimated that the standard would impose hundreds of millions of dollars in compliance costs, but would have an uncertain and likely small benefit to workers.[45]

Writing for the majority, Justice Stevens reasoned that if OSHA's interpretation of the statute was correct, it would "make such a sweeping delegation of legislative power that it might be unconstitutional."[46] Because there are thousands of carcinogens in American workplaces, OSHA's interpretation of the statute would have given the agency the ability to "impose enormous costs that might produce little, if any, discernable benefits."[47] Justice Stevens concluded that "a construction

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[37] Sunstein, *supra* note 36, at 315-16.

[38] *Id.* at 316.

[39] *Id.*

[40] Indus. Union Dep't, AFL-CIO v. Am. Petroleum Inst., 448 U.S. 607, 611-12 (1980).

[41] *Id.* at 612.

[42] *Id.* at 613.

[43] *Id.* at 607.

[44] *Id.* at 628.

[45] *Id.* at 628-30.

[46] *Id.* at 646.

[47] *Id.*

of the statute that avoids this kind of open-ended grant should certainly be favored."[48] A more reasonable interpretation of the Act was that the Secretary must first make a threshold finding that a significant risk of harm existed before promulgating health and safety standards.[49]

A pure nondelegation attack on the OSH Act would have struck the statute down for conferring so much power on the Secretary of Labor without placing the requisite limits on his exercise of discretion. But in the *Benzene* Case, the Supreme Court instead leveraged the nondelegation doctrine as a tool of statutory construction. It interpreted the OSH Act in such a way that it avoided the potential constitutional problem. One major advantage of this approach, Sunstein points out, is that applying a canon of statutory construction is a much easier task for a reviewing court than applying the more challenging intelligible principle test, which requires making judgments of degree.[50]

Finally, the nondelegation doctrine may remain relevant because the democratic values that it serves remain relevant. If these values appear to be under threat, courts may re-invigorate the doctrine in response. One of the clearest articulations of these values occurs in Justice Rehnquist's concurrence in the *Benzene* case. While the majority side-stepped the nondelegation question through statutory interpretation, Justice Rehnquist would have struck down the OSH Act, arguing that the Court "ought not to shy away from our judicial duty to invalidate unconstitutional delegations of legislative authority."[51] He cited three key functions of the non-delegation doctrine: (1) ensuring that important choices of social policy are made by the branch of the government most responsive to the public will (Congress), (2) guaranteeing that recipients of delegated authority receive guidance in the form of an intelligible principle, and (3) enabling courts to test the exercise of that authority against some concrete standard.[52] In a discussion of the values served by the nondelegation doctrine, Sunstein notes that another result of forcing Congress to make certain decisions is that it may raise the burdens and costs of making federal law, which could be seen as protective of individual liberty.[53] Furthermore, requiring Congress to provide guidance also serves rule of law values, furnishing fair notice to those subject to a law and preventing unelected bureaucrats from exercising their discretion in an arbitrary way.[54] Finally, requiring Congress to provide clear standards could also be a check against powerful interest groups that might lobby for parochial interests.[55] The importance of these functions have prompted many commentators to urge that the nondelegation doctrine be reinvigorated.[56]

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[48] *Id.*

[49] *Id.* at 642.

[50] Sunstein, *supra* note 36, at 321.

[51] *Am. Petroleum Inst.,* 448 U.S. at 686.

[52] *Id.* at 685.

[53] Sunstein, *supra* note 36, at 319-20.

[54] *Id.*

[55] *Id.*

[56] *See, e.g.*, David Schoenbrod, *Separation of Powers and the Powers That Be: The Constitutional Purposes of the Delegation Doctrine*, 36 AM. U. L. REV. 355, 356 (1987)(arguing that the nondelegation doctrine safeguards public welfare and individual values and should be revived); Joseph Postell, *From*

3. Are Delegations to Private Parties Permissible?

The majority of nondelegation decisions have analyzed whether and how Congress can delegate legislative authority to the President, administrative agencies, or courts. There have been fewer decisions, and less written, about whether Congress may delegate legislative authority to private parties. The conventional nondelegation doctrine requires that legislative delegations to governmental entities be limited by some intelligible principle. Does the same standard apply for delegations to private parties, or is any legislative delegation to a private party forbidden?[57] Currently, both positions have proponents, and there is no Supreme Court case which definitively addresses this question.

The D.C. Circuit emphatically endorsed the position that any legislative delegation to private parties is invalid in the 2013 *Amtrak* case. In *Amtrak*, the contested provision of the Passenger Rail Investment and Improvement Act of 2008 (PRIIA) tasked Amtrak and the Federal Railway Administration with jointly developing standards related to on-time performance and service quality.[58] These standards would then have bound railway freight carriers.[59] The Association of American Railroads charged that this scheme was an unconstitutional delegation of legislative power to Amtrak, a private entity.[60] In its discussion, the D.C. Circuit flatly rejected the validity of delegation to private parties. "Federal lawmakers," it wrote, "cannot delegate regulatory authority to a private entity."[61] Assigning regulatory authority to a private party is "legislative delegation in its most obnoxious form," it concluded, quoting *Carter v. Carter Coal Company.*[62] In *Carter Coal*, the Supreme Court struck down a provision of the Bituminous Coal Conservation Act of 1935 which allowed two-thirds of coal producers in a district to fix maximum hours and minimum wages for coal miners in that district.[63] This was "legislative delegation in its most obnoxious form," in the eyes of the Supreme Court because "it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business."[64] In other words, delegations to private parties may create problems that are not present in delegations to government agencies. Therefore, the D.C. Circuit reasoned, "even an intelligible principle cannot rescue a statute empowering private parties to wield regulatory authority."[65] The court concluded that Congress may authorize private parties to participate in proposing

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Administrative State to Constitutional Government, The Heritage Foundation (Dec. 7, 2012), http://www.heritage.org/political-process/report/administrative-state-constitutional-government#Part1.

[57] Calvin R. Massey, *The Non-Delegation Doctrine and Private Parties*, 17 GREEN BAG 2d 157, 160 (2014).

[58] Ass'n of Am. Railroads v. U.S. Dep't of Transp., 721 F.3d 666, 668 (D.C. Cir. 2013), vacated and remanded sub nom. Dep't of Transp. v. Ass'n of Am. Railroads, 135 S. Ct. 1225 (2015).

[59] *Id.*

[60] *Id.* at 670.

[61] *Id.*

[62] Carter v. Carter Coal Co., 298 U.S. 238 (1936).

[63] *Id.* at 311.

[64] *Id.*

[65] *Ass'n of Am. Railroads*, 721 F.3d at 671.

regulation (citing *Sunshine Anthracite Coal Company v. Adkins*[66]), but only if that role is to "aid" a government agency which ultimately retains the discretion to approve, disapprove, or modify regulations.[67] Although the Supreme Court reversed the D.C. Circuit in the *Amtrak* case, it did so in a way that avoided squarely confronting the question of delegation to private parties. Amtrak, it decided, was actually a government entity, not a private party,[68] and so therefore it did not have to address whether or when a delegation to a private party is permissible.[69]

In contrast to the D.C. Circuit Court's position in *Amtrak*, others have argued that the rule for legislative delegations to private parties is the same that applies to government entities: a delegation is valid as long as an intelligible principle is supplied. Alexander Volokh reasons that the nondelegation doctrine is fundamentally about whether Congress has given up so much power that it has abdicated its responsibilities, not about who receives power from Congress.[70] While the D.C. Circuit in *Amtrak* grounds its opposition to private delegations in *Carter Coal*, Volokh contends that this is a misreading of *Carter Coal*, and that *Carter Coal* is fundamentally a Due Process Clause case, not a nondelegation case.[71] Indeed, the Court's reasoning in *Carter Coal* does seem unclear. In the paragraph in which it discusses the private delegation, the Court opens by roundly condemning "legislative delegation in its most obnoxious form," but the paragraph ends by concluding that the delegation is "clearly arbitrary, and so clearly a denial of rights safeguarded by the due process clause of the Fifth Amendment."[72] It is not clear what is doing the work here: the nondelegation doctrine in the form of a blanket prohibition on private delegations, or the Due Process Clause. Moreover, Volokh argues that the Supreme Court upheld a private delegation in Currin v. Wallace, which shows that private delegations are not per se illegal.[73] In *Currin v. Wallace*, the Supreme Court upheld the constitutionality of the Tobacco Inspection Act, which made the operation of a certain regulation contingent on two-thirds of tobacco growers voting in favor of it.[74] The Court wrote that Congress may exercise its legislative authority in prescribing the conditions of its application.[75] Just as Congress conferred authority on the

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[66] In *Sunshine Anthracite Coal Co. v. Adkins*, the Supreme Court upheld the Bituminous Coal Act of 1937, which authorized local boards of coal producer to propose minimum coal prices, but which would be approved, disapproved, or modified by the Bituminous Coal Division of the Department of the Interior. 310 U.S. 381, 399 (1940).

[67] *Ass'n of Am. Railroads,* 721 F.3d at 671.

[68] Dep't of Transp. v. Ass'n of Am. Railroads, 135 S. Ct. 1225, 1233 (2015).

[69] However, in his concurrence, Alito did address this issue. In the event that Amtrak and the FRA were unable to agree on joint standards, the PRIIA provided for binding arbitration to settle the dispute. Because this individual was likely a private party, the respondent argued that this was unlawful delegation to a private party. Dep't of Transp. v. Ass'n of Am. Railroads, 135 S. Ct. 1225, 1236 (2015)(Alito, J., concurring). Alito wrote: "I agree with the parties: If the arbitrator can be a private person, this law is unconstitutional." *Id.* at 1237.

[70] Alexander "Sasha" Volokh, *The Shadow Debate over Private Nondelegation in Dot v. Association of American Railroads*, CATO SUP. CT. REV., 2014-2015, at 369.

[71] *Id.* at 359.

[72] Carter v. Carter Coal Co., 298 U.S. 238, 311(1936).

[73] Volokh, *supra* note 74, at 359.

[74] Currin v. Wallace, 306 U.S. 1, 15 (1939).

[75] *Id.*

President to decide when certain tariff provisions would go into effect in *J.W. Hampton, Jr., & Co. v. United States*,[76] it could also make the exercise of its authority contingent on a two-thirds vote.[77] What is significant about this reasoning, Volokh argues, is that it upholds a private delegation on the same grounds that it upheld a delegation to the President.[78] Therefore, the standard for judging private delegations is the same for delegations to public officials: the intelligible principle test.[79]

In addition to these two positions, Eric Posner and Adrian Vermuele have articulated an alternative understanding of the non-delegation doctrine under which almost any delegation to a private party would be valid. Posner and Vermuele agree that the legislature may not delegate legislative authority to an agent, but argue that when Congress makes a statutory grant of authority, an agent that acts with that authority is, by definition, exercising executive power, not legislative power.[80] The traditional nondelegation rule, they assert, lacks any foundation in constitutional text or structure.[81] In their view, the only thing that the Constitution would forbid is if legislators delegated the authority to vote on federal statutes or to exercise the powers of federal legislators.[82] In other words, Congress may make almost any kind of delegation, and no intelligible principle is required. Furthermore, the identity of the delegate does not matter.[83] Logically, they point out, the delegation question focuses on the abdication of Congress, not the nature of the delegate.[84] Under this view, a Congressional delegation to a private party is almost never invalid, except in the extreme example of a legislator delegating his or her right to vote to a private party.

B. How the USP Was Incorporated into Law

1. The 1906 Pure Food and Drug Law

The 1906 Act had its roots in the tumultuous social and economic changes of the nineteenth century. Industrialization and the growth of corporations created a more impersonal relationship between food producers and drug manufacturers and their respective consumers.[85] And as urban centers grew, overcrowding generated outbreaks of diphtheria, typhoid, and tuberculosis, driving demand for curative "nostrums," many of which were fraudulent or dangerous.[86] Beginning in 1883, Dr. Harvey Wiley, the Chief Chemist of the U.S. Department of Agriculture, conducted

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[76] *J.W. Hampton*, 276 U.S. at 407.

[77] *Currin*, 306 U.S. at 16.

[78] Volokh, *supra* note 74, at 369.

[79] *Id.*

[80] Eric A. Posner & Adrian Vermeule, *Interring the Nondelegation Doctrine*, 69 U. CHI. L. REV. 1721, 1721 (2002).

[81] *Id.* at 1722.

[82] *Id.* at 1723.

[83] *Id.* at 1757.

[84] *Id.*

[85] Dennis R. Johnson, *The History of the 1906 Pure Food and Drug Act and the Meat Inspection Act*, 37 FOOD DRUG COSM. L. J. 5, 6 (1982).

[86] *Id.*

a series of widely publicized investigations that raised public awareness about the danger of adulterated foods and drugs.[87] Although regulating food and drugs had long been considered a function of state governments, there was a growing realization that state legislation was inadequate to confront these problems, either because states lacked the resources to enforce such legislation, or because lack of uniformity in state laws itself created enforcement problems.[88]

The growing demand for national food and drug legislation was sharpened by a series of well-publicized tragedies. In 1898, adulterated canned meat was shipped to U.S. troops in Cuba, allegedly killing more soldiers than Spanish bullets, and prompting the Senate to hold investigatory hearings.[89] In 1901, thirteen children in St. Louis died of tetanus after receiving diphtheria antitoxin which had been carelessly prepared from a horse with tetanus.[90] Reformers pointed to the incident as proof that government supervision was required to safeguard the nation's food and drug supply.[91] Across the country, professional medical associations and women's groups, like the National Women's Christian Temperance Union, lobbied for comprehensive food and drug legislation.[92] But the event that galvanized passage of the 1906 Act was the publication of Upton Sinclair's *The Jungle*. Sinclair's vivid description of the horrifyingly unsanitary conditions that prevailed in meat packing houses in Chicago sparked national outrage.[93] In response, on December 5, 1905, President Theodore Roosevelt forcefully called for legislation to address misbranded and adulterated food and drugs, reinvigorating a stalled Congressional effort.[94] This newly generated momentum came to fruition on June 30, 1906, when the Pure Food and Drug Act was finally signed into law.[95]

This political victory for reformers represented a culmination of years of legislative wrangling. Altogether, there had been more than 100 different food and drug bills, dating back to 1848, which preceded passage of the 1906 Act.[96] Among these numerous bills, the most significant were the 1879 Wright Bill (which would have prohibited the adulteration of food), the Hawley Bill of 1881 (which added a prohibition against adulterated drugs), and the Lee Bill of 1888 (which would have prohibited misbranding, as well as adulteration, of food and drugs).[97] From 1880 until 1905, these bills ran into a variety of obstacles. Some of the earliest bills were adversely reported out of committee on the grounds that the legislation

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[87] Richard Curtis Litman & Donald Saunders Litman, *Protection of the American Consumer: The Muckrakers and the Enactment of the First Federal Food and Drug Law in the United States*, 36 FOOD DRUG COSM. L. Q. 647, 662 (1981).

[88] Charles Wesley Dunn, *Its Legislative History*, 1 FOOD DUG COSM. L. Q. 297, 306 (1946).

[89] Johnson, *supra* note 89, at 7.

[90] Jillian London, *Tragedy, Transformation, and Triumph: Comparing the Factors that Led to the Adoption of the 1860 Adulteration Act in England and the 1906 Pure Food and Drug Act in the United States*, 69 FOOD & DRUG L. J. 315, 328 (2014).

[91] *Id.*

[92] *Id.* at 325.

[93] Litman & Litman, *supra* note 91, at 665.

[94] *Id.*

[95] *Id.* at 667.

[96] Dunn, *supra* note 92, at 298.

[97] *Id.* at 298-99.

unconstitutionally infringed on the purview of the states.[98] Others were favorably reported out of committee, but failed to reach a final vote, or passed the House, but not the Senate, or vice versa.[99]

The final version of the 1906 Act prohibited the manufacture or sale in interstate commerce of adulterated and misbranded food and drugs, provided criminal penalties for violations,[100] and authorized the seizure of offending products.[101] The law defined "drug" for the purpose of the 1906 Act to "include all medicines and preparations recognized in the United States Pharmacopeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals."[102] Under the 1906 Act, a drug was "adulterated" when "sold under or by a name recognized in the United States Pharmacopeia or National Formulary, it differs from the standard of strength, quality, or purity as determined by the test laid down in the United States Pharmacopeia or National Formulary official at the time of the investigation."[103] However, the definition of adulteration also included a so-called "variation clause." If a drug listed in the USP varied in some respect from the published standards, as long as that variation in strength, quality, or purity was "plainly stated upon the bottle, box, or container," it would not be considered adulterated.[104]

This statutory language authorized private organizations, the publishers of the USP and National Formulary (NF), not only to determine what would be considered a "drug," but also what standards drug manufacturers must adhere to in order to avoid the criminal offense of manufacturing adulterated drugs.

In one respect, incorporating the USP and NF into national legislation did not make the United States unique. Pharmacopeias or formularies, collectively known as drug compendia, are reference books whose purpose is to assure drug product standardization by providing specification limits for identity, quality, purity, and potency of drugs and dosages.[105] Referencing such pre-existing standards saves legislatures from duplicating the work of creating standards. But what was unusual in this case was that the compendia referenced in the 1906 Act were developed and published by private organizations. Writing in 1953, Peter Urdang cited a 1926 article appearing in *The Chemist and Druggist* which surveyed the national pharmacopeias of 23 different countries and noted that of the 23, only two were the products of private initiative: the pharmacopeias of the United States and Venezuela.[106] In the 21 other countries, government departments or governmental

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[98] *Id.* at 300.

[99] *Id.* at 301-02.

[100] Pure Food and Drug Act of 1906, Pub. L. No. 59-384, §§1, 2, 34 Stat. 768 (repealed 1938).

[101] *Id.* at §10.

[102] *Id.* at §6.

[103] *Id.* at §7.

[104] *Id.*

[105] Martin Blake, *The Role of the Compendia in Establishing Drug Standards*, 31 FOOD DRUG COSM. L.J. 276, 276 (1976).

[106] George Urdang, *The Development of the Pharmacopeias*, 8 FOOD DRUG COSM. L. J. 69, 87-88 (1953).

appointees were responsible for promulgating the standards appearing in their national pharmacopeias.[107]

Interestingly, one historian notes that while there was great contention within Congress about how food standards should be established for the 1906 Act, there was virtually no controversy at all over the provisions which incorporated the USP and NF standards for drugs.[108] Another historian records that James Beal, Chairman of the USP Board of Trustees, was personally responsible for the fact that the Act adopted the USP and NF as the standards to be used for determining adulteration.[109] In fact, the inclusion of the USP standards into the 1906 Act was not without precedent. In 1848, in response to the growing problem of adulterated foreign drugs during the Mexican-American War, Congress passed the 1848 Drug Import Act.[110] Under the terms of that Act, imported drugs were required to comply with the standards printed in the USP or those appearing in one of a handful of international pharmacopeias, a requirement which was enforced by the inspections of special Customs Service examiners.[111]

2. A Brief History of the United States Pharmacopeia

Historically, it is perhaps unsurprising that Congress would have drawn on the drug standards previously established by the USPC. By 1906, the USP was already a fixture in the American drug manufacturing industry. Although the antecedents of the USP date back to the Sixteenth Century,[112] its immediate roots go back to the founding of the country. Early colonial American physicians and apothecaries largely relied on pharmacopeias published in London and Edinburgh, but after independence, there was growing interest in developing a U.S. pharmacopeia, particularly one that would include drugs native to North America.[113] The man that channeled this general interest into the creation of the USP was Dr. Lyman Spalding. In 1818, Spalding invited medical societies and schools to send delegates to four regional conferences, where delegates would draft versions of a pharmacopeia for submission to a national conference to be held in 1820.[114] After hammering together a compiled version of the Pharmacopeia, the national convention provided for a decennial meeting in 1830 to consider revisions for the book.

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[107] *Id.* at 88.

[108] Dunn, *supra* note 92, at 308.

[109] Dennis Worthen, *Pharmaceutical Legislation: A Historical Perspective*, 10 INTERNATIONAL JOURNAL OF PHARMACEUTICAL COMPOUNDING 20, 23 (2006). Worthen records that Beal was also responsible for suggesting that the "variation clause" be added to the Act, as a way of mollifying any resistance drug manufacturers might have to the incorporation of USP standards. *Id.*

[110] Angela Walch, *A Spurious Solution to a Genuine Problem: An In-depth Look at the Import Drug Act of 1848*, 4 (2002) in Peter Barton Hutt, ed., *Food and Drug Law: An Electronic Book of Student Papers*.

[111] *Id.* at 42.

[112] The first book to bear the label "pharmacopeia" was the *Pharmacopoaea libri tres*, which appeared in Lyon in 1548 and like the USP, was a private publication. Urdang *supra* note 110, at 70. Within the next century, the first national, official pharmacopeias began to appear, including the 1573 *Ricettario Fioerentino* (the official compendium of the Grandduchy of Tuscany) and the 1618 *Pharcopoeia Londinensis* (the official compendium for the "realme of England or the dominions thereof"). *Id.* at 84.

[113] E. Fullerton Cook, *History of the Pharmacopeia*, 1 FOOD DRUG COSM. L.Q. 518, 520 (1946).

[114] *Id.* at 521.

The first USP, published in December 1820, was favorably received, and was even adopted for use by the Surgeon General of the Army.[115] The publication of a national standard meant that, for the first time, a patient taking a particular drug could be sure he was receiving an identical product, whether dispensed in New York, Boston, or Philadelphia.[116] The USP continued to be revised and republished every 10 years.[117] The 1840 edition of the USP was particularly significant in that, for the first time, pharmacists were involved in helping make the revisions.[118] In 1888, the American Pharmaceutical Association published the first NF, which was a collection of formulas for "unofficial" products not included in the USP.[119] (In 1975, the USPC acquired the NF and combined the two publications together into the USP-NF).[120] By 1906, the USP enjoyed wide acceptance in the drug trade as an authoritative reference work.[121]

3. THE 1938 FOOD, DRUG, AND COSMETIC ACT

Although the 1906 Act was replaced in 1938 by the FDCA, the USP was incorporated into the new law in an essentially identical manner.[122] In fact, the FDCA further consolidated the position of this publication with the addition of two new provisions. The first was a provision designed to standardize the process of evaluating drugs to determine if they were adulterated. Following 1906, but prior to 1938, manufacturers were required to adhere to the drug standards of the USP to avoid "adulteration," but there was no specified method of analysis to determine whether a drug met these standards, which was a significant obstacle to enforcement.[123] One of the innovations of the FDCA was the addition of a provision that the determination of a drug's strength, quality, and purity were to be determined, "in accordance with the tests or methods of assay set forth in such compendium."[124] Not only would the USP set the strength, quality, and purity standards for drugs, but it would also determine the formal method used to determine whether a drug was in

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[115] *Id.* at 522.

[116] Blake, *supra* note 109, at 277.

[117] In 1942, the publication cycle of the USP was revised to every five years. The United States Pharmacopeial Convention, USP Milestones—A Timeline (2017), http://www.usp.org/about/history-information-center/usp-milestones-timeline#1900.

[118] Worthen, *supra* note 113, at 22.

[119] Blake, *supra* note 109, at 277.

[120] The United States Pharmacopeial Convention, *supra* note 117.

[121] Walton M. Wheeler, *Validity of "Official" Drug Standards*, 1 FOOD DRUG COSM. L.Q. 588, 593 (1946).

[122] *See* Food, Drug, and Cosmetics Act of 1938, Pub. L. No. 75-717, ch. 765, 52 Stat. 1040 (1938), §201(g)(defining "drug" as "articles recognized in the United States Pharmacopeia, Official Homeopathic Pharmacopeia of the United States, or official National Formulary, or any supplement to any of them"); §501(b)(specifying that a drug is "adulterated" if "it purports to be or is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality and purity fall below, the standard set forth in such compendium"). Although the FDCA incorporates three different publications (the USP, NF, and the Official Homeopathic Pharmacopeia), this paper will focus on the USP in the interest of simplicity. The nondelegation issues are the same for all three publications, but since 1975 the NF has been published by the USPC and nondelegation issues arise more rarely in the context of the Homeopathic Pharmacopoeia.

[123] Edward G. Feldman, *Federal Drug Legislation and the New National Formulary*, 19 FOOD DRUG COSM. L.J. 598, 598-99 (1964).

[124] Food, Drug, and Cosmetics Act, §501(b).

compliance with this standard.[125] The second provision was new language which defined "misbranding." Under the FDCA, a drug was now "misbranded" if it purported to be a drug recognized in a compendium but failed to be packaged or labeled as prescribed in the compendium.[126] This section also provided that the method of packing could be modified with the consent of the Secretary of Agriculture but did not make a similar allowance for labeling.[127]

Since 1938, the FDCA has been amended more than 100 times and has swelled to more than 30 times its original length,[128] but the modern version still incorporates the USP in the same way. Articles recognized in the USP are still part of the Act's definition of "drug."[129] Under current law, a drug is deemed adulterated if "it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium,"[130] where an "official compendium" is defined as "the official United States Pharmacopeia, official Homeopathic Pharmacopeia of the United States, official National Formulary, or any supplement to any of them."[131] The current law also retains the provision that determinations of a drug's strength, quality, and purity, "shall be made in accordance with the tests or methods of assay set forth in such compendium."[132] Finally, the requirement to package and label a drug in accordance with compendium standards also remains unchanged.[133]

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[125]Interestingly, the provision also specified that if the USP or NF failed to specify a testing method, or, if in the judgment of the Secretary, the testing method was "insufficient," the law provided that the Secretary should bring this to the attention of the bodies responsible for revising the USP and NF, and if the bodies failed to respond in a timely manner, the Secretary was to promulgate regulations to specify a testing method. *Id.* So even though the Secretary had no authority to reject the drug standards promulgated by the USP and NF, he did have an ability to do something like an informal veto of the testing methods developed by these bodies.

[126]Food, Drug, and Cosmetics Act, §502(g).

[127]*Id.* Although this provision remains in the Act today, the statutory term "Secretary" is now defined as the Secretary of Health and Human Services rather than the Secretary of Agriculture.

[128]Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, FOOD AND DRUG LAW: CASES AND MATERIALS, 11 (2014).

[129]21 U.S.C. §321(g)(1)("The term "drug" means (A) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C).")

[130]21 U.S.C. §351.

[131]21 U.S.C. §321(j). Again, although the law incorporates all three publications, this paper will focus on the incorporation of the USP.

[132]21 U.S.C. §351.

[133]21 U.S.C. §352(g).

II. IS THE FOOD, DRUG, AND COSMETIC ACT'S INCORPORATION OF THE UNITED STATES PHARMACOPEIA AN UNCONSTITUTIONAL DELEGATION OF LEGISLATIVE POWER?

The incorporation of the USP into the original 1906 Act, and its retention in the FDCA until the present day, presents a puzzle. If the traditional nondelegation doctrine does not forbid delegation to private parties altogether, it requires that Congress, at a minimum, provide such a delegate an intelligible principle to guide the exercise of its discretion. But in the 1906 Act and subsequent legislation, Congress appeared to delegate the power to determine what qualifies as a drug and what standards a drug must meet to avoid prosecution for adulteration or misbranding to a private organization. Moreover, because the definition of "official compendium" includes "any supplement" to the three listed publications,[134] the law incorporates not just the content of the USP as it existed at the time of enactment, but all its future revisions and editions as well. This means that the USPC is authorized by Congress to continue to alter what qualifies as a drug under the statutes and to create or modify legally binding standards that are enforced by criminal penalty.[135] This sweeping delegation of power to the USPC is not accompanied by any statutory language to guide or constrain its conduct. Additionally, the statute does not allow FDA (or any other government entity) to modify or veto additions or revisions to the USP. Any additional articles added to the USP are automatically incorporated in the definition of "drug" and any changes to drug standards are automatically incorporated into law. This statutory arrangement presents obvious constitutional problems for those who believe the nondelegation doctrine forbids any kind of delegation to private parties, as exemplified by the D.C. Circuit Court's opinion in the *Amtrak* case. But the statute's complete lack of any guidance to the USPC also presents serious problems for those like Volokh, who believe delegations to private entities are permissible, but require an intelligible principle. In short, no matter what position on delegation to private parties is adopted, it appears that by writing the USP into the 1906 Act (and retaining it in the FDCA), Congress has violated the nondelegation doctrine. The USP incorporation is constitutionally acceptable only under a non-traditional nondelegation framework like that proposed by Vermuele and Posner, which does not require Congressional provision of an intelligible principle.

Moreover, there are two different ways in which the FDCA's incorporation of the USP violates the traditional nondelegation doctrine. The first violation is that the statute's definition of "drug" rests, in part, on what items are listed in the USP. The definition of "drug" has great practical significance because it determines the reach of the statute and, correspondingly, the jurisdiction of FDA. The second way the USP's incorporation offends the nondelegation doctrine is that the statutory provisions defining the offenses of "adulteration" and "misbranding" allow the USP to unilaterally create and revise drug manufacturing, labeling, and shipping standards

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[134] 21 U.S.C. §321(j).

[135] The law prohibits the adulteration or misbranding of any drug, or the introduction or receipt of a misbranded or adulterated drug in interstate commerce. 21 U.S.C. §331(a)(b)(c). The law provides for imprisonment for not more than one year and/or a fine of not more than $1000. 21 U.S.C. §333.

that have the force of law. Because these two different mechanisms of incorporation raise different policy issues and have been addressed somewhat differently by courts and commentators, they are analyzed separately here in two different sections. Each of these sections describes in further detail how the USP is incorporated into existing law, analyzes the constitutional permissibility of this arrangement, and describes how courts and commentators have addressed the nondelegation issues raised by the incorporation.

A. Does the Incorporation of the United States Pharmacopeia into the Definition of "Drug" Violate the Nondelegation Doctrine?

1. The Problem with Allowing a Private Organization to Determine a Statute's Reach and an Agency's Jurisdiction

The FDCA's definition of "drug" is partly, but not wholly, reliant on the USP. The term "drug" is defined as:

> (A) articles recognized in the official United States Pharmacopeia . . . or official National Formulary, or any supplement to them; (B) articles intended for the use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; (C) articles (other than food) intended to affect the structure or any function of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).[136]

By the plain text of the statute, if an item is listed in the USP, then it qualifies as a drug. However, an item does not have to be listed in the USP in order to qualify as a drug as long as it meets the requirements of clauses (B), (C), or (D). The practical effect of this definition is that, as the USPC adds new items to the USP, it theoretically expands the category of items defined as drugs. Although less likely, it is also possible that, by removing items from the USP, it could contract this category (unless the items being removed would independently qualify as drugs under the other three clauses).

The ability of a private organization to unilaterally manipulate the category of items that qualify as drugs under the statute is not just a curiosity. It has substantial practical significance for both the regulated industry and for FDA as regulator. The FDCA proscribes certain conduct and provides criminal punishment for those who transgress its prohibitions. But its statutory reach is limited to just certain categories of products such as drugs, devices, food, cosmetics, and tobacco products. For a manufacturer, whether a product qualifies as a drug is an exceptionally important question, as it determines whether the manufacturer must comply with the FDCA—or face criminal penalties for failing to do so. It is an equally important question for FDA, because its jurisdiction as an agency is directly tied to the categories of products over which the FDCA gives it authority.[137]

Enabling a private organization to adjust the scope of an agency's jurisdiction raises significant nondelegation concerns because determining the scope of an

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[136]21 U.S.C. §321(g)(1).

[137]Hutt, Merrill & Grossman, *supra* note 132, at 77.

agency's authority is a quintessentially legislative function. In the absence of a delegation from Congress, an agency has no power.[138] Courts have recognized that establishing agency jurisdiction is a uniquely legislative function by refusing to defer to an agency's own interpretation of its jurisdiction when this interpretation clearly conflicts with jurisdictional limits established by Congress and articulated in statutory language. For example, when FDA attempted to assert jurisdiction over tobacco products in 1996 (claiming that nicotine is a "drug" and smokeless tobacco is a "device" under the FDCA), the Supreme Court rejected this interpretation of the FDCA in *Food and Drug Administration. v. Brown & Williamson Tobacco Corporation*, concluding that the statute, as well as other tobacco-specific legislation, made it clear that Congress intended to exclude tobacco from FDA's jurisdiction.[139]

Furthermore, when the Environmental Protection Agency (EPA) declined a petition to issue greenhouse gas regulations under the Clean Air Act, citing extra-statutory reasons for declining to assert its jurisdiction, the Supreme Court rejected this line of reasoning in *Massachusetts v. Environmental Protection Agency*, pointing to the agency's obligation under the statute to protect the public health and welfare.[140] In other words, it is the role of the legislature, through the statutes it creates, to determine agency jurisdiction. When agencies attempt to expand or contract their own jurisdiction in ways forbidden by statute, as in *Brown and Williamson* or *Massachusetts v. EPA*, the courts have re-affirmed this principle.[141] If allowing an agency to determine the extent of its own jurisdiction is problematic, then allowing a private party to determine the extent of an agency's jurisdiction is even more troubling. In enabling the USPC to change the contours of FDA's jurisdiction, Congress appears to have transferred a fundamental legislative power.

However, this grant of authority could still be constitutionally permissible under the nondelegation doctrine. Of course, those who believe that delegation to private parties is always prohibited would find this delegation objectionable on its face. Unlike the *Amtrak* case, where there was some ambiguity about whether Amtrak was a public or private entity, the USPC is unambiguously a private organization, and has been since its inception. But for those who do not believe private delegations are *per se* forbidden, the relevant question here is whether Congress supplied an intelligible principle to guide the USPC.

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[138]*See* City of Arlington, Tex. v. F.C.C., 133 S. Ct. 1863, 1880 (2013) (Roberts, J., dissenting)("Agencies are creatures of Congress; an agency literally has no power to act . . . unless and until Congress confers power upon it"). *See also* Nathan Alexander Sales & Jonathan H. Adler, *The Rest Is Silence: Chevron Deference, Agency Jurisdiction, and Statutory Silences*, 2009 U. Ill. L. Rev. 1497, 1562 (2009) ("Absent a legislative determination that produces a delegation, there is no agency authority at all").

[139]Food & Drug Admin. v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 121-22 (U.S. 2000).

[140]Massachusetts v. E.P.A., 549 U.S. 497, 497-501 (2007).

[141]However, in cases where there is statutory ambiguity, an agency's interpretation of its own jurisdiction receives *Chevron* deference from courts. City of Arlington, Tex. v. F.C.C., 133 S. Ct. 1863, 1864 (2013). This deference is not applicable where the statute clearly forecloses the agency's interpretation.

2. Is there an Intelligible Principle to Guide the Addition or Removal of Items from the United States Pharmacopeia?

Finding an intelligible principle in a statute is typically a low hurdle for a court to surmount. The Supreme Court has "almost never felt qualified to second-guess Congress regarding the permissible degree of policy judgment that can be left to those executing or applying the law,"[142] and cases like *American Trucking* demonstrate that even relatively vague statutory language can be converted to serve as an intelligible principle.

But here the FDCA appears to provide literally no guidance at all to the USPC to help guide its determination as to what items should and should not be included in subsequent revisions. There is also no authorization for FDA to review or veto any amendments. However, there are a few theories under which a court might find an intelligible principle.

First, Congress may have assumed in 1906 that the USPC would continue to use the same criteria for selecting articles to include in the USP that it had been using since 1820. This might be an argument for a sort of implicit intelligible principle. While this is not a completely unreasonable assumption, there is nothing in the statute to preclude the USPC from changing the criteria it uses for inclusion. In fact, this sort of change may be inevitable as an organization evolves and changes over more than a century. Criteria changes may be particularly likely in light of technological changes occurring over this period. In short, there is nothing to prevent the USPC from deviating from any original implicit understanding Congress might have had. It is therefore difficult to characterize such an understanding as an intelligible principle.

Second, it might be possible to infer an intelligible principle from looking at the other parts of the definition of "drug" for a clearer idea of what Congress thought should qualify as a drug. So, for example, an article intended to affect the structure of function of the body, as in clause (C), would be a good candidate for inclusion in the USP. But there are two problems with this proposed intelligible principle. First, without any explicit direction to the USPC from Congress, there is no obligation on the part of the USPC to take the other clauses of the definition into account when determining what items to include in the USP. Second, the rule against surplusage in statutory construction would actually suggest that what is included in clause (A) must somehow be different from what is included in clauses (B) and (C), or (A) would be redundant. This would counsel against trying to derive the meaning of (A) by reference to the other clauses.

Finally, it is possible that the larger statutory purposes of the FDCA supply enough of an intelligible principle to allow this delegation to pass muster. Under this theory, the discretion of the USPC could be adequately channeled by referencing the larger policy goals Congress had in mind when it created the statute. Writing in 1946, the general counsel for Eli Lilly, Walton Wheeler, articulated this position:

> It is apparent that congressional delegations will be upheld if the statute defines clearly the legislative policy and establishes general standards to guide and limit the grantee of the power. It is submitted that the Federal Food, Drug, and Cosmetic Act contains an adequate expression of the

[142] Whitman v. Am. Trucking Associations, 531 U.S. 457, 475 (2001).

> legislative policy and purpose, namely, to close the channels of interstate commerce to adulterated and misbranded articles and to establish such standards as may reasonably be required to protect the public health and the public purse.[143]

More recently, Sunstein has observed that sometimes "an understanding of particular regulatory programs, and their public rationale, will often lead both courts and agencies to a narrower understanding of statutory terms, one that will sharply discipline agency discretion."[144] But there is a significant problem with applying this argument to this particular context, where there is literally no statutory language providing any kind of guidance to the USPC. If the overall purposes of any statute are sufficient to serve as an intelligible principle, then no statutory delegation could ever violate the nondelegation doctrine. Congress could write a statute that gave very sweeping legislative power to a private party (or public agency), place no limits on the entity's discretion, and then reason that the overall purpose of the statute provides enough guidance to qualify as an intelligible principle. The practical effect would be to render the intelligible principle test meaningless. This line of reasoning is also clearly inconsistent with *Schechter*. In the NIRA, Congress had authorized the President to approve industry-generated codes of fair competition.[145] In approving a code, the President was authorized to add or take away from the proposed code whatever he felt in his own discretion was required to effectuate the policy declared by the Act.[146] But the statute's reference to its own purposes as a principle to guide the President was insufficient to save it from being declared an unconstitutional delegation of legislative power.[147] In the eyes of the Court, simply referencing the broader statutory purpose was tantamount to no guidance at all.[148] Unlike the NIRA, the FDCA does not even explicitly direct the USPC to exercise its discretion in accordance with the statutory aims, so there is arguably even less guidance here than in *Schechter*. Appealing to the broader statutory purposes of the FDCA cannot provide an intelligible principle. The inescapable conclusion is that, by delegating a legislative function to the Convention and providing no intelligible principle, the FDCA violates the nondelegation doctrine.

3. How Courts Have Avoided Invalidating the Incorporation of the United States Pharmacopeia into the Definition of "Drug"

Despite its constitutional impermissibility, this delegation in the FDCA's definition of "drug" has survived without being invalidated. There appear to be two different mechanisms through which courts have avoided invalidation. First, FDA's selective reliance on this part of the statutory definition of "drug" meant that when its regulations were challenged, courts have focused on FDA's own inconsistency, rather than the potential nondelegation problem lurking in the statute itself. The

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[143] Wheeler, *supra* note 125, at 597.

[144] Sunstein, *supra* note 29, at 343.

[145] A.L.A. Schechter Poultry Corp. v. United States, 295 U.S. 495, 538 (1935).

[146] *Id.* at 539.

[147] *Id.* at 542.

[148] In concurrence, Cardozo famously wrote, "The delegated power of legislation which has found expression in this code is not canalized within banks that keep it from overflowing. It is unconfined and vagrant . . . " Id. at 551 (Cardozo, J., concurring).

second approach has been to resort to the canon of constitutional avoidance, resulting in an interpretation of the statute that differs from a plain text reading.

The first of these two judicial approaches focused on FDA's inconsistency rather than the constitutional problem with the statute's definition of drug. Although the text of the statute specifies that any article listed in the USP is a drug, FDA has not attempted to regulate all the items in the USP as drugs. Instead, it has only sporadically cited inclusion in the USP as justification for classifying an item as a drug. Therefore, when FDA has attempted to rely on this clause of the definition, courts have focused their attention on this inconsistency. *National Nutritional Foods Association v. FDA* exemplifies this judicial approach. *National Nutritional Foods* was a Second Circuit case in which the manufacturers of vitamin and mineral supplements challenged two FDA regulations on a variety of grounds. One of the challenged regulatory provisions made all dietary supplements containing more than the Recommended Daily Allowance (RDA) of a vitamin or mineral a drug for the purpose of the FDCA.[149] FDA justified this classification by arguing that the minerals and vitamins composing the dietary supplements were listed in the USP, and so were therefore drugs within the meaning of the statute.[150] The question of whether vitamins and minerals above RDA levels qualified as drugs had great practical significance for supplement manufacturers. If such supplements were drugs, then these products would be subject to more elaborate labeling requirements and a more onerous approval process under the FDCA.[151] A straight-forward interpretation of the FDCA would have led inexorably to a ruling in FDA's favor. The vitamins and minerals at issue were listed in the USP. Moreover, the FDCA's definition of drug explicitly includes any articles recognized in the USP.

The Second Circuit could have grappled with FDA's argument by accepting it at face value. If it had, it would then have been compelled to consider whether inclusion in the USP, *on its own*, was sufficient to qualify something as a drug. This approach would have highlighted the power of a private organization to define what a "drug" was and put the nondelegation issue at center stage. Instead of engaging with FDA's argument, the Second Circuit summarily dismissed it. According to the Second Circuit, FDA's position, that inclusion in the USP qualified an item as a drug, could not be taken seriously. FDA's position was flawed because if its logic was followed, it would mean that every vitamin and mineral listed in the USP, even at levels below the RDA, were drugs.[152] This position was at odds with FDA's own regulations, which did not assert that vitamins and minerals below the RDA were drugs.[153] Rather than assess whether inclusion in the USP was sufficient to qualify something as a drug, the court focused on the logical inconsistency of FDA's position. This approach allowed the Second Circuit dispense with FDA's claim without substantively evaluating it.

A few years later, the Second Circuit adopted a similar strategy when an FDA regulation was challenged in *National Nutritional Foods Association v. Mathews*. FDA again cited clause (A), this time to defend a regulation which made

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[149]Nat'l Nutritional Foods Ass'n v. Food & Drug Admin., 504 F.2d 761, 771 (2d Cir. 1974)

[150]*Id.* at 787-88.

[151]*Id.* at 788.

[152]*Id.* at 788-89.

[153]*Id.* at 789.

preparations of Vitamins A and D above certain dosage levels drugs.[154] Again, the Second Circuit rejected FDA's argument. Construing the statutory definition so that it gave FDA "the power to regulate as drugs every item mentioned in the USP and NF solely on the basis of such inclusion" was problematic because it "would give the FDA virtually unlimited discretion to regulate as drugs a vast range of items."[155] Nodding to the potential nondelegation problem, it stated, "an administrator's decision under a regulatory statute, such as the Food, Drug, and Cosmetic Act, must be governed by an intelligible statutory principle."[156] But the Second Circuit did not dwell on the potential nondelegation problem. Instead, it focused on FDA's inconsistency in picking and choosing what items in the USP to regulate as drugs.[157] In the end, the court concluded that just because an article was included in the USP, it did not follow that classifying it as a drug was reasonable.[158] If FDA wanted to rely on this part of the statutory definition, then it must "conform with the rule-making procedure and, through a clear exposition of his rationale, state the justification for his reliance upon recognition in the USP and NF."[159] On an administrative level, this may be a satisfying response to the agency's seeming inconsistency. But the conclusion that FDA must engage in additional administrative procedures in order to classify a USP article as a drug seems puzzling in light of the text of the statute, which automatically makes articles listed in the USP drugs. Why should the agency have to state the justification for its reliance upon recognition in the USP when the FDCA clearly states that inclusion in the USP is sufficient to qualify an article as a drug?

The second judicial approach was to resort to the canon of constitutional avoidance. In *United States v. Article of Drug Ova II*, a district court came the closest of any federal court to directly grappling with the nondelegation problem in the FDCA's definition of drug. In that case, the key issue in dispute was whether a home pregnancy test kit fell under the statutory definition of "drug," and was therefore required to go through the new drug application requirements.[160] FDA took the position that the Ova II test kits qualified as drugs under all three clauses of the definition of drug, including the clause specifying that a drug includes articles recognized in the USP.[161] In evaluating this claim, the court flatly concluded, "The first definition, i.e., recognition of an item in the U.S. Pharmacopeia, National Formulary, etc., cannot be taken literally".[162] It noted that the compendia were privately published and changed from time to time, which raised questions about whether they could have the force of law without "running afoul of the principle that a legislative body may not lawfully delegate its functions to a private citizen or

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[154]Nat'l Nutritional Foods Ass'n v. Mathews, 557 F.2d 325, 336 (2d Cir. 1977).

[155]*Id.* at 336-37.

[156]*Id.* at 337.

[157]*Id.*

[158]*Id.*

[159]*Id.* at 338.

[160]United States v. Article of Drug Ova II, 414 F. Supp. 660, 661 (D.N.J. 1975), aff'd sub nom. United States v. an Article of Drug Ova II, 535 F.2d 1248 (3d Cir. 1976).

[161]*Id.*

[162]*Id.* at 665.

organization."[163] It acknowledged that limited delegations to government agencies were permissible, but observed, "a delegation to private groups, and without such boundaries, is quite another matter."[164] Squarely confronted with the constitutional problem, the court did not try to supply an intelligible principle to save the provision. Instead, it resorted to the canon of constitutional avoidance:

> Since the Congress will not be presumed to have enacted an invalid statute, the first definition, i.e., recognition in the U.S.P. or other named compendium must be read to mean that . . . the recognition of an item in the U.S.P . . . .constitutes evidence that the item is a "drug" as a matter of prima facie proof only, calling on the opposing party to come forward with contrary evidence."[165]

The district court's use of the canon of constitutional avoidance dovetails well with Sunstein's theory that the nondelegation doctrine has "relocated" and now appears as a set of canons of statutory construction.[166] Like the Supreme Court's decision in the *Benzene* case, the court here did not strike down the statute as an overly sweeping delegation of legislative power, but instead interpreted the statute in a way that avoids the constitutional problem.

But the district court's invocation of the canon of constitutional avoidance in *Ova II* presents a problem. The canon of constitutional avoidance requires construing a text in order to avoid serious constitutional problems, but courts can only select an interpretation that is reasonably available from the text.[167] The text of the FDCA, in which the term "drug" is defined as "(A) articles recognized in the official United States Pharmacopeia,"[168] does not seem like it can fairly be interpreted to mean "inclusion in the USP is prima facie proof that an article is a drug." Here, the *Ova II* court *replaced* the meaning of the statute rather than adopting a less troubling interpretation. Interpreting the statute in a way that directly conflicts with the plain text meaning is closer to the canon against absurdity[169] than the canon of constitutional avoidance. By saying that the statute's definition of drug "cannot be taken literally"[170] the district court seems to be saying, in effect, "surely Congress didn't really mean to say that all the items listed in the USP—or that will be added to the USP in the future—are drugs." But it seems far from self-evident that Congress did not intend this result, which perhaps makes the anti-absurdity justification for the

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[163] *Id.*

[164] *Id.*

[165] *Id.*

[166] Sunstein, *supra* note 36, at 316.

[167] Whitman v. Am. Trucking Associations, 531 U.S. 457, 471(2001). *See also* Dep't of Transp. v. Ass'n of Am. Railroads, 135 S. Ct. 1225, 1238 (2015)(Alito, J., concurring)(noting that constitutional avoidance only works when a statute is susceptible to an alternative reading).

[168] 21 U.S.C. §321 (g)(1).

[169] The justification for the absurdity doctrine is that Congress does not always accurately translate its intentions into statutory text (for a variety of reasons) and so the courts, as faithful agents of Congress, will assume that when the application of the statute in a particular case seems to conflict with Congressional intent, the intent rather than the text should prevail. John F. Manning, *The Absurdity Doctrine*, 116 HARV. L. REV. 2387, 2390 (2003).

[170] United States v. Article of Drug Ova II, 414 F. Supp. 660, 665 (D.N.J. 1975), aff'd sub nom. United States v. an Article of Drug Ova II, 535 F.2d 1248 (3d Cir. 1976).

court's interpretation of the statute untenable as well. Whether or not the court's avoidance of the nondelegation problem was legitimate as a matter of statutory construction or not, the effect of its ruling was to further weaken FDA's ability to rely on inclusion in the USP as grounds for asserting jurisdiction over a drug.

The collective result of these court decisions was to rebuff FDA's attempts to rely solely on an article's listing in a compendium to justify classifying it as a drug.[171] As a result, FDA has largely ceased interpreting clause (A) expansively[172] and has relied primarily on the other clauses in the definition of drug. As a practical matter then, to the extent that FDA does not rely on inclusion in the USP as justification for regulation and enforcement, it follows that there would be fewer legal challenges in which courts are confronted with this nondelegation problem. In turn, the lack of legal challenges related to this issue makes it easier for courts to leave the problem unresolved. The fact that an unconstitutional statutory definition has lasted for more than a hundred years may indicate that the nondelegation doctrine is dead. Yet even though courts have avoided a direct nondelegation analysis of the definition, the fact that FDA has been forced to rely on the other clauses of the definition suggests that, in the background, nondelegation norms are shaping outcomes.

B. Does the Incorporation of the United States Pharmacopeia into the Adulteration and Misbranding Provisions of the Food, Drug, and Cosmetics Act Violate the Nondelegation Doctrine?

1. The Problem with Allowing a Private Organization to Define What Conduct Constitutes a Criminal Offense.

The second way in which the FDCA may violate the nondelegation doctrine is by allowing the USPC to establish standards for drug manufacturing, labeling, and packaging that have legally binding effect. As outlined above, the FDCA provides criminal penalties for the adulteration or misbranding of a drug,[173] where adulteration and misbranding are both defined with reference to the standards listed in the USP, or subsequent revisions.[174] Allowing a private entity to create legal standards, when violation may result in criminal sanction, presents an especially troubling nondelegation problem. Many legal commentators have expressed dismay at the extent to which agency-generated regulatory crimes have proliferated, making it increasingly difficult for citizens to have fair notice of when conduct may violate the law.[175] But at least these regulatory crimes are created by public entities whose regulatory actions are constrained by the requirements of the Administrative

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[171] Although FDA's reliance on clause (A) was struck down in the cases just described above, it should be noted that FDA attempts to rely on clause (A) have not always been thwarted by courts. *See, e.g.*, United States v. Articles of Drug . . . Beuthanasia, FOOD DRUG COSM. L. REP. (CCH), ¶ 38,265Z (D. Neb. 1979) (concluding that because the two active ingredients in an animal euthanasia product were listed in the USP, that the product was a drug within the meaning of the FDCA).

[172] Hutt, Merrill & Grossman, *supra* note 132, at 91.

[173] 21 U.S.C. §331(b)

[174] 21 U.S.C. §§351, 352(g).

[175] *See, e.g.*, John Malcolm, *Criminal Law and the Administrative State: The Problem with Criminal Regulations*, THE HERITAGE FOUNDATION (Aug. 6, 2014), http://www.heritage.org/crime-and-justice/report/criminal-law-and-the-administrative-state-the-problem-criminal-regulations.

Procedures Act, such as the requirement to submit to notice-and-comment rulemaking. Private parties are not subject to these requirements. The "lack of notice" problem is therefore intensified when private parties generate legal standards. Furthermore, private organizations are not politically accountable to the public. As previously discussed, the nondelegation doctrine serves several purposes, including guaranteeing democratic accountability, ensuring fair notice, and preventing the arbitrary exercise of power. These interests are particularly relevant when the standards written by private organizations are backed up with the threat of criminal penalties.

Because of the potential for criminal liability, this part of the FDCA's nondelegation problem has received more attention from courts and commentators than the definitional nondelegation problem. Just as Congress failed to provide an intelligible principle to guide the USPC's discretion to add or remove items from the USP, it similarly provided no guidance to constrain the USPC in formulating new standards or revising existing ones. As described in the previous section, it is difficult to argue from Congress' complete silence that it provided an implicit intelligible principle based on the USPC's previous practice or the overall statutory purpose of the FDCA. Despite this clear failure, this incorporation has been defended since its inception in 1906 on several grounds. Because the "intelligible principle" test was not articulated by the Supreme Court until 1928,[176] the pre-1928 justifications of this delegation do not apply the intelligible principle test. After 1928, one strategy was to place less emphasis on the intelligible principle test and simply argue that the delegation was factually similar to other delegations that had been previously approved. The following sections describe and evaluate the various strategies that state courts, commentators, and federal courts have adopted while scrutinizing the constitutionality of this incorporation. Even without reference to the intelligible principle test, each strategy is found lacking on its own terms. Finally, the last section considers how the *Cadden* Court responded to the NECC defendants' nondelegation argument.

2. State Courts Evaluate the Validity of Incorporating United States Pharmacopeia Standards into State Legislation.

State courts were the earliest to wrestle with the nondelegation problems associated with incorporating the USP into drug legislation. Because state governments are based on the separation of powers between branches of government, delegation issues arise at the state as well as federal level.[177] As the regulation of drugs falls under the traditional police powers of states, each state government enacted its own laws to safeguard consumers against adulterated or misbranded drugs. In determining what standards drugs should meet, many states turned to the USP or NF in writing their legislation. In fact, a survey of state laws in 1954 shows that all 48 of the then-existing states had drug laws that incorporated USP standards.[178]

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[176] *J.W. Hampton, Jr*., 276 U.S. at 409.

[177] Jeffery A. Wertkin, *Reintroducing Compromise to the Nondelegation Doctrine*, 90 GEO. L.J. 1055, 1080 (2002).

[178] Sol A. Herzog, *The Pharmacopoeia Stands at the Bar*, 9 FOOD DRUG COSM. L. J. 99, 107-114 (1954).

The earliest significant nondelegation challenge to such a state statute occurred in 1896, a full decade before the 1906 Act. In *State v. Emery*, the defendant was prosecuted for having sold sub-standard cochineal, in violation of an Ohio law which defined a drug as being adulterated if, "when sold under or by a name recognized in the United States Pharmacopoeia, it differs from the standard of strength, quality or purity laid down therein."[179] The defendant had sold cochineal,[180] which complied with the USP standard published in 1880, the version in existence when the statute was enacted, but which fell short of complying with the USP standard published in 1893.[181] In considering which version of the USP should have been admitted as evidence at trial, the Supreme Court of Ohio came down firmly on the side of the defendant. It reasoned that the statute's reference must be to the 1880 version of the USP because, "it is not to be supposed that the legislature intended to adopt, by reference, as part of the penal laws of the state, an edition of the book not then in existence, and of which the legislature could then have no knowledge."[182] To hold that the defendant's sale could be made unlawful by subsequently revising the USP "would be equivalent to holding that the revisers of the book could create and define the offense—a power which belongs to the legislative body, and cannot be delegated."[183] In response to the nondelegation problem, the court emphatically determined that the statute only incorporated the version of the USP existing at the time the statute passed. Incorporating pre-existing standards into the law was permissible; allowing a private party to determine criminal offenses in the future clearly was not. The court selected an interpretation of the statute that avoided the (state) constitutional problem. This is an interesting occurrence of the nondelegation doctrine operating as aid to statutory interpretation, forty years before *Schechter* and *Panama Refining* and more than a hundred years before Sunstein's suggestion that the nondelegation doctrine had re-located into a set of statutory canons.

Two other notable state cases followed a similar trajectory to *Emery*, rejecting an interpretation of state statutes that would incorporate future changes to the USP. In *Commonwealth v. Costello*, a defendant was prosecuted for violating Pennsylvania's Pure Drug Act of 1897, which incorporated the standards of the USP.[184] He challenged the constitutionality of the law on the grounds that it was an invalid delegation of legislative power.[185] The Pennsylvania court concluded that the statute only incorporated the version of the USP in existence at the time of the law's enactment, not subsequent editions.[186] The law should not be construed to include subsequent versions of the USP because "then there should be force in the argument that the editors of the books could . . . exercise . . . legislative power, for they could

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[179]State v. Emery, 55 Ohio St. 364, 369 (1896). Note that in some older references, the word "pharmacopeia" is spelled "pharmacopoeia."

[180]Cochineal is a substance commonly used as a color additive for drugs. L.F. Kebler, *Cochineal Representing the Highest Grade in the Drug Trade*, DRUGGISTS' CIRCULAR AND CHEMICAL GAZETTE (May 1, 1906).

[181]55 Ohio St. at 369.

[182]*Id.*

[183]*Id.*

[184]Commonwealth v. Costello, 1909 WL 3113, at *1 (Pa. Quar. Sess. 1909).

[185]*Id.*

[186]*Id.* at *3.

make that an adulteration and an offence against the statute which was not so at the time the act was approved."[187] The Supreme Judicial Court of Maine followed a similar logic nine years later in 1918. In *State v. Holland*, a pharmacist was charged with illegally keeping whisky, but the pharmacist countered that because whisky appeared in the 1905 edition of the USP, it qualified as a drug, and therefore was permissible for him to possess.[188] But the presiding judge determined that a later revision of the USP, which did not list whisky as a drug, should govern.[189]

Although the question at stake here was about the definition of "drug" as opposed to drug standards, the appellate court adopted an avoidance strategy similar to the two earlier state cases. In contrast to the lower court, the appellate court ruled that the version of the USP in existence at the time of the statute's enactment was the controlling version:

> It is not to be supposed that the Legislature intended to adopt compilations not then made and of whose contents, as affecting the law of this state against the illegal sale and keeping for sale of intoxicating liquors, it could have no knowledge. It knew what the books then recognized as authority included; it could not know what the revisers of later editions might include or exclude.[190]

Moreover, if the statute was construed to incorporate future editions, it "may be open to the objection that it is an unauthorized delegation of legislative power, to the revisers of the future editions," although the court hastened to add, "upon that point we express no opinion."[191]

Although these are interesting examples of how early state court decisions dodged the nondelegation problem associated with incorporating USP standards into law, this particular strategy of avoidance was an unworkable solution for solving the federal problem. The definition of "official compendium" in the FDCA is "the official United States Pharmacopeia, official Homœopathic Pharmacopoeia of the United States, official National Formulary, *or any supplement to any of them*" (emphasis added).[192] This phrasing explicitly anticipates that future revisions of these publications will be incorporated into the law.[193] It is therefore not possible to construe the FDCA so that it only incorporates the USP standards that were in existence at the time the statute was passed in 1938. Nor, from a policy perspective, would such an option be feasible.

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[187] *Id.*

[188] State v. Holland, 104 A. 159, 159 (1918).

[189] *Id.*

[190] *Id.*

[191] *Id.* at 160.

[192] 21 U.S.C. §321(j).

[193] *See also* Wheeler, *supra* note 125, at 589. ("It is apparent that for the purpose of determining the question of adulteration, Congress has purported to adopt all standards set forth in an official compendium, including standards existing at the time of the legislative enactment together with standards to be adopted in the future.")

3. Commentators and Federal Courts Attempt to Defend the Incorporation

The central question, then, is whether the FDCA's incorporation of *future* USP standards in its adulteration and misbranding provisions is a constitutional delegation of power to the USPC. There are five different arguments that can be made that the incorporation of the USP does not violate the nondelegation doctrine. The first argument is that the statute's definition of adulteration does not really delegate legislative power to the USPC; rather, it simply requires that manufacturers truthfully label their products. The second argument is that the "variation" clause of the adulteration provision, which allows manufacturers to deviate from USP standards, prevents the incorporation from being an impermissible delegation. The third argument is that courts have broadly upheld delegations when legislatures make the exercise of a statute contingent upon future factual contingencies, and that the delegation of drug standards to the USPC falls into this general category. The fourth argument is an extension of the third argument and asserts that it is permissible for Congress to look to other organizations in helping define or determine technical matters, and that this is what Congress has done in this delegation to the USPC. The third and fourth arguments are similar, and both acknowledge that Congress has delegated real authority to the USPC but conclude that such a delegation is permissible because it is well within the range of delegations that have been upheld by courts in the past. Finally, the fifth argument is that the Supreme Court has approved delegation to private parties as permissible. This argument is complementary with both the third and fourth arguments in the sense that both the fifth argument, and either the third or fourth argument, must be correct in order to justify the incorporation of USP standards into law. None of these five arguments are legally supportable, and each is addressed in order below.

a. First Argument: The Incorporation of the USP is not Merely a Requirement of Truthful Labeling

In 1946, Walton Wheeler, general counsel for Eli Lilly, made a forceful argument that the FDCA did not delegate any power to the publishers of the official compendia.[194] According to Wheeler, the correct understanding of the adulteration section is that it simply requires that manufacturers label products truthfully.[195] He points out that Section 501(b) declares an "official drug" (one listed in a compendium) to be adulterated if it differs from the strength, quality, or purity standards contained in the compendium, and Section 501(c) makes an "unofficial drug" (one not recognized in a compendium) adulterated if it differs from the strength, purity, or quality that it purports to possess.[196] In other words, he summarizes, "a drug is adulterated if it does not conform to the standards it purports to possess, or, to rephrase the statement, if it is not what its label represents it to be."[197] If a drug purports to be a drug that is listed in the USP, it is professing to meet

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[194] *Id.* at 590.

[195] *Id.*

[196] *Id.* at 591.

[197] *Id.*

the USP standards.[198] A manufacturer who sells a drug that fails to conform to the USP's standards can avoid liability by calling his product by a different name than the one appearing in the USP. By this reasoning, Congress has merely insisted that manufacturers truthfully label their products. Therefore, there is no real delegation of legislative power to the USPC.

However, describing this provision as merely a truthful labeling requirement is logically flawed. This flaw was highlighted by Thomas Christopher in an article in 1951.[199] To illustrate the flaw, Christopher uses the example of a distributor selling sulfur which does not conform with the specifications for sulfur as listed in a compendium. Before any law is passed, the vendor is not purporting that his product conforms with the compendium's specifications; he is simply selling a different version of sulfur.[200] His labeling of the product as sulfur does not, by definition, become untruthful until the law establishes the compendium's specifications as the legal standard for sulfur.[201] It is only after the law elevates the compendium's specifications to the status of law that his product is no longer "sulfur." The real question is still whether it is valid for Congress to allow a private organization to establish the legal standards for such drugs. As Christopher wryly observes, "it is true that . . . a manufacturer may avoid prosecution by proper labeling, but this means, in reality, that a private agency controls labeling."[202] Characterizing the FDCA's adulteration provisions as a truthful labeling requirement simply side-steps the core question of whether this delegation is valid.

b. Second Argument: The Variation Clause Does Not Rescue the Statute from Being an Illegitimate Delegation

Other proponents of incorporating the USP argued that the "variation clause" of the FDCA prevents the statute from being an unconstitutional delegation of power. The "variation clause" allows a drug to vary from the USP standards as long as the variation was "plainly stated" on the drug label.[203] For example, a manufacturer could sell a drug listed in the USP, even if does not meet the USP standards, as long as the product label indicated how the product differed from the USP standard. They argued that the USP incorporation was not a delegation because the variation clause meant that any changes to the compendia would not affect a manufacturer's legal obligations.

James Beal articulated the "variation clause" argument in 1935. Beal was Chairman of the USP Board of Trustees, and the man that historian Dennis Worthen credits as the driving force behind the inclusion of the USP in the 1906 Act.[204] Beal

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[198] *Id.*

[199] Thomas W. Christopher, *Validity of Delegation of Power to a Private Agency-The Pharmacopoeia Provisions*, 6 Food Drug Cosm. L.J. 641, 653 (1951).

[200] *Id.*

[201] *Id.*

[202] *Id.* at 654.

[203] Pure Food and Drug Act, §7. This provision was also adopted into the FDCA in §501(b): "No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard . . . set forth in the compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label." 21 U.S.C. §351(b).

[204] Worthen, *supra* note 113, at 23.

began his defense of the incorporation by discussing *Emery*, the 1896 Ohio case which had ruled that incorporating the current version of the USP into an Ohio statute was valid, but that incorporating future versions of the USP would be an unconstitutional delegation.[205] Because the *Emery* decision "has been generally regarded as equally applicable to Federal laws," its ruling "was really responsible for the insertion of the variation clause in the Federal Food and Drugs Act of June 30, 1906."[206] Beal explains:

> In plain English it [the variation clause] gives the manufacturer the option either of following the standards of the U. S. P. or other standards as he may prefer, provided that if he elects to follow some other standard the label shall plainly indicate the fact. Thus the manufacturer's liability and obligations always remain the same no matter how frequently the standards of the Pharmacopoeia are altered. If the manufacturer is always free to choose the standards with which his preparations shall comply, then no change in the Pharmacopeia can affect his property rights or legal obligations, and consequently there is no exercise of law-making power when the Revision Committee changes the standards of the Pharmacopoeia."[207]

In evaluating this nondelegation problem, Beal focused on the impact the delegation would have on the regulated community. If a manufacturer's legal obligations do not change from one USP edition to the next, then has Congress really delegated any authority to the USPC?

As appealing as Beal's argument is, it also side-steps the fundamental question of whether this delegation of the authority is valid. The variation clause may lower the burden imposed on a regulated community by authorizing deviation from the USP standards when a manufacturer adds appropriate labeling. But the legislature is still allowing a private organization to shape the contours of what is legally permissible and impermissible. Furthermore, it is not entirely clear that Beal's claim that changes to the USP will not affect manufacturers' legal obligations is correct. If a manufacturer's product suddenly becomes legally substandard because the USPC has raised the purity standards for that item in a new edition, the manufacturer now must either alter his manufacturing processes to meet the new standard, or he must change how his product is labeled. Changing a product's labeling may certainly be less of a burden than changing a manufacturing process, but it is still a legal obligation, and will likely require time and expense to ensure compliance. A manufacturer that fails to adequately accomplish either course of action faces criminal prosecution.[208] Just because the cost of compliance with new standards is reduced, it does not logically follow that allowing a private organization to create those standards to begin with is

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[205] J. H. Beal, *The Pharmacopoeia of the United States and the Federal Food and Drugs Act*, 24 J. PHARM. SCI. 759, 764 (1935).

[206] *Id.* at 765.

[207] *Id.*

[208] *See, e.g.*, United States v. 5 One-Pint Bottles & 23 One-Gallon Bottles, More or Less, of Elixir Terpin Hydrate & Codeine, 9 F. Supp. 990, 991 (S.D.N.Y. 1934)(finding that bottles of elixir terpin hydrate and codeine were adulterated because they were sold under a name listed in the National Formulary (NF), did not conform with the NF standards, and that inclusion of the word "special" in the label was not sufficient to meet the requirements for the variation clause exception).

constitutionally permissible. Writing in response to Beal's argument in 1946, Wheeler was dismissive: "It seems clear that an invalid standard cannot be cured by an option to deviate therefrom."[209]

c. Third Argument: The Incorporation of the USP is Not an Example of Making the Operation of the Statute Depend on Future Factual Contingencies

In 1911, a federal court heard a nondelegation challenge to the USP incorporation for the first time in *United States v. Lehn*.[210] The *Lehn* court determined that, although the 1906 Act delegated real authority to the USPC, this delegation was lawful because it was an example of Congress making the operation of the statute depend on factual contingencies.[211] This was a kind of delegation that had been sustained as permissible by the Supreme Court in *Marshall Field & Company v. Clark*.[212] Although the true test of a delegation's lawfulness is whether Congress has supplied an intelligible principle, the *Lehn* court evaluated this delegation seventeen years before the intelligible principle test was articulated in *J.W. Hampton, Jr., & Company. v. United States*.[213] Its analysis was therefore rooted in the line of Supreme Court cases stemming from *Marshall Field*. However, even if the intelligible principle test is set to one side, the *Lehn* court's reasoning is faulty on its own terms because the USP incorporation is not an example of making the FDCA's operation depend on factual contingencies.

In *Lehn*, Judge Hough wrote that, in his judgment, a Supreme Court case from four years prior, *Union Bridge Company v. United States*,[214] was the controlling authority that decided the nondelegation challenge.[215] The *Lehn* defendants had argued that the law's definition of adulteration was an improper delegation of legislative authority after they were charged with shipping jalap[216] which differed from USP standards.[217] Judge Hough saw clear parallels to the factual situation in *Union Bridge*. The statute at issue in that case had authorized the Secretary of War to bring criminal proceedings against a person or corporation controlling a bridge when he determined that the bridge was "an unreasonable obstruction to free navigation . . . on account of insufficient height, width of span, or otherwise."[218] The

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[209] Wheeler, *supra* note 125, at 599-00.

[210] C.C.S.D.N.Y. 1911. This case is not officially reported but the ruling can be found on page 229 of a book published by the Department of Agriculture in 1934. DEP'T OF AGRIC., DECISIONS OF COURTS IN CASES UNDER THE FEDERAL FOOD AND DRUGS ACT 229 (1934). All subsequent references to this case will cite the page numbers as they appear in this publication.

[211] *Id.* at 231.

[212] In Marshall Field & Co. v. Clark, the Court had ruled that a legislature cannot delegate its power to make a law, but it "can make a law to delegate a power to determine some fact or state of things upon which the law makes, or intends to make, its own action depend." 143 U.S. 649, 694 (1892).

[213] *J.W. Hampton, Jr*., 276 U.S. at 409.

[214] 204 U.S. 364 (1907).

[215] *Lehn,* at 231.

[216] Jalap is drug widely used as a purgative. *Jalap*, DRUGGISTS' CIRCULAR AND CHEMICAL GAZETTE (May 1, 1896).

[217] *Lehn,* at 229.

[218] *Union Bridge*, 204 U.S. at 366.

Supreme Court upheld the statute because it determined that Congress had not delegated legislative power to the Secretary of War, but only the duty of ascertaining facts, such as whether or not particular bridges were unreasonable obstructions to navigation.[219] It was an example of making the operation of a statute dependent on future, factual circumstances, a kind of delegation that had been approved in *Marshall Field*. By Judge Hough's reasoning, the incorporation of the USP into the 1906 Act was analogous to Congress' delegation to the Secretary of War in *Union Bridge*.[220] Determining what qualified as "adulterated" was a fact-finding exercise similar to the bridge-evaluation exercise committed to the Secretary of War.[221] Just as the meaning of "unreasonable obstruction to free navigation" would change over time, the meaning of "adulterated" would also likely evolve over the decades.[222] Congress, Judge Hough concluded, had made "a complete and perfect criminal statute, not dependent at the time of its passage on the act of any other power or person," and had wisely provided "for changes in the meaning of the word adulterated."[223]

However, as a defense of the USP incorporation, *Lehn* fails in terms of its own reasoning. Its analysis is suspect because the court erroneously relied on *Union Bridge* as the controlling authority despite striking dissimilarities between the two cases.[224] First, there are significant differences between the circumstances that initiate each delegate's exercise of authority in the two cases. The statute at issue in *Union Bridge* authorized the Secretary to bring criminal charges if he determined a particular bridge was an obstruction to navigation. In contrast to this clear-cut criterion, it is not clear what factual circumstances are to initiate the USPC's revision of drug standards, other than the Convention's own unguided judgment about when the meaning of "adulterated" may need alteration. Second, the conduct authorized by Congress is very different between the two cases. The Secretary of War was only authorized to do one thing if a bridge obstructed navigation: bring criminal charges. The 1906 Act authorized the USPC to develop hundreds of drug standards, along with packaging and labeling requirements. There is something strange about analogizing the development of drug standards, with all the implicit policy judgments entailed, to the Secretary of War's much more limited, and less complex, obligation to bring criminal charges. Finally, the Secretary of War was a government agent, while the USP is a private trade organization. This is a distinction that may have great significance for the law's constitutionality but was never mentioned by the court. Altogether, the *Lehn* court's assertion that this delegation falls into the

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[219] *Id.* at 385.

[220] *Lehn*, at 232.

[221] *Id.*

[222] *Id.*

[223] *Id.* It should be noted that Judge Hough was not alone in thinking that it was desirable to allow the USPC to periodically adjust drug standards. Later commentators such as Walton Wheeler argued that there was no real practical alternative to entrusting this responsibility to the USPC. As scientific knowledge advanced, there would be an ongoing need to adjust drug standards in the face of changing factual circumstances. In 1946 Wheeler predicted: "the validity of Section 501(b) will be sustained on the grounds of practical necessity." Wheeler, *supra* note 125, at 599.

[224] Writing in 1951, Christopher seemed equally baffled by the court's reliance on Union Bridge: "It is difficult to see how such a decision could be a 'controlling authority' for the Lehn . . . decision." Christopher, *supra* note 203, at 652.

category of making a statute operative depending on future factual contingencies seems to miss the mark.

Although the intelligible principle test was not available to the *Lehn* court in 1911, the most telling difference between *Union Bridge* and *Lehn* is the amount of Congressional guidance provided to the two actors. While Congress supplied the Secretary of War with significant guidance to assist his evaluation of bridges, it failed to provide any guidance at all to the USPC. The statute in *Union Bridge* provided direct and specific instruction to the Secretary of War to identify any bridge presenting "an unreasonable obstruction to free navigation . . . on account of insufficient height, width of span, or otherwise."[225] This is specific and concrete guidance on how the Secretary of War was to make a determination. In contrast, Congress gave no guidance to the USPC in the 1906 Act or the subsequent FDCA.[226]

d. Fourth Argument: The Incorporation of the USP Cannot Be Justified as the Adoption of Technical Standards

Another variation of the "future factual contingency" argument is that it is permissible for Congress to look to other organizations (public or private) for assistance in defining or determining matters of a technical nature. Borrowing from other entities to help "fill in" technical details is an extension of the idea that the operation of a law may turn on factual contingencies, where those contingencies may be of a highly technical nature. There are strong policy reasons for allowing this kind of delegation. As the Supreme Court acknowledged in *J.W. Hampton*, some lawmaking may require large numbers of very technical determinations that Congress simply does not have time to make itself.[227] The Supreme Court has affirmed that it is permissible for Congress to delegate these kinds of technical determinations to another body, as long as it provides the requisite amount of guidance.[228]

In evaluating Cadden's nondelegation challenge earlier this year, the district court suggested that the FDCA's incorporation of the USP standards might fall into this category of adopting another organization's technical standards. It reasoned that there was no constitutional prohibition against Congress "looking to best practices in the compounding industry (as distilled in the USP) for assistance in 'defining matters of a technical nature.'"[229] As an example, the district court cited regulations enforced under the OSH Act, many of which were based on industry-formulated standards, and which had been upheld against nondelegation challenges by circuit courts.[230] In one of these cases, *Towne Construction Company. v. Occupational Safety & Health Review Commission, the Sixth Circuit defended OSHA's adoption of a private technical standard, writing,* "the physical impossibility of requiring OSHA independently to set safety standards for every industry job classification and

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[225] *Union Bridge*, 204 U.S. at 366.

[226] In evaluating the statute's incorporation of USP standards, Christopher observed that "as the word is ordinarily understood in legal circles, there is not the slightest trace of a standard in this delegation." Christopher, *supra* note 203, at 653.

[227] *J.W. Hampton, Jr*., 276 U.S. at 407–08.

[228] *Id.* at 408.

[229] *Cadden*, 2016 WL 1948832, at *8.

[230] *Id.*

industrial substance in the country adequately explains and justifies Congress' decision to allow the Secretary to adopt the fruits of private efforts as governmental standards."[231]

While the advantages of adopting the "fruits of private efforts" are evident and appealing, there are some significant differences between the adoption of the private standards in the OSH Act cases referenced by the *Cadden* court and the FDCA's incorporation of USP standards. First, in the OSH Act cases, the agency known as the Occupational Safety and Health Administration (OSHA) had an active role in selecting, or choosing to adopt, the technical standards at issue. In *Towne* and the other cited case, *Associated Builders and Contractors Florida East Coast Chapter v. Miami-Dade City,* a provision of the OSH Act was challenged which directed the Secretary of Labor to promulgate as an occupational safety or health standard any "national consensus standard, and any established Federal standard*,* unless he determines that the promulgation of such a standard would not result in improved safety or health for specifically designated employees."[232] In Associated Builders the agency had adopted the European wind load standard for cranes,[233] and in Towne the agency had required compliance with a crane manufacturer's load limitations.[234] But under this provision of the OSH Act, the Secretary of Labor was free to select any standard that would qualify as a national consensus standard, or he was free to not adopt one if, in his judgment, the standard would not improve health and safety for employees. The FDCA gives FDA no similar discretion to select or reject the standards created by the USPC.

Second, the OSH Act provides an intelligible principle by providing guidance to the Secretary of Labor in terms of what kind of standards to adopt (standards that are in accordance with the "national consensus standard") and what principles are relevant in exercising his discretion (improving safety and health for designated employees). In contrast, the FDCA provides no guidance at all to the USPC.

Third, in these two OSH Act cases, the agency adopted the current or existing versions of the private technical standard. There is no indication in these cases that future changes to these private standards would automatically become binding on the regulated community. In other words, adopting the "fruits of private efforts" in these cases meant the responsible federal agency carefully evaluated potential standards and made a reasoned judgment, based on Congressional guidance, to leverage existing technical standards when making a rule. It did not mean entrusting a private trade organization with the responsibility to unilaterally create legal standards in the future, with no potential for agency review or veto, and no Congressional direction to guide its decision-making. In reality, the strategy of adopting the "fruits of private efforts" is not really in any meaningful sense a delegation at all. The early state cases such as *Emery* recognized this point, and it was the grounds on which those courts upheld the incorporation of the existing versions of the USP in state law and rejected the incorporation of future revisions.

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[231]Towne Const. Co. v. Occupational Safety & Health Review Comm'n, 847 F.2d 1187, 1190 (6th Cir. 1988).

[232]29 U.S.C. §655.

[233]Associated Builders and Contractors Florida E. Coast Chapter v. Miami-Dade Cty., FL, 594 F.3d 1321, 1325 (11th Cir. 2010).

[234]*Towne Const. Co.,* 847 F.2d at 1189.

e. Fifth Argument: The Incorporation of the USP is Likely Unconstitutional Because it is a Delegation to a Private Party

In addition to the argument that the USP incorporation is a kind of delegation that is permissible, a complementary argument is that delegation to private parties such as the USPC is also constitutionally authorized. Writing in 1946, Walton Wheeler admitted that, although the Supreme Court has overwhelmingly sustained the majority of Congressional delegations, most of these cases involved delegations to the President or to government agencies.[235] "But," he asserted, "the fact that the official standards under Section 501(b) are established by non-governmental agencies is not sufficient to condemn them."[236] In support of this conclusion, Wheeler cited a 1908 Supreme Court case, *St. Louis, Iron Mountain, & Southern Railway Company v. Taylor*.[237] In the 1901 Safety Appliance Law, Congress had directed the American Railway Association to designate the standard height for freight car drawbars and to determine the maximum variation of height to be allowed between empty and loaded cars.[238] Within 90 days of the passage of the law, the Association was to certify these determinations to the Interstate Commerce Commission, and these standards would become legally binding.[239] When the constitutionality of this delegation to the American Railway Association was challenged by a plaintiff, the Supreme Court dismissed the claim in one sentence: "Nothing need be said upon this question except that it was settled adversely to the contention of the plaintiff in error in *Buttfield v. Stranahan* . . . and *see Union Bridge Co. v. United States*, 204 U. S. 364, where the cases were reviewed."[240] If the Supreme Court upheld the Safety Appliance Law, which delegated authority to a private party and provided no general guidance there, Wheeler reasoned, then surely delegating standard-creating authority to the USP, despite a lack of guidance, was also permissible.[241]

The Supreme Court's decision in *St. Louis* appears to be one of the strongest available precedents that would suggest that delegations to private parties, especially delegations to establish technical standards, are permissible generally and that the incorporation of the USP is constitutionally authorized. Yet there are three reasons to be cautious about relying on *St. Louis* as controlling precedent for delegations to private parties. The first reason is that the *St. Louis* Court's reliance on *Buttfield* and *Union Bridge* is awkward in light of the factual differences between these cases and the *St. Louis* case. At issue in *Buttfield* was the Tea Inspection Act of 1897, which authorized the Secretary of the Treasury to establish uniform standards of "purity, quality, and fitness" for all imported teas.[242] The Supreme Court upheld the statute's delegation to the Secretary of the Treasury. The statute, it observed, "expresses the purpose to exclude the lowest grades of tea, whether demonstrably of inferior purity,

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[235] Wheeler, *supra* note 125, at 597.

[236] *Id.*

[237] St. Louis, I.M. & S. Ry. Co. v. Taylor, 210 U.S. 281 (1908).

[238] *Id.* at 286.

[239] *Id.*

[240] *Id.* at 287.

[241] Wheeler, *supra* note 125, at 598.

[242] Buttfield v. Stranahan, 192 U.S. 470, 494 (1904).

or unfit for consumption, or presumably so because of their inferior quality." [243] In doing this, Congress had fixed "a primary standard," and "devolved upon the Secretary of the Treasury the mere executive duty to effectuate the legislative policy declared in the statute."[244] Like the statute in Union Bridge, the Tea Inspection Act provided guidance to the Secretary of the Treasury (a "primary standard") which constrained his standard-making efforts. In contrast, Congress provided no such guidance to the American Railway Association in St. Louis. The other striking difference is that the Union Bridge and Buttfield delegations were to government entities, while the St. Louis delegation was to a private party. Given these significant factual differences, it is puzzling that the Supreme Court would cite these two cases without any further analysis or explanation.

A second reason it makes sense to be cautious about leaning on *St. Louis* as support for the validity of incorporating the USP standards into law is that even though both scenarios feature private parties generating legally binding standards, there is a significant difference between the scope of the two delegations. The *St. Louis* delegation to the American Railway Association was limited to the promulgation of just one standard and was a one-time authorization. The delegation to the USPC, in contrast, gives the organization a very broad regulatory role, and one that is not limited in time.

The third reason to be wary of placing too much weight on *St. Louis* as support for the proposition that delegations to private parties are permissible is that its ruling is inconsistent with the Supreme Court's later analysis in *Carter Coal*. In *Carter Coal*, as discussed previously, the Supreme Court struck down a provision of the Bituminous Coal Conservation Act which allowed two-thirds of coal producers in a district to fix maximum hours and minimum wages for coal miners in that district.[245] This delegation to private parties was "obnoxious" in the eyes of the Supreme Court because "it is not even delegation to an official or an official body, presumptively disinterested, but to private persons whose interests may be and often are adverse to the interests of others in the same business."[246] The *Carter Coal* Court's analysis suggests that delegations to private parties are problematic, and perhaps even *per se* impermissible. In weighing these two decisions, it should be noted that *Carter Coal* is not only later than *St. Louis*, but *Carter Coal* explicitly addresses the issue of delegation to private parties, while *St. Louis* never even acknowledges that the American Railway Association is a private organization. For these reasons, it seems reasonable to give *Carter Coal*'s position on private delegation more weight.

However, if we take Volokh's position seriously, the case which most directly grapples with the question of private delegation is not *Carter Coal*, but *Currin*, the case in which the Supreme Court upheld a provision of the Tobacco Inspection Act which made the operation of a regulation contingent on the approval of two-thirds of tobacco growers.[247] Volokh has argued that the *Carter Coal* Court condemned the delegation in that case more on Due Process grounds than on nondelegation

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[243] *Id.* at 496.

[244] *Id.*

[245] Carter v. Carter Coal Co., 298 U.S. 238, 311 (1936).

[246] *Id.*

[247] Currin v. Wallace, 306 U.S. 1, 15 (1939).

grounds,[248] and that the *Currin* ruling demonstrates that delegations to private parties are permissible, provided that an intelligible principle is present.[249]

But while Volokh may be correct to highlight the role that the Due Process rationale played in *Carter Coal*, it is a strained reading of *Carter Coal* that overlooks its strong nondelegation language altogether. Furthermore, even if *Currin* can be read to say that at least some private party delegations are permissible, the stark factual differences between that case and the USP incorporation make *Currin* a weak precedent for justifying the permissibility of the USP's incorporation. In *Currin*, the Supreme Court upheld the Tobacco Inspection Act, which made the operation of a certain regulation contingent on two-thirds of tobacco growers voting in favor of it.[250] Allowing private parties to vote in order to make a specific regulation operative is a far cry from allowing a private party to independently generate hundreds of standards that are automatically legally binding on a regulated community. In the former case, the private party's power is limited to only an up-or-down vote, and only with respect to one regulation. The actual content of the regulation was still created by a public entity. In the latter case, the USPC actually shapes the content of the law itself, with no requirement for approval by a government entity before it becomes legally binding. The automatic incorporation of new USP standards into law is, in some ways, similar to the industry-generated "fair codes" condemned in *Schechter*, except that in *Schechter* the codes were at least subject to Presidential approval or modification, whereas no government entity is required to approve new USP standards before they become law.

In sum, the Supreme Court's private party delegation jurisprudence is somewhat muddled and contradictory. There does not seem to be an easy answer to the question of whether private party delegations are permitted and, if so, whether the standard for those delegations differs from the intelligible principle test. But it does seem clear that there are no past examples of private party delegations that have been upheld as permissible where the scope of authority is as broad, and the guidance so minimal, as the delegation to the USPC in the FDCA.

Although many different arguments have been posed in favor of the constitutionality of the FDCA's incorporation of the USP's standards, all have significant flaws. The "truthful labeling" argument and variation clause arguments essentially avoid fully addressing the nondelegation question inherent in this statutory arrangement. The argument that this delegation of authority is only an example of making the statute operate upon a future contingency, or an example of adopting the "fruits" of another organization's labor, fails when carefully scrutinized in light of past Supreme Court precedent. Even the argument that delegations to private parties more generally are permissible seems far from certain based on past case law.

Most significantly of all, comparison to past nondelegation cases only serves to highlight the utter lack of any kind of intelligible principle in Congress' delegation to the USP. Even if Volokh's position on private delegation is accepted, there does not seem to be any way to overcome the central problem, which is a lack of an

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[248] Volokh, *supra* note 74 at 359.

[249] *Id.*

[250] Currin v. Wallace, 306 U.S. 1, 15 (U.S. 1939).

intelligible principle. This lack of constraint or guidance is particularly troubling given that violation of the USP's standards can result in criminal prosecution.

4. The Cadden *Court's Response*

The *Cadden* Court's response to the NECC defendants' nondelegation argument reflected the same tension that previous courts and commentators faced in reconciling the nondelegation doctrine with the FDCA's expansive delegation to the USPC. In contrast to previous courts, the *Cadden* Court grappled more explicitly with the nondelegation problem raised by the USP incorporation. However, like previous courts, the *Cadden* Court ultimately found a way to side-step the vexing nondelegation problem.

The *Cadden* Court was forthright in describing the nondelegation conundrum. Cadden and his co-defendants argued that when Congress delegates authority to an entity to define a criminal offense, it has only done so in conjunction with specific guidance.[251] When squarely confronted with this problem, the *Cadden* court made some startling admissions:

> Defendants point out (accurately) that the references to the USP in the FDCA are "patchy" and unsystematic, that no guidance is provided directly by Congress (or indirectly through the Food and Drug Administration (FDA)) to the USP's Expert Committees, that the FDA has no discretion to accept or reject the revisions made in the USP by the USPC, and that the FDA has no oversight authority over the USPC . . .
>
> In sum, defendants insist that the virtual absence of an "intelligible principle" renders any attempt by the government to deploy the USP as defining sanctionable conduct under the criminal laws unavailing. To the extent that defendants contend that the government should be estopped from making any argument to the jury that the USP has the force of law, or that violations of its standards constitute criminal offenses, the court agrees (emphasis added).[252]

This judicial recognition that USP standards cannot have the force of law is remarkable given that previous courts have avoided the issue or attempted to justify the incorporation as a permissible form of delegation. The *Cadden* Court's conclusion is also remarkable because it runs counter to a straight-forward interpretation of the FDCA's adulteration and misbranding provisions, which unambiguously *do* give USP standards the force of law.

Ultimately, however, the *Cadden* Court adopted an approach more in keeping with previous courts by side-stepping the central nondelegation issue. Because the USP standards did could not have the force of law, the NECC defendants could not be charged with violating the USP standards.[253] However, the government argued that the defendants were not being charged with violating the USP; rather, they were being charged with perpetrating a scheme to defraud customers by misrepresenting

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[251] *Cadden*, WL 1948832, at *6. *See, e.g.*, Mistretta v. United States, 488 U.S. 361, 375–76 (1989) (describing the detailed guidance Congress had provided to the U.S. Sentencing Commission in the Sentencing reform act) and Touby v. United States, 500 U.S. 160, 166-67 (1991)(characterizing the statutory provision as meaningfully constraining the Attorney General's discretion).

[252] *Cadden*, WL 1948832, at *7–8.

[253] *Id.* at *8.

NECC's compliance with the USP standards.[254] The *Cadden* Court agreed that, understood as a prosecution for fraud, the indictments were constitutionally permissible.[255] In order to ensure that the jury understood that the defendants were not being tried for violating USP standards, the indictments, rich with references to the USP, would not be read or provided in written form to the jury.[256] Moreover, the jury would be instructed that USP standards did not define crimes, and that the defendants' violation of USP standards could only be considered with respect to the issues of misrepresentation, causation, and recklessness.[257] Like courts that had previously assessed the USP incorporation, the *Cadden* Court successfully avoided a head-on collision with the nondelegation doctrine.

The *Cadden* decision leaves several questions unresolved. If the USP incorporation is challenged again in a criminal prosecution, will subsequent courts follow *Cadden*'s reasoning and conclude that the USP standards do not have the force of law? Will prosecutors, aware of the possible constitutional infirmity of the USP incorporation, find ways to charge defendants that do not rely directly on the FDCA's incorporation of USP standards? Charging defendants with fraudulently representing their products as conforming to USP standards, as in the *Cadden* case, might be an attractive alternative route, allowing prosecutors to punish those who violate USP standards while avoiding nondelegation problems. However, there is something troubling about this end-run around the nondelegation doctrine. Does a drug manufacturer fraudulently misrepresent his product as USP-compliant standard simply because he is selling a non-conforming drug in a context where there is an implicit understanding that all drugs must conform to the USP? This would seem like a different case than a drug manufacturer who affirmatively advertised to the public that his products met USP standards when they did not.

If selling a non-conforming product by itself can constitute fraud, then this approach would still give the USP standards the *de facto* force of law, short-circuiting the nondelegation doctrine.

CONCLUSION

The nondelegation problems in the FDCA's definition of "drug" and its adulteration and misbranding provisions have been addressed somewhat differently by commentators and courts since 1906. Courts have mainly adopted an avoidance approach when confronted with the impermissible delegation of authority to the USPC to shape the definition of drug under the statute. In the two *National Nutrition* cases, the Second Circuit ducked the nondelegation issue in favor of focusing on FDA's own inconsistent assertion of jurisdiction. The *Ova II* court engaged in the most extreme strategy of avoidance by adopting a new reading of the definition that directly contradicted the text. When confronted with the nondelegation problem of having a private entity generate legally binding standards, courts and commentators have employed a few different strategies. Some have tried to negate or minimize the Congressional delegation by characterizing the provisions as requirements for

[254] *Id.*

[255] *Id.*

[256] *Id.*

[257] *Id.*

truthful labeling or appealing to the variation clause. Others have confronted the problem more directly and argued that delegation of standards to the USPC is constitutionally permissible based on existing nondelegation case law. Although approaches to resolving the FDCA's nondelegation questions have differed, none convincingly show that the statute's delegation to the USPC is constitutionally permissible. In fact, examining these various strategies reveals significant flaws in each.

Although the Supreme Court's nondelegation jurisprudence has been inconsistent and applied selectively, there does not seem to be any way that the FDCA's incorporation of the USP could qualify as constitutionally permissible under any conventional understanding of the nondelegation doctrine. For those who believe that delegations to private parties are *per se* illegitimate (like the DC Circuit Court in the *Amtrak* case), this delegation to a private trade organization is facially unconstitutional. For those, like Volokh, who argue that delegations to private parties are authorized when accompanied by an intelligible principle, it is hard to see how a delegation that provides literally no guidance to the USPC- and imposes no limitations- could be permissible. The FDCA's incorporation of the USP could only be considered constitutionally acceptable under the unconventional nondelegation theory espoused by Posner and Vermeule, which would find all Congressional delegations permissible except perhaps delegating the power to vote on legislation.[258] This is an understanding of the nondelegation doctrine that the Supreme Court has not adopted.

Given that the FDCA's incorporation of the USP is almost certainly constitutionally invalid, the fact that it has survived, without amendment or invalidation, for more than a hundred years is somewhat astonishing. What accounts for the longevity of this statutory arrangement and the judicial acquiescence it implies? What does its survival imply about the nondelegation doctrine? The different ways that courts have grappled with- or avoided grappling with- the FDCA's nondelegation problem may indicate three different conclusions about the nondelegation doctrine.

One conclusion that could be drawn is that this delegation has survived because the nondelegation doctrine is a constitutional relic that lacks any modern force. In the context of our complex administrative state, where broad Congressional delegations may be increasingly necessary, the nondelegation doctrine is an inconvenient and embarrassing constitutional principle. The *Mistretta* Court wrote in 1989: "In our increasingly complex society, replete with ever changing and more technical problems, Congress simply cannot do its job absent an ability to delegate power under broad general directives."[259] When courts are faced with the challenge of reconciling the practical necessity of broad, minimally-constrained delegations of authority with the FDCA's clear lack of an intelligible principle, perhaps it is unsurprising that they adopted strategies of avoidance.

A second potential conclusion is this judicial history of avoiding outright invalidation supports Sunstein's theory that the nondelegation doctrine is still alive but relocated into a set of statutory canons. The early state cases (such as Emery) and

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[258]Posner & Vermeule, *supra* note 84, at 1723. However, Posner and Vermuele also point out that while delegations to private parties may not raise any delegation issues, they may raise other constitutional issues under the Vesting Clause or Appointments Clause of Article II. *Id.* at 1757-58.

[259]*Mistretta*, 488 U.S. at 372.

the Ova II case are all examples of courts employing the canon of constitutional avoidance to enforce nondelegation norms. In the early state cases, the effect of these rulings was to prevent future editions of the USP from being legally binding. The Ova II ruling prevented FDA from being able to rely solely on an article's inclusion in the USP as grounds for asserting its jurisdiction. Although the Second Circuit rulings in the National Nutrition cases are not an example of a court using statutory interpretation to enforce nondelegation norms, they highlight how the court managed to avoid addressing the nondelegation issue while still ensuring that FDA would be unable to rely on the invalid definitional provision in the future. This collective behavior by the courts suggests a reluctance to wield the nondelegation doctrine in a frontal assault on offending statutes. However, it also suggests that courts still have a commitment to nondelegation norms.

A third conclusion that might be drawn is that this delegation has survived because it has not raised the kinds of accountability, rule of law, and due process concerns that the nondelegation doctrine exists to serve. This theory suggests that, because the USPC has exercised its authority in a disinterested, transparent, and accountable manner, there has been little reason for litigants to challenge the delegation or for courts to invalidate it. As an organization, the USP has adopted procedures to promote transparency,[260] ensure public participation in standard writing and revision,[261] and maintain impartiality.[262] Writing in 1946, Walton Wheeler wrote of the USP's revision procedures, that

> "The risk that arbitrary, selfish or otherwise improper motives would play a significant part in the revision of standards could be dismissed, both as a matter of history and because of the procedures established for the revision of official standards and the representative character of the groups charged with their revision."[263]

So even though the Congressional delegation to the USPC could have theoretically raised concerns about lack of accountability or the arbitrary exercise of power, as a practical matter it has not. This fact may be directly attributable to the USP's success in self-policing, as well as an example of how an organization's adopted procedures, which constrain its own discretion, are an effective substitute for an intelligible principle. The idea that an organization or agency can or should limit its own discretion when a statute fails to provide constraints was most prominently

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[260]The USP Convention provides an extensive overview of how it operates as an organization, describes the process for creating and revising standards works, and makes its by-laws publically available. THE U.S. PHARMACOPEIAL CONVENTION, DEVELOPMENT PROCESS POLICIES AND GUIDELINES (2017), http://www.usp.org/usp-nf/development-process/policies-guidelines.

[261]Similar to the process an agency goes through in notice-and-comment rulemaking, proposed additions and revisions to USP standards are published on the Pharmacopeial Forum, a bimonthly online journal, which invites public feedback. *Id.*

[262]The USP enforces a robust conflict of interest policy for the Members of its Council of Experts and Expert Committee members. THE U.S. PHARMACOPEIAL CONVENTION, CONFLICTS OF INTEREST (2017), https://www.usp.org/sites/default/files/slide_shows/documents/conflicts.pdf.

[263]Wheeler, *supra* note 125, at 598. In 1954, Herzog marveled at the lack of nondelegation challenges related to the incorporating the USP: "It is indeed of interest that there is such a dearth of this type of proceeding. The explanation may be, as already intimated, that the widespread legislative status of the United States Pharmacopoeia . . . coupled with the great respect in which these compilations are held by all elements of the health professions, has seemed so impregnable that no one would venture into the fray." Herzog, *supra* note 182, at 112.

articulated by the D.C. Circuit in *American Trucking*.[264] From a doctrinal perspective, the idea that an agency could "salvage" a statute without an intelligible principle by providing its own was rejected by the Supreme Court.[265] However, the survival of the FDCA's delegation to the USP may show that the D.C. Circuit was not so wrong from a practical perspective. A standardless delegation might survive for a very long time if an agent scrupulously constrains its own discretion with the result that there are no grounds on which an unhappy litigant would have reason to challenge it.[266]

Fundamentally, there is a tension between what the nondelegation doctrine formally requires and the FDCA's broad delegation of power to the USPC as a private trade organization. The fact that both the nondelegation doctrine and this delegation have managed to uneasily co-exist for more than a hundred years mirrors our own ambivalence about how the practical realities of the modern administrative state fit with our traditional constitutional ideals of separation of power, accountability, and rule of law. Just as this larger ambivalence is unlikely to be quickly resolved, it is also unlikely that the conflict between the nondelegation doctrine and the FDCA's delegation to the USPC will be resolved any time soon.

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[264] Am. Trucking Associations, Inc. v. U.S. E.P.A., 175 F.3d 1027, 1038 (D.C. Cir.), opinion modified on reh'g, 195 F.3d 4 (D.C. Cir. 1999), and aff'd in part, rev'd in part sub nom. Whitman v. Am. Trucking Associations, 531 U.S. 457, (2001) ("Where (as here) statutory language and an existing agency interpretation involve an unconstitutional delegation of power, but an interpretation without the constitutional weakness is or may be available, our response is not to strike down the statute but to give the agency an opportunity to extract a determinate standard on its own.")

[265] Whitman v. Am. Trucking Associations, 531 U.S. 457, 473 (2001)("The idea that an agency can cure an unconstitutionally standardless delegation of power by declining to exercise some of that power seems to us internally contradictory").

[266] A closely related idea is that requiring an agency to go through certain procedures in exercising its authority can be a kind of surrogate for congressional guidance. *See* Sunstein, *supra* note 29, at 333. It is possible to see the procedures that the USP has established for standard creation, which may prevent arbitrariness and promote accountability, as successfully substituting for an intelligible principle.