

SUPREME COURT OF THE UNITED STATES

No. 65.—OCTOBER TERM, 1968.

Timothy F. Leary, Petitioner,	} On Writ of Certiorari	
v.		to the United States
United States.		Court of Appeals for the Fifth Circuit.

[May 19, 1969.]

MR. JUSTICE HARLAN delivered the opinion of the Court.

This case presents constitutional questions arising out of the conviction of the petitioner, Dr. Timothy Leary, for violation of two federal statutes governing traffic in marijuana.

The circumstances surrounding petitioner's conviction were as follows. On December 20, 1965, petitioner left New York by automobile, intending a vacation trip to Yucatan, Mexico. He was accompanied by his daughter and son, both teenagers, and two other persons. On December 22, 1965, the party drove across the International Bridge between the United States and Mexico at Laredo, Texas. They stopped at the Mexican customs station and, after apparently being denied entry, drove back across the bridge. They halted at the American secondary inspection area, explained the situation to a customs inspector, and stated that they had nothing from Mexico to declare. The inspector asked them to alight, examined the interior of the car, and saw what appeared to be marijuana seeds on the floor. The inspector then received permission to search the car and passengers. Small amounts of marijuana were found on the car floor and in the glove compartment. A personal search of petitioner's daughter revealed a silver snuff box containing semi-refined marijuana and three partially smoked marijuana cigarettes.

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Petitioner was indicted and tried before a jury in the Federal District Court for the Southern District of Texas, on three counts. First, it was alleged that he had knowingly smuggled marijuana into the United States, in violation of 21 U. S. C. § 176a.¹ Second, it was charged that he had knowingly transported and facilitated the transportation and concealment of marijuana which had been illegally imported or brought into the United States, with knowledge that it had been illegally imported or brought in, all again in violation of § 176a.² Third, it was alleged that petitioner was a transferee of marijuana and had knowingly transported, concealed, and facilitated the transportation and concealment of marijuana, without having paid the transfer tax imposed by the Marijuana Tax Act, 26 U. S. C. § 4741 *et seq.*, thereby violating 26 U. S. C. § 4744 (a)(2).³

¹ Insofar as here relevant, 21 U. S. C. § 176a provides:

"Notwithstanding any other provision of law, whoever, knowingly, and with intent to defraud the United States, imports or brings into the United States marijuana contrary to law, or smuggles or clandestinely introduces into the United States marijuana which should have been invoiced, or receives, conceals, buys, sells, or in any manner facilitates the transportation, concealment, or sale of such marijuana after being imported or brought in, knowing the same to have been imported or brought into the United States contrary to law, or whoever conspires to do any of the foregoing acts, shall be imprisoned

"Whenever on trial for a violation of this subsection, the defendant is shown to have or to have had the marijuana in his possession, such possession shall be deemed sufficient evidence to authorize conviction unless the defendant explains his possession to the satisfaction of the jury."

² See n. 1, *supra*.

³ Insofar as here relevant, 26 U. S. C. § 4744 (a) provides:

"It shall be unlawful for any person who is a transferee required to pay the transfer tax imposed by section 4741 (a)—

"(1) to acquire or otherwise obtain any marijuana without having paid such tax, or

"(2) to transport or conceal, or in any manner facilitate the

After both sides had presented their evidence and the defense had moved for a judgment of acquittal, the District Court dismissed the first or smuggling count.⁴ The jury found petitioners guilty on the other two counts. He was tentatively sentenced to the maximum punishment, pending completion of a study and recommendations to be used by the District Court in fixing his final sentence.⁵ On appeal, the Court of Appeals for the Fifth Circuit affirmed. 383 F. 2d 851 (1967). That court subsequently denied a petition for rehearing and rehearing *en banc*. 392 F. 2d 220 (1968).

We granted certiorari, 392 U. S. 903 (1968), to consider two questions: (1) whether petitioner's conviction for failing to comply with the transfer tax provisions of the Marijuana Tax Act violated his Fifth Amendment privilege against self-incrimination; (2) whether petitioner was denied due process by the application of the part of 21 U. S. C. § 176a which provides that a defendant's possession of marijuana shall be deemed sufficient evidence that the marijuana was illegally imported or brought into the United States, and that the de-

transportation or concealment of any marijuana so acquired or obtained."

The statutory scheme of the Marijuana Tax Act is analyzed in more detail at pp. 5-7, *infra*.

⁴ Petitioner had testified without contradiction that he had obtained the marijuana in New York, and the District Court apparently reasoned that an article taken out of the United States could not be "smuggled" back into the country, as charged by the indictment. See Joint Appendix 60a; 2 Transcript of Record 520, 695; cf. *United States v. Claybourn*, 180 F. Supp. 448, 451-452 (1960).

⁵ See 18 U. S. C. § 4208. Petitioner was tentatively sentenced to 20 years in prison and a \$20,000 fine for violation of § 176a, and to 10 years in prison and a \$20,000 fine for violation of § 4744 (a) (2) (see 26 U. S. C. § 7237 (a)), the prison sentences to run consecutively. The lowest penalty for conviction under § 176a is five years' imprisonment, and no suspension of sentence, probation, or parole is permitted following such a conviction. See 26 U. S. C. § 7237 (d).

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fendant knew of the illegal importation or bringing in, unless the defendant explains his possession to the satisfaction of the jury. For reasons which follow, we hold in favor of the petitioner on both issues and reverse the judgment of the Court of Appeals.

I.

We consider first petitioner's claim that his conviction under the Marijuana Tax Act violated his privilege against self-incrimination.

A.

Petitioner argues that reversal of his Marijuana Tax Act conviction is required by our decisions of last Term in *Marchetti v. United States*, 390 U. S. 39 (1968), *Grosso v. United States*, 390 U. S. 62 (1968), and *Haynes v. United States*, 390 U. S. 85 (1968). In *Marchetti*, we held that a plea of the Fifth Amendment privilege provided a complete defense to a prosecution for failure to register and pay the occupational tax on wagers, as required by 26 U. S. C. §§ 4411-4412. We noted that wagering was a crime in almost every State, and that 26 U. S. C. § 6107 required that lists of wagering taxpayers be furnished to state and local prosecutors on demand. We concluded that compliance with the statute would have subjected petitioner to a "real and appreciable" risk of self-incrimination. We further recognized that the occupational tax was not imposed in "an essentially non-criminal and regulatory area . . .," 390 U. S., at 57,¹ but was "directed to a 'selective group inherently suspect of criminal activities.'"² We found that it would be inappropriate to impose restrictions on use

¹ 390 U. S., at 48, quoting from *Reg. v. Boyes*, 1 B. & S. 311, 330 (1861).

² 390 U. S., at 57, quoting from *Albertson v. SACB*, 382 U. S. 70, 79 (1965).

³ 390 U. S., at 57, quoting from the same sources.

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of the information collected under the statute—a course urged by the Government as a means of removing the impact of the statute upon the privilege against self-incrimination—because of the evident congressional purpose to provide aid to prosecutors. We noted that, unlike the petitioner in *Shapiro v. United States*, 335 U. S. 1 (1948), Marchetti was not required to supply information which had a “public aspect” or was contained in records of the kind he customarily kept.

In *Grosso*, we held that the same considerations required that a claim of the privilege be a defense to prosecution under 26 U. S. C. § 4401, which imposes an excise tax on proceeds from wagering. And in *Haynes* we held for the same reasons that assertion of the Fifth Amendment privilege provided a defense to prosecution for possession of an unregistered weapon under the National Firearms Act, 26 U. S. C. § 5851, despite the fact that in “uncommon” instances registration under the statute would not be incriminating. See 390 U. S., at 96–97, 99.

B.

In order to understand petitioner’s contention that compliance with the Marijuana Tax Act would have obliged him to incriminate himself within the meaning of the foregoing decisions, it is necessary to be familiar with the statutory scheme. The Marijuana Tax Act has two main subparts. The first imposes a tax on transfers of marijuana, the second an occupational tax upon those who deal in the drug. It is convenient to begin with the occupational tax provisions, 26 U. S. C. §§ 4751–4753.

Section 4751 provides that all persons who “deal in” marijuana shall be subject to an annual occupational tax. Subsections require that specified categories of persons, such as importers, producers, physicians, researchers, and millers pay varying rates of tax per year. See §§ 4751 (1)–(4), (6). Persons who “deal in” marijuana.

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but do not fall into any of the specified categories are required to pay \$3 per year. See § 4751 (5). Section 4753 provides that at the time of paying the tax the taxpayer must "register his name or style and his place or places of business" at the nearest district office of the Internal Revenue Service.

The first of the transfer tax provisions, 26 U. S. C. § 4741, imposes a tax "upon all transfers of marijuana which are required by § 4742 to be carried out pursuant to written order forms." Section 4741 further provides that on transfers to persons registered under § 4753 the tax is \$1 per ounce, while on transfers to persons not so registered the tax is \$100 per ounce. The tax is required to be paid by the transferee "at the time of securing each order form."⁹ With certain exceptions not here relevant,¹⁰ § 4742 makes it unlawful for any person, "whether or not required to pay a special tax and register under sections 4751 to 4753," to transfer marijuana except pursuant to a written order form to be obtained by the transferee. A regulation, 26 CFR § 152.69, provides that the order form must show the name and address of the transferor and transferee; their § 4753 registration numbers, if they are registered; and the quantity of marijuana transferred. Another regulation, 26 CFR § 152.66, requires the transferee to submit an application containing these data in order to obtain the form. Section 4742 (d) of the Act requires the Internal Revenue Service to "preserve" in its records a duplicate copy of each order form which it issues.

⁹ The transferor is secondarily liable for the tax. See 26 U. S. C. § 4741 (b).

¹⁰ The exceptions include transfers by or under prescription of a medical practitioner; legal exportation to foreign countries; transfers to government officials; and transfers of marijuana seeds to persons registered under § 4753.

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Another statutory provision, 26 U. S. C. § 4773, assures that the information contained in the order form will be available to law enforcement officials. That section provides that the duplicate order forms required to be kept by the Internal Revenue Service shall be open to inspection by Treasury personnel and state and local officials charged with enforcement of marijuana laws, and that upon payment of a fee such officials shall be furnished copies of the forms.¹¹

Finally, 26 U. S. C. § 4744 (a) makes it unlawful for a transferee required to pay the § 4741 (a) transfer tax either to acquire marijuana without having paid the tax or to transport, conceal, or facilitate the transportation or concealment of, any marijuana so acquired.¹² Petitioner was convicted under the latter subsection. He conceded at trial that he had not obtained an order form or paid the transfer tax.

C.

If read according to its terms, the Marijuana Tax Act compelled petitioner to expose himself to a "real and appreciable" risk of self-incrimination, within the meaning of our decisions in *Marchetti*, *Grosso*, and *Haynes*. Sections 4741-4742 required him, in the course of obtaining an order form, to identify himself not only as a transferee of marijuana but as a transferee who had not registered and paid the occupational tax under §§ 4751-4753. Section 4773 directed that this information be

¹¹ 26 U. S. C. § 6107, which requires that a list of "persons who have paid special taxes" under subtitles D and E of the Internal Revenue Code be kept for public inspection in each principal internal revenue office and that the list be furnished to state and local prosecutors on request, apparently does not apply to payors of transfer taxes. See *Haynes v. United States*, 390 U. S. 85, 99-100 (1968).

¹² The relevant text of § 4744 (a) is set out in n. 3, *supra*.

conveyed by the Internal Revenue Service to state and local law enforcement officials on request.

Petitioner had ample reason to fear that transmittal to such officials of the fact that he was a recent, unregistered transferee of marijuana "would surely prove a significant 'link in a chain' of evidence tending to establish his guilt"¹³ under the state marijuana laws then in effect.¹⁴ When petitioner failed to comply with the Act, in late 1965, possession of any quantity of marijuana was apparently a crime in every one of the 50 States, including New York, where petitioner claimed the transfer occurred, and Texas, where he was arrested and convicted.¹⁵ It is

¹³ *Marchetti v. United States*, 390 U. S. 39, 48 (1968).

¹⁴ It is also possible that compliance with the Act also would have created a substantial risk of incrimination under 21 U. S. C. § 176a, the other federal statute which petitioner was convicted of violating (the relevant text of § 176a is reproduced in n. 1, *supra*). However, the danger of incrimination under state law is so plain that this possibility need not be explored further.

¹⁵ At the time petitioner failed to comply with the Act, 48 States and the District of Columbia had on their books in some form essentially the provisions of the Uniform Narcotic Drug Act. See 9B Uniform Laws Ann. 409-410 (1966). Section 2 of that Act states: "It shall be unlawful for any person to . . . possess . . . any narcotic drug except as authorized in this act." Section 1 (14) defines "narcotic drugs" to include marijuana ("cannabis"). The remaining two States, California and Pennsylvania, also have statutes making it a crime to possess marijuana. See Cal. Code Ann. § 11530 (1961); 35 Pa. Stat. Ann. §§ 780-2 (g), 780-4 (q) (1961).

In 1965, New York and Texas had in effect statutory provisions substantially identical to the above sections of the Uniform Act. For New York, see N. Y. Public Health Law §§ 3301 (21), 3305 (1954); for Texas, see Vernon's Texas Penal Code Ann., Art. 725b §§ 1 (14), 2 (1961). In New York possession of any amount of marijuana was a misdemeanor punishable by up to a year's imprisonment. See N. Y. Penal Law § 1751-a (1) (1954). See also *id.*, § 1751 (2) (1956). In Texas, such possession was a felony punishable by imprisonment for not less than two years and not more than life. See Vernon's Texas Penal Code Ann., Art. 725b, § 23 (1) (1957).

true that almost all States, including New York and Texas, had exceptions making lawful, under specified conditions, possession of marijuana by: (1) state-licensed manufacturers and wholesalers; (2) apothecaries; (3) researchers; (4) physicians, dentists, veterinarians, and certain other medical personnel; (5) agents or employees of the foregoing persons or common carriers; (6) persons for whom the drug had been prescribed or to whom it had been given by an authorized medical person; and (7) certain public officials.¹⁶ However, individuals in the first four of these classes are among those compelled to register and pay the occupational tax under §§ 4751–4753;¹⁷ in consequence of having registered, they are required to pay only a \$1 per ounce transfer tax under § 4741 (a)(1). It is extremely unlikely that such persons will remain unregistered, for failure to register renders them liable not only to an additional \$99 per ounce transfer tax but also to severe criminal penalties.¹⁸ Persons in the last three classes mentioned above appear to be wholly exempt from the order form and transfer tax requirements.¹⁹

Thus, at the time petitioner failed to comply with the Act those persons who might legally possess marijuana under state law were virtually certain either to

¹⁶ See, *e. g.*, Uniform Narcotic Drug Act §§ 3–11, 9B Uniform Laws Ann. 472–496 (1966); N. Y. Public Health Law §§ 3310, 3320–3333 (1966); Vernon's Texas Penal Code Ann., Art. 725b, §§ 5–12 (1961).

¹⁷ See 26 U. S. C. §§ 4753 (1)–(6).

¹⁸ See 26 U. S. C. §§ 4755 (a)(1), 4755 (a)(3), 7237 (a).

¹⁹ 26 U. S. C. §§ 4742 (b)(1)–(2) exempt persons who receive marijuana under medical prescription or directly from a medical practitioner. Title 26 U. S. C. § 4742 (b)(4) exempts transfers to public officials. And the design of the Act strongly suggests that a delivery of marijuana to an employee or agent of a registrant is considered a “transfer” to the registrant himself, see 26 U. S. C. § 4755 (b)(3), 26 CFR §§ 152.41, 152.42, and that delivery to a common carrier is considered a “transfer” to the addressee. See 26 U. S. C. § 4755 (b)(2), 26 CFR § 152.127 (c).

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be registered under § 4753 or to be exempt from the order form requirement. It follows that the class of possessors who were both unregistered and obliged to obtain an order form constituted "a select group inherently suspect of criminal activities." Since compliance with the transfer tax provisions would have required petitioner unmistakably to identify himself as a member of this "select" and "suspect" group, we can only decide that when read according to their terms these provisions created a "real and appreciable" hazard of incrimination.

D.

The Government, however, vigorously contends that when the Act is considered together with the accompanying regulations, and in light of existing administrative practice, its incriminatory aspect will be seen to vanish or shrink to less than constitutional proportions. The Government points first to regulations, 26 CFR §§ 152.22, 152.23, added in 1964, which provide that every applicant for registration under §§ 4751-4753 must show that he is legally qualified to deal in marijuana according to the laws of the jurisdiction in which he is operating, and that the district director shall not permit an applicant to register until the director is satisfied that this is true. The Government then cites two other regulations, relating to applications for order forms under § 4742. The first, 26 CFR § 152.67, provides that such applications "[g]enerally . . . shall be signed by the same person or persons signing the application for registration," but when this is impracticable "they may be signed by another person, provided a power of attorney authorizing such other person to sign the applications . . . has previously been filed. . . ." The second regulation, 26 CFR § 152.68, states that upon receipt of an application the district director "shall" compare

the signature on the application "with that appearing on the application for registration or in the power of attorney," and that "[u]nless the district director is satisfied that the application is authentic, it will not be honored."

The Government asserts that these regulations clearly signify that no person will be permitted to register unless his activities are permissible under the law of his jurisdiction, and that no one will be permitted to obtain an order form and prepay the transfer tax unless he has registered.²⁰ The result, the Government contends, is simply to prohibit nonregistrants like petitioner from dealing in marijuana at all. The Government further asserts that the administrative practice of the Internal Revenue Service and the Bureau of Narcotics has always been consistent with this interpretation, though it concedes that there apparently has never been an attempt by a nonregistrant to prepay the tax. The Government does admit uncertainty as to whether the fact of such an attempt would have been communicated to law enforcement officials; however, it points out that nothing in the statute or regulations appears to compel such disclosure.²¹ The Government argues that the regulations and administrative practice effectively refute the existence of a substantial hazard of incrimination at the time petitioner acquired marijuana: first, because a non-

²⁰ The Government argues that the \$100 per ounce tax was intended to be collected only *civilly*, from those found to have engaged in illegal transfers. See Brief for the United States 19 nn. 23, 29. See also *United States v. Sanchez*, 340 U. S. 42 (1951).

²¹ After our decisions in *Marchetti*, *Grosso*, and *Haynes*, district directors were instructed that such applications should not be disclosed but simply returned to the applicant. See Brief for the United States 17, n. 16.

registrant would have known that he could not obtain an order form and consequently never would have applied; second, because there was no substantial risk that an unsuccessful application would have been brought to the attention of law enforcement officials.

We cannot accept the Government's argument, for we find that Congress did intend that a nonregistrant should be able to obtain an order form and prepay the transfer tax. This congressional intent appears both from the language of the Act and from its legislative history.

We begin with the words of the statute. Section 4741 (a), when read in conjunction with § 4742, imposes a tax upon every transfer of marijuana, with a few exceptions not here relevant.²² Section 4741 (a)(1) states that the tax on registrants shall be \$1 per ounce and § 4741 (a)(2) that the tax on transfers to nonregistrants shall be \$100 per ounce. Section 4741 (b) states that "[s]uch tax shall be paid by the transferee at the time of securing each order form, and shall be in addition to the price of such form." (Emphasis added.) Since § 4742 (b) makes no distinction between the § 4741 (a)(1) tax on transfers to registrants and the § 4741 (a)(2) tax on transfers to nonregistrants, it seems clear that Congress contemplated that nonregistrant as well as registrant transferees should be able to obtain order forms and prepay the tax.

The legislative history also strongly indicates that the Act was intended merely to impose a very high tax on transfers to nonregistrants and not to prohibit such transfers entirely. As a taxing measure, the bill of course originated in the House of Representatives. At the start of the first hearing on the bill, before the House Ways and Means Committee, the committee chairman

²² See n. 10, *supra*.

announced that he had introduced the bill at the request of the Secretary of the Treasury.²³ The transfer provisions of the bill then read essentially as they do now.²⁴ The first witness to appear before the Committee was the Treasury Department's Assistant General Counsel, Clinton M. Hester. He began by stating that the bill's purpose was "not only to raise revenue from the marijuana traffic, but also to discourage the current and widespread undesirable use of marijuana by smokers and drug addicts" ²⁵ He stated that in form the bill was a "synthesis" of the Harrison Narcotics Act, now 26 U. S. C. § 4701 *et seq.*, and the National Firearms Act, now 26 U. S. C. § 5841 *et seq.*²⁶ Both of these statutes compelled dealers in the respective goods to register and pay a special tax. Both prohibited transfer except in pursuance of a written form and imposed a transfer tax. However, the transfer provisions differed in that the Narcotics Act provided that no one except a registrant could legally obtain an order form, see 26 U. S. C. § 4705 (g), while the Firearms Act merely imposed a \$200 tax upon each transfer of a firearm covered by the Act.

The Treasury witness explained that the marijuana tax bill generally followed the plan of the Narcotics Act insofar as it required dealers in marijuana to register and prohibited transfers except by order form. But he testified that because of constitutional doubts:

"[a]t this point, this bill, like the National Firearms Act, departs from the plan of the Harrison Narcotics Act which limits the right to purchase

²³ See Hearings on H. R. 6385 before the House Committee on Ways and Means, 75th Cong., 1st Sess., 5 (1937).

²⁴ See *id.*, at 3-5.

²⁵ *Id.*, at 7.

²⁶ *Ibid.*

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narcotic drugs to persons who are permitted to register under that act.

"[I]n order to obviate the possibility of [an] attack upon the constitutionality of this bill, it, like the National Firearms Act, permits the transfer of marijuana to nonregistered persons upon the payment of a heavy transfer tax. The bill would permit the transfer of marijuana to anyone, but would impose a \$100 per ounce tax upon a transfer to a person who might use it for purposes which are dangerous and harmful to the public" ²⁷

Mr. Hester was also the first witness before the Senate Finance Committee. There he testified in less detail, stating at different points that the purpose of the transfer provisions was "to discourage the widespread use of the drug by smokers and drug addicts," ²⁸ "to render extremely difficult the acquisition of marijuana by persons who desire it for illicit uses," ²⁹ "to prevent transfers to persons who would use marijuana for undesirable purposes," ³⁰ and "through the \$100 transfer tax to prevent the drug from coming into the hands of those who would put it to illicit uses." ³¹

The House and Senate reports describe the purposes of the transfer provisions largely in the language of

²⁷ Hearings on H. R. 6385 before the House Committee on Ways and Means, 75th Cong., 1st Sess., 9 (1937). The doubts about the bill's constitutionality were occasioned by the dissenting opinions in *United States v. Doremus*, 249 U. S. 86, 95 (1919), and *Nigro v. United States*, 276 U. S. 332, 354, 357 (1928). See Hearings on H. R. 6385, *supra*, at 9.

²⁸ Hearings on H. R. 6906 before the Senate Committee on Finance, 75th Cong., 1st Sess., 5 (1937).

²⁹ *Id.*, at 6.

³⁰ *Id.*, at 6.

³¹ *Id.*, at 7.

Mr. Hester's testimony. The House report declares that the purpose was "to discourage the widespread use of the drug by smokers and drug addicts,"³² "to render extremely difficult the acquisition of marijuana by persons who desire it for illicit uses,"³³ and "through the \$100 transfer tax to prevent the drug from coming into the hands of those who will put it to illicit uses."³⁴ In discussing the issue of constitutionality, the report recites that "[t]he law is . . . settled that Congress has the power to enact a tax which is so heavy as to discourage the transactions or activities taxed"³⁵ and states that "[t]hese cases sustain the \$100 tax imposed . . . upon transfers . . . to unregistered persons."³⁶ The Senate report, without discussing constitutionality, otherwise states the purpose of the transfer provisions in the very same words as the House report.³⁷ Thus, the committee reports confirm Mr. Hester's account of the bill's purposes. In short, the legislative history fully accords with the statutory language.

Upon this evidence, we have no hesitation in concluding that the interpretation which the Government would give to the transfer provisions is contrary to the manifest congressional intent that transfers to nonregistrants be taxed, not forbidden. Insofar as the regulations which require comparison of signatures necessarily compel the result urged by the Government, they must be regarded as contrary to the statute and hence beyond the scope of the regulation-making authority which was delegated by Congress.³⁸ It is true that these regulations were

³² H. R. Rep. No. 792, 75th Cong., 1st Sess., 1 (1937).

³³ *Id.*, at 2.

³⁴ *Id.*, at 2.

³⁵ *Id.*, at 3.

³⁶ *Id.*, at 3.

³⁷ See S. Rep. No. 900, 75th Cong., 1st Sess., 2-3 (1937).

³⁸ The regulations, 26 CFR §§ 152.22, 152.23, see *supra*, at 10, which limit registration under § 4763 to persons whose marijuana

promulgated in 1937, and that Congress re-enacted the entire Act in 1954, while they were in effect. However, the scanty legislative history accompanying that re-enactment gives no hint that Congress knew of these particular regulations, much less of the indirect impact which the Government now ascribes to them.³⁹ As we recently noted in *Massachusetts Trustees v. United States*, 377 U. S. 235, 241, 242 (1964), congressional re-enactment of the statute, even without any apparent knowledge of a particular regulation, can "strengthen to some extent" the regulation's claim to validity, but re-enactment cannot save a regulation which "contradict[s] the requirement" of the statute itself. When a regulation conflicts with the statute, the fact of subsequent re-enactment "is immaterial, for Congress could not add to or expand the statute by impliedly approving the regulation." *Commissioner v. Acker*, 361 U. S. 87, 93 (1959).⁴⁰

dealings are legal under relevant state and local laws do not of themselves require the result urged by the Government. In fact, there is strong support in the legislative history for the proposition that illicit consumers of marijuana like petitioner are not entitled to register. The House and Senate reports and the testimony of Mr. Hester before the Senate Finance Committee all state, in identical language, that "[u]nder [the bill's] provisions, all legitimate handlers of marijuana are required to pay occupational taxes" H. R. Rep. No. 792, 75th Cong., 1st Sess., 2 (1937); S. Rep. No. 900, 75th Cong., 1st Sess., 3 (1937); Hearings on H. R. 6906 before the Senate Committee on Finance, 75th Cong., 1st Sess., 6 (1937). In his testimony before the House Ways and Means Committee, Mr. Hester stated explicitly that "those who would consume marijuana are not eligible to register under the bill" Hearings on H. R. 6385 before the House Committee on Ways and Means, 75th Cong., 1st Sess., 8 (1937).

³⁹ See H. R. Rep. No. 1337, 83d Cong., 2d Sess., A325 (1954); S. Rep. No. 1622, 83d Cong., 2d Sess., 482-483 (1954).

⁴⁰ See also 1 K. Davis, *Administrative Law* § 5.07 (1958), and cases there cited.

Nor are we persuaded by the Government's argument that its construction has been followed by the Internal Revenue Service and the Bureau of Narcotics ever since the passage of the Act, and that this "long-standing" interpretation by the agencies charged with administering the Act should be controlling. We have often recognized that, as a general matter, a long-standing, contemporaneous construction of a statute by the administering agencies is "entitled to great weight," *FTC v. Mandel Bros.*, 359 U. S. 385, 391 (1959), and will be "show[n] great deference," *Udall v. Tallman*, 380 U. S. 1, 16 (1965).⁴¹ However, in this instance the Government admits that until our decisions last Term in *Marchetti*, *Grosso*, and *Haynes*, the alleged interpretation had been made known only through the regulations themselves, since there apparently had never been an application by a nonregistrant to prepay the transfer tax. Moreover, in its brief in this Court in *United States v. Sanchez*, 340 U. S. 42 (1951), the United States plainly took the position that the Act imposed only a tax and not a prohibition on transfers to nonregistrants,⁴² implying that at that time the alleged administrative construction was unknown even to those charged with representing the United States in this Court. In these circumstances, the alleged administrative construction can furnish no additional support for the Government's argument.

The foregoing shows that at the time petitioner acquired marijuana he was confronted with a statute which on its face permitted him to acquire the drug legally, provided he paid the \$100 per ounce transfer tax and gave incriminating information, and simultaneously with a system of regulations which, according

⁴¹ See generally *id.*, § 5.06.

⁴² See Brief for the United States, *United States v. Sanchez*, 340 U. S. 42 (1951), at 28-29.

to the Government, prohibited him from acquiring marijuana under any conditions. We have found those regulations so out of keeping with the statute as to be *ultra vires*. Faced with these conflicting commands, we think petitioner would have been justified in giving precedence to the higher authority: the statute.⁴³ “‘Literal and full compliance’ with all the statutory requirements”⁴⁴ would have entailed a very substantial risk of self-incrimination. See *supra*, at 7–10.

The United States has not urged us, as it did in *Marchetti*, *Grosso*, and *Haynes*, to avoid this constitutional difficulty by placing restrictions upon the use of information gained under the transfer provisions. We declined to impose use restrictions in those cases because we found that the furnishing of information to interested prosecutors was a “significant element of Congress’ purposes in adopting” the statutes there involved. *Marchetti v. United States*, 390 U. S. 39, 59 (1968).⁴⁵ The text and legislative history of the Marijuana Tax Act plainly discloses a similar congressional purpose. As has been noted, 26 U. S. C. § 4773 requires that copies of order forms be kept available for inspection by state and local officials, and that copies be furnished to such officials on request. The House and Senate reports both state that one objective of the Act was “the development of an adequate means of publicizing dealings in mari-

⁴³ Any other holding would give rise to additional knotty questions, such as whether petitioner’s nonpayment of the transfer tax should be excused because of his actual or assumed reliance upon the erroneous administrative construction of the statute, under which he would not have been permitted to pay. Cf. *James v. United States*, 366 U. S. 213 (1961).

⁴⁴ *Grosso v. United States*, 390 U. S. 62, 65 (1968), quoting from *Albertson v. SACB*, 382 U. S. 70, 78 (1965).

⁴⁵ See also *Grosso v. United States*, *supra*, at 69; *Haynes v. United States*, 390 U. S. 85, 90–100 (1968).

juana in order to tax and control the traffic effectively.” “In short, we think the conclusion inescapable that the statute was aimed at bringing to light transgressions of the marijuana laws. Hence, as in last Term’s cases, we decline to impose use restrictions and are obliged to conclude that a timely and proper assertion of the privilege should have provided a complete defense to prosecution under § 4744 (a)(2).

E.

There remain the further questions whether this petitioner’s claim of the privilege was timely and whether it was waived. As for timeliness, petitioner did not assert the privilege as a defense to the § 4744 (a) count until his motion for a new trial. The Court of Appeals evidently regarded the claim as timely, for it rejected it on the merits both in its original opinion and in its denial of rehearing. See 383 F. 2d, at 870; 392 F. 2d, at 221–222. The Government does not contend that the claim of the privilege was untimely. Petitioner’s trial occurred before our decisions in *Marchetti*, *Grosso*, and *Haynes*, and the Court of Appeals for the Fifth Circuit had recently rejected an identical self-incrimination claim. See *Haynes v. United States*, 339 F. 2d 30 (1964). Although it would have been preferable for petitioner to have asserted the privilege at trial, we hold that in the circumstances of this case his failure to raise the issue at that time did not amount to a waiver of the privilege. See *Grosso v. United States*, 390 U. S. 62, 70–71 (1968).

In denying Leary’s petition for rehearing, the Court of Appeals, in addition to holding the privilege generally inapplicable to prosecutions under § 4744 (a), found that petitioner’s claim of the privilege was improper because

⁴⁴ H. R. Rep. No. 792, 75th Cong., 1st Sess., 2 (1937); S. Rep. No. 900, 75th Cong., 1st Sess., 3 (1937).

he "took the stand and affirmatively waived the privilege . . . by testifying fully to the details of his acquisition and transportation of marijuana without having paid the tax" 392 F. 2d, at 222. In relying for that proposition on the statement in *Marchetti* that our decision in that case would not provide a shield for any taxpayer who was "outside the privilege's protection," 390 U. S., at 61, we think the Court of Appeals misconceived the thrust of that dictum. The aspect of the self-incrimination privilege which was involved in *Marchetti*, and which petitioner asserts here, is not the undoubted right of an accused to remain silent at trial. It is instead the right not to be criminally liable for one's previous failure to obey a statute which required an incriminatory act. Thus, petitioner is not asserting that he had a right to stand mute at his trial but that he cannot be convicted for having failed to comply with the transfer provisions of the Act at the time he acquired marijuana in 1965. His admission at trial that he had indeed failed to comply with the statute was perfectly consistent with the claim that that omission was excused by the privilege. Hence, it could not amount to a waiver of that claim.

The Government suggests that petitioner waived his right to plead self-incrimination in yet another way, by testifying at trial that he had violated the statute for reasons entirely unrelated to fear of self-incrimination. It is true that some portions of petitioner's testimony indicate that his noncompliance was motivated, at least in part, by his conviction that the Act imposed an illegal tax upon religion or upon the "pursuit of knowledge"⁴⁷ and by his belief that, in consequence of the system of regulations and administrative practice described above, he would not be permitted to pay the tax.⁴⁸ However,

⁴⁷ See Joint Appendix 87a-88a, 89a.

⁴⁸ See Joint Appendix 86a-89a. Of course, a holding that petitioner waived his right to plead self-incrimination by his reliance on

other parts of petitioner's testimony clearly indicate that he also was influenced by an apprehension that by trying to pay the tax he might incriminate himself.⁴⁹ We cannot say that petitioner's testimony, taken as a whole, amounted to a waiver of the privilege. We conclude that petitioner's invocation of the privilege was proper and that it should have provided a full defense to the third count of the indictment. Accordingly, we reverse petitioner's conviction under 26 U. S. C. § 4744 (a)(2).

II.

Next, we consider whether, in the circumstances of this case, the application of the presumption contained in 21 U. S. C. § 176a denied petitioner due process of law.

A.

Insofar as here relevant, § 176a imposes criminal punishment upon every person who:

"knowingly, with intent to defraud the United States, imports or brings into the United States marijuana contrary to law . . . , or receives, conceals,

the erroneous administrative interpretation would require consideration of the further question mentioned in n. 43, *supra*: whether such reliance should provide a defense.

⁴⁹ When first asked on direct examination why he had not paid the transfer tax, petitioner stated: "Well, I knew that I couldn't get such a permission I also know that if I had applied for such a [transfer tax] stamp I would probably subject myself to investigation" Joint Appendix 86a. In response to a similar subsequent question, petitioner said: "I was very certain that I would not be able to pay the tax on the marijuana and that not only would it be taken away from me but I would be subjected to action." Joint Appendix 87a. And when asked whether he had "an honest belief that you could not obtain [an order form]," petitioner replied: "I had a strong and honest belief that I could not get it and it would just cause a lot of publicity and trouble for both the government and myself. And I am not trying to cause trouble" Joint Appendix 89a.

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buys, sells, or in any manner facilitates the transportation, concealment, or sale of such marijuana after being imported or brought in, knowing the same to have been imported or brought into the United States contrary to law"

A subsequent paragraph establishes the presumption now under scrutiny:

"Whenever on trial for a violation of this subsection, the defendant is shown to have or to have had the marijuana in his possession, such possession shall be deemed sufficient evidence to authorize conviction unless the defendant explains his possession to the satisfaction of the jury."

The second count of the indictment charged petitioner with having violated the "transportation" and "concealment" provisions of § 176a.⁶⁰ Petitioner admitted at trial that he had acquired marijuana in New York; had driven with it to Laredo, Texas; had continued across the bridge to the Mexican customs station; and then had returned to the United States. He further testified that he did not know where the marijuana he acquired had been grown.⁶¹

In view of this testimony, the trial court instructed the jury that it might find petitioner guilty of violating § 176a on either of two alternative theories. Under the first or "South-North" theory, a conviction could have been based solely upon petitioner's own testimony that the marijuana had been brought back from Mexico into the United States and that with knowledge of that fact petitioner had continued to transport it. Under the second or "North-South" theory, the conviction would

⁶⁰ As has been noted, the first count charged him with smuggling in violation of § 176a, but the District Court dismissed that count. See *supra*, at 3 and n. 4.

⁶¹ See Joint Appendix 90a.

have depended partly upon petitioner's testimony that he had transported the marijuana from New York to Texas and partly upon the challenged presumption.⁵²

The Government contends that by giving testimony at trial which established all elements of the offense under the "South-North" theory, and by failing to object to the jury instructions on the ground now advanced, petitioner foreclosed himself from raising the point thereafter. We cannot agree. Even assuming that petitioner's testimony did supply all the evidence required for a valid conviction under the "South-North" theory, the jury nevertheless was told that it could alternatively convict with the aid of the presumption under the "North-South" theory. For all we know, the conviction did rest on that ground. It has long been settled that when a case is submitted to the jury on alternative theories the unconstitutionality of any of the theories requires that the conviction be set aside. See, e. g., *Stromberg v. California*, 283 U. S. 359 (1931).

It is true that petitioner did not object to the jury instructions on the basis of the presumption's alleged unconstitutionality.⁵³ However, he did rely upon that ground in his previous motion for a directed verdict at

⁵² With respect to this theory, the trial judge stated near the end of his charge to the jury:

"Now, you might have some difficulty with the question on Count 2

"I mention this a second time because you might be confused about the question of importation.

"We are not talking necessarily about the importation or what the government contends was importation here at the bridge.

"The defendant has told us that he received the marijuana in New York. This statute, of course, is of application throughout the land and the presumption would still apply that the narcotic had been imported illegally unless he explains his possession to the satisfaction of the jury." Joint Appendix 103a-104a.

⁵³ See 2 Transcript of Record 612-614.

the close of the prosecution's case, and urged it again in his subsequent motion for a new trial.⁵⁴ Both motions were denied. The Court of Appeals considered petitioner's constitutional argument on the merits, and rejected it. See 383 F. 2d, at 868-870. In these circumstances, we conclude that the question is properly before us.⁵⁵

B.

By what criteria is the constitutionality of the § 176a presumption to be judged?

Early decisions of this Court set forth a number of different standards by which to measure the validity of statutory presumptions.⁵⁶ However, in *Tot v. United States*, 319 U. S. 463 (1943), the Court singled out one of these tests as controlling, and the *Tot* rule has been

⁵⁴ See 1 Transcript of Record 198-200; 2 Transcript of Record 492, 649.

⁵⁵ We think it irrelevant that petitioner himself testified at trial that he had no knowledge of the marijuana's origin. The Government put in no affirmative evidence of knowledge, and the jury was instructed that it could convict under the "North-South" theory, relying upon the § 176a presumption to permit an inference of knowledge. The trial judge did not mention petitioner's testimony on this point in his instructions to the jury. Since the presumption is by its terms rebuttable, the intended implication must have been that the jury could convict on the basis of the presumption only if it disbelieved the testimony. Cf. *Caudillo v. United States*, 253 F. 2d 513, 518 (1958).

⁵⁶ One test was whether there was a "rational connection" between the basic fact and the presumed fact. See *Mobile, J. & K. C. R. Co. v. Turnipseed*, 219 U. S. 35 (1910); *McFarland v. American Sugar Refg. Co.*, 241 U. S. 79 (1916); *Western & Atl. R. Co. v. Henderson*, 279 U. S. 639 (1929); cf. *Yee Hem v. United States*, 268 U. S. 178 (1925). A second was whether the legislature might have made it a crime to do the thing from which the presumption authorized an inference. See *Ferry v. Ramsey*, 277 U. S. 88 (1928). A third was whether it would be more convenient for the defendant or for the prosecution to adduce evidence of the presumed fact. See *Morrison v. California*, 201 U. S. 82 (1934); cf. *Rossi v. United States*, 289 U. S. 89 (1933); *Yee Hem v. United States*, *supra*.

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adhered to in the two subsequent cases in which the issue has been presented. The *Tot* Court had before it a federal statute⁸⁷ which, as construed, made it a crime for one previously convicted of a crime of violence to receive any firearm or ammunition in an interstate transaction. The statute further provided that "the possession of a firearm or ammunition by any such person shall be presumptive evidence that such firearm or ammunition was shipped or transported or received, as the case may be, by such person in violation of this Act."

The Court, relying upon a prior decision in a civil case,⁸⁸ held that the "controlling" test for determining the validity of a statutory presumption was "that there be a rational connection between the facts proved and the fact presumed." 319 U. S., at 467. The Court stated:

"Under our decisions, a statutory presumption cannot be sustained if there be no rational connection between the fact proved and the ultimate fact presumed, if the inference of the one from the proof of the other is arbitrary because of lack of connection between the two in common experience. This is not to say that a valid presumption may not be rested upon a view of relation broader than a jury might take in a specific case. But where the inference is so strained as not to have a reasonable relation to the circumstances of life as we know them, it is not competent for the legislature to create it as a rule governing the procedure of courts." 319 U. S., at 467-468 (footnotes omitted).

The *Tot* Court reduced to the status of a "corollary" another test which had some support in prior decisions: ⁸⁹

⁸⁷ Section 2 (f) of the Federal Firearms Act, 52 Stat. 1250, 16 U. S. C. § 902 (f).

⁸⁸ *Mobile, J. & K. C. R. Co. v. Turnipseed*, 219 U. S. 35 (1910).

⁸⁹ See n. 56, *supra*.

whether it was more convenient for the defendant or for the Government to supply proof of the ultimate fact which the presumption permitted to be inferred. The Court stated that "[t]he argument from convenience is admissible only where the inference is a permissible one" 319 U. S., at 469. The Court rejected entirely another suggested test with some backing in the case law,⁶⁰ according to which the presumption should be sustained if Congress might legitimately have made it a crime to commit the basic act from which the presumption allowed an inference to be drawn.⁶¹ The *Tot* Court stated simply that "for whatever reason" Congress had not chosen to make the basic act a crime. *Id.*, at 472.

Applying the "rational connection" test, the Court held the *Tot* presumption unconstitutional. The Court rejected the contention that because most States forbade intrastate acquisition of firearms without a record of the transaction or registration of ownership it could be inferred merely from possession that an acquisition which did not meet these requirements must have been interstate, noting the alternative possibilities of unlawful intrastate acquisition and interstate shipment prior to the beginning of state regulation. See *id.*, at 468.⁶²

The two subsequent cases in which this Court ruled upon the constitutionality of criminal statutory presumptions, *United States v. Gainey*, 380 U. S. 63 (1965), and *United States v. Romano*, 382 U. S. 136 (1965), involved companion sections of the Internal Revenue

⁶⁰ See *ibid.*

⁶¹ For example, it was argued in *Tot* that in order to regulate interstate commerce in firearms Congress might have prohibited possession of *all* firearms by persons who had been convicted of crimes of violence.

⁶² The Court declared that there was even less reason to conclude from possession that the acquisition had occurred subsequent to the effective date of the Firearms Act.

Code dealing with illegal stills. The presumption in *Gainey* was worded similarly to the one at issue here; it permitted a jury to infer from a defendant's presence at an illegal still that he was "carrying on" the business of a distiller "unless the defendant explains such presence to the satisfaction of the jury" See 26 U. S. C. §§ 5601 (a)(4), 5601 (b)(2).

We held that the *Gainey* presumption should be tested by the "rational connection" standard announced in *Tot*. We added:

"The process of making the determination of rationality is, by its nature, highly empirical, and in matters not within specialized judicial competence or completely commonplace, significant weight should be accorded the capacity of Congress to amass the stuff of actual experience and cull conclusions from it." 380 U. S., at 67.

Applying these principles, we sustained the *Gainey* presumption, finding that it "did no more than 'accord to the evidence, if unexplained, its natural probative force.'" 380 U. S., at 71.

The presumption under attack in *United States v. Romano*, *supra*, was identical to that in *Gainey* except that it authorized the jury to infer from the defendant's presence at an illegal still that he had possession, custody, or control of the still. See 26 U. S. C. §§ 5601 (a)(1), 5601 (b)(1). We held this presumption invalid. While stating that the result in *Gainey* was entirely justified because "[p]resence at an operating still is sufficient evidence to prove the charge of 'carrying on' because anyone present is very probably connected with the illegal enterprise," 382 U. S., at 141, we concluded:

"Presence is relevant and admissible evidence in a trial on a possession charge; but absent some showing of the defendant's function at the still, its

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connection with possession is too tenuous to permit a reasonable inference of guilt—"the inference of the one from proof of the other is arbitrary" *Tot v. United States*, 319 U. S. 463, 467. *Ibid.*⁶³

The upshot of *Tot*, *Gainey*, and *Romano* is, we think, that a criminal statutory presumption must be regarded as "irrational" or "arbitrary," and hence unconstitutional, unless it can at least be said with substantial assurance that the presumed fact is more likely than not to flow from the proved fact on which it is made to depend.⁶⁴ And in the judicial assessment the congressional determination favoring the particular presumption must, of course, weigh heavily.

C.

How does the § 176a presumption fare under these standards?

So far as here relevant, the presumption, quoted *supra*, at 22, authorizes the jury to infer from a defendant's possession of marijuana two necessary elements of the crime: (1) that the marijuana was imported or brought into the United States illegally; and (2) that the de-

⁶³ Like the Court in *Tot*, we limited ourselves in *Romano* to consideration of the crime Congress actually had defined. We observed that Congress had not chosen to make presence at an illegal still a crime in itself, but had only "declar[ed] presence to be sufficient evidence to prove the crime of possession beyond a reasonable doubt," and concluded that "[t]his approach obviously fails under the standards traditionally applied to such legislation." 382 U. S., at 144.

⁶⁴ Since we find that the § 176a presumption is unconstitutional under this standard, we need not reach the question whether a criminal presumption which passes muster when so judged must also satisfy the criminal "reasonable doubt" standard if proof of the crime charged or an essential element thereof depends upon its use. Cf. *United States v. Adams*, 293 F. Supp. 776, 783-784 (1968). See also *United States v. Romano*, *supra*, at 140-144; Note, *The Constitutionality of Statutory Criminal Presumptions*, 34 U. Chi. L. Rev. 141 (1966).

fendant knew of the unlawful importation or bringing in.⁶⁵ Petitioner argues that neither inference is valid, citing undisputed testimony at his trial to the effect that marijuana will grow anywhere in the United States, and that some actually is grown here.⁶⁶ The Government contends, on the other hand, that both inferences are permissible. For reasons that follow, we hold unconstitutional that part of the presumption which relates to a defendant's knowledge of illegal importation. Consequently, we do not reach the question of the validity of the "illegal importation" inference.

With regard to the "knowledge" presumption, we believe that *Tot* and *Romano* require that we take the statute at face value and ask whether it permits conviction upon insufficient proof of "knowledge," rather than inquire whether Congress might have made possession itself a crime.⁶⁷ In order thus to determine the constitutionality of the "knowledge" inference, one must have direct or circumstantial data regarding the beliefs of marijuana users generally about the source of the drug they consume. Such information plainly is "not within specialized judicial competence or completely commonplace," *United States v. Gainey, supra*, at 67. Indeed, the presumption apparently was enacted to relieve the Government of the burden of having to adduce such evidence at every trial, and none was introduced by the

⁶⁵ The presumption also permits inference of a third element: that the importation or bringing in was with intent to defraud the United States. The permissibility of this inference was not one of the questions presented in Leary's petition for certiorari, and on the view we take of this branch of the case we have no occasion to consider it.

⁶⁶ See 1 Transcript of Record 165, 186-187. Petitioner attempted to introduce further evidence concerning the proportion of domestically consumed marijuana which in fact has been grown in the United States, but the District Court held it irrelevant and therefore inadmissible. See 2 Transcript of Record 517.

⁶⁷ See *supra*, at 26 and n. 63.

prosecution at petitioner's trial. Since the determination of the presumption's constitutionality is "highly empirical," *ibid.*, it follows that we must canvass the available, pertinent data.

Of course, it must be kept in mind that "significant weight should be accorded the capacity of Congress to amass the stuff of actual experience and cull conclusions from it." *Ibid.* However, it quickly becomes apparent that the legislative record does not supply an adequate basis upon which to judge the soundness of the "knowledge" part of the presumption. We have therefore taken other materials into account as well, in an effort to sustain the presumption. In so doing, we have not confined ourselves to data available at the time the presumption was enacted in 1956, but have also considered more recent information, in order both to obtain a broader general background and to ascertain whether the intervening years have witnessed significant changes which might bear upon the presumption's validity.⁶⁸

As has been noted, we do not decide whether the presumption of illegal importation is itself constitutional. However, in view of the paucity of direct evidence as to the beliefs of marijuana smokers generally about the source of their marijuana, we have found it desirable to survey data concerning the proportion of domestically consumed marijuana which is of foreign origin, since in the absence of better information the proportion of marijuana actually imported surely is relevant in deciding whether marijuana possessors "know" that their marijuana is imported.

⁶⁸ A statute based upon a legislative declaration of facts is subject to constitutional attack on the ground that the facts no longer exist; in ruling upon such a challenge a court must, of course, be free to re-examine the factual declaration. See *Block v. Hirsh*, 250 U. S. 135, 154-155 (1921); *Communist Party v. SACB*, 367 U. S. 1, 110-114 (1961).

D.

Since the importation question is a subsidiary one, we take it up first, beginning, of course, with the legislative history of § 176a. The House and Senate committee reports and the floor debates are relatively unhelpful.⁶⁹ More informative are the records of extensive hearings before House and Senate committees.⁷⁰ Near the outset of the Senate committee hearings, the then Commissioner of Narcotics, Harry J. Anslinger, estimated that 90% of all marijuana seized by federal authorities had been smuggled from Mexico, and that "although there is considerable volunteer growth from old plantings in the Middle West . . . , [t]here is very little of the local land used because it just does not have the advantage of the long summer growing and [domestic marijuana] is not as potent as the Mexican drug."⁷¹ A number of officials responsible for enforcing the narcotics laws in various localities estimated that a similar proportion of the marijuana consumed in their areas was of Mexican origin.⁷²

On the other hand, written material inserted in the record of the Senate hearings included former testimony

⁶⁹ See S. Rep. No. 1197, 84th Cong., 2d Sess., 7, 13 (1956); H. R. Rep. No. 2388, 84th Cong., 2d Sess., 3, 6 (1956); H. R. Rep. No. 2546, 84th Cong., 2d Sess., 14 (1956) (conference report); 102 Cong. Rec. 269, 271, 9015, 10688, 12166.

⁷⁰ Hearings on Traffic in Narcotics before a Subcommittee of the House Committee on Ways and Means, 84th Cong., 1st Sess. (1955) (hereinafter cited as House Hearings); Hearings on Illicit Narcotics Traffic before the Subcommittee on Improvements in the Federal Criminal Code of the Senate Committee on the Judiciary, 84th Cong., 1st Sess. (1955) (hereinafter cited as Senate Hearings).

⁷¹ Senate Hearings 18.

⁷² See House Hearings 618, 1071; Senate Hearings 2384, 2471-2472, 4370, 4630. See also House Hearings 889; Senate Hearings 2893, 3488-3490; 102 Cong. Rec. 269, 271.

of an experienced federal customs agent before another Senate committee, to the effect that high-quality marijuana was being grown near the Texas cities of Laredo and Brownsville.⁷³ A written report of the Ohio Attorney General recited that marijuana "may grow unnoticed along roadsides and vacant lots in many parts of the country,"⁷⁴ and a Philadelphia Police Academy bulletin stated that "Plenty of [marijuana] is found growing in this city."⁷⁵

Examination of periodicals and books published since the enactment of the presumption leaves no doubt that in more than a dozen intervening years there have been great changes in the amount and nature of marijuana use in this country. With respect to quantity, one readily available statistic is indicative: the amount of marijuana seized in this country by federal authorities has jumped from about 3,400 pounds in 1956 to about 61,400 pounds in 1967.⁷⁶ With regard to nature of use, the 1955 hearing records and other reports portray marijuana smoking as at that time an activity almost exclusively of unemployed or menially employed members of racial minorities.⁷⁷ Current periodicals and books, on the other hand, indicate that marijuana smoking has

⁷³ See Senate Hearings 3488-3489.

⁷⁴ *Id.*, at 4814.

⁷⁵ *Id.*, at 599. See also Senate Hearings 4167.

⁷⁶ Compare Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 66 (1956), with *id.*, at 43 (1967). These seizures are estimated to represent 10% of the marijuana actually smuggled into the United States. See Joint Appendix 92a.

⁷⁷ See, e. g., J. Rosevear, Pot: A Handbook of Marijuana 118 (1967); Bouquet: Cannabis, Parts III-V, 3 Bull. on Narcotics, No. 1, at 32-33 (1951); Mayor's Committee on Marijuana, The Marijuana Problem in the City of New York 17-25 (1944); Blum, Mind-Altering Drugs and Dangerous Behavior: Dangerous Drugs 24, in President's Commission on Law Enforcement and the Administration of Justice, Task Force Report: Narcotics and Drug Abuse (1967).

become common on many college campuses and among persons who have voluntarily "dropped out" of American society in protest against its values, and that marijuana smokers include a sizeable number of young professional persons.⁷⁸

Despite these undoubted changes, the materials which we have examined point quite strongly to the conclusion that most domestically consumed marijuana is still of foreign origin. During the six years 1962-1967, some 79% of all marijuana seized by federal authorities was seized in attempted smuggling at ports and borders.⁷⁹ The Government informs us that a considerable part of the internally seized marijuana bore indications of foreign origin.⁸⁰ While it is possible that these facts reflect only the deployment of federal narcotics forces, rather than the actual proportion of imported to domestic marijuana, almost all of the authorities which we have consulted confirm that the preponderance of domestically consumed marijuana is grown in Mexico.⁸¹

⁷⁸ See, e. g., J. Rosevear, *supra*, at 117-132 (1967); Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 2, 40 (1966); Blum, *supra*, at 24; Cahn, The User and the Law, in J. Simmons (ed.), *Marijuana: Myths and Realities* (1967); McGlothlin, Toward a Rational View of Marijuana 195-198, in J. Simmons (ed.), *supra*.

⁷⁹ See Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 66 (1962); *id.*, at 28 (1963); *id.*, at 84 (1964); *id.*, at 51 (1965); *id.*, at 45 (1966); *id.*, at 43 (1967).

⁸⁰ See Brief for the United States 40.

⁸¹ See, e. g., Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 36 (1963); *id.*, at 30 (1964); Mandel, Myths and Realities of Marijuana Pushing 58-110, in J. Simmons (ed.), *Marijuana: Myths and Realities* (1967); President's Commission on Law Enforcement and the Administration of Justice, Report: The Challenge of Crime in a Free Society 213 (1967); J. Simmons (ed.), *supra*, at 233; United States Government, Report on the Working of the International Treaties on Narcotic Drugs 17 (1966); *id.*, at 24-25 (1967). Contra, see 1 Transcript of Pretrial

Petitioner makes much of statistics showing the number of acres of domestic marijuana destroyed annually by state and federal authorities, pointing out that if harvested the destroyed acreage could in each year have accounted for all marijuana estimated to have been consumed in the United States,⁸² and that no one knows how many acres escape destruction. However, several factors weaken this argument from domestic growth. First, the number of acres annually destroyed declined by a factor of three between 1959 and 1967,⁸³ while during the same period the consumption of marijuana, as measured by federal seizures, rose twenty-fold.⁸⁴ Assuming constant diligence on the part of those charged with destruction, this would indicate that in 1967 a much smaller share of the market was domestically supplied than in 1959. Second, while the total number of acres annually destroyed has indeed been large enough to furnish all domestically consumed marijuana,⁸⁵ the state-by-state breakdowns which are available for the years 1964–1967 reveal that in each of those years more

Hearing, *United States v. Adams*, 293 F. Supp. 776 (1968), at 67, 76 (testimony of Dr. Richard Schultes, Director of Harvard Botanic Museum). See also J. Rosevear, *Pot: A Handbook of Marijuana* 35, 119–120 (1967).

⁸² In 1967, 1,466 acres were destroyed. See United States Government, Report on the Working of the International Treaties on Narcotic Drugs 30 (1967). Accepting the Bureau of Narcotics' lowest estimate of yield per acre, see Brief for the United States 38, n. 42, this acreage would have supplied over 1,200,000 pounds of marijuana. This is enough for about 18,000,000,000 marijuana cigarettes. See *infra*, at 43 and n. 109.

⁸³ Compare Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 12 (1959), with United States Government, Report on the Working of the International Treaties on Narcotic Drugs 9 (1967). The decline was steady.

⁸⁴ Compare Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 43 (1959), with *id.*, at 43 (1967).

⁸⁵ See n. 82, *supra*.

than 95% of the destroyed acreage was in two midwestern states, Illinois and Minnesota.⁸⁶ The large, recurrent marijuana acreages discovered in those States can plausibly be ascribed to the "volunteer growth from old plantings in the Middle West" about which Commissioner Anslinger testified,⁸⁷ while illicit cultivators of marijuana would be likely to choose States with sparser populations and more favorable climates.⁸⁸ Third and last, reports of the Bureau of Narcotics and testimony of its agents indicate that in its far-reaching investigations the Bureau has never encountered a system for distributing sizeable quantities of domestically grown marijuana.⁸⁹ In contrast, the Bureau has found evidence of many large-scale distribution systems with sources in Mexico.⁹⁰

E.

The Government urges that once it is concluded that most domestically consumed marijuana comes from

⁸⁶ See Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 17 (1965); United States Government, Report on the Working of the International Treaties on Narcotic Drugs 10 (1966); *id.*, at 9 (1967).

⁸⁷ See *supra*, at 31.

⁸⁸ Most authorities believe that more potent marijuana can be grown in a hot, dry climate. See *infra*, at 41 and n. 102.

⁸⁹ See Bureau of Narcotics, Reports on the Traffic in Opium and Other Dangerous Drugs 1956-1967; 2 Transcript of Pretrial Hearing, *United States v. Adams*, 293 F. Supp. 776 (1968), at 37-45; United States Government, Report on the Working of the International Treaties on Narcotic Drugs 17 (1966); *id.*, at 24-25 (1967). But cf. Senate Hearings 3488-3490.

⁹⁰ See, e. g., Bureau of Narcotics, Report on the Traffic in Opium and other Dangerous Drugs (1965), at 23 (seizure of about 1,800 pounds of Mexican marijuana), 23-24 (seizure of about one ton of Mexican marijuana), 24 (seizure of about 3½ tons of Mexican marijuana); *id.* (1966), at 17 (seizure of about 600 pounds of Mexican marijuana). By contrast, the largest reported seizure of marijuana definitely grown in the United States involved only about eight pounds. See *id.*, at 7 (1967). But see also Senate Hearings 3488-3490.

abroad—a conclusion which we think is warranted by the data just examined—we must uphold the “knowledge” part of the presumption in light of this Court’s decision in *Yee Hem v. United States*, 268 U. S. 178 (1925). In that case, the Court sustained a presumption which was virtually identical to the one at issue here except that the forbidden substance was smoking opium rather than marijuana. With respect to the inference of knowledge from possession which was authorized by that presumption, the Court said:

“Legitimate possession [of opium], unless for medical use, is so highly improbable that to say to any person who obtains the outlawed commodity, ‘since you are bound to know that it cannot be brought into this country at all, except under regulation for medical use, you must at your peril ascertain and be prepared to show the facts and circumstances which rebut, or tend to rebut, the natural inference of unlawful importation, or your knowledge of it,’ is not such an unreasonable requirement as to cause it to fall outside the constitutional power of Congress.” 268 U. S., at 184.

The Government contends that *Yee Hem* requires us to read the § 176a presumption as intended to put every marijuana smoker on notice that he must be prepared to show that any marijuana in his possession was not illegally imported, and that since the possessor is the person most likely to know the marijuana’s origin it is not unfair to require him to adduce evidence on that point. However, we consider that this approach, which closely resembles the test of comparative convenience in the production of evidence,⁹¹ was implicitly abandoned in *Tot v. United States*. As was noted previously, the *Tot*

⁹¹ See *supra*, at 25–26 and n. 56.

Court confronted a presumption which allowed a jury to infer from possession of a firearm that it was received in interstate commerce. Despite evidence that most States prohibited unregistered and unrecorded acquisition of firearms, the Court did not read the statute as notifying possessors that they must be prepared to show that they received their weapons in intrastate transactions, as *Yee Hem* would seem to dictate. Instead, while recognizing that "the defendants . . . know better than anyone else whether they acquired the firearms in commerce," 319 U. S., at 469, the Court held that because of the danger of overreaching it was incumbent upon the prosecution to demonstrate that the inference was permissible before the burden of coming forward could be placed upon the defendant. This was a matter which the *Yee Hem* Court either thought it unnecessary to consider or assumed when it described the inference as "natural."⁹²

F.

We therefore must consider in detail whether the available evidence supports the conclusion that the "knowledge" part of the § 176a presumption is constitutional under the standard established in *Tot* and adhered to in *Gainey* and *Romano*—that is, whether it can be said with substantial assurance that one in possession of marijuana is more likely than not to know that his marijuana was illegally imported.

⁹² In refusing to follow this aspect of the reasoning in *Yee Hem*, we intimate no opinion whatever about the continued validity of the presumption relating to "hard" narcotics, which was sustained in *Yee Hem* and is now found in 21 U. S. C. § 174. As will appear, our holding that the § 176a "knowledge" presumption is unconstitutional rests entirely upon a detailed inquiry into the available facts about the state of mind of marijuana users. The facts regarding "hard" narcotics may well be significantly different.

Even if we assume that the previously assembled data are sufficient to justify the inference of illegal importation, see *supra*, at 36, it by no means follows that a majority of marijuana possessors "know"⁹³ that their marijuana was illegally imported. Any such proposition would depend upon an intermediate premise: that most marijuana possessors are aware of the level of importation and have deduced that their own marijuana was grown abroad. This intermediate step might be thought justified by common sense if it were proved that little or no marijuana is grown in this country. Short of such a showing, not here present, we do not believe that the inference of knowledge can be sustained solely because of the assumed validity of the "importation" presumption.

Once it is established that a significant percentage of domestically consumed marijuana may not have been imported at all, then it can no longer be postulated, without proof, that possessors will be even roughly aware of the proportion actually imported. We conclude that in order to sustain the inference of knowledge we must find on the basis of the available materials that a majority of marijuana possessors either are cognizant of the apparently high rate of importation or otherwise have become aware that *their* marijuana was grown abroad.

We can imagine five ways in which a possessor might acquire such knowledge: (1) he might be aware of the

⁹³ Nothing in the legislative history of § 176a is of aid in determining the intended scope of the word "knowing," as it is used in that section. In making that determination, we have employed as a general guide the definition of "knowledge" which appears in the Proposed Official Draft of the Model Penal Code, at 27 (1962). The Code provides:

"When knowledge of a particular fact is an element of an offense, such knowledge is established if a person is aware of a high probability of its existence, unless he actually believes that it does not exist."

proportion of domestically consumed marijuana which is smuggled from abroad and deduce that his was illegally imported (2) he might have smuggled the marijuana himself; (3) he might have learned by indirect means that the marijuana consumed in his locality or furnished by his supplier was smuggled from abroad; (4) he might have specified foreign marijuana when making his "buy," or might have been told the source of the marijuana by his supplier; (5) he might be able to tell the source from the appearance, packaging, or taste of the marijuana itself.

We treat these five possibilities *seriatim*, in light of the available materials, beginning in each instance with the legislative record. We note at the outset that although we have been able to discover a good deal of relevant secondary evidence, we have found none of the best kind possible—testimony of marijuana users about their own beliefs as to origin, or studies based upon interviews in which users were asked about this matter. The committee hearings which preceded passage of § 176a included testimony by many marijuana smokers, but none was ever asked whether he knew the origin of the marijuana he smoked. It should also be kept in mind that the great preponderance of marijuana smokers are "occasional" rather than "regular" users of the drug,⁹⁴ and that "occasional" smokers appear to be arrested disproportionately often, due to their inexpertness in taking precautions.⁹⁵ "Occasional" users are likely to be less informed and less particular about the drug they

⁹⁴ See J. Rosevear, *Pot: A Handbook of Marijuana* 124-125 (1967). It has been estimated that there are 500,000 to 1,000,000 "regular" marijuana smokers in the United States and 3,000,000 to 5,000,000 "occasional" users. See J. Simmons (ed.), *Marijuana: Myths and Realities* 232 (1967).

⁹⁵ See *id.*, at 236; J. Rosevear, *supra*, at 121-125.

smoke;⁹⁶ hence, it is less probable that they will have learned its source in any of the above ways.

The first possibility is that a possessor may have known the proportion of imported to domestic marijuana and have deduced that his own marijuana was grown abroad. The legislative record is of no assistance in evaluating this possibility. Such indirect evidence as we have found points to the conclusion that while most marijuana users probably know that some marijuana comes from Mexico, it is also likely that the great majority either have no knowledge about the proportion which is imported or believe that the proportion is considerably lower than may actually be the case.⁹⁷

The second possibility is that a possessor may know the origin of his marijuana because he smuggled it into the United States himself. The legislative record is unhelpful in estimating the proportion of possessors who fall into this class. Other sources indicate that there are a considerable number of smokers who "smuggle their own," but that the great majority of possessors have obtained their marijuana from suppliers in this country.⁹⁸

The legislative record is also uninformative about the possibility that a possessor may have learned the source of his marijuana by indirect means. Other sources reveal that imported marijuana usually passes through a number of hands before reaching the consumer, and

⁹⁶ See *ibid.*

⁹⁷ See *United States v. Adams*, 293 F. Supp. 776, 780-781, 784-785 (1968).

⁹⁸ See Becker, *Marijuana: A Sociological Overview* 47-50, in D. Solomon (ed.), *The Marijuana Papers* (1966); Mandel, *Myths and Realities of Marijuana Pushing* 58-110, in J. Simmons (ed.), *Marijuana: Myths and Realities* (1967); J. Rosevear, *Pot: A Handbook of Marijuana* 27-37, 117-131 (1967); J. Simmons (ed.), *supra*, at 231-234. It should be remembered that there are estimated to be at least 3,500,000 "regular" or "occasional" marijuana smokers in the United States. See n. 94, *supra*.

that the distribution system is kept secret.⁹⁹ It would appear that relatively few consumers know the origin of their marijuana by indirect means.

The fourth possibility is that the possessor may have specified foreign marijuana when making his purchase or may have been told by his supplier that the marijuana was grown abroad. The legislative record is somewhat more helpful with respect to this possibility, for it does contain statements to the effect that Mexican marijuana is more potent than domestic and is consequently preferred by smokers.¹⁰⁰ However, the legislative record also contains testimony by a customs agent that Texas marijuana is as "good" as that from Mexico.¹⁰¹ Most authorities state that Mexican marijuana generally does have greater intoxicating power than domestic marijuana, due to the higher temperatures and lower humidity usually encountered in Mexico.¹⁰² There are some indications that smokers are likely to prefer Mexican marijuana,¹⁰³ but there is nothing to show that purchasers commonly specify Mexican marijuana when making a "buy." It appears that suppliers of marijuana occasion-

⁹⁹ See authorities cited in n. 98, *supra*.

¹⁰⁰ See *supra*, at 31 (testimony of Commissioner Anslinger); House Hearings 1071-1072, Senate Hearings 4354-4355 (statements of District Supervisor Aman).

¹⁰¹ See Senate Hearings 3488-3489. See also House Hearings 288.

¹⁰² See authorities collected in A. Hodapp, *Marijuana: A Review of the Literature for the Analytic Chemist* 13 (1959); Bouquet, *Cannabis: Parts I-II*, 2 Bull. on Narcotics, No. 4, at 14, 21-22 (1950); Ciba Foundation Study Group No. 21, *Hashish: Its Chemistry and Pharmacology* 33 (1965); J. Simmons (ed.), *Marijuana: Myths and Realities* 230 (1967).

¹⁰³ See authorities cited in n. 100 *supra*; J. Rosevear, *Pot: A Handbook of Marijuana* 32-33, 68 (1967); Boughey, *Pot Scenes East and West* 33-34, in J. Simmons (ed.), *Marijuana: Myths and Realities* (1967); Mayor's Committee on Marijuana, *The Marijuana Problem in the City of New York* 9 (1944); J. Simmons (ed.), *supra*, at 233.

ally volunteer the place of origin,¹⁰⁴ but we have found no hint that this is usually done, and there are indications that if the information is not volunteered the buyer may be reluctant to ask, for fear of being thought an informer.¹⁰⁵ We simply are unable to estimate with any accuracy, on the basis of these data, what proportion of marijuana possessors have learned the origin of their marijuana in this way. It is certainly not a majority; but whether it is a small minority or a large one we are unable to tell.

The fifth possibility is that a smoker may be able to tell the source of his marijuana from its appearance, packaging, or taste. As for appearance, it seems that there is only one species of marijuana, and that even experts are unable to tell by eye where a particular sample was grown.¹⁰⁶ The Court of Appeals for the Ninth Circuit did find in *Caudillo v. United States*, 253 F. 2d 513 (1958), on the basis of trial testimony, that "unmanicured" or "rough" marijuana—that is, marijuana containing some seeds and stems, as well as leaves—was much more likely to come from Mexico than from California; this was because the presence of seeds implied that the plant had been allowed to mature and evidence showed that California growers almost always harvested the plant before that stage. However, we have found nothing to indicate that this distinction holds good in other areas of the country, or that marijuana possessors are likely to realize its significance.

With respect to packaging, there is evidence that Mexican marijuana is commonly compressed into dis-

¹⁰⁴ See J. Rosevear, *Pot: A Handbook of Marijuana* 32-33 (1967).

¹⁰⁵ See *id.*, at 33.

¹⁰⁶ See 1 Transcript of Pretrial Hearing, *United States v. Adams*, 293 F. Supp. 776 (1968), at 16-18, 54 (testimony of Dr. Richard Schultes, Director of Harvard Botanic Museum).

tinctive "bricks" and then wrapped in characteristically Mexican paper.¹⁰⁷ Yet even if it is assumed that most Mexican marijuana bears such distinguishing marks when first brought into this country, there is no indication that they normally are still present when it reaches the consumer. The packaging method just mentioned apparently is intended to facilitate transportation of relatively large quantities of marijuana. A "brick" appears usually to contain about one kilogram of marijuana,¹⁰⁸ and relatively few consumer sales will involve such a large amount, since a kilogram of marijuana will furnish some 3,300 marijuana cigarettes.¹⁰⁹ Smokers appear usually to purchase marijuana by the "bag"—about one-fifth ounce; by the "can"—about one ounce; or by the pound.¹¹⁰ Hence, after importation "[t]he wholesalers will repackage the marijuana into smaller packages, . . . and they will do it in various ways."¹¹¹ We infer that only a small percentage of smokers are likely to learn of the drug's origin from its packaging.

With respect to taste, the Senate hearing record contains the statement of a federal customs agent that "A

¹⁰⁷ See 2 *id.*, at 19-33 (testimony of Narcotics Agent William Durkin). See also Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 17 (1966). But cf. Senate Hearings 3488-3489.

¹⁰⁸ See J. Simmons (ed.), *Marijuana: Myths and Realities* 237 (1967); J. Rosevear, *Pot: A Handbook of Marijuana* 159 (1967); Bureau of Narcotics, Report on the Traffic in Opium and Other Dangerous Drugs 17 (1966). See also Senate Hearings 3489.

¹⁰⁹ See J. Rosevear, *supra*, at 29; Mandel, *Myths and Realities of Marijuana Pushing* 78, in J. Simmons (ed.), *supra*; Senate Hearings 3489.

¹¹⁰ See J. Rosevear, *supra*, at 28. See also Mandel, *supra*, at 78.

¹¹¹ 2 Transcript of Pretrial Hearing, *United States v. Adams*, 293 F. Supp. 776 (1968), at 26 (testimony of Narcotics Agent William Durkin).

good marijuana smoker can probably tell good marijuana from bad."¹¹² As has been seen, there is a preponderance of opinion to the effect that Mexican marijuana is more potent than domestic.¹¹³ One authority states that purchasers of marijuana commonly sample the product before making a "buy."¹¹⁴ However, the agent quoted above also asserted that some "good" marijuana was grown in Texas. And the account of the sampling custom further states that tasting is merely a ritual since "[u]sually the intoxication will not differ much from one cigarette to another" ¹¹⁵ Once again, we simply are unable to estimate what proportion of marijuana possessors are capable of "placing" the marijuana in their possession by its taste, much less what proportion actually have done so by the time they are arrested.

G.

We conclude that the "knowledge" aspect of the § 176a presumption cannot be upheld without making serious incisions into the teachings of *Tot*, *Gainey*, and *Romano*. In the context of this part of the statute, those teachings require that it be determined with substantial assurance that at least a majority of marijuana possessors have learned of the foreign origin of their marijuana through one or more of the ways discussed above.

We find it impossible to make such a determination. As we have seen, the materials at our disposal leave us at large to estimate even roughly the proportion of marijuana possessors who have learned in one way or another the origin of their marijuana. It must also be recognized that a not inconsiderable proportion of domesti-

¹¹² Senate Hearings 3489 (prior testimony of Customs Agent Lawrence Fleishman).

¹¹³ See *supra*, at — and n. 102.

¹¹⁴ See J. Rosevear, *Pot: A Handbook of Marijuana* 31-33 (1967).

¹¹⁵ *Id.*, at 32.

cally consumed marijuana appears to have been grown in this country, and that its possessors must be taken to have "known," if anything, that their marijuana was *not* illegally imported. In short, it would be no more than speculation were we to say that even as much as a majority of possessors "knew" the source of their marijuana.¹¹⁶

Nor are these deficiencies in the foundation for the "knowledge" presumption overcome by paying, as we do, the utmost deference to the congressional determination that this presumption was warranted. For Congress, no less than we, is subject to constitutional requirements, and in this instance the legislative record falls even shorter of furnishing an adequate foundation for the "knowledge" presumption than do the more extensive materials we have examined.

We thus cannot escape the duty of setting aside petitioner's conviction under Count 2 of this indictment.

For the reasons stated in Part I of this opinion we reverse outright the judgment of conviction on Count 3 of the indictment. For the reasons stated in Part II,

¹¹⁶ A careful examination of the lower-court decisions regarding the presumption's constitutionality does not suggest the contrary. All courts of appeals which have ruled on the question have sustained the presumption. See *Caudillo v. United States*, 253 F. 2d 513 (C. A. 9th Cir. 1958); *Costello v. United States*, 324 F. 2d 260, 263-264 (C. A. 9th Cir. 1963); *United States v. Soto*, 256 F. 2d 729, 735 (C. A. 7th Cir. 1958); *Borne v. United States*, 332 F. 2d 565, 567 (C. A. 5th Cir. 1964); *United States v. Gibson*, 310 F. 2d 79, 82 (C. A. 2d Cir. 1962). However, there is no indication that in any of these cases the court had before it or took into account even a fraction of the evidence which we have considered; in one instance, the lack of evidence was expressly stated to be the ground of decision. See *United States v. Gibson*, *supra*. See also *Costello v. United States*, *supra*. The only lower court which conducted a factual inquiry in any way comparable to our own also held the presumption unconstitutional. See *United States v. Adams*, 293 F. Supp. 776 (D. C. S. D. N. Y. 1968).

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we reverse the judgment of conviction on Count 2 and remand the case to the Court of Appeals for further proceedings consistent with this opinion. We are constrained to add that nothing in what we hold today implies any constitutional disability in Congress to deal with the marijuana traffic by other means.

Reversed and remanded.

Mr. CHIEF JUSTICE WARREN joins Part II of the opinion of the Court and, considering himself bound by the decisions in *Marchetti v. United States*, 390 U. S. 39 (1968), *Grosso v. United States*, 390 U. S. 62 (1968), and *Haynes v. United States*, 390 U. S. 85 (1968), concurs in the result as to Part I.

SUPREME COURT OF THE UNITED STATES

No. 65.—OCTOBER TERM, 1968.

Timothy F. Leary, Petitioner,	} On Writ of Certiorari	
v.		to the United States
United States.		Court of Appeals for the Fifth Circuit.

[May 19, 1969.]

MR. JUSTICE BLACK, concurring in the result.

I concur in the Court's outright reversal of the petitioner's conviction on Count 3 of the indictment for the reasons set out in Part I of the Court's opinion.

I also concur in reversal of the petitioner's conviction under Count 2 of the indictment, based on 28 U. S. C. § 176a. That section makes it a crime to import marijuana into the United States or to receive, conceal, or transport it, knowing it to have been imported contrary to law, and then goes on to provide that the mere possession of marijuana shall be "deemed sufficient evidence to authorize conviction unless the defendant explains his possession to the satisfaction of the jury." The trial court in this case charged the jury that proof that petitioner merely had possession of marijuana was sufficient to authorize a finding that he knew it had been imported or brought into the United States contrary to law. It is clear beyond doubt that the fact of possession alone is not enough to support an inference that the possessor knew it had been imported. Congress has no more constitutional power to tell a jury it can convict upon any such forced and baseless inference than it has power to tell juries they can convict a defendant of a crime without any evidence at all from which an inference of guilt could be drawn. See *Thompson v. Louisville*, 362 U. S. 199

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(1960). Under our system of separation of powers, Congress is just as incompetent to instruct the judge and jury in an American court what evidence is enough for conviction as the courts are to tell the Congress what policies they must adopt in writing criminal laws. The congressional presumption, therefore, violates the constitutional right of a defendant to be tried by jury in a court set up in accordance with the commands of the Constitution. It clearly deprives a defendant of his right not to be convicted and punished for a crime without due process of law, that is a trial in federal cases before an independent judge, after an indictment by grand jury, with representation by counsel, an opportunity to summon witnesses in his behalf, and an opportunity to confront the witnesses against him. This right to a full-fledged trial in a court of law is guaranteed to every defendant in Article III of the Constitution, in the Sixth Amendment, and in the Fifth and Fourteenth Amendments' promises that no person shall be deprived of his life, liberty, or property without due process of law—that is, a trial according to the law of the land, both constitutional and statutory.

It is for these reasons, and not because I think the law is "irrational" or 'arbitrary,' and hence unconstitutional," *ante*, p. 28, that I would invalidate this presumption. I am firmly and profoundly opposed to construing "due process" as authorizing this Court to invalidate statutes on any such nebulous grounds. My quite different reasons for holding that the presumption does deny due process of law, that is the benefit of the "law of the land," have been fully set out in many opinions, including, for illustration, my concurring opinion in *Tot v. United States*, 319 U. S. 463, 473 (1943), and my dissenting opinion in *United States v. Gainey*, 380 U. S. 63, 74 (1965).

SUPREME COURT OF THE UNITED STATES

No. 65.—OCTOBER TERM, 1968.

Timonthy F. Leary, Petitioner,	} On Writ of Certiorari	
v.		to the United States
United States.		Court of Appeals for the Fifth Circuit.

[May 19, 1969.]

MR. JUSTICE STEWART, concurring.

I join Part II of the Court's opinion. As to Part I, I have before now expressed my conviction that the Fifth Amendment guaranty against compulsory self-incrimination was originally intended to do no more than confer a testimonial privilege in a judicial proceeding.¹ But the Court through the years has drifted far from that mooring; the *Marchetti* and *Grosso* cases² are simply the most recent in a long line of decisions marking the extent of the drift. Perhaps some day the Court will consider a fundamental re-examination of its decisions in this area, in the light of the original constitutional meaning. Until that day comes, it seems to me that the authoritative weight of precedent permits no escape from the conclusion reached by the Court in this case. I therefore join its opinion and judgment.

¹ See *Grosso v. United States*, 390 U. S. 62, at 76 (concurring opinion); *In re Gault*, 387 U. S. 1, at 80, n. 3 (dissenting opinion).

² *Marchetti v. United States*, 390 U. S. 39; *Grosso v. United States*, 390 U. S. 62.

Changes in §303(f) re Registration of Researchers and
Other Practitioners

? { In the first sentence of §303(f), insert "except for research
purposes" after "substances". Strike out the last sentence of §303(f)
and substitute the following: "A registration permit for the purpose
of bona fide research with Schedule I substances by a practitioner
deemed qualified therefor by the Secretary, [or for the purpose of
administering or otherwise dispensing such substances in the regular
course of professional practice by a practitioner of the healing arts]
may be denied by the Attorney General only on a ground specified in
§304(a) or on the ground that the applicant's past practice furnishes
ground for the belief that the applicant will abuse or unlawfully
transfer such substances or fail to safeguard his supply of such sub-
stances against diversion from legitimate medical or scientific use." 1/

*(Can/Heal
with Sch I
substance...)*

Prescriptions. The following draft version of §309() has two
purposes. First, the Food and Drug Act or international treaty would
govern in determining what is a prescription drug, and the Attorney
General would advise HEW of relevant information in his possession in
this connection. Second, the Attorney General would not be authorized
to permit dispensing of a prescription drug without a prescription but
would still be authorized to permit dispensing of a Schedule II drug
in emergencies on an oral prescription (in accordance with the F&D Act),
where the bill otherwise requires a written prescription.

1/ It is also suggested that the word "permit" be deleted from the term
"registration permit" wherever it occurs.

of FDA
Oral lay approve
Amend §309(a) and (b), page 31, to read:

"Sec. 309. (a) Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, a controlled dangerous substance included in Schedule II which is a prescription drug, as determined under the Federal Food, Drug, and Cosmetic Act or under an international instrument binding upon the United States, may be dispensed only upon the written prescription of such a practitioner: Provided, That in emergency situations, as prescribed by the Attorney General by regulation, such drug may be dispensed upon oral prescription in accordance with section 505(b) of that Act. Prescriptions shall be retained in conformity with the requirements of section 307 of this Act. No prescription for a Schedule II substance may be refilled.

presumpt
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(b) No prescription for a Schedule III substance which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act or as determined under an international instrument binding upon the United States, may be filled or refilled more than six months after the issuance of such prescription or be refilled more than 5 times. The term "issuance", as used in this subsection, includes a renewal of a prescription by the issuing practitioner, orally or in writing, in accordance with the requirements of section 505 of that Act.

"(c) No controlled dangerous substance in Schedule IV may be distributed other than for a medical purpose.

"(d) Whenever it appears to the Attorney General that a drug not yet considered to be a prescription drug under the Federal Food, Drug, and Cosmetic Act should be so considered because of its abuse potential, he shall so advise the Secretary of Health, Education, and Welfare and furnish to him all available data relevant thereto."

Broadening of saving provision for the
Food, Drug, and Cosmetic Act

Strike out subsection (h) on page 26 and insert the following new section at the end of the bill:

"Saving Provision

"Sec. 808. Nothing in this Act, except this title and, to the extent of ^{7 in} any consistency, section 309 of this Act, shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act."

Technical Changes

On page 12, lines 3 and 4, the reference should be to the Department of Health, Education, and Welfare, not to the Food and Drug Administration as such; and in line 7, the reference to the Food and Drug Administration (in ink) should be changed to a reference to the Department of Health, Education, and Welfare. (Should the reference in lines 7 and 8 to the Bureau of Narcotics and Dangerous Drugs not be changed to a reference to the Department of Justice?)

On page 25, in lines 7 and 8 of subsection (f), the phrase "Secretary of the Department of Health, Education, and Welfare" should be changed to read "Secretary of Health, Education, and Welfare".

In title VIII, amendments should be to the Food and Drug Act as such, not to the 1965 amending Act. As a result, the penalty amendments of 1968 seem to have been overlooked.

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April 24, 1969

The Honorable John N. Mitchell
Attorney General of the United States
Department of Justice
Washington, D. C.

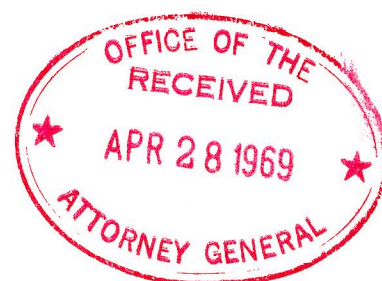
Dear Mr. Attorney General:

I am enclosing three copies of a corrected Section 601 for insertion in the three copies of the "Controlled Substances Act of 1969" delivered to you on Friday, April 18, 1969.

A drafting omission in present Section 601 makes possible the technical argument that registration would enable the registrant to distribute Schedule A substances (high potential for abuse - no medical use) without restriction, despite the provisions of Article VIII. To preclude this ambiguity, we have added subsection (b), expressly restricting distribution of Schedule A substances to the terms of the research exemption authorized by Section 1103(b).

Sincerely,

John A. Wells
John A. Wells



TITLE VI

GENERAL REGULATORY PROVISIONSControl of Manufacture and Distribution

Sec. 601. (a) No person shall manufacture, and no person other than a practitioner shall distribute, any controlled substance unless licensed under Title V of this Act, or registered with the Attorney General pursuant to Section 602 of this Title.

(b) No person shall distribute any controlled psychotropic substance listed on Schedule A of Title IV of this Act except pursuant to an authorization granted under Section 1103(b).

[CORRECTED]

TITLE VI

GENERAL REGULATORY PROVISIONSControl of Manufacture and Distribution

Sec. 601. (a) No person shall manufacture, and no person other than a practitioner shall distribute, any controlled substance unless licensed under Title V of this Act, or registered with the Attorney General pursuant to Section 602 of this Title.

(b) No person shall distribute any controlled psychotropic substance listed on Schedule A of Title IV of this Act except pursuant to an authorization granted under Section 1103(b).

[CORRECTED]

TITLE VI

GENERAL REGULATORY PROVISIONSControl of Manufacture and Distribution

Sec. 601. (a) No person shall manufacture, and no person other than a practitioner shall distribute, any controlled substance unless licensed under Title V of this Act, or registered with the Attorney General pursuant to Section 602 of this Title.

(b) No person shall distribute any controlled psychotropic substance listed on Schedule A of Title IV of this Act except pursuant to an authorization granted under Section 1103(b).

[CORRECTED]

To
John Deane

May 1, 1969

John A. Wells, Esq.
Messrs. Royall, Koegel & Wells
Two Hundred Park Avenue
New York, New York 10017

Dear Mr. Wells:

At the request of the Attorney General,
I am writing to thank you for your letter of April 24,
1969.

The corrected Section 601 will be
inserted in the three copies of the "Controlled
Substances Act of 1969" which you delivered in the
office.

Sincerely,

Secretary to
John N. Mitchell

Royall, Koegel & Wells
Two Hundred Park Avenue
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JOHN B. LOUGHRAN
WILLIAM R. GLENDON
LEO P. LARKIN, JR.
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March 20, 1969

Hon. John N. Mitchell,
Attorney General of the United States
Department of Justice
Washington, D. C.

Re: The "Controlled Dangerous
Substance Act of 1969"

Dear Mr. Attorney General:

This letter and the enclosed memorandum are forwarded as supplements to the memorandum dated March 4, 1969 previously submitted by me with respect to the proposed legislation described above.

When we discussed the above matter on March 5th, you asked whether the administrative hearing and judicial review provided for coverage of new drugs under present law was not unnecessarily complicated and cumbersome. I replied that the present procedure had been carefully worked out by Congress for policy reasons which seemed compelling; that the procedure had worked well since its adoption in 1938; that the area of stringent control, as provided in the Drug Abuse Control Amendments of 1965, should be limited to those drugs which clearly lead to addiction and abuse; that the highly technical decision whether a new drug comes within the area of control indicated by Congress should not be lightly made by the administration but should be made only upon a complete record with full opportunity for proof and cross-examination (followed by judicial review). I further noted that any delay and cumbersomeness of such administrative hearings could be eliminated by energetic action setting early and continuous hearings, followed by an early review of the record and entry of the administrative decision.

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DEPARTMENT OF JUSTICE	
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1. DEPUTY ATTORNEY GENERAL	
2. LEGISLATIVE SEC.	

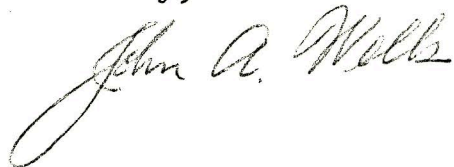
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Proceedings under the special review procedure do not result in excessive delay. Any undue delays which may have been experienced in past or pending cases can be attributed almost without exception to the Government itself. The pending case involving Librium and Valium has been ripe for decision by the appropriate regulatory officials for nearly two years. Their failure to act certainly cannot be attributed to Roche, whose final argument in the case was made on February 28, 1967.

The enclosed supplemental memorandum discusses, in some detail, the point you raised. In my judgment the reasons for preserving the present hearing and judicial review procedure are very forceful. In any event, Roche should not be deprived of its rights to an administrative decision and judicial review (if necessary) under present law. It would be senseless to attempt to substitute legislative fiat for a technical decision and judicial review on the basis of a record that has already been made.

In response to your statement that you would welcome our comments on the proposed legislation as a whole, we are carefully examining the other provisions of the draft bill in the hope that we can make constructive suggestions.

Sincerely,



Enclosures 

Memorandum to:

The Honorable John N. Mitchell,
Attorney General of the United States

Re: Proposed Legislation Entitled
"Controlled Dangerous Substance Act
of 1969." drafted by The Bureau of
Narcotics and Dangerous Drugs,
Department of Justice

ROYALL, KOEGEL & WELLS
200 Park Avenue
New York, New York 10017

Attorneys for
Hoffmann-La Roche, Inc.

March 4, 1969

*File
Guest
Dean*

This memorandum is submitted on behalf of Hoffmann-La Roche, Inc. ("Roche"), a New Jersey corporation, with its principal office at 340 Kingsland Street, Nutley, New Jersey, a manufacturer and distributor of ethical pharmaceutical products. It sets forth the reasons why the proposed legislation entitled the "Controlled Dangerous Substance Act of 1969" (the "bill") should not include two of Roche's products, chlordiazepoxide ("Librium") and diazepam ("Valium").¹

Librium and Valium, since their introduction into commercial channels of drug distribution, are available only for medical use under the professional supervision of a practitioner licensed by law to administer these products in accordance with section 503 of the Food, Drug and Cosmetic Act.

Librium and Valium should not be included in the proposed bill. To include them would unjustly deprive Roche of its right under the Drug Abuse Control Amendments of 1965² to an administrative decision after a lengthy hearing held in the fall of 1966, and of its right, if the administrative decision is unfavorable, to a judicial review. The issue in this proceeding, pending for more than three years, was and is Roche's contention that it would be improper to subject Librium and Valium to further control under the 1965 Act.

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1. These are the names as set forth in the draft of the proposed bill. Throughout this memorandum, however, we will use Roche's proprietary names for these products - Librium and Valium.
 2. 21 U.S.C. § 321 (1965).

The January, 1969 draft of the bill which the Bureau of Narcotics and Dangerous Drugs, Department of Justice, has shown to Roche's representatives, provides in part (Sec. 703 (c)):

"All administrative proceedings, pending before the Bureau of Narcotics and Dangerous Drug Control on the effective date of this enactment shall be continued and brought to final determination in accord with laws and regulations in effect prior to the date of this enactment."

Roche completely agrees that this provision (if it is intended to, and does, protect all pending administrative proceedings and the right to judicial review under present law) is clearly required by the dictates of fairness and the policies previously laid down by the Congress.

The administrative hearing in this matter was concluded in the fall of 1966. It encompassed more than five thousand pages of testimony and several hundred exhibits. To this day, no decision has been handed down. In that hearing Roche clearly demonstrated that Librium and Valium do not have a potential for abuse, and should not be controlled.

But assuming the intent of the draftsmen to preserve present proceedings under the law now in effect, then the inclusion of Librium and Valium in Schedule 3

of the proposed bill (Sec. 104 of the draft) is incorrect. The very purpose of the pending proceeding is to decide whether these products should be controlled. Therefore, they should not be included in the act until the administrative proceedings and judicial review have occurred.

Representatives of the Bureau, at a meeting with Roche, on February 17, 1969, indicated that this mutual inconsistency had occurred to them and stated that they intended to eliminate the preservation of pending proceedings from the bill. They stated that one purpose of the proposed bill was to render moot Roche's pending administrative proceeding. The latest information available to Roche indicates that this section has not, to date, been eliminated.

If the bill is passed without preserving pending proceedings, it will deprive Roche of the administrative hearing already held, of the right to a decision on that record, and of the right to judicial review. It would substitute a legislative fiat for the findings upon the record in the pending proceeding.

Roche respectfully submits that its right to:

- (1) a full administrative review, with a record, and
- (2) a judicial review under the present law, should and must be preserved in any proposed legislation.

The reasons supporting this position will be set forth in the following discussion.

I. THE RIGHT TO HEARING AND JUDICIAL REVIEW UNDER PRESENT LAW.

A. Congressional Policy as Generally Dictated by the Administrative Procedure Act.

In 1946, Public Law 79-404³ (Administrative Procedure Act, the "APA") was enacted, following ten years of painstaking study and detailed drafting. It was described by the House Judiciary Committee as an "... outline of minimum essential rights and procedures."⁴

Embodied in the APA is a "presumption of reviewability" that had been evolved by earlier case law. Absent statutory preclusion, the APA allows judicial review of final agency action "... for which there is no other adequate remedy ..."⁵ The APA embodies the basic presumption of judicial review to one "suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action ..."⁶ It is a codification by Congress of the minimum rules of administrative fairness.

3. 5 U.S.C. §§ 551 et ff.

4. House Comm. on Judiciary, Report No. 1980, U.S. Code Cong. Service, 79th Cong., 2d Sess., p. 1205 (1946).

5. 5 U.S.C. § 704.

6. 5 U.S.C. § 702.

B. Special Review Procedures of the Food,
Drug and Cosmetic Act

Congress has established review requirements in the Drug Abuse Control Amendments of 1965 which are much more stringent than the general requirements prescribed in the APA. Congress has decreed that the special review requirements of the Food, Drug and Cosmetic Act shall apply with respect to the amendment or repeal of regulations designating a drug as having a potential for abuse.⁷

Stated briefly, the 1965 Act requires that a proposal to designate a drug as having a potential for abuse must first be published in the Federal Register. Interested parties must be given an opportunity to present their views orally or in writing, following which the proposal must be acted on by public order. Any person who would be adversely affected by the order may file objections within thirty days specifying the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing. The filing of such objections operates to stay the effective date of the order. At the hearing any interested party may be heard in person or by representative. The Act then contains the following mandate:

7. 21 U.S.C. § 371 (e), (f), and (g).

"As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based."⁸

The section goes on to provide for judicial review of the order in the United States Court of Appeals.

In three recent decisions of the United States Supreme Court⁹ the special review provisions, applicable to the Roche proceeding, were construed as supplementing and expanding the traditional channels of review for proposed regulations. These three important cases (allowing pre-enforcement review of regulations issued under sections of the Food, Drug and Cosmetic Act not governed by the special review procedures) are applicable - a fortiori - to regulations issued under a section of the Act that are, expressly, made subject to special review. Commenting on the judicial review portion¹⁰ of the special review procedure, Mr. Justice Harlan, speaking for the Court, stated:

8. 21 U.S.C. § 371 (e) (3) (Emphasis added).

9. Abbott Laboratories v. Gardner, 387 U.S. 136 (1967); Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967); Gardner v. Toilet Goods Ass'n, 387 U.S. 167 (1967).

10. 21 U.S.C. § 371 (f).

"The provisions ... were supported by those who feared the life-and-death power given by the Act to the executive officials, a fear voiced by many members of Congress ... the Act as it was finally passed compromised the matter (whether review should be of fact or de novo) by allowing an appeal on a record with a 'substantial evidence' test, affording a considerably more generous judicial review than the 'arbitrary and capricious' test available in the traditional injunctive suit." 11

When the Bureau seeks to moot the pending administrative hearing it is acting contrary to the clearly enunciated Congressional policy of requiring special review of highly technical agency determinations concerning chemical properties and physiological effects of particular products. We urgently submit that this would be serious error.

II. ROCHE HAS UTILIZED AND RELIED UPON ITS STATUTORY RIGHT TO A HEARING.

On January 18, 1966, the Commissioner of Food and Drugs, pursuant to authority delegated to him by the Secretary of Health, Education, and Welfare¹² published in the Federal Register¹³ a proposal to amend part 166, Title 21, Code of Federal Regulations, by listing Librium

11. Abbott Laboratories v. Gardner, supra n. 9 at 143.

12. 21 C.F.R. § 2.120 (1966).

13. 31 Fed. Reg. 565 (1966).

and Valium under § 166.3 (c) (1) as "depressant or stimulant drugs" having a potential for abuse because of their depressant effect on the central nervous system. By letter of February 17, 1966, Roche submitted to the Commissioner its comments on the proposed listing of the two products. Thereafter, on March 19, 1966, the Commissioner again published the order proposed on January 18, 1966.¹⁴ Interested parties were given thirty days in which to file objections. Roche filed timely objections to the order of March 19, asserting that the listing of the two products was not justified on the basis of experience and would be contrary to the public interest. Roche requested a full hearing on the record.

As he was required to do by law, the Commissioner issued an order staying the effectiveness of his prior order with respect to Librium and Valium. The matter was set for a hearing beginning on August 8, 1966.¹⁵ Following preliminary conferences, formal hearings were conducted during the period August 8 to November 18, 1966. Oral arguments were received on

14. 31 Fed. Reg. 4679 (1966).

15. 31 Fed. Reg. 9752 (1966).

February 28, 1967. Shortly thereafter, on April 7, 1967, the hearing examiner issued his opinion containing significant findings of fact requested by Roche but nevertheless recommending that the drugs be controlled. The entire record of the case was then forwarded to the Commissioner for his decision.

Except for a motion to disqualify the Assistant General Counsel, Food and Drug Division, from participating in the decision of the case, filed by Roche on April 20 and denied by the Commissioner on April 28, 1967, no further developments have occurred.

On February 7, 1968, President Johnson sent to Congress his Reorganization Plan No. 1 of 1968.¹⁶ The plan proposed the establishment in the Department of Justice of a Bureau of Narcotics and Dangerous Drugs, and the transfer thereto of all functions of the Secretary of Health, Education, and Welfare under the Drug Abuse Control Amendments of 1965, except the function of regulating counterfeit drugs not controlled as "depressant or stimulant drugs." The plan also transferred to the new Bureau the functions of the Treasury Department's Bureau of Narcotics.

16. 4 Weekly Compilation of Presidential Documents 249 (1968).

Following the sixty-day period allowed for Congressional review, the reorganization plan became effective on April 8, 1968. Since the case involving Librium and Valium had not been concluded, responsibility for deciding the Roche case was transferred to the Bureau of Narcotics and Dangerous Drugs in the Department of Justice as of that date. To date, there has been no action by the Director concerning these two products.

III. THE PROPOSED "CONTROLLED DANGEROUS SUBSTANCE ACT OF 1969."

The "Controlled Dangerous Substance Act of 1969" ("the bill") is a proposal, prepared in the Department of Justice in 1968, to obtain for the Bureau new and comprehensive regulatory authority over narcotics and other drugs designated as "dangerous substances." The bill would make extensive revisions in existing statutory law on drug control, and, in sum, raises many grave questions which cannot be discussed here.

As previously stated, however, one provision of the bill is of immediate and vital concern to Roche. This provision lists Librium and Valium in a proposed schedule as a Controlled Dangerous Substance.

The August and December 1968 drafts of the bill made available to the pharmaceutical industry contained no mention of Librium or Valium. Only the latest draft of the bill, made available in January, 1969, provided that these two products would be controlled. Thus, the Bureau is attempting to accomplish by statute what the government heretofore has failed to do by regulation. Moreover, the bill would remove the highly important special review procedure (see Section I, supra) presently provided by law, by authorizing regulations to be issued pursuant to the less comprehensive review provisions for administrative rule making under the Administrative Procedure Act.

Prior to the passage of the Drug Abuse Control Amendments of 1965, the question whether specific named drugs, rather than classes of drugs, should be included in the legislation, was considered by the House Committee on Interstate and Foreign Commerce. The Committee in its report of March 2, 1965, subscribing to the recommendations repeatedly and uniformly expressed by witnesses appearing before it, stated:

"The Committee determined that it would not be desirable to specify drugs other than barbiturates and amphetamines as subject to the controls of the bill, but determined that the other classes of drugs

are to be brought under control of the bill on a case-by-case basis by the Secretary of Health, Education, and Welfare under the standards prescribed in the legislation."

The plight that Roche now finds itself in is apparent. Roche has pursued in good faith the procedure afforded it by Congress to review what it regards as an unjustifiable attempt under law to impose special controls over Librium and Valium. After three long years the government is apparently attempting to scrap all of Roche's efforts and evidence, and to decide the unresolved question by Congressional fiat.

We urge that this is unfair; is bad public policy; and flies directly in the face of repeated demonstrations of both congressional and judicial concern protecting the right to complete hearings, coupled with full administrative and judicial review.

IV. ROCHE'S POSITION IS BASED UPON ITS
FIRM CONVICTION THAT LIBRIUM AND
VALIUM SHOULD NOT BE SUBJECTED TO
CONTROL UNDER THE PROPOSED STATUTE.

Librium and Valium were the first in a new class of unique and versatile therapeutic agents (Benzodiazepines) used for control of common emotional disturbances manifested by fear, anxiety or tension. These benzodiazepines have been demonstrated and confirmed to be vastly different, both chemically and in

their effects on patients, from the barbiturates or any other drugs known at the time of their syntheses. In addition to their value as an effective tranquilizing agent devoid of harmful sedative or hypnotic effects, both Librium and Valium are of significant value in the treatment of alcoholism and Valium is a useful adjunct in the treatment of certain types of convulsive disorders such as epilepsy and skeletal muscular disorders.

An indication of Roche's objective attitude on the listing of its products is seen in the case of Methyprylon (Noludar). When this drug was proposed for listing along with Librium and Valium, Roche, after conducting a review of its data, agreed to the listing of Noludar as a "depressant or stimulant" drug having a potential for abuse. This decision was made on the merits.

On the other hand, based upon the pharmacological actions of Librium and Valium, the medical community's experience with Librium and Valium, and the paucity of reported instances of misuse of these products, Roche is convinced that Librium and Valium do not have the "potential for abuse" which should subject them to specialized Government regulation under the Drug Abuse Control Amendments of 1965.

The Regulation¹⁷ issued by the Commissioner of Food and Drugs, implementing the Drug Abuse Control Amendments of 1965¹⁸ (authorizing him to designate, after investigation, drugs having a potential for abuse because of their depressant or stimulant effect on the central nervous system), specified the criteria for determining whether a drug has a potential for abuse. The criteria includes the extent to which individuals are misusing the product either by over consumption or upon their own initiative, the diversion of the product from legitimate channels and the relationship of the product to a drug that has previously been listed as having a potential for abuse.

All available evidence demonstrates that:

1. individuals are not taking the products in amounts sufficient to create a hazard to their health or to the safety of other individuals or of the community; and

17. 21 C.F.R. §166.2 (1968).

18. 21 U.S.C. §321(v)(3).

2. there is no significant diversion of the products from legitimate channels; and
3. individuals are not taking the products on their own initiative rather than on the basis of medical advice from a practitioner licensed to administer Librium and Valium in the course of professional practice; and
4. the products are not new drugs so related in their action to drugs already listed as having such a potential for abuse as to make it likely that they will have the same abuse potential.

The listing of Librium and Valium as having a potential for abuse requiring controls comparable to those imposed on amphetamines, barbiturates and LSD is not justified by the nature of the products nor on the basis of experience with them. It would result in false and misleading labeling by implying the presence of nonexistent dangers attendant to their use in medical practice. Such a listing would cause the products to be associated, by medical practitioners, pharmacists and others in the health field, and by persons taking the drugs, with barbiturates and similar drugs and would lead to the belief that these drugs are subject to the same abuses. This incorrect impression might interfere with the prescribing of these products by the medical profession and with their utilization by the

patients for whom they were prescribed. Listing of these products could also lead persons who abuse drugs for their depressant effect alone to experiment with Librium and Valium on the false assumption that their action is comparable to that of the barbiturates.

Librium has been in general medical use since 1960 and more than 9 billion capsules of the product have been distributed commercially since its approval by the Food and Drug Administration. Valium has been in general medical use since 1963 and more than 2.8 billion tablets of the product have been distributed commercially since its approval by the Food and Drug Administration. It has been conservatively estimated that more than 30 million patients have now been treated with these two important products.

CONCLUSION

In view of the above, it is submitted that the proposed bill should include a specific provision preserving all rights in pending administrative proceedings under present law, and preserving the right to judicial review.

When Roche's rights in the pending proceeding are thus preserved, Valium and Librium, being the subject of such a proceeding, must be eliminated from the coverage of the proposed bill pending final decision of that case.

If the Bureau wishes our suggestions with respect to other parts of the bill, we shall be glad to submit them upon request.

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