Governmental Enforcement Powers in the Regulation of the Drug Industry

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Perhaps justifiably, most contemporary writing dealing with the "drug problem" in this country treats only one aspect of that subject—the problem of drug abuse. To many people, current attitudes with respect to the use or abuse of drugs seem to herald a change in social, moral, and religious traditions. However, whether the governing of these traditions properly is a legal problem remains unanswered. Existing laws treat drugs as a potential threat to the health and safety of the public, and accordingly, any other than a theoretical discussion of the drug problem must focus on these factors. Under this view the distinction between the "use" and "abuse" of drugs is largely illusory, since distinctions can be drawn only with respect to the magnitude of the threat posed to public health and safety. Although it could be hypothesized that a greater threat is posed by drugs used without knowledge of their potential danger than is posed by those used in complete awareness of potential harm, it seems best for purposes of this Comment to assume that all drugs posing a threat to health and safety should be considered together. To do otherwise would re-entangle the drug problem with social, moral, and religious factors.

It is significant that in past years, public concern has focused on the aspect of the drug problem suggested above: the use of potentially harmful drugs without knowledge of their danger. One need only recall the tragic effects of "Elixir of Sulfanilamide" in 1937, or of the use of thalidomide in the past decade, to observe this fact. In each instance, public opinion has prompted congressional action to protect consumers against the production and distribution of unsafe drugs. It is because of the salutary effect which governmental regulation has had, and because of the voluntary efforts of many members of the drug industry, that the fear of distribution of unsafe drugs by the industry has largely subsided. However, it is difficult to speak in terms of one "drug industry." Perhaps no other industry in the country incorporates quite as many distinct phases of operation, or represents such a large number of economically diverse enterprises, as does the drug industry. In such a complex industry, affect-

2 G. Marcus, The Public Regulation of Drugs, Library of Congress Legislative Reference Service, 1968, at 7. Elixir of Sulfanilamide was a solution of sulfanilamide in diethylene glycol. Although the substance resulted in many deaths, it became the subject of governmental action only because the term "elixir" implied that it was in an alcoholic solution.
3 Id. at 16.
4 Although there are approximately 1,200 manufacturers of "drugs and medicines," the industry ranks 313th in concentration of shares in the industrial market held by the large enterprises.
ing the lives and well-being of so many people, there will always be a need for governmental regulation.

This Comment deals with regulation of all phases of the industry, from production to distribution of drug substances. However, it is not a study of regulation itself, but rather is a survey and analysis of several means used to enforce governmental regulation. It is appropriate at this point to observe that existing law is presently the subject of many rather significant changes. Several proposals for modern drug legislation are now before Congress, one of which, S. 3246, was passed by the Senate on January 28, 1970. That proposal, discussed below, provides for the supplementation and revision of major concepts under existing law, particularly the classification of drugs for purposes of regulation. Although it proposes to repeal many provisions now dealing with narcotics, marijuana, and depressant and stimulant drugs, it leaves substantially in force existing provisions for drugs not falling into any of these categories.

I. THE ENFORCEMENT PATTERN

In 1938, Congress enacted the Federal Food, Drug, and Cosmetic Act, which remains today the basis for governmental regulation of the drug industry. The Act provides for several enforcement measures, each of which is designed to satisfy the need for enforcement of the Act in a specific situation. The first enforcement measure is the authorization of criminal penalties for violation of the Act. These penalties will not be discussed below, because the complex and distinct problems raised by criminal punishment deserve separate and exhaustive discussion. The second means of enforcing the Act is the power of injunction. This power, which prior to 1938 generally was not available to the Government, was considered to be one of the most important enforcement powers granted by Congress. Third, the 1938 Act carried forward from prior legislation.

Moreover, it has been found that no one company accounts for as much as 7% of total prescription sales. Key Facts About the Drug Industry, Pharm. Mfg. Ass'n Pub. (1968).

Although Congress presently is considering many proposals with respect to drugs, three bills deal with a major revision of federal drug laws: (1) S. 1895, introduced by Senator Dodd on Apr. 18, 1969; (2) S. 2590, introduced by Senator Moss on July 10, 1969; and (3) S. 2637, introduced by the late Senator Dirksen on July 16, 1969 (commonly called the Administration Bill). S. 1895 and S. 2637 were the most significant pieces of proposed legislation aimed at major restructuring of the law. In the Senate all three bills were referred to the Senate Judiciary Committee. That Committee incorporated provisions from S. 1895 and S. 2637, and on Dec. 16, 1969, reported a clean bill, S. 3246. On Jan. 28, 1970, that bill passed the Senate by an 82-0 roll-call vote. In the House of Representatives a dispute over committee jurisdiction on the bill resulted in the bill's being split into two bills, each covering a part of what was formerly S. 3246. H.R. 13472, covering only the narcotic drug aspects of the Administration Bill, was referred to the House Ways and Means Committee. H.R. 13473, covering depressants, stimulants, and hallucinogens, was referred to the Committee on Interstate and Foreign Commerce.

721 U.S.C. §§ 301-92 (1964) [hereinafter referred to as Act, or 1938 Act].
8Id. § 333.
9Id. § 332.
and from the procedure traditionally available in admiralty, the power to seize certain property posing a threat to the safety of the public in violation of the Act. Fourth, a provision was included for inspection of certain establishments and property subject to the Act. This provision was subsequently amended and supplemented by administrative regulations to insure that the Government could stay well informed about the operations of persons subject to the Act. The inspection power is at the same time a type of regulation, an enforcement procedure, and a measure aiding the utilization of other enforcement powers. Because of its many uses, the power of inspection has come to be considered one of the most valuable of governmental powers for regulation of the industry. One additional enforcement power discussed below is the administrative subpoena. Although presently it finds little direct application in regulation of the drug industry, the subpoena merits attention here because of its potential value in proposed legislation.

II. INJUNCTION

Present Law. Included in the Federal Food, Drug, and Cosmetic Act of 1938 is section 332, providing for injunction of violations of the Act. Specifically, section 332 grants jurisdiction to federal district courts to restrain violations of certain provisions of section 331. Moreover, section 332 provides that upon trial for violation of an injunction or restraining order, an accused may demand trial by jury. The principal violations of section 331 subject to injunction are:

1. Adulteration or misbanding of any drug;
2. Introduction or delivery for introduction into interstate commerce of an adulterated or misbranded drug;
3. Failure to permit access to or copying of any record as required by section 373 (carriers and receivers or possessors of drugs in interstate commerce);
4. Refusal to permit inspection as authorized by section 374;
5. Manufacture of adulterated or misbranded drugs in any territory;
6. Doing of certain acts relating to the making of counterfeit drugs;
7. Failure to register under section 360;
8. Handling of a stimulant or depressant drug as not authorized under section 360a(a) (person not permitted to do so, or not properly registered), failure to make, keep, or allow inspection of records or premises in accordance with section 360a.

When the 1938 Food, Drug, and Cosmetic Act became effective, it

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12 Lee, supra note 10, at 80.
14 Id. § 374.
19 Id. § 332.
20 Id. § 332(b).
21 Other acts are prohibited by id. § 331, but they are not relevant to this discussion.
was thought that the newly authorized injunctive power would have significant effect in enforcement of the Act.\(^1\) Prior to 1938, without specific statutory authority, courts were reluctant to enjoin acts which also could constitute crimes.\(^2\) However, the basis for this judicial reluctance, the time-honored maxim that "equity will not enjoin a crime," finds no application where injunction is authorized by statute.\(^3\) Moreover, under such a statute there need be no showing of "immediate and irreparable injury."\(^4\) Under section 332, no allegation must be made other than a showing of "cause" for issuance of an injunction—in other words, an allegation that the Act has been violated and that injunctive relief is otherwise appropriate.\(^5\)

The advantages of injunctive power are several.\(^6\) First, the injunction may allow testing of cases which otherwise might not present a "case or controversy" cognizable by the courts. By co-operating and using an injunction proceeding, an alleged violator of the Act and the Government may obtain judicial review of an administrative "decision."\(^7\) Second, an injunction proceeding has the advantage of speed. Because a jury is not required in a proceeding to obtain an injunction,\(^8\) such a suit may find a preferred position on the docket. The speed with which an injunction is obtainable may serve in some instances to protect the public from the movement of unsafe drugs in commerce—which may occur during the pendency of a criminal prosecution. In addition, the injunction permits an alleged violator of the Act to appear in court before action is taken, unlike the situation occurring in condemnation proceedings. Because of this fact, the injunction is potentially valuable in allowing a dispute between an alleged violator and the Government to be settled in court with a minimum of injury to the violator. Again in contrast to a condemnation proceeding, where the alleged violator's product may deteriorate during the course of the proceedings, and, even in the case of a judgment favorable to the violator, leave him without recourse for storage costs, the injunction proceeding allows quick settlement of the question. As originally enacted in 1938, the Food, Drug, and Cosmetic Act provided

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\(^{1}\) See note 10 infra.
\(^{2}\) Developments, Injunctions, 78 Harv. L. Rev. 994, 1013 (1965).
\(^{4}\) Where a statute authorizes an injunction against certain conduct, a showing of "irreparable injury" is not required unless the statute itself imposes such a limitation upon injunctive relief. SEC v. Torr, 87 F.2d 446 (2d Cir. 1937); Conway v. Mississippi State Bd. of Health, 252 Miss. 315, 173 So. 2d 412 (1965); Montana Milk Control Bd. v. Rehberg, 141 Mont. 149, 376 P.2d 508 (1962).
\(^{5}\) See Note, supra note 23, at 1027. However, the elements necessary beyond evidence of violation of the Act are not clear. See F.D. Cosm. L. Rep. 2201 (1969); United States v. Lazere, 56 F. Supp. 730 (N.D. Iowa 1944).
\(^{7}\) Abbott Labs. v. Celabreeze, 312 F.2d 286 (3d Cir. 1961). Abbott was reversed, however, by the Supreme Court in a decision which seems to broaden pre-enforcement review of administrative regulations. 387 U.S. 136 (1967). See also Developments, Deceptive Advertising, 80 Harv. L. Rev. 1005, 1111 (1967).
\(^{8}\) Because an action to obtain an injunction is equitable in nature, there is no right to trial by jury. United States v. White County Bridge Comm'n, 275 F.2d 529 (7th Cir.), cert. denied sub nom. Clippinger v. United States, 364 U.S. 818 (1960).
for seizure only in cases of adulteration or misbranding. Accordingly, the injunction assumed great importance with respect to enforcement of other provisions of the Act. Moreover, movement in interstate commerce was, and is, a prerequisite to seizure in cases of adulteration or misbranding. The injunction serves to fill this gap in governmental seizure power. Although amendments to the 1938 Act changed these situations by broadening the seizure power, the injunction clearly has not been rendered obsolete. Finally, as a practical matter the injunction has potential value to the Government simply as a threat against violation of the Act. Although the risk exists that the violator may continue to commit prohibited acts after an injunction is obtained, contempt proceedings provided by the Act can be quite severe.

Despite the apparently overwhelming advantages of injunction, the power is not without its practical disadvantages. First, it seems clear that application of the injunction power is limited. It can serve no valuable purpose with respect to past violations of the Act, or with respect to situations beyond the control of the violator. Thus, after a shipment of potentially unsafe drugs leaves the hands of the manufacturer and reaches the consumer, an injunction may have little significance. Moreover, as suggested above, an injunction reaches violators of the Act, but does not necessarily reach the violation itself. Even if an injunction is obtained, drugs which are the subject of the violation may have continued to move during the course of the proceeding. Finally, it can be extremely difficult to police a decree of injunction. If the violator is not adequately apprehensive of contempt penalties, the violation may continue.

Several procedural aspects of the injunction may also be thought of as disadvantageous. First, the district court on petition for injunction must make its findings of fact explicit. It seems clear that this requirement may work to the disadvantage of whichever party succeeds in the hearing for injunction, because the explicit findings of fact may afford a better opportunity for reversal of the court's decree. Second, the injunction authorized by the statute, like all injunctions, is within the discretion of the court. The Government assumes the risk that factors aside from the alleged violation may cause its petition for injunction to fail, and accordingly, cause the time spent in seeking the injunction to be wasted. In a situation where the Government cannot afford this risk, the advantage of

30 See United States v. Vitaseal Corp., 345 F.2d 864 (3d Cir.), cert. denied, 382 U.S. 918 (1965). Vitaseal involved seizure of goods ultimately found not to be misbranded or adulterated, and thus not properly subject to seizure. An injunction in the same situation would have been appropriate and enforceable.
31 See note 42 infra, supra note 18, 160 F.2d 816 (8th Cir. 1947).
seizure or other enforcement measures seems clear. Finally, if the injunc-
tion is granted but subsequently violated, the Government may be forced
to present its case in contempt proceedings rather than in proceedings for
violation of the Act. From a purely strategical point of view, such a situa-
tion must be undesirable to the Government.

Proposed Legislation. Under what appears to be the most significant
piece of proposed legislation, S. 3246, existing provisions for injunction
would remain substantially in force. However, it is important to observe
that S. 3246 is, as its title implies, a bill for the regulation of “Controlled
Dangerous Substances.” The effect which it will have is upon the pro-
visions of existing law dealing with narcotic, depressant, stimulant, and
hallucinogenic drugs. For the most part, as has been observed, section
331 of the Act, which enumerates acts subject to injunction under section
332, deals with drugs other than narcotics, depressants, stimulants, and
hallucinogens. However, section 331(q), which prohibits certain acts with
respect to depressant or stimulant drugs, would be repealed by the pro-
posed legislation. Under S. 3246, section 705 provides for injunctive
relief against violations of the proposed Controlled Dangerous Substances
Act, and, accordingly, would accomplish with respect to a broadened class
of dangerous drugs the same general effect now accomplished by section
332 with respect to stimulants and depressants. However, there are some
rather interesting distinctions between the two injunction provisions.
Section 705 differs first, of course, to the extent that substantive regula-
tory requirements (and hence the prohibited acts) of S. 3246 differ from
regulation under present law. The only meaningful comparison which can
be made with respect to violations subject to injunction is between section
331(q) (the basis for injunction relating to stimulants and depressants
under present law) and title V of S. 3246 (prohibited acts subject to in-
junction under section 705). With respect to stimulant and depressant
drugs, an injunction basically may be obtained under section 332 to en-
join certain violations of section 360a:

Section 360a(a) prohibits the manufacturing, compounding, or
processing of stimulant or depressant drugs by anyone other than
certain registered (under section 360) persons, and certain medical,
 quasi-medical, scientific, or supply persons.

Section 360a(b) prohibits the sale, delivery, or other disposal of
depressant or stimulant drugs by anyone other than persons enumer-
ated in section 360a(a), or by certain carriers or warehousemen.

Section 360a(c) prohibits possession of stimulant or depressant
drugs (other than for personal use) by anyone other than persons
enumerated in section 360a(a) or (b).

Section 360(e) prohibits the filling or refilling of prescriptions for

37 S. 3246 is captioned: “A Bill to protect the public health and safety by amending the narcot-
cic, depressant, stimulant, and hallucinogenic drug laws, and for other purposes.” Id.
39 Id. § 705.
depressant or stimulant drugs after a certain time following prescrip-
tion, or for more than a specified number of times during that period.

Section 360a(d) requires that all persons authorized under section
360a(a) to "handle" depressant or stimulant drugs must keep records
of all contacts with such drugs, including the amount and the dispo-
sition of drugs "handled." It further provides for inspection of records
and premises subject to the section.

It is clear that under section 332, an injunction is authorized to prevent
violations in nearly all phases of "traffic" in stimulants and depressants—
from manufacture to final prescription.

Section 705 of S. 3246 is seemingly broader than the injunctive power
now applicable with respect to stimulant and depressant drugs, because
it provides for injunction of all violations of the proposed Controlled
Dangerous Substances Act. Although this would seem to permit injunc-
tion of certain acts (or omissions) not categorized as "prohibited acts," in
reality the apparent breadth may be of little significance. Most of the
provisions of the bill for which injunctive relief would be appropriate
are made prohibited acts under title V. Effectively, S. 3246 would prohibit,
and thus permit injunction for the commission of, all acts with respect to
controlled dangerous substances which section 331(q) now prohibits with
respect to stimulants and depressants. However, unlike provisions of the
present law, the injunction power is expanded by the requirement for
registration of all persons "handling" controlled dangerous substances.
Moreover, the proposed legislation would authorize injunction of (1) im-
portation, (2) exportation, (3) counterfeiting, (4) manufacture outside
the United States with intent to unlawfully import, and (5) "handling"
in a manner not authorized by the registration or license obtained, of cer-
tain classes of controlled dangerous substances. Thus, although some sig-
ificant controls for which injunction is available would be added by
S. 3246, the practical application of the injunction power would be ex-
panded principally by virtue of the inclusion of additional "substances"
in the regulatory scheme of the bill.

Another interesting distinction between the injunction provided under
section 332 of the present law, and that provided in section 705 of S. 3246
is seen in the language of the latter. Section 705 does not adopt the "for
cause shown" language of section 332.44 That phrase has been thought to
instruct the court that an injunction is not to be issued as a matter of
right upon a showing of past conduct by the violator.45 Although it is clear
that no showing of "irreparable injury" is required,46 it appears that under
section 332 evidence of violations of the Act may not by itself constitute
cause for issuance of the injunction.47 Section 705, which dispenses with the

42 Id. §§ 301, 302, 303.
43 "The district courts of the United States . . . shall have jurisdiction, for cause shown, . . .
to restrain violations of section 331 of this title, except paragraphs (e), (f), and (h)-(j) of said
44 See note 24 supra.
45 See note 24 supra.
46 See note 41 supra.
"for cause shown" provision, would seem to authorize an injunction upon a showing that the proposed legislation has been violated—i.e., as a matter of right. However, it is unclear whether the proposed section will accomplish this purpose. Historically, courts have been reluctant to abandon equitable principles governing the issuance of injunctions. In the absence of evidence tending to show present or future violation of the Act, injunctive relief may be considered unnecessary and inappropriate, and accordingly be withheld.

Other language also is omitted from section 705 of S. 3246 which now exists in section 332 of the present law. Section 332 (b) provides:

In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this chapter, trial shall be by the court, or upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 387 of Title 28, as amended. [Emphasis added.]

The provision for trial by jury was probably included to answer possible constitutional objections to the degree of protection available to an accused in contempt proceedings where the act of contempt also may be a crime. However, although the section makes it clear that a jury may be demanded in cases where the contempt also is a crime, it seems to admit the argument that if violation of the injunction does not also constitute a

45 In Hecht v. Bowles, 321 U.S. 321 (1944), the Court considered the question of whether a lower court was vested with the discretion to withhold injunctive relief under the Emergency Price Control Act, ch. 26, § 205, 56 Stat. 33 (1942). That section provides:

> Whenever in the judgment of the administrator any person has engaged or is about to engage in any acts or practices which constitute or will constitute a violation of any provision of section 4 of this act . . . he may make application to the appropriate court for an order enjoining such acts or practices, or for an order enforcing compliance with such provision, and upon a showing by the administrator that such person has engaged in or is about to engage in any such acts or practices a permanent or temporary injunction, restraining order, or other order shall be granted without bond. [Emphasis added.]

Upholding the lower court's reluctance to grant the injunction as a matter of right, the Supreme Court said:

We do not stop to compare the provisions of section (925) with the requirements of other federal statutes governing administrative agencies which, it is said, make it mandatory that those agencies take action when certain facts are shown to exist. We are dealing here with the requirements of equity practice with a background of several hundred years of history. Only the other day we stated that 'An appeal to the equity jurisdiction conferred on federal district courts is an appeal to the sound discretion which guides the determinations of courts of equity.' Meredith v. City of Winter Haven, 320 U.S. 228 . . . The historic injunctive process was designed to deter, not to punish. The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mold each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it. The qualities of mercy and practicality have made equity the instrument for nice adjustment and reconciliation between the public interest and private needs as well as between competing private claims. We do not believe that such a major departure from that long tradition as is here proposed should be lightly implied.

321 U.S. at 329.

46 See note 42 supra. In SEC v. Mono Kearsage Consol. Mining Co., 167 F. Supp. 248 (D. Utah 1958), the court recognized the rule announced in Hecht v. Bowles (see note 45 supra), and determined that even if an injunction statute is mandatory in form, providing that an injunction "shall" issue upon a proper showing, issuance of the injunction is not obligatory on the court, and equitable principles should guide the court's granting or refusal.
violation of the Act, no right to trial by jury is available. Section 705 of S. 3246 does not place this condition on the right to trial by jury, but provides simply that where an injunction is violated, the accused in contempt proceedings may demand trial by jury. In so doing, section 705 avoids this objectionable feature of the present law.

One recent case, *Bloom v. Illinois*,\(^47\) may have a significant effect on the right to deny an alleged violator of an injunction decree the right to trial by jury where the violation does not also constitute a violation of the Act. In *Bloom* the defendant was convicted for criminal contempt and sentenced to two years' imprisonment for attempting to have a falsely prepared will admitted to probate. Although the "offense" which the defendant committed possibly could have constituted the crime of forgery, he was not tried for that crime. Rather, the trial court chose to treat the act as contempt of court. The conviction for contempt was affirmed by the Illinois supreme court,\(^48\) and thereafter the United States Supreme Court granted certiorari.\(^49\) The Court had little difficulty in characterizing the offense as criminal, rather than civil, contempt. Although this characterization has sometimes proven difficult to make,\(^50\) the Court announced what appears to be the recognized definition of criminal contempt: a "public wrong which is punishable by fine or imprisonment or both."\(^51\) The Court determined that criminal contempt is indistinguishable from ordinary criminal conviction, whether or not the contempt also constitutes a violation of other criminal law. It held that where the criminal contempt constitutes a "serious" offense, the right to trial by jury must be afforded the defendant. In so doing, the Court left intact the power of courts to punish contempt for petty offenses without a jury.\(^52\) Although the Court did not make explicit the meaning of "serious" offense, it indicated that the proper test is the gravity of the penalty imposed. Nothing in the Court's opinion suggests whether large fines could constitute "serious" penalties, but such a conclusion would seem appropriate. In cases where no maximum penalty is provided by law for the offense of criminal contempt,\(^53\) the Court determined that the punishment actually imposed should

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\(^{47}\) 191 U.S. 194 (1918).


\(^{49}\) 386 U.S. 1003 (1967).

\(^{50}\) See, e.g., *Yates v. United States*, 227 F.2d 844 (9th Cir. 1955); *Bessette v. W.B. Conkey Co.*, 194 U.S. 324 (1904).

\(^{51}\) 391 U.S. at 201.

\(^{52}\) 21 U.S.C. § 332(b) (1964) provides that contempt proceedings are to be governed by the practice and procedure of proceedings under Clayton Act ch. 323, § 22, 38 Stat. 730 (1914). Although the contempt provisions of § 22 of the Clayton Act were repealed by enactment of 18 U.S.C. § 402 (1964) (Contempts Constituting Crimes), one case prior to that repeal made clear that not all procedural aspects of the Clayton Act were to apply. *United States v. Dean Rubber Co.*, 72 F. Supp. 819 (W.D. Mo. 1947). 18 U.S.C. § 402 (1964) now provides basically two things: (1) A limitation for fines which may be imposed on natural persons, and (2) by reference to 18 U.S.C. § 3691 (1964), trial by jury at the request of the accused if the contempt also constitutes an independent crime. Both § 402 and § 3691 exempt from these provisions certain contempts committed in the presence of the court. The Court in *Bloom* recognized these exemptions as being historically acceptable under the Constitution, and thus found it unnecessary to carve out a specific exception to the rule which it announced.

\(^{53}\) Under 18 U.S.C. § 402 (1964) no limitation is prescribed for corporate offenders, or for contempts committed in the presence of the court.
be scrutinized to test the seriousness of the conviction. Although the decision in Bloom is silent as to other constitutional protections which may be available in the trial of a defendant for criminal contempt, the stage seems set for the finding of additional protections. The effect which these developments may have on contempt proceedings under section 332 seems clear.

Another distinction in the language of the two injunction sections is in their provisions for the procedure to be followed in contempt proceedings. A contempt proceeding under section 332 (b) is governed by Rule 42 of the Federal Rules of Criminal Procedure. That section provides, as does section 332 itself, for a jury trial as discussed above. It also provides for a limitation on the fine which may be imposed on a natural person. However, it could be argued that the incorporation of this provision of the Criminal Code does not have the effect of making other sections of that Code applicable to contempt proceedings. Under decisions holding that contempt proceedings are not criminal in nature unless the contemnuous conduct also is a crime, it would seem that the Federal Rules of Civil Procedure could govern the general procedure of trial for contempt. Indeed, section 705 of S. 3246 expressly provides for the application of those Rules. However, despite these provisions, the decision in Bloom may require substantial deviation from civil procedure in many instances.

III. Inspection

**Present Law.** Necessary for the enforcement of drug laws and regulations is the authority of the Government to inform itself of the practices and operations of persons “handling” drugs. Accordingly, the Food, Drug, and Cosmetic Act provides for two types of inspections. The first is the right of government officials to inspect records or documents which are required by the Act for the express purpose of aiding in the enforcement of drug laws. However, few questions are raised with respect to this sort of inspection and it merits no extensive comment here. The second type of inspection is authorized by sections 355(j), 357(g), 360b (Supp. IV, 1968). Inspections of this type extend to the physical operations of drug “establishments” and property closely related to the handling of drugs, includ-

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54 However, this procedure would seem to be undesirable, because it may require many reversals of convictions and burdensome retrials.
55 For example, it is clear that in a trial for criminal contempt the defendant must be proved guilty “beyond a reasonable doubt.” Gompers v. Bucks Stove & Range Co., 221 U.S. 418 (1911). Moreover, he should be entitled to counsel [Cooke v. United States, 267 U.S. 517 (1925)], notice, a reasonable time to prepare a defense, bail, and an impartial judge. FED. R. CRIM. P. 42.
57 See, e.g., Michaelson v. United States, 266 U.S. 42 (1924); State v. Greenwood, 63 N.M. 156, 315 P.2d 223 (1957).
58 FED. R. CIV. P. 1, 81.
59 The term “handling” is not used in either existing law or the proposed legislation. It is employed in this Comment only for simplification. Provisions under the proposed legislation and existing law differ from each other in the terminology used to describe what is here labeled “handling.” That difference, though not material for purposes of this Comment, should be observed.
ing certain records and documents not necessarily required to be kept under the Act.

In aid of understanding the scope and operation of the inspection power, it is necessary to review the provisions of the sections mentioned above. Section 360 provides basically a registration requirement for certain establishments handling drugs. Subsection (h) makes every registered establishment subject to inspection at least once during every two-year period following registration. Section 360a prohibits the handling of stimulant or depressant drugs by all but certain enumerated classes of persons. Subsection (d) of this section provides for both types of inspections mentioned above: (1) inspections of records or documents required to be kept under the section by persons handling stimulant or depressant drugs, and (2) inspection of the premises and "all things therein" bearing on a violation of section 360a or section 331(q), in order to verify the records required to be kept under the section. It should be noted that the authority under section 360a to inspect the premises is rather restricted in theory, even though it may not be so in practice.\(^6\) The inspection authorized should be limited by the purpose of verifying records required to be kept under the Act. Those records pertain principally to the quantity and disposition of stimulant and depressant drugs handled by the establishment. Accordingly, section 360a does not grant authority to conduct a general inspection of an establishment processing stimulant or depressant drugs. It should also be noted that the language of the section prohibits inspection of (1) financial data, (2) sales data other than shipment data, (3) pricing data, (4) personnel data, or (5) research data.\(^6\)

Section 374 provides the basic limitations on, and procedures to be followed in, inspections authorized under section 360. The basic provisions of this statute may be summarized as follows. First, with the exception of establishments handling prescription drugs, the inspection is limited to establishments handling drugs which have been or will be moved in interstate commerce. Second, the section provides that although the inspection may extend to all things bearing on whether a violation of the Act has been committed if the establishment handles prescription drugs, the five classes of data exempted under section 360a also are exempted from inspection under section 374.\(^6\)

Section 374 does not expressly delineate the scope of the inspection of an establishment which produces neither prescription drugs (covered by section 374 itself) nor stimulant or depress-

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\(^6\) The inspection authorized under § 360 is broader than that authorized under § 360a. Although some establishments under the latter are not subject to inspection under § 360, there are instances where inspection is authorized under either. Accordingly, even though an inspection of an establishment handling stimulant or depressant drugs might exceed the scope authorized by § 360a, the inspection could be justified under § 360. This situation also occurs with respect to other sections. Cf. United States v. Herold, 136 F. Supp. 15 (E.D.N.Y. 1955) (§§ 373, 374).

\(^6\) These five exemptions under § 360a(d)(2)(B) apparently are qualified by the language of § 374(a). The latter section provides that in the case of prescription drug handlers, inspection may extend to personnel data of technical and professional personnel, and to research data concerning certain new drugs and antibiotics. It is not clear whether the reference to § 374(a) by § 360a(d)(2)(B) should incorporate these qualifications unconditionally, or only with respect to prescription drug handlers.

\(^6\) See note 63 supra.
sant drugs (covered by section 360a). Although the inspection of such an establishment reasonably could extend to all things bearing on a violation of the Act, it is arguable that the language of the section excludes from inspection records, files, papers, processes, and controls, which are expressly included in inspections of establishments producing prescription, depressant, or stimulant drugs. Third, the section exempts from inspection, on account of their handling of prescription drugs, the following entities: (1) pharmacies, (2) practitioners, and (3) researchers. Because these entities are exempted from the inspection authorized for handlers of prescription drugs, two conclusions seem possible. First, there is a significant difference between the authorized scope of inspection of handlers of prescription drugs and of handlers of non-prescription drugs. Second, pharmacies, physicians, and researchers are not exempt from all inspection, but only that inspection authorized for handlers of prescription drugs.

Before discussing some of the problems which these inspection provisions have raised, two other important sections dealing with inspection power should be mentioned. First, because the movement of drugs in interstate commerce is an essential element in the right to inspect all but establishments handling prescription, depressant, or stimulant drugs, it is very important that a means for determining this movement be available. Section 373 accomplishes this by requiring all carriers engaged in interstate commerce, and all persons receiving drugs in interstate commerce, to permit designated government officials access to, and the right to copy, all records showing the movement of the drugs in interstate commerce. Second, section 372 provides for the delegation of authority to conduct "examinations and investigations." Under this section, the Secretary of Health, Education and Welfare may delegate authority to conduct inspections to personnel of other federal departments, and to properly commissioned state and municipal personnel.

The power of what may be called "factory" inspection has raised problems since enactment of the Federal Food, Drug, and Cosmetic Act in 1938. The first case to test the original statutory scheme for "compulsory" inspections was United States v. Cardiff. In that case the Supreme Court

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65 See United States v. Crescent-Kelvan, 164 F.2d 382 (3d Cir. 1948); United States v. Herold, 136 F. Supp. 15 (E.D.N.Y. 1955). Each of these cases was decided prior to amendment of § 374 to permit compulsory "factory" inspections. Act of Aug. 7, 1933, ch. 350, § 1, 48 Stat. 476, amending Food, Drug, and Cosmetic Act of 1938, ch. 675, § 704, 52 Stat. 1047, codified at 21 U.S.C. § 374 (1964). However, in each case the court found that authority to enter the establishment (though with the permission of the owner because of the language of the statute at that time) included authority to inspect records only expressly authorized to be inspected in the case of prescription drug handlers. However, a contrary view has been expressed. Aarons, Factory Inspection, 22 Food Drug Cosm. L.J. 407, 408 (1967).

66 This authority may also be derived from § 374 if the person having possession of the information also is subject to that section. See United States v. Herold, 136 F. Supp. 15 (E.D.N.Y. 1951).


interpreted two provisions of the Act. Section 374 originally provided that inspection of premises could be made at reasonable times after making a request and obtaining permission from the owner.\textsuperscript{60} Section 331(f), however, prohibited "refusal to permit entry or inspection as authorized by section 374 of this title."\textsuperscript{7} The Court found the two sections irreconcilable and held section 331(f) void for vagueness. However, in 1953, an amendment to the Act became effective providing for the compulsory inspection which exists under present law.\textsuperscript{71}

The question involved in \textit{Cardiff} was rather narrow. No serious issue was raised with respect to the inspection itself, or with respect to the right of compulsory inspection if the statute were not vague. Subsequently, however, the theory of compulsory inspection caused serious constitutional objections. It was urged before Congress, prior to the amendment of section 374 to provide compulsory inspection, and later in the courts in several cases involving local health inspections,\textsuperscript{72} that warrantless inspections were unconstitutional under the fourth and fourteenth amendments.\textsuperscript{73} However, these objections apparently were answered on the grounds that such administrative inspections were constitutionally permissible either under the "police power" of the states (where the inspection was by state authorities), or because they were inherently "reasonable" and hence not subject to the requirements of the fourth amendment.\textsuperscript{74} Recently, two cases decided by the Supreme Court have made clear that neither of these grounds justifies failure to comply with basic requirements applicable to searches and seizures.

In \textit{Camara v. Municipal Court}\textsuperscript{75} an inspector of the San Francisco Department of Public Health attempted to enter the apartment of appellant to conduct a routine building inspection as authorized by a municipal housing code.\textsuperscript{76} On that and subsequent occasions, the appellant refused to admit the inspector, purportedly because the inspector did not possess a warrant for search of the premises. Appellant was thereafter arrested and charged with refusal to permit a lawful inspection authorized by the municipal code. Filing a writ of prohibition, appellant contended that

\begin{footnotesize}
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\item \textsuperscript{61} 21 U.S.C. § 331 (f) (1964).
\item \textsuperscript{72} H.R. REP. No. 708, 83d Cong., 1st Sess. 24 (1953).
\item \textsuperscript{73} Eaton v. Price, 364 U.S. 263 (1960); Frank v. Maryland, 359 U.S. 360 (1959); Givner v. State, 210 Md. 484, 124 A.2d 764 (1956); City of St. Louis v. Evans, 337 S.W.2d 948 (Mo. 1960); Objections to compulsory inspections are also discussed in Developments, The Federal Food, Drug, and Cosmetic Act, 67 Harv. L. Rev. 632, 690 (1954). See cases cited in id. at n.466.
\item \textsuperscript{74} U.S. CONST. amends. IV, XIV.
\item \textsuperscript{75} It is clear that the fourth amendment protection extends only to "unreasonable" searches. However, the "reasonableness" test has been employed in different ways by the Court, including the interpretation that a search is presumptively unreasonable if not authorized by a valid search warrant. See Stoner v. California, 376 U.S. 483 (1964).
\item \textsuperscript{76} SAN FRANCISCO CAL., MUN. CODE, § 503, as quoted in 387 U.S. at 526; "Authorized employees of the City departments or City agencies, so far as may be necessary for the performance of their duties, shall, upon presentation of proper credentials, have the right to enter, at reasonable times, any building, structure, or premises in the City to perform any duty imposed upon them by the Municipal Code."
\end{itemize}
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the search authorized by the ordinance was not constitutionally permissible under the fourth and fourteenth amendments because it was not pursuant to a warrant and was not conditioned upon probable cause to believe that a violation of the housing code had occurred. The Supreme Court agreed, holding that the nature of the "search" did not justify abandonment of basic constitutional rights. The Court was not persuaded by the argument that because administrative searches are not effected for the purpose of finding evidence of criminal conduct, they may avoid the fourth amendment prohibition of warrantless searches. The Court appeared to find that the privacy of a person's home is protected by the fourth amendment whether or not the search is to find evidence of criminal behavior. However, it observed that many regulatory inspections entailed the threat of criminal prosecution either on the finding of a violation during the inspection, or upon the refusal of an occupant to permit the search. The Court also rejected the contention that most ordinances or laws authorizing regulatory inspections are written with sufficient safeguards against abuse, and that to require prior issuance of a warrant would either prevent valuable inspections or debase the warrant procedure. It determined that an occupant is not fairly apprised of such limitations on the authority of inspectors, and accordingly has no way of knowing whether the inspection is being properly conducted. Moreover, the Court found that the need to interpose a neutral magistrate between a person subject to administrative inspection and the administrative agent is no less urgent than the need to interpose a magistrate between a criminal suspect and the police. Finally, the Court determined that warrantless investigations are not justified on the ground of public policy. It found that public interest justifies only the investigation itself, not the failure to obtain a warrant.

Despite the Court's emphatic pronouncement that a warrantless inspection is not constitutionally permissible, it apparently agreed that routine inspections would be impeded by requiring the same degree of "probable cause" as is required in criminal investigations. Probable cause, the Court observed, is determined by focusing upon the governmental interest which allegedly justifies the intrusion. In the case of regulatory inspections, the Court determined that the reasonableness of the need to inspect should govern. It recognized the value of periodic inspections without knowledge of the existence of substandard conditions, and held that the reasonableness of instituting such an inspection depends on factors such as the passage of time since the last inspection, the nature of the building, and the condition of the area to be inspected. Accordingly, the Court protected the power of government officials to conduct preventative inspections as part of a program of routine investigation. It is significant that the Court's decision, however, does not affect the right of govern-

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78 "It is surely anomalous to say that the individual and his private property are fully protected by the Fourth Amendment only when the individual is suspected of criminal behavior." 387 U.S. at 530.
79 Id. at 538.
mental officers to conduct warrantless investigations and inspections in emergency situations.88

On the same day, the Court decided a case with similar facts. See v. City of Seattle89 involved an attempted fire inspection of a commercial warehouse. Relying on its decision in Camara, the Court held that the regulatory inspection of commercial property, as well as the inspection of private houses, is presumptively unreasonable under the fourth and fourteenth amendments if conducted without a warrant.

The effect which these decisions must have on inspections under section 374 is clear. However, although the decisions could even affect the validity of that section, the Food and Drug Administration has announced that “inspection warrants” will be obtained in all cases where voluntary inspection is refused.90

Proposed Legislation. Section 70391 of S. 3246, which authorizes administrative inspections, would supplement existing provisions for inspection in accordance with the proposed regulatory scheme for controlled dangerous substances. The section clearly reveals the effects of Camara and See, and avoids many of the ambiguities and inconsistencies of present law dealing with inspections. Under the bill, section 360a, which currently authorizes inspections of establishments handling stimulant or depressant drugs, would be repealed.92 However, with the exception of minor conforming amendments, sections 360, 373, and 374 would remain in force.

Section 703 expressly provides for the issuance of administrative “inspection warrants” by state or federal courts. It requires a showing of probable cause for the inspection, but significantly, defines the requisite probable cause as “a valid public interest in the effective enforcement of the act or regulations sufficient to justify administrative inspection of the area, premises, building or conveyance in the circumstances specified in the application for the warrant.” Before the decision in Camara, although it would not then have been necessary, such an internal definition of probable cause could have been of doubtful constitutional validity. However, it is clear that Camara established for administrative inspections a much less demanding type of probable cause than formerly thought necessary to satisfy fourth amendment requirements. Accordingly, the constitutionality of this “internally defined” probable cause seems beyond question. Actually, section 703 goes beyond the requirements discussed in Camara in providing for the manner of execution, the time of expiration, and the procedure for return of the warrant.93 The inspection authorized

88 "[N]othing we say today is intended to foreclose prompt inspections, even without a warrant, that the law has traditionally upheld in emergency situations." Id. at 539.
89 387 U.S. 541 (1967).
90 F.D. Cosm. L. REP. § 2661.40 (1969); see H. TOULMIN, LAW OF FOOD, DRUGS, AND COSMETICS § 37.5 (Supp. 1969).
92 Id. § 901(m).
93 Id. § 703(a)(1).
94 The warrant must direct that it be served during normal business hours; it must state the grounds for its issuance, the identity of persons whose affidavits support it, and the property to be inspected. The warrant expires 10 days after issuance, and return must be made to a designated
by section 703 extends to all "controlled premises," which are defined as:
(1) places where persons registered or exempt from registration are required to keep records, and (2) places where persons registered or exempt from registration are permitted to handle controlled dangerous substances. Although for most purposes this definition includes all places where inspection is necessary, it does not expressly authorize inspection of places required to be registered which are in fact not registered. It would seem more appropriate to define "controlled premises" as "those places required to be registered under this act, whether actually registered or not, and those places exempt from registration."

The scope of the inspection authorized under section 703 for "controlled premises" extends to all things subject to inspection under present law (in the case of prescription, depressant, or stimulant drugs). It also subjects to inspection data concerning personnel and research, which are now exempt from inspection. Finally, section 703 provides for inspections without warrants in five specific situations. The most interesting provision for warrantless inspection is section 703 (b) (4) (e), which provides that such an inspection may be made "in all other situations where a warrant is not constitutionally required." Although it may be doubtful that future constitutional interpretation will expand rather than constrict the right to make warrantless inspections, this provision has the desirable effect of giving inspection agents all of the leeway constitutionally permissible.

One additional aspect of section 703 merits observation but no extensive comment. Noticeably, section 703 does not require that the establishments subject to inspection must be involved in interstate commerce. Although this may significantly ease the Government's burden of proof in many instances, it may not amount to a substantial extension of the inspection power.

IV. Seizure

Present Law. As originally enacted in 1938, section 334 carried forward the basic provisions for seizure and condemnation of drugs which existed under the 1906 Food and Drugs Act. However, the 1938 Act incorporated several major changes. First, it provided that in most situations only one libel proceeding could be instituted against goods alleged to be misbranded. Accordingly, it provided some measure of protection against costly and inconvenient multiple seizure in many instances. Second, after amend-
ment, the Act broadened the power of seizure to apply to misbranded or adulterated goods even after movement in interstate commerce. Third, unlike the 1906 Act, section 334(a) provided for the removal of a libel proceeding to a district of reasonable proximity to the personal defendant’s place of business. Fourth, the 1938 Act gave rise to differing interpretations of several acts constituting violation of the statute, and correspondingly, broadened the reach of the seizure power.

In 1965, amendments to the Food, Drug, and Cosmetic Act significantly broadened the libel, condemnation, and seizure power. What is now section 334(a)(2) was added to the Act, providing for libel and condemnation at any time of stimulant, depressant, and counterfeit drugs, or certain equipment or containers used in their making or handling with respect to which a prohibited act under sections 331(q) or 331(p) has occurred. Accordingly, in the case of stimulant, depressant, or counterfeit drugs, section 334(a)(2) dispenses with the requirement that the substances to be seized must have moved in interstate commerce.

One important aspect relating to the sections above is the right of executive seizure—the right to seize drugs prior to the institution of libel proceedings. When section 334(a)(2) was added to the Act in 1965, subsection (e)(5) was added to section 372 of the Act, authorizing executive seizure of goods prior to institution of libel proceedings under section 334(a)(2). Under subsection (e)(5), agents of the Bureau of Narcotics and Dangerous Drugs are authorized to make such a seizure when they have “reasonable grounds” to believe that the goods are subject to seizure and condemnation under section 334(a)(2). There is no corresponding authority for executive seizure of goods subject to libel and condemnation under section 334(a)(1).

Two important questions have been raised with respect to executive seizure of misbranded or adulterated drugs (i.e., those subject to libel and condemnation under section 334(a)(1)). First, can libel properly be instituted if the drugs are not seize goods wherever found in interstate commerce. Persons whose property was thus seized could, if they desired to defend the property in condemnation proceedings, be forced to defend numerous, geographically separate, seizure actions. The Federal Food, Drug, and Cosmetic Act precluded multiple seizures in many situations, but did leave intact the Government's power to make such seizures in specified instances involving flagrant violations of the Act or great public health hazards. See A. Herrick, supra note 42, at 1193.


93The Federal Food and Drugs Act of 1906 limited seizure to situations in which an article was transported from one state to another for sale, or, having been transported, remained "unloaded, unsold, or in the original unbroken packages." Food and Drugs Act of 1906, ch. 3915, § 10, 34 Stat. 771. It would appear that this limitation was imposed because of contemporary constitutional construction, finding interstate commerce to end after breakage of the original package. See Dahnke-Walker Milling Co. v. Bondurant, 257 U.S. 282 (1921); Leisy v. Hardin, 135 U.S. 100 (1890). However, cases supporting this construction dealt with the question of where state regulation could begin, and not with where federal regulation must end. Id. Accordingly, the limitation on federal seizure jurisdiction, even under the 1906 Act, may not have been necessary.

94To the extent that enforcement powers depend on violation of the 1938 Act, the breadth of such powers can only fully be seen in light of the acts proscribed and the elements necessary to constitute a violation.


97See A. Herrick, supra note 42, at 1184.
seized prior to the proceeding? Second, whether or not there is a requirement for prior seizure of the goods, is there any legal authority for executive seizure without process issued pursuant to libel proceedings? It appears that both of these questions can be answered in the affirmative. Although libel proceedings are basically actions in rem,97 which could indicate that possession of the goods is a prerequisite to jurisdiction, it has been held that a court acquires jurisdiction by the mere filing of the libel, even though it can exercise its power only when the property to be libelled has been seized.98 The question of necessity for seizure prior to institution of a proceeding under section 334 (a) (2) is raised in part by the language in section 334 (b) dealing with procedure. That section provides that “the procedure in cases arising under this section shall conform, as nearly as may be, to the procedure in admiralty.” Historically, admiralty procedure required a prior attachment of goods to be libelled.99 However, in cases under the Food, Drug, and Cosmetic Act, this aspect of admiralty procedure is apparently found inapplicable.100

Although it is not necessary that drugs subject to libel and condemnation under section 334 (a) (1) be seized prior to the institution of proceedings, it has been suggested that the power to do so exists.101 First, it is said that drugs being held or moving in violation of the Act may be characterized as contraband.102 Second, it has been thought that the right of prior seizure under admiralty procedure indicates a corresponding right, even if not a necessity, under the Food, Drug, and Cosmetic Act.103 However, neither of these theories seems entirely satisfactory in light of Congress' failure to provide explicitly for executive seizure in the case of adulterated or misbranded drugs. In the case of seizures relating to stimulant and depressant drugs, there can be no mistake about Congress' intent to provide the power of executive seizure.104

97 Id.
98 United States v. Capon Water Co., 30 F.2d 300 (E.D. Pa. 1929), dismissed sub nom. United States v. 94 Dozen Bottles C.S. Water, 48 F.2d 378 (E.D. Pa. 1930), aff'd, 51 F.2d 913 (3d Cir. 1931); United States v. George Spraul & Co., 185 F. 405 (6th Cir. 1911). Both of these cases were decided under the Food and Drugs Act of 1906. However, the issue apparently was not thought to exist after enactment of the 1938 Act against such a background of judicial decision.
99 See A. Herrick, supra note 42, at 1184.
100 See, e.g., 443 Cans of Frozen Egg Prod. v. United States, 226 U.S. 172 (1912); United States v. 5 Cases, etc., Figlia Mia Brand, 179 F.2d 519 (2d Cir. 1950); note 98 supra.
101 Although it would seem difficult to find authority for this power in the statutory language, many courts in dicta have appeared to acknowledge its existence. See cases cited in note 98 supra. See also A. Herrick, supra note 42, at 1185.
103 See note 101 supra, and accompanying text.
   (e) Any officer or employee of the Department designated by the Secretary to conduct examinations, investigations, or inspections under this chapter relating to depressant or stimulant drugs or to counterfeit drugs may, when so authorized by the Secretary—
   (f) make, prior to the institution of libel proceedings under section 334(a)(2) of this title, seizures of drugs or containers or of equipment, punches, dies, plates, stones, labeling, or other things, if they are, or he has reasonable grounds to believe that they are, subject to seizure and condemnation under such section 334(a)(2).
   In the event of seizure pursuant to this paragraph (f), libel proceedings under section 334(a)(2) of this title shall be instituted promptly and the property seized be placed under the jurisdiction of the court.
Value of Seizure, Libel and Condemnation. Similar to other powers for enforcement of the Food, Drug, and Cosmetic Act, the power of seizure serves a specific purpose in the regulatory scheme. Perhaps the clearest value of seizure, libel, and condemnation lies in the fact that drugs or goods violative of the Act may be prevented from reaching the hands of the consumer. Thus, unlike the injunction, or criminal prosecution, which at best affect persons with control over potentially harmful goods, the seizure provisions of the Food, Drug, and Cosmetic Act reach the goods themselves. Although with respect to seizure of adulterated or misbranded goods there must be (or must have been) movement of the goods in interstate commerce, the goods may even be seized from the consumer once this requirement is satisfied. For the owner of goods subject to libel, however, the remedy is rather harsh. If seizure is threatened, the owner may have little choice but to acquiesce in administrative objections to the goods. Such an owner may choose to defend in libel proceedings against condemnation of the goods, but the cost of so doing, and in many cases the risk that the goods will deteriorate, is prohibitive. The significant threat which seizure poses to the owner of drugs or other goods may effectively grant the administrative body adjudicatory power.

Because section 334 (b) provides that the procedure applicable in libel proceedings is to conform "as nearly as possible" to the procedure in admiralty, many questions are raised with respect to the extent of the application of Admiralty Rules. In the trial of the libel, the better view is that the Federal Rules of Civil Procedure apply. Although this makes applicable deposition and pretrial discovery in accordance with the Rules, other aspects of the proceeding are governed by judicial doctrine develop-

105 The leading case seems to be United States v. Olsen, 161 F.2d 669 (9th Cir.), cert. denied, 332 U.S. 768 (1947). In Olsen a device (within the meaning of the Act) was found to be misbranded, and was seized from the consumer, an individual, pursuant to 21 U.S.C. § 334 (1964). The court of appeals quickly dismissed the consumer's contention that the seizure was not constitutionally permissible. It is interesting to observe the reaction of the federal district court upon the Government's petition for process to seize the device in the case above: "I have before me the petition of the United States Attorney to issue an order of seizure . . . . Of course I must issue the order . . . . The policy of entering private homes to seize articles is governmental madness . . . . I am sad that the policy has to be enforced in this court." United States v. One Article of Device Labeled Spectro-Chrome, 77 F. Supp. 50 (D. Ore. 1948). The constitutionality of § 334 which the court found to be so clear, was supported by the decision in United States v. 935 Cases more or less, etc., Tomato Puree, 136 F.2d 523 (6th Cir. 1943). That case involved a seizure pursuant to process issued in libel proceedings. Although the court upheld the authority of federal officers to seize goods under § 334, its reasoning is not entirely clear. It found first that the libel proceedings are not criminal in nature, and from that finding seemed to conclude that the fourth amendment does not protect against seizure pursuant to civil actions. However, it also determined that there could be no search or invasion if the seizure is for the purpose of deciding whether the goods are fit for use. Finally, it seemed to rest the constitutionality of § 334 upon the commerce clause, finding that seizure such as involved in the case was merely a means appropriate to the end of protecting interstate commerce. It would seem, in light of Camara and other recent cases interpreting the fourth amendment requirement for warrants issued on probable cause, that none of the reasons announced by the court of appeals above effectively answers constitutional objections to summary seizure of goods without at least judicial process in the absence of an emergency situation.


ing around the Food, Drug, and Cosmetic Act. For example, at least one case has held the Government to a higher standard of proof than a mere preponderance of the evidence,\(^{10}\) although no court has held that the Government must establish its case beyond a reasonable doubt. What must be proved, of course, is that the goods themselves are, or are the product of, a violation of the Act.

Another question which has arisen in connection with the seizure of goods pursuant to libel proceedings is the nature of the process to be issued for their seizure—specifically, whether such process must meet requirements imposed on searches and seizures by the fourth amendment. Decisions dealing with this question have interpreted the Admiralty Rules not to require oath or affirmation of probable cause.\(^{11}\) However, in 1966, the Admiralty Rules and the Federal Rules of Civil Procedure were unified.\(^{12}\) Now, supplementary rule C(2) of the Federal Rules of Civil Procedure,\(^{11}\) dealing with complaints in in rem actions, may require oath and affirmation. The rule provides for such oath or affirmation in the filing of complaints for libel, but provides that if the complaint charges a violation of law, it must specify several things, none of which are probable cause for seizure of violative goods. Accordingly, the rule seems to admit the interpretation that no oath or affirmation is necessary.\(^{11}\)

Proposed Legislation. As was observed above, S. 3246 does not purport to deal with all aspects of drug regulation. Accordingly, the bill would leave substantially in force section 334. However, because the bill proposes to regulate a wider range of drugs than formerly covered by the terms “depressant and stimulant drugs” in the 1938 Act and subsequent amendments, all references to “stimulant and depressant” drugs would be eliminated. Several specific effects of the proposed legislation are as follows. First, section 334(a)(1) would remain unchanged. Its application, as now, would be limited to regulation of adulterated or misbranded drugs. Although the question seems fairly raised that executive seizure of adulterated or misbranded goods is not authorized, S. 3246 proposes no changes in that respect to section 334(a)(1). Also, the bill does not effect any

\(^{10}\) Van Camp Sea Food Co. v. United States, 82 F.2d 365 (3d Cir. 1936). The more widely accepted view is announced in United States v. Articles of Drug, etc., “Cal’s Tupelo Blossom U.S. Fancy Pure Honey,” 344 F.2d 288 (6th Cir. 1965).

\(^{11}\) United States v. 935 Cases more or less, etc., Tomato Puree, 136 F.2d 523 (6th Cir. 1943); United States v. 18 Cases of Tuna Fish, 5 F.2d 979 (W.D. Va. 1925). But see United States v. Eight Packages and Casks of Drugs, 5 F.2d 971 (C.C.S.D. Ohio 1918).

\(^{12}\) The former Rules of Practice in Admiralty and Maritime Cases, promulgated by the Supreme Court in 1920, were rescinded effective July 1, 1966. Now in effect are the Supplemental Rules for Certain Admiralty and Maritime Claims, and the Federal Rules of Civil Procedure.

\(^{11}\) Supplemental Admiralty Rule C(2), superceded former Admiralty Rules 21, 22.

\(^{13}\) Although supplemental rule C(2) is said to incorporate former rules 21 and 22, it is not clear whether it also supports the interpretation given those rules, that no oath or affirmation is required. Several views seem possible. First, it may be said that the requirement for oath or affirmation included in the new rule is simply the provision for oath or affirmation required by former rule 22 for instance causes, and accordingly, no such requirement exists in the case of seizures under the Food, Drug, and Cosmetic Act. Second, it could be said that the provision for oath or affirmation under the new rule applies only where the seizure is not for a violation of “any statute of the United States,” which would exempt most seizures under § 334 from the oath or affirmation requirement.
changes in the requirement for movement of adulterated or misbranded goods in interstate commerce prior to seizure. Second, under the bill, section 334 (a) (2) would apply only to seizure of counterfeit drugs, their containers, and related equipment. Provisions in section 334 (a) (2) formerly dealing with stimulant and depressant drugs would be covered by substantive provisions of the bill. Third, section 372 (e) would no longer apply to "stimulant or depressant drugs," since under the bill these drugs largely are regulated as controlled dangerous substances. Although section 372 (e) (5), which now authorizes executive seizure of drugs subject to section 334 (a) (2), would remain in force, it would apply only to seizure of counterfeit drugs in keeping with the changes in the latter section. No attempt is made by the bill to bring adulterated or misbranded drugs within the ambit of section 372 (e) (5), and thus within the express statutory authority for executive seizure.

Section 704 of S. 3246 provides the seizure and forfeiture power for the proposed legislation. The items which would be subject to seizure are:

1. All controlled dangerous substances "handled" in violation of the Act;
2. Raw materials, products, and equipment used or intended for use in "handling" controlled dangerous substances in violation of the Act;
3. Property used or intended for use as a container for items in the first two categories above;
4. Conveyances (except for conveyances of common carriers used unknowingly or a conveyance used by other than the owner in unlawful possession).

The bill provides for both judicial and executive seizures. In the first case the property is to be seized under process issued by a district court having jurisdiction over the property in accordance with the Supplemental Rules for Admiralty and Maritime Claims. Accordingly, the seizure process pursuant to libel proceedings (with process) is identical to that now in effect under rule C(2).

However, it is significant that the bill provides for the seizure of property in certain instances without such process. The instances enumerated by section 704 (b) are:

1. When the seizure is incident to an arrest or pursuant to the execution of a search warrant or administrative inspection warrant;
2. When the property to be seized has been the subject of a prior judgment for the United States;

115 Id. § 704 (a).
116 Id. § 704.
117 The section also provides for seizure and forfeiture of all books, records, and research, including formulas, microfilm, tapes, and data which are used or intended for use in violation of the act. Id.
118 Id. § 704 (b).
119 This is merely the terminology for the new rules. See note 111 supra.
120 See note 112 supra, and accompanying text.
3. When the Attorney General has probable cause to believe that the property is directly or indirectly dangerous to health or safety; or
4. When the Attorney General has probable cause to believe that the property has been used or is intended to be used in violation of the act.

It is important to recognize that under the bill, the seizure provisions apply with equal force to all drugs covered by the proposed legislation—a situation unlike that under existing law.

One objection to the "warrantless" seizure provisions of the bill has been to the breadth of section 704(b)(4) (No. 4 above). It has been urged that provision for seizure of goods without process, where the Attorney General has probable cause to believe that they are to be used in violation of the Act, obviates the necessity of ever obtaining the process. However, as was observed before, this provision does not seem to grant any authority which is not now available under section 334(a)(2) and section 372(e)(5) with respect to stimulant and depressant drugs. Although one way to remedy this problem would be to strike the provision entirely, it would seem that a suitable compromise would be achieved by use of the following language: "When the Attorney General has probable cause to believe that the property has been used or is intended to be used in violation of this Act, and circumstances render it impracticable to obtain judicial process." This language would provide by statute for what is clearly constitutionally permissible in the same manner as section 703 of the bill provides for certain warrantless inspections.

Another objection, with respect to the seizure provisions of the bill generally, is that the property made subject to forfeiture, and hence seizure, imposes an excessively harsh penalty on persons committing a minor or unintentional violation. It is reasoned that an entire business effectively could be closed by seizure of drugs, equipment, and other property merely for failure to comply with a small requirement of the proposed legislation (and perhaps one not related to the goods seized). It is possible that forfeiture and seizure could be limited in application to violations of section 302(a) of the bill—the requirement that persons intending to engage in certain activities relating to controlled dangerous substances register with the Attorney General. However, despite the merit in these objections, it seems clearly unworkable to limit forfeiture to persons who have failed to register. Registration in itself accomplishes little. Even if a "presumption of lawful activity" could be afforded persons properly registered, it is no answer to put such persons entirely beyond the reach of the governmental seizure power.

It is interesting to compare these features of S. 3246, generally, with provisions and developments under existing law commented on above. Although in many ways the provision for executive seizure under the bill...
seems to broaden the seizure power, it is clear that in at least one respect the power of the Attorney General is limited. Under section 372(e)(5), the executive seizure authorized for depressant and stimulant goods is not expressly conditioned upon a showing of probable cause, as is the warrantless seizure authorized by section 705 of the bill. At least arguably under the former provision, a lesser degree of certainty that the Act had been violated would support seizure of goods prior to the institution of libel proceedings. However, the decisions in Camara and See suggest that provisions under existing law may rest on less than solid constitutional ground. It is clear that the Court was silent in those decisions on the effect which the requirement for warrants and probable cause in inspections may have on other areas of the law. Nevertheless, the Court reaffirmed in Camara the principle that under the fourth amendment, a search of private property is unreasonable unless it is authorized by a valid search warrant based on probable cause—a principle which also must apply to seizures. The only exception to this principle which the Court expressly recognized is the entrance of government officials in emergency situations. It cited several cases involving the seizure of unsafe goods to support this exception, but it is not clear whether it interpreted such dangers to public health always to constitute an emergency. It is generally acknowledged that to dispense with the requirement of a warrant in certain instances is not also to dispense with the requirement of probable cause. Although the warrantless seizure provisions of S. 3246 seem to avoid this problem, it seems clear that existing section 372(e)(5) may be subject to attack for not meeting fourth and fourteenth amendment requirements.

V. SUBPENA

One of the most significant enforcement powers under existing drug legislation is the "administrative subpoena" power provided by section 198a. Unlike the other enforcement powers discussed above, section

126 The bill broadens the seizure power principally by making all classes of drugs (controlled dangerous substances) subject to seizure. Id. §§ 704(a)(1), (b).
130 Some of the constitutional questions raised by the seizure power are discussed in Carden, Federal Power To Seize and Search Without a Warrant, 18 Vand. L. Rev. 1 (1964).
131 21 U.S.C. § 198a (1964). Compare the judicial subpoena provided under the Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 337 (1964). At one time the authorization of administrative subpoena was thought to be beyond the power of Congress. However, objections to such subpoenas were principally where they were authorized for use in matters not related to law enforcement or adjudication. Although objections such as these may still have merit with respect to general subpoenas, it should be noted that existing law [21 U.S.C. § 198a (1964)] limits use of the administrative subpoena power to investigations which the Secretary of the Treasury considers necessary to the enforcement of laws relating to marijuana and narcotics. The proposed legislation would not seem to be so restrictive, applying to "any matter relating to the control of dangerous substances." Compare Jones v. SEC, 298 U.S. 1 (1936) (rejecting use of administrative subpoena even for law enforcement) with McGrain v. Daugherty, 273 U.S. 133 (1927) (finding the subpoena to be a part of the legislative function, but not deciding whether the power may be delegated). See Davis, The Administrative Power of Investigation, 56 Yale L.J. 1111, 1120 (1947).
198a is not a part of the Federal Food, Drug, and Cosmetic Act, but rather is a part of the laws relating to narcotics and marijuana. Because these substances are generally not processed by the drug industry, the subpoena power provided by section 198a has not been of direct importance in industrial regulation. However, S. 3246 provides for administrative subpoena in the regulation of controlled dangerous substances, and because of this fact, the administrative subpoena merits attention. Section 198a provides that "for the purpose of any investigation" which the Secretary of the Treasury considers necessary to the enforcement of narcotics and marijuana laws, he is empowered to (1) administer oaths, (2) subpoena witnesses, (3) compel the attendance of witnesses, (4) take evidence, and (5) require the production of any records (including books, papers, documents, and tangible things which constitute or contain evidence) which he finds relevant or material to the investigation. Prior to enactment of section 198a, it was necessary for the Secretary to obtain subpoenas through a federal court. Because of the frequent difficulty in producing sufficient evidence to obtain a judicial subpoena, valuable material and information often was unavailable.

Although the section has not been the subject of much litigation, several recent cases indicate some of the values of the power and at the same time some of the problems raised by its use. In the first case, United States v. Pardo-Bolland, defendants had arranged to meet in New York where they planned to effect the purchase and sale of a substantial quantity of heroin. Upon arrival in New York, one of the defendants, the seller, sent a cablegram to an accomplice, presumably to advise him that he had arrived and was prepared to make the sale. When by accident the buyer and seller failed to meet as planned, the seller sent another cablegram to the accomplice. Although this cablegram, like the first, was "coded," it was apparently for the purpose of verifying the place at which the meeting was to have taken place. In each instance when the cablegram was sent, a federal narcotics agent witnessed the transaction between the sender and the Western Union operator, and obtained a copy of the transmission from the operator. When the defendants subsequently were arrested and charged with violation of the narcotics laws, they contended that the cablegrams were inadmissible as evidence because they were obtained in violation of section 605 of the Federal Communications Act. That section basically provides that no communications agent shall divulge the existence or contents of an interstate or foreign message except in response to a subpoena or on demand of other lawful authority, and that no person unauthorized by the sender shall intercept and divulge the contents of the message. The Government contended (1) that the action of the agent

1[6] The subpoena to which the statute refers is a "subpena issued by a court of competent jurisdiction." Thus, an administrative subpoena would not be authorized by this language for use in obtaining communications.
in obtaining the content of the message constituted a "demand of other lawful authority," or in the alternative, (2) that because the agent determined the existence of the cablegrams from his own independent and lawful observation, and because the content of the cablegrams was also discovered pursuant to an administrative subpoena under section 198a, the evidence was admissible.137 Although the court rejected the Government's first contention, it found the cablegrams admissible on the alternative argument. It determined that even though the agent violated section 605 of the Federal Communications Act in learning the content of the messages, the evidence was admissible because the cablegrams could have been, and were, subpoenaed independently of that violation.

It seems that the principal significance of Pardo-Bolland lies not in the type of evidence found available under the administrative subpoena, but rather in the fact that the subpoena power may render admissible, under certain circumstances, evidence which was obtained illegally by a narcotics agent. There is little question that the "doctrine of independent source" supports the decision in this case.138

However, two recent cases, though reaching a similar result, raise a question about the availability of such information pursuant to an administrative demand. In DiPiazza v. United States139 and United States v. Michigan Bell Telephone Co.140 the Internal Revenue Service attempted to exercise a statutory summons141 in order to obtain records of certain long-distance telephone calls. In DiPiazza records were obtained which tended to implicate the defendant in illegal wagering operations. On trial for violation of wagering tax laws, the defendant contended that the records should not be admissible as evidence because they were obtained in violation of section 605 of the Federal Communications Act. In the second case, attempts by the Government to obtain similar records were unsuccessful because of the telephone company's refusal to comply with the demand. The company, tried for contempt of the Internal Revenue summons, likewise defended on the ground that the records were protected by section 605.

The first issue presented to the court in each case was whether the summons could be employed where it would reveal evidence which could be used in a criminal prosecution. The courts determined on the basis of prior decisions, that if civil tax liability also would be shown by the evidence, the summons would not in itself be improper.142 The second issue  

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137 Apparently the court determined that the administrative subpoena constituted "other lawful authority" within the meaning of the statute.
138 Silverthorne Lumber Co. v. United States, 251 U.S. 385 (1920).
139 415 F.2d 99 (6th Cir. 1969).
140 415 F.2d 1284 (6th Cir. 1969).
142 Although the court treated this question as one of statutory limitation, it appears that a constitutional question may be raised. The statute providing for the Internal Revenue summons (see note 141 supra) seems to limit the use of the summons to instances where the taxpayer's tax liability is to be determined. However, one of the first cases to deal with the question found the summons to enter the domain of the grand jury where it was used for the purpose of gathering information in connection with a criminal prosecution which had already begun. United States v. O'Connor, 118 F. Supp. 248 (D. Mass. 1953). Later, in Boren v. Tucker, 239 F.2d 767 (9th Cir. 1956).
was whether the telephone company in each instance had violated section 605 by the "interception" of calls for the purpose of making and maintaining records. The courts found that such recordkeeping was not an interception within the meaning of the section, and therefore not a violation of the statute. It is significant, however, that the records involved in these instances were only slightly more detailed than the records sent to subscribers at the end of each month for purposes of billing.

The most important issue presented to the courts was whether the demand by the summons would require a "divulgence" in violation of the Federal Communications Act. In DiPiazza the court held that the Internal Revenue summons constituted a "lawful authority" within the meaning of section 605, and therefore was a proper device for obtaining records of communications. However, the fact situation in DiPiazza occurred prior to amendment of section 605, as did the fact situation in Pardo-Bolland. In 1968, Congress enacted the Omnibus Crime Control and Safe Streets Act, which included a revision of section 605 of the Federal Communications Act. The amendment of section 605 and the inclusion of several safeguards against diversion of communications, such as the requirement for a judicial order authorizing interception, may have an effect on decisions such as Pardo-Bolland and DiPiazza. Indeed, the court remanded the case in Michigan Bell Telephone for the district court to determine the effects of the Omnibus Crime Act, since the fact situation in that case arose after amendment of section 605. Although the Omnibus Crime Act generally has increased the controls over the dissemination of communications, nothing in that Act or in the amendment to section 605 would seem to demand a different interpretation of "other lawful authority" than that in the cases above. Nevertheless, until the district court decides the question, the relationship between section 605 and the administrative subpoena power will not be entirely clear.

It is interesting to observe that the proposed provision for administrative subpoena provides, as does existing law, for judicial enforcement of the administrative subpoena. Moreover, failure to comply with the subpoena once the aid of the court has been invoked, may be punished as contempt. Unlike the contempt proceedings provided by existing law in the case of

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1956), the court found that if the summons also produced evidence which would be relevant in determining the taxpayer's tax liability, its use would be proper. The decision in Boren was followed in Birdsell v. United States, 272 F. Supp. 308 (S.D. Fla. 1967), but there the court indicated that even if the summons were used to produce evidence relating to a person's tax liability, a motion to suppress the evidence might be appropriate if the evidence were later offered in connection with criminal prosecution. None of these decisions makes clear the basis for the distinction between use of the summons for civil purposes, and use of it for criminal prosecution. The answer may lie in the decision in DiPiazza. Use of such an administrative demand will be accorded a wide discretion, but the right against self-incrimination may prevent use in criminal proceedings of information thus obtained.

143 18 U.S.C. § 2516 (Supp. IV, 1968). This section requires written application for an order authorizing interception of communications subject to the Federal Communications Act. Among other things, the judge must be satisfied, before issuing the order, that other means of obtaining the information have been tried (or would be fruitless), that interception of a communication is necessary, and that there is probable cause to believe that some crime is being committed.
injunctions, no provision is made in either existing law or proposed law for the nature of the contempt proceedings. Although the question has yet to arise, it seems clear that the decision in *Bloom* may have significant effect on the power to conduct proceedings such as this, without certain safeguards such as the right to trial by jury. Of course, *Bloom*’s effect may not be felt unless the punishment for contempt is sufficiently great to make the contempt a "serious" offense. However, if the failure to comply with the subpoena also constitutes a crime (such as the failure to produce records which must be produced upon demand under the Act), the constitutional question is again raised. Also, the Supreme Court has held that administrative subpoenas are not without constitutional protection in other respects. For example, the Court has held that such subpoenas must be sufficiently specific and limited in scope as not to be unreasonably burdensome.147

VI. CONCLUSION

This discussion of current and proposed legislation demonstrates that the much-amended statutory scheme for the regulation of drugs has been greatly affected by developments in many areas other than law. It is clear that new drug laws are needed. While the proposed legislation alters somewhat the scope of governmental enforcement powers, and generally attempts to incorporate current constitutional doctrine, it is equally clear that even if Congress approves the proposals now before it, much remains to be done.

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