UNITED STATES *v.* AN ARTICLE OF DRUG . . . BACTO-UNIDISK . . . .

CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT.

No. 343. Argued January 23, 1969.—Decided April 28, 1969.

Antibiotic sensitivity disc used as laboratory screening test to help determine proper antibiotic drug to administer to patients *held* not merely a "device" but a "drug" within definition of § 201 (g)(1)(B) of the Federal Food, Drug, and Cosmetic Act and thus subject to pre-market clearance regulations issued pursuant to § 507 of the Act. Pp. 791–801.

392 F. 2d 21, reversed.

Lawrence G. Wallace argued the cause for the United States. With him on the brief were *Solicitor General Griswold, Assistant Attorney General Vinson, Beatrice Rosenberg, Ronald L. Gainer,* and *William W. Goodrich.*

Edward Brown Williams argued the cause and filed a brief for respondent.

MR. CHIEF JUSTICE WARREN delivered the opinion of the court.

At issue here is the scope of the statutory definition of drug contained in the Federal Food, Drug, and Cosmetic Act and the extent of the Secretary of Health, Education, and Welfare's regulatory authority under that definition. The specific item involved in this definitional controversy is a laboratory aid known as an antibiotic sensitivity disc, used as a screening test for help in determining the proper antibiotic drug to administer to patients. If the article is a "drug" within the general definition of § 201 of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1040, 21 U. S. C. § 321 (1964 ed., Supp. II)), then the Secretary can subject it to pre-market clearance regula-

tions promulgated pursuant to § 507 of the Act (21 U. S. C. § 357). Section 507 authorizes the Secretary to require batch certification of any antibiotic product which also meets the general drug definition of § 201. If, on the other hand, the article is merely a "device" under the Act, it is subject only to the misbranding and adulteration proscriptions of the Act and does not have to be pre-tested before marketing; and, of course, if the disc does not fall under either definition, the Act itself is totally inapplicable.

When the discs were marketed without complying with the certification regulations of the Secretary, the Government condemned them pursuant to § 334 of the Act (21 U. S. C. § 331) on the assumption that the discs were drugs and thus validly subject to pre-market regulation. In this action following the condemnation, however, the United States District Court for the Eastern District of Michigan held that the discs were not drugs within the meaning of the Act, suggesting that, if anything, they were devices. It therefore ruled that, since pre-market clearance was not required or authorized, the seizure was improper. The Court of Appeals for the Sixth Circuit affirmed on the same reasoning. We reverse.

I.

Some background information about the development of the discs and the controlling legislation is necessary for an understanding of the determinations made by the Secretary and the courts below. Various antibiotics, known more commonly as "wonder drugs" under such familiar names as penicillin, aureomycin, terramycin, tetracycline, and streptomycin, have proved very useful since World War II in treating numerous infectious diseases.[1] Produced biologically, however, these drugs

[1] See generally L. Goodman & A. Gilman, The Pharmacological Basis of Therapeutics (3d ed., 1965).

tend to vary greatly in their quality and potency unless developed, and thereafter tested, under very carefully controlled conditions. Consequently,[2] Congress enacted § 507 of the Food, Drug, and Cosmetic Act, directing the Secretary of Health, Education, and Welfare to

[2] See H. R. Rep. No. 702, 79th Cong., 1st Sess. (1945). Section 507, as set forth in 21 U. S. C. § 357, reads as follows:

"(a) The Secretary of Health, Education, and Welfare, pursuant to regulations promulgated by him, shall provide for the certification of batches of drugs composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof. A batch of any such drug shall be certified if such drug has such characteristics of identity and such batch has such characteristics of strength, quality, and purity, as the Secretary prescribes in such regulations as necessary to adequately insure safety and efficacy of use, but shall not otherwise be certified. Prior to the effective date of such regulations the Secretary, in lieu of certification, shall issue a release for any batch which, in his judgment, may be released without risk as to the safety and efficacy of its use. Such release shall prescribe the date of its expiration and other conditions under which it shall cease to be effective as to such batch and as to portions thereof. For purposes of this section and of section 352 (*l*) of this title, the term 'antibiotic drug' means any drug intended for use by man containing any quantity of any chemical substance which is produced by a microorganism and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

"(b) Regulations providing for such certifications shall contain such provisions as are necessary to carry out the purposes of this section, including provisions prescribing (1) standards of identity and of strength, quality, and purity; (2) tests and methods of assay to determine compliance with such standards; (3) effective periods for certificates, and other conditions under which they shall cease to be effective as to certified batches and as to portions thereof; (4) administration and procedure; and (5) such fees, specified in such regulations, as are necessary to provide, equip, and maintain an adequate certification service. Such regulations shall prescribe only such tests and methods of assay as will provide for certification or rejection within the shortest time consistent with the purposes of this section."

promulgate regulations establishing such standards of identity, potency, quality, and purity as necessary to ensure the "safety" and "efficacy" of those antibiotics. At present, more than 30 antibiotic drugs are listed (21 CFR § 145.3) with accompanying regulations covering more than 700 pages in the Code of Federal Regulations (21 CFR §§ 141.1–148z.4).

With the proliferation of the various types of antibiotics, doctors found a need for a screening test to help choose which antibiotic to use in treating a particular infection. A diffusion test, using antibiotic sensitivity discs like the one in question here, soon became a widely employed screening method.[3] In this test, a round paper disc, which has been impregnated with a specific antibiotic, is placed in contact with sample cultures, or isolates, of a patient's virus, grown in a special culture medium (agar) from a specimen of the patient's fluid (blood, spinal fluid, sputum, urine, etc.). In those places impregnated with an antibiotic to which the patient's infection is sensitive, no new isolate will grow, leaving a clear area (an "inhibition zone"); in those places impregnated with a drug to which the infection is resistant, the isolate will grow, leaving no clear area. The disc is used, in conjunction with a patient's specimen, in laboratory work exclusively, and never comes in contact with any part of the patient's body itself.

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[3] See generally Bauer, Kirby, Sherris, & Turck, Antibiotic Susceptibility Testing by a Standardized Single Disk Method, 45 American Journal of Clinical Pathology 493 (1966); Petersdorf & Sherris, Methods and Significance of In Vitro Testing of Bacterial Sensitivity to Drugs, 39 American Journal of Medicine 766 (1965); Gould, The Laboratory Control of Antibiotic Therapy, 3 Chemotherapia 477 (1961); Second Report of the Expert Committee on Antibiotics, Standardization of Methods for Conducting Microbic Sensitivity Tests, World Health Organization Technical Report Series No. 210, pp. 12–17 (1961).

The discs had been in general use for some four years when, in 1960, the Secretary of Health, Education, and Welfare determined to regulate them pursuant to § 507. After notice and an opportunity for public participation, the Commissioner of Food and Drugs, under authority delegated by the Secretary, promulgated regulations requiring pre-clearance, batch-testing, and certification of antibiotic sensitivity discs (25 Fed. Reg. 9369). The Commissioner's action, the regulations noted, followed "numerous complaints by the medical profession, hospitals, and laboratory technicians" and a resulting extensive survey of the use of the discs. That study found the discs unreliable in their statements of potency with resulting loss of safety and efficacy, and thus found it "vital for the protection of the public health" to adopt the regulations (25 Fed. Reg. 9370).

This case arose in May 1962 as an *in rem* seizure proceeding against an interstate shipment of a number of cases of sensitivity discs, manufactured by Difco Laboratories, Inc., under the trade name of "Bacto-Unidisk." In condemning the product pursuant to § 301 *et seq.* of the Food, Drug, and Cosmetic Act, the United States claimed, *inter alia,* that the product, as a "drug" within the meaning of the Act, had not been certified nor exempted from certification as required by § 507 (21 U. S. C. § 357) and the regulations thereunder and was therefore misbranded under § 502 (21 U. S. C. § 352).[4] The seizure was proper only if the Secretary's

[4] Section 502, as set forth in 21 U. S. C. § 352, reads, in part, as follows:

"A drug or device shall be deemed to be misbranded—

. . . . . .

"(*l*) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant

regulations subjecting the discs to the pre-market clearance requirements were authorized by the Act. Since the scope of the Secretary's pre-market regulatory power over antibiotic drugs under § 507 depends ultimately on the Act's general definition of "drug" in § 201 (g), the validity of the disc regulations allegedly violated turned on the coverage of the drug definition:

> "For the purposes of this chapter—
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> . . . . . .
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> "(g)(1) The term 'drug' means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph; but does not include devices or their components, parts, or accessories." 21 U. S. C. § 321 (1964 ed., Supp. II).

If, on the other hand, the product was a "device," only the misbranding, adulteration, and labeling provisions of §§ 501 and 502 applied, and the Secretary's disc certification regulations were invalidly promulgated. Although a "device" expressly cannot be a "drug" under the last phrase of the drug definition above, a device is given almost a parallel definition in § 201 (h):

> "The term 'device' . . . means instruments, apparatus, and contrivances, including their components,

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to section 357 of this title, and (2) such certificate or release is in effect with respect to such drug: *Provided,* That this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under section 357 (c) or (d) of this title."

parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals." 21 U. S. C. § 321 (h).

Finally, it was established at trial that of the various definitions given above, the operative ones in this case were § 201 (g)(1)(B) of the drug provision and § 201 (h)(1) of the parallel device definition; [5] the essential question underlying the validity of the regulations, then, was whether the Bacto-Unidisks were "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals."

In resolving this question in the negative and holding the seizure invalid, the District Court noted in a memorandum opinion [6] that the concept of drug is limited in a medical sense to articles administered to man either externally or internally, and ruled that the "evidence affords no basis for the conclusion that the definition of 'drug' in the Federal Food, Drug, and Cosmetic Act . . . was intended by Congress to extend beyond the meaning of that term in medical science, to encompass these sensitivity disks." The District Court pointed out that although a "literal reading" of § 201 (g)(1)(B) "clearly has application to the article libeled herein," enforcing such an application would be "ridiculous and contrary to common sense." The court therefore held that the Bacto-Unidisk did not fall within the purview of the Act for the reason that it was not medically a drug, and

[5] Respondent's witnesses established that sensitivity discs are not listed in the United States Pharmacopoeia or the National Formulary, and thus do not come within that portion of the definition of "drug" in § 201 (g)(1)(A).

[6] The District Court's opinion is unreported; its pertinent findings of fact and conclusions of law are quoted in the opinion of the Court of Appeals, 392 F. 2d 21, 22–23 (1968).

suggested, without deciding, that the discs would be more appropriately classified as "devices" under the Act.

On appeal, the Court of Appeals for the Sixth Circuit affirmed, accepting the District Court's conclusions that the Bacto-Unidisk was not a "drug" in the medical sense of the term and that Congress did not intend the statutory definition of "drug" to be any broader than the medical one. 392 F. 2d 21, 23. The court noted that the discs did aid physicians in the determination of what antibiotic to use for the cure, mitigation, or treatment of disease by furnishing useful information, but held that Congress did not intend to apply the statutory phrase "intended for use in the . . . cure, mitigation, [or] treatment" in such an indirect manner. 392 F. 2d 21, 22. We granted the Government's petition for certiorari because this interpretation of the Act raised issues of importance in the administration of the Federal Food, Drug, and Cosmetic Act (393 U. S. 911 (1968)).

II.

Although there was some testimony below debating the precise extent of the public health dangers posed by the sensitivity discs, the courts below declined to substitute their judgment for that of the Commissioner of Food and Drugs by determining whether his action was really necessary to protect the public health from a purely medical viewpoint. Rather, the courts below quite properly confined the inquiry to an examination of whether the disc regulations, even if medically unwise, were authorized by the Act, and more specifically, by the Act's definition of "drug." Despite the renewed effort here to relitigate the public health issue, we agree with the decision implicitly made by the courts below not to base a resolution of this case on the public need for, or medical wisdom of, the Secretary's regulations requiring pre-market clearance of antibiotic sensitivity discs. It

is enough for us that the expert agency charged with the enforcement of remedial legislation has determined that such regulation is desirable for the public health, for we are hardly qualified to second-guess the Secretary's medical judgment. Our sole concern is whether the statute's definition of "drug" authorizes the disc regulations contested here; and while we agree with the lower courts' limited conception of the issue, for reasons outlined below, we reverse their disposition of it.

Respondent's primary contention here is that the sensitivity discs are not subject to any of the provisions of the Act because Congress did not intend it to cover articles used so *indirectly* in the "cure, mitigation, [and] treatment" of disease. Respondent uses the same two-step analysis relied on by the courts below: (1) Congress did not intend to write the drug definition more broadly than does the medical profession, and (2) the medical concept of drug is limited to articles that are administered to man either internally or externally. Alternatively, respondent argues, even if the Act's "intended for use" language does cover the discs, they must clearly be classified as devices. In view of the legislative history discussed below and the broad, remedial purpose of the Act itself, however, we hesitate to give the critical language such a narrow, restrictive reading in the absence of congressional direction to do so, and we therefore reject the contention that the discs do not properly fall within the purview of the Act. For the same basic reasons, we furthermore reject the argument that the discs, once found to come under the Act's coverage, must be classified specifically as devices and not drugs.

We need not stop to parse the language of the Act's definition of drug, for the District Court found, and the parties do not disagree here, that a literal reading of the words "intended for use in the . . . cure, mitigation, [or] treatment" of disease "clearly has application" to

the Bacto-Unidisk. Although respondent again urges that the disc itself does not "treat" a patient in the same way an antibiotic does in terms of personal application, the disc plays at least some role in the selection of the appropriate drug. Thus, the essential question for our determination is whether Congress intended the definition of drug to have the broad coverage the courts below and the parties agree its words allow. Viewing the structure, the legislative history, and the remedial nature of the Act, we think it plain that Congress intended to define "drug" far more broadly than does the medical profession. The reason for including a separate, almost parallel, definition of "devices" in the Act is, as the legislative history shows, relevant to congressional intent. It is therefore helpful to consider both the question of the Act's initial application and the question of the drug-device dichotomy at the same time.

III.

At the outset, it is clear from § 201 that the word "drug" is a term of art for the purposes of the Act, encompassing far more than the strict medical definition of that word. If Congress had intended to limit the statutory definition to the medical one, it could have so stated explicitly, or simply have made reference to the official United States Pharmacopoeia (or the National Formulary), as it did in the first of the three subsections of § 201 (g)(1), and let the definition rest there. The historical expansion of the statute's definition, furthermore, clearly points out Congress' intention of going beyond the medical usage. The 1906 Food and Drug Act, for instance, defined "drug" in a rather limited way to include "all medicines and preparations recognized in the United States Pharmacopoeia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, miti-

gation, or prevention of disease of either man or other animals." 34 Stat. 768, 769. As subsequent congressional action clearly indicates, however, the scope of that original definition has since been greatly enlarged.

The enactment of the 1938 Federal Food, Drug, and Cosmetic Act illustrates the expansion of the definition of drug. One of the changes contemplated in S. 2800, an early version of the Act,[7] defined "drug" to include

> "(1) all substances and preparations recognized in the United States Pharmacopoeia, Homoeopathic Pharmacopoeia of the United States, or National Formulary or supplements thereto; and (2) all substances, preparations, and *devices* intended for use in the cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) all substances and preparations, other than food, and all devices intended to affect the structure or any function of the body." (See S. Rep. No. 493, 73d Cong., 2d Sess. (1934).) (Emphasis added.)

Senator Copeland of New York, who sponsored the Act, remarked about the inclusion of the word "devices" in his prepared statement introducing S. 2800 as follows:

> "The present law defines drugs as substances or mixtures of substances intended to be used for the cure, mitigation, or prevention of disease. This narrow definition permits escape from legal control of all therapeutic or curative devices like electric belts, for example. It also permits the escape of

[7] The earliest versions were S. 1944, 73d Cong., 1st Sess. (1933), and S. 2000, 73d Cong., 2d Sess. (1934). S. 2800 was succeeded by S. 5, 74th Cong., 1st Sess. (1935). S. 5 died in the House, but was succeeded by S. 5, 75th Cong., 1st Sess. (1937), and was the bill eventually enacted into law, as supplemented by S. 3073, 75th Cong., 2d Sess. (1937), and H. R. 9341, 75th Cong., 3d Sess. (1938).

Most of the Act's legislative history is reprinted in C. Dunn, Federal Food, Drug, and Cosmetic Act (1938).

> preparations which are intended to alter the structure or some function of the body, as, for example, preparations intended to reduce excessive weight. There are many worthless and some dangerous devices and preparations falling within these classifications. S. 2800 contains ample authority to control them." (78 Cong. Rec. 8960 (1934).)

The definition was revised in S. 5, 74th Cong., 1st Sess. (1935), to include substances, preparations, and devices intended for *diagnostic* purposes, as well as for cure, mitigation, treatment, or prevention of disease (S. 5, § 201 (b), S. Rep. No. 361, 74th Cong., 1st Sess. (1935)).[8] As the inclusion of the word "diagnosis" came before the Senate for consideration, a controversy developed on the floor, aimed more at the word "devices," which was not then before the Senate, than at the word "diagnosis." 79 Cong. Rec. 4841–4845 (1935).[9] Senator Clark contended that it was not proper to classify devices as drugs, and that diagnostic devices were so broadly defined as to make even a bathroom scale a drug:

> "[I]f the devices ought to be outlawed, they ought to be outlawed, and I have no objection to that; but to maintain that a purely mechanical device is a drug and to be treated as a drug in law and in logic and in lexicography is a palpable absurdity, in my opinion." *Id.*, at 4841.

In answer to Senator Clark's remark that a bathroom scale would be classified as a drug, Senator Copeland made the following comment:

> "Mr. President, I desire to state the effect of this amendment. There are on the market certain electrical devices. A man takes hold of the handles of the machine, and the indicator spins around.

[8] See Dunn, *supra*, n. 7, at 214, 237, 239.

[9] *Id.*, at 286–296.

> It stops at 'appendicitis,' or it stops at 'meningitis' . . . . Such a device is manifestly a fraud upon society. That is what the amendment is designed to deal with." *Id.*, at 4842.

Despite Senator Copeland's proffered explanation, there was continued criticism during the Senate debates (79 Cong. Rec. 4905–4920, 5215–5234)[10] of the definition on the ground that it would lead to the incongruous result of calling the following items "drugs": shoulder braces (*id.*, at 4841), radium belts (*ibid.*), electrical devices (*id.*, at 4842), bathroom weight scales (*ibid.*), and hospital air conditioning apparatus (*id.*, at 5231).[11] The opposition finally settled on "crutches" (*id.*, at 4913)[12] to signify the ultimate absurdity of the drug definition's broad coverage.

As a result of the criticism on the Senate floor, Senator Copeland proposed an amendment to add a definition of "device" to parallel that of drug, an amendment which was included [13] when the bill was returned to the Senate Committee on Commerce and later agreed to by the Senate without debate. (*Id.*, at 8351–8355.[14]) The

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[10] *Id.*, at 348–385, 429–476.

[11] *Id.*, at 429 (remarks of Senator Clark).

[12] *Id.*, at 369. Senator Bailey of North Carolina remarked:

"I do not think the President of the United States would tolerate for a moment a piece of legislation that described crutches as 'drugs' and advertising as 'adulteration,' carrying the English language and the law very far."

[13] The substitute committee report noted only that: "A definition of devices is provided paralleling that of drugs. This expansion of the definition of the term 'drug' and the inclusion of devices are essential if the consumer is to be protected against a multiplicity of abuses not subject to the present law." (S. Rep. No. 646, 74th Cong., 1st Sess. (1935).) See Dunn, *supra*, n. 7, at 477.

[14] *Id.*, at 495–496.

ultimate effect of the various amendments, of course, was still to include devices under the control of the Act for the first time, the goal Senator Copeland had originally set out to achieve. As Congressman Chapman of Kentucky explained to the House after the bill had passed the Senate, "For the first time it is proposed in a bill before Congress to control therapeutic devices . . . . There are hundreds of worthless contrivances being sold to and used by gullible people. Suffice it to say that a fake contraption for the cure of consumption is just as serious a menace to health as is a worthless drug sold for the same disease." 80 Cong. Rec. 10236 (1936).[15] According to the Chief of the Food and Drug Administration, the reason for providing a separate definition of devices, instead of using Senator Copeland's original drug definition, was simply to avoid "the incongruity of classifying certain devices, such as the electric belt, therapeutic lamps, and so forth, as drugs . . . ." (Testimony given during hearings held on S. 5 by a subcommittee of the House Committee on Interstate and Foreign Commerce, 74th Cong., 1st Sess. (1935).[16]) Because of that incongruity as "pointed out by the Senate in the last consideration of the bill," the official explained, "[t]hey felt it proper to provide an independent definition of 'devices.'" Thus, it is clear that two parallel definitions were provided for semantic reasons only; for the purposes of the Act, the two definitions had the same effect of subjecting both drugs and devices to the adulteration and misbranding provisions. No practical significance to the distinction between the two words arose until the pre-market clearance provisions, similar to the certification regulations for antibiotics enacted in 1945, were added after a drug

[15] *Id.*, at 571.

[16] *Id.*, at 1235, 1247.

tragedy in the fall of 1937.[17] (S. 3073, 75th Cong., 2d Sess.) The excepting clause of § 201 (g)(1), stating clearly that a drug cannot be a device, was also added in 1938 (S. 5, 75th Cong., 3d Sess., H. R. Rep. No. 2139).

The historical expansion of the definition of drug, and the creation of a parallel concept of devices, clearly show, we think, that Congress fully intended that the Act's coverage be as broad as its literal language indicates—and equally clearly, broader than any strict medical definition might otherwise allow. Strong indications from legislative history that Congress intended the broad coverage the District Court thought "ridiculous" should satisfy us that the lower courts erred in refusing to apply the Act's language as written. But we are all the more convinced that we must give effect to congressional intent in view of the well-accepted principle that remedial legislation such as the Food, Drug, and Cosmetic Act is to be given a liberal construction consistent with the Act's overriding purpose to protect the public health, and specifically, § 507's purpose to ensure that antibiotic products marketed serve the public with "efficacy" and "safety." Cf. *United States* v. *Sullivan,* 332 U. S. 689, 693–695 (1948); *United States* v. *Dotterweich,* 320 U. S. 277, 283–284 (1943).

IV.

Respondent's alternative contention, that even if its product does fall within the purview of the Act, it is plainly a "device" and therefore by definition necessarily

[17] This was the "Elixir-Sulfanilamide" tragedy of September-October, 1937, where nearly 100 persons died as the result of consuming an untested drug. See Report of the Secretary of Agriculture on Deaths Due to Elixir Sulfanilamide-Massengill (submitted in response to S. Res. 194 of November 16, 1937), in Dunn, *supra,* n. 7, at 1316–1327.

not a "drug," must also be rejected, we believe, in light of the foregoing analysis. At the outset, it must be conceded that the language of the statute is of little assistance in determining precisely what differentiates a "drug" from a "device": to the extent that both are intended for use in the treatment, mitigation and cure of disease, the former is an "article" and the latter includes "instruments," "apparatus," and "contrivances." Despite the obvious areas of overlap in definition, we are not entirely without guidance in determining the propriety of the Secretary's decision below, given the overall goals of the Act and its legislative history.

More specifically, as we have previously held in an analogous situation where the statute's language seemed insufficiently precise, the "natural way" to draw the line "is in light of the statutory purpose" (*SEC* v. *Ralston Purina Co.*, 346 U. S. 119, 124–125 (1953)).[18] Since the patient will tend to derive less benefit and perhaps some harm from a particular antibiotic if, though the drug itself was properly batch-tested, it was not the proper antibiotic to use, it was entirely reasonable for the Secretary to determine that the discs, like the antibiotics they serve, are drugs and similarly subject to pre-clearance certification under § 507. An opposite conclusion might undercut the value of testing the antibiotics themselves, for such testing would be a useless exercise if the wrong drug were ultimately administered, even partially as the result of an unreliable disc.

Furthermore, the legislative history, read in light of the statute's remedial purpose, directs us to read the classification "drug" broadly, and to confine the device exception as nearly as is possible to the types of items

[18] Cf. *Cawley* v. *United States*, 272 F. 2d 443, 445 (C. A. 2d Cir. 1959): "[U]nless they explicitly forbid it, the purpose of a statutory provision is the best test of the meaning of the words chosen."

Congress suggested in the debates,[19] such as electric belts, quack diagnostic scales, and therapeutic lamps, as well as bathroom weight scales, shoulder braces, air conditioning units, and crutches. In upholding the Secretary's determination here, without deciding the precise contours of the "device" classification, we need only point out that the exception was created primarily for the purpose of avoiding the semantic incongruity of classifying as drugs (1) certain quack contraptions and (2) basic aids used in the routine operation of a hospital—items characterized more by their purely mechanical nature than by the fact that they are composed of complex chemical compounds or biological substances. Finally, we are supported in the decision to uphold the FDA's determination that the sensitivity discs fall under the coverage of the Act and specifically under the drug provision thereof by the knowledge that the classification of these discs as drugs may not be as contrary to common medical usage as the District Court and respondent would have us believe.[20]

In upholding the Secretary's construction of the Act, we are not unmindful of our warning that "[i]n our anxiety to effectuate the congressional purpose of protecting the public, we must take care not to extend the scope of the statute beyond the point where Congress indicated it would stop." *62 Cases of Jam* v. *United States,* 340

[19] Cf. *AMP Inc.* v. *Gardner,* 389 F. 2d 825, 830 (C. A. 2d Cir.), cert. denied *sub nom., AMP Inc.* v. *Cohen,* 393 U. S. 825 (1968), petition for rehearing pending.

[20] See W. Dorland's Illustrated Medical Dictionary 449 (24th ed., 1965), where "drug" is defined as "Any chemical compound or any non-infectious biological substance, not used for its mechanical properties, which may be administered to or used on or for patients, either human or animal, as an aid in the diagnosis, treatment or prevention of disease or other abnormal condition, for the relief of pain or suffering, or to control or improve any physiological or pathological condition."

U. S. 593, 600 (1951). Our holding here simply involves an obvious corollary to that principle, that we must take care not to narrow the coverage of a statute short of the point where Congress indicated it should extend.

Reversed.

MR. JUSTICE DOUGLAS, being of the view that an antibiotic sensitivity disc used by physicians to aid them in determining what antibiotic drug, if any, to give to a patient, is a "device" as defined in § 201 (h)* of the Act, not a "drug" as defined in § 201 (g), would affirm the judgment.

*"The term 'device' . . . means instruments, apparatus, and contrivances . . . for use in the diagnosis . . . of disease in man . . . ." It would indeed be difficult to write a clearer description of an antibiotic sensitivity disc.