IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 94-20402

PROFESSIONALS and PATIENTS FOR CUSTOMIZED CARE,

Plaintiff-Appellant,

v.

DONNA SHALALA, ET AL.,

Defendants-Appellees.

Appeal from the United States District Court
For the Southern District of Texas

(June 15, 1995)

Before WISDOM, WIENER and PARKER, Circuit Judges.

WIENER, Circuit Judge:

In this challenge brought pursuant to the Administrative Procedure Act (APA),[1] Plaintiff-Appellant Professionals and Patients for Customized Care (P2C2) contends that the district court erred in concluding that Food & Drug Administration (FDA) Compliance Policy Guide 7132.16 (CPG 7132.16) is not a substantive rule and thus is not subject to the APA's notice-and-comment requirement. Finding no reversible error, we affirm.

I

FACTS AND PROCEEDINGS

In 1992, the FDA promulgated CPG 7132.16 to address what the agency perceived to be a burgeoning problem in the pharmaceutical

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[1]5 U.S.C. §§ 500-576 (1988).

industry))the manufacture of drugs by establishments with retail pharmacy licenses. Pharmacies have long engaged in the practice of traditional compounding, the process whereby a pharmacist combines ingredients pursuant to a physician's prescription to create a medication for an individual patient. This type of compounding is commonly used to prepare medications that are not commercially available, such as diluted doses for children and altered forms of medications for easier consumption.

Pharmacies that practice traditional compounding are regulated primarily by state law,[2] and the drugs that they blend are exempt from many federal misbranding provisions.[3] Drug manufacturers and their products, however, are subject to rigorous federal oversight.

By the 1990s, the FDA had become aware that many establishments with retail pharmacy licenses were purchasing large quantities of bulk drug substances; combining those substances into specific drug products before ever receiving any valid prescriptions; and then marketing those drug products to practitioners and patients. The FDA suspected that establishments

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[2]"[P]harmacies" that dispense drugs "upon prescriptions of practitioners" for their patients, "and which do not manufacture . . . [or] compound . . . drugs . . . for sale other than in the regular course of their business of dispensing or selling drugs" are exempt from particular FDA registration requirements and inspections. See 21 U.S.C. § 360(g)(1) (requiring drug manufacturers to register with the FDA); id. § 374 (granting FDA agents right to inspect certain facilities).

[3]Id. § 353(b)(2). Although the Act does not expressly exempt "pharmacies" or "compounded drugs" from the new drug, adulteration, or misbranding provisions, the FDA as a matter of policy has not historically brought enforcement actions against pharmacies engaged in traditional compounding.

engaged in this large-scale speculative "compounding" were doing so to circumvent those new drug, adulteration, and misbranding provisions of the Food, Drug, and Cosmetic Act (Act)[4] that regulate the manufacture of drugs.

To combat this perceived problem, the FDA issued CPG 7132.16, in an effort to establish the following "policy":

> POLICY
>
> FDA recognizes that a licensed pharmacist may compound drugs extemporaneously after receipt of a valid prescription for an individual patient . . . .
>
> Pharmacies that do not otherwise engage in practices that extend beyond the limits set forth in this CPG may prepare drugs in very limited quantities before receiving a valid prescription, provided they can document a history of receiving valid prescriptions that have been generated solely within an established professional practitioner-patient-pharmacy relationship and provided further that they maintain the prescription on file for all such products dispensed at the pharmacy as required by state law.
>
> If a pharmacy compounds finished drugs from bulk active ingredient materials considered to be unapproved new drug substances, as defined in 21 CFR 310.3(g), such activity must be covered by an FDA-sanctioned investigational new drug application (IND) that is in effect in accordance with 21 U.S.C. Section 355(i) and 21 CFR 312.
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> . . .
>
> Pharmacies may not, without losing their status as retail entities, compound, provide, and dispense drugs to third parties for resale to individual patients.
>
> FDA will generally continue to defer to state and local officials (sic) regulation of the day-to-day practice of retail pharmacy and related activities. . . .
>
> FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions against entities and responsible persons when the scope and nature of a

[4] 21 U.S.C. §§ 301-392.

> pharmacy's activity raises the kind of concerns normally associated with a manufacturer and that results in significant violations of the new drug, adulteration, or misbranding provisions of the Act.

This CPG goes on to identify nine factors that the FDA "will consider" in determining whether to initiate an enforcement action, but explains that the "list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case."

The FDA issued CPG 7132.16 without complying with APA notice-and-comment procedures,[5] as the agency considered CPG 7132.16 to be for internal guidance. The FDA explains that CPG 7132.16 was intended to be used within the agency, primarily by FDA district offices, as an aid in identifying those pharmacies that manufacture drugs under the guise of traditional compounding.[6]

P2C2, an organization comprising individuals and entities engaged in the practice of pharmacy, interprets CPG 7132.16 differently. Soon after CPG 7132.16 issued, the FDA notified some of the organization's members that their activities were more consistent with drug manufacturing than with traditional compounding, and that they and their products were thus subject to the regulations applicable to drug manufacturers. On behalf of those and other members, P2C2 filed suit in federal district court, claiming that CPG 7132.16 is invalid because it is a substantive rule issued in violation of the APA's notice-and-comment

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[5]See 5 U.S.C. § 553.

[6]See Notice, 57 Fed. Reg. 10906 (1992).

requirement. The FDA responded that P2C2 lacked standing and that its claim was not ripe, but the district court disagreed. Both parties then filed cross motions for summary judgment, which the trial court denied, finding that there remained genuine issues of material fact. Following a two-day bench trial, the district court made extensive findings of fact and conclusions of law, and ruled that CPG 7132.16 is either an "interpretative rule" or "policy statement," but it is not a "substantive rule." Consequently, held the district court, the FDA was exempt from complying with the APA's notice-and-comment requirements, and CPG 7132.16 was validly promulgated.

P2C2 timely appealed, contending that the district court erred in concluding that CPG 7132.16 was not a substantive rule. The FDA responded that the district court had correctly held that CPG 7132.16 was not a substantive rule, and reurged its ripeness and standing arguments.[7]

II

ANALYSIS

A. Standard of Review

We review for clear error the district court's findings of fact. We consider de novo the court's conclusions of law,[8] which include the court's ruling that CPG 7132.16 is not a "substantive

[7]P2C2 argues that the government "waived" its jurisdictional arguments by failing to file a cross-appeal of that judgment. We, of course, have an independent obligation to determine our jurisdiction, with which in this case, we find we are vested.

[8]Fed. R. Civ. P. 52(a).

rule."[9]

B. THE PROPER CHARACTERIZATION OF CPG 7132.16

All parties agree that under the APA, CPG 7132.16 is a "rule," and its promulgation constituted "rulemaking."[10] But the APA exempts from notice-and-comment procedures "interpretative rules, general statements of policy, [and] rules of agency organization, procedure, or practice."[11] In contrast, if a rule is "substantive,"[12] the exemption is inapplicable, and the full panoply of notice-and-comment requirements must be adhered to scrupulously. The "APA's notice and comment exemptions must be narrowly construed."[13]

If CPG 7132.16 were a substantive rule it would be unlawful, for it was promulgated without the requisite notice and comment. The pivotal issue in this case, therefore, is whether CPG 7132.16 is a substantive rule. Although the APA itself does not define "substantive rules," "interpretive rules," or "statements of policy," courts over the years have developed a body of jurisprudence that is helpful in drawing the necessary))but often

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[9]Phillips Petroleum Co. v. Johnson, 22 F.3d 616, 619 (5th Cir.), modified on other grounds, No. 93-1377, 1994 WL 484506 (June 10, 1994), cert. denied, 115 S. Ct. 1816 and 115 S. Ct. 1817 (1995).

[10]See 5 U.S.C. § 551(4); see Phillips Petroleum Co., 22 F.3d at 619 n.2.

[11]See 5 U.S.C. § 553(b)(3)(A), (d)(2).

[12]Substantive rules are also referred to as "legislative rules" or "regulations."

[13]United States v. Picciotto, 875 F.2d 345, 347 (D.C. Cir. 1989).

illusory[14])distinctions among the three types of rules. It is that body of law, much of which comes from our colleagues of the District of Columbia Circuit, to which we now turn.

In Community Nutrition Institute v. Young,[15] the D.C. Circuit reiterated two "criteria" to which courts have looked to distinguish substantive rules from nonsubstantive rules:

> First, courts have said that, unless a pronouncement acts prospectively, it is a binding norm. Thus . . . a statement of policy may not have a present effect: "a `general statement of policy' is one that does not impose any rights and obligations" . . . .
>
> The second criterion is whether a purported policy statement genuinely leaves the agency and its decisionmakers free to exercise discretion.[16]

The court further explained that "binding effect, not the timing, . . . is the essence of criterion one."[17] In analyzing these criteria, we are to give some deference, "albeit `not overwhelming,'" to the agency's characterization of its own rule.[18] While mindful but suspicious of the agency's own characterization,

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[14]See Community Nutrition Inst. v. Young, 818 F.2d 943, 946 (D.C. Cir. 1987) (recalling that courts and commentators have described the distinction between substantive and interpretative rules or policy statements as, inter alia, "tenuous," "fuzzy," "blurred," "baffling," and "enshrouded in considerable smog").

[15]818 F.2d 943 (D.C. Cir. 1987).

[16]Id. at 946 (quoting American Bus Ass'n v. United States, 627 F.2d 525, 529 (D.C. Cir. 1980) (quoting Texaco v. FPC, 412 F.2d 740, 744 (3d Cir. 1969)); see Batterton v. Marshall, 648 F.2d 694, 702 (D.C. Cir. 1980).

[17]Community Nutrition Inst., 818 F.2d at 946 n.4.

[18]Id. at 946 (quoting Brock v. Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 537 (D.C. Cir. 1986) (stating that "there is deference and there is deference))and the degree accorded to the agency on a point such as this is not overwhelming").

we follow the D.C. Circuit's analysis in determining whether CPG 7132.16 is a substantive rule under the APA, focusing primarily on whether the rule has binding effect on agency discretion[19] or severely restricts it.[20] As we noted in Panhandle Producers & Royalty Owners Ass'n v. Economic Regulatory Administration[21]:

> "A properly adopted substantive rule establishes a standard of conduct which has the force of law. In subsequent administrative proceedings involving a substantive rule, the issues are whether the adjudicated facts conform to the rule and whether the rule should be waived or applied in that particular instance. The underlying policy embodied in the rule is not generally subject to challenge before the agency.
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> A general statement of policy, on the other hand, does not establish a `binding norm.' It is not finally determinative of the issues or rights to which it is addressed. The agency cannot apply or rely upon a general statement of policy as law because a general statement of policy only announces what the agency seeks to establish as policy. A policy statement announces the agency's tentative intentions for the future. When the agency applies the policy in a particular situation, it must be prepared to support the policy just as if the policy statement had never been issued. An agency cannot escape its responsibility to present evidence and reasoning supporting its substantive rules by announcing binding precedent in the form of a general statement of policy."[22]

1. Agency Deference: FDA's Characterization

In analyzing whether an agency pronouncement is a statement of policy or a substantive rule, the starting point is "the agency's

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[19]See Avoyelles Sportsmen's League, Inc. v. Marsh, 715 F.2d 897, 908 (5th Cir. 1983) (stating that substantive rules, "grant rights," "impose obligations," "produce other significant effects on private interests," or "have substantial legal effect").

[20]Id. (stating that substantive rules "narrowly constrict the discretion of agency officials by largely determining the issue addressed").

[21]847 F.2d 1168 (5th Cir. 1988).

[22]Id. at 1174-75 (5th Cir. 1988) (quoting Pacific Gas & Elec. Co. v. FPC, 506 F.2d 33, 38-39 (footnotes omitted)).

characterization of the rule."[23] It is undisputed that the FDA has consistently classified the instant rule as a statement of policy. The rule is self-described as "Policy," and it was promulgated as a "compliance policy guide." In addition, the FDA has steadfastly insisted, both before us and before the district court, that CPG 7132.16 was intended to propound policy.

Further, the FDA chose to promulgate the information contained in this rule in the form of a compliance policy guide, which FDA regulations classify as an "advisory opinion."[24] An advisory opinion "may be used in administrative or court proceedings to illustrate acceptable and unacceptable procedures or standards, but not as a legal requirement."[25] Both of these factors))the description as "policy" in the CPG itself and the fact that compliance policy guides do not have binding effect))militate in favor of a holding that CPG 7132.16 is not a substantive rule.

But as we observed in Brown Express, Inc. v. United States,[26] "`[t]he label that the particular agency puts upon its given exercise of administrative power is not, for our purposes, conclusive; rather, it is what the agency does in fact.'"[27] We

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[23]Metropolitan Sch. Dist. v. Davila, 969 F.2d 485, 489 (7th Cir. 1992), cert. denied, 113 S. Ct. 1360 (1993).

[24]See 21 C.F.R. § 10.85(d)(3) (1994).

[25]Id. § 10.85(j).

[26]607 F.2d 695 (5th Cir. 1979).

[27]Id. at 700 (quoting Lewis-Mota v. Secretary of Labor, 469 F.2d 478, 481 (2d Cir. 1972)); accord Phillips Petroleum Co. v. Johnson, 22 F.3d 616, 619 (5th Cir. 1994) ("`The label that the particular agency puts upon its given exercise of administrative

therefore turn now to those matters of substance.

2. Binding Effect of CPG 7132.16

A touchstone of a substantive rule is that it establishes a binding norm. As the Eleventh Circuit has observed:

> The key inquiry . . . is the extent to which the challenged policy leaves the agency free to exercise its discretion to follow or not to follow that general policy in an individual case, or on the other hand, whether the policy so fills out the statutory scheme that upon application one need only determine whether a given case is within the rule's criteria. As long as the agency remains free to consider the individual facts in the various cases that arise, then the agency action in question has not established a binding norm.[28]

P2C2 argues that CPG 7132.16 establishes a binding norm, as it imposes on compounding pharmacists significant new obligations. Most of these new obligations are manifested in the nine "factors," which, according to P2C2, are tantamount to binding norms. The district court found that the nine factors merely provide guidance to help FDA agents distinguish traditional compounding from drug manufacturing, and that the factors are not finally determinative of whether a particular pharmacy is violating the Act. According

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power is not, for our purposes, conclusive . . . .'"), modified on other grounds, No. 93-1377, 1994 WL 484506 (June 10, 1994), cert. denied, 115 S. Ct. 1816 and 115 S. Ct. 1817 (1995). For the same reason, the fact that we previously found another FDA compliance policy guide to be a policy statement is not dispositive whether CPG 7132.16 is a policy statement. See, e.g., Southeastern Minerals, Inc. v. Harris, 622 F.2d 758, 766 (5th Cir. 1980) ("Because the FDA issued the [CPG] as a general statement of agency policy, it was not required to comply with the formal rulemaking requirements of the [APA].").

[28]Ryder Truck Lines, Inc. v. United States, 716 F.2d 1369, 1377 (11th Cir. 1983), cert. denied, 466 U.S. 927 (1984); see also Vietnam Veterans of Am. v. Secretary of Navy, 843 F.2d 528, 537 (D.C. Cir. 1988) (stating that a valid policy statement can "affect the agency's decisionmaking").

to the court, enforcement actions are brought only for violations of the Act, and CPG 7132.16 merely restates a longstanding FDA position regarding the traditional practice of pharmacy; it does not represent a change in FDA policy and does not have a significant effect on pharmacy practice or traditional compounding. To ascertain whether CPG 7132.16 creates binding norms, we first consider its plain language and then address the manner in which it had been implemented by the FDA.

a. Plain Language of CPG 7132.16

CPG 7132.16 provides, in pertinent part, that:

> FDA may, in the exercise of its enforcement discretion, initiate federal enforcement actions against entities and responsible persons when the scope and nature of a pharmacy's activity raises the kind of concerns normally associated with a manufacturer and that results in significant violations of the new drug, adulteration, or misbranding provisions of the Act. In determining whether to initiate such an action, the agency will consider whether the pharmacy engages in any of the following acts:
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> 1. Soliciting business . . . to compound specific drug products . . . .
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> 2. Compounding, regularly, or in inordinate amounts, drug products that are commercially available in the marketplace and that are essentially generic copies of commercially available, FDA-approved drug products.
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> 3. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-approved facility.
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> 4. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
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> 5. Using commercial scale manufacturing or testing equipment for compounding drug products.
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> 6. Compounding inordinate amounts of drugs in anticipation

of receiving prescriptions in relation to the amounts of drugs compounded after receiving valid prescriptions.

7. Offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

8. Distributing inordinate amounts of compounded products out of state.

9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

The foregoing list of factors is not intended to be exhaustive and other factors may be appropriate for consideration in a particular case.

We observe initially the statement in CPG 7132.16 that the FDA "will consider" the nine factors in determining whether to initiate an enforcement action against a pharmacy. We also note that, even though the mandatory tone of the factors is undoubtedly calculated to encourage compliance, CPG 7132.16 affords an opportunity for individualized determinations. It expressly provides that "[t]he foregoing list of factors is not intended to be exhaustive," recognizes that "other factors may be appropriate for consideration in a particular case," and states that, even if the factors are present, the FDA retains discretion whether to bring an enforcement action.[29] In this regard, CPG 7132.16 is analogous to the rule reviewed in Guardian Federal Savings & Loan Ass'n v. Federal Savings & Loan Insurance Corp.,[30] which the D.C. Circuit held to be a statement of policy, exempt from APA notice-and-comment

[29]CPG 7132.16 ("FDA, may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . " (emphasis added)).

[30]589 F.2d 658 (D.C. Cir. 1978).

requirements.[31]

The substantive content of the limits themselves also favors a finding that CPG 7132.16 does not create binding norms. The rule does not contain specifications of precise quantities or limits that, once exceeded, trigger a mandatory FDA response. The factors provide, for example, that only the compounding or distributing of "inordinate amounts" of drugs is impermissible, but nowhere does the rule further define "inordinate amounts." As such, CPG 7132.16 leaves to the sound discretion of the FDA the determination when a particular quantity has exceeded the amount considered to be within the bounds of traditional compounding. The fact that none of the nine factors listed in CPG 7132.16 establish "fixed criteria to control the agency's decisions" distinguishes CPG 7132.16 from other FDA rules that have been held to be substantive.[32]

P2C2 relies primarily on two cases, Bellarno International Ltd. v. FDA,[33] and Community Nutrition Institute v. Young,[34] but both are easily distinguished.[35] In those two cases, and unlike here,

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[31]Id. at 666-67 (noting that provision providing that FSLIC examiner "may reject audit" afforded individualized determination necessary to offset otherwise "mandatory tone of specifications for audits and auditors").

[32]Avoyelles Sportsmen's League, Inc. v. Marsh, 715 F.2d 897, 910 (5th Cir. 1983) (citing cases).

[33]678 F. Supp. 410 (E.D.N.Y. 1988).

[34]818 F.2d 943 (D.C. Cir. 1987).

[35]P2C2 also refers us to Northwest Tissue Center v. Shalala, 1 F.3d 526 (7th Cir. 1993), but that case is completely inapposite. In Northwest Tissue Center v. Shalala, the court had previously found that the provision at issue was an interpretative rule, not a regulation, and the only remaining

FDA rules were found to create binding norms, for they removed all discretion from the agency by creating a statutory scheme that reduced the agency's role to that of mechanically "determin[ing] whether a given case is within the rule's criteria."[36]

At issue in Community Nutrition was an FDA "action level," which provided that "[a]ny food that contains aflatoxin in excess of 20 [parts per billion (ppb)] is . . . considered by FDA to be adulterated under section 402(a)(1) . . . and therefore may not be shipped in interstate commerce."[37] The action level established a statutory scheme whereby once a precise level of aflatoxin was detected, the FDA had no choice but to detain the food. The FDA conceded at oral argument that it would be "daunting" to try to convince a court that the agency could prosecute a producer for shipping corn with less than 20 ppb, and the court noted that "this type of cabining of an agency's prosecutorial discretion can in fact rise to the level of a substantive . . . rule."[38]

The FDA's discretion was similarly restricted in Bellarno International, which concerned a FDA "import alert" that ordered the "automatic[]" detention of all pharmaceuticals classified by

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issue was whether a particular provision in the Act))not the APA))imposed notice-and-comment requirements.

[36]Ryder Truck Lines, Inc. v. United States, 716 F.2d 1369, 1377 (11th Cir. 1983), cert. denied, 466 U.S. 927 (1984).

[37]Community Nutrition Inst., 818 F.2d at 946 n.4. Aflatoxin is a by-product of certain common molds that grow on various crops, including corn. Id. at 945 n.1.

[38]Id. at 948 (citing Nader v. CAB, 657 F.2d 453 (D.C. Cir. 1981) and Guardian Fed. Sav. & Loan Ass'n v. FSLIC, 589 F.2d 658, 666-67 (D.C. Cir. 1978)).

tariff regulations as "American Goods Returned (AGR)," i.e., pharmaceuticals initially produced in the United States, exported for distribution abroad, and subsequently returned for sale in the United States. As in Community Nutrition, once a precisely defined criterion was satisfied))in Community Nutrition, 20 ppb of aflatoxin; in Bellarno International, that the pharmaceutical was an AGR))then a prescribed FDA action automatically followed. Consequently, the rule reduced the function of the FDA to that of rote "determin[ation] whether a given case is within the rule's criteria."[39] When viewed in light of the rules in Community Nutrition and Bellarno International, it is clear that the nine factors identified in CPG 7132.16 are not the type of criteria that courts have traditionally characterized as "binding norms."[40]

b. FDA's Enforcement of CPG 7132.16

P2C2 urges that, even if the plain language of the rule does not create a binding norm, the agency has treated CPG 7132.16 as though it establishes binding norms, and thus we should hold that it does. P2C2 reminds us that the pertinent inquiry is not only what CPG 7132.16 states that the agency will do, but also "what the agency does in fact.'"[41]

P2C2 relies on numerous informal agency communications as

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[39]Ryder Truck Lines, Inc., 716 F.2d at 1377.

[40]See also Avoyelles Sportsmen's League, Inc. v. Marsh, 715 F.2d 897, 910 (5th Cir. 1983) (listing cases in which "fixed criteria" created binding norms).

[41]Brown Express, Inc. v. United States, 607 F.2d 695, 700 (5th Cir. 1979) (quoting Lewis-Mota v. Secretary of Labor, 469 F.2d 478, 481 (2d Cir. 1972)).

evidence that the FDA has treated CPG 7132.16 as establishing a binding norm. P2C2 cites in particular to evidence that, since CPG 7132.16's promulgation: (1) the FDA has used the nine factors listed in CPG 7132.16 when inspecting pharmacies, and has relied on those factors to determine whether federal enforcement actions were warranted; (2) in numerous letters the FDA has warned pharmacists that they were engaged in drug manufacturing, rather than traditional compounding, because they were conducting some, or all, of the activities listed in CPG 7132.16, and (3) the FDA has furnished copies of CPG 7132.16 to pharmacists who inquired about the legal restrictions on drug compounding. P2C2's reliance is misplaced.

The fact that FDA inspectors refer to CPG 7132.16 to help determine whether a pharmacy is engaged in traditional compounding or drug manufacturing is not particularly probative whether the rule is substantive. We would expect agency employees to consider all sources of pertinent information in performing that task, whether the information be contained in a substantive rule, an interpretive rule, or a statement of policy. Indeed, what purpose would an agency's statement of policy serve if agency employees could not refer to it for guidance?

More probative of the nature of CPG 7132.16, however, is the language used by the FDA in warning letters to pharmacies. In one such letter, the FDA wrote that firms engaged in activities that "exceed the limits of CPG 7132.16 are considered manufacturers and are subject to all the provisions of the Act." We would not

dispute that if this statement were viewed in a vacuum, one could be led to conclude that the FDA was in fact treating CPG 7132.16 as a binding norm. But statements are not to be considered out of context or in isolation, and in that very same letter the FDA clearly stated that CPG 7132.16 was only used by the agency as "internal guidance." Moreover, informal communications often exhibit a lack of "precision of draftsmanship" and such internal inconsistencies are not unexpected, which is why such documents are generally entitled to limited weight.[42] We cannot conclude, in light of all of the other circumstances, that these warning letters are sufficient to transform CPG 7132.16 into a substantive rule.

As with that use of CPG 7132.16, we do not find particularly probative the fact that the FDA enclosed copies of CPG 7132.16 in letters responding to some pharmacists' questions regarding the legality of compounding activities. In that correspondence, the agency pointed out that CPG 7132.16 is "policy" and explained further that "[t]his document includes a list of factors which the FDA feels differentiates [sic]" traditional compounding from drug manufacturing. The FDA noted in particular that "[t]his list is not intended to be exhaustive, and other situations or factors may be considered in particular cases." By so doing, the letters made clear that CPG 7132.16 was used for guidance, but that the FDA retained discretion to conduct an individualized inquiry and to consider other factors outside the list. CPG 7132.16, for example,

[42]See Community Nutrition Inst. v. Young, 818 F.2d 943, 948 (D.C. Cir. 1987).

provides that pharmacies engaged in nontraditional compounding are subject to certain provisions of the Act, and the FDA explains in warning letters that a pharmacy's compounding may be subject to regulation under the Act.

We cannot conclude that the FDA has treated the factors in CPG 7132.16 as binding norms. Rather, the agency has used CPG 7132.16 for guidance to help identify those pharmacies that might be engaged in drug manufacturing activities under the guise of compounding.

2. Degree of Enforcement Discretion Accorded FDA

Even if CPG 7132.16 does not create binding norms, argues P2C2, the rule so narrowly constricts FDA enforcement discretion that the CPG should be deemed to be a substantive rule.[43] P2C2 contends that CPG 7132.16 acts essentially to identify those pharmacies against which the FDA will bring enforcement actions, thereby denying the agency any semblance of discretion. We disagree.

True, the FDA had even greater discretion in bringing enforcement actions before CPG 7132.16 issued; prior to that time inspectors were apparently provided with no official guidance whatsoever. In that sense, therefore, CPG 7132.16 has "channeled" the FDA's enforcement discretion, providing direction))where once there was none))by helping to determine whether a pharmacy is engaged in traditional compounding or drug manufacturing. But all

[43]The concept of constricted enforcement discretion is closely related to that of "binding norms," as both reduce the leeway with which the agency can perform its tasks.

statements of policy channel discretion to some degree))indeed, that is their purpose. The more cogent question therefore is whether CPG 7132.16 is so restrictive in defining which pharmacies are engaged in drug manufacturing that it effectively removes most, if not all, of the FDA's discretion in deciding against which pharmacies it will bring an enforcement action. We cannot read CPG 7132.16 that restrictively.

CPG 7132.16 makes clear that it was not intended to foreclose the agency's exercise of its discretion in bringing an enforcement action. In fact, the rule expressly refers to the discretionary nature of bringing such actions:

> [T]he agency may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . when the scope and nature of a pharmacy's activity raises the kinds of concerns normally associated with a manufacturer and that results in significant violations of the new drug, adulteration, or misbranding provisions of the Act.[44]

The D.C. Circuit has in some cases "given decisive weight to the agency's choice between the words `may' and `will,'"[45] but we need not go so far today.

We further observe that the language of CPG 7132.16 that purports to distinguish traditional compounding from drug manufacturing is imprecise and discretionary))not exact and certain. The rule, for example, states what action the FDA "may"

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[44]CPG 7132.16 (emphasis added).

[45]Cathedral Bluffs Shale Oil Co., 796 F.2d 533, 538 (D.C. Cir. 1986); see Community Nutrition Inst., 818 F.2d at 947 & n.6 (stating that use of "mandatory" language "is a powerful, even potentially dispositive, factor" that rule is substantive).

take in its "discretion" to address "significant violations"; it does not mandate a particular agency response once precisely fixed thresholds are exceeded.[46] CPG 7132.16 also expresses that the list of nine factors is neither dispositive nor exhaustive. Although CPG 7132.16 may assist the FDA in identifying pharmacies engaged in the manufacture of drugs, it clearly leaves to the sound discretion of the agency in each case the ultimate decision whether to bring an enforcement action.

Undaunted, P2C2 argues that CPG 7132.16 is analogous to the parole board rules (the Rules) held to be substantive in Pickus v. United States Board of Parole.[47] But that analogy fails when we recognize that the Rules considered in Pickus are quite different from the nine factors of the instant case. The Rules in Pickus, which purported to provide guidance whether a prisoner was entitled to parole, were divided into nine general categories and then further subdivided into thirty-two subcategories, going into

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[46]Compare CPG 7132.16 ("[T]he agency may, in the exercise of its enforcement discretion, initiate federal enforcement actions . . . when . . . a pharmacy's activity . . . results in significant violations" of the Act (emphasis added)) and Guardian Fed. Sav. & Loan Ass'n v. FSLIC, 589 F.2d 658, 666 (D.C. Cir. 1978) (holding FSLIC pronouncement regarding audits to be statement of policy as violations "may" result in rejection of audit) with Community Nutrition Inst., 818 F.2d at 947 ("[A]n action level . . . define[s] the level of contamination at which food will be deemed to be adulterated." (emphasis in original)) and American Bus Ass'n v. United States, 627 F.2d 525, 532 (D.C. Cir. 1980) (finding ICC rule to be substantive where it "is unequivocally `couched in terms of command . . . . It repeatedly says and implies `the Commission will; it nowhere says or implies `the Commission may.'" (emphasis in original) (citation omitted)).

[47]507 F.2d 1107 (D.C. Cir. 1974).

exacting detail as to how the Board was to determine whether an applicant was entitled to parole. Because the Rules were so minutely detailed, reasoned the D.C. Circuit, they "narrowed [the decisionmaker's] field of vision, minimizing the influence of other factors." As such, the court concluded that the Rules were substantive and therefore subject to APA notice-and-comment. Compared to the Rules in Pickus, however, the nine factors listed in CPG 7132.16 are broad, general, elastic, and far less inclusive. As a result, they do not have the same restrictive effect on agency decisionmakers as do the Rules.

In sum, nowhere does CPG 7132.16 draw a "line in the sand" that, once crossed, removes all discretion from the agency. We cannot agree with P2C2, therefore, that CPG 7132.16 so significantly restricts the discretionary role of the FDA in determining whether to bring an enforcement action against a pharmacy as to transform it into a substantive rule. In our view, CPG 7132.16 merely identifies some indicia of drug manufacturing; it neither compels the conclusion that a pharmacy is engaged in drug manufacturing nor provokes an automatic or nondiscretionary response from the agency. Rather, FDA inspectors are free to consider in toto those nine factors, as well as others, and then, based on that guidance and their own judgment, decide whether the pharmacy in question is engaged in drug manufacturing. Such is the nature of a discretionary rule, not of a substantive one.

3. Statement of Policy or Interpretative Rule?

The district court held that CPG 7132.16 is not a substantive

rule, finding it to be either a statement of policy or an interpretative rule. Although our plenary determination that the rule is not substantive is sufficient to affirm the district court's judgment, we continue, albeit briefly, to explain how CPG 7132.16 fits into the narrow exemptions from the APA notice-and-comment requirements.

a. Statement of Policy

As we recently explained, "[a] general statement of policy is a statement by an administrative agency announcing motivating factors the agency will consider, or tentative goals toward which it will aim, in determining the resolution of a substantive question of regulation."[48] This definition fits CPG 7132.16 to a tee, as in it the FDA announced some of the factors that it will consider in resolving "a substantive question of regulation," i.e., whether a pharmacy is engaged in traditional compounding or drug manufacturing.

b. Interpretative Rule

CPG 7132.16 could arguably be considered an interpretative rule as well. As the Supreme Court recently observed, interpretative rules "do not have the force and effect of law" and are used to advise the public how an agency will apply its regulations in certain circumstances.[49] In the same vein, we have

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[48]Phillips Petroleum Co. v. Johnson, 22 F.3d 616, 620 (5th Cir.), modified on other grounds, No. 93-1377, 1994 WL 484506 (June 10, 1994), cert. denied, 115 S. Ct. 1816 and 115 S. Ct. 1817 (1995).

[49]Shalala v. Guernsey Memorial Hosp., 115 S. Ct. 1232, 1236-37 (1995).

noted that:

> Generally speaking, it seems to be established that `regulations,' `substantive rules,' or `legislative rules' are those which create law, usually implementary to an existing law; whereas interpretative rules are statements as to what the administrative officer thinks the statute or regulation means.[50]

Interpretative rules thus "remind[] parties of existing statutory duties, or `merely track[]' the statutory requirements and thus `simply explain[] something the statute already require[s].'"[51] We are convinced that CPG 7132.16 could aptly be characterized as an interpretative rule. It reminds parties of the existing regulations that pertain to drug manufacturing and explains the FDA's view of what distinguishes drug manufacturing from traditional compounding. It clarifies, rather than creates, law.[52]

c. Substantive Change in Regulations

If an agency pronouncement is to be an interpretative rule or a statement of policy, though, it cannot "effect[] a substantive

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[50]Brown Express, Inc. v. United States, 607 F.2d 695, 700 (5th Cir. 1979) (quoting Gibson Wine Co. v. Snyder, 194 F.2d 329, 331 (D.C. Cir. 1952)); Sekula v. FDIC, 39 F.3d 448, 457 (3d Cir. 1994) ("Interpretative rules are not intended to alter legal rights, but to state the agency's view of what existing law requires.").

[51]National Family Planning v. Sullivan, 979 F.2d 227, 236-37 (5th Cir. 1992) (quotations omitted); see Chrysler Corp. v. Brown, 441 U.S. 281, 302 n.31 (1979 (An "interpretative rule is one "issued by an agency to advise the public of the agency's construction of a statute and rules which it administers.").

[52]Chrysler Corp., 441 U.S. at 303 ("The central question is essentially whether an agency is exercising its rule-making power to clarify an existing statute or regulation, or to create new law, rights, or duties in what amounts to a legislative act."); see id. at 302 n.31 (stating that an interpretative rules is one "issued by an agency to advise the public of the agency's construction of the statute and rules which it administers").

change in the regulations."[53] P2C2 posits that CPG 7132.16 effects such a substantive change, arguing that never before did the FDA regulate compounding activities. But there is nothing new or changed about the law that CPG 7132.16 clarifies.

The district court found that CPG 7132.16 does not plow new legal ground, as the rule expressly states that "traditional compounding activity is not the subject of this CPG 7132.16." Moreover, the FDA introduced into evidence warning letters proving that long before CPG 7132.16 issued the agency had instituted enforcement actions against pharmacies engaged in drug manufacturing under the guise of compounding.

In conclusion, we are satisfied that the district court did not clearly err in finding that the rule announced in CPG 7132.16 does not effect a substantive change to already applicable regulations, but that it merely provides guidance on an old problem))unregulated drug manufacturing. As we agree, then, that CPG 7132.16 is not a substantive rule, and thus is not subject to APA notice-and-comment requirements, the district court's judgment is, in all respects,

AFFIRMED.

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[53] Guernsey Memorial Hosp., 115 S. Ct. at 1236; National Family Planning, 979 F.2d at 237 (stating that purported interpretative rule or statement of policy may be deemed substantive rule if it "`effects a change in existing law or policy" (quoting Powderly v. Schweiker, 704 F.2d 1092, 1098 (9th Cir. 1983)); see, e.g., Phillips Petroleum Co. v. Johnson, 22 F.3d 616, 620 (5th Cir. 1994) ("An announcement stating a change in the method by which an agency will value [natural gas liquid products] is not a `general statement of policy.'"), modified on other grounds, 1994 WL 484506, cert. denied, 115 S. Ct. 1816 and 115 S. Ct. 1817 (1995).