PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

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No. 04-1175

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WEDGEWOOD VILLAGE PHARMACY, INC.,
IN THE MATTER OF ESTABLISHMENT
INSPECTION OF:
d/b/a WEDGEWOOD PHARMACY,

*Appellant*

v.

UNITED STATES OF AMERICA

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On Appeal from the United States District Court
for the District of New Jersey
(District Court No. 03-cv- 03438)
District Judge: Honorable Jerome B. Simandle

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Argued: November 16, 2004

Before: McKEE and CHERTOFF,[*] *Circuit Judges*, and
BUCKWALTER,[**] *District Judge*.

(Filed: September 1, 2005)

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[*]Judge Chertoff heard oral argument in this case but resigned before this opinion was filed. The decision is filed by a quorum of the panel. 28 U.S.C. § 46(d).

[**]Honorable Ronald L. Buckwalter, United States District Judge for the Eastern District of Pennsylvania, sitting by designation.

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OPINION

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McKee, *Circuit Judge*

Wedgewood Village Pharmacy appeals the District Court's order affirming the Magistrate Judge's denial of Wedgewood's motion to quash an administrative warrant issued to agents of the Food and Drug Administration. Wedgewood argues that it is exempt from FDA inspection under provisions of the Food, Drug, and Cosmetic Act (the "FDCA"), 21 U.S.C. § 301 *et seq*. Wedgewood also contends that it was denied procedural due process. For the reasons that follow, we hold that Wedgewood was not exempt from FDA inspection under the FDCA, and that issuance of the warrant did not deny

Wedgewood procedural due process. Accordingly, we will affirm the decision of the District Court.

## I. Background

Wedgewood is a pharmacy specializing in compounding drugs used for treating humans and animals. "Compounding" refers to the process of modifying prescription drugs to meet the specific needs of individual patients.

> Drug compounding is a process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a medication tailored to the needs of an individual patient. Compounding is typically used to prepare medications that are not commercially available, such as medication for a patient who is allergic to an ingredient in a mass-produced product. It is a traditional component of the practice of pharmacy, and is taught as part of the standard curriculum at most pharmacy schools . . . .

*Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360-61 (2002) (internal citation omitted).

Drug compounding is frequently regulated by states "as part of their regulation of pharmacies," and the FDA was content to allow the states to regulate compounding for "approximately . . . 50 years after the enactment of the FDCA." *Id*. at 361. However, the FDA eventually became concerned that some pharmacies were "manufacturing and selling drugs

under the guise of compounding, thereby avoiding the FDCA's [regulation of new drugs]." *Id*. at 362. Accordingly, in 1992, the FDA issued a Compliance Policy Guide (the "CPG"), "which announced that the 'FDA may, in the exercise of its enforcement discretion, initiate enforcement actions . . . when the scope and nature of a pharmacy's activities raises the kinds of concerns normally associated with a manufacturer and . . . results in significant violations of the new drug, adulteration, or misbranding provisions of the [FDCA].'" *Id*.

Pursuant to the regulatory authority of the FDCA and concerns that had been raised about the scope and nature of Wedgewood's drug compounding and related activities, on March 10, 2003, FDA Agent Margaret Sands applied for a warrant to inspect Wedgewood's facilities. In her warrant application, Sands stated that the FDA sought to:

> have access to production and distribution records to determine the extent to which [Wedgewood's] activities are consistent with those of a drug manufacturer rather than a retail pharmacy, and to evaluate the extent of violations of the [FDCA], including the new drug and new animal drug approval requirements, and the Act's adulteration provisions."

App. A14.

In the warrant application, the FDA cited several reasons for the inspection, and noted that the DEA had requested FDA assistance for an inter-agency investigation of Wedgewood because of the pharmacy's failure to report the theft of certain

controlled substances that were believed to have been consumed in several overdoses by high school students in October, 2001. App. A03. [1]

Although the FDCA provides pharmacies with a limited exemption from intrusive inspection subject to certain conditions, the FDA asserted in its application that Wedgewood did not qualify for the exemption because Wedgewood was not operating strictly as a retail business as is required for the statutory exemption. The application asserted that: in early 1998, Wedgewood had shipped over 1,000 vials of Poison Ivy Extract without receiving the requisite prescriptions for specific patients; in May 2002, Wedgewood had acquired an encapsulation machine which could be used for large-scale drug manufacturing; in 2001 and 2002, it had purchased bulk quantities of substances in excess of the amounts normally associated with a retail pharmacy, including enough diazepam (the active ingredient in Valium) to manufacture over one million 10 mg doses during a six-month period, an amount "typical of a commercial drug manufacturer"; and it routinely produced veterinary drugs in bulk, without receiving specific veterinary prescriptions. App. 06-09.

Each of these acts suggested to the FDA that Wedgewood's operations exceeded those of a retail pharmacy. Accordingly, the FDA believed that Wedgewood did not

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[1]The DEA obtained a separate warrant to search Wedgewood's facilities. The legality of that warrant is not at issue in this appeal.

qualify for the limited statutory exemption afforded retail pharmacies under the FDCA. App. A06-11. Although the FDCA does not require the FDA to obtain a warrant for an administrative inspection, the FDA chose to request a warrant because, "based on past agency experience with Wedgewood Pharmacy," the FDA expected that Wedgewood would attempt to refuse the inspection. App. A03. The Agency also recognized that its current information regarding Wedgewood's business practices was not entirely conclusive, and that it needed the full inspection in order "to determine the extent to which this firm's activities are consistent with those of a drug manufacturer rather than a retail pharmacy." That would, in turn, determine whether Wedgewood was exempt from full inspection under the FDCA. App. A14. The FDA even referred to the warrant it sought as "a preemptive inspection warrant." *Id*.[2]

A Magistrate Judge granted the application on March 10, 2003, and the warrant was served on Wedgewood two days later. Wedgewood's owner, George Malmberg, initially refused to cooperate with the inspection. However, when informed that he would be arrested pursuant to 21 U.S.C. § 331(e) if he continued to deny access, Malmberg acquiesced. In acquiescing, he attached a statement to the records he turned over to the FDA stating that he was complying because of the

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[2] For a detailed recitation of the averments in the warrant application, see *In the Matter of Establishment Inspection of: Wedgewood Village Pharmacy, Inc. ("In Re Wedgewood")*, 270 F. Supp. 2d 525, 530-33 (D.N.J. 2003).

"actually stated threat" that he would "be immediately taken into custody and all the pharmacy's computers, records and more will be immediately seized and removed from the pharmacy." App. A23.

On March 17, 2003, Wedgewood filed a motion to quash the warrant. In its motion, Wedgewood claimed that 21 U.S.C. § 374(a)(2)(A) grants state-licensed pharmacies a total exemption from inspection by the FDA. Wedgewood also argued that the FDA had acted in bad faith in obtaining the warrant and that the FDA had not shown probable cause to search the pharmacy. App. A32. After the motion was filed, the FDA agreed to suspend its search pending resolution of the dispute. Thereafter, the Magistrate Judge ordered Wedgewood to preserve documents and other items within the scope of the warrant, but he denied Wedgewood's motion to quash the warrant. In a well reasoned and comprehensive opinion, Magistrate Judge Rosen concluded that Wedgewood was not exempt from inspection, and that the warrant did not abridge Wedgewood's right to procedural due process of law. *In Re Wedgewood*, 270 F. Supp. 2d at 530-33. That ruling was subsequently affirmed by the District Court, and this appeal followed.

## II. Jurisdiction.

Before addressing the merits of this appeal, we must first decide if we have jurisdiction. Our jurisdiction is limited to "final decisions of the district courts," and the decision before us is arguably interlocutory. *See* 28 U.S.C. § 1291. The District Court relied upon *In re Consolidated Rail Corp.* 631

F.2d 1122 (3d Cir. 1980), and *Babcock & Wilcox Co. v. Marshall*, 610 F.2d 1128 (3d Cir. 1979), in treating Wedgewood's motion to quash as a "non-dispositive" motion. It could therefore be ruled upon by a Magistrate Judge.[3]

Ordinarily, in order for us to have jurisdiction over the District Court's refusal to quash a subpoena, the subpoenaed party must refuse to comply with the subpoena and suffer the sanction of a contempt citation. *Cobbledick v. United States*, 309 U.S. 323, 326-28 (1940) (holding that a denial of a motion to quash a grand jury subpoena is not final and therefore not appealable). The subpoenaed party may then challenge the warrant's validity in defending against the imposition of sanctions. The ruling on that defense is a final order that we can review on appeal. However, in *Cobbledick*, the Court acknowledged that it has recognized exceptions to this general rule. For instance, in *Ellis v. Interstate Commerce Commission*, 237 U.S. 434 (1915), the Court exercised jurisdiction over an appeal from an order granting a motion to compel testimony before the Interstate Commerce Commission. The Court distinguished that situation from a denial of a motion to quash a grand jury subpoena, noting that the former "may be deemed self-contained, so far as the judiciary is concerned." 309 U.S. at

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[3] Had the District Court found the motion to be dispositive, the role of the Magistrate Judge would have been limited to the issuance of a Report and Recommendation which the District Court would review de novo. *United States v. Raddatz*, 447 U.S. 667, 673-74 (1980).

330. In such cases, the Court found, it is proper for an appellate court to exercise jurisdiction, even if the complaining party has not yet faced a contempt citation.

Several Circuit Courts of Appeals have relied upon *Cobbledick* when holding that orders enforcing warrants and subpoenas are final and appealable orders. *See Doe v. United States (In re Admin. Subpoena)*, 253 F.3d 256, 261 (6th Cir. 2001) ("In the case of administrative subpoenas, parties may immediately appeal District Court orders enforcing these subpoenas, as the Supreme Court has deemed them to be 'self-contained, so far as the judiciary is concerned[.]'" (*quoting Cobbledick*, 309 U.S. at 330)); *United States v. Bailey (In re Subpoena Duces Tecum)*, 228 F.3d 341, 345-46 (4th Cir. 2000) ("The appealability of District Court orders enforcing subpoenas issued by government agencies in connection with administrative investigations has been regarded differently [from orders enforcing grand jury subpoenas], however. . . . These orders are considered 'final' for purposes of 28 U.S.C. § 1291 because there is no ongoing judicial proceeding that would be delayed by an appeal."); *United States v. Construction Prods. Research*, 73 F.3d 464, 469 (2d Cir. 1996) ("There is a different rule, however, in administrative proceedings. A District Court order enforcing a subpoena issued by a government agency in connection with an administrative investigation may be appealed immediately without first performing the ritual of obtaining a contempt order.")

In *International Brotherhood of Electrical Workers v. United States EEOC*, 398 F.2d 248, 251 (3d Cir. 1968), we observed that *Cobbledick* drew a "distinction between judicial

and administrative proceedings." However, we thereafter concluded that this exception was somewhat limited. Thus, in *Babcock & Wilcox*, we held that "[a] denial of a motion to quash an inspection warrant should be no more appealable than . . . a denial of a motion to quash a grand jury subpoena." 610 F.2d at 1133. We reiterated that principle in *Conrail*, finding again that an order denying a motion to quash a warrant is ordinarily not appealable. *See* 631 F.2d at 1123-24.

Yet, in *Shea v. Office of Thrift Supervision*, 934 F.2d 41 (3d Cir. 1991), we limited the scope of *Babcock* and *Conrail*. There, we concluded that an order granting a motion to enforce an administrative subpoena, unlike a denial of a motion to quash, was final and hence appealable. *See* 934 F.2d at 46 & n.9.[4] Thus, while we may ordinarily exercise jurisdiction over appeals of orders granting motions to enforce administrative subpoenas, we generally cannot exercise appellate jurisdiction over decisions denying motions to quash. Since Wedgewood is appealing the denial of a motion to quash an administrative warrant, it can be argued that we have no jurisdiction.

However, our analysis cannot end there because the jurisprudence in this area rests upon a party being able to challenge the validity of the warrant in the subsequent contempt proceeding. If the party cannot do so, we may exercise

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[4] Although at least one Court of Appeals has questioned the logic of this distinction, *see Reich v. National Eng'g & Contracting Co.*, 13 F.3d 93, 96 n.2 (4th Cir. 1993), it remains the law of this circuit.

jurisdiction over an appeal directly from the denial of the initial motion without requiring that the subpoenaed party endure a contempt citation. As the Court observed in *Cobbledick*, "[d]ue regard for efficiency in litigation must not be carried so far as to deny all opportunity for the appeal contemplated by the statutes." 309 U.S. at 329. Thus, we had appellate jurisdiction in *Babcock & Wilcox*, because the warrant had already been executed and there was no meaningful way for the aggrieved party to challenge it in a contempt proceeding. Although Wedgewood's posture is somewhat different, we believe that analogous considerations control our jurisdictional analysis here.

Under 21 U.S.C. §§ 331(e), (f) and 333(a)(1), refusing to permit an inspection authorized by the FDCA is a criminal offense punishable by up to one year of imprisonment and a fine of up to $1000. Although one who refuses to permit such an administrative inspection could conceivably challenge the validity of the warrant in a subsequent criminal prosecution, we see no reason to require Wedgewood to risk criminal prosecution merely to obtain appellate review of an administrative warrant. Moreover, penalties for civil contempt are limited to measures that may be appropriate to compel compliance with the underlying order and to compensate the opposing party for losses sustained as a result of the noncompliance. *See United States v. United Mine Workers*, 330 U.S. 258, 303-04 (1947). Those penalties are therefore proportional to the noncomplying party's resistance to the warrant. Here, however, the penalties Wedgewood could face for noncompliance could potentially far exceed the harm resulting from its noncompliance. Accordingly, we conclude

that the District Court's order refusing to quash the administrative warrant is tantamount to a final order.

## III. Discussion.[5]

### A. Wedgewood Is Not Exempt From Inspection Under the FDCA.

Wedgewood argues that it is exempt from all FDA inspections under 21 U.S.C. § 374(a). That section provides that employees and agents designated by the Secretary are permitted to "enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce" and "to inspect, at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment . . . and all pertinent equipment, finished and unfinished materials, containers, and labeling therein." *Id.* § 374(a)(1). In the case of "any factory, warehouse, establishment, or consulting laboratory in which

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[5] We review the denial of a motion to quash an administrative warrant or subpoena for abuse of discretion. *Cf. NLRB v. Frazier*, 966 F.2d 812, 815 (3d Cir. 1992). "An abuse of discretion arises when 'the District Court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact.'" *Id.* (quoting *International Union v. Mack Trucks, Inc.,* 820 F.2d 91, 95 (3d Cir. 1987)). The District Court's legal conclusions are, of course, reviewed de novo.

prescription drugs, nonprescription drugs intended for human use, or restricted devices are manufactured, processed, packed, or held" the section also provides:

> [T]he inspection shall extend to all things therein (including records, files, papers, processes, controls, and facilities) bearing on whether prescription drugs, nonprescription drugs intended for human use, or restricted devices which are adulterated or misbranded within the meaning of this chapter, or which may not be manufactured, introduced into interstate commerce, or sold, or offered for sale by reason of any provision of this chapter, have been or are being manufactured, processed, packed, transported, or held in any such place, or otherwise bearing on violation of this chapter.

*Id.* However, the statute specifically exempts certain types of pharmacies from this enhanced inspection authority (the enhanced inspection authority set forth above is hereafter referred to as the "records provision").[6] The exemption provides as follows:

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[6]Wedgewood correctly notes that the provision authorizes the FDA to search more than a pharmacy's records. In referring to the third sentence as the "records" provision, we do not mean to suggest that the search authority granted by that provision is limited to records.

> (2) The provisions of the third sentence of paragraph (1) [the records provision] shall not apply to—
> (A) pharmacies which maintain establishments in conformance with any applicable local laws regulating the practice of pharmacy and medicine and which are regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice, and which do not, either through a subsidiary or otherwise, manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their business of dispensing or selling drugs or devices at retail . . .

*Id*. § 374(a).

Wedgewood argues that it is exempt from inspection under the records provision pursuant to the exemption of § 374(a)(2)(A), and that this applies to the general inspection authority contained in the first sentence. According to Wedgewood, since the inspection authority under the records provision extends "to all things therein," it follows that the exemption from that authority necessarily means that the FDA has no inspection authority over pharmacies such as Wedgewood. We disagree.

Wedgewood's reading of the statute is inconsistent with

the text of § 374(a). Even assuming *arguendo* that Wedgewood is exempt from the records provision, the text of the statute does not justify extending that provision to the FDA's general authority to inspect "any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce." Rather, the exemption granted to pharmacies under § 374(a)(2)(A) only applies, by its own terms, to the "third sentence of paragraph (1)," *i.e.*, the records provision. The general inspection authority contained in the first sentence is not circumscribed by that exemption. It is therefore clear that the text of § 374(a) authorizes the FDA to inspect pharmacies such as Wedgewood.

Despite the clarity of the statute, Wedgewood argues that "there is nothing in the legislative history indicating that Congress intended to create distinct inspection rights. Once FDA has inspected for 'all things therein,' pray tell, for what else . . . can the FDA inspect, since there is not theoretically, grammatically, mathematically, or actually more than 'all.'" Appellant's Br. at 17-18. Our statutory construction inquiry need not include legislative history when, as here, the text of a statute is unambiguous. *See Malloy v. Eichler*, 860 F.2d 1179, 1183 (3d Cir. 1988). Nevertheless, we note that Wedgewood's reliance on legislative history does not produce the result Wedgewood claims.

The general inspection authority contained in the first sentence of § 374(a) was originally enacted by Congress as part of the Federal Food, Drug, and Cosmetic Act of 1938. *See* Pub.

L. No. 75-717, 52 Stat. 1040.[7] Both the enhanced inspection authority under the third sentence of § 374(a)(1) and the exemption granted to pharmacies under § 374(a)(2)(A) were enacted as part of the Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780. That statute specifically stated that "[n]othing in the amendments made by subsections (a) and (b) of this section [including the exemption granted to compliant pharmacies] shall be construed to negate or derogate from any authority of the Secretary existing prior to the enactment of this Act." *See id.* § 201(d), 76 Stat. at 793. Thus, Congress clearly stated by the very terms of the 1962 amendments that those amendments were not intended to alter the FDA's preexisting authority. That authority included the general inspection authority now contained in the first sentence of § 374(a).[8]

Wedgewood nonetheless argues that Congress enacted the 1962 amendments in response to *United States v. Herold*, 136 F. Supp. 15 (E.D.N.Y. 1955). That decision upheld the FDA's authority to search pharmacies under the FDCA.

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[7]For an in depth discussion of the legislative history of the FDCA, *see In Re Wedgewood*, 270 F. Supp. 2d at 538-543.

[8]As enacted in 1938, the inspection authority now contained in the first sentence of § 374(a) provided that a designated official was authorized to enter a covered facility "after first making request and obtaining permission of the owner, operator, or custodian thereof." This provision was amended in 1953 to remove the consent requirement. *See* Pub. L. No. 83-217, 67 Stat. 476 (1953).

Therefore, according to Wedgewood, Congress must have intended the amendments to overrule that decision in its entirety.

*Herold* did hold that 21 U.S.C. § 374(a) grants FDA the authority to inspect pharmacies. However, the analysis did not stop there. Rather, the court went further and held that the authority to inspect extended to a pharmacy's records, provided that "permission to inspect the records is given by an authorized person." *Id.* at 16.[9] In urging its interpretation of *Herold,* and of the 1962 amendments to the FDCA, Wedgewood points to nothing in the text or legislative history of the 1962 act that supports its conclusion that Congress intended to overrule *Herold* in its entirety. Indeed, the more logical interpretation of the 1962 amendments is simply that Congress sought to overrule that provision of *Herold* permitting pharmacy searches to extend to records. Had Congress sought to overrule *Herold* in its entirety, it could have drafted § 374(a)(2)(A) so that it applied to the first *and* third sentence of § 374(a)(1). Since it did not, we see no reason to adopt the tortured reading of § 374 that Wedgewood suggests. We therefore conclude that Wedgewood is not exempt from FDA inspection.

### B. Wedgewood Is Not Entitled To The Records

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[9]The defendant in *Herold* had argued that the FDA could only examine a pharmacy's records under a related provision, 21 U.S.C. § 373, which permits inspection of records on the condition that the evidence obtained not be used in any subsequent prosecution. *See* 136 F. Supp. at 16.

**Exemption.**

Our conclusion that the FDA possesses some authority to inspect pharmacies such as Wedgewood does not end our inquiry because the inspection authority contained in the first sentence of § 374(a)(1) is quite limited and clearly does not extend to a pharmacy's books and records. Since the FDA seeks access to Wedgewood's records, it must demonstrate that it has the authority to search Wedgewood under both the first and third sentences of § 374(a)(1). The exemption contained in § 374(a)(2)(A) prohibits the FDA from relying on the records inspection authority contained in the third sentence in searching pharmacies that meet the requirements of that section. Thus, if Wedgewood is a "compliant pharmacy"—meaning that it meets these requirements—it is exempt from the records provision. In its warrant application, the FDA claimed that it had probable cause to believe that Wedgewood does not, in fact, qualify for the exemption. Wedgewood has insisted throughout this litigation that not only does it qualify for the exemption but that the FDA has no authority to determine if Wedgewood is exempt from the records provision.

A pharmacy qualifies for the exemption under § 374(a)(2)(A) if it (1) complies with "applicable local laws regulating the practice of pharmacy and medicine"; (2) is "regularly engaged in dispensing prescription drugs or devices, upon prescriptions of practitioners licensed to administer such drugs or devices to patients under the care of such practitioners in the course of their professional practice"; and (3) does not "manufacture, prepare, propagate, compound, or process drugs or devices for sale other than in the regular course of their

business of dispensing or selling drugs or devices at retail."

The FDA contends that it has probable cause to believe that Wedgewood engages in practices that qualify as "large-scale" compounding or manufacturing and therefore the third requirement is not met. Wedgewood admits that it engages in compounding but asserts that it does so "in the regular course of [its] business of dispensing or selling drugs or devices at retail." Therefore, it argues that it qualifies for the exemption under § 374(a)(2)(A).

Nowhere in § 374 does Congress define "compounding" or a pharmacy's "regular course of business." In 1997, however, Congress enacted a statute which both exempted compounded drugs from the new drug approval requirements of the FDCA and simultaneously defined the extent to which pharmacies were permitted to engage in the practice without violating the FDCA. *See* Food and Drug Administration Modernization Act of 1997 ("FDAMA") § 127, Pub. L. No. 105-115, 111 Stat. 2296, 2328 (1997). Under the language of the FDAMA, pharmacies were permitted to compound only "for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation . . . or . . . in limited quantities before the receipt of a valid prescription for such individual patient." *Id.*

The provision did not remain law for long. As a result of two court decisions, Section 127 of the statute, which contained the compounding language, was invalidated on unrelated grounds. *See Western States*, 535 U.S. at 377; *Western States Med. Ctr. v. Shalala*, 238 F.3d 1090 (9th Cir.

2001).[10] In the wake of these decisions, the FDA outlined the criteria it would use to assess "what types of compounding might be subject to enforcement under current law." *See* CPG 460.200. The CPG lists nine factors that the FDA will consider in deciding whether a pharmacy may be violating the FDCA by engaging in manufacturing under the guise of compounding. The list includes factors such as the volume of drugs that a pharmacy compounds, whether the pharmacy compounds in anticipation of prescriptions, except in limited quantities, and whether the pharmacy compounds copies of drugs that are otherwise available.[11] While the CPG is more specific than the

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[10]The issue in *Western States* concerned a provision of the FDAMA that prohibited pharmacies from advertising compounded drugs. The Court of Appeals for the Ninth Circuit had held the provision unconstitutional and, finding it not severable from the rest of Section 127, struck down the entire section. *See* 238 F.3d at 1098. The Supreme Court affirmed that part of the Court of Appeals' decision finding the advertising provision unconstitutional but did not review the severability question. 535 U.S. at 360.

[11] The entire list of factors include:

> 1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
>
> 2. Compounding drugs that were withdrawn or

removed from the market for safety reasons. . . .

3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.

4. 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-registered facility.

5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.

6. Using commercial scale manufacturing or testing equipment for compounding drug products.

7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.

8. Compounding drug products that are commercially available in the marketplace or that

FDAMA, the language of the two provisions is very similar.

Here, Magistrate Judge Rosen afforded the CPG deference under the standards of *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837 (1984), even though the CPG was not the product of notice and comment rulemaking. However, we need not determine the precise level of deference, if any, owed the CPG because the FDA need only show that the factors outlined in the CPG for determining compounding are a reasonable basis upon which to initiate an inspection under the FDCA. We agree that the factors set forth in the CPG are reasonable and that they reflect the FDA's "careful consideration . . . over a long period of time." *Barnhart v.*

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> are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.
>
> 9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.

*Walton*, 535 U.S. 212, 222 (2002).[12] Given the averments of the warrant application here, it was therefore reasonable for the FDA to conclude that Wedgewood may be engaged in activity inconsistent with its status as a retail pharmacy.

**C. Wedgewood Was Not Denied Procedural Due Process of Law.**

Determining the extent to which a pharmacy may compound drugs in its "regular course of business" does not address the level of process due Wedgewood when the FDA attempts an inspection under the records provision. Here, Wedgewood asserts that the *ex parte* proceeding violated its due process rights. Before Magistrate Judge Rosen, Wedgewood apparently argued that it is entitled to a proceeding that is tantamount to a full declaratory judgment action in order to have an appropriate opportunity to demonstrate that it is eligible for the exemption contained in § 374(a)(2)(A). *See In Re Wedgewood*, 270 F. Supp. 2d at 538. However, before us, Wedgewood claims that its own assertion that it is in compliance with § 374(a)(2)(A) was sufficient to deny the FDA the right to inspect.[13]

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[12]As the opinion by the Magistrate Judge explains, the current language is a successor to an earlier CPG (CPG 7132.16, which dates to 1992) issued by the FDA prior to the passage of the FDAMA.

[13] That claim is sufficiently frivolous on its face that its lack of merit is self evident. It may, in fact, be an example of what Magistrate Judge Rosen had in mind in referring to

We agree that the statute poses a dilemma of sorts in that it will often be impossible to determine with precision whether a pharmacy qualifies for the § 374(a)(2)(A) exception without first conducting an administrative inspection of that facility. Magistrate Judge Rosen aptly described the situation as "a statutory paradox" because "the exemption in Section 374(a)(2)(A) divests the FDA of authority to inspect in some limited fashion, but the FDA cannot establish whether or not the exemption applies without obtaining information." *In re Wedgewood*, 270 F. Supp. 2d at 551. Nevertheless, we agree that the procedure the FDA used here did not violate Wedgewood's due process rights. As the FDA stresses, there is no warrant requirement under § 374(a). Indeed, as noted above, refusing a legitimate inspection request is a criminal violation of the FDCA, regardless of whether a warrant was first obtained.

Although Wedgewood correctly notes that it did not have an opportunity to be heard before the warrant issued and the inspection began, Wedgewood did have an opportunity to challenge that inspection before it was concluded, and it did so before the Magistrate Judge in proceedings on its motion to quash. Magistrate Judge Rosen correctly concluded that the FDA had probable cause to obtain the warrant and denied Wedgewood's motion, thus allowing the FDA to proceed with the inspection.

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Wedgewood's statutory argument as "a lesson in obfuscation." *In Re Wedgewood*, 270 F. Supp. 2d at 538.

We are therefore hard-pressed to understand how Wedgewood can now argue that it was denied due process of law by an *ex parte* application for an inspection warrant before a neutral Magistrate Judge when the FDA did not have to obtain a warrant under the FDCA in the first place. Accordingly, we hold that Wedgewood's due process rights were not violated.

Furthermore, we agree that the FDA's reliance on the apparent volume of compounding is a reasonable means of determining whether that pharmacy is compounding in the "regular course of its business of dispensing or selling drugs or devices at retail." Indeed, were we to adopt Wedgewood's view that the volume of compounding is irrelevant, much of the FDCA would become a nullity. If a pharmacy could compound an unlimited quantity of drugs, supposedly in anticipation of individual prescriptions, then it could essentially act as a commercial drug manufacturer and totally circumvent the approval requirements of the FDCA.[14]

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[14]Wedgewood argues throughout its brief that the regulation of pharmacies is a matter that has been traditionally left to the states. This argument misses the point of the FDA's efforts. The FDA, as its brief makes clear, wanted to inspect Wedgewood because it believes that the pharmacy is engaged in the large-scale manufacture of drugs. Although regulation of pharmacies may traditionally have been left to the states, regulation of the manufacture of prescription drugs is an area where the federal government has primary authority pursuant to the FDCA.

Moreover, as Magistrate Rosen noted, the standard of probable cause required for an administrative warrant is less than required for a criminal warrant. *See Camara v. Municipal Court of San Francisco*, 387 U.S. 523, 538 (1967). As the Supreme Court has explained: "[w]hen a dealer chooses to engage in [a] pervasively regulated business and to accept a federal license, he does so with the knowledge that his business records, [and stock] will be subject to effective inspection."*United States v. Biswell,* 406 U.S. 311, 316, (1972). Although we have not previously had to determine if the regulatory scheme of the pharmaceutical industry is sufficiently pervasive to implicate the *Biswell/Camara* doctrine, Magistrate Judge Rosen noted that the Courts of Appeals for the Eighth, Ninth, and Sixth Circuits have held that the level of regulation of that industry is sufficient to permit a warrantless search under the Fourth Amendment. *See In Re Wedgewood*, 270 F. Supp. 2d at 535 (citing *United States v. Jamieson-McKames Pharms., Inc.,* 651 F.2d 532 (8th Cir. 1981), *United States v. Argent Chem. Labs., Inc.,* 93 F.3d 572 (9th Cir. 1996), and *United States v. Acklen,* 690 F.2d 70, 75 (6th Cir. 1982)). We need not decide that specific question here. Rather, it is sufficient to note that the level of regulation is relevant to balancing the competing interests here and determining the procedural protection Wedgewood was entitled to.

Agent Sands' warrant application was detailed and specific, and (with the possible exception of issues of the staleness of some of her averments) might easily have satisfied even the higher standard required to obtain a criminal search warrant under the Fourth Amendment. Wedgewood's history, its failure to report a theft of drugs as required by state law, its

acquisition of equipment used in commercial manufacturing of drugs, and the volume of substances it was purchasing certainly established grounds to believe that it may be engaged in commercial compounding in violation of the FDCA.[15] Wedgewood does not dispute these facts. Rather, it simply repeats its argument that volume is irrelevant for purposes of determining whether a pharmacy is engaging in compounding or manufacturing outside of the "regular course of [its] business." We cannot agree.

## III. Conclusion.

For the reasons set forth above, we hold that Magistrate

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[15] As noted earlier, Wedgewood had recently purchased an encapsulation machine, which is used in large-scale manufacturing, as well as a "commercial scale mixture." In addition, as also noted above, the warrant alleged that the pharmacy had purchased enough diazepam to produce over one million 10 mg tablets. In its brief, Wedgewood explains the quantities of drugs by stating that a large portion of its pharmaceutical practice involves "equine medicine, and that horses, given their weight and size, receive larger Diazepam doses than humans." Appellee's Br. At 22. However, even if true, that would not negate the concerns the FDA expressed in its application to inspect Wedgewood to determine if it was involved in manufacturing or illegal compounding in violation of the FDCA. Indeed, before the Magistrate Judge, Wedgewood conceded that 11.5 kilograms of diazepam "is a lot." *See In Re Wedgewood*, 270 F. Supp. 2d at 553.

Judge Rosen correctly found that probable cause existed to conclude that Wedgewood did not satisfy the requirements of the exemption contained in § 374(a)(2)(A), and he therefore correctly denied Wedgewood's motion to quash. Accordingly, we will affirm the District Court's decision upholding Magistrate Judge Rosen's order.