United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 3, 1995 Decided March 1, 1996

No. 94-1689

CHARLES G. DICOLA,
PETITIONER

v.

FOOD AND DRUG ADMINISTRATION,
RESPONDENT

On Petition for Review of an Order of the
Food and Drug Administration

Robert A. Dormer argued the cause for petitioner, with whom *Roger C. Thies* and *Alan G. Minsk* were on the briefs.

Andrew E. Clark, Attorney, U.S. Department of Justice, argued the cause for respondent, with whom *Frank W. Hunger,* Assistant Attorney General, *Eugene M. Thirolf, Jr.,* Director, *and Lawrence G. McDade,* Deputy Director, Office of Consumer Litigation, U.S. Department of Justice, were on the brief. *Gerald C. Kell,* Attorney, U.S. Department of Justice, entered an appearance.

Before: BUCKLEY, GINSBURG, and TATEL, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* GINSBURG.

GINSBURG, *Circuit Judge*: Charles DiCola petitions this court for review of a final order of the Food and Drug Administration permanently debarring him from "providing services in any capacity" to the pharmaceutical industry. Finding no merit in any of the three constitutional claims he raises, we deny the petition.

I. Background

From 1980 to 1990 DiCola worked for Bolar Pharmaceutical Company, Inc. As General Manager of Production and Vice President of Operations, he was responsible for supervising the manufacture and distribution of Bolar's drug products.

In 1992 DiCola pled guilty to violations of the Food, Drug, and Cosmetic Act, as currently codified at 21 U.S.C. §§ 331(e) & (k), 333(a)(2), to wit, adulterating a drug product, within the meaning of 21 U.S.C. § 351(a)(2)(B), and failing to keep accurate batch production records, as

required by 21 U.S.C. § 355(j)(1). Specifically, DiCola directed Bolar employees to manufacture a drug using ingredients and following procedures different from those that had been approved by the Food and Drug Administration and to conceal the differences from the FDA by preparing false records. DiCola paid a fine and served a prison sentence.

Prior to DiCola's guilty plea but still several years after the conduct to which he confessed, the Congress passed the Generic Drug Enforcement Act of 1992, an amendment to the FDCA. 21 U.S.C. §§ 335a-335c. In the 1992 Act, the Congress reported having found "substantial evidence [of] significant corruption" in the drug approval process, and the need for measures "designed to restore and to ensure the integrity of the ... process and to protect the public health." 21 U.S.C. § 335a note (quoting Pub. L. No. 102-282, § 1(c)). To that end, the Congress required the Secretary of Health and Human Services to debar anyone convicted of a felony related to the federal regulation of drug products from thereafter "providing services in any capacity to a person that has an approved or pending drug product application." 21 U.S.C. § 335a(a)(2).

In February 1993 the Secretary, proposing to debar DiCola, notified him of his right to a hearing if he could establish a genuine issue of fact relevant to the proposed debarment. *See* 21 U.S.C. § 335a(i). DiCola requested the hearing but raised no issue of fact. Instead, he objected to his proposed debarment on the ground that it would violate the Ex Post Facto and Double Jeopardy Clauses of the United States Constitution (Article I, § 9 and Amendment V, respectively). In addition, DiCola claimed that the vagueness of the proposed order of debarment—which reiterated the terms of § 335a(a)(2) without further specification—would prevent him from engaging in "activities [that] could not adversely affect the regulatory process or public health and safety" and thus impose upon him a penalty "unrelated to any valid regulatory purpose." Specifically, DiCola informed the FDA that prior to his conviction he had been "employed as a salesman of printing materials including labels and labeling used with drug products" and that he feared "such activities might be debarred because of the vagueness of [§ 355a(a)(2)] combined with the FDA's lack of interpretation." In a follow-up letter, DiCola asked the FDA to define the phrase "service in any capacity" and to indicate whether DiCola's renewed employment as a salesman of drug labels and

labeling would indeed be precluded by his debarment.

In November 1993 the Secretary denied DiCola's request for a hearing, rejected DiCola's constitutional claims, and permanently debarred him. 58 Fed. Reg. 59,044. As for DiCola's request for clarification, the Secretary concluded that the statutory phrase "provide services in any capacity" is "clear on its face." To wit: "A debarred individual cannot provide any type of service to a person that has an approved or pending drug product application." *Id.* at 59,045/2. To DiCola's objection that the phrase, read literally, describes conduct unrelated to any valid regulatory purpose, the Secretary responded that the

> Congress can legitimately achieve [its] purpose [of protecting the public health] by prescribing "all services" due to the serious administrative difficulties involved in distinguishing between those positions clearly related to drug regulation from those clearly not regulated. These difficulties would include the problem of ascertaining the exact nature of the employee's relationship with the employer as well as defining what constitutes a sufficient nexus with the regulatory scheme under all circumstances.

Id. at 59,045/2-3.

When the Secretary denied his petition for reconsideration, DiCola petitioned this court for review of the final debarment order. Here he renews his claims that the order violates the double jeopardy and ex post facto clauses of the Constitution and reasserts as a deprivation of due process his claim that the order does not give him adequate notice of what conduct it prohibits. The parties agree that DiCola raised these issues before the agency, that no material facts are in dispute, and that this court should review DiCola's legal arguments de novo.[*]

II. Analysis

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[*]In a footnote to his opening brief, DiCola suggests that, properly interpreted, § 335a does not apply retroactively. The FDA answers, also in a footnote, that DiCola has waived the issue because he failed to raise it before the agency. In his reply brief DiCola, who again relegates the matter to a footnote, does not claim that he did raise the issue before the FDA. As the parties have argued the issue in the margins, so too do we dispose of it.

Because DiCola apparently concedes his failure to raise the issue of statutory construction before the agency, we hold that this circuit's waiver doctrine precludes him from raising the issue in his petition for review. *See State of Ohio v. U.S.E.P.A.,* 997 F.2d 1520, 1528-29 (D.C. Cir. 1993) (interests in agency autonomy and judicial efficiency both served by extending waiver doctrine to "purely legal" statutory interpretation claim not raised during rulemaking). As DiCola notes, we recognize an exception to the waiver doctrine where "a matter of great public importance" is at stake. *Id.* DiCola's waiver is not likely, however, to have an adverse impact upon anyone but himself.

The validity of DiCola's debarment under the double jeopardy and ex post facto clauses of the Constitution depends upon whether it is a wholly remedial or in part a punitive measure. *DeVeau v. Braisted,* 363 U.S. 144, 160 (1960) ("The mark of an ex post facto law is the imposition of what can fairly be designated punishment for past acts [or] ... whether the restriction of the individual comes about as a relevant incident to a regulation of a present situation"); *United States v. Halper,* 490 U.S. 435, 446-451 (1989) (discussing "whether and under what circumstances a civil penalty may constitute punishment for the purpose of the Double Jeopardy Clause"). The Supreme Court's decision in *United States v. Halper, supra,* governs that question. DiCola's due process claim turns upon whether the terms of the debarment order, which are prescribed by the statute itself, provide him with fair notice of the conduct they forbid.

A. The Double Jeopardy and Ex Post Facto Claims: Punishment vs. Remediation

In *Halper, supra,* the Supreme Court gave us what the Second Circuit has aptly dubbed a "rule of reason," *see United States v. Certain Real Property and Premises,* 954 F.2d 29, 34 (1992), for the resolution of disputes such as this:

> [T]he determination whether a given civil sanction constitutes punishment in the relevant sense requires a particularized assessment of the penalty imposed and the purposes that the penalty may fairly be said to serve.
>
> [A] civil sanction that cannot fairly be said solely to serve a remedial purpose, but rather can only be explained as also serving either retributive or deterrent purposes, is punishment, as we have come to understand this term. [A] defendant who already has been punished in a criminal prosecution may not be subjected to an additional civil sanction to the extent that the second sanction may not fairly be characterized as remedial, but only as a deterrent or retribution.

Halper, 490 U.S. at 448-49. DiCola argues that a debarment imposed pursuant to § 335a(a) must be regarded as punitive because of its (1) broad sweep, (2) unlimited duration, and (3) origin in the purpose of the Congress (as reflected in legislative history) to punish. The Seventh Circuit recently rejected the same arguments and endorsed the agency's view of the matter, holding that a debarment under § 335a(a) is "solely remedial." *See Bae v. Shalala,* 44 F.3d 489, 497 (7th Cir. 1995). For the reasons set forth below, so do we.

1. Breadth. DiCola argues that the statutory terms, which the agency incorporated into the order, describe "more than those activities that are rationally related to the drug approval process";

as a result, he urges, the debarment is "so broad as to be excessive and serves no valid [*i.e.,* remedial] regulatory purpose." For example, says DiCola, under the order he cannot be employed by "a construction company that builds a drug manufacturing facility," "a telephone company that provides service to a drug company," or "a company that prints labels approved by FDA for a drug company."

The FDA concedes that in some applications the literal terms of the statute (and hence of the order) would be "absurd." We take this as an acknowledgment that the FDA must construe and apply those terms with an eye to the remedial purpose of the statute and that this remedial purpose does not justify a literal reading of those terms. If the FDA had not wisely conceded the point, we would have insisted upon it in order to save the statute from constitutional infirmity under the double jeopardy clause. *See DeBartolo Corp. v. Florida Gulf Coast Building and Construction Trades Council,* 485 U.S. 568, 575 (1988).

Having conceded that the statute and the debarment order cannot mean quite what they say, the FDA nevertheless defends the terms of both as necessary in order to avoid two administrative difficulties. The first is the problem of "ascertaining the exact nature of [an] employee's relationship with [his] employer," and the second is the difficulty of "defining what constitutes a sufficient nexus with the regulatory scheme under all circumstances." 58 Fed. Reg. 59,045/2-3. The latter problem explains the agency's unwillingness to write its debarment order in terms more specific than those of the statute. We will focus upon that problem when we take up DiCola's due process claim. For the moment, we confine our attention to the first problem identified by the FDA; it is the one that explains why the agency believes that the remedial purpose of the statute justifies a broader scope of debarment than DiCola believes it does.

DiCola does not dispute that in some cases the agency may encounter genuine difficulty in "ascertaining the exact nature of [his] relationship with [an] employer." Indeed, we think it quite reasonable for the FDA to be concerned about any employment that might create an opportunity for regular and frequent contact between DiCola and the management of a drug company. The agency would find it very difficult, if not impossible, to assure itself and the public that DiCola is not, through that contact, actually selling advice or other services related to the circumvention of federal

regulation. This is reason enough for making the debarment sufficiently broad to cover DiCola's employment as a salesmen of labels and printing services to the pharmaceutical industry, to take his example. *See Siegel v. Lyng,* 851 F.2d 412, 416, 417-18 (D.C. Cir. 1988). We remind the agency, however, that even its legitimate concern with prophylaxis has its limits, and the debarment order must not be applied beyond them.

2. Duration. With exceptions not relevant here, debarment under 21 U.S.C. § 335a(a)(2) is permanent. § 335a(c)(2)(ii), (d)(3)(B) and (4)(D). The permanence of the debarment can be understood, without reference to punitive intent, as reflecting a congressional judgment that the integrity of the drug industry, and with it public confidence in that industry, will suffer if those who manufacture drugs use the services of someone who has committed a felony subversive of FDA regulation. *See* 21 U.S.C. § 355a note. That judgment may proceed from a skeptical view of the malleability of individual men and women, *see Hawker v. New York,* 170 U.S. 189, 196 (1898) ("It is not open to doubt that the commission of crime ... has some relation to the question of character. It is not, as a rule, the good people who commit crime"); or from a greater concern with the cost of an error visited upon the public than with the cost of an error felt only by the excluded felon, *see id.* at 197 ("Doubtless, one who has violated the criminal law may thereafter reform, and become in fact possessed of a good moral character. But the legislature has power in cases of this kind to make rule of universal application"); or more likely from the cumulative force of both sentiments.

DiCola urges us to distinguish the many cases construing various employment restrictions as remedial on the ground that none involved a debarment of breadth and duration comparable to the debarment imposed upon him by the FDA, yet he offers no reason to suppose that the agency's legitimate enforcement concerns, which account for the breadth, will fade over time. For the present purpose, therefore, the remedial understanding of the congressional judgment that the debarment should be permanent is not unreasonable.

3. Purpose. The legislative history that DiCola cites indicates that the legislators who spoke to the 1992 Act appreciated and approved its deterrent (*i.e.,* punitive) as well as its remedial effects. That history does not indicate that they regarded either the scope or the duration of the debarment

required by § 335a(a) as punitive, however. The remarks upon which DiCola relies were addressed to the 1992 Act as a whole, rather than to the mandatory debarment provision specifically. Because the Act also provided for civil penalties, 21 U.S.C. § 335b, which obviously are punitive, we cannot say with the needed confidence that the legislature intended debarment to be at all punitive. The legislative history, therefore, hardly offers the "unmistakable evidence of punitive intent," *Flemming v. Nestor,* 363 U.S. 603, 619 (1960), that would impel a court to hold that § 335a(a) violates the double jeopardy clause or that its application in this case violates the ex post facto clause. *Id.* at 617 ("Judicial inquiries into Congressional motives are at best a hazardous matter, and when that inquiry seeks to go behind objective manifestations it becomes a dubious affair indeed").

B. The Due Process Claim: Herein of Vagueness

"Two principal concerns undergird the requirement that governmental enactments be sufficiently precise: *first,* that notice be given to those who may run afoul of the enactment and, *second,* that the enactment channel the discretion of those who enforce it." *United States v. Thomas,* 864 F.2d 188, 194 (D.C. Cir. 1988); *see Connally v. General Construction Co.,* 269 U.S. 385, 391 (1926). Of these, the second is the greater, *id.* (citing *Kolender v. Lawson,* 461 U.S. 352, 358 (1983)), yet DiCola focuses upon the first. He argues that the debarment order requires him to guess, at his peril, what employment it prohibits.

The precision required by due process varies, of course, with "the nature of the enactment." *Village of Hoffman Estates v. Flipside, Hoffman Estates, Inc.,* 455 U.S. 489, 498 (1982). The Constitution is most demanding of a criminal statute that limits First Amendment rights; yet even there it requires only a "reasonable specificity to provide fair notice," and not "that a person contemplating a course of behavior know with certainty whether his or her act will be found to violate the proscription." *Thomas,* 864 F.2d at 195. Still "greater leeway" is permissible in a statute regulating business activities: "[N]o more than a reasonable degree of certainty can be demanded and it is not unfair to require that one who deliberately goes perilously close to an area of proscribed conduct shall take the risk that he may cross the line." *Throckmorton v. Nat'l Transportation Safety Board,* 963 F.2d 441, 444-45 (D.C. Cir. 1992) (citing *Boyce Motor Lines v. United States,* 342 U.S.

337, 340 (1952)).

Literally construed, the order debarring DiCola establishes a fairly simple rule of conduct: Do not provide any service to a drug manufacturer, either directly as an employee or indirectly as the employee of a company that provides such a service. As noted earlier, however, literal application of the order would also be excessive when measured by the remedial purpose of the statute that it implements. The FDA chose, nonetheless, not to write the debarment order in terms more specific than those in the statute because of the difficulty inherent in "defining what constitutes a sufficient nexus with the regulatory scheme under all circumstances." 58 Fed. Reg. 59,045/2-3. DiCola does not deny that this is a problem, but he does not even try to show that there might be a standard that would provide better notice to persons debarred without unduly restricting the agency's ability to take appropriate action in the unanticipated case sure to arise.

Moreover, that the statute and the order must be construed not literally but with reference to their remedial purpose does not render them unconstitutionally vague. As we have said, the remedial purpose of the statute constrains the FDA's discretion to sanction DiCola for a violation, and DiCola is on notice that, without prior approval from the FDA, he gets close to the pharmaceutical industry at his peril. *Cf. Throckmorton,* 963 F.2d at 443, 444 (sustaining prohibition against flying an aircraft "so close to another as to create a collision hazard").

For the most part, DiCola should have little or no trouble determining whether his debarment precludes his availing himself of a particular opportunity. He professes not to know whether he may work as a cook in the cafeteria of a drug company or even whether he may sell goods to a food service contractor that operates a drug company's cafeteria. We think it quite clear, however, that all direct employment by a drug company, whether in the board room or the cafeteria or somewhere in between, comes within the remedial scope of the debarment order; such employment would raise the risk to which we have alluded and concomitantly increase the supervisory burden upon the FDA. Just as clearly, DiCola's selling provisions to a food service contractor that in turn operates a drug company's cafeteria is not even within the literal scope of the debarment order.

The hard cases involve DiCola's employment by an enterprise that provides goods or services

to a drug manufacturer—which is not to say that all such cases are hard. Indeed, the FDA concedes that it would be "ludicrous" to apply the debarment so as to sanction DiCola for "doing janitorial work at a telephone company" that provides service to a drug manufacturer. The agency does not say why it would be ludicrous, but surely the answer is that the position in question would not put DiCola into regular contact with the management of a drug company. Other types of employment by a supplier of goods or services to a drug company might do just that.

It is therefore fanciful for DiCola to say that he can only "guess" at the meaning of the debarment order; he will usually have a pretty good idea whether a position with a firm that is not itself a drug manufacturer runs afoul of the remedial purpose for which he has been debarred from providing services to a drug house. As we have said before, it is often sufficient, so far as due process is concerned, "that the proscription mark out the rough area of prohibited conduct, allowing law-abiding individuals to conform their conduct by steering clear of the prohibition." *Thomas,* 864 F.2d at 194.

Finally, DiCola is not utterly without relief from such real uncertainty, if any, as he may face. At oral argument counsel for the FDA represented that DiCola may seek a prospective ruling about a specific employment opportunity by filing a "citizen's petition" with the agency. DiCola conceded this and that the FDA has said it will endeavor to respond to such petitions within 60 days, but claims that the agency has, in fact, kept some citizens' petitions pending for years. Given the nature of DiCola's interest, the opportunity to obtain a prospective ruling would be worthless if the agency unreasonably delayed its response to his inquiry. If DiCola in fact encounters unreasonable delay, however, he may petition this court for a writ of mandamus, *see Telecommunications Research & Action v. F.C.C.,* 750 F.2d 70, 79 (D.C. Cir. 1984); in such an action the court will consider that DiCola's livelihood may be at stake, *id.* at 80, and "need not find any impropriety lurking behind agency lassitude in order to hold that agency action is unreasonably delayed," *id.*

III. Conclusion

For the foregoing reasons, DiCola's petition for review of the FDA's order debarring him from providing services in any capacity to the pharmaceutical industry is

Denied.