United States Court of Appeals

For the Seventh Circuit
Chicago, Illinois 60604

Submitted January 4, 2006*
Decided January 5, 2006

Before

Hon. RICHARD A. POSNER, *Circuit Judge*

Hon. DANIEL A. MANION, *Circuit Judge*

Hon. ILANA DIAMOND ROVNER, *Circuit Judge*

No. 05-1077

BALDEV R. BHUTANI,
Petitioner,

v.

UNITED STATES FOOD AND DRUG ADMINISTRATION and MICHAEL O. LEAVITT,** Secretary, Department of Health and Human Services,
Respondents.

Petition for Review of an Order of the United States Food and Drug Administration

---

*After an examination of the briefs and the record, we have concluded that oral argument is unnecessary. Thus, the appeal is submitted on the briefs and the record. *See* Fed. R. App. P. 34(a)(2).

** Pursuant to Fed. R. App. P. 43(c), we have substituted Michael O. Leavitt for Tommy G. Thompson as the named respondent.

O R D E R

Baldev Raj Bhutani, the former president of a generic drug manufacturing company, petitions this court for review of a final order of the United States Food and Drug Administration ("FDA") permanently debarring him from rendering services to persons with approved or pending drug applications. The debarment resulted from Bhutani's felony convictions for violating the Federal Food, Drug, and Cosmetic Act ("FDCA"). We deny the petition.

In 1996 a jury found Bhutani guilty of seven felony offenses including six counts of violating the FDCA, 21 U.S.C. §§ 331(a),(e),(k), and 333(a)(2), for, among other things, introducing adulterated generic drug products into interstate commerce from 1988 to 1989. After this court heard two appeals of Bhutani's criminal case, *see United States v. Bhutani*, 266 F.3d 661 (7th Cir. 2001), *United States v. Bhutani*, 175 F.3d 572 (7th Cir. 1999), and while Bhutani was serving his 30 month sentence for his crimes, the FDA notified Bhutani in 2003 that it proposed to debar him under the Generic Drug Enforcement Act ("GDEA"), 21 U.S.C. §§ 335a-335c. The GDEA was enacted in 1992, before Bhutani's convictions but several years after his criminal conduct. The GDEA mandates permanent debarment for any individual "convicted of a felony under Federal law for conduct . . . relating to the regulation of any drug product" under the FDCA. *Id.* § 335a(a)(2)(B). The FDA also informed Bhutani that he had an opportunity for an evidentiary hearing if he presented specific facts demonstrating a genuine and substantial issue of fact.

Under § 335a(a)(2)(B), the only fact relevant to Bhutani's debarment was whether he had been convicted of felonies for conduct related to the regulation of a drug product under the FDCA. Because he acknowledged that he had qualifying felony convictions, in December 2004 the FDA denied his request for an evidentiary hearing. The agency also rejected Bhutani's legal arguments that debarment was unconstitutional and barred by equitable defenses. The FDA issued an order permanently debarring Bhutani from "providing services in any capacity to a person that has an approved or pending drug product application." 21 U.S.C. § 335a(a)(2)(B); Baldev Raj Bhutani, 69 Fed. Reg. 70148 (Dep't of Health and Human Servs. and Food and Drug Admin. Dec. 2, 2004) (denial of hearing; final debarment order).

On appeal, Bhutani raises two constitutional issues: that his debarment violates the Ex Post Facto and Double Jeopardy Clauses of the Constitution. These are pure questions of law that we review de novo. *See Bae v. Shalala*, 44 F.3d 489, 492 (7th Cir. 1995). Bhutani argues that his debarment under § 335a(a)(2)(B) violates the prohibition against ex post facto laws because the GDEA—the law authorizing his debarment—was passed only after he had engaged in the conduct

giving rise to his FDCA felony convictions. But we have already held that permanent debarment under such retroactive application of the GDEA does not offend the Ex Post Facto Clause because debarment is a remedial, not punitive, sanction. *Bae*, 44 F.3d at 496 ("The GDEA's civil debarment penalty is solely remedial," so the ex post facto prohibition is inapplicable); *see also DiCola v. FDA*, 77 F.3d 504, 507 (D.C. Cir. 1996) (same).[1]

Bhutani next asserts that his debarment is prohibited by the Double Jeopardy Clause because he has already been convicted and sentenced for his conduct. But double jeopardy precludes only multiple criminal punishments, not civil sanctions. *See Hudson v. United States*, 522 U.S. 93, 99 (1997). Determining whether debarment is criminal or civil requires a two-step analysis. First, we look to the statute to see if the legislature expressly or impliedly intended that the sanction be criminal or civil. *Id.* Although § 335a(a)(2)(B) does not specifically characterize debarment as civil, the Supreme Court has held that if authority to debar is vested in an administrative agency (such as the FDA in this case), it "is prima facie evidence that Congress intended to provide for a civil sanction." *Hudson*, 522 U.S. at 103. Since Bhutani has offered nothing to rebut this prima facie evidence, § 335a(a)(2)(B) is presumptively a civil sanction.

Second, we examine whether there is the "clearest proof" that § 335a(a)(2)(B) is nonetheless so punitive that it transforms what Congress deemed a civil sanction into a criminal penalty. *Hudson*, 522 U.S. at 100. Because we held in *Bae* that debarment is remedial, it is therefore neither punitive nor criminal. The Supreme Court's analysis in *Hudson* two years after *Bae* confirms this conclusion. *Hudson* held that there was "little evidence" that a debarment sanction prohibiting further participation in banking activities was so punitive as to transform the civil penalty into a criminal penalty. The Court reasoned that debarment has not historically been viewed as punishment, does not come into play only upon a finding of scienter, and is not akin to imprisonment. *Id.* at 104. The Court also found that even though the underlying conduct for imposing debarment might also be criminal, this alone was not enough to make debarment criminally punitive. *Id.* at 105. Finally, although debarment sanctions are meant to deter others from similar conduct—an objective of criminal punishment—"deterrence may serve civil as well as criminal

---

[1] Bhutani also argues that the GDEA cannot be applied retroactively as a matter of statutory construction. Because he did not expressly raise or develop the issue of statutory construction before the FDA, we will not consider it here. *See Myron v. Chicoine*, 678 F.2d 727, 731 (7th Cir. 1982) (collecting cases); *see also DiCola* 77 F.3d at 506 n.* (by not raising the issue before the FDA, petitioner waived appellate review of whether GDEA could be applied retroactively as a matter of statutory law).

goals." *Id.* (internal quotation and citation omitted). Under this authority, Bhutani's permanent occupational debarment under the GDEA is a civil sanction, so double jeopardy is not offended. *See DiCola*, 77 F.3d at 507.

Bhutani raises other nonconstitutional issues which we can readily dispose of. He claims that the FDA arbitrarily and capriciously failed to examine the "exculpatory" evidence of the consent and voluntary agreements he made with the FDA in 1991 to bring his drug product into compliance with the FDCA. He asserts that the agreements are evidence that there was an "implied contract" in which the FDA promised to forgo all future action against him and that the FDA should therefore be "estopped" from debarring him. But the 1991 agreements do not state or imply that the FDA promised to release Bhutani from additional remedial sanctions in general, or debarment in particular. Indeed, these agreements are understandably silent about debarment because the GDEA debarment provision was not even enacted until 1992.

Next, Bhutani argues that the FDA was arbitrary and capricious by not considering the facts underlying his convictions, which he believes are mitigating. But these facts are irrelevant to debarment since the only issue under § 335a(a)(2)(B) is whether he had a prior felony conviction for violating the FDCA. "Congress adopted a bright-line rule excluding from the generic drug industry all individuals with prior felony convictions relating to the approval or regulation of any generic drug product." *Bae*, 44 F.3d at 495. Bhutani's related argument that the FDA erred by not giving him a hearing fails for the same reason—the only issue of material fact was whether Bhutani had been convicted of felonies for conduct related to the regulation of a drug product under the FDCA, and since he admitted that he was, a hearing was not required.

Bhutani next argues that the FDA should be barred from bringing suit under the doctrine of laches because the agency took too long to initiate debarment proceedings. He claims this delay prejudiced him because his "evidence" is now stale. Laches bars an action only if the plaintiff's delay in bringing suit is unreasonable and if the delay "materially prejudices the defendant." *Smith v. Caterpillar, Inc.,* 338 F.3d 730, 733 (7th Cir. 2003). But in this case, even if there were an unreasonable delay and even assuming that laches can be invoked against the federal government, *see United States v. Administrative Enterprises, Inc.*, 46 F.3d 670, 672-73 (7th Cir. 1995), Bhutani can't show he was prejudiced because the only material issue is whether Bhutani had prior FDCA-related convictions. Since he concedes the fact of these convictions, the absence of any other evidence is immaterial and therefore nonprejudicial.

Finally, Bhutani contends that the FDA should have subjected him to five-year, as opposed to permanent, debarment. However, § 335a(c)(2)(A)(ii) mandates

permanent debarment for individuals like Bhutani who are penalized under § 335a(a)(2). *See* 21 U.S.C. § 335a(c)(2)(A)(ii). Permanent debarment is therefore both authorized and required.

Accordingly, the petition for review is DENIED.