

Tab 2-14

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University Medical Center of Southern Nevada v.  
Shalala  
D.D.C.,1998.United States District Court,District of Columbia.  
UNIVERSITY MEDICAL CENTER OF  
SOUTHERN NEVADA, Plaintiff,

v.

Honorable Donna E. SHALALA, Secretary,  
Department of Health & Human Services,  
Defendant.

No. Civ.A. 97-0560(JHG).

May 13, 1998.

University medical center which had been excluded from participation in drug pricing agreement program under Public Health Services Act (PHSA) sued Secretary of Health and Human Services (HHS), alleging that HHS had improperly calculated its disproportionate share adjustment percentage. On cross-motions, the District Court, Joyce Hens Green, J., held that any injury suffered by center due to improper calculation was not redressable, and center thus lacked standing, where it was automatically ineligible to participate in program due to its simultaneous participation in group drug purchasing agreements under PHSA.

Defendant's motion for judgment on the pleadings granted, and remaining motions denied.

West Headnotes

**[1] Federal Civil Procedure 170A ↪103.2**

170A Federal Civil Procedure

170AII Parties

170AII(A) In General

170Ak103.1 Standing

170Ak103.2 k. In General; Injury or  
Interest. Most Cited Cases**Federal Courts 170B ↪12.1**

170B Federal Courts

170BI Jurisdiction and Powers in General

170BI(A) In General

170Bk12 Case or Controversy  
Requirement170Bk12.1 k. In General. Most Cited  
Cases

Article III standing is threshold jurisdictional question that must be resolved in plaintiff's favor before proceeding to merits of case. U.S.C.A. Const. Art. 3, § 2, cl. 1.

**[2] United States 393 ↪82(1)**

393 United States

393VI Fiscal Matters

393k82 Disbursements in General

393k82(1) k. In General. Most Cited Cases  
Injury suffered by university medical center when Department of Health and Human Services (HHS) determined, based on allegedly erroneous calculation of its disproportionate share adjustment percentage, that center was ineligible to participate in drug pricing agreement program under Public Health Services Act (PHSA), was not redressable, and center thus lacked standing to challenge calculation, where center also participated in group drug purchasing agreements, making it automatically unable to qualify as covered entity which could participate in pricing agreement program; because center was ineligible regardless of proper calculation, court intervention could not provide tangible benefit. U.S.C.A. Const. Art. 3, § 2, cl. 1; Public Health Service Act, § 340B, as amended, 42 U.S.C.A. § 256b.

**[3] Federal Civil Procedure 170A ↪103.3**

170A Federal Civil Procedure

170AII Parties

170AII(A) In General

170Ak103.1 Standing

170Ak103.3 k. Causation;  
Redressability. Most Cited Cases

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Fundamental question underlying redressability requirement, which must be met for plaintiff to have standing under Article III, is whether plaintiff personally would benefit in a tangible way from court's intervention. U.S.C.A. Const. Art. 3, § 2, cl. 1.

**[4] Federal Civil Procedure 170A ⇨ 103.3**

170A Federal Civil Procedure

170AII Parties

170AII(A) In General

170Ak103.1 Standing

170Ak103.3 k. Causation;

Redressability. Most Cited Cases

In general, when government action or inaction is challenged by party who is target or object of that action, there is ordinarily little question that action or inaction has caused him injury, and that judgment preventing or requiring action will redress it; accordingly, such a party satisfies redressability requirement for Article III standing when he shows that favorable decision will relieve discrete injury to himself, and need not show that favorable decision will relieve his every injury. U.S.C.A. Const. Art. 3, § 2, cl. 1.

\*5 Elliott Bruce Adler, Powell, Goldstein, Frazer & Murphy, Washington, DC, for Plaintiff.

Sheila Mae Lieber, U.S. Dept. of Justice, Washington, DC, Scott Sutherland Harris, U.S. Attorney's Office, Washington, DC, Alina Semo Kofsky, U.S. Dept. of Justice, Washington, DC, for Defendant.

**MEMORANDUM OPINION AND ORDER**

JOYCE HENS GREEN, District Judge.

This action concerns defendant's administration of the Drug Pricing Program enacted as § 340B of the Public Health Service Act. 42 U.S.C. § 256b. Specifically, plaintiff University Medical Center of Southern Nevada ("UMC") alleges that defendant improperly excluded UMC from the list of entities eligible to receive drug discounts under the 340B program. Presently pending are plaintiff's Motion for Summary Judgment; defendant's Motion for Judgment on the Pleadings or, in the Alternative, for Summary Judgment; plaintiff's Motion to

Supplement the Record and to Permit the Taking of Discovery; plaintiff's Motion to Strike Defendant's Statement of Material Facts; and plaintiff's Motion to Strike Defendant's Response to plaintiff's Statement of Material Facts in Dispute. Upon careful consideration of the entire record in this matter, the Court concludes that plaintiff lacks constitutional standing. Therefore, this action will be dismissed.

*Statutory Setting*

Concerned about the drug prices charged to facilities treating low-income persons, in 1992 Congress amended the Public Health Services Act by adding § 340B entitled "Drug Pricing Agreements" (the "340B program").<sup>FN1</sup> Under that section, the Secretary of the Department of Health and Human Services was instructed to enter into agreements with manufacturers of covered drugs so that the amount manufacturers charged "covered entities" for those drugs did not exceed a price calculated according to a specified formula. 42 U.S.C. § 256b(a)(1). To be eligible to purchase drugs from manufacturers under the Secretary's drug pricing agreements, a facility had to both qualify as a "covered entity," 42 U.S.C. § 256b(a)(4), and meet the list of other requirements found in § 340(a)(5).<sup>FN2</sup>

FN1. Section 340B was enacted on November 4, 1992, Veterans Health Care Act of 1992 § 602, 106 Stat. 4943, 4967, 42 U.S.C. § 256b (Nov. 4, 1992), and took effect on December 1, 1992. 42 U.S.C. § 256b(a)(1).

FN2. 42 U.S.C. § 256b(a)(5). The § 340B(a)(5) provisions preclude facilities from receiving duplicate discounts or rebates, *id.* § 256b(a)(5)(A); prohibit the resale of drugs purchased under the § 340B program, *id.* § 256b(a)(5)(B); require the participating facility to allow

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compliance audits, *id.* § 256b(a)(5)(C); and provide for sanctions for non-compliance with the duplicate discount/rebate prohibition and the no-sale provision, *id.* § 256b(a)(5)(D). These requirements are not at issue in this case.

Section 340B defined twelve different types of facilities that could qualify as covered entities. *Id.* § 256b(a)(4). One specific type of “covered entity” is at issue here: those hospitals providing health care services to low-income patients that “had a disproportionate share adjustment percentage ... greater than 11.75 percent” (a “disproportionate share hospital”). *Id.* § 256b(a)(4)(L).<sup>FN3</sup> The “disproportionate share adjustment percentage” (“DSH”) is a complex calculation involving the percentages of low-income Medicaid and non-Medicaid patients treated, the hospital's number of beds, and the hospital's location, *see* 42 U.S.C. § 1395ww(d)(5)(F); the precise details of the calculation are not at issue in this case.

FN3. In addition, to qualify as a “covered entity,” a “disproportionate share” hospital had to be located in one of the fifty states or the District of Columbia and not be certain psychiatric, rehabilitation, pediatric, long-term or cancer facilities. 42 U.S.C. § 1395ww(d)(1)(B). The hospital must also be owned or operated by a unit of State or local government, be a public or private non-profit corporation formally granted powers by a unit of State or local government, or be a private non-profit hospital that has a contract with a State or local government to provide health care services to low income persons who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under that title. 42 U.S.C. § 256b(a)(4)(L)(i). These requirements are not at issue in this case.

In addition, the statute specifically precluded “disproportionate share hospitals” from “obtain[ing] covered outpatient drugs through a group purchasing organization or other group purchasing

arrangement.” *Id.* § 256b(a)(4)(L)(ii). In other words, a “disproportionate share hospital” could not participate in two drug price-reducing arrangements at the same time, but had to choose between the price negotiated under the 340B program and prices it could obtain as part of a group purchasing arrangement.

#### *Factual Background*

The following facts are not disputed. UMC's initial eligibility for the 340B program was based on its Fiscal Year 1991 cost report, which reflected a disproportionate share adjustment percentage (“DSH”) of less than 11.75%. Therefore, because UMC's reported DSH did not meet the 11.75% threshold, UMC was not included on the initial list of covered entities. In 1992-93, UMC's 1991 cost report was audited. As a result of this audit, on August 30, 1993, the auditing organization issued a final Notice of Program Reimbursement based on the audited 1991 cost report showing that UMC's correct DSH was greater than 11.75%.

Based on the results of the audit, in January 1994, UMC wrote to defendant's Office of Drug Pricing to explain that the hospital's DSH had initially been calculated incorrectly, but was now known to be greater than 11.75% and to request inclusion in the 340B program based on a DSH of greater than \*7 11.75%. On April 1, 1994, UMC's auditor wrote to defendant's Health Care Financing Administration, stating that UMC's DSH for the 1991 fiscal year was greater than 11.75%.

Prior to implementation of the 340B program, UMC had participated in group drug purchasing agreements. UMC continued to participate in these group purchasing agreements while its 1991 cost report was being audited and during the time that it wrote to defendant seeking inclusion on the “covered entity” list.

On July 12, 1994, the Director of the Medicaid Bureau wrote to Congresswoman Barbara Vucanovich to report that effective July 1, 1994, UMC had been added to the list of entities eligible to participate in the 340B program. After July

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1994, UMC continued to press defendant to include it on the covered entity list retroactive to December 1, 1992; defendant refused to do so. In March 1997, UMC filed this suit.

According to UMC, the entire focus of this case should be the fact that its disproportionate share adjustment percentage, recalculated after the audit, was greater than 11.75%. However, that narrow focus overlooks a clear statutory requirement that bars plaintiff from any relief. Because UMC participated in drug purchasing agreements, it was statutorily precluded from participation in the 340B program, 42 U.S.C. § 256b(a)(4)(L)(ii), and is entitled to no relief. Without the possibility of relief, UMC's injury is not redressable in this action and UMC lacks constitutional standing.

[1] Article III standing is a threshold jurisdictional question that must be resolved in plaintiff's favor before proceeding to the merits of the case. *Steel Company v. Citizens for a Better Env't*, 523 U.S. 83, 118 S.Ct. 1003, 1012-15, 140 L.Ed.2d 210 (1998). As the United States Supreme Court recently reiterated, "the 'irreducible constitutional minimum of standing' contains three requirements." *Id.* 523 U.S. 83, 118 S.Ct. at 1016 (1998) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)). First and foremost, there must be alleged (and ultimately proven) an injury in fact—a harm suffered by the plaintiff that is concrete and actual or imminent, not conjectural or hypothetical. Second, there must be causation—a fairly traceable connection between plaintiff's injury and the complained-of conduct of the defendant. And third, there must be redressability—a likelihood that the requested relief will redress the alleged injury. This triad of injury in fact, causation, and redressability comprises the core of Article III's case-or-controversy requirement, and the party invoking federal jurisdiction bears the burden of establishing its existence.

*Id.* 523 U.S. 83, 118 S.Ct. at 1016-17 (internal citations omitted).

[2] In this case, the parties do not seriously dispute the injury-in-fact or causation elements of standing. To paraphrase plaintiff, the Secretary's refusal to include UMC on the list of covered entities deprived UMC of the full measure of benefits available under the 340B Program, particularly discounts from drug manufacturers. Pl.'s Reply Br. in Supp. of Mot. for Summ. J. at 5-6; see Def.'s Opp'n to Pl.'s Mot. for Summ. J. at 3 ("the covered outpatient drug discounts [UMC] allegedly forewent from December 1, 1992 to July 1, 1994"). On the other hand, the parties do sharply dispute whether such injury is redressable.<sup>FN4</sup>

FN4. Defendant argues that plaintiff's injury is not redressable because plaintiff ultimately seeks monetary damages in the form of retroactive rebates for covered drugs purchased between December 1, 1992, and July 1, 1994, and defendant is not authorized to provide monetary relief. See Def.'s Mot. for J. on the Pleadings, or in the Alternative, for Summ. J. pp. 21-24. Since the Court agrees that plaintiff lacks standing, noting *infra* her reasons for that determination, it is unnecessary to address defendant's reasoning.

[3][4] The fundamental question underlying the redressability requirement "has always been the same: whether a plaintiff 'personally would benefit in a tangible way from the court's intervention.'" *Steel Co.*, 523 U.S. at ---n. 5, 118 S.Ct. at 1017 n. 5 (quoting *Warth v. Seldin*, 422 U.S. 490, 508, 95 S.Ct. 2197, 45 L.Ed.2d 343 (1975)). As a \*8 general rule, "[w]hen government action or inaction is challenged by a party who is a target or object of that action ... 'there is ordinarily little question that the action or inaction has caused him injury, and that a judgment preventing or requiring the action will redress it.'" *Minnesota Citizens Concerned for Life v. Federal Election Comm'n*, 113 F.3d 129, 131 (8th Cir.1997) (quoting *Lujan*, 504 U.S. at 561-62, 112 S.Ct. 2130). Such a party satisfies the redressability requirement "when he shows that a favorable decision will relieve a discrete injury to himself. He need not show that a favorable decision will relieve his every injury." *Id.* (citing

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*Larson v. Valente*, 456 U.S. 228, 243 n. 15, 102 S.Ct. 1673, 72 L.Ed.2d 33 (1982) (plurality opinion)).

In this case, however, the relief that UMC seeks <sup>FN5</sup> cannot be granted by this Court or by defendant because that relief would violate a clear statutory provision. When Congress enacted § 340B, it specified that a “disproportionate share hospital,” such as UMC, could be considered a “covered entity” eligible to participate in the 340B program only if that hospital “does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.” 42 U.S.C. § 256b(a)(4)(L)(iii). In its papers, UMC forthrightly admits that:

FN5. According to the Complaint, UMC seeks the following relief:

A. That the Court declare that the Secretary's interpretation of the statutory provision operates to deny Plaintiff its full disproportionate share hospital discount required by statute, and is therefore in violation of the Public Health Services Act, the Administrative Procedures Act, and the Constitution;

B. That the Court declare that the Plaintiff was a covered entity under Section 340B of the Public Health Service Act and, as such, was and remains eligible for retroactive discounts on covered outpatient drugs purchased by UMC on or after December 1, 1992;

C. That the Court order the Secretary to take all steps necessary to include the Plaintiff on the list of eligible entities, as described under 59 Fed.Reg. 25110 such that Plaintiff may recover the rebates for all covered outpatient drugs it purchased from December 1, 1992 through the present;

D. That the Court award Plaintiff its costs and attorney's fees as allowed by law; and

E. That the Court grant such other and further relief as is proper in the premises.

Compl. pp. 13-14.

the applicable statute and guidelines published by ODP prohibited a covered entity from participating in any Group Purchasing Organization (“GPO”) or other group purchasing arrangement for the purpose of buying any of the drugs covered by the 340B Program. *This was a condition for eligibility separate and apart from the DSH-factor threshold.* Also, as described earlier in Section III(C) [of plaintiff's Motion for Summary Judgment], *supra*, UMC, when confronted with the unfortunate reality of exclusion from the 340B Program, continued purchasing certain of the outpatient drugs covered by the 340B Program through its group purchasing arrangements.

Pl.'s Mot. for Summ. J. pp. 30-31 (emphasis added); *see also* Affidavit of William R. Hale, Chief Executive Officer of University Medical Center of Southern Nevada (attached to Pl.'s Mot. for Summ. J.), ¶ 12 (“UMC had no alternative but to continue its use of pre-existing group purchasing arrangement that had been in effect since before the advent of the 340B Program”); Pl.'s Statement of Material Facts as to which there is No Genuine Issue ¶ 12 (“UMC ... continued with its group purchasing arrangements because it had no other choice and had to secure whatever price discounts it could.”). Because UMC continued to purchase covered drugs through a group purchasing arrangement, it was statutorily precluded from eligibility for the 340B program.

Congress clearly expressed its intent that the 340B program prohibit “double-dipping” into two drug price-reducing mechanisms. *See* 42 U.S.C. § 256b(a)(4)(L)(ii) (prohibition on participation in group purchasing agreements); *id.* § 256b(a)(5)(A) (prohibition on concurrent discounts through 340B program and title XIX of the Social Security Act). Because UMC elected, for whatever reason, to continue participation in its pre-existing group purchasing agreements, it cannot now also claim eligibility for the 340B program discounts. The intervention of this Court \*9 cannot provide UMC with any tangible benefit. *See Steel Co.*, 523 U.S. at --- n. 5, 118 S.Ct. at 1017 n. 5. Therefore, UMC's injury is not redressable and it lacks standing to bring this suit.

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After thorough consideration of the entire record in this matter, it is hereby

**ORDERED** that, because plaintiff University Medical Center of Southern Nevada lacks constitutional standing, defendant's Motion for Judgment on the Pleadings is **granted** on the grounds stated in this Opinion; and it is

**FURTHER ORDERED** that plaintiff's Motion for Summary Judgment; plaintiff's Motion to Supplement the Record and to Permit the Taking of Discovery; plaintiff's Motion to Strike Defendant's Statement of Material Facts; and plaintiff's Motion to Strike Defendant's Response to plaintiff's Statement of Material Facts in Dispute are **denied**.

IT IS SO ORDERED.

For the reasons stated in the Court's Memorandum Opinion and Order issued this date, judgment on the pleadings is hereby entered in favor of defendant Donna E. Shalala, Secretary, Department of Health and Human Services and against plaintiff University Medical Center of Southern Nevada.

IT IS SO ORDERED.

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