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FLAG ON THE PLAY: THE NINTH CIRCUIT'S END-RUN AROUND IMPLIED RIGHTS OF ACTION RUNS AFOUL IN COUNTY OF SANTA CLARA v. ASTRA, USA INC.

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FLAG ON THE PLAY: THE NINTH CIRCUIT'S END-RUN AROUND IMPLIED RIGHTS OF ACTION RUNS AFOUL IN COUNTY OF SANTA CLARA v. ASTRA, USA INC.

Brooke E. Burns[1]

I. False Start: An Overview of the Problem, Current Legal Situation, and Casenote

In 2007, aggregate prescription drug expenditures in the United States totaled over $287 billion.[2]

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[2] See Prescription Drug Costs: Background Brief – Issue, **KaiserEdu.Org**, http://www.cms.gov/National HealthExpendData/downloads/proj2009. pdf (last updated Feb. 2010) [hereinafter Drug Costs] (discussing how "in recent history, increases in prescription drug costs have outpaced other categories of health care spending, rising rapidly throughout the latter half of

Although the recessionary effects in 2008 reduced U.S. prescription drug spending to $234.1 billion, the Department of Health and Human Services ("HHS") projects that drug spending will increase twofold by 2019 and reach $457.8 billion.[3] Based on the most

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the 1990s and early 2000s"); see also James M. Hoffman et al., Projecting Drug Expenditures – 2009, **Am J Health-Syst Pharm (Vol 66 Feb. 01, 2009)**, at 237, available at http://www.imshealth.com/deployed files/imshealth/Global/Content/StaticFile/Drug_Expenditure_Forecast_2009.pdf [hereinafter Hoffman] (reporting that "from 2006 to 2007, total drug expenditures increased by 4.0% with total spending rising from $276 billion to $287 billion").

[3] See Prescription Drug Trends, **KFF.Org**, http://www.kff.org/rxdrugs/upload/3057-08.pdf (last updated May 2010) [hereinafter Drug Trends] (reasoning why drug spending will double by 2019). According to HHS projections:

> The average annual increase in drug spending from [2007] is projected to increase from 3.2% in 2008 to 5.2% in 2009 (reflecting growth in the use of

recent estimates by the Health Resources and Services administration ("HRSA"), drug expenditures by 340B

> prescription drugs per person, driven by an increase in the use of anti-viral drugs related to the H1N1 virus), and then rise to 7.3% in 2019 (reflecting increases in drugs prices, the number of new drug approvals, and the share of expensive specialty drugs). Drug spending as a percent of overall national health spending is projected to increase somewhat from 10.0% in 2008 to 10.2% in 2019.

Id. at 3 (describing outlook for future); see also Truffer Christopher J. et al., Health Spending Projections Through 2019: The Recession's Impact Continues, **Health Affairs 29, No.3 (March 2010),** available at http://www.scribd.com/doc/26374791/By-Christopher-J-Truffer-Sean-Keehan-Sheila (last visited October 11, 2010) (theorizing that "the economic recession and rising unemployment-plus changing demographics and baby boomers aging into Medicare-are among the factors expected to influence health spending during 2009-2019").

entities alone accounted for at least $4 billion.[4] The "rising cost of pharmaceuticals, . . . aging population and increased [utilization] of costly specialty drugs" has pressured 340B entities (federally-qualified health centers) and other health care providers to seek cost containment measures.[5]

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[4] See Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, **Hearing Before the H. Comm. on Energy and Commerce Subcomm. On Oversight and Investigations 1 (Dec. 15, 2005)** (testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections Office of Inspector General, U.S. Department of Health and Human Services), available at http://oig.hhs.gov/testimony/docs/2005/340bHouseE&C12-05.pdf [hereinafter Oversight] (determining that "based on the most recent HRSA estimates, 340B entities spent $4 billion on covered outpatient drugs in calendar year 2005").

[5] See Drug Costs, supra note 1, (explaining why "spending on prescription drugs continues to be an important heath care concern"); see also Hoffman, supra note 1, at 237 (commenting that "in health

Both the public and private sector have attempted to relieve pressures driving prescription spending by implementing utilization, pricing, and regulatory strategies.[6]

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plans, hospitals, and other health care organizations, drug costs continue to be a substantial operating expense and a frequent target for cost containment"). Policymakers and administrators specifically target spending on specialty drugs to contain costs. Id. at 249 (indicating that "specialty medications are one of the primary areas of medication expenditure growth").

[6] See Drug Trends, supra note 2, (concluding that "three main factors drive changes in prescription drug spending: changes in the number of prescriptions dispensed (utilization), price changes, and changes in the types of drugs used."); see also Drug Costs, supra note 1, (explaining increased growth in spending on pharmaceuticals). Factors contributing to this rate of growth include: 1) increased utilization and demand for prescription drugs; 2) types of prescriptions written; 3) price increases; 4) research and Development; 5) advertising and marketing; and 6) the

Pharmaceutical manufacturers' concessions to provide discounts to 340B entities and Medicaid rebates to states, however, have appeared disingenuous as drug prices continue to escalate.[7] Further, concerns regarding the pharmaceutical industry's profit margins have overshadowed the benefits that pharmaceutical manufacturers' products provide.[8]

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role of patent laws. Id. (listing factors responsible for rapid and continued increase in drug spending).

[7] See Id. (finding that "rising prescription costs have led many to call for greater government involvement in regulating the pharmaceutical industry, particularly since prices for brand pharmaceutical products are considerably higher in the U.S. than in countries where governments take a more active role in negotiating prices and regulating profits").

[8] See e.g., **145 Cong. Rec. H23047 (Sept. 28, 1999)** (statement of Rep. Allen) (commenting that "remarkable achievements [of prescription drugs] are today overshadowed by the exorbitantly high prices consumers in America are being required to pay for these

prescription drugs"); Drug Costs, supra note 1, (announcing that "pharmaceutical manufacturing was the most profitable industry in the U.S. from 1995 to 2002"); Drug Trends, supra note 2, (reporting that "from 1995 to 2002, pharmaceutical manufacturers were the nation's most profitable industry (profits as a percent of revenues)"). . . . [and] . . . ranked 3rd in profitability in 2003 and 2004, 5th in 2005, 2nd in 2006, and 3rd in 2007 and 2008"); Top Industries: Most Profitable, **Fortune: Fortune 500 Annual Ranking (April Issue)**, available at http://money.cnn.com/magazines/fortune/fortune500/2009/performers/industries/profits/ (ranking Pharmaceuticals as third on list of most profitable industries for having profits of 19.3% in 2008). But see R. Levy, Costs and Benefits of Pharmaceuticals: the value equation for older Americans, **Care Manag J. 2002 Spring 3(3): 135-42**, available at http://www.ncbi.nlm.nih.gov/pubmed/12632880 (advocating that "[b]enefits from new pharmaceuticals for outweigh their costs"); Drug Costs, supra note 1, (advocating that increasing drug costs have been associated with "advances in pharmaceuticals [that] have transformed health care

Although prescription drug spending only accounts for ten percent of overall health care spending, the staggering number of Americans reliant on pharmaceuticals has driven further reforms via the Health Care and Education Reconciliation Act and the Patient Protection and Affordable Care Act.[9] While there are compelling policy arguments that

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over the last several decades"). Costly pharmaceuticals may, however, preempt the need for more expensive hospitalization or surgery later in life. Id. (reasoning that "today, many health problems are prevented, cured, or managed effectively for years through the use of prescription drugs").

[9] See id. (acknowledging that "although still only a modest part of total health care spending in the U.S (10%), with so many people relying on prescriptions, the cost implications loom large for the American public, health insurers, and government payers"). The number of Americans reliant on pharmaceuticals is astounding. Id. (citing that "in 2007, 90% of seniors and 58% of non-elderly adults rely on a prescription medicine on a regular basis").

pharmaceutical manufacturers are not adequately regulated, increased government involvement will not necessarily correlate with decreased drug prices.[10] Conversely, increased government regulation may in fact create a disincentive for pharmaceutical manufacturers, harming the very patients that the government contracts to benefit.[11]

Due to "the frequency with which the government employs contracts as instruments of federal policy, recent years have been marked by a wave of cases involving third-party beneficiary claims under contracts with agencies of the federal government."[12]

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[10] See id. (presenting opponents' argument that "government involvement will not guarantee lower prices, may have unintended consequences for the rest of the market, and would negatively affect patients").

[11] See id. (implying that "regulatory actions would stifle industry incentives to invest in research and development of new therapies").

It is no coincidence that this rise in number of cases asserting third party beneficiary claims is commensurate to the fall in the number of cases asserting an implied right of action.[13] Because the Supreme Court has increasingly limited the ability of a third party to bring an implied right of action claim, private parties have pursued third party beneficiary claims instead.[14] As a result, a

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[12] See Lori A. Alvino, Note, Who's Watching the Watchdogs?, 103 **Colum. L. Rev.** 893, 918 (2003) (suggesting that third party claims have arisen to evade Court's limitations on ability of courts to find implied causes).

[13] See Jon Waters, Note, The Property in the Promise: A Study of the Third Party Beneficiary Rule, 98 **Harv. L. Rev.** 1109, 1176, 1178 (commenting that "a third party beneficiary claim is more likely to prevail than [an implied right of] action on the statute").

[14] See Robert S. Adelson, Note, Third Party Beneficiary & Implied Right of action Analysis: The Fiction of One Governmental Intent, 94 **Yale L.J.** 875, 875 (1985)

considerable circuit split has resulted as to whether federal common law provides a private right of action to a third party beneficiary absent a statutory remedy.[15] The Ninth Circuit's decision in County of

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(reasoning that because "the Supreme Court's increasingly restrictive view of implied rights of action," "in recent third-party beneficiary claims arising from welfare-related public contracts has grown significantly"); see also Amy M. Reichbach, Note, The Power Behind the Promise: Enforcing No Child Left Behind to Improve Education, 45 **B.C. L.REV.** 667 (2004) [hereinafter Reichbach] (suggesting that private parties sue as third party beneficiaries instead to enforce No Child Left Behind Act of 2001).

[15] For further discussion of the circuit split on whether a third party beneficiary claim may be asserted absent statutory provision for an implied right of action see infra, notes 82-87 and accompanying text.

Santa Clara v. Astra USA, Inc.[16], therefore, deepens an existing Circuit split by holding that a third party can bring a private right of action for breach of contract under federal common law, even though the governing statute neither expressly nor impliedly provides for this right.[17]

This Casenote addresses the Ninth Circuit's end-run around recent Supreme Court's jurisprudence, arguing that the Ninth Circuit created a third party beneficiary claim to avoid the Supreme Court's restrictions imposed on implied right of action claims.[18] This Casenote also discusses the false

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[16] County of Santa Clara v. Astra USA, Inc. 588 F.3d 1237 (9th Cir. 2009).

[17] For further discussion of how the Ninth Circuit's decision deepens existing circuit split see infra, notes 124-27 and accompanying text.

[18] For further discussion of the analysis of Ninth Circuit's decision see infra, notes 111-18 and accompanying text. For further discussion of Supreme Court jurisprudence see infra, notes 71-81 and

dualism of the two rights in the context of contracts between private parties and the government, identifying a problem that is not specific to the pharmaceutical industry.[19] Moreover, this Casenote explains the Ninth Circuit's holding in light of recent Supreme Court jurisprudence, the Circuit split, and the impact not only on the pharmaceutical industry but the greater impact on the partnership between the private and public sector.[20]

Part II begins by discussing how the Medicaid Act, Section 340B Program, and PPA are inextricably

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accompanying text. For further discussion of third party beneficiary claims see infra, notes 35-42 and accompanying text.

[19] For further discussion of the impact of the Ninth Circuit's decision see infra, notes 142-59 and accompanying text.

[20] See id. (discussing impact in detail)

intertwined.[21] Part II also navigates recent Supreme Court jurisprudence regarding an implied right of action and how Circuit courts have inconsistently applied this reasoning to third party beneficiary status.[22] In Part III, the factual and procedural background of Santa Clara are explored.[23] Part IV of this Casenote analyzes the divergent holdings of the district court and Ninth Circuit.[24] Part V of this Casenote discusses why this issue in not specific to the pharmaceutical industry, explaining that the Ninth

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[21] For further discussion of the statutory framework see infra, notes 26-61 and accompanying text.

[22] For further discussion of the judicial framework see infra, notes 71-81 and accompanying text.

[23] For further discussion of the factual background and procedural posture see infra, notes 88-103 and accompanying text.

[24] For further discussion of the narrative and critical analyses see infra, notes 104-41.

Circuit's decision will create immediate effects on the pharmaceutical industry, interrupt the administration of both the Medicaid and Section 340B programs going forward, and potentially create a disincentive for other industries to enter into future contracts with the government.[25] Further, part VI of this Casenote discusses the danger of allowing the Ninth Circuit's decision to stand, exploring the potential ramifications for all entities contracting with the government.[26] Finally, part VI emphasizes that the questionable reliability of third-party beneficiary claims will continue to arise because many federal statues implement congressional mandates

[25] For further discussion of the impact of the Ninth Circuit's decision see infra, notes 142-59 and accompanying text.

[26] For further discussion of the conclusion see infra, notes 160-63 and accompanying text.

through contracts between private parties and the government.[27]

II. Illegal Block in the Back(ground): The Genesis and Evolution of the Present Issue

The Pharmaceutical Pricing Agreement ("PPA") is not a "conventionally negotiated contract."[28] Drug Manufacturers ("Manufacturers") enter into the PPA with the Secretary of Health and Human Services ("Secretary of HHS") as a precondition of

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[27] See id. (warning of future effects of Ninth Circuit's decision)

[28] See County of Santa Clara v. Astra, USA Inc., 588 F.3d 1237, 1248 n.13 (explaining that PPA cannot be understood without giving context of Medicaid program). The Manufacturers must enter PPA in order to participate in Medicaid. Id. (suggesting that Manufacturers would not likely enter into a drug pricing program without "an overwhelmingly powerful incentive").

participating in State Medicaid contracts.[29] Although the PPA expressly contracts Manufacturers with the government, the PPA's intended purpose is to ensure that Manufacturers provide Section 340B covered entities ("340B entities") with outpatient and over-the-counter drugs at a discounted price.[30] As a result,

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[29] See Senate Report 111-089: Sec. 1651 Prescription Drug Rebates, **Committee Reports 111 Congress (2009-2010)**, available at http://thomas.loc.gov/cgibin/cpquery/?&sid=cp111mY39a&refer=&r_n=sr089.111&db_id=111&item=&sel=TOC_342898& (last visited October 14, 2010) (stating that "Section 340B of the Public Health Service Act (PHSA), requires pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program, to enter into a pharmaceutical pricing agreement (PPA)").

[30] See id. (commenting that "[u]nder these PPAs, manufacturers agree to provide discounts on covered outpatient drugs purchased by public health facilities, called covered entities").

340B entities rely on both the Manufacturers' execution and adherence to the PPA.[31]

The PPA gives the Secretary of HHS the power to oversee and enforce the conditions of the PPA.[32] The textual language of the PPA explicitly allows the Secretary of HHW to exercise administrative remedies if either the 340B entities or the Manufacturers are

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[31] See generally Pharmaceutical Pricing Agreement, **HRSA.gov**, available at ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf (Feb. 2, 2006) [hereinafter PPA] (indicating Manufacturers must enter into and adhere to PPA in order for Section 340B entities to benefit from lower prices for prescription drugs).

[32] See id. (stating Secretary of HHS's authority to enforce contracts, investigate noncompliance with contracts, terminate contracts if necessary, require monetary reparations due to noncompliance, and utilize alternative dispute resolution process). For a further discussion of the Secretary of HHS's responsibilities under PPA see, infra, notes 66-70.

noncompliant.[33] Moreover, the PPA explicitly provides Manufacturers with both administrative remedies and the possibility to terminate the contract.[34] The PPA, however, neither explicitly nor impliedly grants 340B entities a private right to enforce the statutory provisions.[35]

Although the PPA expressly states that the contract should be interpreted both according to federal common law and consistent with the federal statute, it is unclear whether the absence of an implied right of action under the statute precludes a third party beneficiary from asserting a private right

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[33] For a further discussion of the Secretary of HHS's enforcement capabilities see, infra, notes 66–70.

[34] See PPA, supra note 29 at § II (listing Manufacturers' responsibilities).

[35] See County of Santa Clara v. Astra, USA Inc., 588 F.3d 1237, 1247 (9th Cir. 2009) (stating that PPA "says nothing about the covered entities' remedies, whether judicial or administrative").

of action under federal common law.[36] In private party contracts, a third party beneficiary can assert a private right of action even without privity to the original contract.[37] The third party's private right of action arises where the third party is an intended beneficiary of the contract as opposed to merely an incidental beneficiary.[38] The third party's private

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[36] For further discussion of the language and intent of PPA, see infra notes 29.

[37] See id.f (discussing third party beneficiary rule).

[38] See Santa Clara, 588 F.3d at 1244 (quoting Klamath Water Users Protective Ass'n v. Patterson, 204 F.3d 1206, 1211 n.2 (9th Cir. 1999)) (stating that "'the intended beneficiary may enforce the duty' by suing as a third party beneficiary of the contract, whereas an 'incidental beneficiary acquires no right against the promisor'").

right vests when the third party relies on the original parties' performance of the contract.[39]

In contracts between private parties and the government, however, the burden is much higher for a third party to establish intended beneficiary status.[40] As a result, third parties are presumed to be incidental beneficiaries and, therefore, do not possess the requisite status to enforce the contract.[41]

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[39] See id. (emphasis added) (asserting that "under federal common law of contracts, '[b]efore a third party can recover under a contract, it must show that the contract was made for its direct benefit–that it is an intended beneficiary of the contract'").

[40] See id. at 1244 (stating that "demonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task").

[41] See Orff v. United States, 358 F.3d 1127, 1145 (9th Cir. 2004) (stating that "parties that benefit from a government contract are generally assumed to be incidental beneficiaries").

If, however, the third party can demonstrate that both the original parties to the contract and the contract itself clearly intended to confer heightened beneficiary status on the third party, then the third party can rebut the presumptive status as an incidental beneficiary.[42] Nevertheless, even if a third party can satisfy the heightened status as an intended third party beneficiary in theory, the trend in recent case law does not support that this recognized status translates into an enforceable right in court.[43] Intended third party beneficiaries, therefore, may possess the requisite status typically

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[42] See id. (stressing that incidental beneficiaries "may not enforce the contract absent a clear intent to the contrary").

[43] For further discussion of recent law trending away from courts creating private rights of action, see infra, note 71-81.

required to bring suit, but may lack judicial remedies.[44]

A. Piling On: Statutory Framework

1. Medicaid

On July 30, 1965, Congress enacted Title XIX of the Social Security Act, creating Medicaid as a public assistance program for disadvantaged populations.[45]

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[44] For further discussion of recent Supreme Court jurisprudence see, infra, note 71-81.

[45] See e.g., Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (codified in amended form at 42 U.S.C. § 1396 (1976)) (enacting grants to states for medical assistance programs to create Medicaid); Improving Medicaid, **U.S. Department of Heath and Human Services**, available at http://www.hhs. gov/medicaid/ (last visited October 14, 2010) (stating that Medicaid "became law in 1965 . . . [to provide] medical long-term assistance to people who meet certain eligibility criteria"); Medicaid Program - General Overview, **Centers for Medicare and Medicaid Services**,

Although currently the largest funding source for medical services and drug coverage for low-income and low-asset individuals and families, Medicaid was originally enacted as a legislative "afterthought" to Medicare.[46] Intended to be a "safety net" for eligible

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http://www.cms.gov/MedicaidGen Info/ (describing how "Medicaid is available only to certain low-income individuals and families who fit into an eligibility group that is recognized by federal and state law").

[46] See e.g., Title XIX of Social Security Act of 1965 (enacting Medicaid in same legislation that created Medicare); Improving Medicaid, **U.S. Department of Heath and Human Services**, available at http://www.hhs.gov/medicaid/ (stating that "Medicaid is the largest source of funding for medical and health-related services for people with limited income"); S. REP. NO. 404, 89th Cong., 1st Sess. 74-76, reprinted in **U.S. Code Cong. & Ad. News** 1943, 2014-15 (1965) (explaining how Medicaid program consolidated health care services for indigent that were previously provided though scattered programs).

beneficiaries to receive health coverage, Medicaid quickly outgrew this role as the scope of eligible beneficiaries expanded.[47] Increased Medicaid enrollment coupled with the increasing costs of pharmaceuticals placed an incredible financial strain on the Medicaid program.[48]

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[47] See Medicaid Program – Medicaid Eligibility Overview: Are You Eligible, **Centers for Medicare and Medicaid Services**, available at http://www.cms.gov/MedicaidEligibility/02_AreYouEligible_.asp#TopOfPage (last updated Dec. 14, 2005) (discussing how many individuals and groups qualify for Medicaid by meeting basic requirements).

[48] See The Basics: The Medicaid Drug Rebate Program, **Centers for Medicare and Medicaid Services**, available at http://www.cms.gov/MedicaidDrugRebateProgram/downloads/StateStrategiestoLowerMedicaidPharmacyCosts [hereinafter Basics] (discussing "cost-cutting mechanisms" to lower Medicaid costs due to high cost of pharmaceuticals); see also Christie Provost Peters, National Health Policy Forum – The Basics: The Medicaid Drug Rebate Program, **National**

Despite joint funding by the state and federal government, concerns arose regarding Medicaid's ability to shoulder the burden of the high costs of pharmaceuticals.[49] Medicaid needed relief from costly

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Health Policy Forum (April 13, 2009), available at http://www.nhpf. org/library/the-basics/Basics_ MedicaidDrugRebate_04-13-09.pdf [hereinafter Peters] (stating that "controlling drug expenditures is a challenge for states: rising prices, high drug utilization, and increases in the Medicaid population all contribute to the growth of Medicaid outpatient prescription drug expenditures").

[49] See e.g., Improving Medicaid, **U.S. Department of Health and Human Services**, available at http://www. hhs.gov/medicaid/ (stating that Medicaid is "jointly funded by the Federal and State governments"); Peters, see infra, note 46 (stating that "spending on outpatient prescription drugs accounts for a substantial share of total Medicaid expenditures"); Basics, see infra, note 46 (discussing strategies to implement due to "increasing prescription drug costs").

drug expenditures to ensure that beneficiaries' access to pharmaceuticals would not suffer.[50] To remedy this concern, Congress enacted the Omnibus Budget Reconciliation Act in 1990 ("OBRA") and established the Medicaid Drug Rebate Program ("MDRP").[51]

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[50] See Basics, infra, note 46 (explaining that cost-cutting mechanisms "have allowed states to reduce their pharmacy expenditures and maintain beneficiary access to a vital part of their overall healthcare").

[51] See Medicaid Program–Medicaid Drug Rebate Program Overview, **Centers for Medicare and Medicaid Services**, available at http://www.cms.gov/Medicaid DrugRebateProgram/ (last visited October 14, 2010) (stating that MDRP was created by OBRA'90 and "requires a drug manufacturer to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services (HHS) for states to receive Federal funding for outpatient drugs dispensed to Medicaid patients").

2. Medicaid Drug Rebate Program

Under the MDRP, drug Manufacturers ("Manufacturers") must enter into an agreement with the Secretary of Health and Human Services ("Secretary of HHS") in order to participate in Medicaid.[52] Under the contracts, Manufacturers agree to provide rebates to the States in exchange for Medicaid coverage of their prescription outpatient drugs.[53] According to

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[52] See id. (discussing how Medicaid Act requires Manufacturers to "sign . . . [MDRP] . . . in order to have its drugs covered by Medicaid"); see also 42 U.S.C. § 1396r-8 (enumerating legislation regarding "payment for covered outpatient drugs" as determined by contract between Manufacturers and Secretary of HHS).

[53] See 42 U.S.C. § 1396r-8(b) (enumerating terms of rebate agreement that was created to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies); see Peters, infra, note 46 (explaining that "Medicaid Drug Rebate Program helps lower Medicaid spending on outpatient prescription drugs by ensuring states receive discounts similar to those provided to

the contracts, Manufacturers agree to provide Medicaid with a "Best Price".[54] As a result of the MDRP,

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private purchasers"); see Centers, infra, note 7 (stating that "approximately 550 pharmaceutical companies . . . and forty nine states" participate in MDRP).

[54] See Peters, infra, note 46 (stating that "rebate amounts pharmaceutical manufacturers must pay are based on manufacturer-reported pricing data, namely the best price and average manufacturer's price (AMP) for each drug, which are based on the prices and financial concessions (for example, volume discounts, other rebates, etc.) available to private purchasers"). A drug's best price and AMP are reported to the Centers for Medicare & Medicaid Services (CMS) by the manufacturer, however, they are not publicly available."). Id. (discussing confidentiality of pricing information); see also 42 U.S.C. § 1396r-8(c) (explaining determination of rebate amounts and defining "Best Price"). In general, "Best Price" is:

however, Manufacturers did not have an incentive to continue to discount drugs because they would have to extend the additional discounts to Medicaid.[55]

> The lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355 (c)]), the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States" with some exceptions).

Id. (defining "Best Price"); see also 42 U.S.C. § 1396r-8(k)(1) (defining "Average Manufacturer Price ("AMP") as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade").

[55] See e.g., Medicaid: Changes in Best Price for Outpatient Drugs Purchased by HMOs and Hospitals, **United States General Accounting Office**, (GAO/HEHS-94-

Manufacturers, therefore, raised their best prices in an effort to counterbalance the deductions they were

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194FS, Aug. 5, 1994), available at http://archive.gao.gov/t2pbat2/152225.pdf (confirming concerns that "after OBRA, drug manufacturers might try to minimize the rebates to state Medicaid programs by increasing best prices and reducing best price discounts for drugs purchased"); How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry, **Congressional Budget Office (January 1996)**, available at http://www.cbo.gov/ftpdocs/47xx/doc4750/1996Doc20.pdf (explaining that "pharmaceutical manufacturers are much less willing to give large private purchasers steep discounts off the wholesale price when they also have to give Medicaid access to the same low price"); Medicaid: Changes in Drug Prices Paid by VA and DOD Since Enactment of Rebate Provisions, **United States General Accounting Office (GAO/HRD-91-139, Sept. 18, 1991)**, available at http://archive.gao.gov/t2pbat7/144939.pdf (explaining that "manufacturers would increase prices to purchasers that previously received large discounts").

required to give for Medicaid.[56] An increase in Manufacturers' best prices, however, resulted in an increased burden on federal- and state-supported providers, ultimately undermining the anticipated savings that Medicaid was created to provide.[57] To remedy this burden, Congress enacted Section 340B of

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[56] See How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry, **Congressional Budget Office (January 1996)**, available at http://www.cbo.gov/ftpdocs/47xx/doc4750/1996Doc20.pdf (explaining how manufacturers negotiate discounts by "balanc[ing] the decline in price on current sales against the increase in profits from the new sales that a larger discount will bring").

[57] See id. (stating that "although the basic rebate has lowered Medicaid's expenditures on outpatient prescription drugs, spending on prescription drugs by non-Medicaid patients may have increased as a result of the Medicaid rebate program).

the Public Health Service Act ("PHSA") in November 1992.[58]

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[58] See e.g., Section 602 of Veterans Health Care Act of 1992 (creating PHSA); Medicaid Exclusion Tutorial, **U.S. Department of Health and Human Services: Health Resources and Services Administration** (last visited October 14, 2010), available at http://www.hrsa.gov/opa/medicaidexclusion.htm (stating that legislation created Section 340B to prevent Manufacturers' further increases in Best Prices by "set[ting] up a mechanism to ensure that manufacturers did not pay a "duplicate discount" on a drug claim"); Introduction to 340B Drug Pricing Program, **U.S. Department of Health and Human Services: Health Resources and Services Administration** (last visited October 14, 2010), available at http://www.hrsa.gov/opa/introduction.htm (stating that "340B Drug Pricing Program resulted from enactment of Public Law 102-585, the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act"). The 340B pricing program was instituted to provide drugs at a lower cost to 340B entities. Id. (commenting that "Section 340B limits the cost of

3. Section 340B Drug Pricing Program

Under the Section 340 drug pricing program ("340B"), Manufacturers participating in Medicaid must enter into a second agreement with the Secretary of HHS, known as a Pharmaceutical Pricing Agreement ("PPA"), to provide "covered entities" with discounts on covered outpatient drugs.[59] As government-supported

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covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals").

[59] See e.g., Section 340B of PHSA of 1992, 42 U.S.C. § 256b (identifying PPA as prerequisite of participating in Medicaid). The statute requires the following:

> The Secretary [of HHS] shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that

facilities, Section 340B covered entities ("340B entities") serve the most vulnerable patient populations.[60] As a result, the PPA stipulates that

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> begins after November 4, 1992, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

Id. (discussing general terms and requirements of PPA); see What is the 340B Program?, **HRSA – Pharmacy Services Support Center** (last visited October 14, 2010), available at http://pssc.aphanet.org/about/whatisthe340b.htm (explaining that Manufacturers enter separate pricing separate pricing agreements with Secretary of HHS to provide "outpatient drugs to certain covered entities . . . at a reduced price").

[60] See Glossary of Pharmacy-Related Terms, **Health Resources and Administration**, available at http://www.hrsa.gov/opa/glossary.htm (last visited October 14, 2010) (explaining that "covered entities" is "the statutory name for facilities and programs eligible to

Manufacturers must provide 340B entities with a "Ceiling Price" discount comparable to the Best Price discount Manufacturers provide under the MDRP.[61] The

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purchase discounted drugs through the Public Health Service's 340B drug pricing program"). Covered entities include the following:

> Covered entities include federally qualified health center lookalike programs; certain disproportionate share hospitals owned by, or under contract with, State or local governments; and several categories of facilities or programs funded by Federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, STD and TB grant recipients, and family planning clinics.

Id. (designating entities that qualify as covered entities). For a further discussion of defining covered entities, see infra, note 92 (providing statutory definition of "covered entities").

[61] See Glossary of Pharmacy-Related Terms, **Health Resources and Administration**, available at http://

Ceiling Price discount, however, is more than just comparable as the same Average Manufacturer Price ("AMP") used to determine the Best Price is also used

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www.hrsa.gov/opa/glossary.htm (last visited October 14, 2010) (defining "340B Ceiling Price" as "the maximum price that manufacturers can charge covered entities participating in the Public Health Service's 340B Drug Pricing Program). The 340B discounted is calculated as follows:

> The 340B discount is calculated using the Medicaid rebate formula and is deducted from the manufacturer's selling price rather than paid as a rebate. Compared to a drug's Average Manufacturer Price (AMP), covered entities receive a minimum discount of 15.1% for brand name drugs and 11% for generic and over-the-counter drugs and are entitled to an additional discount if the price of the drug has increased faster than the rate of inflation.

Id. (explaining how 340B discounted is calculate).

to calculate the Ceiling Price.[62] MDRP's Best Price and 340B's Ceiling Price are, therefore, inextricably intertwined via the AMP.[63]

4. Calculation, Enforcement, and Conflicting Interests

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[62] See 42 U.S.C. § 256b(10)(b) (stating that AMP should be interpreted to have same meaning as term from Section 1927(k) in the Social Security Act); see also 42 U.S.C. § 1396r-8(k)(1), supra, note 52 (stating statutory definition of "average manufacturer price").

[63] See generally PPA, supra note 29 (incorporating Manufacturers' statutory drug pricing obligation to report AMP and Ceiling Price in accordance with provisions of MDRP); see also 42 U.S.C. § 256b(a)(1) (incorporating same AMP and BP pricing methodology of MDRP by prohibiting Manufacturers from charging 340B entities amounts that exceed "average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. § 1396 et seq.] in the preceding calendar quarter, reduced by [a] rebate percentage").

Because the Ceiling Price formula incorporates the same pricing methodology as the MDRP, discrepancies regarding 340B Ceiling Price calculations cannot be resolved in isolation.[64] If there is an alleged error in the calculated Ceiling Price, then there is likely a corresponding error in the Best Price.[65] States and 340B entities, however, have conflicting interests regarding desirable Best Prices and Ceiling Prices, causing further

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[64] See Brief of the United States of America as Amicus Curiae in Support of the Judgment Below, County of Santa Clara v. AstraZeneca Pharm. LP, No. 09-15216, 2009 WL 4089524, at 6 [hereinafter Gov't Brief] (suggesting that attempts to enforce 340B's pricing requirements would interfere with MDRP because both programs rely on same AMP calculations).

[65] See id. at 11 (explaining that MDRP's best price calculations under Medicaid Act are in turn used to calculate ceiling prices under 340B Act).

complications.[66] Due to the complex nature of the pricing calculations and the interconnectedness of the MDRP and 340B, the PPA identifies the Secretary of HHS

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[66] See id. at 15 (explaining that MDRP and 340B create conflicting incentives for beneficiaries under respective programs). The are conflicting incentives for the following reasons:

> The government observed that high AMPs generally increase ceiling prices that Manufacturers can charge 340B entities, resulting in undesirable prices that 340B entities are forced to pay. The Conversely, the government noted high AMPs generally increase the Medicaid rebates that States receive, resulting in substantial revenue returned to the states. States, therefore, are prefer high AMPS while 340B entities prefer low AMPS.

Id.

as the appropriate authority to handle any discrepancies regarding Ceiling Price calculations.[67]

Similar to the Medicaid Act, the 340B Act designates the Secretary of HHS to enforce the statutory requirements of the contract.[68] Specifically, the PPA provides that the Secretary of HHS is entitled to "reasonable access" to Manufacturers' records to ensure compliance with pricing calculations.[69] If there is reason to suspect

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[67] See id. (discussing how conflicting incentives highlight need to leave administration and enforcement of both programs with Secretary of HHS).

[68] See generally 42 U.S.C. § 256b (identifying Secretary of HHS as having authority to administer and enforce PPA); see also 42 U.S.C. § 1369r-8 (identifying Secretary of HHS as having authority to ensure parties' compliance with Medicaid Act).

[69] See PPA, supra note 29 at § III Secretary's Responsibilities (providing that Secretary of HHS can initiate an investigation on the basis of suspicion, from request by 340B entity, or request from

that a Manufacturer is noncompliant, the Secretary of HHS can initiate an informal dispute resolution process.[70] If the Secretary of HHS finds that a Manufacturer is noncompliant, the Secretary can require the Manufacturer to reimburse the 340B entity or terminate the noncompliant Manufacturer's contract.[71] Despite the PPA's reference to available

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Manufacturer to determine parties are complying with agreement).

[70] See id. at IV(a)(3) (stating that "Secretary [of HHS], at his discretion, will initiate an informal dispute resolution process").

[71] See id. at IV(c) (discussing Secretary of HHS's enforcement capabilities). The Secretary of HHS is appointed by Congress to do the following:

> If Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process.

administrative remedies and general federal common law, the statute does not expressly provide that third parties can assert a private cause of action.[72]

> If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

Id.

[72] See id. (PPA discusses informal dispute resolution process conducted by Secretary of HHS). See id. at VII(g) (stating that "the Agreement should be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme").

B. Holding(s): Judicial Framework

1. Supreme Court Jurisprudence

Attempting to strike a balance between rigid historical sentiments and modern contract law, the Supreme Court has limited judicial remedies available to third parties asserting either common law rights or implied rights of action.[73] Absent explicit congressional authority, the Court has been hesitant to provide judicial remedies to third parties under

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[73] See Erie R. Co. v. Tompkins, 304 U.S. 64, 78 (1938) (stating that "there is no general federal common law"). Compare to Mobil Oil Expl. & Producing Se., Inc v. United States, 530 U.S. 604 (expressing that federal common law principles control for government contracts). See generally Restatement (Second) of Contracts § 302 (setting forth conditions required for contract to confer third party rights and distinguishing between rights of intended and incidental beneficiaries).

common law.[74] Further, the Court requires a heightened standard for third parties asserting common law rights

[74] See e.g. City of Milwaukee v. Illinois, 451 U.S. 304, 312 (1981) (stating that "federal courts, unlike state courts, are not general common-law courts and do not possess a general power to develop and apply their own rules of decision"); United States v. Standard Oil Co., 332 U. S. 301, 313 (stating that federal courts, unlike state courts, are courts of limited jurisdiction to "create new common law liabilities"); Texas Indus., Inc v. Radcliff Mat'ls, Inc., 451 U.S. 630, 646 (1981) (rejecting common law claim because only Congress possessed authority to create claim for contribution under federal antitrust statutes); Northwest Airlines, Inc. v. Transport Workers Union of Am., 451 U.S. 77, 95 (1981) (holding petitioner did not have right to assert claim under either federal common law or under federal statute); Wheeldin v. Wheeler, 373 U.S. 647, 651 (1963) (holding Congress did not create "a cause of action for abuse of the subpoena power by a federal officer, at least where the subpoena was never given effect; and the complaint failed to state a federal cause of action").

to enforce government contracts.[75] The Court, therefore, recognizes that general federal common law

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[75] See generally Restatement (Second) of Contracts § 313 (applying § 302 to government contracts). See e.g., Orff v. United States, 358 F.3d 1137, 1145 (9th Cir. 2004), aff'd on other grounds, 545 U.S. 596 (stating that "parties that benefit from a government contract are generally assumed to be incidental beneficiaries . . . [not intended beneficiaries and] . . . may not enforce the contract absent a clear intent to the contrary"); Smith v. Cent. Ariz. Water Conservation Dist., 418 F.3d 1028, 1035 (expressing that third-party beneficiary status is difficult to establish in context of government contract); Kremen v. Cohen, 337 F.3d 1024, 1029 (9th Cir. 2003) (stating that a "more stringent test applies" when private party is attempting to claim third party beneficiary status to government contract).

does not create a private right of action absent congressional authorization.[76]

Similarly, the Court has shifted away from recognizing implied right of action claims by third parties, especially when the governing statute neither

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[76] See e.g. Mertens v. Hewitt Associates, 508 U.S. 248 (1993) (rejecting common law claim that federal common law created right to non-fiduciaries because ERISA did not explicitly provide for one); Virginia Bankshares v. Sandberg, 501 U.S. 1083, 1102 (1991) (emphasizing that "recognition of any private right of action for violating a federal statute must ultimately rest on congressional intent to provide a private remedy"); Texas Indus., Inc v. Radcliff Mat'ls, Inc., 451 U.S. 630, 640 (1981) (rejecting common law claim that federal common law or federal statutes intended to allow federal courts "to fashion the right to contribution urged by petitioner"); Wheeldin v. Wheeler, 373 U.S. 647, 651 (1963) (stating that "as respects the creation by the federal courts of common-law rights, it is perhaps needless to state that we are not in the free-wheeling days antedating Erie").

expressly nor impliedly provides for one.[77] Previously, the Court relied on Cort v. Ash's[78] four-part balancing test to determine when a private cause of action should be implied from a statute.[79]

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[77] See e.g. Alexander v. Sandoval, 532 U.S. 275 (2001) (establishing that presence of Executive Branch's intent to create third party rights does not overcome absence of congressional intent to create one); Cort v. Ash, 422 U.S. 66 (1975) (finding that implying right of action was inconsistent with statute's purpose and plaintiff could seek recovery in state court).

[78] Cort v. Ash, 422 U.S. 66 (1975).

[79] See id. at 78 (discussing how to determine whether a private remedy is implicit in a statute not expressly providing one). There are four factors to determine whether a private remedy is implicit:

> (1) whether plaintiff is part of special class of people intended to be protected by statute;

Subsequently, however, the Court recognized that legislative intent should be the "ultimate question"; a lack of intent, therefore, automatically preempts any judicial involvement.[80] Additionally, the Court

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(2) whether legislative history suggests that Congress intended to either create or deny private right of action;

(3) whether granting an implied cause of action would effectuate purpose of statute; and

(4) whether cause of action is type that should be left to state law).

Id. (discussing four factors that indicate implied right of action); see also Erwin Chemerinsky, Federal Jurisdiction § 6.3 at 384 (4th ed. 2003) (stating that "[f]or the most part, the Court refused to create causes of action" when applying Cort v. Ash's four-part test).

[80] See Cannon v. University of Chicago, 441 U.S. 677, 730 (1979) (Powell, J., dissenting) (arguing that Cort v. Ash's four-part test "cannot be squared with the doctrine of the separation of powers . . . [and] . . . [t]he time has come to reappraise our standards for

now mandates a heightened standard for third parties seeking to enforce Spending Clause legislation.[81]

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the judicial implication of private causes of action."); see also Touche Ross & Co. v. Redington, 442 U.S. 560 (adopting new approach than Cort v. Ash by relying more on congressional intent). Id. at 576 (arguing that "the first three factors in Cort . . . are ones traditionally relied upon in determining legislative intent"). Id. at 578 (asserting that "[t]he ultimate question is one of congressional intent, not one of whether this Court thinks that it can improve upon the statutory scheme that Congress enacted into law").

[81] See Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981) (arguing that because Spending Clause legislation "is much in the nature of a contract . . . if Congress intends to impose a condition on the grant of federal monies, it must do so unambiguously"); see also Alexander v. Sandoval, 532 U.S. 275, 286 (finding that intended third party beneficiaries of Spending Clause legislation cannot assert private causes of action to enforce statutory

Resisting temptation to violate the separation of powers, the Court has gradually given more deference to congressional intent to determine availability of judicial remedies.[82] By recognizing the importance of the statutory language, the Court has recognized private rights of action only when the statute demonstrates an affirmative congressional intent to

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requirements without implied or express right provided under statute). See e.g. Barnes v. Gorman, 536 U.S. 181 (2002); Davis v. Monroe County Bd. of Educ., 526 U.S. 629 (1999); Franklin v. Gwinett County Pub. Sch., 503 U.S. 60 (1992).

[82] See e.g. Stoneridge Inv. Partners, LLC v. Scientific-America, Inc., 552 U.S. 148 (2008) (stating that "in the absence of congressional intent, the Judiciary's recognition of an implied private right of action necessarily extends ins authority to embrace a dispute Congress has not assigned it to resolve"); Sandoval, 532 U.S. 275 at 286-87 (2001) (asserting that when congressional intent is absent "a cause of action does not exist and courts may not create one").

create a private remedy.[83] District courts, however, have allowed third parties to assert third party beneficiary claims and, therefore, strategically avoid limitations imposed on implied right of action claims.[84]

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[83] See e.g. Gonzaga Univ. v. Doe, 536 U.S. 273 (2002) (emphasis added) (stressing that courts must "first determine whether Congress intended to create a federal right"); Thompson v. Thompson, 484 U.S. 174 (1988) (discussing premise of implied right of action as congressional intent to confer private cause of action); Middlesex County Sewerage Auth. v. National Sea Clammers Ass'n, 453 U.S. 1 (1981) (stating that "the key to the inquiry is the intent of the Legislature"); California v. Sierra Club, 451 U.S. 287 (1981) (asserting that "the ultimate issue is whether Congress intended to create a private right of action").

[84] See Reibach, supra note 13 (suggesting that plaintiffs bring third party beneficiary claims rather than claims asserting implied rights of action in order to enforce the statute). See e.g. United States

2. Circuit Split

As a result of the Supreme Court's "increasingly restrictive view of implied rights of action," district courts have been flooded with an increased number of third party beneficiary claims under various federal laws.[85] Circuits are split on whether a

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v. Erika Inc., 456 U.S. 201, 206-08 (holding that judiciary could not act further and was "at an end" because Congress did not intend to create judicial remedy); Tenet v. Doe, 544 U.S. 1, 8 (2005) (holding that preclusion of judicial review under Totten v. United States, 92 U.S. 105 (1876) applies "[n]o matter the clothing in which [plaintiffs dress their claims").

[85] See e.g., Correctional Services Corporation v. Malesko, 534 U.S. 61, 67 n.3 (2001) (declining to infer remedy for private right of action because Supreme Court has "retreated from [its] previous willingness to imply a cause of action where Congress has not provided one"); Wilkie v. Robbins, 551 U.S. 537 (2007); Ashcroft v. Iqbal, 129 S.Ct. 1937, 1948

private right of action is available under federal common law when the statute neither expressly nor impliedly provides for one.[86] The Second, Sixth, and

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(2009) (holding that "implied causes of action are disfavored"). But see D.g. v. Henry, 594 F. Supp. 2d 1273, 1281 (N.D. Okla 2009) (Adoption Assistance and Child Welfare Act of 1980); Rogers v. U.S. Army, NO H-06-1389, 2007 U.S. Dist. LEXIS 30056, at n.38 (S.D. Tex. Apr. 23, 2007) (Davis-Bacon Act); Sabeta v. Baptist Hosp. of Miami, Inc., 410 F. Supp. 2d 1224, 1233-34 (S.D. Fla 2005) (Section 501(c)(3) of the tax code); Charlie & Nadine H. v. Whitman, 83 F. Supp. 2d 476, 502 (D.N.J. 2000) (Adoption Assistance Act and Child Abuse Prevention and Treatment Act); Brug v. National Coal. for the Homeless, 45 F. Supp. 2d 33, 41 (D.D.C. 1999) (affirmative action guidelines for government contractors); In re Lake States Commodities, Inc., 936 F. Supp. 1461, 1470 & n.13 (N.D. Ill 1996) (Commodities Exchange Act § 13(a)).

[86] See D'Amato v. Wisconsin Gas Co., 760 F.2d 1474, 1478 n.3 & n.4 (7th Cir. 1985) (criticizing Sixth Circuit's decision in Hoopes v. Equifax, Inc., 611

Tenth Circuits have held that a third party beneficiary cannot bring suit when there is no implied right of action under the statute.[87] Relying on the Court's recent jurisprudence to limit implied rights of action, these Circuits contend that allowing a third party beneficiary claim is an "impermissible end-run around" an implied right of action claim.[88]

F.2d 134 (6th Cir. 1979) for "failing" "to distinguish between" whether private rights of action may arise under statute or whether common law claims may be brought under "third party beneficiary theory").

[87] See e.g., Grochowski v. Phoenix Constr, 318 F.3d 80 (2d Cir. 2003); Hoopes v. Equifax, Inc., 611 F.2d 124 (6th Cir. 1979); Hodges v. The Atchison, Topeka & Santa Fe Ry. Co., 728 F.2d 414 (10th Cir. 1984).

[88] See Grochowski at 86 (holding that there is "no presumption in favor of a right to bring suit" as third party beneficiaries when there is no private remedy provided in statute because "common-law claims are clearly an impermissible `end run' around the [statute's] failure to provide a remedy").

The Ninth, Federal, Seventh, Third, Fourth and First Circuits, however, have held that common law third party beneficiary principles may provide a private right of action even when one does not exist under the statute.[89] Reasoning that general federal common law governs contractual obligations of the government, these Circuits have held that third party beneficiary status "inheres" common law rights to assert a claim.[90]

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[89] See e.g. County of Santa Clara v. Astra USA, Inc., 588 F.3d 1237 (9th Cir. 2009); Dewakuku v. Martinez, 271 F.3d 1031 (Fed. Cir. 2001); D'Amato v. Wisconsin Gas Co., 760 F.2d 1474 (7th Cir. 1985); Nguyen v. The U.S. Catholic Conf., 719 F.2d 52 (3d Cir. 1983); Perry v. Housing Auth. of Charleston, 664 F.2d 1210 (4th Cir. 1981); Falzarano v. United States, 607 F.2d 506 (1st Cir. 1979).

[90] See D'Amato, 760 F.2d at 1478 (finding that absence of implied right under statute does not preclude common law claims because causes of action are distinct).

III. Instant Replay: Factual Background and Procedural Posture

A. Unsportsmanlike Conduct?: Factual Background

The litigation in Santa Clara arose out of a 2003 report by the Office of Inspector General ("OIG") of the Department of Health and Human Services ("DHHS") that indicated that drug manufacturers ("Manufacturers") were overcharging Section 340B covered entities ("340B entities") for covered outpatient and over-the-counter drugs.[91] Specifically, the OIG's reports indicated that Manufacturers had

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[91] See County of Santa Clara v. Astra USA, Inc., 2006 WL 1344572, n.1 (N.D.Cal.) (stating that OIG's March 2003 report was "entitled 'Pharmaceutical Manufacturers Overcharged 340B-Covered Entities' and provided evidence that caused "concerns about overcharges"); see also Santa Clara, 588 F.3d at 1242, supra note 2 (discussing OIG's 2003, 2004, and 2005 reports regarding specifics of Manufacturers' overcharges).

overcharged 340B entities since 1999.[92] Further, the reports suggested that Manufacturers would continue to do so because their overcharges went unchecked by the Health Resources and Services Administration

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[92] See id. (stating that OIG's March 2003 report identified that Manufacturers' "overcharges during the one-year period ending September 1999 totaled $6.1 million"). See id. (stating that OIG's June 2004 report "concluded that covered entities overpaid $41.1 million in the month of September 2002"). See id. (stating that OIG's October 2005 report that "the government's pricing data could interfere with HRSA's ability to monitor the Section 340B program" due to its inaccuracy and unreliability). See id. (stating that OIG's 2006 report "estimated that covered entities overpaid $3.9 million in June alone); see also Santa Clara, 2006 WL 1344572, n.10 (stating that "the 2004 OIG report found that 97% of §340B covered entities sampled had been overcharged in 2002"). See id. (explaining that extrapolating overcharges of $41.4 million in September 2002 would equal nearly $500 million in overcharges for entire year).

("HRSA").[93] Despite admitting error in calculating the Manufacturers' overcharges, the OIG maintained that 340B entities had overpaid for drugs due to Manufacturers' inflated ceiling prices.[94]

The County of Santa Clara ("Santa Clara") which functions as a 340B entity, filed suit against Astra USA, Inc. and nine other Manufacturers for PPA pricing violations.[95] As a stipulation of the contract,

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[93] See id. (stating OIG's general findings "that HRSA was not adequately overseeing the Section 340B program" to ensure that entities pay correct ceiling prices).

[94] See id. (stating that OIG's June 2004 report was withdrawn due to allegedly inappropriate ceiling prices reported by Centers for Medicare and Medicaid Services). See id. (stating that OIG did not retreat from general findings of HRSA's inadequate oversight of Section 340B program).

[95] See id. (identifying Santa Clara and other Section 340B entities as "a number of county-operated medical facilities . . . which are covered entities within the

meaning of § 256b(a)(4) and PPA § I(e)"). See generally Section 340B of Public Health Service Act 42 U.S.C. § 256b(a)(4) (defining "covered entity" and listing qualified entities). According to the statute, a variety of entities qualify: health centers, family planning projects, entities receiving grants, state-operated drug purchasing assistance programs, black lung clinics, hemophilia diagnostic treatment centers, and state- or locally-operated hospitals. Id. (defining "covered entity"); see also PPA, supra note 29 at § I(e) (defining "covered entity" as "certain Public Health Service grantees, 'look-alike' Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a) of the [Public Health Service] Act"). See Santa Clara, 588 F.3d 1237, 1237 (listing manufacturers as: Astra USA, Inc.; AstraZeneca Pharmaceuticals LP; Aventis Pharmaceuticals, Inc.; Bayer Corporation; Bristol-Meyers Squibb Company; Pfizer, Inc.; Schering-Plough Corporation; Tap Pharmaceutical Products, Inc.; Zenecca Inc.; ZLB Behring LLC; SmithKline Beecham Corporation;

Manufacturers agree to charge 340B entities a discounted price for outpatient and over-the-counter drugs.[96] Extrapolating from the OIG's reports,

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SmithKline Beecham Corporation, dba GlaxoSmithKline; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.").

[96] See Santa Clara at 1246 (citing H.R.Rep. No. 102-384(II), at 7-8 (1992)) (emphasizing that Manufacturers are incentivized to enter PPA and provide lower prices on drugs to provide to underprivileged, underinsured, or uninsured in order to receive Medicaid matching funds). See id. at 1241 (stating that 340B entities "are able to purchase prescription drugs at a discount from drug manufacturers under a standardized agreement between the federal government and the drug companies"); see also Section 602 of Veterans Heath Care Act of 1992, Pub.L. No. 102-585, 106 Stat. 4943, 4967 (stating that "provision, entitled 'Limitation on Prices of Drugs Purchased by Covered Entities,' requires the Secretary of Heath and Human Services to: enter into an agreement with each manufacturer of covered drugs" to provide drugs at discount prices).

therefore, Santa Clara alleges that Astra USA, Inc. and the other nine Manufacturers have overcharged Santa Clara and other county and county-operated medical facilities for outpatient and over-the-counter drugs since 1999.[97]

B. Roughing the Passer: Procedural Posture

On August 16, 2005, Santa Clara filed a putative class action suit in California state court.[98] On

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[97] See id. at 1242 (explaining that Santa Clara relied on OIG's reports to allege that "Manufacturers have systematically overcharged its medical facilities, and all similarly situated covered entities, for covered drugs").

[98] See id. (explaining "genesis of the present appeal"); see also County of Santa Clara v. Astra, 2006 U.S. 9th Cir. Briefs 16471 (9th Cir. Nov. 22, 2006) (explaining course of proceedings); see generally F.R.C.P. Rule 23 and 28 U.S.C.A § 1332(d) (stating rules governing class actions suits).

behalf of itself and other 340B entities, Santa Clara claimed that Astra USA Inc. and nine other major Manufacturers violated the California False Claims Act and the California Unfair Competition Law.[99] In

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[99] See e.g., Santa Clara, 533 F.3d at 1242 (identifying Santa Clara and other Section 340B entities as "a number of county-operated medical facilities . . . which are covered entities within the meaning of § 256b(a)(4) and PPA § I(e)"); County of Santa Clara v. Astra, 2006 U.S. 9th Cir. Briefs 16471 (9th Cir. Nov. 22, 2006) (stating that plaintiffs consisted of "the County of Santa Clara, its health agency, the Santa Clara Valley Health and Hospital System, and seven §340B medical facilities that the County funds"); Section 340B of Public Health Service Act 42 U.S.C. § 256b(a)(4), supra note X (defining "covered entity" and requirements to be eligible for participation in outpatient drug pricing program); Social Security Act 42 U.S.C. § 1396r-8(a)(5)(B) (defining "covered entity"). Under the Social Security Act, a covered entity is defined as:

January 2006, the Manufacturers removed the suit to the U.S. District Court for the Northern District of California and Santa Clara amended its complaint for the first time.[100] The federal district court granted

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> An entity described in section 340B(a)(4) of the Public Health Service Act [42 USCS § 256b(a)(4)] and a children's hospital described in section 1886(d)(1)(B)(iii) [42 USCS § 1395ww(d)(1)(B)(iii)] which meets the requirements of clauses (i) and (iii) of section 340B(b)(4)(L) of the Public Health Service Act [42 USCS § 256b(b)(4)(L)] and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account he percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this title [42 USCS §§ 1396 et seq.].

Id.

[100] See Santa Clara, 533 F.3d at 1243 (stating that "after the Manufacturers removed the action to federal

the Manufacturers' motion to dismiss the state-law claims, but with leave to amend.[101] Santa Clara amended its complaint for a second time, adding additional claims and alleging that the 340B entities were entitled to damages because they were intended beneficiaries of the PPA.[102]

Similar to the fate Santa's Clara's first amended complaint, the district court granted the Manufacturers' second motion to dismiss but did not

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district court, Santa Clara amended its complaint for the first time").

[101] See id. (reporting that "the district court granted the Manufacturers' motion to dismiss, but with leave to amend").

[102] See id. (indicating Santa Clara filed second amended complaint). See id. (listing Santa Clara's additional claims for second amended complaint to include "breach of the PPA, breach of the implied covenant of good faith and fair dealing, negligence and quantum meruit").

extend further benevolence to Santa Clara.[103] The district court denied Santa Clara's motion to file a third amended complaint, holding that neither the statute nor the PPA reflected an intent to grant private parties the right to sue to enforce the statutory pricing requirements.[104] Santa Clara appealed the dismissal of the breach of contract claim under the PPA.[105] The Ninth Circuit reversed and held

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[103] See id. (affirming that Santa Clara's second amended complain "fared no better than the first"). See id. (asserting that "the district court granted the Manufacturers' second motion to dismiss").

[104] See id. (indicating district court "denied as futile Santa Clara's subsequent motion for leave to file a third amended complaint"). See County of Santa Clara v. Astra USA, Inc., 2006 WL 1344572 (N.D.Cal.) (reasoning that "a prior full-scale amendment opportunity having been granted, leave to amend is not granted again").

that federal common law provides a breach of contract claim for 340B entities to enforce the statutory pricing provisions incorporated into the PPA.[106]

IV. Encroachment: The Ninth Circuit Substitutes Its Judgment for that of Congress

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[105] See Santa Clara, 588 F.3d at 1243 (stating that "Santa Cara appeals only the district court's rejection of its PPA breach of contract claim").

[106] See id. (agreeing with district court that "covered entities are intended direct beneficiaries of the PPA"). See id. at 1237 (reversing district court's holding by finding that "statute governing drug pricing agreement did not displace federal common law contractual claims"). See id. at 1243 (reasoning that Section 340B entities "have the right as third parties to bring claims for breach of that contract . . . [and] . . . "that allowing such suits under PPA is consistent with Congress's intent in enacting the Section 340B program"). See id. (recognizing 340B entities' rights " even though the statute itself does not create a federal private cause of action").

A. Offside: The Ninth Circuit Controverts the District Court, Previous Holdings Within the Circuit, and Supreme Court Jurisprudence

1. District Court's Analysis

With a deferential nod to Supreme Court precedent, Ninth Circuit weight of authority and the legislative history of 42 U.S.C. 256b, the district court held that the PPA's failure to satisfy the "clear intent" requirement precluded Santa Clara from asserting a breach of contract claim as a third-party beneficiary.[107] Recognizing Santa Clara's second

[107] See County of Santa Clara v. Astra USA Inc., 2006 U.S. Dist. Lexis 33047 at 7 (citing Robins Dry Dock & Repair Co. v. Flint, 275 U.S. 303, 307-08, 48 S.Ct. 134, 72 L.Ed. 290 (1927)) (adding second prong to Robins' test to require that third parties attempting to enforce PPA under federal common law must do more than just demonstrate that government contract was intended to directly benefit third parties). Building from the Robins' minimal requirement test, the district court held:

> The PPA require[s] that [the agreement] must be construed under general common law. Under

> federal common law, an entity may sue on a contract to which it is not a party if (1) the signatories intended it to benefit directly, and (2) intended it to have the right to sue for performance.

Id. (explaining entity must satisfy two-part test in order to enforce PPA as third-party beneficiary). See id. (quoting Klamath Water Users Protective Ass'n v. Patterson, 204 F.3d 1206, 1211 (9th Cir. 1999) (explaining "the 'clear intent' requirement"). The Klamath court held:

> The intended beneficiary need not be specifically or individually identified in the contract, but must fall within a class clearly intended by the parties to benefit from the contract . . . parties that benefit from a government contract are generally assumed to be incidental beneficiaries, and may not enforce the contract absent a clear intent to the contrary.

Id. (emphasis added). See id. at 7-8 (applying "the 'clear intent' requirement" used in four Ninth Circuit cases "governing third-party benefits under federal contracts" to determine that Santa Clara could not

assert breach of contract claim because PPA did not clearly intend to confer 340B entities with rights). See, e.g., Klamath Water Users Protective Ass'n v. Patterson, 204 F.3d 1206, 1211 (9th Cir. 1999) (stating that "parties that benefit from a government contract . . . may not enforce the contract absent a clear intent to the contrary") (emphasis added); Orff v. United States, 358 F.3d 1137, 1145, 1147, n.5 (9th Cir.. 2004) (finding "no precise language of the contract for a 'clear intent' to rebut presumption that the farmers are merely incidental beneficiaries" as required by law in Ninth Circuit); Smith v. Cent. Ariz. Water Conservation Dist., 418 F.3d 1028, 1035-38 (9th Cir. 2005) (indicating contractual language did not "meet the 'clear intent' standard required for intended third-party beneficiary status" and refusing to "infer a contracting party's required intent from complete silence"); Tyler v. Cuomo, 236 F.3d 1124 (9th Cir. 2000) (failing to explicitly mention clear intent requirement but finding presence of contract provision essentially indicated clear intent to enable homeowners to have standing as third party beneficiaries); see also 2006 U.S. Dist. Lexis 33047

amended complaint as a masked revision of the first, the District Court of the Northern District of California again rejected Santa Clara's previously

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at 8-9 (referencing other courts of appeals' and legislative history of 42. U.S.C. 256b to "reinforce the conclusion that 340Bs are not third-party beneficiaries"). See, e.g., Holbrook v. Pitt, 643 F.2d 1261, 1271 (7th Cir. 1981) (looking to "the legislative history and purpose of the Section 8 program . . . to interpret parties' intentions" and holding tenants in HUD-insured projects were third party beneficiaries); Audio Odyssey, Ltd. V. United States, 255 F.3d 512, 521 (8th Cir. 2001) (reviewing background legislation of Small Business Act to determine plaintiff had status as third-party beneficiary). See id. at 7,8 (referencing language in §§§§ II(a), IV(c), V(b), VII(g) of PPA to demonstrate that "provisions clearly benefitted covered entities" but were not dispositive to reflect "a clear intent to confer actionable rights" on 340B entities).

asserted state-law claims.[108] Further, the district court denied Santa Clara's request to file a third amended complaint, preempting any future acts of artful pleading.[109]

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[108] See Santa Clara, 588 F.3d at 1243 (describing how district court dismissed Santa Clara's various claims in second amended complaint just as court previously dismissed first amended complaint); see also County of Santa Clara v. Astra USA Inc., 2006 WL 1344572 (N.D. Cal.) at 2 (discussing how Santa Clara's second amended complaint "reiterate[d] claims in the first amended complaint" and added new claims). For a further discussion of Santa Clara's second amended complaint, see supra, note 99 (listing additional claims Santa Clara included in second amended complaint and recognizing new claims as equally unsuccessful).

[109] See Santa Clara, 588 F.3d at 1243 (granting Manufacturers' motion to dismiss Santa Clara's breach of contract claim and denying opportunity to file "futile" third amended complaint). For a further discussion of the district court's refusal to allow

Notwithstanding the PPA's intent to directly benefit Santa Clara and other 340B entities, the district court opined that the PPA did not necessarily impute 340B entities with heightened status to seek judicial remedies.[110] The district court held that

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Santa Clara to file a third amended complaint, see supra, notes 98–103, (denying Santa Clara's motion for leave to file third amended complaint because of Santa Clara's previous opportunity to file second amended complaint).

[110] See County of Santa Clara v. Astra USA, Inc., U.S. Dist. Lexis 33047 at 30 (quoting Committee on Energy and Commerce, H.R. Rep. No. 102-384(II) at 7, 10-12 (1992)) (explaining why 340B entities like Santa Clara were intended to directly benefit from PPA but not bring suit to enforce pricing requirements). Interpreting the Committee on Energy and Commerce's opinion, the district court held:

> The legislative history of 42 U.S.C. was intended "to enable [covered] entities to stretch scarce Federal resources as far as possible. . . ." The Committee's emphasis on aiding covered entities

neither the statute nor the PPA reflected an intent to grant private parties the right to enforce the PPA's pricing requirements, reasoning that "[i]t strain[ed] credulity" that Manufacturers would have made themselves vulnerable to "a crushing number of lawsuits" from "more than 12,000 covered entities."[111]

> suggests that Congress intended to benefit them directly. It does not, however, make clear that Congress wanted to confer upon them new rights to sue.

Id.

[111] See id. at 29–30 (quoting Restatements §§ 302, 313 of Contracts) (explaining "considerations [that] militate against third-party beneficiary status to 340B entities and to [Santa Clara]"). The District Court explained that Santa Clara's breach of contract claim could not go forward for the following three reasons:

> Plaintiff relies on the Restatement's assertion that "[i]n some cases an overriding policy, which may be embodied in a statute, requires recognition of such a right without regard to the

> intention of the parties." First, an overriding policy is not enough in light of Ninth Circuit law requiring a 'clear intent' in the contract. Second, plaintiff is not the only party situated to enforce the contract, nor is this action its only means to do so. The government may bring suit. It or plaintiff can engage in the dispute-resolution process. These facts weaken the value of a policy recognizing contract rights here. Third, comment d of Section 302 is trumped by Section 313 of the Restatement, which rejects third-party rights on government contracts whenever it would 'contravene the policy of the law . . . prescribing remedies for [] breach.' The policy of the law here is to remedy breaches via government action or the dispute-resolution process.

Id. (emphasis added). Although the District Court recognized that granting 340B entities the right to enforce the statute "might effectuate certain goals of the statute," the District Court argued that "the 'clear intent' required to confer such rights" was absent. Id. at 30 (explaining why 340B entities could

not assert breach of contract claim to enforce PPA). See id. at 26-27 (quoting Barnhart v. Peabody Coal Co., 537 U.S. 149, 168, 123 S.Ct. 748, 154 L.Ed.2d. 653 (2003) (explaining that allowing Santa Clara to enforce PPA would also subvert role of Secretary of HHS). The district court explained that the PPA precludes third parties from enforcing the pricing requirements for the following reasons:

> The [PPA] assign[s] the role of requiring reimbursements to the Secretary [of HHS]. To analyze this, we borrow[ed] the statutory-construction canon "expressio unius est exclusio alterius" ("the inclusion of one thing suggests the exclusion of all others"). This canon suggests that when the parties gave this power to the Secretary [of HHS], they intended to deny it to all others. . . . If all of the more than 12,000 covered entities had standing to enforce the price controls, manufacturers would be subject to a crushing number of lawsuits, all arising out of the same contract. It strains credulity to suggest that the manufacturers agreed to face such a threat.

Id. (discussing overwhelming exposure to potential liability that Manufacturers would not likely subject themselves to). See e.g., Office of Pharmacy Affairs, Statistical Reports, Growth of 340B Covered Entity Sites at http://opanet.hrsa.gov/opa/Report/StatisticalReport.aspx (showing how number of covered entities continues to increase over time); Price v. Pierce, 823 F.2d 1114, 1121 (7th Cir. 1987) (finding that inference of third-party standing due to potentially large applicant pool is both counterintuitive and inconsistent with Restatement § 313(2) provision on third-party beneficiaries of government contracts). The Price court stated that inferring third-party beneficiary status was "less plausible" for the following reasons:

> The parties suggested that there might be 30,000 eligible persons in DuPage County alone, one of three counties in which the apartments at issue in this case are located. Of course many such suits might fail for want of standing, but that is not a good argument for deeming the plaintiffs third-party beneficiaries. On the contrary, the original parties to a contract would hardly want

Additionally, the District Court of the Northern District of California concluded that the availability of administrative remedies was further proof that the PPA did not intend to confer third parties with rights to enforce the statutory pricing requirements.[112]

> to create rights of action in so indefinite a class as to raise a serious question whether the members would actually be allowed to enforce their rights. It is implausible that the developers, IHDA, or HUD ever intended to impose so novel and ill-defined a burden on themselves or that it would advance the objectives of the Section 8 program if they did; so wide a net of liability could make developers reluctant to participate in the program.

Id.

[112] See County of Santa Clara v. Astra USA, Inc., 2006 U.S. Dist. Lexis 33047 at 8-9 (discussing how "administrative guidelines approved pursuant to 42 U.S.C. 256b provide a voluntary, informal process to resolve disputes between manufacturers and health-care providers"). Conceding that the PPA's "dispute-

Absent valid breach of contract claim, the district court deemed the need to address primary jurisdiction and federal preemption issues as moot.[113]

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resolution process may not be 'elaborate', [the district court held that] its existence nevertheless suggests that health-care providers should not be able to bring claims under the [PPA]" for the following reasons:

> [A regulatory emphasis on] conciliation and informal resolution of complaints suggests strongly that [Congress] did not intend a conflicting private remedy . . . to be available. To conclude otherwise would mean Congress had purposefully established an elaborate administrative procedure whose effectiveness Congress intended to be undermine will-nilly through the institution of private lawsuits.

Id. at 9 (quoting D'Amato v. Wis. Gas Co., 70 F2d 1474, 1481-82 (7th Cir. 1985).

[113] See id. at 11 (finding "no need to consider defendants' argument concerning primary jurisdiction

2. Ninth Circuit's Analysis

Reversing the district court's deferential decision, the Ninth Circuit held that 340B entities were intended beneficiaries of the PPA and, therefore, could enforce the statutory pricing requirements under general federal common law.[114] Despite acknowledging

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[and] federal preemption" because "all claims are dismissed on other grounds").

[114] See County of Santa Clara v. Astra USA Inc., 588 F.3d 1237, 1241 (9th Cir. 2009) (reversing district court's "dismissal of the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim"). See id. at 1243 (9th Cir. 2009) (quoting Smith v. Centr. Ariz. Water Conservation Dist., 428 F.3d 1928, 1034 (9th Cir. 2005) (referencing contractual language that "federal law controls the interpretation of the PPA, which is a "contract[] entered into pursuant to federal law and to which the government is a party" and which expressly provides that it "shall be construed in accordance with Federal common law"); See also PPA § VII(g) (stating that "the

that the PPA neither expressly nor impliedly provides third parties with private rights of action, the Ninth Circuit reasoned that "allowing such suits under the PPA [was] consistent with Congress's intent in enacting the Section 340B program."[115] Further, the

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[PPA] shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme"). See id. at 1241 (applying federal common law of contracts and holding that "the covered entities are intended direct beneficiaries of [the PPA] and thus have the right to enforce the agreements' discount provision against the Manufacturers and sue them for reimbursement of excess payments"). See id. at 1244 (analyzing both PPA's contractual language and contracting parties' intent "persuaded [Ninth Circuit] that covered entities are intended beneficiaries of the PPA and, accordingly, that Santa Clara has stated a breach of contract claim on a third party beneficiary theory").

[115] See Santa Clara at 1243, 1252 (recognizing that 42 U.S.C. 256b "itself does not "create a federal private

Ninth Circuit "rejected the Manufacturers' argument that primary jurisdiction [was] appropriate," disregarding the role of the Secretary of HHS and

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cause of action" but "allow[ed] Santa Clara's [breach of] contract claim to go forward [because it] [was] consistent with Congress's intent in enacting the legislative scheme"). The Ninth Circuit reasoned that that the breach of contract claim was consistent with Congress's intent for the following reasons:

> In acceding to the PPA, the Manufacturers undertook a specific responsibility to the covered entities, . . . "agree[ing] to charge covered entities a price for each unit of the drug that does not exceed" the ceiling price of that drug. . . . The legislative history makes plain that Congress intended to . . . [conserve federal resources and increase access to eligible patients] . . . by enabling covered entities . . . to obtain discounted prices on covered drugs through the PPAs.

See id. at 1245-46 (quoting PPA § (II)(a)) (emphasis added).

dismissing the availability of administrative remedies.[116]

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[116] See id. at 1252 (stating that "invoking primary jurisdiction [was] not appropriate" because Santa Clara's breach of contract claim "could plausibly be adjudicated without [Department of] HHS's expertise"). See id. at 1251 (declining to invoke primary jurisdiction "which would require that Santa Clara's contract claim be stayed or dismissed without prejudice pending its referral to the Secretary [of HHW] for agency resolution"). Providing background regarding the doctrine of primary jurisdiction, the Ninth Circuit explained:

> The doctrine of primary jurisdiction "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts. "[P]rimary jurisdiction is properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to

> a regulatory agency. The doctrine does not require that all claims touching on an agency's expertise first be decided by the agency, however.

See Syntek Semiconductor Co., Ltd. V. Microchip Tech. Inc., 307 F.3d 775, 780 (9th Cir. 2002) (quoting Brown v. MCI WorldCom Network Servs., Inc., 277 F.3d 1166, 1172 (9th Cir. 2002)). To determine why primary jurisdiction was not appropriate here, the Ninth Circuit considered the following factors:

> "(1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant tot a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration."

See Santa Clara, 588 F.3d at 1252 (quoting Syntek, 307 F.3d at 781). However, the Ninth Circuit also added the following caveat:

> In determining whether to invoke primary jurisdiction, we also consider the procedural

> posture of the case. At the motion to dismiss stage, we apply a standard derived from Rule 12(b)(6) jurisprudence: whether the complaint plausible asserts a claim that would not implicate the doctrine. Having been advised of the Secretary's views we conclude that Santa Clara's, we conclude that Santa Clara's complaint does not require referral under this standard. At this stage, the nature of the breaches Santa Clara will seek to prove is unclear, but the Secretary has indicated that at least some possible disputes could be resolved by a court without [Department of] HHS's expertise.

Id. (declining to "invoke primary jurisdiction at this time"). See id. at 1250, n.18 (discussing that § 256b provides "a number of remedies against covered entities" but "does not 'expressly provide' any remedies to covered entities). See, *e.g.*, § 256b(a)(5)(C) (emphasis added) ("A covered entity shall permit the Secretary and [manufacturers] . . . to audit . . . records of the entity that directly pertain to the entity's compliance" with the program.); (a)(5)(D) ("If the Secretary finds . . .

that a covered entity is in violation . . . the covered entity shall be liable . . . ."). Reaffirming Santa Clara's suit as "compatible with the Section 340B program's objectives," the Ninth Circuit held that judicial remedies were more appropriate for the following reasons:

> Although the Secretary may terminate the PPA with a manufacturer for a violation of its provisions, this remedy is a matter of contract, not statute. Reflecting this paucity of statutory authority, [Department of] HHS's regulations establish only an informal, nonexclusive dispute resolution process, in which neither covered entities nor manufacturers are required to participate. Nothing in the statute suggests that Congress intended that DHHS create a substitute, administrative remedial scheme for covered entities to invoke against manufacturers. Thus, there is nothing "additional" about the federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the PPA.

To overcome the difficulty in establishing 340B entities' ability to enforce the PPA, the Ninth Circuit reasoned that Santa Clara had an inherent right to sue as an intended beneficiary."[117] The Santa

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See Santa Clara, 588 F.3d at 1251 (discussing why administrative remedies did not provide adequate alternative remedy). See also PPA § VI(c) (providing Secretary with ability to terminate PPA and Manufacturers with ability to participate in informal dispute resolution process but failing to indicate available remedies for 340B entities). See also, Golt v. United States, 186 F.3d 1158, 1164 (9th Cir. 1999) (explaining that federal common law invalidated administrative remedies provided by Civil Service Reform Act but that statute was silent regarding employee's ability to assert "a discrete remedy . . . pursuant to federal common law").

[117] See Santa Clara, 588 F.3d at 1244, (acknowledging that "demonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task"); see also Kremen v. Cohen, 337 F.3d 1024, 1029 (9th Cir. 2003)

(quoting Klamath Water Users Protective Ass'n v. Patterson, 204 F.3d 1206, 1211 (9th Cir. 1999)(emphasizing that "when a contract is with a government entity, a more stringent test applies [because] 'parties that benefit are generally assumed to be incidental beneficiaries, and may not enforce the contract absent a clear intent to the contrary'"). See Santa Clara at 1244) (stating that "any intended beneficiary has the [inherent] right to enforce the obligor's duty of performance; the right to sue inheres in one's status as an intended beneficiary"). The Ninth Circuit, however, mischaracterized Klamath's test which requires that "the contract must establish not only an intent to confer a benefit, but also 'an intention . . . to grant [the third party] enforceable rights.'" See Kremen at 1029 (quoting Klamath at 1211) (discussing heightened "clear intent" requirement when contract involves government entity). Instead, the Ninth Circuit established that 340B entities were intended beneficiaries simply because they directly benefitted from the PPA, reasoning:

> Under federal common law of contracts, "[b]efore a third party can recover under a contract, it

Clara court held that the district court erred in imposing a second requirement that the contract contain an express right-to-sue provision.[118]

> must show that the contract was made for its direct benefit – that it was an intended beneficiary of the contract." . . . The PPA sets forth the contracting parties' clear intent to directly benefit the covered entities.

See Santa Clara at 1244, 1247 (quoting Klamath at 1210) (emphasis added).

[118] See id. at 1244 (rejecting "the suggestion that the availability of a third party contract claim is conditioned on the contract's inclusion of a provision expressly granting the third party the right to sue"). See id. at 1245 ("disavowing any absolute requirement that the contract expressly provide for third party enforcement"). See id. at 1244-45 (referencing Restatement (Second) of Contracts § 304 (1981)) (stating that "a third party who is an intended beneficiary of a contract may sue to enforce the contract or to obtain appropriate remedy for breach"). See id. at 1245 (asserting that "to require

Distinguishing the present case from previous cases, the Ninth Circuit reasoned that the second requirement only applied to members of the public who were incidental, not intended, beneficiaries of the contract.[119] Concluding that neither the PPA nor 42

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additionally of intended beneficiaries that the contract by its terms provide for third party enforcement would read the distinction between incidental and intended beneficiaries out of the federal common law of contracts").

[119] See id. at 1244, 1245 (claiming present case can be distinguished from previous cases within Ninth Circuit that have "rejected plaintiff's claims to be intended beneficiaries" for not satisfying "'clear intent' hurdle"). See e.g., Smith v. Cent. Ariz. Water conservation Dist., 418 F.3d 1028, 1037 (9th Cir. 2005) (rejecting "statement[s] of purpose"); Orff v. United States, 358 F.3d 1137, 1145, 1147 (9th Cir. 2004) (rejecting "explicit reference to a third party" and contract that "operates to the [third parties'] benefit and was entered into with [them] in mind"); Kremen v. Cohen, 337 F.3d 1024, 1029 (9th Cir. 2003)

U.S.C. § 256b afforded covered entities with adequate administrative remedies, the court in Santa Clara was "unmoved" by Manufacturers' arguments regarding vulnerability to lawsuits and unwanted disclosure of confidential pricing information.[120] Curiously,

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(rejecting vague contractual language); Klamath v. Water Users Protective Ass'n v. Patterson, 204 F.3d 1206, 1212 (9th Cir. 1999) (rejecting "recitation of interested constituencies" and "[v]ague, horatory pronouncements"). See Santa Clara at 1245 (claiming that eliminating second prong "reaffirm[ed] Klamath's 'clear intent' principle with respect to intended beneficiary status). See id. (emphasis added) (clarifying that "if the plaintiff is an intended beneficiary . . . then the third party contract claim can go forward").

[120] See id. at 1248 (quoting D'Amato v. Wisconsin Gas Co., 760 F.2d 1474, 1482 (9th Cir. 1985) (stating that "in sum, neither the PPA nor § 256b establishes an exclusive 'elaborate administrative procedure," that – were such a procedure to exist – would signal the parties' intent to deny covered entities the right to

however, the Ninth Circuit half-heartedly left open the possibility of deferring to the Secretary of HHS at a later time.[121]

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enforce the PPA through litigation as intended beneficiaries"). See id. (holding that "the breadth and indefiniteness of a class of beneficiaries is entitled to some weight in negating the inference of intended beneficiary status"). But see Hook v. State of Ariz., Dep't of Corr., 972 F.2d 1012, 1014-15 (9th Cir. 1992) (recognizing that all inmates of Arizona prison system were intended beneficiaries because constituted well-defined class); Santa Clara, 588 F.3d at 1248 ("numbers alone are not determinative" to prevent suit). See id. (discussing that confidentially provision does not preclude suit because "provision itself . . . contemplates that such information could well be subject to disclosure for purposes of enforcing the PPA's discount pricing requirements beyond any actions the Secretary [of HHS] might initiate").

[121] See id. at 1252 (declining "to invoke primary jurisdiction at this time, but leav[ing] open the

B. Illegal Substitution: The Ninth Circuit Enables 340B Entities to Bring Suit as Third-Party Beneficiaries

By creating a private right of action under general federal common law, the Ninth Circuit circumvented the Supreme Court's limitations on implied rights of action.[122] Recognizing that the statute neither expressly nor impliedly conferred 340B entities with a private right of action, the court in Santa Clara should not have enabled 340B entities to assert standing as third-party beneficiaries simply because they directly benefitted from the PPA.[123]

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possibility that the district court may decide after further factual development that referral to the Secretary [of HHS] is appropriate").

[122] See id. at 1244 (emphasis added) (rejecting "the suggestion that the availability of a third party contract claim is conditioned on the contract's inclusion of a provision expressly granting the third party the right to sue").

Alternatively, even if 340B entities had standing as third-party beneficiaries, the Ninth Circuit should have conceded its inability to provide a judicial remedy.[124] Policy concerns arise that preempting 340B

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[123] See id. at 1243 (recognizing that "the statute itself does not create a federal private right of action" but finding that "covered entities are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract").

[124] See e.g. Stoneridge Investment Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 164-65 (2008) (explaining that "the Judiciary's recognition of an implied private right of action necessarily extends its authority to embrace a dispute Congress has not yet assigned it to resolve"); Gonzaga University v. Doe, 536 U.S. 273, 286 (2002) (rationalizing that "where the text and structure of a statue provide no indication that Congress intends to create new individual rights, there is no basis for a private suit"); Grochowski v. Phoenix Construction, 318 F.3d 80 (2d Cir. 2003) (foreclosing third-party beneficiary

entities' ability to assert breach of contract claims would preclude third parties with a vested interest from ensuring that Manufacturers' adhered to statutory drug pricing requirements.[125] Deference to Supreme Court jurisprudence and preservation of the separation of powers, however, clearly outweigh any mitigating policy concerns.[126]

Santa Clara's holding deepens an already substantial 5-3 circuit split by allowing 340B

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claim because statute did not confer private right of action).

[125] See Santa Clara, 588 F.3d 1237, 1251 (concluding that "permitting covered entities to sue as intended beneficiaries of the PPA is therefore wholly compatible with the Section 340B program's objectives").

[126] See Alexander v. Sandoval, 532 U.S. 275, 286-87 (2001) (commenting that "privates rights of action to enforce federal law must be created by Congress" even if private rights of action are "desirable . . . as a policy matter" or "compatible with the statute").

entities to enforce the PPA even though the statute does not provide for this right.[127] Directly conflicting with the decisions of the Second, Sixth and Tenth Circuits, the Ninth Circuit incorrectly held that the absence of an implied right of action under a federal statute did not preclude a private party's common law third-party beneficiary claim.[128] The

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[127] For a further discussion of the circuit split, see supra notes 82-87.

[128] See e.g., Davis v. United Air Lines, Inc., 575 F.Supp. 677, 680 (E.D.N.Y. 1983) (Weinsten, J.) (observing that "the same considerations largely determine" private party's right to sue as third-party beneficiary as whether private party has implied right of action); Grochowski v. Phoenix Constr., 318 F.3d 80 (2nd Cir. 2003); Hodges v. The Atchison, Topeka & Santa Fe. Ry. Co., 728 F.2d 414 (10th Cir. 1984); Hoopes v. Equifax, Inc., 611 F.2d 134 (6th Cir. 1979). For a further discussion of the decisions in the second, sixth, and tenth circuits, see supra notes 82-87.

decision in Santa Clara rested on attenuated reasoning that 340B entities were intended beneficiaries of the contract and, therefore, were entitled to enforce the statutory requirements contained in the PPA.[129] The

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[129] See Orff v. United States, 358 F.3d 1127, 1147 n. 5 (9th Cir. 2004) (emphasizing importance of examining "precise language of the contract for 'clear intent' to rebut the presumption that the [third parties] are merely incidental beneficiaries"). The Ninth Circuit relied on Orff's reasoning to rationalize that covered entities were intended beneficiaries of the PPA and, therefore, were entitled to bring a breach of contract claim under general federal common law. See Santa Clara, 588 F.3d 1237, 1244 (using analysis from Orff to find that 340B entities were intended beneficiaries of the PPA and, therefore, not only qualified but were entitled to sue as third party beneficiaries). Unlike the five other appellate courts that have held that private parties could sue absent an implied right of action, the Ninth Circuit went one step further by claiming that 340B entities were entitled to do so. See Davis, 575 F.Supp. at 680 (qualifying that "[a]

Second, Sixth, and Tenth Circuits, however, have held that allowing this suit is "an impermissible 'end-run' around" the absence of an implied right of action under the statute.[130]

The Ninth Circuit's decision not only controverts the weight of authority within the circuit but also disregards four decades of the Supreme Court's

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plaintiff may sue as a third-party beneficiary of the contract mandated by [a] statue").

[130] See e.g., Grochowski, 318 F.3d at 86 (recognizing that because "no private right of action exists under the relevant statute, the plaintiffs efforts to bring their claims as state common-law claims are clearly an impermissible 'end run' around the [Act]"); Hodges v. Atchison, Topeka & Santa Fe Ry. Co., 728 F2d 414 (10th Cir. 1984) (holding that "a third-party beneficiary" argument is "another aspect of the implied rights of action argument"); Hoopes v. Equifax, Inc., 611 F.2d 134, 135 (6th Cir. 1979) (dismissing common law claim because statute did "not authorize a private cause of action").

jurisprudence limiting implied rights of action.[131] Clutching to an outdated view, the decision in Santa Clara ignores recent Supreme Court jurisprudence and attempts to resurrect a "view [that] has long since been 'abandoned.'"[132] Further, the Ninth Circuit's

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[131] See e.g., Correctional Services Corp. v. Malesko, 534 U.S. 61, 67 n.3 (2001) (warning that Supreme Court has "retreated from [its] willingness to imply a cause of action where Congress has not provided one"); Sandoval, 532 U.S. at 287 (quoting J. I. Case Co. v. Borak, 377 U.S. 426, 433) (stating that Supreme Court has relinquished "understanding . . . that 'it is the duty of the courts to be alert to provide such remedies as are necessary to make effective the congressional purpose' expressed by a statute"); Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Curran, 456 U.S. 353, 401 (1982) (Powell, J., dissenting) (noting "fundamental legal error" of "basing a finding of an implied cause of action under a federal statue on common-law principles").

decision "amount[s] to judicial encroachment on Congress's purview over the remedies available for violations of federal statutes."[133]

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[132] See Sandoval, 532 U.S. at 287 (refusing to "revert . . . to the understanding of private causes of action" because Supreme Court has "sworn off the habit of venturing beyond Congress's intent"). The Supreme Court has consistently and more fervently rejected judicially-created remedies absent congressional intent. See e.g., Sosa v. Alvarez-Machain, 542 U.S. 692, 727 (2004; see Gonzaga Univ. v. Doe, 536 U.S. 273, 285 (2002); Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 173 (1994); Touche Ross & Co. v. Redington, 442 U.S. 560, 568 (1979).

[133] See Brief of Pharmaceutical Research and Manufacturers of America (PhRMA) as Amicus Curiae in Support of Petitioners, County of Santa Clara v. AstraZeneca Pharm. LP, No. 09-1273 (9th Circ. May 21, 2010) at 6, available at http://www.scotusblog.com/case-files/cases/astra-usa-inc-v-santa-clara-county/ [hereinafter PhRMA Brief] (stating contrary view would

By ignoring the well-established principle that the absence of congressional intent precludes courts from creating private causes of action, the Ninth Circuit places itself at odds with the Supreme Court.[134] Although the court in Santa Clara creatively

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violate "core separation of powers principles: Private rights of action to enforce federal law, like substantive federal law itself, must be created by Congress"). See e.g., Sandoval, 532 U.S. at 286 (indicating that "the judicial task is to interpret the statute Congress has passed to determine whether it displays an intent to create not just a private right but also a private remedy"); Gonzaga, 536 U.S. at 286 (cautioning against judicial recognition of private causes of action absent congressional intent); Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson, 501 U.S. 350, 365 (1991) (stating that "[r]aising up causes of action where a statute has not created them may be a proper function for common-law courts, but not for federal tribunals").

[134] See Sandoval, 532 U.S. at 286-87 (stating that "without [congressional intent], a cause of action

reasoned that 340B entities were entitled to federal common law claims for breach of contract, the Ninth Circuit's decision intentionally usurped legislative powers traditionally reserved to Congress.[135] By providing 340B entities with judicial remedies, the court in Santa Clara flouted Congress's judgment to appoint the Secretary of HHS to enforce pricing discrepancies.[136] In addition to subverting

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does not exist and court may not create one"); Virginia Bankshares v. Sandberg, 501 U.S. 1083, 1102 (1991); Wheeldin v. Wheeler, 373 U.S. 647, 651 (1963.)

[135] See e.g., Sandoval, 532 U.S. at 286-87 (emphasizing that Congress, not courts, may create causes of action to enforce a statute); Northwest Airlines, Inc. v. Transport Workers Union of Am., 451 U.S. 77, 95 n.34 (1981) (quoting New Jersey v. New York, 283 U.S. 336, 348) (stating "federal common law is 'subject to the paramount authority of Congress').

[136] See City of Milwaukee v. Illinois, 451 U.S. 304, 314 (commenting that federal common law is only "resorted to in absence of an applicable Act of

congressional intent, the Ninth Circuit's decision threatens to thwart the administration of both the Medicaid and 340B programs.[137]

Notwithstanding appropriate deference to the law of contracts to interpret the PPA, the Ninth Circuit mischaracterized the role of federal common law in the context of government contracts.[138] Further, the court

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Congress"). Here, the 340B program was an applicable Act that specifically designated that the Secretary of HHS would handle all pricing discrepancies. See 42 U.S.C. § 1396r-8(b)(3)(A)-(B) (discussing Congress vested Secretary of HHS with authority to ensure audit and investigate Manufacturers to ensure compliance with PPA).

[137] See Gov't Brief, supra note 62 at 9, 11 (emphasis in original) (warning that private right of action would "squarely implicate [HHS's] oversight of" Medicaid and would disrupt operation of "both [340B and Medicaid] programs").

[138] See Santa Clara v. Astra USA, Inc., 588 F.3d 1237, 1243, 1245 (9th Cir. 2009) (citing Smith v. Cent.

in Santa Clara overreached by appropriating 340B entities with status as intended beneficiaries simply because they directly benefitted from the PPA.[139] Moreover, the Ninth Circuit pushed the envelope by claiming that 340B entities were entitled to sue to enforce the drug pricing requirements of the PPA.[140]

Ariz. Water Conservation Dist., 418 F.3d 1028, 1034 (9th Cir. 2005)) (concluding that "federal law controls the interpretation of the PPA, which is a 'contract[] entered into pursuant to federal law and to which the government is a party" and, therefore, clear intent to directly benefit 340B entities entitles them to sue as third-party beneficiaries).

[139] See id. at 1244, 1246 (extrapolating from § 256b's general purpose to find that 340B entities directly benefitted from PPA and, therefore, could assert common law claims as intended beneficiaries).

[140] See id. at 1244 (reasoning that 340B entities directly benefitted from PPA and, therefore, were entitled to assert third-party beneficiary claims

The Ninth Circuit misrepresented the availability of administrative remedies, permitting federal common law to override congressional intent in order to provide 340B entities with judicial remedies.[141] Notwithstanding the reasoning that allowing private causes of action was consistent with statutory intent and avoided "plac[ing] the entire burden of enforcement" on the Secretary of HHS, the absence of a statutory remedy does not invite judicial augmentation.[142] Although courts must ascertain the

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because "the right to sue inheres in one's status as an intended beneficiary").

[141] See id. at 1250–51 (inferring that because "§ 256b does not 'expressly provide' any remedies to covered entities" covered entities could not invoke Secretary of HHS to initiate informal dispute resolution process on their behalf).

[142] See Price v. Pierce, 823 F.2d 1114, 1121 (7th Cir 1987) (discussing sensibility of relieving burden on government agency by carving out individual responsibility of private parties).

remedies created by Congress, the Ninth Circuit cannot justify judicial activism because federal common law claims tug at its heartstrings.[143] Particularly where Congress has "intentionally withheld a remedy . . . [courts] . . . must refrain from providing one because it is in those situations that 'appropriate judicial deference' is especially due."[144]

V. Interference: The Ninth Circuit's Immediate, Short-Term, and Large-Scale Impact

The Ninth Circuit's decision will have dramatic and far-reaching consequences, extending beyond the

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[143] See PhRMA Brief, supra note 132, at 8 (stating that "federal common law is a uniquely poor source of authority to trump the remedies determination made by Congress").

[144] See Wilson v. Libby, 535 F.3d 697, 709 (D.C. Cir. 2008 (quoting Schweiker v. Chilicky, 487 U.S. 412, 423 (1988)), cert. denied, 129 S. Ct. 2825 (2009) (declaring that absence of statutory remedy is not invitation for judicial activism).

pharmaceutical industry's coin purse to the seven million contractors that annually enter into contracts with the federal government.[145] Enabling 340B entities to assert private rights of action will expose

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[145] See Kevin R. Kosar, Privatization and the Federal Government: An Introduction, **Congressional Research Service Report for Congress 16 (Dec. 28, 2006) (CRS Report)**, available at http://www.fas.org/sgp/crs/misc/RL33777.pdf (reporting that in recent years, the number of federal contractors has increased, topping seven million"); see also Brief For the Chambers of Commerce of the United States of America as Amicus Curiae Supporting Petitioners, Astra USA, Inc., et al. v. County of Santa Clara, No. 09-1273 (May 20, 2010), available at http://www.scotusblog.com/case-files/cases/astra-usa-inc-v-santa-clara-county/, at 2 (discussing implications of Ninth Circuit's decision on "millions of American businesses [that] annually enter into contracts with the federal government in a wide range of industries including construction, manufacturing, transportation, and utilities").

Manufacturers to unjustified and costly litigation.[146] Further, the Ninth Circuit's decision subverts the Secretary of HHS's role, frustrating the administration of both the Medicaid and 340B programs going forward.[147] Moreover, imposing unforeseen

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[146] See Santa Clara v Astra USA, Inc., 588 F.3d 1237, 1248 n.12 (9th Cir. 2009) (citing Growth of 340B Covered Entity Sites From 01/1998 to Present, **Department of Health and Human Services – Office of Pharmacy Affairs**, available at http://opanet.hrsa.gov/opa/Report/StatisticalReport.aspx) (last visited October 14, 2010) (discussing that an estimated 13,000 covered entities would qualify to bring suit when opinion was drafted). The Ninth Circuit, however, was not persuaded that this large number of potential plaintiffs would preclude suit. Id. (holding that court was "unmoved by the Manufacturers' protest that they 'surely would not have agreed to subject themselves to a large number of lawsuits'").

[147] See 42 U.S.C. §1396r-8(b)(3)(A)-(B) (indicating that Congress intended to provide Secretary of HHS

liability to third parties will create a disincentive for contractors to enter into future government contracts, "disserv[ing] the interests of millions of Americans whose lives are improved through public-private partnerships embodied in government contracts" similar to the PPA.[148]

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with oversight responsibility of regulatory scheme); see also PhRMA Brief, supra note 132, at 13 (warning that "in addition to running counter to this Court's recent jurisprudence, the Ninth Circuit's decision will have sweeping ramifications on the regulatory scheme"). The Ninth Circuit's decision disregards congressional intent to designate the Secretary of HHS with enforcement capabilities. Id. at 14 (stating that "the Ninth Circuit examined only the authorities created by the 340B statute itself . . . and its apparent belief that the 340B statute does not give [the Secretary of] HHS robust enforcement authorities thus misses the point").

[148] See e.g., Chamber Brief, supra note 144, at 10 (asserting that Ninth Circuit's decision threatens to negatively impact relationship between public and

A private right of action under the PPA would permit potentially 15,582 entities (2908 of which currently reside in states within the Ninth Circuit) to sue hundreds of drug manufacturers based on the manufacturers' pricing and sales data for more than 35,000 drugs sold.[149] Because Santa Clara challenges

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private sector); Boyle v. United Technologies, 487 U.S. 500 (1988) (Scalia, J.). (stating that "[t]he imposition of liability on Government contractors will directly affect the terms of Government contracts: either the contractor will decline to manufacture the design specified by the Government, or it will raise its price"); Martha Minow, Public and Private Partnerships: Accounting for the New Religion, 116 **Harv. L. Rev.** 1229, 1231-32, 1267 (2003) (discussing interlocking of public-private sector through federal contracts to manage public schools, run prisons, oversee welfare programs, provide drug-abuse counseling, and offer employment training).

[149] See Covered Entity Data Extract, **Department of Health and Human Services - Office of Pharmacy Affairs**, available at http://opanet.hrsa.gov/opa/CE/

all AMPs and BPs by the nine Manufacturers over a seven year period, the Manufacturers will be exposed to extensive and burdensome third party litigation for years.[150] Further, the Patient Protection and

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CEExtract.aspx (last visited October 14, 2010) (reporting number of covered entities in states in Ninth Circuit: 72 in Alaska, 230 in Arizona, 1464 in California, 96 in Hawaii, 125 in Idaho, 110 in Montana, 66 in Nevada, 298 in Oregon and 447 in Washington).

[150] See Santa Clara v. Astra USA Inc., 588 F.3d 1237, 1242 (9th Cir. 2009) (explaining OIG's reports that 340B entities relied on to determine that Manufacturers "have systematically overcharged [Santa Clara's] medical facilities, and all similarly situated covered entities, for covered drugs"). Although the OIG admitted that one of its reports was calculated improperly, the OIG "did not retreat, however, from its other, more general findings that HRSA was not adequately overseeing the Section 340B program." Id. (acknowledging that exact amount of overcharging was unclear but arguing that there was

Affordable Care Act of 2010 ("PPACA"), as amended by the Health Care and Education Reconciliation Act of 2010 ("Health Care Reform Law"), expands the number of qualifying 340B entities by forty percent, increasing the potential plaintiff pool beyond an already unmanageable number.[151] Nevertheless, the imposition of substantial liability and burdensome litigation on Manufacturers pales in comparison to the effect that the Ninth's Circuit's decision will have on the administration of both the Medicaid and the Section 340B programs.[152]

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enough evidence to conclude that Manufacturers were noncompliant).

[151] See Patient Protection & Affordable Care Act, Pub. L. No. 111-48, § 7101, 124 Stat. 119 (2010) (expanding categories to include certain children's hospitals, free standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals).

[152] See 42 U.S.C. § 256b(b) (stating that "the terms 'average manufacturer price', 'covered outpatient

Because the Section 340B and Medicaid programs are administered through contracts incorporating the same pricing components, the Ninth Circuit's holding frustrates congressional oversight of two major health care acts.[153] Further, providing private parties with judicial remedies to challenge 340B pricing components

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drug', and 'manufacturer' have the meaning given such terms in section 1927(k) of the Social Security Act [42 U.S.C. § 1396r-8(k)]"). Because there can only be one AMP and BP at a time for a given drug, a private right of action would directly interfere with the government's ability to administer both the Medicate Rebate and Section 340B programs. See PhRMA Brief, supra note 132, at 13 (asserting that "by inviting the courts into the determination of AMP and BP at the behest of purported third-party beneficiaries, the decision below threatens far-reaching uncertainty, disuniformity, and destabilization").

[153] See Pharmacy Affairs & 340B Drug Pricing Program - Glossary of Pharmacy-Related Terms: 340B Ceiling Price, **U.S. Department of Health and Human Services: HRSA** (last visited October 14, 2010), available at

will lack both uniformity in voice and capability possessed by the Secretary of HHS.[154] Moreover,

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http://www.hrsa.gov/opa/glossary.htm (indicating that "[t]he 340B discount is calculated using the Medicaid rebate formula and is deducted from the manufacturer's selling price rather than paid as a rebate"). Because the 340B and Medicaid programs are inextricably intertwined, the Ninth Circuit's decision affects government assistance programs that are massive in size and scope; see also PhRMA Brief, supra note 132, at 15 (commenting that "the scope of the programs and operations implicated by [Santa Clara's] suit is massive").

[154] See Chamber Brief, supra note 144, at 7 (determining that judicially-created remedies will create confusing and conflicting standards). The government reasoned that private enforcement cannot function for the following reason:

> Given the sheer size, scope, and complexity of the 340B Program and the Medicaid Rebate Program, the Ninth Circuit should not have the last word on whether drug manufacturers may be exposed to

judicially-created pricing overhauls will exacerbate the tension between the competing interests of the States and 340B entities.[155] Allowing private parties

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> massive unanticipated claims and varying and possibly conflicting obligations as courts sort through what is the "correct" AMP or BP.

Id. (implying that Secretary of HHS is better equipped to enforce complex pricing requirements); see also PhRMA Brief, supra note 132, at 18 (stating that "coherent guidance as to the proper treatment of ambiguous issues can only emerge if there is a single interpreter" and Secretary of HHS "is only entity in a position to prove uniform and definitive answers").

[155] See Id. at 21 (discussing conflicting interests between States and 340B entities). Tension exists between States and 340B entities for the following reasons:

> The Government uses AMP both to set the amount manufacturers must pay in Medicaid rebates to States and to establish the 340B ceiling price that may be charged to 340B entities. The interests of States and 340B entities in this

to challenge Section 340B pricing components, therefore, will affect both the consistency and certainty of future drug pricing.[156]

> respect are often directly opposite. In most circumstances, the lower the AMP, the lower a product's price to a 340B entity. Conversely, in most circumstances, the higher the AMP, the more a state Medicaid agency receives in rebates from manufacturers. On the myriad issues for which there is no definitive statutory or regulatory guidance, 340B entities will advocate an interpretation that reduces AMP, while States will advocate an interpretation that increases it.

Id. (discussing "the complexity of regulatory pricing regime generally and the interrelationship between the Medicaid rebate program and the 340B program").

[156] See id. (indicating that "the critical pricing metrics that [Santa Clara] seeks to attack are note designed for 340B entities' benefit, but are the product of a more complicated regulatory system that serves multiple ends").

The ramifications of the Ninth Circuit's decision, however, are not limited to the immediate context of this case.[157] Expanding private enforcement of a federal statute will inevitably raise the "costs of doing business," creating a disincentive for businesses to enter into multi-billion dollar government contracts.[158] Further, contractors'

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[157] See Chamber Brief, supra note 144, at 13 (illustrating that "the Ninth Circuit's methodology, which would permit a private plaintiff to bring suit to enforce statutory requirements as a third-party beneficiary of a contract in the absence of a statutory right of action, could apply whenever a government contract incorporates an underlying statutory or regulatory requirement")

[158] See Stoneridge v. Investment Partners, LLC v. Scientific-Atlanta, Inc., 552 U.S. 148, 163-64 (2008) (analyzing "practical consequences" of increasing liability on contracting parties would cause them to "be deterred from doing business"); see also Chamber Brief, supra note 144, at 14 (referencing Federal

inability to feasibly litigate all third-party claims will encourage "plaintiffs with weak cases to extort

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Procurement Report: FY 2007, **Federal Procurement Data System**, at 2, available at tinyurl.com/2007fpdsreport) (stating that "in 2007 alone, American companies conducted approximately $460 billion of business with the federal government-more than twice as much as a decade earlier"). In 2007, the money involved in public-private partnerships was as follows: manufacturing ($164 billion); professional, scientific, and technical services ($123 billion); construction ($31 billion); transportation ($8 billion); and utilities ($2 billion). Id. at 31-34 (listing substantial funds involved in government contracts with different sectors of economy). Additionally, the money involved in government contracts and agencies in 2007 was as follows: Department of Energy ($23 billion); Health and Human Services ($14 billion); Housing and Urban Development ($12 billion); and Veterans Affairs ($12 billion). Id. at 10 (discussing sizable contracts with private sector).

substantial settlements from innocent [defendants]."[159] Ironically, the people who ultimately benefit from the government contracts will be forced to bear the costly effects of litigation.[160] As a result, the government will be forced to reincentivize contractors to "offset the potential costs of third-party litigation and thereby induce companies to enter into government contracts."[161] The Ninth Circuit's decision,

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[159] See Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 558 (2007) (discussing litigation tactics that "take up the time of a number of other people, with the right to do so representing an in terrorem increment of the settlement value").

[160] See Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A., 511 U.S. 164, 189 (1994) (discussing how costs of defending against litigation will be either absorbed and borne by investors and employees or passed on to consumers).

[161] See Chamber Brief, supra note 144, at 15 (determining that increased liability would directly

therefore, disrupts the public-private sector relationship, creating instability for existing government contracts and disincentives for prospective ones.[162]

VI. Under Review: The Ninth Circuit's Decision Warrants a Closer Look By the Supreme Court

It is not the role of the judiciary to substitute its judgment for that of Congress.[163] The Ninth

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burden Manufacturers but would indirectly burden government to counter Manufacturers' disincentive to "engage in business with the government going forward").

[162] See id. (warning that "the most serious of those consequences is the chilling effect the ninth Circuit's approach promises to have on business activity between the private and public sectors").

[163] See e.g., Northwest Airlines, Inc. v. Transport Workers, 451 U.S. 77, 95 n.33-34 (1981) (quoting New Jersey v. New York, 283 U.S. 336, 348) (asserting that Supreme Court has "consistently . . . emphasized that

Circuit, however, ignored this bedrock principle and created an end-run around Supreme Court jurisprudence, allowing 340B entities to assert private causes of action as third-party beneficiaries.[164] The decision

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the federal lawmaking power is vested in the legislative, not the judicial, branch of government; therefore, federal common law is 'subject to the paramount authority of Congress'"); Marbury v. Madison, 5 U.S. 137 (1803) (delineating separation of powers between Congress and Judiciary to carve out role of Judiciary).

[164] See Santa Clara v. Astra USA, Inc., 588 F.3d 1237, 1244 (reasoning that 340B entities were entitled to bring suit because "any intended beneficiary has the right to enforce the obligor's duty of performance"). To support this reasoning, the Ninth Circuit bypassed "the truism that federal common law . . . is 'subject to the paramount authority of congress.'" See id. at 1249 (referencing United States v. Texas, 507 U.S. 529, 534 (1993) (reasoning that that PPA did not "expressly provide" 340B entities with remedies and, therefore, indicated that "Congress [did not] 'speak

in Santa Clara has far-reaching implications that will affect millions of Americans and billions of dollars.[165] Because recent health care reform will further amplify the tension between congressional intent and federal common law, the Supreme Court must address whether a private party may assert a federal common law claim as a third-party beneficiary absent an implied right of action.[166]

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directly' to a question addressed by the federal common law").

[165] See Chamber Brief, supra note 144, at 3, 14 (implying that Ninth Circuit's decision "threatens to create a discincentive for businesses to enter into government contracts in the future-an outcome that would disserve the interests of millions of Americans" and jeopardize "approximately $460 billion of business with the federal government" that "American companies conducted" "in 2007 alone").

[166] See Question Presented: Docket No. 09-1273 Astra USA, Inc. V. Santa Clara County, CA, **Supreme Court of the United States: Supreme Court Documents - Questions**

Presented, available at http://www.supremecourt.gov/qp/09-01273qp. pdf (identifying that question presented is "whether in the absence of a private right of action to enforce a statute, federal courts have the federal common law authority to confer a private right of action simply because the statutory requirement sought to be enforced is embodied in a contract"); see also Drug Trends, supra note 2, (reporting that recent health care reform has enabled additional entities to qualify as 340B entities). The affects of health care reform will include:

> In the coming years, implementation of various provisions of PPACA will affect prescription drug coverage, utilization, prices, and regulation. Coverage and utilization of prescription drugs will be expanded by PPACA's health insurance mandate and premium and cost-sharing subsidies; the designation of prescription drugs as an essential health benefit to be covered by private health plans through the new health benefit Exchanges and by Medicaid for newly eligible adults; and Medicare's prescription drug rebate, cost-sharing, and catastrophic threshold changes.

> Prices charged to government programs will be affected by changes to Medicaid rebate requirements and expansions to the Section 340B program. Prescription drug regulation will be affected by the new process for licensure of biosimilar versions of brand name biological products and by drug labeling requirements. These and other PPACA changes will ultimately impact national spending for prescription drugs in ways yet to be seen.

Id. (summarizing future effects of current heath care reform initiatives).