No. 09-1273

IN THE
Supreme Court of the United States

ASTRA USA, INC., ET AL.,
Petitioners,
v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit

BRIEF OF A COALITION OF 340B ENTITY GROUPS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae is a coalition ("Coalition") of eight organizations that collectively represent thousands of "safety net" providers and programs throughout the United States that participate in the 340B drug discount program. These safety net providers – otherwise known as "covered entities" – furnish or arrange for health care services to disproportionately high numbers of patients who are indigent, uninsured, underinsured, chronically ill, and/or otherwise vulnerable. As such, they qualify to participate in the Public Health Service 340B Drug Pricing Program ("340B program"), which entitles them, if they enroll, to receive deep discounts on covered outpatient drugs. 340B providers are highly dependent on public funding – including federal grants, Medicaid, Medicare and state and local subsidies – so the discounts they receive under the program allow them to stretch their tax-supported dollars further in caring for our nation's poorest and most vulnerable populations. The eight Coalition members are:

- Hemophilia Alliance
- National Alliance of State and Territorial AIDS Directors
- National Association of Counties
- National Association of Public Hospitals and Health Systems

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amicus curiae* represents that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amicus*, its members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amicus* also represents that all parties have consented to the filing of this brief, and letters reflecting their blanket consents to the filing of *amicus* briefs have been filed with the Clerk.

- National Family Planning and Reproductive Health Association
- National Health Care for the Homeless Council
- Planned Parenthood Federation of America
- Safety Net Hospitals for Pharmaceutical Access

The Coalition files this brief to apprise the Court of the insufficiency of the 340B administrative enforcement program for the periods at issue here. The Coalition has worked for years to solicit government support in investigating and remedying overcharge problems and to gain enhanced federal enforcement in assuring that its members are charged no more than the correct 340B ceiling prices. Congress was well aware of the agency's inability to engage in stringent enforcement measures, and it sought to resolve these problems when it enacted the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148 (Mar. 23, 2010), 124 Stat. 119 (2010). By its terms, however, PPACA applies only to drugs purchased on and after January 1, 2010. PPACA, §7101(e)(1). As such, its remedial protections are not available as to the claims raised in this case.

SUMMARY OF ARGUMENT

For the periods at stake here, the court of appeals correctly recognized that the administrative enforcement framework for the 340B program was fatally flawed both in theory and practice. On paper, the operative statutory and pharmaceutical pricing agreement ("PPA") provisions lacked meaningful procedures or mechanisms to enable covered entities to pursue administrative grievances as to drug pricing or to allow the relevant federal oversight agency, the Health Resources and Services Administration

("HRSA"), to redress those complaints. The sole means for covered entities to do so involved an informal dispute resolution process that was entirely voluntary in nature. In practice, HRSA's informal dispute resolution process has been invoked infrequently not only because of its voluntary nature but also because HRSA has been ill-equipped to pursue or investigate complaints or to issue meaningful determinations on claims that were filed. The evidence as to the inefficacy of the 340B administrative enforcement process is overwhelming and irrefutable.

Indeed, when it established the 340B program, Congress deliberately directed that the Secretary of the Department of Health and Human Services ("Secretary" and "HHS") enter into contractual PPAs with drug manufacturers – contracts that would invariably result in legal rights accruing to affected third-party beneficiaries, including covered entities. There is no evidence – and petitioners have cited none – that Congress was unaware of or oblivious to the implications of that mandate for covered entities seeking to exercise their new rights. Certainly, Congress was entitled to make the judgment that the ability of third-party beneficiaries to vindicate their contractual rights in court would protect them from any deficiencies or lapses in administrative enforcement.

Later, Congress became starkly aware of these significant administrative enforcement failings, and with the enactment of PPACA erected a much more rigorous administrative enforcement process to cover claims on and after January 1, 2010. Congressional recognition of the necessity for such reforms should not be construed, however, as evidence that Congress has always relied upon and preferred administrative

enforcement. Rather, it should be interpreted as a recognition by Congress that the existing administrative enforcement process was wholly inadequate. These factors – Congress's earlier mandate that contracts be utilized and its later determination that administrative enforcement was insufficient – should weigh heavily in allowing contractual actions by covered entities to bolster enforcement on pre-PPACA claims.

ARGUMENT

I. COVERED ENTITIES ARE THE INTENDED BENEFICIARIES OF THE PROGRAM AND ARE HEAVILY DEPENDENT ON 340B SAVINGS TO SUPPORT THEIR SAFETY NET MISSION

According to the 340B program's legislative history, Congress enacted the 340B law to enable covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384,102d Cong., pt. 2, at 12 (2d Sess. 1992). HRSA's elaboration of this congressional intent is instructive.

> The purpose of the 340B program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. Additional program resources are generated if drug acquisition costs are lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts. [2]

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[2] HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section (cont'd)

It is therefore evident that, by establishing the 340B program, Congress intended to benefit not only safety net providers but also the taxpayers on whom these providers are so dependent for funding. Because lower cost drugs create "additional program resources" for 340B providers, taxpayers do not have to shoulder as much of the cost of indigent care.

Covered entities eligible for participation in the 340B program include certain high-Medicaid disproportionate share hospitals ("DSH"), as well as specified federal grantees, including federally qualified health centers ("FQHCs"), FQHC "look-alikes," state-operated AIDS drug assistance programs ("ADAPs"), Ryan White CARE Act Part A, Part B, and Part C Programs, tuberculosis, black lung, family planning and sexually transmitted disease clinics, hemophilia treatment centers, public housing primary care clinics, homeless clinics, Urban Indian clinics, and Native Hawaiian health centers. Most recently, under PPACA, several new covered entities have been deemed eligible for 340B program participation, including critical access hospitals and certain freestanding cancer hospitals, freestanding children's hospitals, rural referral centers, and sole community hospitals. According to the government, over 14,000 covered entity sites participate in the 340B program.[3]

Covered entities serve high volumes of the nation's most vulnerable, and often most impoverished, patient populations. The 340B law lists 17 categories of covered entities. Among them are the following:

340B of the Public Health Service Act (July 2005), http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.

[3] HRSA, *Enrollment in 340B Program to Provide Affordable Medications Begins for Newly Eligible Safety-Net Health Care Providers* (Aug. 2, 2010).

Public hospitals – Providing more than 43 million ambulatory care visits annually,[4] public hospitals offer the full spectrum of high quality, coordinated health care to their communities, regardless of an individual patient's ability to pay. They provide 19 percent of uncompensated hospital care nationwide, even though they represent just two percent of the nation's hospitals. As a result of the patient populations they serve, safety net hospitals operate with exceptionally thin margins and rely on public programs like Medicaid and the 340B program to continue to provide appropriate health care services to vulnerable, low-income patients. In 2008, Medicaid and other government programs accounted for nearly two-thirds of these hospitals' net revenues. More than 80 percent of the increase in overall patient care volumes during the second quarter of 2010 (compared to the beginning of the recession) is due to serving additional uninsured or Medicaid patients.[5]

Community health centers – Health centers serve 1 in 7 uninsured individuals nationally, including 1 in 5 of the low income, uninsured. Their patient populations include the homeless, residents of public housing, migrant farm workers, and others with emergent and chronic care needs. Approximately 70 percent of health center patients live in poverty.[6] Community health centers save the national

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[4] National Association of Public Hospitals and Health Systems, *America's Public Hospitals and Health Systems, 2008* (Feb. 2010), http://www.naph.org/Main-Menu-Category/Publications/Safety-Net-Financing/Characteristics-2008.aspx.

[5] The 340B Coalition, *340B Program Expands Access to Pharmaceutical Care and Reduces Cost to Taxpayers* ("Expands Access").

[6] National Association of Community Health Centers ("NACHC") (2010), http://www.nachc.org/. Because (cont'd)

health care system between $9.9 billion and $17.6 billion annually by helping patients to avoid emergency rooms and make better use of preventive services.[7]

Ryan White clinics and programs – The Ryan White Program provides primary health care, pharmaceutical treatments, and support services for low-income people with HIV/AIDS and treats over 500,000 HIV-positive individuals in all 50 states, the District of Columbia, Puerto Rico and the Pacific Island jurisdictions. According to the Centers for Disease Control and Prevention, approximately 1,039,000 to 1,185,000 people in the country are living with HIV; of those individuals, approximately 421,873 are living with AIDS. Through public health systems, nonprofit clinics, community health centers and other providers, the Ryan White Program is designed to be the payer of last resort for individuals with HIV and AIDS. [8]

Hemophilia treatment centers – Hemophilia treatment centers provide comprehensive care to individuals with bleeding and clotting disorders. Mor-

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FQHCs operate under a comprehensive regulatory scheme under 42 U.S.C. §254b and 42 U.S.C. §1396d, which afford them unique status under federal law, NACHC is not taking a position in this case. However, accounting for the circumstances of the parties to the brief who have attempted to have overcharges and other issues resolved through the processes described, NACHC concludes that the process had no teeth and in no instance was effective in correcting an alleged violation or other violation. According to NACHC, it is unimaginable that Congress would have impaired or intended to impair rights of actual enforcement that would inhere to the individual entities covered by the law.

[7] Id.

[8] HRSA, *About the Ryan White HIV/AIDS Program* (2010), http://hab.hrsa.gov/aboutus.htm.

tality rates and hospitalization rates for bleeding complications from hemophilia are 40 percent lower among people who receive care in hemophilia treatment centers than among those who do not receive this care. Significant medical cost savings are realized over the life of the patient through these centers.[9]

Family planning clinics – Federally-funded family planning clinics are focused on providing preventive care to keep women, men and teens healthy, and to help women and couples plan their families. Each year, these grantees and sub-grantees provide essential health care, including routine gynecological exams, breast and cervical cancer screenings, contraceptive services, sexually transmitted infection testing and treatment, and HIV testing and education to more than three million patients, the vast majority of whom have incomes at or below 150 percent of the federal poverty level. More than six in 10 patients who receive care at women's health centers consider it their primary source of health care, which makes these centers a critical entry point into the health care system for millions of low-income, uninsured and underinsured individuals.

Covered entities often act as the "medical home" for their patients, offering primary care, family planning, mental health services, maternal and child health care, and health education and social service support such as teenage pregnancy programs, substance abuse education, and child abuse prevention. Because their patient populations are disproportionately represented by African Americans, Native

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[9] The Hemophilia Alliance, *The 340B Program & Hemophilia* (2010), http://hemoalliance.org/documents/AllianceBro_final2_D0034182.pdf.

Americans, Asians, Latinos and other ethnic or racial groups, they are dedicated to providing services in the language of their constituency and in a culturally sensitive manner.

Covered entities also serve a disproportionate share of patients with special health care needs, including the elderly, low-income children and families, trauma patients, victims of violent crime, and persons with chronic conditions such as HIV/AIDS, hemophilia, tuberculosis, mental illness, and diabetes. Many of these patients are from homeless shelters, school-based clinics, juvenile centers, and other governmental facilities. [10]

Covered entities play a vital role in the lives of their patients. In 1992, the year that the 340B law was enacted, Congress heard testimony about the critical role of safety net providers in serving the Medicaid population. Testimony by the executive director of a Los Angeles clinic – which subsequently enrolled in the 340B program as a Ryan White grantee, family planning clinic, and community health center – was particularly compelling. In the testimony, the executive director recounted a series of circumstances in which the clinic had made a profound difference in its patients' lives and health. In one example cited by the executive director, a woman came to regard the clinic as a lifeline and the center of her family and universe after testing positive for HIV. In another example, when a prenatal patient developed severe anemia, health educators from the clinic discovered that her Special Supplemental Food

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[10] Planned Parenthood Action Center, *340B Programs Help Low-Income Individuals and Their Health Care Providers* (2010), http://www.plannedparenthoodaction.org/positions/340b-program-helps-low-income-individuals-their-health-care-providers-628.htm.

Program for Women, Infants and Children Program allotment was being consumed by the nine other members of her household. The support staff met with the woman's housemates and explained the importance of reserving enough food for the woman and her unborn child. On another occasion, a prenatal patient confided to clinic staff that she wanted labor induced early, so that her boyfriend would stop beating her. After receiving counseling and a referral to a shelter, the woman gave birth and named the child after the clinic counselor. Finally, the executive director recounted a circumstance in which the cultural sensitivity and shared cultural experience of clinic staff played a vital role in dissuading a young man from committing suicide rather than disclose to his family that he was HIV positive.[11]

Overall, 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest among us, regardless of ability to pay. For these entities, the 340B program is a vital and indispensable tool to help offset the costs of uncompensated or under-compensated care. The program enables covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B program, many pharmacies would be forced to restrict access greatly or, in some cases, shutter their doors. For these reasons, ensuring the accuracy of 340B discounts and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

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[11] Larry S. Gage & William H. von Oehsen, *Managed Care Manual: Medicaid and State Health Reform* 7-4 (1995).

II. THE 340B PROGRAM WAS DEVOID OF AN EFFECTIVE ADMINISTRATIVE ENFORCEMENT MECHANISM FOR ADDRESSING MANUFACTURER OVERCHARGES

The petitioners assert that, in this case, "Congress has 'occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency.'" Petitioners' Brief at 44, *quoting City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981). From this, they reason that any private remedies for 340B entities must be limited to those established by Congress and that, since Congress did not expressly provide such a remedy, there is none. *Id*. *See also Middlesex Cnty Sewage Auth. v. Nat'l Sea Clammers Assoc.*, 456 U.S. 1, 21-22 (1981); *Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 93-94 (1981).

A careful examination of the administrative enforcement framework prior to the recent enactment of PPACA reveals, however, that it was neither elaborate nor extensive. Indeed, it was skeletal in nature and has therefore prevented the agency from providing meaningful program oversight and enforcing program requirements. This fact prompted Congress to alter the enforcement framework radically in PPACA.

A. There Were No Viable Or Effective Administrative Remedies To Protect Against Manufacturer Non-Compliance

The pre-PPACA 340B statute itself contained no administrative enforcement mechanisms. *See* 42 U.S.C. §256b (2009). The Medicaid drug rebate statute did specify that, if the Secretary terminated a Medicaid drug rebate agreement, the termination also extended to the manufacturer's 340B PPA. 42

U.S.C. §1396r-8(b)(4)(B)(iv). As described later, both Congress and the HHS Office of Inspector General ("OIG") were concerned about the lack of meaningful administrative enforcement tools under 340B, and the agency itself conceded that the termination sanction was so draconian and potentially counterproductive that it was not utilized.

Likewise, there are no 340B administrative enforcement regulations issued by the agency, a reflection undoubtedly of the paucity of statutorily based enforcement tools accorded it.

The statutorily required PPA for the 340B program does include an enforcement mechanism not directly referenced in the statute.[12] Under that agreement, the Secretary may initiate an informal dispute resolution process with drug manufacturers based on alleged non-compliance, failure to submit required reports, or submission of false information. By its own terms, however, the process does not preclude manufacturers or the Secretary from exercising such other remedies as may be available by law. PPA at ¶ IV(c).

More importantly, when HRSA developed published standards pertaining to the informal dispute resolution process, it imposed major restrictions that have hamstrung any effective administrative enforcement. 61 Fed. Reg. 65406 (Dec. 12, 1996). Although the standards were avowedly designed to cover all types of 340B claims that drug manufacturers might have against 340B covered entities and that 340B covered entities might have against drug manufacturers (*id.* at 65412), they also contained

[12] The version of the PPA relied upon by the parties is reprinted at Pet. App. 165a-181a.

significant limitations that the agency itself took repeated pains to emphasize:

> The Department is overseeing the implementation of section 340B of the PHS Act and as such, is offering a ***voluntary*** dispute resolution mechanism to expedite this process. ***No manufacturer or covered entity is required to avail itself of this process before resorting to other available measures***. *** The dispute resolution process is a ***voluntary*** process. Manufacturers or entities are only encouraged to participate in the process before seeking other remedies.

Id. at 65411 (emphasis added).[13]

The voluntary nature of this informal dispute resolution process eviscerated any effectiveness it might have otherwise had. No manufacturer or entity, alleged to have violated 340B requirements, was likely to submit itself to the process. Indeed, as reflected in the sections below, despite significant and repeated efforts by 340B entities to draw the agency's attention to issues and problems, such complaints were subsumed by an administrative black hole from which they never emerged.

In light of this, it is odd that the United States admits that States may file suits against drug manufacturers to enforce Medicaid drug rebate obligations but claims that 340B entities could not do so to redress 340B claims. Brief for the United States at 34 n.14. As such, the United States reaches the paradoxical conclusion that non-federal entities involved

[13] The agency never explained what these other available measures or remedies were, although it appeared to concede that they existed.

in the Medicaid drug rebate program may sue to enforce the requirements of that program but that the intended beneficiaries of the 340B program were powerless to do so despite the absence of a meaningful and rigorous administrative enforcement process. The Coalition has no doubt that the ability of States to bring such actions is essential to the Medicaid drug rebate program's enforcement structure. At the same time, however, there is absolutely no reason to think that legal actions by 340B entities will somehow upset or erode the federal government's administrative enforcement of the 340B program, especially given the tenuous nature of that enforcement as the Coalition now explains.

B. In Actual Practice, Manufacturers Can Overcharge Covered Entities With Impunity

In the sections that follow, the Coalition presents examples of the inefficacy of HRSA's dispute resolution process as well as the agency's limited ability to respond to appeals for oversight by covered entities and Coalition members. These examples make clear that the pre-PPACA dispute mechanism, as referenced in the PPA and HRSA guidelines, was a vacant promise that did not, to the best of the Coalition's collective knowledge, function to resolve a single dispute involving alleged 340B overcharges against a manufacturer. [14] This failure may be traced to the lack of adequate funding and resources for HRSA as well as the lack of an effective oversight

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[14] In preparation for the drafting of this brief, SNHPA submitted an expedited Freedom of Information Act request to HRSA on Nov. 8, 2010, seeking a list of all dispute resolution claims filed with the agency since the 340B program's inception as well as the status of each claim. No response has yet been received.

and enforcement mechanism that could be utilized by the agency.

The Court may note that most of the examples involve Safety Net Hospitals for Pharmaceutical Access ("SNHPA"), which represents over 600 of the hospitals participating in the 340B program, including DSH, children's, and rural hospitals. SNHPA is the only Coalition member that advocates exclusively on drug pricing matters, especially issues relating to the 340B program. As such, SNHPA often undertakes initiatives that benefit not only its member hospitals, but also the broader 340B provider community. The examples described below are among those initiatives.

In reciting these examples, the Coalition does not want to imply that manufacturers never took corrective action to address past overcharges nor that HRSA was completely unhelpful in facilitating such actions. To the contrary, there are several instances in which manufacturers and HRSA worked together to make sure that covered entities were made whole after an overcharge was discovered. In each of these instances, however, the remedial actions were initiated by the manufacturer or were otherwise possible based on the manufacturer's willingness to cooperate. The concerns raised here relate to situations in which manufacturers have been uncooperative in addressing pricing disputes. The Coalition's point is that, in instances where manufacturers may be uncooperative, there is no effective administrative measure to remedy the disputes. The Coalition also recognizes that HRSA has had to cope with the lack of an adequate enforcement framework with which to ensure program compliance. The examples set forth in this portion of the Coalition's brief should thus not

be construed as being critical of the agency itself but of the limitations of the enforcement and oversight framework within which the agency has had to operate.

Accordingly, in light of the facts set forth below, and given that the OIG has repeatedly noted that HRSA lacked the authority and resources to monitor the 340B program adequately,[15] petitioners' assertion that covered entities had an adequate remedy in the existing dispute resolution mechanism is a hollow one. Moreover, limiting covered entities to a remedy that has repeatedly been shown to be ineffectual serves to foreclose them from any remedy at all. This is an unfathomable result which, although indisputably in the best interests of the petitioners, would leave 340B providers, and the taxpayers who support them, utterly unprotected from drug overcharges that threaten to deplete the "scarce resources" that the 340B program was specifically intended to protect.

1. Use Of The Dispute Resolution Process Failed

Over the past decade, the Coalition and its members have made repeated attempts to bring manufacturer overcharge problems to the attention of the agency, and to seek agency intervention to address these problems. In many instances, covered entities made specific requests for dispute resolution which were left unaddressed by HRSA, whether due to lack

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[15] OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program,* OEI-05-02-00072, at 15 (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf; OIG, *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-0060, at 4 (Mar. 2003), http://oig.hhs.gov/oas/reports/region6/60100060.pdf. ("2003 Report").

of resources, staff, or authority. In this section, the Coalition presents a few examples of the overall failings of the voluntary dispute resolution mechanism, as to alleged manufacturer overcharges.

On May 26, 2009, SNHPA, on behalf of eight member hospitals, filed a request for dispute resolution with HRSA regarding drug manufacturer Nycomed's refusal to provide 340B discounts for the drugs Digifab and Crofab.[16] These drugs are often used in hospital emergency departments to counteract an overdose of digoxin (used for treatment of various heart conditions) and as an antivenin to treat snake bites. Despite the fact that these drugs were properly considered "covered outpatient drugs" for which 340B discounts should have been available, Nycomed refused to provide 340B discounts to covered entities or, in the alternative, imposed overly-burdensome reporting requirements for emergency room use.[17]

In its request for dispute resolution, SNHPA noted that, prior to exercising its option to invoke HRSA's voluntary dispute resolution process, it had made good faith efforts to resolve the dispute directly with Nycomed. Given the lack of success of these efforts, SNHPA requested that HRSA intervene:

> [w]e ask your assistance in requiring Nycomed to provide a 340B price for Crofab and Digifab

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[16] Letter from Stuart Gordon, Director, Legal and Regulatory Affairs, SNHPA, to Jimmy Mitchell, HRSA Office of Pharmacy Affairs ("OPA") Director (May 26, 2009).

[17] This reporting requirement violated longstanding HRSA guidelines that prohibit manufacturers from requiring covered entities to fill out forms or perform other tasks as a condition of receiving 340B discounts. Requiring additional documentation from covered entities also violated HRSA's audit guidelines, which provide that audits may not be performed absent the submission of an audit workplan to HRSA. Id.

> and credit the purchases of covered outpatient drugs made by the [petitioning] hospitals with the applicable discount amount for the period of time that a 340B price has not been provided.[18]

SNHPA followed up repeatedly with HRSA regarding the status of the dispute resolution request between the months of June 2009 and May 2010. During that time, HRSA failed to process or adjudicate the complaint or to take any steps toward achieving a resolution. Crofab and Digifab did finally appear on wholesaler lists at 340B prices for the second quarter of 2010, although this development was voluntary on the manufacturer's part and not the result of HRSA intervention. Still, the matter is not fully resolved: the recent availability of these drugs at 340B prices does not relieve Nycomed of the obligation to provide retroactive refunds to 340B providers, back to 2001. These discounts, to which covered entities were lawfully entitled and which now span a nine-year period, represent a substantial debt that remains unaddressed as a result of HRSA's inability to follow through on SNHPA's dispute resolution request, which specifically requested intervention "for the period of time that a 340B price has not been provided."[19]

HRSA also did not respond to a dispute resolution request pertaining to manufacturers' refusals to provide 340B pricing on an expensive specialty drug, by incorrectly claiming that the drug was unavailable. This was the case with respect to intravenous immune-globulin ("IVIG"), a sterile preparation of concentrated antibodies recovered from the pooled plas-

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[18] Id.
[19] Id.

ma of healthy donors. IVIG plasma products are used to manage serious conditions, including immune system disorders and related illnesses.[20]

In the late 1990's, SNHPA learned that its member hospitals were having difficulty procuring sufficient amounts of IVIG to meet the needs of their patients. SNHPA members also complained that, even when they were able to obtain an adequate amount of IVIG, it was only available at prices that were higher than the statutory ceiling price to which they were entitled.[21] The limited availability of IVIG at 340B prices was a serious concern for covered entities, especially because expensive specialty drugs like IVIG products comprise a large portion of many hospitals' outpatient pharmacy expenses.[22]

In an effort to gain a more comprehensive understanding of these problems, SNHPA conducted a survey of its members regarding the accessibility of IVIG. The survey results revealed that, although only about 20 percent of its member hospitals were able to procure IVIG at 340B prices, a much higher percentage – approximately 70 percent – were able to obtain at least some amount of IVIG at higher prices from a wholesaler or other drug distributor.[23] Thus, according to the SNHPA study, IVIG was frequently available for purchase, but not at the discounted 340B prices to which covered entities were legally entitled. In sum, manufacturers appeared to be impro-

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[20] Public Hospital Pharmacy Coalition, *Access to IVIG By Safety Net Hospitals Participating in the 340B Drug Discount Program,* at 7 (Sept. 2006), http://www.ashp.org/s_ashp/docs/files/DShort_IVIGAccesssafetynethospSept06.pdf.

[21] Id. at 6.

[22] Id.

[23] Id. at 5.

perly withholding 340B sales to covered entities in lieu of higher prices charged under more lucrative, commercial contracts.

In July 2006, frustrated by manufacturers' intransigence, a SNHPA member hospital notified HRSA via e-mail of its problems in purchasing IVIG at 340B prices. Specifically, the hospital representative noted that, while it had been unable to purchase IVIG at 340B prices, it had been able to obtain the product at non-340B prices. In response to this correspondence, HRSA asked whether, through its e-mail, the hospital was requesting that the agency initiate the dispute resolution process. The hospital representative assented, stating that "[i]t seems that the informal dispute resolution process…would be the appropriate way to address the unavailability of IVIG at 340B prices...please proceed as appropriate and help me know what other information might be needed as you move forward." HRSA did not act upon this dispute resolution request and never followed up with the hospital regarding the request or to ask for additional information.[24]

2. Requests For HRSA To Intervene Or Take Action Failed

While HRSA has had some success in informally facilitating refunds to covered entities for manufacturer overcharges outside of the dispute resolution process, the agency's successes are necessarily limited to circumstances in which manufacturers have been willing to provide such refunds. Moreover, until the last few years, HRSA has not received direct funding from Congress to administer the 340B pro-

[24] Email from Burnis Breland, Columbia Regional Healthcare System Director of Pharmacy and Clinical Research to Jimmy Mitchell, HRSA OPA Director (July 31, 2006).

gram and, therefore, OPA has had to rely upon fewer than ten dedicated employees. Perhaps for these reasons, even where covered entities or Coalition members have made general appeals for information or intervention in light of suspected or proven overcharges, HRSA has often remained unresponsive. For example, between June 2004 and October 2005, SNHPA and its members sent at least six e-mails to HRSA regarding potential 340B overcharges, but received no meaningful response from HRSA.

First, on June 11, 2004, SNHPA sent an e-mail to HRSA on a member's behalf inquiring why a manufacturer's 340B price for propofol was higher than the group purchasing organization ("GPO") price.[25] The inquiry did not receive a response. In July 2005, SNHPA contacted HRSA twice on behalf of another member to inquire why a manufacturer had not provided the member with information on 340B pricing.[26] HRSA responded that it was "trying to get in touch with the manufacturer," but provided no further response on the issue.[27] Again, on October 15, 2005, SNHPA sent an e-mail to HRSA on behalf of a member to inquire why the Hospira GPO price was lower than the 340B price.[28] On October 25, 2005, SNHPA sent another e-mail to HRSA asking for clarification as to why the Hospira GPO price was lower

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[25] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (June 11, 2004).

[26] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (July 5, 2005); email from Ted Slafsky, SNHPA Executive Director, to HRSA (July 18, 2005).

[27] Email from HRSA to Ted Slafsky, SNHPA Executive Director (July 22, 2005).

[28] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (Oct. 15, 2005).

than the 340B price.[29] SNHPA did not receive a response to either inquiry.

Similarly, on October 10, 2005, a SNHPA member alerted SNHPA that the 340B pricing for Lilly insulins ($20 per vial) was almost 50 percent higher than the GPO price ($11 per vial).[30] SNHPA asked HRSA to look into the matter, [31] and HRSA responded with general information about Lilly inpatient pricing and encouraged the member to convert the prime vendor pricing to obtain lower a price.[32] On October 11, 2005, the SNHPA member replied to this ambiguous response, and asserted that HRSA's prime vendor program suggestion "still doesn't explain why PHS Lilly insulin is almost 50 percent higher than [the] GPO [price]."[33] SNHPA asked HRSA to look into the matter, and HRSA provided no further response on this issue.

SNHPA members have also urged HRSA to address price adjustments and limited distribution to covered entities. In August 1999, for example, a SNHPA member hospital contacted HRSA, a distributor, and manufacturer regarding a rebate for an overpayment, and noted that no response was received as of January 20, 2000.[34]

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[29] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (Oct. 25, 2005).

[30] Email from Donna Evans, UAB Hospital Senior Pharmacist, to Ted Slafsky, SNHPA Executive Director (Oct. 10, 2005).

[31] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (Oct. 10, 2005).

[32] Email from Jimmy Mitchell, HRSA OPA Director to Ted Slafsky, SNHPA Executive Director (Oct. 10, 2005).

[33] Email from Donna Evans, UAB Hospital Senior Pharmacist, to HRSA (Oct. 11, 2005).

[34] Facsimile from Mary Mazzara, Pharmacy Director, to Ted Slafsky, Executive Director, SNHPA (Jan. 20, 2000).

In addition, SNHPA itself has sought to direct HRSA's attention to the problem of manufacturer overcharges and to solicit a response from the agency. In 2000, concerned that the extent of 340B overcharges by manufacturers might be significant, SNHPA approached HRSA about performing a study that would track the various 340B prices paid by a group of hospitals over a one-year period, for a defined set of covered outpatient drugs.[35] SNHPA's plan was to provide HRSA with the results of the price comparison study, which HRSA would then review to determine if the hospitals in the study were overcharged and, if so, how much they were overcharged in the aggregate. By aggregating the overcharges, SNHPA reasoned, HRSA could avoid disclosing specific 340B ceiling prices, but could still provide a useful assessment of the scope of the problem. HRSA agreed to the request and, on December 1, 2000, SNHPA provided HRSA with prices on approximately 146 drugs purchased by six hospitals participating in the study.[36]

On January 22, 2001, HRSA responded by identifying 37 of the 146 drugs for which "significant" overcharges had occurred.[37] In a follow-up conversation with HRSA regarding the results of the government's analysis, SNHPA learned that the 37 drugs were sold at prices at least 10 percent higher than the statutory ceiling prices, and that many of the overcharges were in excess of 100 percent. According to HRSA,

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[35] Letter from William Von Oehsen, SNHPA Counsel, and Ted Slafsky, SNHPA Executive Director, to Jimmy Mitchell, Director, OPA (Dec. 1, 2000).

[36] Id.

[37] Letter from Jimmy Mitchell, Director, OPA, to William von Oehsen, SNHPA Counsel and Ted Slafsky, SNHPA Executive Director (Jan. 22, 2001).

several other drugs were overcharged but were not included in the list of 37, because the amount of the overcharge was less than 10 percent. Subsequent to this analysis, undertaken by HRSA itself, SNHPA repeatedly urged the agency, in meetings and via telephone, to take action to address the overcharge problems. HRSA did not do so.

As is reflected in the examples above, the voluntary dispute mechanism did not function to address the overcharge concerns of covered entities. In addition, due to lack of adequate staffing and resources, HRSA was often unable to provide responses to inquiries from 340B program participants or to take the initiative in addressing evidence of manufacturer overcharges.

3. *OIG And Congressional Pressure Failed*

The limitations of the 340B oversight mechanism raised concerns with both the OIG and Congress.

As is discussed in respondent's brief, a series of OIG reports, issued in March 2003 and June 2004, confirmed that drug manufacturers were overcharging 340B covered entities for drugs.[38] Respondent's Brief at 11-12. These reports further concluded that HRSA lacked the authority, information, and resources with which to prevent such overcharges. In the 2003 Report, entitled *Pharmaceutical Manufacturers Overcharged 340B Covered Entities*, the OIG estimated that five manufacturers had overcharged covered entities by a total of $6.1 million during the one-year period ending on September 30, 1999, for eleven prescription drugs. According to the 2003 Report, the overcharges occurred because the manufac-

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[38] 2003 Report at 4; OIG, *Appropriateness of 340B Drug Prices,* OEI-05-02-00070 (June 2004) ("2004 Report").

turers incorrectly excluded sales to HMO repackagers from their best price determinations. Because Medicaid rebates are calculated using formulas that are based upon a drug's "best price," the manufacturers, by omitting the reduced drug prices charged HMO repackagers, effectively excluded the lowest drug price from their total best price calculation. The Medicaid rebate amount was consequently miscalculated, based upon an inflated best price figure that excluded the repackager prices.[39]

This deception caused state Medicaid programs to overpay for drugs due to a reduced rebate amount, and also – as the 2003 Report concluded – resulted in overcharges to 340B covered entities. This was so because the formula used to determine 340B prices is based on the Medicaid drug rebate amount. When the calculation of "best price" and therefore the Medicaid rebate amount is incorrect, the calculation of the 340B discount will also be incorrect.[40] As a result, covered entities that purchased 340B drugs from HMO repackagers paid inflated prices for these drugs.[41]

In July 2004, in a follow-up to the 2003 and 2004 Reports that documented egregious manufacturer overcharges, Senator Charles Grassley, Chairman of the Committee on Finance, wrote to the Secretary and the HRSA Administrator. Senator Grassley requested that HHS disclose, among other things, its findings regarding the full extent of manufacturers' misreporting of best price, the full range of drugs that had been subject to repackager overcharges, the total overcharge for each covered entity, and the re-

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[39] 2003 Report at 3.
[40] Id. at 3.
[41] Id. at 4.

fund or credit plan that was developed for each covered entity affected by repackaging and the refund or credit recovered.[42]

In a response dated September 14, 2004, HRSA stated that the manufacturers involved in the repackaging schemes had been asked to determine the extent of the miscalculations of best prices and 340B prices for fiscal years including 1999, as well as the extent of overcharges for drugs that were not included in the 2003 survey.[43] According to HRSA, these manufacturers had also been asked to implement corrective action plans. HRSA also released names of four of the manufacturers involved in the repackaging schemes – Aventis, Bristol-Myers Squibb ("BMS"), GlaxoSmithKline ("GSK"), and TAP Pharmaceuticals.[44] HRSA discussed its proposed action plan and stressed the importance of implementing this plan before the agency would consider supporting any legislation or statutory changes that would increase HRSA's enforcement powers. HRSA also emphasized its view that the agency's compliance and enforcement tactics, and specifically its dispute resolution process, remained effective.[45]

Approximately one year later, having received no word from HRSA regarding the progress of its efforts to obtain information and cooperation from manufac-

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[42] Letter from Senator Charles E. Grassley, Chairman of the Committee on Finance, to The Honorable Tommy G. Thompson, HHS Secretary, and Dr. Elizabeth M. Duke, HRSA Administrator (July 23, 2004).

[43] "*HRSA Requests Refunds from Rx Manufacturers*," Federal Drug Discount and Compliance Monitor, Vol. 1, No. 5 (Nov. 2004), 1.

[44] Id.

[45] Id.

turers, Senator Grassley wrote to the HRSA Administrator again. Senator Grassley noted the following:

> In response to my letter of July 23, 2004, you stated that HRSA was sending letters to four drug companies – Aventis, Bristol-Myers Squibb, GSK, and TAP Pharmaceuticals – requesting that each develop "corrective action plans" for refunding or crediting the entities affected by the overcharges. It is my understanding that, with the exception of GSK's product Flonase, these companies have not issued refunds to 340B providers or indicated to HRSA that they intend to do so. Likewise, I understand that these companies have not followed through on HRSA's request to determine whether they overcharged 340B entities for other products.[46]

Senator Grassley was correct in his observations. In December 2005, as a result of growing concerns regarding deficiencies in the oversight of the 340B program, as highlighted by multiple OIG Reports addressing overcharge abuses by manufacturers,[47] the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing on "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency." During this hearing, testimony was provided by the OIG regarding its concerns with

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[46] Letter from Senator Charles E. Grassley, Chairman of the Committee on Finance, to Dr. Elizabeth M. Duke, HRSA Administrator (Sept. 1, 2005).

[47] OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program,* OEI-05-02-00072, at 15 (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf; 2003 Report.

340B program administration. An OIG representative testified that:

> Our work has led us to conclude that the 340B program may not be functioning as intended, which was to ensure that appropriate discounts on drugs are available to entities. Specifically, our work has found a number of deficiencies in program oversight as well as broader programmatic issues that impact HRSA's ability to administer the program.[48]

Testimony was also provided by HRSA. In one exchange, HRSA's Deputy Administrator underscored the absence of an effective administrative enforcement system:

> MS. DEGETTE. …Now, according to the recent – the OIG report, even if your agency was able to accurately determine the drug manufacturers' ceiling prices, you wouldn't have the authority to enforce compliance to impose penalties, and so the OIG recommends that your agency seek legislation to give you that authority, including the ability to impose penalties. But in your response you said that HRSA does not want to establish penalties for violation. So my question is, how are you going to enforce compliance by drug manufacturers if there is no punishment for violations?
>
> MR. WILLIAMS. Well, this is a – we have one big penalty, which is to get them to leave the

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[48] *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, Hearing Before the Subcomm. on Oversight and Investigations of the H. Committee on Energy and Commerce, 109th Cong., H. Hrg. 109-108 (2006, http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf at 7 (testimony of Stuart Wright).

> Medicaid program or the 340B program. That's a very large penalty, which, as the IG correctly points out, the penalty is worse really than the problem we are trying to resolve.[49]

In a second exchange, the Deputy Administrator confirmed that HRSA had indeed been unsuccessful in obtaining manufacturer cooperation in resolving the repackager matters, and tacitly acknowledged that HRSA's dispute resolution process had never been utilized.[50]

In short, both Congress and the OIG identified serious shortcomings in HRSA's administrative enforcement of the 340B program and HRSA itself admitted these deficiencies. Yet none of this galvanized the agency to implement more effective administrative enforcement measures.

4. The False Claims Act Has Been Of Very Limited Utility In 340B Cases

Because of the lack of a non-voluntary dispute resolution mechanism with which HRSA could compel manufacturer refunds for overcharges, covered entities have been forced to go "outside" of the existing dispute mechanism in order to obtain relief from such overcharges. SNHPA, acting as liaison to the Department of Justice ("DOJ"), has sought to pursue restitution for a variety of manufacturer overcharges through False Claims Act ("FCA") settlements that resulted from manufacturers' overcharges to Medicaid. To that end, SNHPA conducted several meetings with DOJ and Assistant United States Attorneys, educating them about the link between the Medicaid rebate amount and 340B discounts. Unfortunately,

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[49] Id. at 33.
[50] Id. at 34-35.

despite SNHPA's urging, DOJ has never undertaken an action to address manufacturer overcharges on behalf of covered entities alone, and it is unclear whether the FCA can be invoked to recover a 340B overpayment. Regardless, covered entities have been limited to "piggybacking" on Medicaid rebate settlements in order to obtain relief.

Because they were not parties, however, covered entities were excluded from the actual Medicaid settlement negotiations, and the extent to which covered entity overcharges were addressed was therefore entirely within the discretion of government prosecutors. In some instances, covered entities were omitted entirely from the overcharge settlements with Medicaid, and, in other instances, they recovered relatively small amounts. For example, as noted in the Respondent's Brief at 9-10, following the disclosure of a repackager or "lick and stick" scheme by one whistleblower, petitioner Bayer settled federal FCA charges for $257 million and pled guilty to criminal charges in a Medicaid fraud settlement. $2.5 million of the settlement was awarded to 340B covered entities. A whistleblower suit also caused petitioner GSK to pay $87 million in restitution to Medicaid. Covered entities received approximately $9.4 million from this settlement. Petitioner BMS paid a settlement of $515 million to resolve allegations brought under the FCA, of which $124,000 was recovered by covered entities. Petitioner Aventis resolved consolidated FCA cases in a $95.5 million settlement, of which 340B entities recovered $7.3 million.

Again, the relatively small amounts received by covered entities as part of these Medicaid settlements were brokered by the DOJ and manufacturers

in negotiations that excluded covered entities. The disparity between the Medicaid and 340B reimbursement amounts thus raises questions as to whether the 340B settlements are reflective of actual overcharge amounts. Nonetheless, because of the limitations of the existing 340B dispute resolution process and oversight mechanism, covered entities were forced to accept the compensation provided under these agreements as their only available means of recovery, absent initiating litigation on their own behalf – the issue now before this Court.

* * * * *

The examples in this section represent but a sampling of the numerous instances in which the government has not responded to covered entity concerns or communications regarding manufacturer abuses, could not follow through with its own voluntary dispute resolution process, or was unable to compel manufacturer accountability in the face of evidence of manufacturer overcharges. Nevertheless, they underscore an obvious conclusion: the existing administrative mechanisms for addressing allegations of manufacturer overcharges were entirely inadequate, and HRSA, until now, has lacked the tools, resources, framework, and authority with which to protect covered entities adequately against manufacturer overcharges. The lack of a meaningful or effective oversight or dispute resolution mechanism has resulted in uncompensated overcharges that threaten to erode the ability of covered entities to carry out their mission of serving the nation's poor and most vulnerable.

III. THE 340B REFORMS IN PPACA EVIDENCE CONGRESS'S KEEN AWARENESS THAT ADMINISTRATIVE ENFORCEMENT WAS SORELY LACKING

Given the tide of overwhelming discontent with the administrative enforcement of 340B requirements and OIG and congressional frustration with bureaucratic lassitude, it is unsurprising that Congress ultimately decided to make major changes to the 340B program in PPACA. The United States readily admits that PPACA "materially alters the 340B statutory framework by establishing a comprehensive administrative procedure to resolve claims by covered entities and to provide refunds and other remedies for violations." Brief for the United States at 10. It also notes that, although those reforms do not apply to the claims involved here, they will result in an "exclusive" administrative procedure in which claims related to the 340B program will then be "subject to judicial review pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §701 *et seq.*" *Id.* at 7 and 10.

In a failed attempt at intellectual legerdemain, however, the United States insists that this is further proof Congress has never intended that 340B entities be able to initiate private litigation to achieve enforcement. *Id.* at 10, 26, and 33. The Coalition believes that, to the contrary, the PPACA reforms underscore Congress's original determination that such actions were an integral and indispensable aspect of 340B enforcement. Indeed, Congress could well have concluded that, given the time and expense involved, the existence of contractual rights of action by financially hard-pressed 340B entities was not a

sufficient substitute for rigorous enforcement at the administrative level.

The changes made by PPACA to the 340B enforcement program are not mere tweaks to the prior system. Rather, they represent fundamental reforms and are an overt acknowledgment that the existing ***administrative*** enforcement system was both inadequate and unacceptable. Under Section 7102 to PPACA, entitled "Improvements to 340B Program Integrity," the Secretary must undertake extensive measures aimed at both manufacturer and covered entity compliance. 42 U.S.C. §256b(d)(1) and (2). With respect to drug manufacturers, these include:

- developing a system by which HHS may verify the accuracy of ceiling prices;
- establishing procedures for manufacturers to issue refunds to covered entities where there were overcharges;
- providing internet access for covered entities to the applicable ceiling prices;
- creating a mechanism for the reporting of subsequent rebates and other discounts and the appropriate crediting and refunding to covered entities;
- selective auditing of manufacturers and wholesalers; and
- imposing civil money penalties for overcharges.

Similar modifications are aimed at enabling HHS and drug manufacturers to monitor compliance by covered entities with 340B requirements. *Id*. at §256b(d)(2).

Additionally, the Secretary is required to issue regulations that establish and implement an administrative process to resolve claims by covered entities

as to overcharges and claims by manufacturers as to non-compliance by covered entities. *Id.* at §256b(d)(3)(A). These procedures must include remedies and enforcement of the determinations as well as deadlines and mechanisms for litigating these claims administratively. *Id.* at §256b(3)(A) and (B). Notably, Congress specified that:

> The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a ***formal agency decision*** and shall be ***binding*** upon the parties involved, unless ***invalidated by an order of court of competent jurisdiction***.

Id. at §256b(d)(3)(C) (emphasis added). In other words, as the United States has conceded, Congress not only directed that there be a meaningful administrative forum for 340B claims but also specifically provided for judicial review of those administrative determinations. Brief for the United States at 7.

On September 20, 2010, HHS issued advanced notice of proposed rulemaking and requested comments concerning how it should devise such an administrative process.[51] 75 Fed. Reg. 57233. In this notice, HHS admitted that, prior to PPACA, HRSA did not have a required administrative dispute resolution process and, in a notable understatement, acknowl-

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[51] Under Section 7102(a) of PPACA, 42 U.S.C. §256b(d)(3)(A), the Secretary was to publish administrative dispute resolution regulations for 340B within 180 days of enactment. Because the Secretary missed this deadline, it is not possible at this juncture to define the exact parameters of that process but, presumably, it will be mandatory, establish a meaningful process to adjudicate claims, and allow for judicial review of final agency determinations.

edged that its prior process had been underutilized. *Id.* at 57233, 57234.

At bottom, petitioners and the United States basically contend that, prior to PPACA, there was neither transparency nor accountability in the 340B program and that Congress deliberately constructed it that way. To the contrary, as the Ninth Circuit recognized, Congress specifically directed the use of PPAs where 340B covered entities would be third party beneficiaries and, as such, could vindicate their rights pursuant to suits seeking contractual remedies. To hold otherwise is to accept the notion that Congress was consciously indifferent to the lack of administrative enforcement of 340B requirements and intent on ensuring the unavailability of program-related remedies. Such a notion does not square with PPACA's 340B reforms. More importantly, in the context of this case, it does not accord with the fact that Congress expressly directed that contractual arrangements be utilized as a vehicle for imposing statutory requirements on manufacturers. As an intended beneficiary of those PPA contracts, the respondent is entitled to sue to seek relief for their breach to vindicate its rights as well as to safeguard the medical needs of its patients and the financial interests of the taxpayers underwriting the costs of indigent care.

CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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