[PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 01-16782

D. C. Docket No. 00-00837-CV-N-S

UNITED STATES OF AMERICA,

Plaintiff-Appellant,

versus

BAXTER INTERNATIONAL, INCORPORATED; BAXTER HEALTHCARE CORPORATION, et al.,

Defendants-Appellees,

PLAINTIFFS' STEERING COMMITTEE,

Defendant-Intervenor-Appellee.

Appeal from the United States District Court
for the Northern District of Alabama

(September 15, 2003)

Before TJOFLAT, ANDERSON and CUDAHY*, Circuit Judges.

ANDERSON, Circuit Judge:

This case grows out of the 1995 settlement of a class-action products liability suit against manufacturers of silicone breast implants. The settlement resulted in the creation of a reimbursement mechanism by which several settling manufacturers agreed to cover certain health care expenses incurred by or on behalf of qualified members of the plaintiff class. The Government, as intervenor, sought to recover for medical bills it paid on behalf of Medicare beneficiaries who received treatment related to silicone breast implants. The district court dismissed the Government's complaint in intervention for failure to state a claim. We conclude that the dismissal was in error. We therefore reverse and remand.

I. BACKGROUND

A. Historical Background

The underlying case is result of an order by the Judicial Panel on Multi-District Litigation, which consolidated all then-pending products liability claims against the manufacturers of silicone breast implants into a single action before the United States District Court for the Northern District of Alabama. The exact

*Honorable Richard D. Cudahy, United States Circuit Judge for the Seventh Circuit, sitting by designation.

details of the underlying claims are not of significance to the disposition of the appeal before us. It is enough to observe that, in general, the plaintiffs allege that they suffered, or fear that they will contract, a variety of systemic illnesses traceable to silicone breast implants, necessitating in some instances that the implants be surgically removed at considerable expense.

The litigation resulted in a settlement valued at $4.2 billion that initially involved eight defendant manufacturers (the "Lindsey settlement"). On September 1, 1994, after conducting a fairness hearing, the district court approved the terms of the Lindsey settlement, with modifications. See In re Silicone Gel Breast Implant Litig., No. CV 92-P-10000-S, MDL No. 926, Civ. A. No. CV94-P-11558-S, 1994 WL 578353 (N.D. Ala. Sept. 1, 1994) (approving modified settlement and redefining parameters of class membership). Subsequently, one of the larger defendants, Dow Corning, declared bankruptcy, and several other defendants (apparently dissatisfied with the court-imposed modifications) chose not to participate in the settlement, leaving the following companies as appellees now before us: Baxter International, Inc.; Bristol-Myers Squibb Co., Minnesota Mining and Manufacturing Co. ("3M"); Union Carbide Corp.; and Union Carbide Chemical & Plastics Co.

After the modifications were publicized to class members, and after the settlement was restructured to take account of Dow Corning's bankruptcy filing, the district court gave final approval to the settlement by order of December 22, 1995. This became known as the "Revised Settlement Program," or RSP. The participating implant manufacturers are referred to collectively as "the RSP Defendants,"[1] the appellees before us.

The revised settlement class covered personal injury or death claims by members of a class consisting of: persons who received silicone breast implants before June 1, 1993; all children born to mothers with breast implants before April 1, 1994; and their spouses or other relatives. The Government,[2] as well as a number of private insurers, moved to intervene prior to approval of the settlement for purposes of asserting claims for reimbursement of medical claims paid on behalf of class members. The district court denied these motions as premature. Its

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[1]The settlement agreement purported to make the class claimants, rather than the RSP Defendants, liable for reimbursement claims by the Government or by other insurers. The district court did not, however, render its decision based on any agreement by the parties that the RSP Defendants were not liable. Wisely, none of the defendants attempts to argue here that parties could override a statutory right of action afforded to the Government by a contractual arrangement to which the Government was not a party.

[2]When this case was initiated, the agency administering the Medicare program was known as the Health Care Financing Administration (HCFA), a subunit of the Department of Health and Human Services (HHS). Subsequently, the unit was renamed as the Centers for Medicare and Medicaid Services (CMS). For simplicity, we refer to the intervenor/appellant here as "HHS," "the Government" or "Medicare."

order stated, in pertinent part: "The court will consider these issues at a later time, before any distributions... are made, and hopefully on the basis of motions that in some appropriate manner identify the persons on whose behalf subrogation claimants have paid medical expenses, rather than simply assert a general claim against the class."

In accordance with the settlement, the RSP Defendants created a Claims Office to review the documentation submitted by prospective class members and determine what level of benefits, if any, applicants were eligible to receive. Also as part of the claims process, the district court appointed an Escrow Agent, who is responsible for overseeing the investment and disbursement of the settlement proceeds. The position has been held since its inception by Edgar C. Gentile, III. The district court granted the Escrow Agent, as an agent of the court, "judicial immunity" for actions taken in his quasi-judicial capacity, unless he acts in the clear absence of jurisdiction.

The settlement resulted in the creation of two funds relevant to this case. The principal fund, called the RSP Settlement Fund (or sometimes MDL 926 Settlement Fund) is the account from which claims are paid. The second, the Common Benefit Fund, was created by a surcharge on the RSP Defendants for

purposes of paying legal fees and expenses incurred for the "common benefit" of all claimants. Both funds are administered by the Escrow Agent.

The RSP Defendants made their first payment into the settlement fund in January of 1996, and at the direction of the district court, the Escrow Agent began issuing settlement payments to class members in mid-1996. According to the Government's Complaint, about 81,000 claimants had received some payment from the RSP as of April 1999. To date, more than 400,000 women have registered as potential claimants, and the RSP Defendants have paid more than $1 billion into the RSP Settlement Fund. More than 52,000 breast implant recipients opted out of the settlement class, according to the Complaint, and the Defendants have made payments outside the RSP process to an unspecified number of them.

It is not clear from the record to what extent the RSP Defendants carried liability insurance coverage (other than "self insurance," about which more will be said shortly) for the events giving rise to the class members' claims, or to what extent these defendants have received compensation from such insurance for payments made into the two settlement funds. It is apparent that the implant companies had at least some liability coverage, because the settlement agreement expressly provides for the Defendants' insurers to have access to the otherwise

confidential records of class claimants. We therefore take as established for purposes of this appeal that some third-party insurance coverage exists.

Beginning in 1995 and continuing through March of 2000, the Government entered into a series of "tolling agreements" with the RSP Defendants while negotiating over the Government's access to information about the settlement participants, for purposes of determining which class members may have received Government health benefits for which the Government was entitled to reimbursement. Under these tolling agreements, the Defendants agreed that they would not argue laches, statute of limitations or similar "timeliness" defenses if the Government was forced to file suit. In exchange, the Government agreed to forego filing suit during settlement negotiations. Negotiations between the Government and the RSP Defendants did not produce an agreement. Consequently, in March of 2000, the Government filed the complaint in intervention giving rise to this appeal.

B. The Medicare Secondary Payer (MSP) Statute

The Government's Complaint initially relied on two distinct but related statutes and their accompanying regulations: (1) the Medicare Secondary Payer ("MSP") statute, 42 U.S.C. § 1395y(b), and (2) the Medical Care Recovery Act

("MCRA"), 42 U.S.C. § 2651. Although all of the Government's claims were dismissed, it is appealing only the dismissal of the MSP claim.[3]

The MSP is actually a collection of statutory provisions codified during the 1980s with the intention of reducing federal health care costs. See Zinman v. Shalala, 67 F.3d 841, 845 (9th Cir. 1995) ("The transformation of Medicare from the primary payer to the secondary payer with a right of reimbursement reflects the overarching statutory purpose of reducing Medicare costs."); Provident Life & Accident Ins. Co. v. United States, 740 F. Supp. 492, 498 (E.D. Tenn. 1990) ("The intent of Congress in shifting the burden of primary coverage from Medicare to private insurance carriers was to place the burden where it could best be absorbed."). In a nutshell, the MSP declares that, under certain conditions, Medicare will be the secondary rather than primary payer for its insureds. Consequently, Medicare is empowered to recoup from the rightful primary payer (or from the recipient of such payment) if Medicare pays for a service that was, or should have been, covered by the primary insurer. Although the statute is

[3]While the MSP statute is directed at recovery from "primary plans," the MCRA statute is directed at recovery from tortfeasors. It provides that, where the Government is obliged to pay for the medical care of a person who is injured "under circumstances creating tort liability upon some third person... to pay damages therefor," the Government has the right to recover from the tortfeasor (or their insurers) the "reasonable value" of the care it provides. 42 U.S.C. § 2651(a); see United States v. Haynes, 445 F.2d 907, 908-09 (5th Cir. 1971) (discussing history and purpose of MCRA statute).

structurally complex – a complexity that has produced considerable confusion among courts attempting to construe it – the MSP's function is straightforward. As we explained in Cochran v. HCFA, 291 F.3d 775, 777 (11th Cir. 2002):

> [I]f payment for covered services has been or is reasonably expected to be made by someone else, Medicare does not have to pay. In order to accommodate its beneficiaries, however, Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly.

Medicare originated as a series of amendments to the Social Security Act enacted in 1965, providing a source of payment for hospital care for those over 65. The program was, for the most part, the primary source of payment for its beneficiaries even when another source of coverage existed. However, the 1965 amendments also provided that coverage would be secondary to workers' compensation benefits, and that any payment to or on behalf of a Medicare beneficiary eligible for workers' compensation benefits would be contingent upon reimbursement. See S. Rep. No. 404 at § 1862, 89th Cong., 1st Sess. (1965), *reprinted at* 1965 U.S.C.C.A.N. 1965, 2127-28 ("no payment may be made... for any item or service for which payment has been made, or can reasonably be expected to be made, under a workman's compensation law or plan of the United States or a State. Any payment ... with respect to any [such] item or service must

be conditioned on reimbursement being made to the appropriate trust fund for such payment if any when notice or other information is received that payment for such item or service has been made under such a law or plan."); see also Parkview Hosp., Inc v. Roese, 750 N.E.2d 384, 388 (Ind. Ct. App. 2001) (discussing early history and evolution of MSP statute). That language became the template for the modern MSP provision.

In pertinent part, the MSP statute in its current form provides:

> (A) In general
> Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that –
>
> > ...(ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance.
> >
> > In this subsection, the term "primary plan" means... a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies.[4]
>
> (B) Repayment required

[4]Part of the dispute in this case revolves around the meaning and scope of the statutory term "self-insured plan." Two HHS regulations are pertinent. Under 42 C.F.R. § 411.50(b), a "self-insured" plan "means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." Under 42 C.F.R. § 411.21, a "plan" is defined as "any arrangement, oral or written, by one or more entities, to provide health benefits or medical care or assume legal liability for injury or illness."

(i) Primary plans

Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information is received that payment for such item or service has been or could be made under such paragraph.

(ii) Action by United States

In order to recover payment under this subchapter for such an item or service, the United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service (or any portion thereof) under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity), or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service, and may join or intervene in any action related to the events that gave rise to the need for the item or service.

(iii) Subrogation rights

The United States shall be subrogated (to the extent of payment made under this subchapter for such an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

42 U.S.C. §1395y(b)(2)(A)-(B). Subparagraph (b)(3)(A), which is referenced above, provides for a private right of action, with double damages available, if a primary plan "fails to provide for primary payment (or appropriate reimbursement) in accordance with" the preceding MSP regulations. See 42 U.S.C. § 1395y(b)(3)(A).

Pursuant to these provisions of the MSP statute, HHS has enacted regulations setting forth the means by which the Government can bring an action to recoup payments from a primary coverage plan. These regulations read, in pertinent part:

> If a Medicare conditional payment is made, the following rules apply:
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> (a) *Release of information*. The filing of a Medicare claim by or on behalf of the beneficiary constitutes an express authorization for any entity, including State Medicaid and workers' compensation agencies, and data depositories, that possess information pertinent to the Medicare claim to release that information to CMS. This information will be used only for Medicare claims processing and for coordination of benefit purposes.
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> (b) *Right to initiate recovery*. CMS may initiate recovery as soon as it learns that payment has been made or could be made under workers' compensation, any liability or no-fault insurance, or an employer group health plan...
>
> ...(e) *Recovery from third parties*. CMS has a direct right of action to recover from any entity responsible for making primary payment. This includes an employer, an insurance carrier, plan, or program, and a third party administrator...
>
> ...(g) Recovery from parties that receive third party payments. CMS has a right of action to recover its payments from any entity, including a beneficiary, provider, supplier, physician, attorney, state agency, or private insurer that received a third party payment.

(h) Reimbursement to Medicare. If the beneficiary or other party receives a third party payment, the beneficiary or other party must reimburse Medicare within 60 days.

(i) Special rules. (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed as required by paragraph (h) of this section, the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.

42 C.F.R. § 411.24. Additionally, the regulations define "prompt" or "promptly," when used in connection with third-party payments, to mean "payment within 120 days after receipt of the claim." 42 C.F.R. § 411.21.

The MSP, in its present form, originated with enactment of the Omnibus Budget Reconciliation Act ("OBRA") of 1980, Pub.L. No. 96-499, § 953, 94 Stat. 2599 (1980). OBRA amended the Medicare Act to provide that Medicare payments "may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made (as determined in accordance with regulations) ... under an automobile or liability insurance policy ... or under no fault insurance."[5]

[5]As the measure was originally proposed in the House, Medicare would have been secondary only to automobile insurance; a Senate amendment, adopted in conference, added no-fault and liability insurance. See House Confc. Rep. No. 96-14, 96th Cong., 2d Sess. 133, *reprinted in* 1980 U.S.C.C.A.N. 5903, 5924.

Since enacting the MSP statute, Congress has expanded its reach several times, making Medicare secondary to a greater array of primary coverage sources, and creating a larger spectrum of beneficiaries who no longer may look to Medicare as their primary source of coverage.[6] More significantly for our purposes, Congress has repeatedly clarified and augmented the Government's powers to recoup conditional Medicare payments from primary sources.

The Deficit Reduction Act ("DERFA") of 1984 conferred on the Government a direct right of action to recover its payments from any entity "which would be responsible for payment" under a "law, policy, plan or insurance," and provided that the Government would be subrogated to the right of any individual or entity to receive payment. DERFA also modified the original wording of the secondary payment provision by adding the modifier "promptly," so that the pivotal phrase dictated that a Medicare payment "may not be made with respect to any item or service to the extent that payment has been made, or can reasonably be

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[6]In the Omnibus Budget Reconciliation Act of 1981, Congress augmented the MSP to provide that Medicare would be secondary to group health coverage for end-stage renal patients. H. Res. 3982, 97th Cong., 1st Sess., 95 Stat. 357 (1981) at § 2146. In the Tax Equity and Fiscal Responsibility Act ("TERFA") of 1982, Congress made Medicare the secondary payer for "working aged" employees and their spouses between the ages of 65 and 69 belonging to large employer group health plans (covering twenty or more workers). H. Res. 4961, 97th Cong., 2d Sess., 96 Stat. 324 (1982) at § 116. In the Omnibus Budget Reconciliation Act ("OBRA") of 1986, Congress made Medicare the secondary payer for disabled individuals enrolled in large employer group health plans. H. Res. 5300, 99th Cong., 2d Sess., 100 Stat. 1874 (1986) at § 9319.

expected to be made promptly ... with respect to such item or service, under a workman's compensation plan or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance(.)" H. Res. 4170, 98th Cong., 2d Sess., 98 Stat. 494 (1984) at § 2344. In OBRA 1986, Congress added the private right of action for double damages codified at 42 U.S.C. § 1395y(b)(3)(A). It also added the cross-reference to that section in § 1395(b)(2)(B)(ii), which enables the Government to collect double damages "in accordance with" the new private right of action. H. Res. 5300, 99th Cong., 2d Sess., 100 Stat. 1874 (1986) at § 9319.

II. THE DECISION BELOW

The Government's Complaint advanced nine counts: (1) a claim for reimbursement against the RSP Defendants as third-party payers under the MSP; (2) double damages against the RSP Defendants as third-party payers under the MSP; (3) single damages under the MSP against the RSP Defendants as entities that caused payments to be made, or received such payments, from product liability insurers; (4) a subrogation claim under the MSP against disbursements from the MDL Settlement Fund and/or the Common Benefit Fund; (5) a claim for declaratory relief that the RSP Defendants are liable under the MSP to reimburse Medicare for past payments to breast implant patients, and are obligated under 42

C.F.R. § 411.25 to provide Medicare with notice of all payments to Medicare beneficiaries; (6) a single damages claim under the MSP against the Escrow Agent as a person who received payment from the RSP Defendants and/or from product liability insurers to pay the claimants; (7) a claim for injunctive relief under the MSP to enjoin the Escrow Agent from making disbursements to Medicare patients pending resolution of Medicare's MSP claims and to compel disclosure of identifying information concerning all past or contemplated settlement payments to Medicare beneficiaries; (8) a claim for injunctive relief similar to Count VII under the MCRA, and (9) a demand under the MCRA for payment from the MDL Settlement Fund of the Government's reasonable costs for paying for care of Medicare patients for injuries alleged to be caused by a breast implant. Thus, Counts I through VII arose under the MSP or its regulations, while counts VIII and IX arose under the MCRA.[7]

The district court (after first granting the Plaintiffs' Steering Committee the right to intervene) granted the motions to dismiss filed by the RSP Defendants, the Escrow Agent, and the Plaintiffs' Steering Committee, finding that the Government had failed to state a claim upon which relief could be granted.[8]

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[7]As noted above, the Government has now abandoned its MCRA claims.

[8]The opinion below was published as In re Silicone Gel Breast Implant Products Liability Litig., 174 F. Supp. 2d 1242 (N.D. Ala. 2001).

The court first evaluated whether the Government had a claim for reimbursement under 42 U.S.C. § 1395y(b), the MSP statute. The court found that – whether the Government was bringing a direct action in its own right under the statute or was acting as the subrogee to the patient's rights – an essential element to state a claim under the MSP was to identify both the services provided and the patient who received them. In addition to the need for the Defendants to know the identity of the patients and the amount in dispute, the court noted that the beneficiaries themselves are interested parties and have the right to challenge the reimbursement request and to petition the Government to waive its claim.

The court rejected the Government's argument that it was unable to plead the identity of the beneficiaries in question because of the settlement's confidentiality provisions. The court found that the Defendants were under no statutory duty to collect information about the identity of potential claimants, and that absent such a duty, it was irrelevant whether the settlement was structured with the purpose of evading disclosure. Because the Government had an alternative means of relief – like any other insurer, it could file a petition for reimbursement with the RSP Claims Office – the court found no need to relieve the Government from compliance with the MSP statute or the pleading standards of Fed. R. Civ. P. 8(a).

Next, the court considered whether the Government was entitled to reimbursement under 42 C.F.R. § 411.24(i), the "double payment" regulation adopted pursuant to the MSP. Under Section 411.24(i), a "third party payer" may be required to reimburse Medicare if it paid a provider or a claimant when it knew, or should have known, that Medicare had made a conditional primary payment as provided by the MSP. The district court found this regulation inapplicable, because the relevant portion of the MSP statute applies only to insurers or "self-insured plans." The court rejected the Government's contention that the implant manufacturers could be viewed as "self-insured plans." The RSP Defendants were thus outside the coverage of the statute and not subject to the "double payment" regulation.

Further, the court found that the Government had no direct right of action against a third-party payer that had already made payment to its insured, because such a payer was no longer "required or responsible... to pay" as provided by the MSP statute, § 1395y(b)(2)(B)(ii). The Government may proceed against such an insurer only in its role as subrogee, the court held. Relying on Health Ins. Ass'n of America v. Shalala, 23 F.3d 412 (D.C. Cir. 1994) ("HIAA"), and on general principles of common law, the court held that, as a subrogee, the Government was required to "plead and prove [that] the third-party payer knew or should have

known of Medicare's conditional payments at the time payment was made to the beneficiary." Because, in the district court's view, the Government failed to do so, its claims under the "double payment" provision were fatally flawed.

The court declined to adopt the Government's interpretation that the existence of the MSP statute itself puts insurers on constructive notice that they must inquire into whether Medicare has paid a beneficiary before they pay a claim. Rather, citing HIAA, the court held that "knowledge" requires the Government to show that, at the time it paid the claim, the insurer had "direct information... or information necessary to draw the conclusion" that Medicare had made a conditional payment to the particular recipient. It was insufficient, the court held, that the Government's prior intervention in the case *generally* alerted the Defendants that Medicare might have paid some claims.

The court rejected the Government's contention that the Defendants' knowledge was a factual matter to be proven at trial. The court observed that the Government's own complaint alleged that the RSP Defendants "did not ascertain" whether Medicare had made payments on behalf of any of the RSP claimants. With that assertion, the court felt that the Government had effectively pled itself out of court.

Next, the court addressed whether the Government could bring a claim in Count II against the RSP Defendants for double damages pursuant to 42 U.S.C. § 1395y(a)(3)(A) and 42 C.F.R. § 411.24(c)(2). Having held that the Defendants were not liable even for single damages, the district court summarily rejected the Government's claim for double damages.

Similarly, the district court summarily rejected the Government's claims for declaratory relief (Count V) and injunctive relief (Count VII). The court then considered whether any of the defendants could be liable under the MSP as entities that "received payment," as provided in 42 U.S.C. § 1395y(b)(2)(B)(ii). (Although the court acknowledged that the Government's claim under this section ran against both the RSP Defendants and the Escrow Agent, its discussion focused almost exclusively on the role of the Escrow Agent.) First, the court – again relying on HIAA – held that a mere "pass-through" could not be said to have "received" payment under any ordinary understanding of that term, since "receipt" suggests a degree of autonomous control. Further, the court observed that the term "recover" in the statute suggested that the Government must proceed against an entity actually in possession of the money – either the ultimate payer or the ultimate payee – and not an entity that temporarily held the money and relinquished it. Additionally, the court observed that the Defendants did not fit either the statute's

or HHS regulations' illustration of who qualifies as an entity that receives payment: the statute uses the illustration "any physician or provider," while 42 C.F.R. § 411.24(g) refers to "a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." All of those entities, the court observed, are likely to be ultimate recipients of payment rather than mere conduits. Where an entity has merely remitted payment as a pass-through, the court held, that entity is reachable only through 42 C.F.R. §§ 411.24(i), which requires proof of knowledge of Medicare's prior payment that is lacking in this case.

III. DISCUSSION

We review a district court's grant of a motion to dismiss for failure to state a claim *de novo*. Abate of Georgia, Inc. v. Georgia, 264 F.3d 1315, 1315 (11th Cir. 2001). A motion to dismiss a complaint in intervention is reviewed under the same standard applicable to consideration of a motion to dismiss the original plaintiffs' complaint. Southwest Ctr. for Biological Diversity v. Berg, 268 F.3d 810, 819-20 (9th Cir. 2001). In evaluating the sufficiency of a complaint under Rule 12(b)(6), courts must be mindful that the Federal Rules require only that the complaint contain "a short and plain statement of the claim showing that the pleader is entitled to relief(.)" Fed. R. Civ. P. 8(a). In applying Rule 12(b)(6), "a complaint

should not be dismissed for failure to state a claim unless it appears beyond a doubt that the [complainant] can prove no set of facts in support of his claim which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45-46, 78 S.Ct. 99, 102 (1957).

The district court granted the motion on two grounds: first, that the Government's Complaint was defective because it did not include the identity of the recipients of federal health care benefits and the nature of the expenditures, and second, that the MSP statute did not entitle the Government to proceed on its chosen theories against these defendants. Thus, we must consider both whether the Government has viable claims under the applicable law, and, if so, whether the Government's pleading was sufficient to invoke the MSP.

A. Sufficiency of Complaint

The district court held that, "at a minimum," a complaint under the MSP statute must identify the Medicare beneficiaries for whose care reimbursement is sought. Because the Complaint here failed to do so, the court held, the MSP counts were subject to dismissal.

Because the Federal Rules embody the concept of liberalized "notice pleading," a complaint need contain only a statement calculated to "give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it

rests." Conley, 355 U.S. at 47, 78 S.Ct. at 103; see also Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC, 148 F.3d 1080, 1086 (D.C. Cir. 1998) ("[A] plaintiff need not allege all the facts necessary to prove its claim."). We have observed that the threshold of sufficiency to which a complaint is held at the motion-to-dismiss stage is "exceedingly low." See In re Southeast Banking Corp., 69 F.3d 1539, 1551 (11th Cir. 1995) ("[F]or better or for worse, the Federal Rules of Civil Procedure do not permit district courts to impose upon plaintiffs the burden to plead with the greatest specificity they can.").

Rule 24 requires merely that an intervenor's petition "shall state the grounds [for intervention] and shall be accompanied by a pleading setting forth the claim or defense for which intervention is sought." Fed. R. Civ. P. 24(e). "The determination of whether the proposed intervenor's complaint states a cause of action is controlled by the general rules on testing a pleading; the factual allegations of the complaint are assumed to be true... and the pleading is construed liberally in support of the pleader." Pin v. Texaco, Inc., 793 F.2d 1448, 1450 (5th Cir. 1986) (internal quotes and citation omitted); accord County of Santa Fe v. Public Serv. Co. of N.M., 311 F.3d 1031, 1035 (10th Cir. 2002).

The Supreme Court has said in the context of a standing determination that "[a]t the pleading stage, general factual allegations of injury resulting from the

defendant's conduct may suffice, for on a motion to dismiss we presume that general allegations embrace those specific facts that are necessary to support the claim." Nat'l Org. for Women, Inc. v. Scheidler, 510 U.S. 249, 256, 114 S.Ct. 798, 803 (1994) (quoting Lujan v. Defenders of Wildlife, 504 U.S. 555, 561, 112 S.Ct. 2130, 2137 (1992)). In Swierkiewicz v. Sorema, N.A., 534 U.S. 506, 511, 122 S.Ct. 992, 997 (2002), the Court held that in the employment discrimination context, a complaint is not subject to dismissal for failure to state a claim merely because it fails to "plead facts establishing a prima facie case" of discrimination. As the Court emphasized there:

> The liberal notice pleading of Rule 8(a) is the starting point of a simplified pleading system. ... Rule 8(a) establishes a pleading standard without regard to whether a claim will succeed on the merits. 'Indeed, it may appear on the face of the pleadings that a recovery is very remote and unlikely but that is not the test.'

Id. at __, 122 S.Ct. at 999 (quoting Scheuer v. Rhodes, 416 U.S. 232, 236, 94 S.Ct. 1683 (1974)).

Courts typically allow the pleader an extra modicum of leeway where the information supporting the complainant's case is under the exclusive control of the defendant. See Peters v. Amoco Oil Co., 57 F. Supp. 2d 1268, 1284-85 (M.D. Ala. 1999) (holding that complaint setting forth general allegations about nature of conspiracy was sufficient despite heightened pleading standard applicable to

conspiracy claims under Fed. R. Civ. P. 9(b), where information about extent of alleged conspiracy was within defendants' exclusive control); see also Quality Foods de Centro America, S.A. v. Latin American Agribusiness Dev. Corp., 711 F.2d 989, 995 (11th Cir. 1983) (holding that liberalized consideration of complaint espoused in Conley "is particularly true in an antitrust suit where the proof and details of the alleged conspiracy are largely in the hands of the alleged co-conspirators.").

The situation presented here – an intervenor bringing a claim on the basis of injury to a large group of others, the identities of whom the intervenor claims cannot be determined without discovery – is not unlike that commonly presented in a class action, such as the one that underlies our case. In a class action, it is sufficient that a complaint generally give the defendant notice of the nature and scope of the plaintiffs' claims; it is not necessary that the class representatives plead evidence or otherwise meet any burden beyond the minimal Rule 8 standard. See 7B WRIGHT, MILLER & KANE, FEDERAL PRACTICE & PROCEDURE § 1798 (2d ed. 1986) at 417-18 ("All of the pleading provisions of the federal rules are applicable in class actions and operate in much the same fashion as they do in other litigation contexts. ... No greater particularity is necessary in stating a claim for relief in a class action than in other contexts."); Alba Conte & Herbert B. Newberg, 6

NEWBERG ON CLASS ACTIONS § 18:46 (4th ed. 2003) ("It is not necessary... that class members be specifically identified; the plaintiff need not name names. In addition, the complaint need not set forth the exact number of class members. It is sufficient to indicate the approximate size of the class and provide or describe facts making ultimate identification of class members possible when that identification becomes necessary."). Indeed, the Supreme Court's seminal statement of the standard for dismissal, Conley, involved a class action by African-American railroad clerks who alleged that their union had breached its duty of fair representation by discriminating against them.

In view of the foregoing, we find that the district court applied too exacting a standard when it found the Government's Complaint fatally deficient for failing to identify each member of the plaintiff class on whose behalf Medicare made a conditional payment.[9] The crucial information that the district court here found

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[9]In determining the required elements of a proper complaint, the district court placed principal reliance on In re Dow Corning Corp., 244 B.R.705 (E.D. Mich 1999), which involved Government claims under the MSP and MCRA seeking reimbursement from a manufacturer that opted out of this litigation. See id. at 713 (detailing necessary contents of Government's claims). Significantly, Dow Corning arose in the context of a Chapter 11 proceeding to validate the cramdown of a plan of reorganization, pursuant to 11 U.S.C. § 1129(b)(1), not in the context of a Rule 12(b)(6) motion to dismiss. Consideration of a § 1129(b)(1) motion requires the court to review evidence and resolve issues of fact. Thus, the Government did not have the benefit of the deferential review afforded to allegations at the motion-to-dismiss stage. Dow Corning's standard for what constitutes an adequately supported objection to the validation of a § 1129(b)(1) reorganization is of limited usefulness in determining what an ordinary civil complaint in intervention must contain.

necessary to complete the Government's Complaint – "the Medicare beneficiaries who have received benefits from the defendants" – is outside the Government's control. At best, the Government may be able to generate a list of all patients who received treatment for breast implant-related medical conditions during the period covered by the RSP settlement.[10] Such a list would be wildly over-inclusive, as it could include: patients whose implants were not manufactured by any of the RSP Defendants; patients who had their implants removed for reasons other than tortiously inflicted injury; patients who opted not to participate in the settlement; and patients participating in the class whose application for RSP benefits may (for whatever reason) not be approved by the Claims Office so that they will never receive payment. The Government could not in good faith purport to be bringing its Complaint on behalf of such a patently inaccurate list of beneficiaries. See Fed. R. Civ. P. 11(b) ("By presenting to the court... a pleading, written motion, or other paper, an attorney or unrepresented party is certifying that to the best of the person's knowledge, information, and belief, formed after an inquiry reasonable under the circumstances... the allegations and other factual contentions have

[10]Even this is a dubious assumption. Many women will doubtless have received Medicare-compensated treatment for generic symptoms not specifically identified on their providers' bills as related to breast implants, or perhaps not diagnosed as implant-related until later in the course of treatment.

evidentiary support"). While the Government might be able to arrive at a rough approximation, the RSP Defendants (either directly or through the Claims Office) have access to: (1) the names of the approximately 400,000 registered potential claimants, and (2) the approximately 81,000 people whose claims, to date, have been deemed worthy of payment. They are, consequently, in the far more advantageous position to compile an accurate list of Medicare patients for whom MSP payments have been made or requested.[11]

The pleading standards urged by the RSP Defendants are akin to the heightened requirements of Fed. R. Civ. P. 9, which apply to claims of fraud, mistake, duress and other "special matters." Where Rule 9 is implicated, plaintiffs must plead not only the general nature of their injuries but also the specifics of how and when they were injured. See, e.g., Brooks v. Blue Cross & Blue Shield of Florida, Inc., 116 F.3d 1364, 1380-81 (11th Cir. 1997) (under Rule 9(b), plaintiff alleging fraud must plead "(1) the precise statements, documents, or misrepresentations made; (2) the time, place, and person responsible for the

[11]The district court believed that the Government was required to plead the names of Medicare patients who have actually received payment from the Defendants. Because tens of thousands of pending claims remain to be evaluated by the RSP Claims Office, even if the Government were able to produce a perfectly accurate list in compliance with the district court's standards, such list would be obsolete essentially from the day of submission due to the ongoing claims adjudication process. We fail to see how the conduct of this litigation would be aided by forcing Medicare at this initial stage to produce what will necessarily be a grossly inaccurate and constantly changing claimant list.

statement; (3) the content and manner in which these statements misled the Plaintiffs; and (4) what the defendants gained by the alleged fraud"); Coffey v. Foamex L.P., 2 F.3d 157, 161-62 (6th Cir. 1993) (Rule 9(b) requires plaintiff in fraud case "at a minimum, to allege the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud"). By implication, then, a complaint governed by the ordinary standard of Rule 8 – and there is no dispute that Rule 8 applies here – need not allege the particulars of each instance of injury in order to survive a motion to dismiss.[12]

It is significant here that, out of a class of 400,000 potential claimants, it appears beyond dispute that at least some class members will have received conditional Medicare payments.[13] No one suggests to the contrary. Therefore,

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[12]The Defendants argue that it would be inequitable to allow Medicare to proceed on the basis of an unspecific complaint when the Government failed to request access to the names of the RSP claimants – a request that the district court had indicated it might view favorably. Whether or not the Government conducted itself with optimal diligence is not conclusive. A complaint that is otherwise satisfactory under Rule 8 – as is this one – does not become inadequate merely because the complainant had access to more detailed information but failed to include it. (We note that the district court did not rely on the Government's failure to move for disclosure of the identity of the RSP claimants as a basis for dismissing the Complaint.)

[13]In a sworn declaration submitted to the district court in May 2000, the Government reported that 457 people (140 who participated in the RSP settlement and 317 who opted out) had identified themselves to HHS as having received payment from the breast implant litigation. This number hints at the immense litigation management problems that would ensue if the

given the benefit of discovery, it appears not only possible but in fact inevitable that the Government will turn up a number of claims eligible for reimbursement. That the Government cannot now provide a name, date and dollar amount corresponding to any particular Medicare payment for which reimbursement is owed does not indicate beyond doubt that it has "no case," which is what a court must find to grant a motion to dismiss.[14]

Finally, we note that requiring the Government to plead with the specificity Defendants seek would run counter to the intent of the MSP statute. In carrying

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Government were forced to plead the individualized medical and payment histories of each of its beneficiaries.

[14]Our facts materially differ from those presented in City of Birmingham v. American Tobacco Co., 10 F. Supp. 2d 1257 (N.D. Ala. 1998), on which the district court relied. In City of Birmingham, which involved a somewhat analogous claim for recovery of health care expenses under a state statute, the district court found that the plaintiffs were required to plead details about each patient and each expenditure for which reimbursement was sought. In that non-class action, however, there was considerable doubt as to whether the plaintiffs could identify even a single person for whose care they were entitled to reimbursement, and information as to the patients' identities and medical history was within the *plaintiffs'* exclusive control. It is also noteworthy that, even in City of Birmingham, the court did not dismiss the complaint outright, but rather, granted the plaintiffs leave to amend.

For similar reasons, we do not find the principal case cited by Defendants, Health Care Serv. Corp. v. Brown & Williamson Tobacco Corp., 208 F.3d 579 (7th Cir. 2000), to be on point. In Brown & Williamson, the Seventh Circuit upheld the dismissal of a subrogatory claim by various Blue Cross/Blue Shield associations suing tobacco companies to recover for smoking-related health care expenses for their insureds. Although the court did find the complaint lacking because it failed to plead the identity of the parties insured, its principal weakness was a failure to show either a right to recovery or a basis for federal jurisdiction, both of which are supplied in our case by the MSP statute. Moreover, as with City of Birmingham, Brown & Williamson did not arise out of an underlying class action, which (in our case) itself serves to give the defendants notice of the universe of patients for whose expenses reimbursement may be sought.

out its principal purpose of shifting the burden of paying for health care from Medicare to private insurers, the MSP creates as a practical matter a need for insurers to determine, before paying a disputed liability claim (involving among its alleged damages medical expenses likely to have been paid by Medicare), whether the Government has made a conditional payment, upon peril of being forced to pay the same claim twice. As the second payer, such insurer is in a position to determine which claim has been, or is at risk of being, paid twice, while Medicare, as the first payer, is not. Because the statute is built on the recognition that Medicare frequently will not know which of its payments has been subsequently duplicated by an insurer, it would – in this unique setting of a class action involving thousands of claimants – defeat the purpose of the statute to require that the Government identify each patient, procedure, and payment amount at the pleading stage without benefit of discovery.

We readily conclude that the district court erred in dismissing the complaint for failure to identify the beneficiaries for whose care reimbursement is sought.

B. Scope of MSP Statute

1) Were Medicare's payments conditioned on reimbursement?

The RSP Defendants argue here that the Government's right to recoup its payments never arose, because under the terms of the MSP statute, Medicare's

payments were not "conditional" at all. The disputed statutory provisions, 42 U.S.C. §§ 1395y(b)(2)(A) and (b)(2)(B), provide:

> (A) In general
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> Payment under this subchapter may not be made, except as provided in subparagraph (B), with respect to any item or service to the extent that –
>
> > (i) payment has been made, or can reasonably expected to be made, with respect to the item or service as required under [regulations governing group health plans], or
> >
> > (ii) payment has been made or can reasonably be expected to be made promptly (as determined in accordance with regulations) under a workmen's compensation law or plan of the United States or a State or under an automobile or liability insurance policy or plan (including a self-insured plan) or under no-fault insurance. ...
> >
> > In this subsection, the term "primary plan" means a group health plan or large group health plan, to the extent that clause (i) applies, and a workmen's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no fault insurance, to the extent that clause (ii) applies.
>
> (B) Repayment required
>
> > (i) Primary plans
> >
> > Any payment under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement to the appropriate Trust Fund established by this subchapter when notice or other information

> is received that payment for such item or service has been or could be made under such paragraph.

Defendants argue that subparagraph (A) operates as a limitation on the right of reimbursement in subparagraph (B), so that a Medicare payment is conditioned on reimbursement only if "payment has been made or can reasonably be expected to be made promptly" by another insurer. In other words, Defendants argue that Medicare is entitled to reimbursement only if Medicare pays after payment from a primary insurance source either has already been made or is expected promptly. Otherwise, in Defendants' view, Medicare's payment is unconditional and may not be recouped.

Grammatically, Defendants' interpretation is a possible reading of the statute. However, we think the much more plausible interpretation of the statute is that Medicare would endeavor not to pay where a "primary plan" has paid or is expected to pay promptly, but any payment that Medicare does make is secondary and is subject to reimbursement from sources of primary coverage under the statute. This more plausible interpretation is also a grammatically correct construction of the language of the statute. The crucial phrase in § 1395y(b)(2)(B)(i) – "to which subparagraph (A) applies" – plausibly modifies "any item or service," meaning any item or service covered by a primary plan as defined

in the last paragraph of §1395y(b)(2)(A). The court in Brown v. Thompson, 252 F. Supp. 2d 312, 317 (E.D. Va. 2003) recently rejected Defendants' interpretation, and adopted the interpretation we adopt today. The Brown court held:

> [T]he reference in subparagraph B to 'item or service to which subparagraph A applies' must refer only to that portion of subparagraph A that defines a primary plan. In other words, the reference to subparagraph A in subparagraph B serves simply to define the universe of reimbursable payments to consist of those where primary coverage exists. ... Properly construed, therefore, subparagraph B requires reimbursement for a payment, as here, that 'has been made' from a 'primary plan' as defined in subparagraph A.

It is clear that an item or service paid by a primary plan defined in the last paragraph of subparagraph (A) is, in the language of subparagraph (B), an "item or service to which subparagraph (A) applies." In other words, subparagraph (A) applies by defining the universe of reimbursable payments.

Our interpretation is further supported by a close examination of the language of subparagraphs (A) and (B). Subparagraph (B) refers to payments "with respect to any item or service to which subparagraph (A) applies." This would include any payments contemplated by subparagraph (A). Turning to subparagraph (A) to ascertain what payments it contemplates, we see that it contemplates that Medicare should not pay if payment has been made or is reasonably expected from a group health plan (subparagraph (A)(i)), and that

Medicare should not pay if payment has been made or can reasonably be expected to be made promptly under plans including liability insurance or self-insured plans (subparagraph (A)(ii)). By contrast subparagraph (A) clearly contemplates Medicare will pay when it does not reasonably expect prompt payment by such primary obligors – precisely the payments which Defendants argue are not reimbursable. We believe that the much more plausible interpretation of the statutory language indicates that these payments are reimbursable. These are payments "with respect to any item or service to which subparagraph (A) applies" because subparagraph (A) defines their universe and contemplates Medicare paying them.

Although only our more plausible interpretation comports with the purpose of the statute, see infra, the two grammatically correct potential interpretations mean that the statute might be considered ambiguous. Where such ambiguity exists, the reasonable interpretation of the agency charged with implementing the statute is entitled to judicial deference, under the principles enumerated by the Supreme Court in Chevron USA, Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 937, 104 S.Ct. 2778 (1984).

The first step in the two-step Chevron review is to determine whether Congress has "directly and unambiguously spoken to the precise question at issue."

Georgia Dept. of Med. Assistance v. Shalala, 8 F.3d 1565, 1567 (11th Cir. 1993) ("Georgia DMA") (quoting Chevron, 467 U.S. at 842-43, 104 S.Ct. at 2781-82). If so, the court's inquiry is at an end, for it must honor Congress' clearly expressed intent. Determining whether Congress has unmistakably addressed the issue requires looking at "the particular statutory language at issue, as well as the language and design of the statute as a whole." Georgia DMA, 8 F.3d at 1567 (citing Sullivan v. Everhart, 494 U.S. 83, 89, 110 S.Ct. 960, 964 (1990)).

If Congress has not directly addressed the issue, or the statutory provision is ambiguous, we come to the second stage of Chevron: whether the agency's construction of the statute is reasonable and consistent with congressional intent. If so, we must accede to it. See Dawson v. Scott, 50 F.3d 884, 887 (11th Cir. 1994) ("Agency interpretation is reasonable and controlling unless it is 'arbitrary, capricious, or manifestly contrary to the statute.'") (quoting Chevron, 467 U.S. at 844, 104 S.Ct. at 2782); Bigby v. INS, 21 F.3d 1059, 1063 (11th Cir. 1991) ("[W]e defer to an agency's reasonable interpretation of a statute it is charged with administering."). The consistency of an agency's interpretation over time is a factor in determining the level of deference due. Good Samaritan Hosp. v. Shalala, 508 U.S. 402, 417, 113 S.Ct. 2151, 2161 (1993); see also Teamsters v. Daniel, 439 U.S. 551, 566 n. 20, 99 S.Ct. 790, 800 n. 20 (1979) ("It is commonplace in our

jurisprudence that an administrative agency's consistent, longstanding interpretation of the statute under which it operates is entitled to considerable weight.").

Here, we find that HHS – which was expressly delegated by Congress to formulate rules implementing the MSP statute – has consistently taken the position that Medicare payments are conditional and subject to recoupment regardless of whether another insurer can be expected to render a prompt primary payment. We start with the agency's notion of what it means for a Medicare payment to be "secondary." HHS regulations state that "'[s]econdary', when used to characterize Medicare benefits, means that those benefits are payable only to the extent that payment has not been made and cannot reasonably be expected to be made under other insurance that is primary to Medicare." 42 C.F.R. § 411.21. In other words, the regulation rejects Defendants' interpretation, and embraces our interpretation – that conditional medical payments are made to beneficiaries whose primary coverage has not yet paid and is not expected to pay promptly.

In updating its regulations to account for congressional revisions in 1984 through 1987, the agency stated its understanding that "Medicare makes conditional primary payment only if the other insurer will not pay promptly." Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 53

Fed. Reg. 22335, 22336 (proposed June 15, 1988). Similarly, in characterizing Congress' 1987 revisions to the secondary payment provisions regarding coverage for end-stage renal patients, HHS stated: "Medicare may not make conditional primary payments on behalf of an ESRD beneficiary who is covered by an employer group health plan if the plan 'can reasonably be expected' to pay." Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41717 (Oct. 11, 1989); see also Medicare Program, Services Covered Under Automobile Medical, No-Fault, or Liability Insurance; Services Furnished to ESRD Beneficiaries Who Are Covered Under Employer Group Health Insurance, 48 Fed. Reg. 14802, 14807 (April 5, 1983) ("Congress clearly intended that Medicare not pay first when there is a reasonable expectation that the employer plan will pay as promptly as Medicare. ... Medicare will be primary payer for items and services not covered by the employer plan and will make conditional primary payments if the intermediary or carrier determines that the employer plan will not pay promptly."). These and other authoritative HHS interpretations evidence that the agency has always understood that it will endeavor not to make payments where a payment has already been made by, or can reasonably be expected to be made by, a primary insurer, but that payment may be made conditionally under §

1395y(b)(2)(B) when Medicare does not reasonably expect prompt primary coverage payment.

We find the agency's interpretation to be in accord with the structure, history and purpose of the MSP statute, all of which plainly indicate that Congress wanted Medicare's payments to be secondary and subject to recoupment in all situations where one of the statutorily enumerated sources of primary coverage could pay instead. It is readily apparent that the interpretation evidenced in the HHS regulations, which we also adopt, correctly implements the statutory purpose. The RSP Defendants do not deny that the clear statutory purpose of the Medicare Secondary Payer statute was to make Medicare's obligation secondary to that of designated primary obligors, with the intention of reducing federal health care costs. This statutory purpose is universally accepted. It is also clear that HHS' interpretation would fulfill the congressional purpose, while Defendants' interpretation would frustrate that purpose.[15]

Next we turn from the foregoing general purpose of the statute to the specific language which Defendants argue supports their interpretation: "Any payment

[15]If Medicare's payments were conditional only if Medicare paid when the primary obligor had already paid or was expected to pay promptly, as Defendants would have us hold, then the vast majority of Medicare payments for services also covered by primary obligors would not be conditional. This is so because the only payments Defendants want to label as conditional are the very payments which § 1395y(b)(2)(A) provides Medicare should not make at all. Thus, Congress' cost-saving measures would have borne little or no fruit.

under this subchapter with respect to any item or service to which subparagraph (A) applies shall be conditioned on reimbursement ....” § 1395y(b)(2)(B)(i). Defendants argue that subparagraph (A) refers to situations where the primary obligor has already paid or can be expected to pay promptly; thus, Defendants argue that Medicare payments are conditional only in such situations. However, subparagraph (A) makes is clear that those are the very situations in which Medicare should endeavor not to pay. Thus, Defendants' interpretation would require us to indulge the illogical premise that Congress intended for Medicare to pay claims that it knew for a fact had already been paid, or were about to be paid, by the primary obligor – the very claims which the statute clearly contemplates that Medicare would endeavor not to pay.

Thus, both the general statutory purpose, and the purpose evident in the very language upon which Defendants rely, is manifestly inconsistent with Defendants' interpretation. By contrast, our interpretation, and that adopted by the regulations, fully implements the general congressional purpose, and is consistent with both the purpose and the precise language of §§ 1395y(b)(2)(A) and (B). In our view, Congress intended that Medicare would *always* be secondary to the sources of primary coverage enumerated in the statute.

Our interpretation not only fulfills the statutory purpose, but is consistent with the congressional intent as evidenced in the legislative history. Congress quite clearly expressed its understanding of how the secondary payment mechanism was designed to work in 1984, when enacting amendments that clarified the government's direct and subrogatory rights against third-party payors

> The bill establishes the statutory right of medicare [sic] to recover directly from a liable third party, if the beneficiary himself does not do so, and to pay a beneficiary, or on the beneficiary's behalf pending recovery where such third party is not expected to pay promptly.

H.R. Rep. No. 98-432, at 1803 (1984), *reprinted in* 1984 U.S.C.C.A.N. 697, 1417 (emphasis added). Unmistakably, Congress intended that contingent payments made because the primary payer was not expected to pay promptly would be subject to recovery.

The legislative history of the MSP indicates that it originated as a device to recoup payments from automobile insurance coverage. See Mason v. American Tobacco Co., 212 F. Supp. 2d 88, 93 (E.D.N.Y. 2002) (quoting original House bill, which referred only to "automobile insurance"). It is not at all uncommon for automobile insurance claims to be litigated and thus to take more than 120 days to be resolved. See, e.g., Waters v. Farmers Texas County Mut. Ins. Co., 9 F.3d 397 (5th Cir. 1993) (denying summary judgment on MSP claim arising out of

automobile accident three years earlier and remanding case for trial). The same is true of workers' compensation claims, which have been included within the scope of the MSP since its inception. Indeed, Medicare regulations specifically contemplate recovery where the third-party payment is the result of a judgment or a litigation settlement, which as a practical matter will almost always take more than 120 days. See 42 C.F.R. §411.37 (providing that Medicare will deduct from its recovery a pro rata share of attorney fees and other "procurement expenses" incurred to secure a judgment or settlement). Congress fully contemplated such delays when it provided for Medicare to pay contingently. See H.R. Rep. No. 1167, 96th Con., 2d Sess., at 389 (1980) ("Medicare will ordinarily pay for the beneficiary's care in the usual manner and then seek reimbursement from the private insurance carrier after, and to the extent that, such carrier's liability under the private policy for the services has been determined."). If the Defendants' interpretation were correct, it could well preclude recovery from automobile liability or workers' compensation insurance – the very sources for which the MSP was designed – since those sources routinely pay claims more than 120 days after the provision of medical treatment.

The historical evolution of these statutory provisions also supports the interpretation adopted by the agency. When Congress expanded the secondary

payer provision in the Omnibus Budget Reconciliation Act of 1981 so that it would include those enrolled in federal employee health plans and end-stage renal patients covered by group health plans, the provision read as follows:

> (2)(A) In the case of an individual who is entitled to benefits under [Medicare] part A or is eligible to enroll under part B ... payment under this title may not be made, except as provided in subparagraph (B), with respect to any item or service furnished during the period described in subparagraph (C) to the extent that payment with respect to expenses for such item or service (i) has been made under any group health plan ... or (ii) the Secretary determines will be made under such a plan as promptly as would otherwise be the case if payment were made by the Secretary under this title.
>
> "(B) Any payment under this title **with respect to any item or service to an individual described in subparagraph (A)** during the period described in subparagraph (C) shall be conditioned on reimbursement to the appropriate Trust Fund established by this title when notice or other information is received that payment for such item or service has been made under a plan described in subparagraph (A).

See H. Res. 3982, 97th Cong., 1st Sess., 95 Stat. 357 (1981) (emphasis added). Thus, in the 1981 version, it is clear that subparagraph (B) incorporates subparagraph (A) only to indicate that the two subparagraphs apply to the same set of individuals – those entitled to benefits under Medicare Part A or eligible to enroll in Medicare Part B – not to the same set of payments.

In the Tax Equity and Fiscal Responsibility Act of 1982 (TERFA), Congress revised the MSP provision so as to make Medicare the secondary payer for

"working aged" recipients under age 70 and their spouses enrolled in employer group health plans. TERFA added the following conditional payment provision to 42 U.S.C. § 1395y:

> (3)(A)(i) Payment under this title may not be made, except as provided in clause (ii), with respect to any item or service furnished ... to an individual who is over 64 but under 70 years of age ... who is employed at the time such item or service is furnished to the extent that payment with respect to expenses for such item or service has been made, or can reasonably be expected to be made, under a group health plan ...
>
> (ii) Any payment under this title with respect to <u>any</u> item or service ... shall be conditioned on reimbursement to the appropriate Trust Fund ... when notice or other information is received that payment for such item or service has been made under a group health plan.

H. Res. 4961, 97th Cong., 2nd Sess., 96 Stat. 324 (1982) (emphasis added). The conditional payment provision, in this iteration, patently applied to <u>any</u> item or service for which a group health plan might pay. It in no way limited the Government's right of recovery to those items or services for which a third-party payment was made or reasonably anticipated before Medicare made its payment.

Congress again amended the MSP in 1986 with the purpose, *inter alia*, of prohibiting employer group health plans from offering lesser benefits to senior citizens based on their Medicare eligibility. At that point, the "secondary payer" provision read:

> (4)(A)(i) A large group health plan may not take into account that an active individual is eligible for or receives benefits under this title ...
>
> "(ii) Payment may not be made under this title, except as provided in clause (iii), with respect to any item or service to the extent that payment has been made, or can reasonably be expected to be made, with respect to the item or service as required under clause (i).
>
> "(iii) Any payment under this title **with respect to any item or service to which clause (i) applies** shall be conditioned on reimbursement to the appropriate Trust Fund established by this title.

See H. Res. 5300, 99th Cong., 2nd Sess.,100 Stat. 1974 (1986). In this incarnation, Medicare's right of reimbursement in subparagraph (A)(iii) (what is now subparagraph (B)) refers back to and incorporates subparagraph (A)(i), which concerns the duty of large group health plans to render primary payment. Again, this version makes clear that the reference to subparagraph (A) in Medicare's right of reimbursement merely characterizes the broad category of coverage to which Medicare will be secondary. It cannot possibly be read as limiting Medicare's right of recovery to payments made after a group health plan has already paid or is expected to pay.

The current wording of the MSP was adopted as part of the Omnibus Budget Reconciliation Act of 1989, H. Res. 3299, 101st Cong., 1st Sess., 103 Stat. 2186 (1989). There is no indication in the legislative history that, between 1986 and

1989, Congress changed its mind and decided that Medicare should cease being the secondary payer for a substantial subset of claims.[16] Although the 1989 amendments obscured the clarity of the prior versions of the conditional payment provision, we cannot glean from this obscurity an unambiguous legislative purpose to narrow the MSP in the way that Defendants urge.

Our view is further sharpened by Congress' addition of the modifier "promptly" in 1984. Defendants have offered no logical explanation, and we can discern none, for why Congress would have intended to divest Medicare of the right to pursue recovery if payment from another insurer was probable, yet – because of a coverage dispute – unlikely to occur within the 120-day window of

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[16]To the extent that there is any record of legislative intent at all, it indicates that Congress was dissatisfied that Medicare was not recouping as much from primary payers as it could; there is not the slightest indication of congressional sentiment that Medicare was recovering too much. See 136 Cong. Rec. S13419-01 (daily ed. Sept. 19, 1990) (statement of Sen. Roth) ("Unfortunately, performance under the MSP Program has not measured up. Failure to follow the MSP law is costing the taxpayer billions of dollars. ... Studies by the General Accounting Office and the inspector general of the Department of Health and Human Services have repeatedly identified the MSP program as gushing with leaks of Federal tax dollars."); 135 Cong. Rec. S11848-01 (daily ed. Sept. 26, 1989) (statement of Sen. Durenberger) (discussing, in context of FY 1990 appropriations bill for health agencies, inadequacy of expenditures by Medicare intermediaries on MSP recoupment activity). In the 1989 OBRA legislation containing the confusing passage which is the subject of this dispute, Congress simultaneously enacted measures augmenting Medicare's ability to identify the existence of primary coverage, by giving HHS access to data from the IRS and the Social Security Administration. In so doing, Congress indicated in its statement of intent that "[u]nder current law, HHS is unable to identify all Medicare secondary payer situations, principally because HHS is unable to identify cases in which Medicare beneficiaries have primary coverage through a spouse's plan." H.R. Rep. 101-247, at 1021, *reprinted in* 1989 U.S.C.C.A.N. 1906, 2492 (1989). Nothing in the statement of intent indicates a desire to restrict Medicare's ability to recover conditional payments, or a realization that the 1989 amendments would be so construed.

"promptness."[17] Rather, it is apparent that the concern for "promptness" is motivated by a desire to prevent either the health care provider or the patient from going without compensation for a prolonged period while an insurance dispute is being resolved. Indeed, that is exactly how Congress – in enacting an earlier iteration of the MSP – explained its insertion of the term "promptly" in determining when Medicare may pay conditionally. See H.R.Rep. No. 208, 97th Cong., 1st Sess. 955, 956 (1981), *reprinted in* 1981 U.S.C.C.A.N. 396, 1318 ("The payment arrangements contemplated by the conferees are intended to minimize patient anxiety about the source of payment and to avoid delays in reimbursement for expenses incurred in connection with the use of [medical] equipment, supplies or services."); see also Nat'l Ass'n of Patients on Hemodialysis & Transplantation, Inc. v. Heckler, 588 F.Supp. 1108, 1128 (D.D.C. 1984) (explaining that Congress' decision to allow Medicare to pay conditionally when group health plan was not expected to render prompt payment "was a response to the conferees' concern about patient anxiety regarding the source of promptness of payment and delays in reimbursement"); Brown, 252 F. Supp. 2d at 319 ("The sole purpose of the phrase

[17]Suppose, for instance, that a Medicare patient was injured as the result of a multi-party automobile accident in which each motorist carried private insurance, yet each insurer refused to pay until liability could be sorted out among the participants. Even though it was certain that some insurer would ultimately pay – the only question being which – Defendants' interpretation would deprive Medicare of the ability to lay claim to the insurance proceeds if Medicare made a conditional payment on the basis that private payment was not "promptly" forthcoming.

'reasonably expected to be made promptly' in subparagraph A is to ensure that needed Medicare payments are not delayed to the detriment of a Medicare beneficiary"). It is for that reason that, even where Medicare reasonably anticipates that another insurer will pay eventually, it may pay conditionally if the dispute over primary coverage is likely to last more than 120 days.

Although the agency interpretation finds overwhelming support in the congressional purpose and legislative history, the case law has been less uniform. Several courts have accepted Defendants' view that Medicare's payment is conditional and subject to recoupment only in the circumstances described in one portion of subparagraph (A): the rightful primary insurer has paid, or is expected to do so promptly. See In re Dow Corning Corp, 250 B.R. 298, 348 (Bankr. E.D. Mich. 2000); In re Diet Drugs, No. MDL 1203, Civ.A. 99-20593, 2001 WL 283163 at * 11 n.20 (E.D. Pa. March 21, 2001); In re Orthopedic Bone Screw Prod. Liability Litig., 202 F.R.D. 154, 167-68 (E.D. Pa. 2001).[18]

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[18]In Thompson v. Goetzmann, 315 F.3d 457 (5th Cir. 2002), the Fifth Circuit originally accepted the premise that the Government's right of recovery under the MSP was limited to situations in which another primary coverage source had paid or was expected to pay promptly. See id. at 468. Upon the Government's petition for rehearing en banc, however, the panel withdrew its opinion and issued an amended opinion which, while reaching the same ultimate result, no longer relied upon the limited construction of subparagraph (A) that Defendants advance here. See Thompson v. Goetzmann, 337 F.3d 489 (5th Cir. 2003) (amending initial Goetzmann decision). In a preface to the amended opinion, the court stated that, while it remained convinced that the statute's wording supported its original conclusion that the Government may not collect from a primary plan unless such plan is expected to pay promptly, it

However, in Cochran v. HCFA, 291 F.3d 775 (11th Cir. 2002), our dicta read the statute in accordance with the Government's more expansive view. See id. at 777 ("In order to accommodate its beneficiaries ... Medicare does make conditional payments for covered services, even when another source may be obligated to pay, if that other source is not expected to pay promptly."). That is the way most other courts have interpreted it. See Rybricki v. Hartley, 792 F.2d 260, 262 (1st Cir. 1986) (Breyer, J.) ("Taken literally, [the MSP] simply says (in respect to a Medicare subscriber with a private source of insurance), 'if we can be reasonably certain that the insurance company will pay, Medicare won't pay; if we cannot be certain, Medicare will pay, but then, if the company pays you, you must reimburse Medicare.'") (parenthetical in original); accord Evanston Hosp. v. Hauck, 1 F.3d 540, 544 (7th Cir. 1993) (citing Rybricki, "[t]he Medicare law ... forbids payment where a third party can reasonably be expected to make prompt payment," and conversely, Medicare is allowed to pay conditionally where contested tort litigation cannot be expected to yield prompt payment); Smith v.

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recognized that its interpretation risked producing an "absurd result ... [that] precludes the right to reimbursement from any disputed or potentially disputed funds," since a disputed fund could never be expected to pay promptly. See id. at 492. We agree with the most recent Fifth Circuit opinion that the interpretation urged by Defendants, and accepted by the courts cited above, produces an absurd result. Moreover, we point out in the text above that this result is not indicated by the plain language of the statute. Rather, our construction is a much more plausible construction of the plain language of the statute.

Farmers Ins. Exchange, 9 P.2d 335, 338-39 (Colo. 2000) (en banc); Brown, 252 F. Supp. 2d at 317; Oregon Ass'n of Hospitals v. Bowen, 708 F. Supp. 1135, 1140-41 (D. Ore. 1989); Vogt v. Wausau Hosp., Inc., No. 93-2707, 1994 WL 246552 at * 2 (Wis. Ct. App. 1994); see also Thomas J. Nyzio, *Medicare Recovery in Liability Cases*, S.C. LAWYER, May/June 1996, at 20, 21-22 ("Under the statute, payment may not be made with respect to any item or service to the extent that payment has been made, or prompt payment... can reasonably be expected to be made, under a liability or no fault insurance policy or plan. However, payments can be made in the event that a provider will not receive prompt payment from a third party payer or from the proceeds of a liability settlement or judgment. These payments, however, are conditioned on reimbursement to Medicare in the event that payment for the same services is received from a liability or no fault insurer.") (citations omitted); Susan G. Haines & Tomas D. Begley, Jr., *Workers' Compensation Medicare Set-Aside Trusts*, ABA Brief/Practice Tips (Fall 2001) ("Medicare may make a conditional payment for services if Medicare does not reasonably expect the third-party insurer to make its primary payment promptly.").

In summary, we conclude that the agency's interpretation is eminently reasonable. Indeed, the agency's interpretation follows the most plausible interpretation of the statutory language, and is the only construction of the

language which is consistent with the clear statutory purpose. Both the legislative history and the uninterrupted history of revisions to the MSP statute support this interpretation. We have no doubt that payments made by Medicare on behalf of breast-implant patients were conditioned upon reimbursement if the patients later recovered from one of the primary sources enumerated in 42 U.S.C. § 1395y(b)(2)(A).

2) Do the RSP Defendants qualify as "self-insured," so that their payments to the class members were made "under a primary plan" and thus subject to a recoupment action under the MSP statute?

The Government contends that the RSP Defendants are liable under the MSP statute on the basis that they operated under a "self-insured plan."[19] The parties dispute whether the Government's Complaint alleged the existence of a self-insured plan with sufficient detail. In its opinion, 174 F. Supp. 2d at 1254-55, the district court expressed its relevant holdings in several articulations, which we number for ready reference:

(1) that a "'self-insured plan' connotes some type of formal arrangement ..."

(2) " ... by which funds are set aside and accessed to cover future liabilities;"

[19]The Government concedes that the RSP settlement mechanism, which antedated the Government's Medicare payments, is not a "self-insured plan" as that term is understood in 42 U.S.C. § 1395y(b)(2)(A)(iii). Rather, the Government's theory is that the individual companies were each operating under a plan of self-insurance in which they arranged to purchase third-party liability coverage and self-insure up to the amount of their policies' deductibles.

(3) "[P]ayments [by a tortfeasor], without more, [do not] constitute a 'plan' of self-insurance;"

(4) "The mere absence of insurance purchased from a carrier does not necessarily constitute a 'plan' of self-insurance" (quoting 54 Fed. Reg. 41727 (Oct. 11, 1989); and

(5) "Payments of deductibles ... do not constitute a 'plan' of self-insurance." We agree with the district court as to the first, third and fourth holdings, but not as to the second and fifth.

There is remarkably little legal authority (none binding in our Circuit) categorically defining what it means to operate a "self-insurance plan." Black's Law Dictionary defines "self-insurance" as: "The practice of setting aside a fund to meet losses instead of insuring against such through insurance. A common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance." BLACK'S LAW DICTIONARY 1220 (5th ed. 1979). The first sentence of the dictionary definition suggests that an advance set-aside of funds would usually be a part of a self-insurance plan.[20] See Jackson v. Donahue, 457

[20]However, the second sentence is not inconsistent with the commonly understood practice of self-insuring up to a certain amount, and then covering any excess with insurance, often with no set-aside of funds.

A more recent edition of Black's defines "self-insurance" as simply: "A plan under which a business sets aside money to cover any loss." The same edition defines "self-insured retention" as: "The amount of an otherwise-covered loss that is not covered by an insurance policy and that

S.E.2d 524, 528 (W.Va. 1995) ("The phrase 'self-insurance' means, generally, the assumption of one's own risk and, typically, involves the setting aside of a special fund to meet losses and pay valid claims(.)"); COUCH ON INSURANCE 3D § 10:1 (stating that, while "[t]he term 'self-insurance' has no precise legal meaning," it generally implies "the same sort of underwriting procedures that insurance companies employ," such as estimating likely losses and setting aside reserves).

Other authorities, however, suggest a more elastic definition. See In re Amatex Corp., 107 B.R. 856, 872 (Bankr. E.D. Pa. 1989) ("Self insurance is best compared to the familiar 'deductible' amount referenced in most insurance policies. It is common knowledge to anyone who has ever filed an insurance claim subject to same that the deductible must be exhausted before the liability of the insurer begins."); 22 APPLEMAN ON INS. 2d § 140.5 (Eric Mills Holmes, ed., 2003) at 407 n.67 ("True self-insurance occurs when an entity retains all risks against which it might otherwise insure. This type of self-insurance is popular among governmental entities as a result of statutory immunity or costs. Another type of self-insurance occurs when an entity purchases liability insurance for a certain limit and any

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[usually] must be paid before the insurer will pay benefits." BLACK'S LAW DICTIONARY 807, 1365 (7th ed. 1999). This definition, like its predecessor, suggests that self-insurance can be understood both as the practice of setting aside a reserve to pay claims, and the practice of paying a deductible before third-party coverage becomes effective.

amount of exposure thereof is retained by the entity."); see also Sears, Roebuck & Co. v. IRS, 972 F.2d 858, 861 (7th Cir. 1992) (stating, in context of dispute over tax treatment of insurance transaction between related corporate entities, that "'[s]elf- insurance' is just a name for the lack of insurance – for bearing risks oneself."); Beech Aircraft Corp. v. United States, 797 F.2d 920, 922 (10th Cir. 1986) (stating, in tax case similar to Seventh Circuit's Sears, Roebuck, that "[s]elf-insurance is not the equivalent of insurance. If one having an insurable risk retains the risk of his own loss, there is no risk transfer, and the arrangement is self-insurance."); In re North American Royalties, Inc., 276 B.R. 860, 864 (Bankr. E.D. Tenn. 2002) (holding, in construing contract of insurance, that "[t]he term 'self-insured' means that the plan sponsor... does not have insurance; it pays the expenses from its income."). These and other authorities strongly indicate that "self-insurance" is an unscientific and imprecise term, the interpretation of which varies with the context.

Our understanding of what it means to operate under a "self-insured plan" is informed by HHS regulations, to which – because of Congress' express delegation and the agency's recognized expertise in the area – we are duty-bound to defer if they are reasonable. For purposes of the MSP statute, HHS regulations define a "plan" of insurance as including "any arrangement, oral or written, by one or more

entities, to ... assume legal liability for injury or illness." 42 C.F.R. § 411.21. Inclusion of the term "oral" suggests an intent to reach informal, *ad hoc* arrangements in addition to traditional insurance policies; obviously, no standard insurance company issues coverage verbally. In addition, the regulations provide the following definition of a "self-insured" plan: a "[s]elf-insured plan means a plan under which an individual, or a private or governmental entity, carries its own risk instead of taking out insurance with a carrier." 42 C.F.R. § 411.50(b).

HHS has purposefully adopted a broad definition of what it means to be self-insured. For instance, the agency does not limit its definition to plans that are certified to operate as self-insurers by state insurance regulators. In enacting its inclusive definition, the agency explained that to do otherwise would enable a responsible party to elude MSP liability by paying a claim out of pocket instead of submitting the claim to its liability insurer – a mechanism not unlike the RSP compensation process here. See Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 53 Fed. Reg. 22335, 22339-40 (proposed June 15, 1988). Of particular significance here, HHS has expressly defined a "liability insurance payment" for purposes of the MSP statute to include: "A payment to cover a deductible required by a liability insurance policy, by any individual or

other entity that carries liability insurance or is covered by a self-insured plan." 42 C.F.R. § 411.50(b).

The agency's view is especially persuasive in the absence of a universally accepted and authoritative definition of "self-insured plan" which Congress might have contemplated in drafting the statute. Thus, the district court's first articulation – that a self-insured plan connotes some type of *ex ante* arrangement to assume legal liability for medical expenses – is consistent with the regulation, to which we agree deference is due.[21] For the same reason, we agree that the district court's third articulation – that a tortfeasor's mere payment, without more, would not constitute a plan of self-insurance – is consistent with the regulations, as is its fourth – that the mere absence of insurance does not necessarily constitute a plan of self-insurance. See Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41727 (Oct. 11, 1989) ("We note that the mere absence of insurance purchased from a carrier does not necessarily constitute a

[21]To the extent that the district court meant by its term "formal" arrangement something more than that the arrangement must be *ex ante* and must be an arrangement, albeit oral, to assume legal liability or pay for medical expenses, the district court would have required more than the regulations; we see no warrant for requiring more.

'plan' of self-insurance."). In other words, without a plan or prearrangement, there can be no self-insured plan.[22]

However, it is apparent from the foregoing quotations from the regulations that the district court's second and fifth holdings are inconsistent with the regulations. The district court's fifth holding is squarely inconsistent with the regulation's affirmative provision that a "liability insurance payment" includes "an out-of-pocket payment, including a payment to cover a deductible required by a liability insurance policy, by any entity that carries liability insurance or is covered by a self-insured plan." 42 C.F.R. § 411.50(b). There is nothing in the plain meaning of the statute which might preclude the agency's interpretation to include within the self-insured concept the commonly occurring circumstance of an individual or entity planning ahead of time to assume responsibility and liability for certain risks up to a designated amount, and to procure an insurance policy to cover

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[22]We see no tension between our position and that in the cases cited by Defendants, United States v. Philip Morris, Inc., 116 F. Supp. 2d 131 (D.D.C. 2000), and Mason v. American Tobacco Co., 212 F. Supp.2d 88 (E.D.N.Y. 2002). In each case, the district court dismissed MSP claims seeking Medicare reimbursement from tobacco companies accused of tortiously injuring their customers. In Philip Morris, the Government's claim was found flawed because it merely made the conclusory allegation that the defendants were "responsible" for payment under the MSP without advancing a basis – and, specifically, without alleging the existence of a coverage plan. Id. at 146. In Mason, the plaintiffs' claim rested solely on the theory that a large corporation without insurance that was accused of inflicting a tortious injury was, by definition, operating a self-insured plan. There was no suggestion that the tortfeasor had purchased supplemental insurance and made arrangements to cover the deductible out of its own funds. See id. at 92. We agree with these courts to the extent that they hold that the MSP requires the existence of some sort of plan as opposed to a mere *post hoc* assumption of liability.

the excess. As we have seen, the relevant statutory term "self-insured plan" has no precise legal meaning, seems to be interpreted by some authorities more rigidly, but is interpreted by other authorities to include precisely such a combination of self-insurance up to a certain amount with the excess to be covered by an insurance policy. Consistent with the latter authorities, common experience teaches us that planning such a combination of deductibles and insurance policies is often referred to as self-insurance. Because the statute has no unambiguous meaning in this regard, deference is due to the regulation, and the district court's contrary holding cannot stand.

We also disagree with the district court's second holding, that self-insurance requires a set-aside of funds to cover the risks assumed. Even the sparse legal authority which suggests that there usually will be a reserve for losses, also indicates that "self insurance" has no precise legal meaning. Other authorities suggest there is no absolute need for a set-aside of funds. We see no basis in the statute or in any well-established meaning of the statutory term "self-insured plan" to conclude that the term unambiguously requires a set-aside of funds. Thus, we look to the regulations. We conclude that an absolute requirement that funds be set aside is plainly inconsistent with the thrust of the regulations: that a self-insurance plan encompasses any arrangement, even an oral one, to assume such risks, 42

C.F.R. § 411.21; and that it encompasses the combination of deductibles and insurance policies discussed above, which in common experience often do not include a set-aside of funds. 42 C.F.R. § 411.50(b). See also 42 C.F.R. § 411.50(b) (defining "self-insured plan" as a plan to carry one's "own risk instead of taking out insurance," a definition requiring only a "plan" and no other formalities).[23] There being no unambiguous requirement in the statutory term "self-insured plan" that a set-aside of funds is necessary, and the same being plainly inconsistent with the thrust of the regulations, we vacate the district court's holding requiring a set-aside as a prerequisite for a "self-insured plan."

We recognize that the Fifth Circuit in Thompson v. Goetzmann, 315 F.3d 457 (5th Cir. 2002); *opinion withdrawn and reissued as amended on other grounds*, 337 F.3d 489 (5th Cir. 2003), extensively discussed the meaning of a self-insured plan in this statute, and concluded that "a 'primary plan' of 'self-insurance' requires an entity's *ex ante* adoption, for itself, of an arrangement for (1) a source of

[23]The Defendants' suggestion that the word "instead" means that "self-insurance" can exist *only* in an arrangement including no insurance is wholly without merit. Not only would that be a grudging construction of the language, it would be inconsistent with the thrust of 42 C.F.R. § 411.50(b), which contemplates a combination of insurance policies and deductibles, and with the clear weight of authority that an entity can self-insure for a designated amount and purchase coverage for liability exceeding the designated amount. See, e.g., BLACK'S LAW DICTIONARY 1220 (5th ed. 1979) (explaining, in defining self-insurance, that "[a] common practice of businesses is to self-insure up to a certain amount, and then to cover any excess with insurance.").

funds, and (2) procedures for distributing these funds when claims are made against the entity." Id. at 463.

We note first that we fully agree with the Fifth Circuit that the term "plan" in the statutory term "self-insured plan" clearly contemplates an *ex ante* arrangement. This is clear in both the statute and the regulation. It is probable that this is the extent of the holding in Goetzmann, and that the balance of the foregoing quotation from the Fifth Circuit case is dicta. Apparently the only issue in Goetzmann was whether a single, discreet, settlement by a tortfeasor with a single plaintiff whereby the tortfeasor paid the plaintiff with its own funds, without more, constituted a "self-insured plan."[24] We agree with this holding because that circumstance would not entail a "plan" or *ex ante* arrangement. It is probable therefore that what the Fifth Circuit said about setting aside funds and procedures is dicta.

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[24]The following quotations from Goetzmann indicate that these were the facts, thus defining the holding:

- "[W]e ... also agree with the other district courts that have concluded that an alleged tortfeasor who settles with a plaintiff is not, ipso facto, a 'self-insurer' under the MSP statute." Id. at 462.
- "[I]t is wrong for the government to contend that an entity's negotiating of a single settlement with an individual is sufficient, in and of itself, for such entity to be deemed as having a 'self-insurance plan.'" Id. at 463 (emphasis in original).
- "[N]owhere does the MSP statute mention or even suggest that an alleged tortfeasor who settles a single claim with a single plaintiff falls within the ambit of the statute's category of a 'self-insurance' plan." Id. at 464.
- "But [the defendant] has only negotiated a discreet settlement with a single plaintiff and paid that plaintiff accordingly. It is simply a non sequitur for the government to infer from 'payment responsibility' in tort a preexisting primary plan of self-insurance." Id. at 465 (emphasis in original).

We respectfully disagree with the Goetzmann dicta to the effect that there cannot be a self-insured plan absent a setting aside of the funds and formal procedures. We agree with Goetzmann that the statutory term "self-insured plan" should be read in the context of a "primary plan." However, especially because the statutory definition of a primary plan expressly includes self-insured plans, we see nothing in that context requiring either a set-aside of funds or formal procedures. See 42 U.S.C. § 1395y(a)(2)A) ("In this subsection, the term 'primary plan' means ... a workman's compensation law or plan, an automobile or liability insurance policy or plan (including a self-insured plan) or no-fault insurance") (parenthetical in original). We gather from the Fifth Circuit opinion that it derived its concept of the scope and limit of the term "self-insured" from the "ordinary meaning" of that term, which it derived in turn from several legal authorities, principally the Couch treatise. However, as noted above, even the legal authority relied upon by Goetzmann acknowledged that there was no precise legal meaning, and while some authorities suggest that a set-aside of funds and formal procedures often accompany self-insured plans, other authorities, as noted above, suggest otherwise. Goetzmann does not alter our conclusion that there is no precise legal meaning for the statutory term "self-insured plan" that is well-established enough to rise to the

level of rendering a statutory term unambiguous.[25] Accordingly, it is appropriate to look to the regulations to which we owe deference.[26]

Applying the foregoing principles to the instant complaint, it is here alleged that "the RSP defendants were self-insured against the risk of products liability claims by breast implant recipients, and paid such claims from self-insured funds or

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[25]The Goetzmann court also rejected the Government's argument that the statute was ambiguous. Again, however, it appears likely that the court was focusing on the precise facts of the case and its narrow holding – that a discreet settlement by a single tortfeasor out of its own funds would not by itself (that is, without any prearrangement or plan) constitute a self-insured plan. This seems likely because, as discussed above, there is no precise legal meaning of the statutory term sufficiently well-established to rise to the level of rendering it unambiguous with respect to the Goetzmann dicta to the effect that a set-aside of funds and formal procedures are required. In other words, the statute may well be unambiguous with respect to the requirement of a plan or *ex ante* arrangement, but it is not with respect to the Goetzmann dicta. To the extent the Fifth Circuit intended to hold otherwise, we respectfully disagree.

[26]We note that the Goetzmann court relied heavily on a questionable assumption regarding the interaction of the MSP statute and the aforementioned Medical Care Recovery Act, 42 U.S.C. § 2651. Because the express purpose of the MCRA is to impose liability upon tortfeasors to repay the Government for the reasonable value of health care furnished to a tortiously injured party, the Goetzmann court found that reading tortfeasor liability into the MSP "would, in effect, eliminate the need for the MCRA, or at least condemn some of Congress' language in the MCRA to the scrap heap of surplusage." Id. at 465. However, the Goetzmann reasoning does not resolve this perceived conflict, as it would itself render superfluous that portion of the MSP statute imposing liability on an entity "required or responsible" to pay under a "primary plan" of self-insurance – i.e., a self-insured tortfeasor. The Goetzmann view would also render superfluous a substantial portion of the Government's subrogatory right conferred by the MSP statute, because establishing the liability of the patient's insurer to Medicare necessarily may require bringing a subrogation action against the tortfeasor. Moreover, Goetzmann's perception of an overlap between the coverage of the MCRA and the MSP may be in error. See United States v. Philip Morris, Inc., 116 F. Supp. 2d 131, 140-44 (D.D.C. 2000) (holding, after extensive analysis of statute's legislative history, that MCRA applies exclusively to federal health care expenditures other than Medicare, such as coverage for military personnel and their dependents); accord In re Diet Drugs, Nos. MDL 1203, CIV.A, 99-20593, 2001 WL 283163 (E.D. Pa. March 21, 2001) at *7-*8.

retained earnings." The allegation that the Defendants self-insured "against the risk ... of claims" indicates that the plan or arrangement existed before the claims did, thus satisfying the requirement of an *ex ante* arrangement to assume legal liability. Moreover, there are suggestions in the record that the plan or arrangement may have included a combination of self-insurance with respect to certain amounts and the purchase of insurance policies as to other amounts, precisely the kind of combination of deductibles and insurance policies deemed by the regulations to constitute a self-insured plan. We readily conclude that, with respect to the self-insured plan issue, the allegations are sufficient to survive a challenge under Rule 12(b)(6).[27]

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[27]We discern no merit in the argument pressed by the Steering Committee intervenors that the RSP Defendants' payments are excepted from the reach of the MSP statute because they are not directly pegged to the amount of health care expenses incurred by the class members. Courts have uniformly concluded that a settlement agreement that includes a non-itemized element of compensation for a plaintiff's medical care is "for" medical expenses, even if the exact share or amount is indeterminate. See Share Health Plan of Illinois, Inc. v. Alderson, 674 N.E.2d 69, 72 (Ill. App. Ct. 1996) (holding that HHS can recover Medicare payments from beneficiary's lump-sum settlement of tort claim "regardless of whether and how amounts are designated"); see also Wilson v. Washington, 10 P.3d 1061, 1067 (Wash. 2000) (en banc) (finding that state Medicaid lien attached to entire amount of patient's medical malpractice settlement, not just amount earmarked for medical expenses); accord Calvanese v. Calvanese, 710 N.E.2d 1079, 1082 (N.Y. 1999). That interpretation is consistent with HHS' own understanding. See Medicare Program; "Without Fault" and Waiver of Recovery from an Individual as it Applies to Medicare Overpayment Liability, 63 Fed. Reg. 14506, 14514 (proposed March 25, 1998) ("Since liability payments are usually based on the injured or deceased person's medical expenses, liability payments are considered to have been made 'with respect to' medical services related to the injury even when the settlement does not expressly include an amount for medical services.").

3) Can the RSP Defendants be forced to repay Medicare, when it is undisputed that they had no actual knowledge of Medicare's specific payments on behalf of particular beneficiaries?[28]

The Government argues that the district court erred in dismissing the Government's subrogation claim pursuant to Rule 12(b)(6). As both parties and the district court understood, the Government clearly has subrogation rights to obtain reimbursement of its conditional payments. Section 1395y(b)(2)(B)(iii) provides:

> (iii) Subrogation rights
>
> The United States shall be subrogated (to the extent of payment made under this subchapter for an item or service) to any right under this subsection of an individual or any other entity to payment with respect to such item or service under a primary plan.

In granting the Rule 12(b)(6) dismissal, the district court rejected the Government's subrogation claim, apparently either requiring proof that the RSP Defendants actually knew they were paying tort claimants whose medical expenses had already

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[28] At the outset, we agree with the district court that dismissal was not warranted on the grounds that the Government failed to plead that it attempted to recoup its duplicate payments from the Medicare beneficiaries in the plaintiff class before seeking recoupment from the Defendants; it was adequately pled. We decline to address and express no opinion on the merits of Defendants' argument that the Government is obligated to seek reimbursement first against each member of the plaintiff class before pursuing reimbursement from the RSP Defendants, because the issue is not necessary to our holding, and because the issue was inadequately addressed by the district court and inadequately briefed on appeal. The Defendants are free to assert this argument on remand, and the district court should address it anew after appropriate development of the record and briefing with respect to the agency's policies and practices, and with respect to the relevant statutes, regulations, and other authorities.

been paid by Medicare, or applying an unrealistically strict perception of constructive knowledge. At one point, the district court said that the Government had affirmatively pled facts defeating its claim, in that its complaint acknowledged that the RSP Defendants "did not ascertain" whether any of the tort claimants to be paid had actually received Medicare benefits. We reject this ground without need for further discussion; in effect, the district court required actual knowledge, and we hold that constructive knowledge is sufficient. Our discussion henceforth will focus on constructive knowledge.

We presume that Congress legislates against the backdrop of established principles of state and federal common law, and that when it wishes to deviate from deeply rooted principles, it will say so. See United States v. Texas, 507 U.S. 529, 534, 113 S.Ct. 1631, 1634-35 (1993) ("Statutes which invade the common law ... are to be read with a presumption favoring the retention of long-established and familiar principles, except when a statutory purpose to the contrary is evident. In such cases, Congress does not write upon a clean slate. In order to abrogate a common-law principle, the statute must speak directly to the question addressed by the common law.") (internal quotes and citations omitted). It is well established at common law that a tortfeasor that pays a settlement to a claimant with knowledge – *actual or constructive* – that another entity has a subrogation claim against the

proceeds is not insulated from suit by the subrogee by virtue of the incorrect payment. See Dadeland Dodge, Inc. v. American Vehicle Ins. Co., 698 So.2d 929, 931 (Fla. Dist. Ct. App. 1997) (holding that tortfeasor that has constructive knowledge of insurer's perfected right of subrogation cannot rely on insured's release to preclude insurer's claim for reimbursement); accord State Farm Fire & Cas. Co. v. Pacific Rent-All, Inc., 978 P.2d 753, 770 (Hawaii 1999); Aetna Cas. & Surety Co. v. Norwalk Foods, Inc., 480 N.Y.S.2d 851, 852 (N.Y. Civ. Ct. 1984); see also Poole Truck Line, Inc. v. State Farm Mut. Auto. Ins. Co., 294 S.E.2d 570, 571-72 (Ga. Ct. App. 1982) (because state law makes no-fault automobile coverage mandatory, tortfeasor can be charged with constructive knowledge that motorist carried insurance and that motorist's insurer had a statutory right of subrogation, thus precluding tortfeasor from invoking its settlement with injured motorist to bar insurer's subrogation claim).

In a case involving the Government's subrogation rights under this same statutory provision, the D.C. Circuit has held that a party, standing in the shoes filled by the RSP Defendants in this case, can avoid reimbursing Medicare under the instant statutory provisions only if its payment to the wrong party was made without knowledge (either actual or constructive). HIAA, 23 F.3d at 418 ("If a third party payor wants to avoid having to make two payments for the same service,

it should refrain from paying someone whom it knows or should know that HCFA already has paid."). Further defining the content of constructive knowledge in the instant context, the D.C. Circuit cited with approval the agency's interpretation that constructive knowledge is satisfied when the third-party payor has in its possession direct information that Medicare has made a conditional payment, or has in its possession information necessary to draw the conclusion that Medicare has made such a payment.[29] The D.C. Circuit interpreted the latter reference to mean that third-party payors would be expected to draw certain inferences based on published Medicare procedures. Id.

We believe that the constructive knowledge standard is fully consistent with the intent of the MSP statute, and indeed necessary if the statute is to fulfill its purpose. The overriding purpose of the MSP statute was to allocate primary responsibility for the payment of claims to private insurance, where available.

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[29]The HIAA definition of constructive knowledge is essentially identical to that proffered by Defendants from the affidavit of HHS administrator Paul J. Olenick, which the Government submitted in HIAA as its statement of when HHS will consider an insurer to have the requisite knowledge to trigger liability under 42 C.F.R. § 411.24(i)(2). See Def. Ex. B ("A third party payer 'learns' of a Medicare conditional primary payment when it receives information which makes it aware, or should make it aware, that Medicare has made a conditional primary payment. This would be the case when the third party payer receives direct information that Medicare has made a conditional payment or when it receives the information necessary to draw the conclusion that Medicare has made a primary payment.") (emphasis in original).

Between two sources of coverage, the insurer that pays second is in the superior position to prevent an erroneous or misdirected payment. The first payer can avoid such an outcome only by refusing to pay at all. Congress foreclosed that option in 42 U.S.C. §§ 1395y(b)(2)(A) and (b)(2)(B) by providing for Medicare to pay first where payment from the primary insurer was not reasonably forthcoming. When Medicare pays, therefore, it is paying "in the dark" – it does not know, and *cannot* know, whether someone else will pay.[30] By contrast, when the primary insurer later pays, Medicare's prior payment will normally be a matter of ascertainable fact.

In light of the well-established common law of subrogation, consistent with the purposes of the MSP statute, and following the D.C. Circuit, we hold that either knowledge or constructive knowledge is sufficient. Thus, if the RSP Defendants

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[30]HHS and Congress have repeatedly flagged Medicare's inability to ascertain the existence of alternative sources of coverage as a weakness in the secondary payer program. See, e.g., Dept. of Health and Human Serv., Office of the Inspector Gen. ("HHS IG"), Survey of Medicare Payments to Workers' Compensation Recipients in the State of Florida, No. A-04-01-07003 (January 2003) at 6 ("Unfortunately, the system as currently structured does not provide a standard procedure that ensures that Medicare is informed of all [workers' compensation] settlements"); HHS IG, Medicare Prepayment Review: MSP Procedures at Carriers, No. OEI-07-89-01683 (August 1991) at 2 (citing estimate that, based on random sampling of processed by private contractors, "Medicare lost in excess of $600 million in FY 1988 due to unidentified primary payment sources"). Overlapping coverage is particularly difficult to detect where, as here, the Medicare payment and the insurance payment go to different recipients (Medicare's to the doctor or hospital, and the alleged tortfeasors' directly to the patient). In light of this well-recognized weakness, it is therefore reasonable for the agency to interpret the MSP, and Congress' subsequent revisions of it, as imposing the risk of loss on the alternative payer for failing to determine whether Medicare has already paid for the same service.

had either knowledge or constructive knowledge that some of the recipients of the funds they were paying out had received breast implant-related medical treatment for which Medicare already paid, then the RSP Defendants would be liable to reimburse the Government pursuant to § 1395y(b)(2)(B)(iii).

We need not at this early stage of the litigation attempt to define the precise scope of the constructive knowledge that will trigger liability, because we conclude that the Government's allegations in that regard survive Rule 12(b)(6).[31] The Government has alleged that the RSP Defendants structured the settlement in a manner so as to avoid learning any identifying information about the class members, including their Medicare eligibility. A party that willfully blinds itself to a fact, as the Complaint here alleges occurred, can be charged with constructive knowledge of that fact.[32] See Williams v. Obstfeld, 314 F.3d 1270, 1278 (11th Cir.

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[31]We note that the Federal Rules provide that the defendants' knowledge is an element that "may be averred generally," thus eschewing the particularity standard that applies to other mental-state elements (fraud, mistake) under Rule 9. See Fed. R. Civ. P. 9(b).

[32]We need not at this stage decide the significance of the facts that might be developed in this regard. However, it is clear that a party should not be able to avoid constructive knowledge and shield itself from statutory liability by consciously avoiding information which would constitute constructive knowledge and result in liability. In addition to facts that might be developed in this regard on remand, the district court might also address the relevance and significance of knowledge in fact obtained during the claims process, and whether such knowledge should be imputed to the RSP Defendants or whether they should be deemed to have consciously avoided same. At this early stage, and without development of the relevant facts, analysis by the district court, or adequate briefing from the parties, we decline to address this issue further and express no opinion as to its resolution.

In this regard, the parties have discussed whether an entity standing in the shoes of the

2002) (stating in context of civil RICO action that "[u]nder the doctrine of willful blindness or deliberate ignorance, which is used more often in the criminal context than in civil cases, knowledge can be imputed to a party who knows of a high probability of illegal conduct and purposely contrives to avoid learning of it."); Commodity Futures Trading Commission v. Sidoti, 178 F.3d 1132, 1136-37 (11th Cir. 1999) (holding, in context of commodities fraud action, that "the element of knowledge may be inferred from deliberate acts amounting to willful blindness to the existence of fact or acts constituting conscious purpose to avoid

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RSP Defendants has a duty to investigate for the benefit for the Government to discover Medicare's involvement. The discussion of the parties revolved around 42 C.F.R. § 411.25(a) ("If a third party payer learns that [HHS] has made a Medicare primary payment for services for which the third party payer has made or should have made primary payment, it must give notice to that effect to the Medicare intermediary or carrier that paid the claim."). In light of our decision that the Government's allegations survive Rule 12(b)(6), and in light of the discovery that will be available to the Government on remand that may reveal to the Government any information that investigation by the Defendants could have yielded, thus possibly mooting the duty-to-investigate issue, we decline to address it at this stage. To the extent that the district court's discussion (see In re Silicone Gel, 174 F. Supp. 2d at 1257) constitutes a holding that Medicare cannot interpret § 411.25(a) to require an insurer to inquire into the existence of a prior Medicare payment, we note that the district court did not address whether the agency had interpreted its regulation, or the significance thereof. See, e.g., Medicare Program; Medicare Secondary Payment, 59 Fed. Reg. 4285, 4286 (Jan. 31, 1994) (explaining the statute and regulations concerning third-party payors with primary obligations to which Medicare is secondary, and suggesting pursuant to 42 C.F.R. § 411.25 that where there has been delay in paying by the primary obligor, it should assume that Medicare made a conditional payment: "A beneficiary who is eligible for Medicare files a claim for primary payment with a third party payer, the claim is denied, the beneficiary appeals, and the denial is reversed. (The third party payer should assume that Medicare made a conditional primary payment in the interim.)"). If the duty to investigate issue should become a live one on remand, then the district court should address the issue afresh conducting an appropriate analysis, e.g., ascertaining any relevant agency interpretation and determining the extent of Chevron deference, if any.

enlightenment."). The Complaint therefore sufficiently alleges constructive knowledge, despite the Government's concession that the Defendants did not acquire actual knowledge of Medicare's conditional primary payments.[33]

For all of the foregoing reasons, we conclude that the Government's allegations of constructive knowledge are sufficient, and the Government's subrogation claim under §1395y(b)(2)(B)(iii) survives the Rule 12(b)(6) challenge.[34]

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[33]In responding to the motion to dismiss, the Government asked the district court for leave to amend its Complaint to plead knowledge with more detail if the court were to find that knowledge was a required element at the pleading stage. The district court denied that motion, having found that the Government had no viable claim under the MSP regardless of how it was pled. Because we reverse the district court's legal determination as to the viability of the Government's case, the district court's reason for denying leave to amend is no longer valid and that denial is accordingly vacated.

[34]The text of Part III.B(3) of this opinion has focused only on the Government's § 1395y(b)(2)(B)(iii) subrogation claim for double payment (relating to the primary obligor's liability to reimburse Medicare even though it has already paid the Medicare beneficiary). In its brief on appeal, the Government also argued, in somewhat summary fashion, that in such situation it also has a direct cause of action for double payment pursuant to §1395y(b)(2)(B)(ii), and that the "direct action for double payment" is not conditioned upon a determination that the primary obligor paid the Medicare beneficiary even though it knew or should have known that Medicare had already covered relevant expenses. In other words, the Government argues that § 1395y(b)(2)(B)(ii) creates a strict liability "direct cause of action for double payment." We note that the D.C. Circuit in HIAA, 23 F.3d at 417, apparently rejected this argument, inferring from the language of the statute that the Government had a claim against the "required or responsible" entity until that entity made payment, and thereafter had a claim against the person who received such payment. See 42 U.S.C. §1395y(b)(2)(B)(ii) ("The Untied States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service ... under a primary plan ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service"). The district court, following the D.C. Circuit, rejected the Government's argument on the same ground.

We need not in this case decide whether the inference drawn by the D.C. Circuit and the

district court is the only reasonable interpretation of the statute, because we reject the Government's argument in this case on other grounds. The only support for its position proffered by the Government in this case is 42 C.F.R. §411.24(i), which provides in relevant part:

> (i) *Special rules*. (1) In the case of liability insurance settlements and disputed claims under employer group health plans and no-fault insurance, the following rule applies: If Medicare is not reimbursed [by the recipient of the insurance payment] ... the third party payer must reimburse Medicare even though it has already reimbursed the beneficiary or other party.
>
> (2) The provisions of paragraph (i)(1) of this section also apply if a third party payer makes its payment to an entity other than Medicare when it is, or should be, aware that Medicare has made a conditional primary payment.

However, we do not believe that the regulation supports the Government's litigation position of strict liability without regard to knowledge or constructive knowledge. The regulation indicates that a third-party payor who pays the patient is still liable for a "double payment" to Medicare in two situations: (1) when the source of the third-party payment is a liability insurance settlement or a disputed claim under group insurance or no fault coverage, or (2) when other circumstances give the third-party payor knowledge or constructive knowledge of Medicare's prior payment. Both the language of the regulation and the explanation provided by HHS in promulgating the regulation suggest that the distinction between subparagraphs (1) and (2) is not between strict liability and liability only if there is knowledge or constructive knowledge. Rather, the use of the term "disputed claims" in subparagraph (1) indicates that HHS was singling out cases in which the third party would not pay until after considerable delay – which delay, coupled with the existence of the MSP statute and regulations, HHS apparently deems to be sufficient to constitute constructive knowledge that Medicare will have made a conditional payment. The explanation provided by HHS in promulgating its final version of the rule focuses upon constructive knowledge or "awareness," and bears out this interpretation:

> We agree that when an employer group health plan (EGHP) or no-fault insurer routinely pays primary benefits on behalf of a Medicare beneficiary without knowledge of Medicare's primary payment, the insurer has acted responsibly and should not be liable for reimbursing HCFA if HCFA is unable to recover from the party that received the insurer's primary payment. However, if a third party pays an entity other than Medicare even though it was, or should have been, aware that Medicare had made a conditional primary payment, the third party must reimburse Medicare. ... Liability insurers <u>should be aware</u> of Medicare involvement, and therefore should not pay a claim without first checking to find out if Medicare has made conditional payments. The EGHP or no-fault insurer <u>should be aware</u> that, if the claim was disputed, Medicare may have made a conditional payment.

4) Does the MSP's "double damages" provision apply to a payer that has paid the beneficiary but fails to promptly pay the Government's "double payment" reimbursement claim?

Medicare's right of action for double damages originates in Section 1395y(b)(2)(B)(ii), entitled "Action by United States." It provides that "the United States may bring an action against any entity which is required or responsible under this subsection to pay with respect to such item or service (or any portion thereof)

Medicare as Secondary Payer and Medicare Recovery Against Third Parties, 54 Fed. Reg. 41716, 41721 (Oct. 11, 1989) (emphasis added). Thus, neither the language of the regulation nor the official explanation at promulgation supports the Government's assertion of strict liability in this case. Rather, the regulation and official interpretation indicate that constructive knowledge is required.

Having rejected the Government's only authority for imposing strict liability with respect to a "direct cause of action for double payment" under § 1395y(b)(2)(B)(ii), we conclude that this case should proceed with the law of the case being that the Government must prove at least constructive knowledge to prevail in its claim for double payment under either § 1395y(b)(2)(B)(ii) or § 1395y(b)(2)(B)(iii).

As we noted in the text with respect to our discussion of the subrogation claim for double payment, we need not at this early stage of the litigation define the precise scope of constructive knowledge that will trigger liability, because constructive knowledge in the form of willful blindness has been amply pleaded in this case. Moreover, the contours of constructive knowledge were not adequately addressed by the district court and have not been adequately addressed in the briefs on appeal.

Although the district court opinion, the briefs on appeal, and this opinion have focused on the "double payment" claim, nothing in this opinion precludes the district court on remand from entertaining a Government claim pursuant to the "direct action for single payment," i.e., where the RSP Defendants have not yet paid or the RSP claimants have not yet received such payment. See 42 U.S.C. § 1395y(b)(2)(B)(ii) ("In order to recover payment under this subchapter for ... an item or service, the United States may bring an action against any entity which is required or responsible ... to pay with respect to such item or service ... under a primary plan ... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service") (parenthetical in original).

under a primary plan (and may, in accordance with paragraph (3)(A) collect double damages against that entity)" (emphasis added). Paragraph (3)(A), which the provision incorporates, then establishes a private cause of action for double damages "in the case of a primary plan which fails to provide for primary payment (or appropriate reimbursement) in accordance with such paragraphs (1) and (2)(A)."[35] There is no dispute that, under subparagraph (2)(B)(ii), the Government can sometimes bring a double damages action. The only disagreement is whether the qualifier "or appropriate reimbursement" empowers Medicare to recover double damages from an entity that has made its primary payment to the beneficiaries but fails to make a duplicate payment to Medicare on demand.

The district court ultimately rejected the Government's double damages claim on the same rationale that it dismissed its single damages claim. However, we have already reversed the district court's holding with respect to the Government's single damages claim. See Part III.B., *supra*. Accordingly, we also reverse the district court's dismissal of the Government's double damages claim and vacate the district court's rulings in that regard. While we expect the district court

[35]Paragraph (1) pertains to the responsibility of group health plans to assume primary responsibility for the coverage of their Medicare-eligible beneficiaries, and is not implicated here.

on remand to address the double damages claim on a clean slate, we offer a few comments to call attention to several pertinent matters.

We note that the statute is not clear as to when the Government is entitled to more than single damages. The statute gives the Government the right to seek double damages "in accordance with paragraph (3)(A)," see 42 U.S.C. § 1395y(b)(2)(B)(ii). Paragraph (3)(A) in turn establishes a private cause of action for double damages if a primary plan "fails to provide for primary payment (or appropriate reimbursement) in accordance with ... paragraphs (1) and (2)(A)." Paragraph (1) prohibits an employer group health plan from offering lesser coverage to employees over 65 or their spouses on the basis of their Medicare eligibility. Paragraph (2)(A) defines which sources of outside coverage will be primary with respect to Medicare. The pivotal ambiguity is in the term "reimbursement," which can plausibly refer either to the insurer's obligation to reimburse Medicare (the Government's view), or the insurer's duty to reimburse the injured party for out-of-pocket medical expenses (the Defendants' view), or both.

The pertinent regulations to which we owe deference are codified at 42 C.F.R. §§ 411.24(c)(1) and (c)(2). In these regulations, HHS draws a distinction between claims in which the insurer willingly repays Medicare versus those in

which Medicare is forced to litigate. Only in the second category of cases, according to the regulations, will the Government demand double damages. The Government cited the regulations in its Complaint, but did not rely on § 411.24(c) in its briefs to the district court or here. The district court did not pass on whether the regulations were authorized by and consistent with the statute, nor – so far as we can find – has any other federal court.

Another matter to which the district court should give attention is whether the proof required to establish entitlement to double damages is the same as that required for single damages, and if that seems suggested by the statutory language, whether it makes sense in light of the statutory structure and purpose. Finally, if the same proof or standard is suggested for both single and double damages, the court should consider whether that would be inconsistent with the common-law principle that an award of multiple damages usually requires a heightened showing of wrongful intent.

5) Can either the MSP Defendants or the Escrow Agent be sued under the MSP as an entity that "received payment" from a primary plan?

The Government argues that the MSP Defendants can be sued under § 1395y(b)(2)(B)(ii) as entities that "received payment" from a primary plan, on the basis that they received payment from their liability carriers. The Government

further argues that the Escrow Agent is reachable under the same provision because it received payment from the MSP Defendants and/or their insurance companies. The district court dismissed both contentions on the basis that, under the common understanding of the term "received," the statute covers only the ultimate recipient of the payments – not someone merely handling the money as a conduit.

The pertinent statutory passage provides that "the United States may bring an action against any entity which is required or responsible under this subsection to pay... or against any other entity (including any physician or provider) that has received payment from that entity with respect to the item or service(.)" 42 U.S.C. § 1395y(b)(2)(B)(ii). Under the doctrine of *ejusdem generis*, "when an enumeration of specific things is followed by some more general word or phrase, then the general word or phrase will usually be construed to refer to things of the same kind or species as those specifically enumerated." City of Delray Beach v. Agricultural Ins. Co., 85 F.3d 1527, 1534 (11th Cir. 1996); see also Snapp v. Unlimited Concepts, Inc., 208 F.3d 928, 934 (11th Cir. 2000) ("We must interpret 'a general statutory term ... in light of the specific terms that surround it.'") (quoting Hughey v. United States, 495 U.S. 411, 419, 110 S.Ct. 1979, 1984 (1990)).[36]

[36]In Snapp, we examined a provision in the Fair Labor Standards Act, 29 U.S.C. § 216(b), providing that "[a]ny employer who violates the provisions of section 215(a)(3) of this title shall be liable for such legal or equitable relief as may be appropriate... including without limitation

Applying *ejusdem generis* here, we can assume that Congress intended the term "any other entity" to be understood with reference to "physician" and "provider," and to encompass only entities of like kind.

The agency's implementing regulation, 42 C.F.R. § 411.24(g), lists as examples of entities liable as recipients: "a beneficiary, provider, supplier, physician, attorney, State agency or private insurer that has received a third party payment." This list is broader than that furnished by the statute, but even the agency's examples all are entities that would be receiving payment under a claim of right or entitlement to retain it.

The Escrow Agent clearly is not of like kind to a doctor or provider. The uncontested evidence is that the Escrow Agent acts in a purely ministerial role serving the district court. All of the discretionary decisions about which claims to honor are made by the Claims Office, which is a separate entity.[37] The Escrow Agent is limited to petitioning the court if he wishes to refrain from making a payment. His only real power appears to be in making sure that the RSP

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employment, reinstatement, promotion, and the payment of wages lost and an additional equal amount as liquidated damages." Applying the principle of *ejusdem generis*, the Snapp court held that punitive damages were entirely unlike the remedies enumerated in the statute, all of which were intended to compensate the plaintiff rather than punish the defendant; therefore, we held that punitive damages were not intended by Congress as part of the remedial scheme. Id. at 935.

[37]When a potential class member appeals the denial of her claim, the appeal goes first to the Claims Administrator and then to the district court, not to the Escrow Agent.

Defendants continually contribute enough money to sustain the settlement fund, which does not equate to discretion over the payment of claims.

In HIAA, the D.C. Circuit invalidated as exceeding HHS' statutory authority the former 42 C.F.R. § 411.24(e), which provided that Medicare's direct right of action under 42 U.S.C. § 1395y(b)(2)(B)(ii) extended to a third-party administrator of an employer self-insurance plan as an entity charged with "making primary payment." The court held that the statute contemplated liability only for parties who were responsible *for payment*, not merely responsible for the ministerial function of *making* the payment. The court likened HCFA's interpretation to extending liability to the bank on which the health insurers benefit checks were drawn, even though the bank obviously had no discretion over whether and to whom payment was made. Id. at 416-17.

In 1996, Congress amended the MSP, reinstating in part provisions struck down by HIAA. Specifically, the 1996 amendments to § 1395y(b)(2)(B)(ii) provide that the Government "may not recover from a third-party administrator under this clause in cases where the third-party administrator would not be able to recover the amount at issue from the employer or group health plan and is not employed by or under contract with the employer or group health plan at the time the action for recovery is initiated(.)" Although this legislation evidences

congressional intent to reach third-party administrators under certain circumstances, it does not assist the Government here, since it is conceded that Gentile is an agent of the court, neither employed by nor under contract with the RSP Defendants.[38]

Finally, any analogy between the Escrow Agent and a third-party administrator is inapt. While it is true that Congress has clarified that HHS can sometimes lodge a claim against a third-party administrator even where the administrator is merely a "pass-through" who is not ultimately responsible for paying the claimant, the potential analog to a third-party administrator in our case is the Claims Office, not the Escrow Agent. A self-insurer hires a third-party administrator to do what the Claims Office is doing here: to decide who gets paid and how much. The Government, however, did not name the Claims Office or its

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[38]The only case the Government cites supporting its position that a trustee-like entity could be regarded as having "received" the money it handles is King v. United States, 379 U.S. 329, 85 S.Ct. 427 (1964). King arose under an entirely different statutory scheme – it evolved out of a Chapter 11 bankruptcy proceeding. The court-appointed "distributing agent" in that case (significantly, the president of the bankrupt company as opposed to a disinterested functionary) was held to be personally liable for having depleted the bankruptcy estate by paying private claims before paying the Government, because of his considerable authority to object to the way the estate was distributed. The King court strictly limited the holding to its facts. See id., 379 U.S. at 339, 85 S.Ct. at 432 ("We are not prepared to articulate any general rule defining the responsibility of distributing agents to make and press... objections [to a plan of distribution]. We hold only that King, on the facts of this case, did have such a responsibility. As president of the debtor corporation he must have been aware of the Government's potential claim(.)"). It is a considerable stretch to apply such a limited, fact-specific holding to our entirely different context.

administrator as defendants. Consequently, the district court was correct in dismissing Count VI against the Escrow Agent.[39]

We reach a different conclusion, however, as to the RSP Defendants. Section 411.24(g) of the regulations lists an "insurer" as an example of a party that may be liable as having received payment. As we have seen, the MSP treats self-insured entities as "insurers." The structure of the underlying transaction here – the RSP manufacturers paid into the settlement fund out of their own earnings, then submitted claims to their liability carriers for partial reimbursement – is not unlike that commonly occurring in which one insurance carrier re-insures or carries excess liability coverage, thus making it both a payer (to its insured) and a recipient (in relation to its re-insurer). We believe that is the sort of arrangement HHS contemplated in including insurers and state agencies among the class of parties

[39]From the comments of counsel for the Government at oral argument, and from the parties' discussion at the hearing before the district court on May 15, 2000, we discern that the Government's main interest in laying a claim for reimbursement against the Escrow Agent was to keep the Agent in the case as a party so that he would be subject to any order granting appropriate injunctive relief. We note that Count VII, seeking injunctive relief against the Escrow Agent, is still alive, see Part III.B.(6), *infra*. Thus, pending further developments in the district court on remand, the Escrow Agent remains a party. In any event, we believe that the district court would retain the ability to direct the Escrow Agent's management of the settlement funds as required to preserve the Government's rights, whether or not substantive claims remain against him, either pursuant to the court's supervisory powers, or by retaining him or joining him to afford appropriate relief to the parties.

that could be liable on the basis of receiving payment.[40] The RSP Defendants do not argue that the regulation is invalid, and we see nothing unreasonable in the regulation as applied to this case.

The record is devoid of detail about the role of the Defendants' liability insurance carriers. If our understanding is correct – that the RSP companies initially financed the settlement, then filed claims with their insurers, which will provide reimbursement based on their independent evaluation of the class members' claims – then the district court's description of the RSP Defendants as mere intermediaries between their insurance companies and the class members is not accurate. Rather, it appears that the RSP Defendants would keep the insurance companies' payments to reimburse them for what they paid the class members. Consequently, it is conceivable that the Government could prove that the RSP Defendants "received payment" from a third party within the meaning of the statute.

6) Does the Government have a claim under the MSP statute for declaratory and injunctive relief (Counts V and VII)?

[40]The references to "a State agency" and "a private insurer" in § 411.24(g) indicate that HHS believes a party can be a recipient of payment even if all it is receiving is reimbursement for its own prior payments, rather than (as with a doctor) a fee for services rendered.

In addition to damages, the Government's Complaint sought: (1) a declaratory judgment that the RSP Defendants are liable under the MSP to reimburse Medicare for past payments to breast implant patients, and are obligated to provide Medicare with notice of all payments to Medicare beneficiaries, and (2) an injunction prohibiting the Escrow Agent from making disbursements to Medicare patients pending resolution of the Government's claims, and to compel disclosure of identifying information concerning all past or contemplated settlement payments to Medicare beneficiaries.

Although both declaratory relief and injunctive relief may be unnecessary depending on further developments on remand, the entire landscape of this case has changed with our disposition of this appeal. We prefer for the district court to evaluate the need for such relief in the first instance in light of the new landscape.[41] We therefore vacate the dismissal of the Government's claims for declaratory and injunctive relief, which will enable the district court to fashion the most appropriately tailored remedy.[42]

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[41]For example, it is not beyond doubt that there may be need of injunctive relief to afford complete relief to the parties.

[42]We suspect that most of the Government's requests for injunctive relief will be effectively moot in any event. Because we reinstate the bulk of the Government's substantive claims for damages, discovery can now proceed and the Government will thereby gain access to the information it sought by way of a declaratory or injunctive order. In light of this likely mootness, we do not address the Defendants' arguments regarding whether, and to what extent,

VII. CONCLUSION

We reverse the district court's dismissal of Counts I, II, III and IV as they regard the RSP Defendants. We also vacate the district court's dismissal of the Government's requests for declaratory and injunctive relief in Counts V and VII. Finally, we affirm the district court's dismissal of Count VI, which sought reimbursement from the Escrow Agent as an entity receiving payment.[43]

AFFIRMED IN PART, REVERSED IN PART, AND REMANDED.

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the MSP statute allows for declaratory or injunctive relief as a remedy.

[43] As noted, the Government has abandoned Counts VIII and IX.