

# Hot Topics:

*Medicare Settlement Reporting Requirements;  
MDL Master Complaints after Twombly and  
Iqbal; and Ex parte Communication with  
Treating Physicians in an MDL Setting*

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## *Medicare Settlement Reporting Requirements; MDL Master Complaints after Twombly and Iqbal; and Ex parte Communication with Treating Physicians in an MDL Setting*

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### **I. MMSEA Mandatory Reporting: Medicare Wants to Know**

Section 111 of the Medicare, Medicaid and SCHIP Extension Act of 2007 (“MMSEA” or “Section 111”), 42 U.S.C. §1395y(b)(8), obligates entities that resolve certain claims with Medicare beneficiaries to report details of the settlement to the federal government. Noncompliance can result in \$1000 *per day, per claim* penalties. The agency that administers Medicare and runs the reporting program, the Centers for Medicare and Medicaid Services (“CMS”), issued an updated Section 111 User Guide in February 2010 that delays reporting deadlines but requires time-sensitive actions to demonstrate compliance. *See* MMSEA Section 111 Medicare Secondary Payer Mandatory Reporting User Guide, Liability Insurance (Including Self-Insurance), No-Fault Insurance, and Workers’ Compensation User Guide, Version 3.0 (Feb. 22, 2010) (“User Guide”), *available at* <http://www.cms.hhs.gov/mandatoryinsrep/>.

Section 111 requires entities to (1) determine if a settlement or payment is reportable, (2) confirm whether a claimant is a Medicare beneficiary, (3) identify whether the insured or its insurer has the reporting responsibility, and (4) collect and submit information on reportable settlements. Reporting entities should be cognizant of state and federal privacy and confidentiality obligations implicated in the reporting process and looming issues related to the Medicare Secondary Payer (“MSP”) program.

#### **A. Statutory Justification for Reporting Obligations**

Congress enacted Section 111 to help CMS identify lawsuit settlements and other payments to Medicare beneficiaries. The reporting process notifies CMS of a Medicare beneficiary’s receipt of a settlement related to injuries for which Medicare has paid medical expenses. Under existing MSP provisions, Medicare can recover expenses made on behalf of a beneficiary from anyone who receives the settlement (plaintiff or plaintiffs’ counsel) or pays the settlement (settling defendants and/or their insurers). *See* 42 U.S.C. §1395y(b)(2)(B); 42 C.F.R. §§411.24, 411.37. The Medicare lien permits the federal government to pursue the defendant even *after* the settlement is paid to the claimant. *Id.* If Medicare is forced to file a lawsuit to recover conditional payments, it can seek double damages from these parties. *Id.* Section 111 requires defendants to self-disclose settlements to CMS so the government can pursue the beneficiary—or the defendant itself—to recoup medical expenses.

#### **B. Determining Which Entity Has the Reporting Obligation**

Section 111 applies to “liability insurance (including self-insurance), no fault insurance, and workers compensation” plans and arrangements. 42 U.S.C. §1395y(b)(8)(F). CMS broadly interprets self-insurance to include entities that carry their own risk. CMS holds that “[s]elf-insurance or deemed self-insurance can be demonstrated by a settlement, judgment, award, or other payment to satisfy an alleged claim (including any deductible or copay on a liability insurance, no-fault insurance, or workers’ compensation law or plan) for a business, trade or profession.” User Guide at 244. Therefore, even if an entity has liability insurance and is not self-insured as that term is commonly known in the insurance industry, an entity’s payment of a deductible or copay to a claimant is considered self-insurance for purposes of Section 111. As CMS notes, “such deductibles and co-payments constitute liability self-insurance, and require reporting by the self-insured entities.” *Id.* at 245.

CMS's February 2010 updated User Guide eases the regulatory burden on insureds by placing the reporting duty on the insurer in the typical liability settlement situation. In general, the insurer incurs the reporting responsibility when the insured's settlement amount is limited to its deductible. In this instance the insurer must report the deductible amount and any excess. The insured incurs the reporting responsibility if the share of the settlement for which the insured finances exceeds its deductible or if the insured pays the settlement without recourse to insurance. The insured must also report if it pays the settlement directly to the claimant then seeks reimbursement from its insurer under a policy that provides for coverage beyond a certain limit (such as reinsurance, excess, umbrella, or stop-loss policies). Multiple defendants (or their insurers) that are subject to joint and several liability must each report the full settlement. *See CMS Alert, "Who Must Report" (Feb. 24, 2010), available at <http://www.cms.hhs.gov/MandatoryInsRep>.*

Under fronting policies, the insured retains the reporting obligations to the extent that it pays the claim. The reporting obligation attaches to the original payment by the insurer on behalf of the insured; a reporting insurer's subrogation action against another insurer is not reportable.

CMS identifies the entity with the reporting duty as the responsible reporting entity ("RRE"). RREs cannot "contract away" reporting obligations to a third party reporting vendor or administrator. Even if the agent makes decisions regarding payment, the duty to report and accompanying noncompliance penalties apply to the RRE.

Third party administrators or insurers of group health plans that provide coverage to Medicare beneficiaries, and defendant-insurers that assume responsibility for ongoing medical expenses, typically in the workers' compensation context, are subject to similar reporting obligations. Group health plans and ongoing medical expenses reporting are beyond the scope of this article.

## **C. Identifying Reportable Events**

### **1. Settlement, judgment, award or "other payment"**

In general, RREs must report a settlement, judgment, award or "other payment" (collectively referred to as "settlements") with or to Medicare beneficiaries that are finalized after October 1, 2010, and release liability for medical expenses. User Guide at 6.

Reportable events include traditional liability settlements or other claim resolution strategies and nonmonetary payments. CMS has repeatedly suggested that health care providers may also need to report write-offs, no-bills and other risk management or patient goodwill gestures. CMS interprets write-offs as an indication of payment responsibility analogous to a settlement. Similarly, CMS has suggested that reporting obligations may apply to a clinical trial sponsor's agreement to pay for medical expenses related to the trial. This expansive interpretation of Section 111's reporting requirements is a significant unresolved aspect of the reporting program. Hospital risk management activities such as write-offs and agreements by clinical trial sponsors to assume liability of trial participants are not reportable until further guidance is issued by CMS. However, CMS recommends that RREs that engage in such activities should track them beginning October 1, 2010, so they can be reported if required. *See CMS Alert (Feb. 24, 2010).*

A swap of an allegedly defective product in exchange for a new item and a release of liability for medical expenses is likely a reportable event if the value of the new product exceeds the threshold amount. *See infra* Section I.C.5.

That Medicare was neither billed nor paid for a specific claim is not a factor in determining if a settlement or payment is reportable. Even if the RRE knows that Medicare was not billed, the settlement or payment related to that claim may still need to be reported if it meets the other Section 111 criteria.

## **2. Date of settlement**

Settlements finalized on or after October 1, 2010, must be reported. Reporting duties arise when the settlement is signed or approved by a court (if necessary). If there is no written agreement, the reporting obligation arises with the payment.

## **3. Claimant's Medicare status**

The reporting rules apply if the claimant is a Medicare beneficiary at the time of settlement. Upon submission of a Social Security or Medicare health insurance claim number ("HICN"), Medicare will confirm whether a claimant is a Medicare beneficiary. Note that individuals under age 65 with certain disabilities or conditions can qualify for Medicare.

## **4. Nature of claim**

A settlement of a claim for medical expenses or one that releases potential liability for alleged medical expenses or "has the effect of releasing medicals" is subject to the reporting rules. User Guide at 85. Reporting cannot be avoided by joint agreements that the settlement does not cover medical expenses. CMS concedes it is unresolved whether a settlement that releases a defendant from potential liability for medical expenses that are not expressly alleged must be reported. In a recent teleconference, CMS suggested it would issue additional guidance on this issue. CMS Section 111 Town Hall Teleconference (Feb. 25, 2010).

## **5. Amount of settlement**

Liability settlements finalized before December 31, 2011, are exempt from reporting if less than \$5000. The exemption reduces to \$2000 between January and December 2012 and to \$600 between January and December 2013.

## **6. Date of "incident"**

RREs generally are not required to report settlements where the date of incident was before December 5, 1980. CMS defines the DOI as the date of the accident for "an automobile wreck or other accident." User Guide at 124. However,

[f]or claims involving exposure (including, for example, occupational disease and any associated cumulative injury) the DOI is the date of first exposure. For claims involving ingestion (for example, a recalled drug), it is the date of first ingestion. For claims involving implants, it is the date of the implant (or date of the first implant if there are multiple implants).

*Id.* An important and ill-defined exception extends the scope of reportable exposure events, specifically asbestos and other environment exposure allegations:

For claims involving "exposure," [the December 5, 1980, cutoff] means that there was no exposure on or after December 5, 1980, alleged, established, and/or *released*. If any exposure for December 5, 1980 or a subsequent date was claimed and/or *released*, then Medicare has a potential recovery claim and the RRE must report for Section 111 purposes.

*Id.* at 86 [emphasis added]. The controlling factor is the date of alleged physical exposure to the asbestos (not manifestation of injury).

The typical general release language releases liability for exposure “from all time,” including potential (but not alleged) exposure from after 1980. Accordingly, the User Guide’s instructions can be read to require RREs to report general releases. CMS recognizes this concern and may issue additional guidance on how to specify the dates of exposure. CMS is bound by neither stipulations between litigants nor affidavits by claimants regarding dates of exposure. Until such guidance issued, RREs should consider reporting all asbestos settlements subject to such general releases.

CMS is also expected to issue additional guidance on identifying and reporting mass torts settlements involving large numbers of plaintiffs, counsel, and defendants.

## **D. Safe Harbor Regulatory Developments**

### **1. CMS model language form**

CMS has provided a model form for use in obtaining Social Security and/or HICNs from the claimant. RREs cannot fulfill their reporting duties without one of these identifiers. If the claimant completes section III of the model form acknowledging his refusal to provide Social Security/Medicare Identification numbers, CMS will consider the reporting entity to be in compliance with its Section 111 requirements. In such instances, the reporting entity does not need to submit a report (even if the claim is reportable and even if the reporting entity later learns the claimant is a Medicare beneficiary). MMSEA Section 111 HICN, SSN Collection, NGHP Model Language (Aug. 24, 2009), available at <http://www.cms.hhs.gov/MandatoryInsRep>.

The exception does not apply if the RRE has actual knowledge that the claimant is a Medicare beneficiary. RREs such as health care providers that have a claimant’s HICN or otherwise know their Medicare status cannot take advantage of the reporting safe harbor.

Executing the safe harbor form requires the claimant to acknowledge that their refusal to provide the information potentially constitutes a violation of Medicare coordination of benefits requirements; therefore, few claimants can be expected to cooperate. CMS recognizes that this potential scenario puts reporting entities at risk of noncompliance for no fault of their own. Therefore, CMS suggests that RREs develop a process to try to obtain the information and carefully document all efforts to obtain a signed safe harbor form, including proof of receipt documents. CMS has not clarified what steps should be taken in this regard to meet the safe harbor requirements, and additional guidance is expected.

### **2. Compliance deadlines**

The February 2010 User Guide notes that a reporting entity can remain in compliance by timely registering for the reporting process, completing the testing cycle, and submitting punctual and accurate reports; or alternatively, communicating with the Medicare as to why it cannot keep on schedule. Entities that have a “reasonable expectation of having claims to report” must register in enough time to allow a full calendar quarter for testing before submitting reports. CMS Alert “NGHP RRE Compliance” (Feb. 24, 2010). In order to stay on schedule to adhere to the compliance guidelines, entities that expect to report should register by September 30, 2010, to allow for a calendar quarter of testing before first quarter 2011 reporting deadlines. No exemptions are currently provided for small businesses or isolated settlements (such as one reportable event *per year*).

Reports are electronically submitted every quarter during a preassigned seven-day reporting window. The initial reports are due between January 1 and March 30, 2011, and must include settlements signed on or after October 1, 2010.

## **E. Confidentiality Obligations**

Section 111 reporting requires electronic exchange of the settlement amount and information on the claimant such as Social Security number and medical details. Accordingly, RREs should be aware of state and federal privacy and confidentiality issues raised by Section 111 reporting. *See* Supporting Statement for the MMSEA Section 111 Reporting Provisions at 16 (Aug. 8, 2008).

For example, RREs must sign a Section 111 Data Use Agreement (“DUA”) with the federal government. *See* User Guide at 113. The DUA requires RREs to implement administrative, technical, and physical safeguards against unauthorized use, access, and disclosure of the reported information; train personnel on the confidentiality obligations; and grant CMS access for security inspections, among other duties. The DUA notes that personnel who have access to the information must be advised of such safeguards and of the “administrative, civil and criminal penalties for noncompliance contained in applicable Federal laws.” User Guide at 113.

The DUA also requires RREs to ensure that any vendors hired to assist with reporting duties also fulfill these obligations. Accordingly, contracts with vendors should reflect the DUAs requirements and allocate responsibility for Section 111 penalties.

Section 111 reporting requires insureds (even if they are not the RRE) to collect and disclose Social Security numbers and significant amounts of personal and medical information on the claimant. Accordingly, defendants should be aware of applicable privacy obligations, including but not limited to the Health Insurance Portability and Accountability Act and its attendant regulations, *see* 45 C.F.R. part 160 *et seq.*; state-specific privacy statutes; and breach notification requirements such as the recently enacted Health Information Technology for Economic and Clinical Health Act, enacted as part of the Recovery Act. Contracts with third party reporting vendors (if any) should allocate responsibility for obligations and penalties under applicable law.

Section 111 mandates disclosure of the settlement amount regardless of any confidentiality agreement between the parties. CMS contends that it is entitled to the settlement information because Section 111 serves a coordination of benefits purpose. *See* 42 C.F.R. §411.24(a); CMS MMSEA Section 111 Teleconference Tran., at 34 (Jan. 22, 2009). Accordingly, RREs should be aware that Section 111 information will be maintained in a governmental database. It seems unlikely that such information would be released under the Freedom of Information Act (“FOIA”) due to the FOIA exemption for requests that intrude on personal privacy. *See* 5 U.S.C. §552(b)(6) (2000). CMS agrees, noting in a December 15, 2009, teleconference that federal privacy restrictions would likely preclude disclosure of information on individual settlements. However, it is unclear whether federal privacy limitations would prohibit disclosure of de-identified, aggregated settlement information--for example, the total amount settled by a defendant in a given year or for a specific alleged product defect. CMS contends that logistical challenges render such disclosure unlikely since the information is not organized in aggregated form. Such information will, however, be used by CMS to identify secondary payer circumstances and facilitate recovery efforts.

## **F. Penalties and MSP Recovery**

An RRE that fails to comply with the Section 111 reporting requirements is subject to a civil money penalty of \$1000 *per day* of noncompliance, *per claim*. 42 U.S.C. §1395y(b)(8)(E). For example, a ten-day delay in submitting reports on five settlements could result in a \$50,000 penalty. CMS noted in 2008 that guidelines for penalty assessment (and presumably the standards and procedures for appeals) would be issued before

enforcement; but as of March 2010 no such guidelines had been released. CMS concedes there are no “bright lines” for enforcement but noted that penalty deliberations would take into account whether an entity “ma[de] the effort” to comply with the reporting requirements. CMS MMSEA Section 111 Teleconference Tran., at 45 (Feb. 25, 2009).

In the meantime, RREs should revise release and settlement documents to reflect the reporting requirements, including indemnification provisions for penalties. Although not required by Section 111, developing MMSEA fact sheets to confirm the reportable information with plaintiffs may resolve future disagreements over accuracy—especially if Medicare commences recovery efforts against the beneficiary based on the report.

Similarly, contracts with third party vendors who assist with reporting (if any) should allocate financial responsibility for penalties imposed due to the third party’s acts or omissions.

Section 111 does not change Medicare’s existing authority under the MSP program to recover conditional payments from settling defendants, even after the settlement is funded. The Section 111 materials and CMS-hosted teleconferences have carefully avoided substantive analysis of lien-related issues. Nonetheless, four factors suggest greater enforcement of the government’s ability to recover Medicare liens. First, the MSP statute was amended in 2003 (with subsequent regulatory revisions in the following years) to clarify the government’s ability to pursue defendants for recovery actions. *See, e.g.*, Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. 108–173. Second, the Section 111 reporting process notifies the federal government of settlements that may be subject to “Medicare lien” recovery actions. Third, the federal government has recently filed aggressive MSP recovery lawsuits seeking double damages against both settling defendants and plaintiffs’ counsel. *See United States v. Stricker*, C/A No. 1:09-02423-KOB (N.D. Ala. Dec. 2, 2009); *United States v. Harris*, C/A No. 5:08-102 (N.D. W.Va. Mar. 26, 2009). Finally, political rhetoric from both sides of the aisle feed efforts to reduce “waste, fraud and abuse” in the Medicare system, including recovery of improper conditional payments to beneficiaries.

## **G. Conclusion**

CMS has left unresolved many issues related to Section 111 reporting, including but not limited to (1) implementation of the Safe Harbor provisions, (2) assessment of nonreporting penalties, (3) mass tort and risk management reporting, (4) determining the RRE during insurance coverage disputes between insureds and insurers, and (5) most significantly, minimizing MSP consequences and liabilities of Section 111 reporting. Regulatory authorities have suggested additional guidance will be issued before the October 1, 2010, deadline to begin tracking reportable incidents.

## **II. MDL Master Complaints after *Twombly* and *Iqbal***

For 50 years, courts applied the *Conley v. Gibson* test to motions to dismiss, which required that “a complaint should not be dismissed for failure to state a claim unless it appears *beyond doubt* that the plaintiff can prove *no set of facts* in support of his claim which would entitle him to relief.” 355 U.S. 41, 45-46 (1957) [emphasis added]. In 2007, the Supreme Court replaced this standard with a plausibility standard, requiring that a complaint plead enough facts to state a claim for relief that is plausible on its face. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007). The Court’s logic was that because a court must accept a complaint’s factual allegations—but not legal conclusions—as true, complaints must include enough factual allegations to make a cause of action plausible, and not simply recite the cause of action’s legal elements. *Twombly*, 550 U.S. at 555 [internal quotation omitted]. In *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the Court held that the plausibility

standard applied to all complaints in civil actions. The upshot is that a plaintiff may “not unlock the doors of discovery . . . armed with nothing more than conclusions.” *Id.* at 1949-50.

*Twombly* and *Iqbal* have generated tremendous discussion and debate in and out of the courtroom. In less than three years, *Twombly* and *Iqbal* have been discussed in tens of thousands of cases, nearly 300 law review articles, and more than 125 treatises. The ramifications of these cases are debated by legal academics and by bloggers, and have attracted the attention of the U.S. House of Representatives and the Senate, which are considering legislation to restore the *Conley* pleading standard. See Open Access to Courts Act of 2009, H.R. 4115, 11th Cong. (2009) (in committee); Notice Pleading Restoration Act, S.1504, 11th Cong. (2009) (in committee).

Against this backdrop, MDL defendants must decide whether to file 12(b)(6) motions and press for a master complaint. Important considerations include the practical impact of the plausibility standard, strategy for precedent-building in light of case-specific circumstances, whether sufficient groundwork has been laid for the MDL court to apply the plausibility standard to the master complaint, and the likelihood that the standard also applies to affirmative defenses.

### **A. Practical Impact**

Despite the extensive debate over the issue, the impact on the number of motions to dismiss filed and percentage of motions to dismiss granted remains unclear. Some data suggests that the percentage of motions to dismiss granted has remained steady while other studies show that the percentage of motions granted has increased. Moreover, review of individual decisions reveals that courts considering complaints that allege similar types of facts in support of similar causes of action reach different results. The uncertainty of the practical impact of *Twombly* and *Iqbal* underscores the need to consider the individual circumstances of each case before filing motions to dismiss.

The Federal Judicial Center compiled data regarding motions to dismiss from 94 district courts from January 2007 through December 2009 (*i.e.*, pre- and post-*Twombly* and *Iqbal*). See Federal Judicial Center, *Motions to Dismiss Information on Collection of Data* (Feb. 12, 2010), at [http://www.uscourts.gov/rules/Motions\\_percent20to\\_percent20Dismiss.pdf](http://www.uscourts.gov/rules/Motions_percent20to_percent20Dismiss.pdf). The data reveals that the percentage of motions to dismiss granted during this period remained steady, generally hovering between 35 and 40 percent. Several law review articles, however, note that the grant rate of motions to dismiss Title VII cases, disability cases, and civil rights cases jumped by well over ten percent after *Twombly* and *Iqbal*. See Patricia Hatamyar, *The Tao of Pleading: Do Twombly and Iqbal Matter Empirically*, 59 Am. U. L. Rev. 553 (2010), available at <http://www.wcl.american.edu/journal/lawrev/59/59-3.cfm>; Joseph A. Seiner, *Pleading Disability*, 51 B.C. L. Rev. 95, (2010), available at <http://www.bc.edu/schools/law/lawreviews/bclawreview.html>.

The likely difference between the Federal Judicial Center data and the dismissal rates discussed in the law review articles is that the Federal Judicial Center report was derived from docket searches for motions to dismiss regardless of the grounds whereas the authors of the law review articles conducted more targeted searches for *Twombly* and *Iqbal*. Professor Hatamyar performed a statistical analysis of a random sample of 12(b)(6) motions from 1200 cases (500 before *Twombly* and 500 after, and 200 cases after *Iqbal*), and found that courts granted 46 percent of the motions before *Twombly*, 48 percent of the motions after *Twombly*, and 56 percent of the motions after *Iqbal*. Patricia Hatamyar, *The Tao of Pleading: Do Twombly and Iqbal Matter Empirically*, 59 Am. U. L. Rev. 553, 556 (2010), available at <http://www.wcl.american.edu/journal/lawrev/59/59-3.cfm>. Professor Seiner reviewed 500 decisions regarding 12(b)(6) motions in the disability context decided one year before and one year after *Twombly*, and found that even though courts were inconsistent in whether they used the *Twombly* standard or the older *Conley* standard, the percentage of motions to dismiss that were

either granted or granted in part rose from 64.4 percent to 78.5 percent. Joseph A. Seiner, *Pleading Disability*, 51 B.C. L. Rev. 95, 118 (2010), available at <http://www.bc.edu/schools/law/lawreviews/bclawreview.html>.

Moreover, the plausibility standard is subject to interpretation by lower courts, and complaints that allege similar facts can meet different fates. For example, in *Taggart v. Moody's Investors Service*, No. 06-CV-3388, 2007 WL 2076980 (S.D.N.Y. July 17, 2007), the plaintiff brought, among other things, a discrimination claim against her former employer under the Americans with Disabilities Act. The defendant moved to dismiss on 12(b)(6) grounds. Although the plaintiff alleged “undiagnosed maladies,” “sudden abdominal crisis,” “deliberate needle surgery,” a parasite infection that was “severely crippling both physically and mentally,” and Lyme disease, the district court granted the defendant’s motion, reasoning that the plaintiff had failed to sufficiently allege a disability under the ADA and the *Twombly* pleading standard. *Id.* at \*\*7-8. In *Cox v. True North Energy*, 524 F. Supp. 2d 927 (N.D. Ohio 2007), the plaintiff also brought, among other things a discrimination claim against her former employer under the ADA. The plaintiff alleged that she suffered from kidney cancer, and defendant moved to dismiss arguing, as in *Taggart*, that plaintiff did not sufficiently allege a disability. *Id.* at 944. The district court, however, denied the motion, reasoning that whether a plaintiff is disabled is a fact-based inquiry that “is not generally motion to dismiss territory,” and “it is at least plausible under the facts as alleged that Cox was disabled by virtue of the life threatening cancer . . . .” *Id.* at 944, 945 [quotation omitted].

The plausibility standard has led to mixed results in drug and device litigation, too. For example, in *Jozwiak v. Stryker Corp.*, 6:09-cv-1985-Orl-19GJK, 2010 WL 743834 (M.D. Fla. Feb. 26, 2010), defendant-manufacturers of pain pumps moved to dismiss the plaintiff’s complaint for failure to state a claim as to, among other things, design defect. In support of her claim, the plaintiff alleged that each manufacturer designed, manufactured, marketed, and sold the pain pump that was installed during her surgery (but she did not identify which manufacturer manufactured her pain pump), that the pain pump was designed to deliver anesthetic pain medication that defendants should have known was toxic, that her pain pump contained anesthetic pain medicine, and that she suffered injuries. *Id.* at \*6. The court denied the defendants’ motion and ruled that these facts were sufficient to establish each element of the plaintiff’s design-defect claim. In *Frey v. Novartis Pharmaceuticals Corp.*, 642 F. Supp. 2d 787 (S.D. Ohio 2009), Novartis moved to dismiss the plaintiff’s complaint for failure to state a claim as to—among other things—design defect. In support of her claim, the plaintiff alleged the same kind of facts that the plaintiff alleged in *Jozwiak*, namely that Novartis designed, manufactured, marketed, and sold Trileptal, that Trileptal was designed to be an anticonvulsant-antiseizure medicine that caused health risks that Novartis downplayed, that plaintiff ingested Trileptal, and that she suffered injuries. *Id.* at 789-90. In contrast to the ruling in *Jozwiak*, however, the district court granted Novartis’s motion to dismiss the plaintiff’s design-defect claim, ruling that the plaintiff “simply provided a formulaic recitation of the elements of a claim . . . [and has] not alleged any facts that would permit the Court to conclude that there was a defect in the design . . . and that the defect was the proximate cause of Amanda Frey’s alleged injuries.” *Id.* at 795. Regardless of the overarching benefit to the plausibility standard, each of these cases underscores that courts may reach different results even with similar facts alleged in support of similar causes of action.

## **B. Strategic Impact**

Given the uncertain practical consequences, defendants should not view the *Twombly* and *Iqbal* plausibility standard as a silver bullet. As a general matter, defendants should evaluate the circumstances surrounding each complaint rather than filing 12(b)(6) motions as a matter of course. First, the research conducted to date does not seem to indicate that defendants will be hugely more successful under the plausibility standard than they were under the *Conley* standard. Second, defendants should consider the negative precedential effect of inconsistent results. Third, if defendants file 12(b)(6) motions as a matter of course, the motions may serve

as fodder for the plaintiffs' bar to continue lobbying Congress to pass legislation reverting to the *Conley* pleading standard. Fourth, plaintiffs may be less inclined to move to strike defendants' affirmative defenses under *Twombly* and *Iqbal* if defendants do not challenge the sufficiency of the complaint.

As a practical matter, before an MDL is formed, defendants should evaluate which of the handful of complaints filed warrant 12(b)(6) motions. In addition to the facts pled in the complaints, considerations include the jurisdiction, the likelihood of success, and post-*Twombly* and *Iqbal* decisions in the jurisdiction. Moreover, selectively filing motions to dismiss has several potential benefits: narrowing and elucidating the discovery issues that the defense is likely to face in the specific case and in the upcoming MDL, generating positive precedent, signaling to the plaintiffs' bar that boilerplate complaints that are devoid of plaintiff-specific factual allegations will be challenged, and not fueling the plaintiffs' bar's lobbying efforts to get Congress to pass the pending legislation that would revert to the *Conley* pleading standard.

### C. Applicability to Master Complaints

Master complaints are generally held to be subject to Rule 12 motions. See, e.g., *In re Katrina Canal Breaches Litig.*, 309 Fed. Appx. 836, 838 (5th Cir. 2009) (*per curiam*) (affirming Rule 12 dismissal of master complaint). The *Twombly* and *Iqbal* plausibility standard should likewise apply to master complaints. See *Southeast Laborers Health & Welfare Fund v. Bayer*, 655 F. Supp. 2d 1270 (S.D. Fla. 2009) (dismissing portions of plaintiffs' master complaint after applying the plausibility standard); *In re FEMA Trailer Formaldehyde Prods. Liab. Litig.*, MDL No. 07-1873, 2008 WL 5217594 (E.D. La. Dec. 12, 2008) (denying motion to dismiss portions of master complaint after applying plausibility standard).

Other courts, however, have shied away from applying the plausibility standard to master complaints. For example, in *In re Digitek Products Liability Litigation*, 2:08-md-01968, 2009 WL 2433468 (S.D. W. Va. Aug. 3, 2009), the court denied the defendants' motion to dismiss and weakened the plausibility standard by considering the master complaint an "administrative device" with "its focus on facilitating management of the litigation, as opposed to being a primary operative pleading." *Id.* at \*8 (note, however, that the cases cited in support of the proposition were not in the context of a motion to dismiss). Likewise, in *In re Nuvaring Products Liability Litigation*, the court issued a series of orders declining to apply the plausibility standard to the defendants' motion to dismiss the master complaint, noting that it never "contemplated that Rule 12(b) motion practice would be pursued . . . against the master complaint," nor that the master complaint would be a substitute for all of the individual complaints. 4:08-md-1964, 2009 WL 3427974, at \*1 (E.D. Mo. Oct. 23, 2009); 2009 WL 2425391 (E.D. Mo. Aug. 6, 2009). Rather, the court wrote that the master complaint should be viewed as "an administrative tool to place in one document all of the claims at issue in this litigation." 2009 WL 3427974, at \*1. (The *Nuvaring* court ended up striking the master complaint after defendants moved to certify the court's order for interlocutory appeal, and later refused to rule on the defendants' motions to dismiss each individual complaint, instead issuing a blanket order denying them. The court noted that the defendants may reassert the motions as to the individual complaints upon remand to the transferor courts. See 2009 WL 4825170 (E.D. Mo. Dec. 11, 2009).)

In light of several courts' decisions to refrain from applying the plausibility standard to master complaints because they are "administrative device[s]" or because no one intended that they would be subject to Rule 12 motions, defendants should make clear to the court and the plaintiffs at the outset of the MDL that the master complaint should be subject to the requirements of the Rules of Civil Procedure (*i.e.*, the Rule 8 pleading requirements and the Rule 12 defenses).

## D. Applicability to Affirmative Defenses

Although there is no circuit court guidance, the majority of district courts that have been confronted with whether the *Twombly* and *Iqbal* plausibility standard applies to affirmative defenses have concluded that it does. See, e.g., *Hayne v. Green Ford Sales, Inc.*, 2:09-cv-02202, 2009 WL 5171779 (D. Kan. Dec. 22, 2009) (listing cases). Typically, these courts reason that applying the plausibility standard to affirmative defenses is consistent with the similarity of F.R.C.P. 8(a) (complaints) and 8(b) (defenses), the Rule 12(f) requirement that affirmative defenses be adequately pled, and the need to reduce frivolous affirmative defenses. For example, in *Hayne*, the court found that “[i]t makes no sense to find that a heightened pleading standard applies to claims but not to affirmative defenses. In both instances, the purpose of the pleading requirements is to provide enough notice to the opposing party that indeed there is some plausible, factual basis for the assertion . . . .” *Id.* at \*3.

The minority of courts that have rejected application of *Twombly* and *Iqbal* to affirmative defenses have interpreted the Supreme Court’s rulings narrowly, noting that *Twombly* interpreted Rule 8(a)(2), which says that a pleading must contain “a short and plain statement of the claim showing that the pleader is entitled to relief,” whereas Rule 8(c)(1), which addresses affirmative defenses, states only that “a party must affirmatively state any avoidance or affirmative defense,” and makes no requirement that affirmative defenses discuss facts. See, e.g., *Charleswell v. Chase Manhattan Bank, N.A.*, 01-119, 2009 WL 4981730, at \*4 (D.V.I. Dec. 8, 2009); *Romantine v. CH2M Hill Eng’rs, Inc.*, 09-973, 2009 WL 347469, at \*1 (W.D. Pa. Oct. 23, 2009).

## III. *Ex parte* Communication with Treating Physicians in an MDL Setting

Although arguments that MDL defendants should be permitted to interview the plaintiffs’ treating physicians *ex parte* have not fared well, several alternatives may yield better results, including bringing state-specific motions regarding physician-patient-privilege laws rather seeking umbrella case management orders; moving for a limited scope of plaintiff’s *ex parte* communications, such as only discussions concerning the plaintiff’s course of treatment; and moving to allow *ex parte* interviews in order to search for consulting experts.

Typically, defendants argue that precluding them from conducting *ex parte* interviews of plaintiffs’ treating physicians is unfair because counsel for plaintiffs may engage in *ex parte* interviews. Thus, a risk of bias arises by allowing only plaintiffs’ side of the story to be shared before depositions, as well as a risk that plaintiffs’ counsel will intimidate the physicians. Moreover, defendants argue that the plaintiffs have waived any physician-patient privilege when they filed their lawsuits, and that the physicians are ordinary fact witnesses whom defendants should be allowed to informally interview. Accordingly, defendants argue, either both parties should be permitted to conduct *ex parte* interviews of plaintiffs’ treating physicians, or neither party should. Unfortunately, these arguments have not persuaded courts. See *In re Ortho Evra Prods. Liab. Litig.*, 1:06-40000, 2010 WL 320064 (N.D. Ohio Jan. 20, 2010) (denying defendants’ request that neither party be permitted to interview plaintiffs’ treating physicians *ex parte*, and allowing plaintiffs’ counsel to engage in *ex parte* contacts); *In re Nuvaring Prods. Liab. Litig.*, 4:08MD1964, 2009 WL 775442 (E.D. Mo. Mar. 20, 2009) (ruling that counsel for plaintiffs could engage in *ex parte* contact, but counsel for defendant could not); *In re Kugel Mesh Hermia Repair Patch Litig.*, 07-1842ML, 2008 WL 2420997 (D.R.I. Jan. 22, 2008) (denying motion to allow defendants to interview plaintiffs’ treating physicians *ex parte*); *In re Vioxx Prods. Liab. Litig.*, 230 F.R.D. 473 (E.D. La. 2005) (ruling that counsel for plaintiffs could engage in *ex parte* contact, but counsel for defendant could not); *In re Baycol Prods. Litig.*, 219 F.R.D. 468 (D. Minn. 2003) (denying motion to allow defendants to interview plaintiffs’ treating physicians *ex parte*); but see *In re: Orthopedic Bone Screw Prods. Liab. Litig.*, 1996 WL 530107, at \*2 (E.D. Pa. 1996) (allowing defendants to conduct *ex parte* interviews “as permitted by applicable state law”).

Plaintiffs have offered various rebuttals, two of which have caught courts' attention: allowing defendants to conduct *ex parte* interviews would conflict with the physician-patient confidential relationship; and defendants have access to plaintiffs' medical records and discovery responses, so interviewing the physicians is unnecessary. The most common result is that defendants may not interview plaintiffs' treating physicians *ex parte*, but counsel for plaintiffs may (although sometimes the scope of the interview is limited to discussion of the plaintiffs' course of treatment).

In all the cases cited above, defendants appear to have moved for an umbrella order permitting them to interview plaintiffs' treating physicians *ex parte*. Despite *ex parte* contacts with physicians being governed by state law (which makes fashioning umbrella orders difficult), defendants may have adopted such a blanket strategy for several reasons, including considerations specific to the litigation, such as the manner in which case-specific discovery was scheduled and the law of the states at issue.

Depending upon the circumstances of the MDL, two alternative courses may yield more defendant-friendly results.

### **A. State-Specific Motions**

Instead of seeking an umbrella or case management order at the outset of discovery to govern *ex parte* communications for all cases, defendants should consider waiting until a case-specific discovery schedule is set to raise the issue. Defendants can ask that the plaintiffs' agree that both parties may contact plaintiffs' treating physicians *ex parte*.

In the almost certain event that plaintiffs reject this proposal, defendants should move for separate orders to allow *ex parte* communications under the state law governing each plaintiff's case. This approach will require the court to analyze the physician-patient privilege law of each applicable state and make it more difficult for the court to issue a blanket order denying the defense's ability to conduct *ex parte* interviews. For example, in *Baycol*, the court undertook an exhaustive analysis of Minnesota's doctor-patient privilege law, which made it more difficult to deny defendants' request for *ex parte* interviews. In contrast, the courts in *Ortho Evra*, *Nuvaring*, and *Kugel* undertook brief analyses, and issued blanket orders applying to all cases regardless of the state law at issue.

In each motion, the defendants should set forth two additional alternative arguments. First, defendants should argue that, if the court determines that only the plaintiffs may interview their treating physicians *ex parte*, the interviews should be limited to the physicians' treatment of the plaintiffs and may not stray to issues of alleged corporate misconduct, company documents, issues about sufficiency of warnings, or general causation issues.

Courts have adopted this limited approach before. In *In re Ortho Evra*, defendants moved the court for a restriction of this nature, arguing that allowing the plaintiffs to engage in unfettered *ex parte* discussions with physicians would result in an unfair advantage by plaintiffs lobbying their theories of liability and causation. The court agreed with defendants, and limited the plaintiffs' *ex parte* discussions to the plaintiffs' course of treatment, noting that "Plaintiffs' counsel will not act in a manner which would result in woodshedding or gaining an unfair advantage by ambush when engaged in *ex parte* contact with treating physicians. Such conduct will not be tolerated." 2010 WL 320064, at \*2. Likewise, in *In re Nuvaring*, defendants moved for a qualified protective order that would allow them to interview plaintiffs' treating physicians *ex parte*. In the alternative, defendants argued that, if the court found that only plaintiffs could interview the treating physicians *ex parte*, the interviews should be limited to the plaintiffs' medical condition. The plaintiffs agreed to this restriction at the hearing on defendants' motion, and the court ruled that it would govern all *ex parte* interviews. 2009 WL 775442, at \*\*2-3.

Defendants should also argue that, if the court determines that the plaintiffs can engage in unfettered *ex parte* communications with their treating physicians, then defendants should be permitted to engage in *ex parte* communications as to issues *unrelated* to plaintiffs' treatment. Although this approach has not been argued in the MDL context, it would not run afoul of state physician-patient privilege laws because discussion of the plaintiffs' treatment would be off limits. Moreover, if plaintiffs are allowed to discuss non-plaintiff-specific issues, giving defendants this same opportunity would ensure fairness and provide the physician with a balanced discussion of issues in the litigation. Even if judges are disinclined to adopt this approach, it may sway them that limiting plaintiffs' counsel's discussion to each plaintiff's course of treatment is the sensible result, which is still a decent outcome for defendants.

## **B. Searching for Consulting Experts**

Although the defendants may not be permitted to interview the plaintiffs' physicians *ex parte* to discuss the plaintiffs' treatments, they may be permitted to interview the physicians to assess the physicians' aptitudes to serve as consulting experts. For example, in *In re Seroquel Products Liability Litigation*, 6:06-md-1769, 2008 WL 821889 (M.D. Fla. Mar. 21, 2008), AstraZeneca moved the court for an order to allow it to meet *ex parte* with Florida physicians about their serving as defense experts. AstraZeneca stressed to the court that the physicians, although they may be treaters of certain plaintiffs, would not serve as experts in those plaintiffs' cases. *Id.* at \*1. The plaintiffs' opposed the motion as a "poorly disguised attempt" to bias the physicians. *Id.* Although Florida law forbids *ex parte* communication with the plaintiffs' treating physicians, the court found that the law did not prevent AstraZeneca from contacting the physicians with regard to other cases, and the court allowed AstraZeneca to contact the plaintiffs' treating physicians as long as AstraZeneca did not discuss the treatment of specific patients and the physicians were not retained as experts in their patients' cases. *Id.* at \*\*2-3.

Defendants should follow this course with caution, however. The *Seroquel* decision was driven in large part by AstraZeneca's showing that collectively plaintiffs' treating physicians in Florida numbered more than 3100, such that AstraZeneca would find it difficult to retain experts who were unassociated with a plaintiff or a potential plaintiff. In contrast to the *AstraZeneca* court, the court in *In re Kugel Mesh Hernia Repair Patch Litigation*, 07-1842ML, 2008 WL 4372809 (D.R.I. Sept. 19, 2008), was unpersuaded when defendants argued that more than 1000 cases pending in Rhode Island made it difficult for them to retain experts. In denying defendants' motion to allow them to interview and retain plaintiffs' treating physicians as consulting or testifying experts, the *Kugel* court reasoned that defendants' right to retain experts was "significantly outweighed" by plaintiffs' right to confidentiality in their medical matters." *Id.* at \*1. Likewise, in *In re Guidant Corp. Implantable Debrillators Products Liability Litigation*, 05-1708, 2007 WL 2049016 (D. Minn. July 6, 2007), the court was confronted with the issue of the defendant contacting the plaintiffs' treating physicians to serve as consulting experts. Although the court permitted Guidant to contact the plaintiffs' physicians, it warned that "Guidant and its attorneys are walking a tight rope, one which they may slip off at any time." *Id.* at \*2.

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