



several of its affiliates, seek reversal of the trial court's ruling. For the reasons that follow, we affirm.<sup>1</sup>

## I. BACKGROUND

### A. The Ancure Device

The medical instrument at the center of this dispute is the "Ancure Endograft System" (Ancure Device), a Y-shaped, synthetic vascular graft with an accompanying delivery catheter. The Ancure Device is used in the repair of an abdominal aortic aneurysm, a potentially life-threatening condition arising from the development of a weak area in the abdominal portion of the wall of the aorta. As a result of this weakness, the artery balloons and, in more severe cases, ruptures. Abdominal aortic aneurysms generally require open abdominal surgery to repair. However, the Ancure Device provides an alternative to traditional "open repair" surgery. The device is implanted by making small incisions in the arteries of the patient's groin and threading the delivery catheter upward through blood vessels to where the graft is put in place to support the weakened area. The Ancure Device was developed by Endovascular Technologies, Inc. (EVT), in the 1990s. Guidant acquired EVT in 1997. In September 1999, the United States Food and Drug Administration (FDA) approved the Ancure Device for sale.

### B. The Insurance Policies

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<sup>1</sup>This is the third time that the parties have appeared before us. See Allianz Insurance Co. v. Guidant Corp., 373 Ill. App. 3d 652 (2007); Allianz Insurance Co. v. Guidant Corp., 355 Ill. App. 3d 721 (2005). The facts presented in this opinion are taken from those prior decisions in addition to the record on appeal.

Allianz and Zurich Specialties London Limited (Zurich), Gerling Konzern Allgemeine Versicherungs--AG (Gerling), Liberty International Insurance Company (Liberty), American International Specialty Lines Insurance Company (AISLIC), Westchester Fire Insurance Company (Westchester), and Lumbermens Mutual Casualty Company (Lumbermens) (collectively the Excess Insurers and, together with Allianz, the Insurers),<sup>2</sup> insured Guidant and four of its affiliates, Guidant Sales Corporation, Origin Medsystems, Inc., Advanced Cardiovascular Systems, Inc., and EVT (collectively the Affiliates and, together with Guidant, the Policyholders).

This litigation involves two distinct policy periods. The first policy period is from September 1, 2000, to September 1, 2001 (Year One). In July 2000, the Policyholders provided Allianz with a completed application for Year One coverage. After receiving and approving the application, Allianz, the first-layer carrier, issued a "claims made" commercial umbrella liability insurance policy.<sup>3</sup> The policy provided limits of coverage of \$25 million per occurrence and \$25 million in the aggregate for claims in excess of a self-insured retention (SIR) of \$5 million per occurrence and

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<sup>2</sup>In an order dated July 23, 2008, we granted unopposed motions to dismiss Zurich, Liberty, and Westchester as parties to this appeal.

<sup>3</sup>A "claims made" insurance policy is "[a]n agreement to indemnify against all claims made during a specified period, regardless of when the incidents that gave rise to the claims occurred." Black's Law Dictionary 809 (7th ed. 1999).

\$8 million in the aggregate.<sup>4</sup> Subsequent layers of Year One coverage were provided by Gerling, AISLIC, Lumbermens, and Westchester.

Allianz later issued a policy providing coverage to the Policyholders for the second policy period, from September 1, 2001, to September 1, 2002 (Year Two). This policy provided limits of coverage of \$25 million per occurrence and \$25 million in the aggregate for claims in excess of an SIR of \$5 million per occurrence and \$10 million in the aggregate. The Excess Insurers issued various one-year policies in excess of the Allianz policy for Year Two. During both Year One and Year Two, the policies issued by the Excess Insurers "followed form" to the Allianz policies, that is, the Excess Insurers' policies adopted virtually the same terms and conditions as the Allianz policies. The issues presented in this appeal involve coverage issued by the Insurers to the Policyholders for Year One.

### C. The Batch Clause

The Allianz policies contain, and the non-Allianz policies incorporate, the following "Batch Clause," which is the focus of the instant litigation:

"It is agreed that the policy section, Definitions, (6) 'Occurrence', with respect to 'products-completed operations hazard' is amended to include the following[:]

The term 'batch' means all products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum[.]

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<sup>4</sup> A SIR is defined as "[t]he amount of an otherwise-covered loss that is not covered by an insurance policy and that [usually] must be paid before the insurer will pay benefits." Black's Law Dictionary 1365 (7th ed. 1999).

The term 'advisory memorandum' is any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of 'bodily injury' or 'property damage' from a product in use[.]

Coverage does not apply to any loss, claim, or 'suit' which arises out of a defect or deficiency which was known or suspected prior to the retroactive date shown in this policy[.]

When this endorsement is attached to your policy, all losses arising from a single 'batch' of your product will be considered to be one 'occurrence[.]' Therefore, when multiple losses are considered to be one 'occurrence' you must only meet a single 'self-insured retention' amount[.] Likewise, our limit of liability due to 'bodily injury' and 'property damage' is limited to that of a single 'occurrence[.]'

All claims made by persons or organization [sic] seeking damages because of 'bodily injury' or 'property damage' arising out of one batch will be deemed to have been made at the time the first of those claims is made against you[.]"

#### D. The Recall

Soon after the Ancure Device was approved by the FDA, EVT became aware of various malfunctions in the delivery catheter that was used to insert the graft. Some of these malfunctions resulted in the delivery system becoming improperly lodged in patients' bodies, often requiring the removal of the delivery system by traditional open surgical repair. In response to these problems with the delivery system, some EVT sales representatives developed a procedure to break or cut the handle of the delivery system when it became lodged and could not be removed without resorting

to traditional open surgical repair. This procedure, which became known as the "Handle-Breaking Technique," was not presented to the FDA for approval.

On March 16, 2001, Guidant issued a press release stating that it was voluntarily halting the production and sale of the Ancure Device. According to the press release, this action was taken "as a result of Guidant's identification of certain deficiencies in the company's ANCURE-related regulatory processes and communications with the [FDA]." The press release explained that these deficiencies "are limited to \*\*\* regulatory issues associated with the deployment system of the product" and that patients already implanted with the Ancure Device "are not affected by this action." At the time of the recall, more than 7,600 devices had already been sold. Guidant followed up the press release with three "Dear Doctor" letters. Those letters were issued on March 21, 2001, March 31, 2001, and May 2, 2001.

Meanwhile, the FDA initiated an investigation into EVT regarding its failure to make certain disclosures about the performance of the Ancure Device. In 2003, the federal government filed criminal charges and a civil action against EVT for failing to report problems with the Ancure Device. On June 12, 2003, EVT pleaded guilty to 10 charges, including misbranding and making false statements to government regulators. As a result of the plea agreement, EVT paid the federal government \$92.4 million, which included a forfeiture of \$10.9 million, a criminal fine of \$32.5 million, and a civil settlement of \$49 million.

#### E. The Underlying Product Liability Claims

After the Insurers' policies took effect on September 1, 2000, the Policyholders began to receive product liability claims involving the Ancure Device. For purposes of the coverage issue presented under the claims-made policies at issue here, the underlying Ancure claims fall into three

categories: claims made in Year One, claims made in Year Two, and claims made after the termination of the Year Two policies.

### 1. Claims Made in Year One

Two Ancure claims were made during Year One--the Carter claim and the Krupa claim. In handwritten letters dated March 9, 2001, and April 7, 2001, Harry Carter alleged that the Ancure Device had failed to "stay deployed properly when inserted into [his] aorta and left and right femoral iliac artery." Carter further alleged that "the right branch closed up, shutting off blood flow through the right iliac artery" and that "a second operation was necessary to correct the condition." Guidant settled the Carter claim for \$10,000 prior to litigation.

In a letter dated June 14, 2001, Ray Krupa complained that the Ancure Device was not accurately labeled in that it was "approximately 4 cm shorter than the packaging information" indicated. As a result of this alleged defect, Krupa stated, he had been required to undergo open-repair surgery. The Krupa claim was settled prior to litigation for \$200,000.

### 2. Claims Made in Year Two

During Year Two, between 14 and 17 more Ancure claims were made.<sup>5</sup> All of the Year Two claims have been resolved.

### 3. Claims Made after the Termination of the Year Two Policies

Hundreds more Ancure claims were made following the conclusion of Year Two on September 1, 2002. Some of these claims have been resolved while others are pending in court or the subject of tolling agreements.

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<sup>5</sup>The parties dispute the number of claims made in Year Two. For purposes of this appeal, the dispute is not material.

#### G. The Illinois and Indiana Lawsuits

This coverage litigation commenced on November 6, 2003, when Allianz filed a complaint in the circuit court of Du Page County, Illinois, against Guidant, seeking, inter alia, a declaration that the "policies issued to Guidant do not provide coverage for claims, losses, or liabilities related to the Ancure Device." All of the Excess Insurers and the Affiliates were later added. Thereafter, the Insurers filed a consolidated complaint against the Policyholders. Two days after Allianz sued Guidant in Illinois, the Policyholders filed a separate coverage action in Marion County, Indiana, against the Insurers. In their complaint, the Policyholders alleged that the Insurers had breached their duties to defend and indemnify the Policyholders for losses stemming from the Ancure Device and sought a declaration that they are entitled to coverage for the Ancure claims.

#### H. The Summary Judgment Rulings in Illinois

On March 8, 2006, the Insurers filed a motion for partial summary judgment in the Illinois action, arguing that the insurance policies in effect during Year One do not afford coverage for any Ancure claims. Specifically, the Insurers argued that (1) the Policyholders had not established coverage for Year One, because the Ancure claims actually made during that period do not exceed the applicable SIR, and (2) the Batch Clause had not been triggered, so losses on claims made after Year One could not be aggregated with those actually made in Year One to exhaust the SIR for that year. The Policyholders opposed the motion and filed a cross-motion for partial summary judgment on the ground that the Batch Clause was indeed triggered in Year One.

On June 12, 2006, the Illinois court granted the Insurers' motion for partial summary judgment regarding Year One coverage and denied the Policyholders' cross-motion for partial summary judgment (the Illinois Year One Ruling). The court agreed with the Insurers that the losses

associated with the two Ancure claims made during Year One do not exceed the applicable SIR. The court then rejected the Policyholders' argument that the Batch Clause allowed them to aggregate all Ancure claims regardless of whether those claims arose out of "the same known or suspected defect or deficiency." Instead, the court agreed with the Insurers that the only reasonable interpretation of the Batch Clause is that, for claims to be aggregated, those claims must involve persons seeking damages arising out of products that have the same defect or deficiency. As the court stated:

"I think if you apply the rules of English grammar to the definition of batch, one would reach the inescapable conclusion that the clause 'which have the same known or suspected defect or deficiency' modifies the word batch, and the known or suspected defect or deficiency is further modified by the clause which is identified by the same advisory memorandum.

I believe that applying these rules of English grammar one is left with the inescapable conclusion that batch refers to all products of the same type which have the same known or suspected defect or deficiency, and not all products of that same type, regardless of whatever deficiency or defect it noted.

I think the [Insurers'] interpretation of the batch clause is the correct one under rules of common sense and rules of English grammar and rules giving words their ordinary meaning."

On July 5, 2006, the Policyholders moved for reconsideration of the Illinois Year One Ruling. This motion was denied on August 1, 2006. At the time it was entered, the Illinois Year One Ruling did not include language that it was enforceable or appealable, and none of the parties requested the inclusion of such language. See 210 Ill. 2d R. 304(a) (providing that "[i]f multiple parties or

multiple claims for relief are involved in an action, an appeal may be taken from a final judgment as to one or more but fewer than all of the parties or claims only if the trial court has made an express written finding that there is no just reason for delaying either enforcement or appeal or both").

On August 28, 2006, the Insurers moved for summary judgment regarding the extent of their coverage obligation for the Year Two policy period. In their motion, the Insurers argued that there is no coverage under the Year Two policies because: (1) the Policyholders' losses in Year Two do not exceed the applicable SIR; (2) the "Dear Doctor" letters do not constitute "advisory memorand[a]" as that term is defined in the Batch Clause; and (3) the "Dear Doctor" letters do not warn about the defects alleged in any of the claims made in Year Two. On March 2, 2007, the Illinois court denied the Insurers' motion for partial summary judgment regarding Year Two coverage (the Illinois Year Two Ruling). The court found that there were genuine issues of material fact regarding (1) whether the losses incurred by the Policyholders with respect to claims made in Year Two exceeded the applicable SIR; and (2) whether the "Dear Doctor" letters constituted "advisory memorand[a]" under the Batch Clause. The court also found that, unlike with respect to the Illinois Year One Ruling, Guidant introduced evidence that potentially showed that the Batch Clause applied to aggregate claims made in Year Two with claims made in subsequent years.

#### I. The Summary Judgment Ruling in Indiana

On September 26, 2006, Guidant filed a motion for partial summary judgment in the Indiana action, seeking a declaration that Allianz had a duty to defend it on the underlying Ancure claims and that Allianz breached its duty by failing to do so.<sup>6</sup> The Policyholders contended that, contrary

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<sup>6</sup>The motion was directed only at Allianz, but the Excess Insurers opposed the motion, "to dispute the Policyholders' interpretation of the Allianz Policy to which their policies follow form."

to the analysis in the Illinois Year One Ruling, the Batch Clause had been triggered in Year One, thereby giving rise to a duty to defend under Allianz's primary policy. All of the Insurers contested the Year One coverage issue on the merits. Moreover, they filed their own motion for partial summary judgment on the Year One coverage issue, essentially reiterating the arguments made in Illinois.

On March 23, 2007, the Indiana court issued two separate orders. In one of the orders, the court denied the Insurers' motion for partial summary judgment (the Indiana Batch Clause Order), stating in relevant part:

"The Court finds as a matter of law based upon the uncontroverted material facts that coverage for at least some Ancure claims was triggered in Year 1 by operation of the Batch Clause.

\* \* \*

First, the Court finds that the Batch Clause provides coverage for claims arising from a batch of products, regardless of whether the claims for which coverage is sought allege the same or different product 'defects or deficiencies.' \*\*\* The Policyholders have identified a batch of pre-recall Ancure devices. The Policyholders have also shown through uncontroverted evidence that the \$5 million per occurrence SIR applicable in Year 1 has been exhausted as to claims arising from that batch of products.

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Second, and in the alternative, even if the Court did not accept the Policyholders [sic] reasonable interpretation of the language of the Batch Clause, and then found the clause to

be ambiguous \*\*\* such ambiguity \*\*\* would be construed against the Insurers and in favor of coverage.

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Third, and also in the alternative, the Insurers' motion must be denied in all events, because the Policyholders have raised genuine issues of material fact as to whether one or more 'batches' (as the Insurers construe the term) existed, or may yet exist, that would trigger coverage for the Year 1 claims even under the Insurers' reading of the Batch Clause."

The Indiana court acknowledged the contrary holding in the Illinois Year One Ruling, but stated that it was "unable to concur in [the Illinois court's] construction of the Batch Clause." The Indiana Batch Clause Order was not certified as a final and appealable order by the Indiana court. See Indiana Trial Rules 54(B), 56(C). Moreover, the Insurers did not seek such certification and they did not appeal the ruling.

In the other order entered on March 23, 2007, the Indiana court granted partial summary judgment in the Policyholders' favor on the issue of Allianz's duty to defend (the Indiana Duty-to-Defend Order). The court based its decision on the "mere potential for coverage" and "potential \*\*\* exhaustion of the SIR." The court stated that it "need not consider \*\*\* the Batch Clause \*\*\* or the SIR" in reaching its decision. Despite this statement, a footnote in the Indiana Duty-to-Defend Order purports to incorporate by reference the Indiana Batch Clause Order.<sup>7</sup> Furthermore, the court found "no just reason for delay" and certified the Indiana Duty-to-Defend Order such that it could be

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<sup>7</sup>Similarly, a footnote in the Indiana Batch Clause Order purports to incorporate by reference the Indiana Duty-to-Defend Order. The text of both footnotes is set forth later in this opinion.

immediately appealed. See Indiana Trial Rules 54(B), 56(C). On April 19, 2007, the Insurers appealed the Indiana Duty-to-Defend Order.

#### J. Further Proceedings In Illinois

Meanwhile, on April 30, 2007, the Insurers filed a motion for a finding pursuant to Supreme Court Rule 304(a) (210 Ill. 2d R. 304(a)), that the Illinois Year One Ruling was enforceable and appealable. In its motion, the Insurers argued that, because of the Illinois Year Two Ruling, which found that factual issues regarding coverage under Year Two precluded summary judgment, there was no longer a valid reason for delaying an appeal on the Illinois court's finding as a matter of law that there was no coverage under Year One. The Policyholders opposed the request, and, on May 23, 2007, they filed a motion to reconsider, asking the court for the second time to vacate the Illinois Year One Ruling. The Policyholders argued that, under the full faith and credit clause of the United States Constitution (U.S. Const., art. IV, §1), Indiana's subsequent grant of partial summary judgment to the Policyholders in its Duty-to-Defend Order, which "expressly incorporated the \*\*\* findings and conclusions" of the Indiana Batch Clause Order, was entitled to collateral-estoppel effect with respect to the Illinois Year One Ruling. The Insurers objected to the Policyholders' request. They contended that the Indiana Duty-to-Defend Order was not entitled to collateral-estoppel effect, because it was entered nine months after the Illinois Year One Ruling and it did not rely on an interpretation of the Batch Clause.

On July 11, 2007, the Illinois court heard oral argument on both the Insurers' motion for a Rule 304(a) finding and the Policyholders' second motion to reconsider the Illinois Year One Ruling. The court denied the Policyholders' motion to reconsider, stating:

"I think this entire argument displays a fundamental misapplication of the doctrine of collateral estoppel. Collateral estoppel relates to application of a prior judgment to pending litigation. There is absolutely nothing in the doctrine of collateral estoppel that would require this Court to go back and vacate a prior order that had been entered as a result of a subsequent decision in a sister state.

Leaving aside the issue of whether [the Indiana Duty-to-Defend O]rder addressed the [SIR] or the Batch Clause, which I don't believe it did by its expressed terms, I think that this Court is not required to reconsider a prior ruling on the basis of what [the Indiana court] may have decided in a subsequent action, so for that basis I'm going to deny the motion to reconsider."

The court also granted the Insurers' Rule 304(a) motion, finding that "there is no just reason to delay enforcement or appeal" of the Illinois Year One Ruling. The Policyholders then filed the instant appeal.

#### K. Decision of the Court of Appeals of Indiana

On April 17, 2008, after the parties submitted their briefs to this court, the Indiana Court of Appeals issued an opinion reversing the Duty-to-Defend Order entered by the Indiana trial court. Allianz Insurance Co. v. Guidant Corp., 884 N.E.2d 405 (Ind. App. 2008). The Indiana Court of Appeals held that the trial court erred in concluding that the Policyholders were required to establish only the "potential," rather than the actual, exhaustion of the SIR to trigger the duty to defend. Allianz Insurance Co., 884 N.E.2d at 420. The court then stated:

"Although the trial court's analysis was erroneous, we may affirm summary judgment if it is sustainable on any theory or basis found in the record. [Citation.] The only way in

which summary judgment can be properly granted in the Policyholders' favor on their claim for breach of the duty to defend is if we find that they did, in fact, establish that the Batch Clause was triggered as a matter of law and there are no questions of fact regarding the exhaustion of the SIR." Allianz Insurance Co., 884 N.E.2d at 420.

Since the Policyholders conceded that the only two Ancure claims made during Year One were insufficient to exhaust the SIR, the court considered whether the Batch Clause had been triggered.

Ultimately, the reviewing court found that the Batch Clause had not been triggered, because the "Dear Doctor" letters relied upon by the Policyholders to activate the Batch Clause did not qualify as "advisory memorand[a]" as that term is defined in the insurance policies. Allianz Insurance Co., 884 N.E.2d at 421-22. The court explained:

"Rather than informing health professionals of a risk of bodily injury stemming from the Ancure Device, all of the letters sought to do the opposite; namely, they sought to assure the physician community that, notwithstanding regulatory and communication deficiencies, the product itself was safe and effective." Allianz Insurance Co., 884 N.E.2d at 422.

Based on this finding, the court determined that the Batch Clause could not have been triggered, the SIR could not have been exhausted, and the Insurers had no duty to defend the Year One claims. Allianz Insurance Co., 884 N.E.2d at 422-23. The court also concluded that, "for a group of products to qualify as a batch, they must share the same defect or deficiency." Allianz Insurance Co., 884 N.E.2d at 422 n.9. The court found no evidence of record "establishing that the claims sought to be aggregated by the Policyholders are based on products that share the same defect or deficiency." Allianz Insurance Co., 884 N.E.2d at 422 n.9. The Policyholders have since asked the Indiana Supreme Court to review the decision of the Indiana Court of Appeals.

## II. ANALYSIS

### A. Full Faith and Credit

On appeal, the Policyholders contend that we need not even reach the merits of the Illinois Year One Ruling. According to the Policyholders, pursuant to the full faith and credit clause of the United States Constitution (U.S. Const., art. IV, §1), the Indiana trial court's "judgment" has collateral-estoppel effect as to the Illinois Year One Ruling.<sup>8</sup> Initially, we address the Insurers' response that the Policyholders have forfeited this issue by failing to plead collateral estoppel. Collateral estoppel is an affirmative defense. Midwest Physician Group, Ltd. v. Department of Revenue, 304 Ill. App. 3d 939, 952 (1999). Generally, to avoid surprise to the opposing party, an affirmative defense must be set out in a party's answer to a complaint or it will be considered forfeited. Cordeck Sales, Inc. v. Construction Systems, Inc., 382 Ill. App. 3d 334, 376 (2008). In this case, however, the Policyholders' answer was filed long before March 23, 2007, when the Indiana orders giving rise to the claim of collateral estoppel were entered. Thus, the Policyholders could not have pleaded the affirmative defense at the time they filed their answer to the Insurers' complaint. See Tarzian v. West Bend Mutual Fire Insurance Co., 74 Ill. App. 2d 314, 324 (1966) (holding that affirmative defense that arose immediately prior to trial is available without pleading). We also find that the element of "surprise" is absent here. The Insurers were parties to the suit in Indiana, and they do not dispute that they participated in the Indiana action. In fact, they appealed the Indiana Duty-to-Defend Order. Accordingly, we decline to find forfeiture and we address the merits of the Policyholders' claim of collateral estoppel.

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<sup>8</sup>The same argument was the subject of a motion to bifurcate that accompanied the Policyholders' opening brief. We denied the motion to bifurcate on December 28, 2007.

The Policyholders assert that, under the doctrine of collateral estoppel, the Indiana "judgment" was entitled to preclusive effect in Illinois on the question whether the Batch Clause was triggered in Year One and the SIR thereby satisfied. The Policyholders acknowledge that the Insurers tendered the Batch-Clause-interpretation issue to the Illinois court first and that the Illinois court issued a ruling in the Insurers' favor before the Indiana court issued its decisions. However, they assert that the Insurers did not obtain a final ruling from the Illinois court on the matter until after the Indiana court entered a final judgment resolving the same issue against the Insurers. Thus, they reason, the Indiana judgment must control over the Illinois Year One Ruling, which, although entered earlier, was not final when the Indiana judgment was entered. The Policyholders ask us to vacate the Illinois Year One Ruling pending the conclusion of appellate proceedings in Indiana. The Insurers respond that neither of the two orders entered by the Indiana court on March 23, 2007, precludes consideration of the policy-interpretation issue presented here. They point out that, although the Indiana Duty-to-Defend Order contained language indicating that it was final and appealable, that order expressly declined to rely on the Batch Clause for support. The Insurers further note that, while the Indiana Batch Clause Order did address the policy-interpretation issue, that order is not final and appealable.

Collateral estoppel, also referred to as issue preclusion, is an equitable doctrine of judicial origin created to prevent relitigation of previously adjudicated claims. Ballweg v. City of Springfield, 114 Ill. 2d 107, 113 (1986); see also Du Page Forklift Service, Inc. v. Material Handling Services, Inc., 195 Ill. 2d 71, 77 (2001); Tofany v. NBS Imaging Systems, Inc., 616 N.E.2d 1034, 1037 (Ind. 1993) ("Generally, collateral estoppel operates to bar a subsequent re-litigation of the same fact or issue where that fact or issue was necessarily adjudicated in a former suit and the same

fact or issue is presented in the subsequent lawsuit"); Eichenberger v. Eichenberger, 743 N.E.2d 370, 374 (Ind. App. 2001) ("Issue preclusion bars subsequent relitigation of the same fact or issue where that fact or issue was necessarily adjudicated in a former suit and the same fact or issue is presented in a subsequent action"). The doctrine is founded upon the principle of judicial economy. Ballweg, 114 Ill. 2d at 113; Tofany, 616 N.E.2d at 1039 ("Collateral estoppel promotes judicial economy; in particular, it reduces the amount of court time devoted to retrying previously litigated issues"). The full faith and credit clause of the United States Constitution extends the doctrine of collateral estoppel to judgments entered in foreign states. U.S. Const., art. IV, § 1 ("Full Faith and Credit shall be given in each State to the public Acts, Records, and judicial Proceedings of every other State"); see also In re Liquidation of Legion Indemnity Corp., 373 Ill. App. 3d 969, 974 (2007) (noting that the full faith and credit clause extends doctrine of res judicata to judgments entered in other states); Raikos v. Nehring, 527 N.E.2d 1141, 1146 (Ind. App. 1988) (considering whether the full faith and credit clause applied with regard to Illinois judgment and claim of issue preclusion).

Traditionally, there are three threshold requirements for the application of collateral estoppel. Gumma v. White, 216 Ill. 2d 23, 38 (2005); Illinois Health Maintenance Organization Guaranty Ass'n v. Department of Insurance, 372 Ill. App. 3d 24, 35 (2007); In re C.M., 675 N.E.2d 1134, 1137 (Ind. App. 1997). First, the issue decided in the prior adjudication must be identical to the issue presented in the suit in question. Gumma, 216 Ill. 2d at 38; Bojrab v. John Carr Agency, 597 N.E.2d 376, 379 (Ind. App. 1992). Second, there must have been a final determination on the merits in the prior adjudication by a court of competent jurisdiction. LaSalle Bank National Ass'n v. Village of Bull Valley, 355 Ill. App. 3d 629, 635 (2005); In re C.M., 675 N.E.2d at 1137. Finally, the party against whom the estoppel is asserted must have been a party to or in privity with a party to the prior

adjudication. Gumma, 216 Ill. 2d at 38; In re C.M., 675 N.E.2d at 1137. Even if the threshold requirements are established, the doctrine's application depends on certain other circumstances. See American Family Mutual Insurance Co. v. Savickas, 193 Ill. 2d 378, 388 (2000) ("Even when the threshold requirements are satisfied, the doctrine should not be applied unless it is clear that no unfairness will result to the party sought to be estopped"); Reising v. Guardianship of Reising, 852 N.E.2d 644, 649 (Ind. App. 2006) (noting that, once threshold elements of collateral estoppel are met, the court must consider whether the party against whom the judgment is pled had a full and fair opportunity to litigate the issue in previous litigation and whether it would be otherwise unfair under the circumstances of the particular case to apply collateral estoppel); In re C.M., 675 N.E.2d at 1137 (same).

Although the elements of collateral estoppel are essentially identical under both Illinois and Indiana law, those elements are analyzed differently in each state. For this reason, the parties dispute whether Illinois or Indiana law should apply to our collateral-estoppel analysis. The parties rely on conflicting rulings regarding whether the forum state may apply its own rules of collateral estoppel when deciding the effect of a foreign judgment. Compare Morris B. Chapman & Associates, Ltd. v. Kitzman, 193 Ill. 2d 560, 565 (2000) (applying Missouri law in determining whether Illinois claim is barred as res judicata by a Missouri court judgment), with Finley v. Kesling, 105 Ill. App. 3d 1, 7 (1982) ("[I]t has been recognized that the forum [s]tate may apply its own rules of collateral estoppel" when deciding the effect of a foreign judgment). We need not resolve this dispute, however, for we reach the same result under the law of either state. We address the issue under Illinois law first.

In Illinois, the applicability of the doctrine of collateral estoppel is a question of law, which we review de novo. In re A.W., 231 Ill. 2d 92, 99 (2008). Our supreme court has held that, for the purpose of applying the doctrine of collateral estoppel, "finality requires that the potential for appellate review must have been exhausted." Ballweg, 114 Ill. 2d at 113. In this case, the Insurers appealed the Indiana Duty-to-Defend Order to the Indiana Court of Appeals. After the parties filed their briefs in this cause, the Indiana Court of Appeals issued a decision reversing the judgment of the trial court, remanding the cause, and denying the Policyholders' request for rehearing. Allianz Insurance Co., 884 N.E.2d 405. The Policyholders then filed a petition to transfer the cause to the Indiana Supreme Court. That court has yet to rule on the petition. Accordingly, under Illinois law, the doctrine of collateral estoppel would not apply, because the Indiana Duty-to-Defend Order, which purports to incorporate the Indiana Batch Clause Order, is not yet final.

The same result follows under Indiana law, albeit for a different reason. Under Indiana law, whether one judgment has collateral-estoppel effect as to a second judgment is also a question of law subject to de novo review. See Kieler v. C.A.T., 616 N.E.2d 34, 36 (Ind. App. 1993). Applying Indiana law, we find that the Illinois court did not err in concluding that the Indiana court's orders of March 23, 2007, do not have collateral-estoppel effect as to the Illinois Year One Ruling.<sup>9</sup>

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<sup>9</sup>As noted above, the Indiana Court of Appeals has since reversed the Indiana trial court. This ruling would seemingly render the Policyholders' collateral-estoppel argument moot, as the positions of both the Illinois and the Indiana courts would now be aligned. However, it is the Policyholders' position that the opinion of the Indiana Court of Appeals is not "certified and final," because they have petitioned the Indiana Supreme Court for transfer. Thus, they reason, the judgment of the Indiana trial court is still valid. See In re Big Raccoon Conservancy District, 363 N.E.2d 1004, 1009

At the outset, we note that throughout their briefs the Policyholders refer to an Indiana "judgment" rendered on March 23, 2007. However, as set forth in the background section of this decision, the Indiana trial court actually entered two separate orders on March 23, 2007--the Duty-to-Defend Order and the Batch Clause Order. This distinction is significant. Under Indiana law, for collateral estoppel to preclude the relitigation of an issue, that identical issue must have been decided expressly and finally in a prior judgment. Indianapolis Downs, LLC v. Herr, 834 N.E.2d 699, 704 (Ind. App. 2005) ("Collateral estoppel does not extend to matters that were not expressly adjudicated and can be inferred only by argument"); Bojrab, 597 N.E.2d at 379. In this case, the issue that the Policyholders argue is precluded concerns the interpretation of the Batch Clause. The Indiana trial court did not decide this issue in any final judgment. Of the two orders entered by the Indiana trial court on March 23, 2007, only the Duty-to-Defend Order expressly states that there is no just reason for delay and expressly directs the entry of a final judgment. See Indiana Trial Rule 54(B) ("A judgment as to one or more but fewer than all of the claims or parties is final when the court in writing expressly determines that there is no just reason for delay, and in writing expressly directs entry of judgment, and an appeal may be taken upon this or other issues resolved by the judgment; but in other cases a judgment, decision or order as to less than all the claims and parties is not final"); Indiana Trial Rule 56(C) ("A summary judgment upon less than all the issues involved in a claim or with respect to less than all the claims or parties shall be interlocutory unless the court in writing

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(Ind. App. 1977) ("A judgment is final pending appeal"). Accordingly, we proceed under the notion that, despite the reviewing court's opinion, the Indiana trial court's decision remains valid until the Indiana Supreme Court either denies the petition to transfer or resolves the case after allowing the petition to transfer.

expressly determines that there is no just reason for delay and in writing expressly directs entry of judgment as to less than all the issues, claims or parties"). However, the Indiana trial court declined to address the policy-interpretation issue in its Duty-to-Defend Order. The court found that the "mere potential for coverage" and the "potential \*\*\* exhaustion of the SIR" were sufficient to trigger the duty to defend. Therefore, the court concluded that it did not have to address the Batch-Clause-interpretation issue, which was "more properly made in resisting the duty to indemnify." Thus, the Indiana court expressly stated that its judgment on Allianz's duty to defend did not turn on the Batch-Clause-interpretation issue.

Moreover, while the Indiana Batch Clause Order did interpret the Batch Clause, that order did not include the language required by Indiana Trial Rules 54(B) and 56(C) to make the ruling final and appealable.<sup>10</sup> We can conceive of no reason for the Indiana court to have issued two separate orders, designating one final and appealable and the other not, if it intended both of the orders to have conclusive effect. See Rabel by Rabel v. Midwestern Electric, Inc., 550 N.E.2d 340, 341 (Ind. App. 1990) ("Our rules specifically state a partial summary judgment order which does not include the required language \*\*\* 'shall be,' interlocutory").

The Policyholders insist that the Indiana Duty-to-Defend Order should be read to include findings on the Batch-Clause-interpretation issue because of footnotes in both of the Indiana orders. The footnote in the Duty-to-Defend Order provides:

"The Court has simultaneously heard and considered the Insurers' Motion for Partial Summary Judgment re 'Year 1 Policies,' which was filed January 4, 2007. That motion and

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<sup>10</sup>Our finding that the Indiana Batch Clause Order is not final under Indiana law provides an alternate basis for a lack of finality under Illinois law.

the instant motion present certain overlapping issues regarding coverage under Year 1 and the 'Batch Clause' contained in the subject policies. Accordingly, for the sake of completeness, all findings and conclusions set forth in the Order denying the Insurers' motion regarding Year 1 coverage are incorporated by reference in this [Duty-to-Defend] Order, and vice versa."

Similarly, the footnote in the Batch Clause Order states:

"The Court has simultaneously heard and considered the Policyholders' Motion for Partial Summary Judgment Re: Allianz Insurance Company's Duty to Defend, which was filed September 26, 2006. That motion and the instant motion present certain overlapping issues regarding coverage under Year 1 and the 'Batch Clause' contained in the subject policies. Accordingly, for the sake of completeness, all findings and conclusions set forth in the Order granting the Policyholders' Motion on the Duty to Defend are incorporated by reference in this [Batch Clause] Order, and vice versa."

We are not persuaded that the inclusion of these footnotes renders final the findings on the Batch-Clause-interpretation issue. The language of the footnotes makes clear that their inclusion was only to address certain unidentified "overlapping" issues. Equally clear is the notion that the interpretation of the Batch Clause is not one of those overlapping issues. The Indiana court made this plain when it stated in the Duty-to-Defend Order that it did not address the Batch-Clause-interpretation issue in its ruling on the Policyholders' motion for partial summary judgment as to Allianz's duty to defend.

The Policyholders also insist that the Indiana court could not have ruled on its motion for partial summary judgment regarding Allianz's duty to defend without interpreting the Batch Clause.

In support of this position, the Policyholders cite language from the Indiana Duty-to-Defend Order indicating that Allianz's duty to defend arose "upon the exhaustion of the SIR in August 2003." They also cite to case law for the proposition that a judgment is conclusive as to those matters that were necessary to reach the judgment, whether or not expressly set forth and regardless of whether the rendering court's stated reasons for its judgment are inconsistent or mistaken. Ultimately, we do not find this argument persuasive. Under Indiana law, "[t]here is no estoppel where anything is left to conjecture as to what was necessarily involved and decided." Peterson v. Culver Educational Foundation, 402 N.E.2d 448, 461 (Ind. App. 1980); see also Indianapolis Downs, LLC, 834 N.E.2d at 704 ("Collateral estoppel does not extend to matters that were not expressly adjudicated and can be inferred only by argument"). Despite its inclusion of the statements that the Policyholders cite, the Indiana trial court expressly based its ruling on the "potential" for coverage and therefore decided that it would not have to address the Batch-Clause-interpretation issue in making its duty-to-defend ruling. Thus, the Policyholders' attempt to avoid the Indiana court's own language is based purely on "conjecture."

Moreover, we fail to see how the principle behind collateral estoppel would be promoted by the doctrine's application in this case. The parties litigated the Batch-Clause-interpretation issue in Illinois prior to litigating the issue in Indiana. The Illinois court entered its Year One Ruling resolving the Batch-Clause-interpretation issue in the Insurers' favor prior to the date the Indiana court entered its Duty-to-Defend and Batch Clause Orders. The Illinois court also denied the Policyholders' initial motion for reconsideration of its Year One Ruling prior to the date the Indiana court entered its orders. In other words, under the procedural posture of this case, the parties did not "relitigate" the Batch-Clause-interpretation issue in Illinois after the Indiana court entered its orders.

To the contrary, as the Indiana court itself recognized, the Batch-Clause-interpretation issue had already been litigated and decided in Illinois prior to the date the Indiana court entered its orders on March 23, 2007. Since the Batch-Clause-interpretation issue had been argued and decided in Illinois prior to the date the Indiana court entered the orders alleged to have preclusive effect, the principle underlying the doctrine of collateral estoppel--judicial economy--would not be served. In fact, all of the time and work devoted to this issue by the parties and the Illinois court would go for naught. See Freeman United Coal Mining Co. v. Office of Workers' Compensation Program, 20 F.3d 289, 294 (7th Cir. 1994) (noting that the purpose of collateral estoppel is to prevent relitigation of the same issues in a subsequent case and that the reasons for the doctrine are "hardly served" where the effort of litigation has already been undertaken).

In sum, we conclude that the Indiana "judgment" did not have collateral-estoppel effect with respect to the Illinois Year One Ruling. Under Illinois law, neither the Indiana Batch Clause Order nor the Indiana Duty-to-Defend Order is final, because the potential for appellate review has not been exhausted. Further, under Indiana law, the Indiana Batch Clause Order was not designated as final and appealable, and the Indiana Duty-to-Defend Order, which was so designated, expressly declined to consider the Batch-Clause-interpretation issue.

#### B. Batch Clause

We now address the Policyholders' claim that the Illinois trial court erred in granting summary judgment in favor of the Insurers on the Batch-Clause-interpretation issue. "The construction of an insurance policy and a determination of the rights and obligations thereunder are questions of law for the court which are appropriate subjects for disposition by way of summary judgment." Crum & Forster Managers Corp. v. Resolution Trust Corp., 156 Ill. 2d 384, 391 (1993).

Summary judgment is appropriate where the pleadings, depositions, affidavits, and admissions on file, if any, reveal that there is no genuine issue of material fact and that the moving party is entitled to judgment as a matter of law. Legion Insurance Co. v. Empire Fire & Marine Insurance Co., 354 Ill. App. 3d 699, 703 (2004). We review a grant of summary judgment de novo (Virginia Surety Co. v. Northern Insurance Co. of New York, 362 Ill. App. 3d 571, 573 (2005)) and may affirm on any basis in the record, irrespective of whether the trial court relied on that ground or whether its reasoning was correct (Fabiano v. City of Palos Hills, 336 Ill. App. 3d 635, 641 (2002)).

Insurance policies are interpreted in accordance with the principles of contract construction. Aurelius v. State Farm Fire & Casualty Co., 384 Ill. App. 3d 969, 973 (2008). The cardinal rule of contract construction is to ascertain and give effect to the intent of the parties. Aurelius, 384 Ill. App. 3d at 973. The best indication of the parties' intent is the language of the contract itself. Farmers Automobile Insurance Ass'n v. Wroblewski, 382 Ill App. 3d 688, 696 (2008). In construing an insurance policy, the contract must be read as a whole, giving meaning to all terms in the policy. Clarendon America Insurance Co. v. 69 West Washington Management LLC, 374 Ill. App. 3d 580, 585 (2007). "If the words used in the policy are clear and unambiguous, they must be given their plain, ordinary, and popular meaning." Central Illinois Light Co. v. Home Insurance Co., 213 Ill. 2d 141, 153 (2004). The fact that the parties disagree about the interpretation of a particular provision does not render the provision ambiguous. Liberty Mutual Fire Insurance Co. v. St. Paul Fire & Marine Insurance Co., 363 Ill. App. 3d 335, 341 (2005). Rather, a policy will be deemed ambiguous where its words are susceptible to more than one reasonable interpretation. Benedict v. Federal Kemper Life Assurance Co., 325 Ill. App. 3d 820, 824 (2001). A provision that is found to

be ambiguous and that limits the insurer's liability will be construed in favor of the insured. Jones v. Country Mutual Insurance Co., 371 Ill. App. 3d 1096, 1099 (2007).

Under the claims-made policies at issue here, the only Ancure claims that could potentially implicate the Year One policies are those claims of which the Policyholders received written notice between September 1, 2000, and September 1, 2001. It is undisputed that the only two such claims were the Carter claim, which was resolved for \$10,000, and the Krupa claim, which was resolved for \$200,000. Standing alone, the two Year One claims do not exhaust the applicable SIR. As a result, the Policyholders attempt to exhaust the SIR by aggregating the Year One claims with claims made in later years pursuant to the Batch Clause.

The parties agree that whether aggregation is permissible under the terms of the policy turns on the last sentence of the Batch Clause. To place that sentence in context, we again reproduce the language of the Batch Clause in its entirety:

"It is agreed that the policy section, Definitions, (6) 'Occurrence', with respect to 'products-completed operations hazard' is amended to include the following[:]

The term 'batch' means all products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum[.]

The term 'advisory memorandum' is any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of 'bodily injury' or 'property damage' from a product in use[.]

Coverage does not apply to any loss, claim, or 'suit' which arises out of a defect or deficiency which was known or suspected prior to the retroactive date shown in this policy[.]

When this endorsement is attached to your policy, all losses arising from a single 'batch' of your product will be considered to be one 'occurrence[.]' Therefore, when multiple losses are considered to be one 'occurrence' you must only meet a single 'self-insured retention' amount[.] Likewise, our limit of liability due to 'bodily injury' and 'property damage' is limited to that of a single 'occurrence[.]'

All claims made by persons or organization [sic] seeking damages because of 'bodily injury' or 'property damage' arising out of one batch will be deemed to have been made at the time the first of those claims is made against you[.]"

After reviewing the Batch Clause, we conclude that the trial court's ruling in favor of the Insurers was correct for three reasons. First, the trial court's interpretation of the insurance policy is supported by the plain and unambiguous language of the Batch Clause. Second, the "Dear Doctor" letters relied upon by the Policyholders do not constitute "advisory memorand[a]" as that term is defined in the Batch Clause. Third, to the extent that the "Dear Doctor" letters constitute "advisory memorand[a]," none of the Year One claims involves a defect or deficiency that is identified in any of the "Dear Doctor" letters. We address each finding in turn.

According to the Policyholders, the Batch Clause "unambiguously 'batches' together products not lawsuits." (Emphasis in original.) The Policyholders contend that the Batch Clause aggregates "all claims arising out of a 'batch' of products suspected of having the same suspected defect." (Emphasis added.) Thus, the Policyholders assert, the court must "determine if a product 'batch' exists without reference to the contents of any particular underlying claim." We conclude that the Policyholders' interpretation of the policy is not reasonable, because it ignores the plain and unambiguous language of the Batch Clause.

The Batch Clause allows a policyholder to aggregate "[a]ll claims \*\*\* seeking damages because of 'bodily injury' or 'property damage' arising out of one batch." Therefore, determining whether claims made in different years may be aggregated requires a two-part inquiry. Initially, the particular "batch" must be identified. The term "batch" is defined by reference to a group of "products." A "batch" consists of a group of "all products which have the same known or suspected defect or deficiency which is identified by the same advisory memorandum." Thus, to qualify as a "batch," all products must share the same suspected defect or deficiency identified by the insured. See Allianz Insurance Co., 884 N.E.2d at 422 n.9. In asserting that a "batch" consists of products "suspected of having" a defect, the Policyholders read into the definition language that does not appear.

The Policyholders' claim, that the court must determine if a product "batch" exists without reference to the contents of any particular underlying claim, ignores the second part of the inquiry, which requires an examination of the last sentence of the Batch Clause. The only claims that may be aggregated are those "seeking damages because of 'bodily injury' or 'property damage' arising out of" the relevant "batch," the definition of which requires products having the same known or suspected defect identified by the insured in the same advisory memorandum. Thus, there must be a causal nexus between the claims and the product defect. Without commonality of defect, or a connection between that defect and an advisory memorandum, a claim cannot form the foundation of a "batch." For this reason, we reject the Policyholders' claim that, as long as multiple losses involve a particular product with any defect at all, the losses may be aggregated, regardless of whether the claims at issue involve a common product defect. In so arguing, the Policyholders ignore the principle that a policy is to be read as a whole, giving meaning to all its terms. Clarendon

America Insurance Co., 374 Ill. App. 3d at 585. In particular, the Policyholders repeatedly disregard the fact that to be aggregated the claims must be "seeking damages because of 'bodily injury' or 'property damage' arising out of" products with the same known or suspected defect or deficiency. (Emphases added.)

The Policyholders also claim that certain "rules of grammar" support their reading of the Batch Clause or, at the very least, the notion that their reading of the policy is reasonable. First, the Policyholders cite to a "proximity to modifier" rule. See W. Strunk & E. White, *The Elements of Style* 30 (3d ed.1979) ("[m]odifiers should come, if possible, next to the word they modify"). The Policyholders' reliance on this rule is unpersuasive. The Policyholders' argument revolves around replacing the term "batch" in the last sentence of the Batch Clause with that term's definition, so that it reads "[a]ll claims made \*\*\* because of 'bodily injury' \*\*\* arising out of all products which have the same known or suspected defect." (Emphasis in original.) The Policyholders then parse the highlighted language, claiming that certain phrases were intended to modify particular phrases appearing before them. Thus, for instance, the Policyholders claim that the clause "the same known or suspected defect" modifies the clause "all products which have." As the Insurers point out, however, this exercise ignores the fact that this entire section of the Batch Clause collectively modifies and limits the "claims" that are "batched," *i.e.*, "claims \*\*\* seeking damages because of 'bodily injury' \*\*\* arising out of" products with the defect identified in the advisory memorandum.

The Policyholders also rely on an "anti-surplusage" rule, arguing that the Insurers' interpretation of the Batch Clause effectively deletes the clause "all products which have" from the provision. However, it is the Policyholders' interpretation that renders meaningless key portions of the Batch Clause by urging an interpretation that considers the phrase "all products" in a vacuum

while ignoring that these referenced products must share the same known or suspected defect or deficiency and that this defect or deficiency must exist in all claims sought to be aggregated. The Policyholders' failure to consider the entire context of the Batch Clause results in their flawed interpretation that "all products" must be batched even if the claims are brought because of different defects in those products.

The Policyholders further argue that "common sense" shows that their reading of the Batch Clause is reasonable because, in other factual circumstances, that reading could reduce rather than increase the Insurers' liability. However, hypothetical factual situations are simply irrelevant, especially where, as here, the trial court's interpretation of the provision at issue is supported by the provision's plain and unambiguous language.

Applying the foregoing interpretation of the Batch Clause to the facts of this case reveals that the claims made in Year One did not seek damages because of bodily injury arising out of products having the same defect as in claims made in subsequent years. The only two claims made in Year One were the Carter and the Krupa claims. Before the trial court, counsel for the Policyholders opined that the "bulk" of Ancure claims made after Year One related to bodily injury resulting from a defect in the Ancure delivery system:

"[The Ancure Device] that's implanted in the aorta, right about there, through a very intricate process, as you can imagine.

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It's--when implanted, it's been a highly successful product, and it's saved a lot of people's lives. The difficulty is that [sic] Guidant faces in the underlying cases is that it's very difficult to put one of those in, and that's what the case is really about."

Neither the Carter claim nor the Krupa claim involved difficulties with the implantation of the Ancure Device. The Carter claim involved an allegation that the Ancure Device failed to remain deployed after the delivery process had been completed. The Krupa claim involved an allegation that the Ancure Device was four centimeters shorter than the packaging indicated. In fact, the Policyholders acknowledged that the Ancure claims made in Year One and those made in subsequent years did not seek damages because of bodily injury arising out of products sharing the same defect. Counsel for the Policyholders told the trial court that he was "not sure what the Carter claim involved" because "it's not material." Counsel also represented that, while there were "isolated other packaging issues in some of the claims that were made following the lapse of the Allianz policy," these claims "were not the bulk of the claims we're talking about." Because neither of the two claims made in Year One sought damages because of bodily injury related to a deployment failure occurring during the implantation of the Ancure Device, the Policyholders' attempt to aggregate the Year One claims with claims made after Year One must fail.

Even if we had found the Policyholders' interpretation of the Batch Clause to be reasonable, we would still affirm the trial court for, contrary to the Policyholders' position, the "Dear Doctor" letters do not constitute "advisory memorand[a]" as that term is defined in the Batch Clause. The Batch Clause defines an "advisory memorandum" as "any communication issued by you to inform health professionals or other appropriate persons or firms of a risk of 'bodily harm' or 'property damage' from a product in use." In this case, the Policyholders rely on three "Dear Doctor" letters as their "advisory memorand[a]." However, an examination of these documents reveals that none of them communicates "a risk of 'bodily harm' or 'property damage' from a product in use." We examine each letter individually.

The first "Dear Doctor" letter is dated March 21, 2001. It states in relevant part:

"On Friday, March 16, [2001,] Guidant Corporation announced its decision to halt the marketing of the Ancure Endograft System and recall products in the field. This action is being taken as a result of Guidant's identification of certain deficiencies in its regulatory process and communications with [the] FDA. These deficiencies primarily relate to failures in communicating problems with the deployment of the endograft, not the graft itself. While Endovascular Solutions believes that the graft can be safely and effectively deployed with appropriate techniques, the company did not correctly communicate either to [the] FDA or the physician community how to address deployment problems with the device." (Emphasis added.)

The letter continues, "[p]lease be assured that the Ancure Endograft implanted product is safe and effective; supported by extensive positive long-term data. These actions are NOT related to the performance of the Ancure Endograft." (Emphasis in original.) The letter also announced a "controlled plan" to allow physicians to continue to implant the Ancure Device, provided certain conditions are met.

The second "Dear Doctor" letter is dated March 31, 2001. The second letter indicates that Guidant had been working closely with the FDA "to review deficiencies primarily related to failures in communicating problems with the deployment of the graft." The letter further states:

"While we believe the graft can be safely and effectively deployed using appropriate techniques, the company did not correctly communicate either to [the] FDA or the physician community on how to address deployment problems with the device. Guidant does not believe these issues affect the graft itself." (Emphasis added.)

The letter also informs physicians that the FDA had agreed to continue the "controlled plan."

The third and final "Dear Doctor" letter is dated May 2, 2001. That letter attributes the recall to "the fact that [Guidant] had identified various deficiencies in our regulatory and quality systems during recent audits." The letter describes these "regulatory and quality issues" as follows:

"1) We made certain changes to improve the ANCURE System delivery system but did not submit those changes to [the] FDA for its approval prior to making the changes. While we believe that these changes improved the delivery system, we recognize and accept [the] FDA's position that these changes should have received FDA approval before implementation.

2) We also did not report to [the] FDA field observations regarding deployment issues with the ANCURE System. These observations generally involved difficulties encountered during device deployment.

3) We also should have updated the Instructions for Use (IFU) to include techniques to resolve intra-operative difficulties associated with the graft deployment.

4) In addition, we found issues with certain of our internal systems including complaint handling, documentation, training and manufacturing systems."

The May 2, 2001, letter also references "recent tests of the ANCURE System packaging." In this regard, the letter relates:

"[Guidant] discovered conflicting results in shelf life packaging tests. The packaging 'passed' some of the tests but did not pass others. Next, we performed a health hazard assessment on this packaging issue. We analyzed our database and found no reported cases where an ANCURE System device caused a patient infection. We also reviewed the

literature for similar sterile products used in the operating room. Based on those reviews, we calculated the incremental risk of patient infection related to these packaging issues to be less than one in a million. Based on these findings, we do not believe that there is a safety issue relating to this packaging matter."

In closing, the May 2, 2001, letter assures physicians that "these issues do not affect the long-term safety or performance of this graft."

We find no language in any of these letters that is meant to communicate to health-care professionals a risk of bodily harm. The first two letters reference certain "deficiencies" in Guidant's regulatory process and communications with the FDA. However, the letters also represent that the Ancure Device can be "safely and effectively deployed" regardless of these deficiencies. Indeed, despite the deficiencies in Guidant's regulatory process and communications with the FDA, the letters also describe a plan for continued implantation of the Ancure Device. Likewise, the May 2, 2001, letter does not communicate a risk of bodily harm. Although that letter references a "packaging issue" resulting in "an incremental risk of patient infection," Guidant itself discounts this risk in the letter, calculating the risk "to be less than one in a million" and concluding that there is no safety issue related to the packaging matter.

The Policyholders also suggest that a "Technical Update on Deployment" (Technical Update), which accompanies the March 21, 2001, letter and is referenced in the March 31, 2001, letter, advised of the requisite risk of bodily harm. The Technical Update includes a section titled "ADDITIONAL WARNINGS AND PRECAUTIONS." The Policyholders assert that "[t]he only possible reason for such 'warnings and precautions' was a perceived risk of bodily injury." However, the Technical Update is merely a general update to the literature for the Ancure Device. Indeed, the

letters that reference the Technical Update indicate that it is provided "as a guide to additional deployment techniques for use in the procedure." The letters further suggest that the Technical Update was developed so that the FDA would agree, as part of the "controlled plan," to allow physicians to continue to use the Ancure Device. Moreover, the updated procedures referenced in the Technical Update do not warn of a risk of bodily injury even if adherence to some of the procedures may ultimately affect a patient's blood flow. Accordingly, the Technical Update does not convert the "Dear Doctor" letters into "advisory memorand[a]."

The Policyholders query, if the "Dear Doctor" letters were not written to inform doctors of a risk to their patients, what was their purpose? After a review of the letters it is evident that the purpose of the letters was to inform medical professionals of the controlled plan, to assure them of Guidant's belief that the Ancure Device remained safe and effective, and to advise them to continue with routine follow-ups for those patients already implanted with the device.

Finally, we point out that, even if we were to consider the "Dear Doctor" letters "advisory memorand[a]," we would still affirm the trial court's ruling. The Policyholders contend that the first two "Dear Doctor" letters advise of risks of injury related to the implantation procedure while the third "Dear Doctor" letter references an "incremental risk" of patient infection as a result of "quality" and "packaging" issues. However, neither of the Year One claims involved these types of defects. As noted previously, the only two claims made during Year One were the Carter and Krupa claims. The Carter claim involved an allegation that the Ancure Device failed to remain deployed after the delivery process had been completed. The Krupa claim involved an allegation that the Ancure Device was four centimeters shorter than the packaging indicated. Accordingly, the Year One claims cannot be aggregated with claims made in later years to exhaust the applicable SIR.

The Policyholders suggest that it is irrelevant whether the claims made in Year One involved the defects identified in the advisory memoranda because, regardless of whether the claims alleged bodily injury because of those particular defects, all of the Ancure Devices shared these defects. This argument is based on a flawed interpretation of the Batch Clause and ignores the express requirement that the "same known or suspected defect or deficiency [be] identified by the same advisory memorandum." (Emphasis added.) Accordingly, we reject this argument.

In sum, we conclude that the trial court's ruling granting summary judgment in favor of the Insurers was correct because the trial court's interpretation of the insurance policy is supported by the plain and unambiguous language of the Batch Clause, the "Dear Doctor" letters relied upon by the Policyholders do not constitute "advisory memorand[a]" as that term is defined in the Batch Clause, and the "Dear Doctor" letters do not warn about defects at issue in the Year One claims.

### III. CONCLUSION

For the reasons set forth above, we affirm the judgment of the circuit court of Du Page County.

Affirmed.

ZENOFF, P.J., and HUTCHINSON, J., concur.