Product Recall Insurance: It’s Not Just for Food Contamination Anymore¹

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INTRODUCTION

Every year, pharmaceutical companies and medical device manufacturers recall dozens of products because they are defective or could pose a serious health risk. In 2014, 61 medical devices were recalled, and 42 drugs were recalled. Most were categorized as “Class 1” recalls or were listed because, according to the FDA, “there is a reasonable chance that they could cause serious health problems or death.”

Consumer electronics, too, have been plagued by recalls in recent years: from personal computing (Hewlett-Packard recalled over 5 million power cords in 2014, and Lenovo an additional 500,000, due to fire risks) to televisions (VIZIO recalled 245,000 televisions in 2014, and JVC an additional 27,000 due to rip-over risks) to phones and accessories (Fitbit recalled 1,000,000 tracking bands in 2014 due to a risk of skin irritation, and Apple recalled an undisclosed number of iPhones due to battery life issues). Automobile recalls totaled 70 in December 2014 alone. And this is to say nothing of the food industry, which has experienced an average of ten recalls per week in recent years.

In the past, many industries tended to absorb recall expenses as a “cost of doing business.” Now, however, specialty insurance products exist that may fill the apparent gap in coverage between standard comprehensive general liability (CGL), errors and omissions (E&O), and first-party property damage and business interruption insurance policies. Once the province of food producers and consumer products manufacturers, specialized insurance is now available expressly to cover a whole host of recall-related expenses arising in a wide variety of industries.

Even when the policyholder has purchased product recall and crisis management insurance, however, such policies, like all insurance, are not without their own restrictions and exclusions. In the absence of such specialized insurance coverage, CGL, E&O and first-party insurance policies might cover some of the costs of product recalls under certain circumstances, but only after the policyholder overcomes several significant limitations on coverage. Policyholders and insurers alike must be conversant in the different coverages available – and not available – under different policy forms.

3 US Food and Drug Administration. List of Class 1 Drug Recalls, supra note 2.
This paper presents an overview of current offerings in the insurance market (including sample policy forms), key policy provisions that determine the nature and extent of coverage for a product recall under different policy types, and recent case law addressing coverage for recall-related events.

DISCUSSION

I. PART ONE - WHAT DOES A “RECALL” POLICY COVER

A. Specialty Policies Available in Today’s Insurance Market

Although product recalls have been around since the Tylenol tampering incident of the 1980s, product recall insurance is still a relatively new and non-standardized type of coverage. Insurance companies offer varying coverages for tampering and contamination – the oldest type of recall coverage – and for recall expenses, adverse publicity, and even crisis management expenses in some newer policies.\(^\text{10}\)

1. Tampering / Contamination Policies

Specialty insurance policies created and developed to address product contamination issues have evolved extensively over the past 15 years. Modern versions provide coverage for myriad costs related to product contamination. Companies competing in a broad range of industries, including food, life sciences, consumer goods, component parts and auto manufacturing, are able to gain coverages under Product Contamination Insurance (PCI) policies generally not found within standard insurance portfolios, including first-party coverages as well as, sometimes, third-party coverages. PCI policies also may provide critical crisis management consultant coverage, which could prove the difference between a company surviving a crisis management event or succumbing to catastrophic circumstances.

Product contamination insurance commonly provides coverage for accidental contamination, malicious tampering and product extortion. In brief, accidental contamination coverage is provided when accidental or unintentional contamination, impairment or mislabeling of a product takes place during processing or manufacture and the use or consumption of such product has or would (or “likely would” or “probably would” or “will”) result in bodily injury or property damage.\(^\text{11}\) Malicious tampering coverage involves the actual or alleged intentional, malicious and illegal adulteration of products so as to render the product dangerous or unfit for use. Coverage for product extortion concerns a threat to commit malicious tampering in order to gain ransom monies. Importantly, PCI policies do not cover all recalls; they typically only cover a recall that is triggered by one of the aforementioned events. See Section I.B.1., below.

2. Product Withdrawal / Crisis Management Policies

The necessity and popularity of product contamination insurance has created a market for expanded coverage offerings. Now, in addition to product contamination insurance, insurers have also developed product recall insurance policies, which differ somewhat from product contamination policies. While property policies in most circumstances require a physical damage trigger, and contamination policies usually require the policyholder’s product in fact to be contaminated, “recall” policies are designed to

\(^{10}\) Specimen policy forms are attached at the end of this paper. See Attachments 1 through 8.

\(^{11}\) How certain or likely the potential injury or damage must be is the subject of much of the litigation regarding this type of insurance. See Section C, below.
respond to a recall occasioned by the determination that there is a threat, whether or not anyone has been harmed, and whether or not there has been actual contamination.\textsuperscript{12}

For example, a Chubb “Product Withdrawal and Crisis Management Insurance – Life Science” form promises to pay for withdrawal expenses resulting from a “Class 1 recall.”\textsuperscript{13} “Class 1 recall” is defined as a product recall or withdrawal “because of a situation in which there is a reasonable probability that the use of, or exposure to, such product will cause serious adverse health consequences or death.”

Specialty insurance has also been extended to cover adverse publicity and crisis management. “Crisis management service” under the Chubb policy form, for example, includes coverage for “professional services or advice provided by a crisis management service firm in connection with a Class 1 recall.” Adverse publicity coverage involves reporting in the media or the release of a government publication where an insured or its product is identified as being involved with an insured event, such as malicious contamination.\textsuperscript{14} Adverse publicity and crisis management coverages may be provided as standalone coverage or as part of contamination coverage, often by amendatory endorsement, and sometimes with sublimits that cap the amount of insurance available.

3. Industry-Specific Recall Coverage

In order to address issues related to specific industries, insurers have also developed industry-specific specialty policies. Companies involved with the automobile and life sciences industries often face tougher regulatory environments and have different supply chain considerations from other industries. Specialty crisis policies, which provide coverages similar to those offered under product contamination and product recall policies, have been developed to address the specific exposures faced by these industries.\textsuperscript{15}

The advantages of specialty crisis policies are two-fold; in the event of a recall, they provide companies with a team of experts they usually cannot afford or are unable to timely assemble for critical assistance. Additionally, the policies provide coverages that are either not found or are precluded or excluded from coverage within a standard insurance portfolio, such as economic damages.\textsuperscript{16} However, because a single insurance form or policy has not been developed, these specialty crisis policies provide different coverages and contain similar but different definitions. Moreover, insurers and brokers also may work together to develop manuscript wordings to address a company’s specific exposures. Such customized wordings may depart substantially from more standardized insurance agreements.

B. Key Provisions

It is critical to understand exactly what triggers coverage under a specialty insurance policy. The policy’s insuring agreement and definitions are key to this understanding.

\textsuperscript{12} Outside of North America, to trigger government recall coverage, an order by a governmental authority and harm caused by the use or consumption of the product may be required by the policy language.

\textsuperscript{13} Att. 1, Chubb, Product Withdrawal and Crisis Management Insurance, Form 80-02-6427 (Ed. 8-04).

\textsuperscript{14} See, e.g., Att. 2, ACE, Adverse Publicity Coverage Endorsement, Form REC-7546 (01/13).

\textsuperscript{15} See, e.g., Att. 3, Catlin, Automotive Product Recall Insurance; Att. 4, Catlin, Consumer Durables Insurance; Att. 5, ACE Recall Plus Insurance For Consumer Goods, REC-7521 (01/13); Att. 6, ACE Recall Plus Insurance For Component Parts, REC-7523 (01/13); Att. 7, Catlin, Pharmaceutical Product Contamination. See also Chubb life sciences promotional materials, available at http://www.chubb.com/businesses/cci/chubb15598.html (listing analytical laboratories, dietary supplement companies, healthcare product service organizations, medical device companies and pharmaceutical/biotechnology companies among the industries they insure).

\textsuperscript{16} See, e.g., Att. 8, Catlin Financial Loss Extension 1120145.
1. The Insuring Agreement: What Triggers Coverage

   a. Contamination Policies

PCI policies typically provide coverage for recall-related costs when product contamination has in fact occurred, but not when it is merely suspected. For example, ACE’s “Recall Plus” insurance policy form promises to reimburse for losses caused by an “insured event,” which means “accidental contamination or malicious tampering.” “Accidental contamination” in turn is defined as

any accidental or unintentional contamination, impairment or mislabeling of an insured product(s), which occurs during or as a result of its manufacture, production, processing, mixing, blending, compounding, packaging or distribution, provided that the use or consumption of the insured product(s) has resulted in or would result in bodily injury or property damage.17

None of the terms in this definition is modified by the words “suspected,” “potential,” “possible,” or even “probable.” By the definition’s plain terms, there must be contamination (period), and that contamination must have resulted in or would – not “likely” or “probably” would – result in bodily injury or property damage.

Although very few insurance coverage decisions have been rendered about modern PCI policies, to date most courts that have ruled have hewn closely to the policy language and found no coverage for suspected or potential contamination. See Section C, below.

The issue of actual versus potential contamination is particularly important for companies further down supply chains, who may never receive contaminated or harmful product but are nevertheless required to conduct a product recall. One only has to review recent recall history involving products such as peanut butter or hydrolyzed vegetable protein to understand that many companies involved with the affected supply chains were only concerned with products that might have been contaminated as opposed to products that actually were demonstrated to be contaminated.

   b. Recall/Withdrawal Policies

Recall policies, which are not limited to actual contamination events, typically focus on the probability of injury rather than the existence of actual contamination or defects. For example, Chubb offers recall insurance for Class 1 recalls, which are those involving a “situation in which there is a reasonable probability that the use of, or exposure to, such product will cause serious adverse health consequences or death.”18

ISO’s Product Withdrawal Coverage Form agrees to reimburse “product withdrawal expenses,” defined to include suspected defects:

“Product withdrawal” means the recall… of your products, or products which contain your products, because of known or suspected defects in your product, or known or suspected product tampering, which has

17 Att. 9, ACE, Recall Plus Insurance for Consumable Products Policy Form (REC-7519 (01/13) (internal quotations omitted).
18 Att. 1, Chubb, Product Withdrawal and Crisis Management Insurance, Form 80-02-6427 (Ed. 8-04).
caused or is reasonably expected to cause bodily injury or physical injury to tangible property other than your product.\textsuperscript{19}

Here, actual contamination is not required. Instead, a defect may only be suspected. On the other hand, that defect must be “reasonably expected” to cause injury or damage. Thus, if a product is considered defective but would not result in bodily injury or property damage, coverage might not be available, depending on the terms of the policy and the “reasonableness” of the expectation of harm.

2. Types of Potentially Covered Costs

The types of costs or expenses covered under specialty crisis policies usually include the costs of the recall itself (e.g., repair/replacement, disposal, notification, employee overtime, temp workers, transportation, warehousing/storage); often include related losses that result from the recall (e.g., business interruption, loss of gross profit, rehabilitation costs, redistribution, increased cost of working, product extortion/ransom costs, as well as pre-recall costs, extra expense); and sometimes include liability for third-party costs (e.g., customer loss of gross revenue, third-party recall costs, product liability and defense costs). As coverage for most of these costs or expenses are either precluded or excluded under a standard insurance portfolio, these specialty policies may provide vital coverages for losses incurred during a crisis management event. On the other hand, because such coverages have not been standardized, different insurers offer different levels and types of coverage. For example, Chubb has a life science recall policy form that excludes replacements, refunds and lost profits from the definition of “withdrawal expenses.”\textsuperscript{20} ISO’s Limited Product Withdrawal Expense Endorsement (a narrow CGL endorsement) excludes lost profits, expenses for regaining goodwill, lost market share, or other costs of restoring and rehabilitating the product; and it also excludes defense costs for claims asserted against the policyholder for liability to a third party for a product recall.\textsuperscript{21}

Some insurance companies offer coverage for some of the aforementioned loss types. For example, Swiss Re stated in a 1998 brochure that coverage for lost profits and lost market share is available, but recommended sublimiting such coverage and “defin[ing] precisely how indemnifications of this type are to be quantified.” Swiss Reinsurance Company, “Product Recall and Product Tampering Insurance” at 40-41 (1998).

The inclusion or exclusion of the costs of rehabilitating a product and regaining the company’s goodwill and brand reputation is significant. Often such business costs far outstrip the expenses associated with the physical recall itself. See Brad Murlick, “Contemporary Product Recall Issues and Strategies for Remediation,” ABA Section of Litigation, Insurance Coverage Litigation Committee CLE Seminar (February 29, 2008).

Product contamination and product recall policies also might provide critical pre- and post-crisis consultant coverage. When a company faces a product crisis event, it will need a team of experts to help it survive the onslaught of customer, governmental and regulatory inquiries, intrusions and investigations. Supply chains are littered with the names of companies no longer in existence because they were unable to survive a product crisis event. Specialty crisis policies provide companies with the ability to engage a panel of experts in public relations, governmental interaction, root cause investigation, laboratory testing,

\textsuperscript{19} Att. 10, Insurance Services Office, Product Withdrawal Coverage Form (CG 00 66 12 04) (internal quotations omitted).

\textsuperscript{20} Att. 1, Chubb, Product Withdrawal and Crisis Management Insurance, Form 80-02-6427 (Ed. 8-04).

\textsuperscript{21} Att. 11, Insurance Services Office, Limited Product Withdrawal Expense Endorsement (CG 04 36 04 13).
contamination identification, manufacturing or production processing and legal assistance before and after a crisis. Pre-crisis consultancy can assist a company with preparation for a crisis event, including the review or creation of a crisis response plan. When the event takes place, these specialty crisis policies provide a company with a hotline number used to immediately engage its team of experts. If a company begins to search for experts after a crisis event commences, it usually finds that its actions are too little and too late.

3. What Recall Policies May Not Cover

Like all insurance, coverage under specialty contamination, recall and crisis policies is bounded by their terms, which necessarily include the policy’s definitions, conditions and exclusions.

In addition to the issues described above, specialty recall policies are generally not designed to provide coverage for mere quality issues. Contamination and recall insurance policies are meant to address product exposures that result in or could result in bodily injury or property damage – not product performance failures or warranty issues that have no bearing on such harms. That being said, however, certain insurers may offer product guarantee coverage for certain industries.

Like other types of insurance policies, specialty policies also contain certain exclusions that bar coverage for losses arising out of certain circumstances. Exclusions vary widely from insurer to insurer and from policy form to policy form; therefore, policyholders must be diligent in reviewing and understanding what coverage they have.

Predictably, intentional and wrongful violations of governmental regulations or industry best practices are often excluded under specialty policies. Similarly, circumstances of which an insured had actual or constructive knowledge before the policy’s inception are usually excluded.

Some policies also exclude losses attributable to circumstances involving a competitor’s product; although, coverage may be available for product refusal, regardless of the cause of the refusal.

Some specialty policies also may exclude coverage for third-party liability claims attributable to the use or consumption of an insured product, which would ordinarily be covered under a company’s third-party liability policy.

Insurers also may seek to avoid coverage for costs they deem unrelated to the contamination or the recall, such as recall-related advertising costs that replace the company’s normal advertising expenses in the same amount. Costs and expenses related to the design or redesign of products also are typically excluded.


At the time of this writing, only one court case had been decided involving insurance coverage under a recall policy issued to a life science company (the Abbott Labs decision below), although that case involved rescission and alleged misrepresentation issues rather than the coverage terms of the policies. Otherwise, very few insurance coverage decisions have been rendered about modern PCI policies issued to any industry. Nevertheless, those cases that have been decided in the past few years, predominantly

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22 See id. (exclusion a).
23 See id. (listing exclusions for losses arising out of a “known defect” (exclusion f), “pollution-related expenses” (exclusion k) and “chemical transformation” (exclusion c), among others).
involving food industry, may contain clues as to the future of recall coverage claims and litigation in life sciences and other industries.

1. **Case Allowing Coverage Under Specialty Recall Policy**

   a. **Abbott Laboratories: $84 Million Award to Insured for Recall of Anti-Obesity Drug (Illinois).**

In *Certain Underwriters at Lloyd’s, London v. Abbott Laboratories*, 2014 IL App (1st) 132020, 16 N.E.3d 747, 384 Ill.Dec. 354, an Illinois appeals court found coverage under product recall insurance policies (the “Policies”) that had been issued by Certain Underwriters at Lloyd’s, London (“Underwriters”) to Abbott Laboratories (“Abbott”). The court considered whether Abbott had made material misrepresentations on its applications for insurance, as well as Underwriters’ response and timing in regard to receipt of information about the alleged misrepresentations.

During the process of securing coverage from Underwriters, Abbott acquired another pharmaceutical company – Knoll Pharmaceutical Company (“Knoll”). Abbott timely provided notice of the acquisition of Knoll to Underwriters. As required under the Policies, Abbott submitted applications to Underwriters regarding the additional risks associated with the acquisition. The applications contained questions regarding whether Abbott had any knowledge of any current situation, fact, or circumstance that might lead to a claim under the policies, to which Abbott answered “no.”

After Abbott had signed the final insurance application, but before all of the Underwriters had agreed to the terms of coverage, The Wall Street Journal ran an article regarding the possibility that the Food and Drug Administration (“FDA”) may order that certain of Knoll’s weight-loss drugs be recalled from the market. An Abbott representative advised Underwriters about the article, but did not forward a copy of it. Underwriters and Abbott eventually reached agreement as to the additional premium tied to the acquisition. Abbott then paid the premium and provided a copy of the Wall Street Journal article to Underwriters. Underwriters accepted the premium payment.

A few months later Abbott recalled the weight-loss drug and tendered a claim to Underwriters under the policies. After requesting additional documentation and entering a tolling agreement regarding the claims related to the recall, Underwriters ultimately filed a complaint seeking to rescind the Policies based on misrepresentations on the insurance applications. Abbott counter-claimed. During the bench trials that followed, the judge found that Abbott did not make material misrepresentations in its applications, and that Underwriters had waived their rights to a rescission claim. Ultimately, a judgment was entered against Underwriters for $84.5 million – the full limits of the Policies – as well as post-judgment interest.

Underwriters appealed and Abbott cross-appealed. The appellate court affirmed the trial court finding that the evidence showed that the insured did not intend to make material misrepresentations in its applications for the Policies. The court found that Abbott timely and sufficiently disclosed regulatory issues with the drug at issue. In addition, the court found that Underwriters accepted the additional premium for Knoll, waiving their right to rescind the Policies. Further, the appellate court found that there was a bona fide dispute over coverage, so an award of statutory fees and costs to Abbott was not warranted.

Ultimately, the court found that Abbott was entitled to coverage under the product recall policies. In reaching its determination, the court considered the timeline within which Underwriters sought to rescind
the Policy and found that they had waived their right to rescission. The court held that an insurer who wishes to rescind a policy needs to do so as soon as they learn of the information upon which they base the rescission.

2. Cases Disallowing Coverage Under PCI Policy

   a. **Ruiz Food Products: No Coverage for Mere Risk of Contamination, and Recall is not “Impairment” Under a Product Contamination Policy (9th Cir.).**

   In *Ruiz Food Products*, the insured produced “Tornados,” a frozen Mexican food product which included a beef spice mix. The beef spice mix contained hydrolyzed vegetable protein (HVP) manufactured by Basic Food Flavors. Ruiz Food Products (“Ruiz”) initiated a recall of its Tornado product due to possible salmonella contamination of the HVP, but test results came back negative for salmonella. The Ninth Circuit affirmed the district court’s conclusion that “there was no coverage under the Catlin policy, which insured against ‘accidental or unintentional contamination, impairment or mislabelling of an Insured product(s), which occurs during or as a result of its production, preparation, manufacture, packaging or distribution . . . .’” *Ruiz Food Products, Inc. v. Catlin Syndicate Limited*, 2014 WL 7243262 at *1 (C.A.9 (Cal.)), argued and submitted Dec. 12, 2014 (unpublished). The Court reasoned that since the tests for salmonella in Ruiz’s products came back negative, there was no evidence of actual contamination as required to trigger coverage under the policy. In addition, the court found that the recall itself did not constitute an “impairment” of an insured product under the policy. Finally, the Ninth Circuit held that “[b]ecause there was no coverage under the policy, Catlin did not breach the duty of good faith and fair dealing.” *Ruiz* thus follows the majority of cases involving contamination policies, which require actual contamination of an insured’s product, not merely potential contamination to trigger coverage. *See Fresh Express Inc. v. Beazley Syndicate 2623/623, 199 Cal.App.4th 1038 (Cal.App. 6 Dist. Sep. 08, 2011); Little Lady Foods, Inc. v. Houston Casualty Company, 819 F. Supp. 2d 759, 2011 U.S. Dist. LEXIS 115491 (E.D. N.D. Il.); Caudill Seed & Warehouse Co. v. Hous. Cas. Co., 835 F. Supp. 2d 329, 331 (W.D. Ky. 2011).*

   b. **Windsor Food Quality Company: No Recall Coverage where “Insured Product” Not Contaminated and No Injuries Reported (California).**

   In 2008, Windsor Food Quality Company, Ltd. (Windsor) purchased ground beef from Westland/Hallmark Meat Company, the slaughterhouse whose operations were suspended by the U.S. Department of Agriculture (USDA) because of its now notorious use of non-ambulatory disabled cattle—or “downer” cows. *Windsor Food Quality Company, Ltd. v. The Underwriters of Lloyds of London*, E058324, 2015 WL 514341 (Cal. Ct. App. Feb. 6, 2015) (unpublished opinion). Rather than submit to an inspection and comply with other USDA and FSIS regulations, Westland voluntarily recalled its beef. *Id.* at *2. Windsor then conducted its own voluntary recall of its products incorporating Westland’s beef, incurring approximately $3 million in recall costs. Windsor had purchased a Contamination Products Insurance policy from Lloyd’s, which covered as an “Insured Product” “all products including their ingredients and components once incorporated therein of the Insured that are in production or have been manufactured, packaged or distributed by or to the order of the Insured....” The policy covered accidental product contamination for adulterated ingredients supplied by a third party, but only if some injury occurs within 120 days of consumption of the product. Here, no injuries had been reported. *Id.*
Lloyd’s denied coverage and litigation ensued. The California Court of Appeal ultimately found no coverage for three reasons. First, the alleged contamination was not of an “Insured Product”: Windsor had not shown that “there was contamination or tampering with its product during or after manufacture, not before Windsor began the process…. [and] not because one of its ingredients supplied by a third party was adulterated.” *Windsor Food*, 2015 WL 514341 at *4.

The Court also found that Westland’s recall was based on Westland’s failure to notify it about the “downer” cows, rather than any actual contamination or tampering. *Id.* at *5. Without actual contamination of or tampering with Westland or Windsor’s products, coverage was not triggered.

Last, the court found that no Insured Event had taken place because, even if Westland’s ingredients had been adulterated, the policy required injuries within 120 days of consumption. Here, no injuries were reported. *Id.*

The dissent, however, protested that the majority did not properly construe the policy. According to Judge King:

> [T]he policy does not clearly and explicitly state what the majority says it does. Within the context of the present matter, the more reasonable reading of the policy is that the product, and all of its ingredients, are insured for adulteration regardless of when the adulteration occurs. Thus to the extent there are two reasonable interpretations, the policy is ambiguous and should be construed against the insurer; the summary judgment should be denied.

*Id.* at *8* (King, J., dissenting). At the time of this writing, no appeal has yet been filed. If the parties do not settle, the California Supreme Court may yet have a say in this case’s ultimate outcome.

3. **Recent Cases Finding Potential Coverage Under Specialty Recall Policies and Allowing Cases To Proceed**

a. **Tri-Union Seafoods: Voluntary Recall in Response to FDA Advisory Survives Motion to Dismiss (S.D. Cal.).**

In *Tri-Union Seafoods, LLC v. Starr Surplus Lines Insurance Co.*, No. 3:14cv2282, slip op. (S.D. Cal. Feb. 5, 2015), the insured recalled canned shellfish products which were sourced, in part, from Korean suppliers who, according to a U.S. FDA advisory, no longer met certain sanitation standards and whose products – in this case molluscan shellfish (oysters, clams, mussels and scallops) – might have been exposed to human fecal waste and contaminated with the norovirus. *Tri-Union*, slip op. at 20-25 (order denying motion to dismiss). Tri-Union’s PCI policy covered “accidental contamination” if use or consumption of its product “has resulted in or would result in clear, identifiable, internal or external visible physical symptoms of bodily injury…..” The policy also covered accidental contamination that causes product to be “injurious to health or unfit for human consumption and as a result… a recall order by the competent authority is imminent in order to comply with regulations on food safety.” *Id.*, slip op. at 21.

Tri-Union filed a claim with Starr Surplus under its PCI policy, but the insurer denied coverage, arguing that the recall was based on alleged rather than actual contamination. After Tri-Union sued, Starr sought to dismiss the lawsuit on this basis, among others; but the Southern District of California disagreed.
In denying the motion to dismiss, the court found that at the motion to dismiss stage, Tri-Union’s allegations, including that the FDA advisory caused it to issue a voluntary recall (in part in order to avoid a formal FDA enforcement action), were sufficient to allege accidental product contamination that occurred as a result of its operations and that would result in clear, identifiable, internal or external visible symptoms. *Id.*, slip op. at 25.

b. **Hot Stuff Foods**: Factual Dispute as to Likelihood of Bodily Injury under PCI Policy Precluded Summary Judgment (8th Cir.).

In *Hot Stuff Foods, LLC v. Houston Cas. Co.*, 2014 U.S. App. LEXIS 21727 (8th Cir. S.D. Nov. 17, 2014), the Eighth Circuit, reversing the trial court’s grant of summary judgment for the policyholder, determined that an issue of fact existed as to whether the consumption of breakfast sandwiches containing MSG “may likely result” in physical symptoms of bodily injury, sickness or disease in order to trigger coverage under an Accidental Product Contamination Policy and further held that the insurer’s denial of coverage was made in good faith.

Hot Stuff Foods, LLC, submitted a claim to its Accidental Product Contamination insurer for the voluntary recall of its Sausage Breakfast Sandwiches containing the food additive Monosodium Glutamate (MSG), a flavor enhancer that must be disclosed on a food product’s label pursuant to USDA and FDA regulations. The labels for some of Hot Stuff’s breakfast sandwiches did not properly declare that MSG was present in the sausage product. Under the governing regulations at the time, the recall was categorized as Class III, meaning the use of the product would not cause adverse health consequences.

Hot Stuff sought coverage for losses sustained as a result of the recall, including lost gross profits. The insurer denied coverage on the ground that the claim did not involve an “Accidental Product Contamination,” which the policy defined as “any accidental or unintentional mislabeling of the insured’s products, provided that within 120 days of the consumption or use of such product either resulted, or may likely result, in physical symptoms of bodily injury, sickness or disease or death of any person.”

The Eighth Circuit’s decision came down to dueling expert opinions. Although both experts acknowledged that MSG can cause illness in specific sensitive subsets of the population, they disagreed as to whether the dosage of MSG contained in the mislabeled breakfast sandwiches would “likely result” in illness. Indeed, the Court noted that approximately 150,000 cases of the recalled product had been consumed with no reported adverse health results. Accordingly, the Court reversed the lower court’s ruling that, as a matter of law, consumption of the MSG-containing product “may likely result” in bodily injury and remanded the case for trial on that issue of fact.

c. **Wornick**: Adverse Publicity May Trigger Coverage Under PCI Policy Even if No Actual Contamination (S.D. Ohio).

In *Wornick Co. v. Houston Casualty Co.*, 2013 U.S. Dist. LEXIS 62465 (S.D. Ohio May 1, 2013), the insured, Wornick, was an assembler of “meals-ready-to-eat (“MRE”),” which included dairy shake packets manufactured by Trans-Packers Services Corp (“Trans-Packers”). As a supply-chain integrator, Wornick purchased the component items for MREs from manufacturers, consolidated them into a final MRE package, and sold them to the Government. The dairy shake packets contained instant dried milk that Trans-Packers purchased from Franklin Farms East, Inc. who, in turn, purchased from Plainview Milk Products Cooperative (“Plainview”).
Salmonella was found in some of the dairy shake packets at the Trans-Packers facility. As a result, the FDA began an investigation and found salmonella at Plainview’s facilities. Subsequently, Plainview, Trans-packers, and Wornick instigated recalls for the products. Ultimately, salmonella was not found in Wornick’s MREs as the batch that was positive for salmonella was never sent to Wornick.

Wornick then sought coverage under its Malicious Product Tampering/Accidental Product Contamination Insurance Policy, arguing that the MREs were subject to recall for failing to meet product specifications, that the MREs were impaired by the potential contamination, and that Government reports implying that the MREs were contaminated triggered coverage under the Policy’s publicity coverage.

On the first issue, the court found that because the Government had rejected the batch of MREs containing recalled dairy packets, “the evidence, albeit scant, [was] sufficient to create a genuine issue of fact on the question of whether the MREs suffered a fault in design specification or performance amounting to an Accidental Product Contamination.”

Further, agreeing with the reasoning in Ruiz, the court found that neither the recall “of dairy shake packets nor the inclusion in the MREs of diary shake packets that would later be subject to a recall constitute an ‘impairment’ as that term is used in the definition of Accidental Product Contamination in this specific policy.” The Court stated that “‘impairment’ should be interpreted more narrowly to mean damaged, weakened, or diminished due to a defect or flaw in the product itself.”

However, the Court’s opinion did find coverage possible even in the absence of actual contamination, under the Policy’s publicity clause. The Policy defined “Accidental Product Contamination” to include “PUBLICITY implying [contamination],” and defined “Publicity” as “[t]he reporting of an actual or alleged [accidental product contamination] . . . in local, regional or national media . . . or any governmental publication where the Named Insured’s [products] and the Named Insured are specifically named.” 2013 U.S. Dist. LEXIS 62465 at *4 (emphasis added).

Under those terms, the Court found that government “Do Not Consume” orders which specifically named Wornick’s products constituted “Publicity” within the meaning of the policy, and concluded that a dispute of fact remained about whether Wornick’s losses resulted directly from such publicity. The Court came to this conclusion despite that Wornick’s products had not actually been contaminated, emphasizing that the Policy’s publicity definition encompassed “actual or alleged” contamination. Requiring “actual physical symptoms or physical damage in the event that there is merely publicity that implies contamination of the product,” the Court said, would make “the inclusion of the word ‘alleged’ . . . meaningless.”

The Court ultimately denied both parties’ motions for summary judgment, finding that there were genuine issues of fact remaining as to whether there was a fault in design specification or performance amounting to an Accidental Product Contamination; whether there was a basis for Publicity coverage; and whether the insurer had acted in bad faith in denying Wornick’s claims.

II. PART TWO - COVERAGE FOR RECALLS UNDER NON-RECALL POLICIES

Companies also may have coverage for certain types of recall expenses under standard commercial general liability (CGL) and first-party property insurance policies. Several recent decisions, including one involving a dietary supplement recall, may shed light on how such policies might be interpreted in the context of life sciences and other industries.
A. **Product Recall Coverage Under CGL Insurance Policies**

The recall or “sistership” exclusions of CGL policies purport to bar the recovery of recall expenses. The recall provision typically provides:

Damages claimed by you for any loss, costs or expenses incurred by you or others for the loss of use, withdrawal, recall, inspection, repair, replacement, adjustment, removal or disposal of:

1. “Your product”;
2. “Your work”; or
3. “Impaired property”;

if such product, work, or property is withdrawn or recalled from the market or from use by any person or organization because of a known or suspected defect, deficiency, inadequacy or dangerous condition in it.

Though this clause generally excludes recalls from coverage, important exceptions exist. The case law discussed below illustrates the parameters of the “recall exclusion.”

1. **Cases Allowing Coverage Under CGL Policies**

Notwithstanding the recall or sistership exclusion, a CGL’s property damage provisions should cover property damage that occurs when the insured’s defective work or components become physically incorporated into another’s product—rendering the third party’s product unusable—and requiring that the third party’s product be recalled. Three recent cases demonstrate this coverage principle.24

   a. **Wisconsin Pharmacal: Incorporation Results in Third-Party Property Damage and Recall Not Barred by Recall Exclusion (Wisconsin)**

In *Wisconsin Pharmacal Co., LLC v. Nebraska Cultures of California, Inc.*, 856 N.W.2d 505, 519 (Wis. Ct. App. 2014), the recall exclusion did not bar coverage for a claim involving the insured supplier’s negligent provision of an incorrect ingredient that rendered other ingredients in a dietary supplement manufacturer’s final product unusable when incorporated. *Id.*

Nebraska Cultures and Jeneil Biotech, the insureds, sought coverage for their liability to the dietary supplement maker under the property damage portion of its CGL policy, which covered “physical injury to or destruction of tangible property, including consequential loss of use thereof” and “loss of use of

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24 For additional authority discussing this issue, see *Amerisure Mut. Ins. Co. v. Hall Steel Co.*, No. 286677, 2009 WL 4724303, at *5 (Mich. Ct. App. Dec. 10, 2009) (recall exclusion did not apply where third party, not insured initiated recall; CGL policy covered recovery of defective windshield wiper brackets); *Watts Indus., Inc. v. Zurich Am. Ins. Co.*, 18 Cal. Rptr. 3d 61, 64 (2004), as modified on denial of reh’g (Sept. 15, 2004) (predecessor company of municipal water systems parts supplier entitled to coverage under CGL property-damage clause where parts began leaching lead into water and replacement costs contributed to damages; “[L]oss that results from physical contact . . . because [property] is incorporated and not merely contained (as a piece of furniture is contained in a house but can be removed without damage to the house), must be removed, at some cost [constitutes physical injury]”); *Nat’l Union Fire Ins. Co. of Pittsburgh v. Terra Indus., Inc.*, 346 F.3d 1160 (8th Cir. 2003) (incorporation of benzene into carbon dioxide found in soft drink constituted property damage under CGL policy) (applying Iowa law); *Cytosol Labs., Inc. v. Fed. Ins. Co.*, 536 F. Supp. 2d 80, 93 (D. Mass. 2008) (saline solution manufacturer not entitled to coverage for distributor’s recall of manufactured and supplied solution) (applying Massachusetts law).
tangible property which has not been physically injured or destroyed.” *Id.* at 511. They argued that the wrong ingredient’s incorporation caused these types of damages to the final dietary supplement. *Id.* The suppliers further contended that “the raw materials could not . . . be extracted from the finished product,” and the unnecessary ingredient therefore damaged the final product. *Id.*

The court agreed. It was undisputed that incorporation rendered the final supplements unusable and that they were discarded as a result. *Id.* In addition the manufacturing process, which required putting all the raw materials into a blender and pulverizing them for insertion into capsules, resulted in the incorporation of the wrong ingredient into other property. *Id.* Because the insured’s product physically damaged another’s, the product manufacturer suffered covered property damage under the policy.

The court held also that the recall exclusion did not prevent coverage, but did not elaborate on its reasoning. *Id.* at 519. However, the court did explain why the “impaired property” exclusion did not apply. This exclusion applies to:

- tangible property, other than “your product” or “your work”, that cannot be used or is less useful because:
  - It incorporates “your product” or “your work” that is known or thought to be defective, deficient, inadequate or dangerous; or
  - You have failed to fulfill the terms of a contract or agreement;

  *if such property can be restored to use* by:
  - The repair, replacement, adjustment or removal of “your product” or “your work”; or
  - Your fulfilling the terms of the contract or agreement.

*Id.* (emphasis added). Given the manufacturing process, it was undisputed that the finished product could not be “restored to use” because the incorrect ingredient could not be removed or separated from the finished product. As a result, the final product was not impaired property, and coverage was available.

b. **Paramount Concrete: Third-Party Property Damage Not Barred by Recall Exclusion (D. Conn.)**

A similar result was reached in *Harleysville Worcester Ins. Co. v. Paramount Concrete, Inc.*, 10 F. Supp. 3d 252 (D. Conn. 2014). In that case, Paramount, the insured, provided a defective concrete product called “shotcrete” to a swimming pool builder who used it in nineteen pools. *Id.* at 257. The pool manufacturer sued Paramount in a products liability action and received a verdict of over $2.7 million. *Id.* at 258. Paramount then sought coverage under the property damage portion of its CGL policy, arguing that incorporation of the shotcrete had caused tangible property damage to the pools. *Id.* at 260.

The court agreed. “The liquid shotcrete, once it dried, became inextricably intertwined with other components such as rebar and coping, which combined to create finished pools.” *Id.* at 261. As a result, the defective concrete caused property damage to the larger system (cracking and leaking) and Paramount’s liability to the pool manufacturer was a covered claim under the insuring agreement of the policy. *Id.* Also, because the concrete had already failed and caused property damage, no product was being withdrawn from the market as contemplated under the sistership exclusion. Since Paramount sought
coverage for damage actually caused by its defective product, the recall exclusion did not apply. Id. at 269-270.

c. Shade Foods: Inextricable Incorporation of Product Covered Property Damage, Not Impaired Property (California)

When wood splinters became physically incorporated into almond clusters that were sold to a cereal manufacturer, the cost of the cereal company’s recall-like response was covered by the almond supplier’s CGL insurance. Shade Foods, Inc. v. Innovative Prods. Sales & Marketing, Inc., 78 Cal. App. 4th 847, 867 (2000).

The insurance company denied coverage on the grounds that the claim was merely for diminution in economic value, not property damage, and that the nut clusters were excluded “impaired property,” which the policy defined as:

> tangible property, other than your product or your work that cannot be used or is less useful because: [¶] a. It incorporates your product or your work that is known or thought to be defective, deficient, inadequate or dangerous ... if such property can be restored to use by: [¶] ... The repair, replacement, adjustment or removal of your product ... .”

Id. at 866 (emphasis in original).

The court disagreed, holding that the presence of wood splinters, “a potentially injurious material,” caused property damage to the nut clusters and cereals into which they were incorporated. Id. at 865. In addition, the nut clusters and cereal were not excluded as “impaired property” because the defective nuts had become so incorporated that the cereal could not be “restored to use by . . . repair, replacement, adjustment or removal” of the wood-contaminated almonds. Id. at 867. Thus, incorporation of a defective product into another product constitutes covered property damage if the defective product “causes physical damage to the whole” and cannot reasonably be isolated and removed.

2. Cases Disallowing Coverage Under CGL Policies

a. Hillside Bottling: Endorsement Providing Limited Product Recall Coverage Served as Evidence that Sistership Exclusion Applied to Loss (New Jersey)

In Atl. Mut. Ins. Co. v. Hillside Bottling Co., Inc., 903 A.2d 513, 520 (N.J. App. Div. 2006), the coverage issue turned on whether the services performed by the insured (Hillside), which consisted of mixing together the ingredients of soft drinks, resulted in the insured’s product or the product of its customers. The problem arose during the mixing process. As carbonation was being introduced into the beverages, ammonia leaked from the carbo-cooler and contaminated the sodas. The court held that because Hillside’s work in creating carbonated beverages was defective, its faulty workmanship claim did not constitute “property damage” under the policy’s insuring agreement and was, therefore, barred under established New Jersey law. See Weedo v. Stone-E-Brick, Inc., 405 A.2d 788 (N. J. 1979). The court also rejected Hillside’s claim under the sistership exclusion. According to the court, the essential focus of this exclusion is to eliminate coverage for the cost of recalling apparently undamaged products to search for damaged components otherwise not yet discovered. Hillside, 903 A.2d at 522. Despite Hillside’s protestations to the contrary, the court found that the final soda mixture was Hillside’s product and that
recall initiated by Hillside included beverages without regard to whether there were actually contaminated. Additionally, Hillside had bargained for a limited Product Recall endorsement to its policy, which worked to Hillside’s disadvantage. Hillside’s own recall costs were in fact covered, but only up to a sublimit of $25,000, under a separate, limited product recall coverage endorsement it had purchased. See id. at 522-23. As the court saw it, the fact that Hillside opted to purchase that endorsement supported its determination that recall-related costs were not included in the general insuring agreements.

b. Titanium Industries: Defective Titanium, Even Though Incorporated in Another’s Product, Did Not Constitute Property Damage (New Jersey)

Also in contrast to Shade Foods, no coverage was found under a CGL policy in a case involving defective titanium bars the insured sold to Biomet, an orthopedic implant manufacturer. Titanium Indus., Inc. v. Fed. Ins. Co., 2014 WL 4428324, at *1 (N.J. Super. Ct. App. Div. Sept. 10, 2014) (per curiam). Biomet used the titanium to manufacture screws that were ultimately incorporated into its products. Id. The parties stipulated that this defect “existed when [the insured titanium manufacturer] received the titanium from its supplier, continued while the material was present at [the insured’s] facility, and existed when the material was shipped to [the implant manufacturer].” Id. Biomet issued a recall of implants containing the defective titanium and returned the unaltered bars remaining in its stock to the insured. Id.

Federal Insurance Company denied the titanium manufacturer’s claim for coverage on the grounds that the insured could not establish the requisite physical injury to tangible property. According to Federal, the defective condition of the titanium never changed; thus, there cannot be “property damage” under the insuring provisions of the policy. The New Jersey Superior Court Appellate Division agreed. The court found that the damages recovered from the insured titanium manufacturer resulted solely from its breach of contract and defects in the insured’s own work. Under New Jersey law, faulty workmanship is not a covered event under a CGL policy absent identifiable damage to a third party’s property (or a bodily injury claim). Nonetheless, the insured argued that coverage should still be available because Biomet had created screws from the titanium to use in its devices, and it was the screws—not the titanium—that had failed, Id. at *7. The court rejected this argument. It held that this argument implicitly assumed that the machining of the titanium into screws had “been sufficiently transformed [the titanium] so that it [wa]s something else, that is, some other property that was damaged.” Id. Rather, according to the court, the titanium was not so transformed. Id.

In the process, the court distinguished Newark Ins. Co. v. Acupac Packaging, Inc., 746 A.2d 47 (N.J. Super. Ct. App. Div. 2000). In that case, the court held that coverage was available to an insured manufacture of laminated lotion pacquettes, where defective pacquettes attached to cards in magazines leaked and caused damage to the cards and magazines. The Titanium Industries court held that, unlike in Acupac, where packets were sold to a card seller who appended them to magazines, the titanium blocks were machined into screws but “otherwise unaltered and [] not appended to other property that was, itself, damaged.” Titanium Indus., 2014 WL 4428324, at *8. This was “a process anticipated by the parties' relationship and the terms of the long-term supply agreement.” Id. at *8

B. Product Recall Coverage Under First-Party Property Policies

First-Party Property Policies have been held to cover contamination—including contamination resulting in a recall—notwithstanding the presence of contamination exclusions in most such policies.
Contamination exclusions typically exclude “contamination including but not limited to the presence of pollution or hazardous material.”

There is a seldom invoked exception to this exclusion, however, based upon unusual wording in the contamination exclusion. Specifically, contamination is “exclude[d] . . . unless directly resulting from other physical damage not excluded by this Policy.” Some courts have interpreted such language to mean that contamination resulting from “otherwise covered” perils may be covered. See, e.g., Leprino Foods Co. v. Factory Mut. Ins. Co., 453 F.3d 1281, 1289 (10th Cir. 2006). In Leprino, for example, the court reversed a summary judgment finding that a fact question existed as to whether a covered peril, like a pipe break or spill, might have contaminated some cheese. Id.

But a court reached an opposite conclusion in HoneyBaked Foods, Inc. v. Affiliated FM Ins. Co., 757 F. Supp. 2d 738, 749 (N.D. Ohio 2010). In that case, the policy provided as follows:

This policy does not insure against loss or damages caused by [contamination, including but not limited to pollution]; however, if direct physical loss or damage insured by this policy results, then that resulting direct physical loss or damage is covered.

Id. at 748-49. The HoneyBaked case involved ham that became contaminated with bacteria. Id. at 748. In seeking to avoid the contamination exclusion, the insured argued that a hollow roller in its conveyor system harbored the bacteria that eventually made its way to the ham. HoneyBaked contended that it was the hollow roller, and not the contamination, that caused its loss. Id. Accordingly, the exception to the exclusion should apply. The court rejected this argument, concluding instead that the bacteria deposited on the hams caused the loss, not the hollow roller. Since the only preceding cause of the loss was expressly excluded contamination, the court reasoned that the exception did not reinstate the insured’s coverage. Id. The court also distinguished Leprino based upon different policy language.

Notwithstanding policy language to the contrary, the court left open the possibility that the insured might still be covered for its loss under the “reasonable expectation of the insured” doctrine. Confused as to whether Ohio had adopted such a doctrine, the court instructed to parties to propose questions on this issue for certification to the Ohio Supreme Court, id. at 752, however, the Ohio Supreme Court declined to answer the certified question. HoneyBaked Foods, Inc. v. Affiliated FM Ins. Co., 947 N.E.2d 681 (Ohio 2011).

III. PART THREE - WHEN THE QUESTION IS HOW MUCH, NOT WHETHER COVERAGE EXISTS

When coverage for a company’s recall expenses is clear, some policyholders are surprised to learn that adjustment of the loss involves its own issues, some of which could reduce the ultimate amount paid on a recall claim. Below are some key considerations for the practical handling of a recall claim.

A. Special Considerations for Adjustment of Product Recall Claims

1. Documentation requirements

The need for impeccable documentation cannot be underestimated. Policyholders must know what to document and how best to document it. Several factors can influence a company’s insurance recovery:
• **Traceability** – Insurers will typically ask Insureds to support that the product (or at least most of the product) that is being recalled is the same product at risk. Furnishing documentation supporting original production, shipment and if applicable incorporation can be important.

• **Quantities** of recalled product – Insurers will reconcile quantities recalled and destroyed with original quantities at risk. This could be in almost any unit of measure. Pallets, cases, kilograms, etc.

• **Out of pocket expenses** – Insurers will require copies of contracts, invoices, and proof of payment for all of the hard costs related to the recall. This could include handling, destruction, investigation, remediation, customer credits, refunds, coupon programs, public relations, and other costs.

• **Internal expenses** – Insureds should be prepared to provide payroll records (time cards, work logs, payroll reports, etc.) for internal charges being claimed related to the recall. As previously noted, Insureds will need to demonstrate that they’re incremental to normal to get paid.

• **Business interruption/lost profits** – Insureds will need to provide support for both projected financial results but for the recall and actual financial results historically and during the loss period. Documentation needed to support a business interruption/lost profits claim may include monthly or weekly financials, budgets, forecasts, and operational data. Note that the operational data typically required for claim purposes may be much more granular than just financials (i.e. customer level sales, inventories, production, etc.).

2. **Timing**

The length of time that it can take to prepare, submit and settle a product recall claim can vary significantly. As a general rule of thumb, it takes approximately two and a half times the period of time to prepare and submit a claim to get it settled. Insurers often have their own team of experts reviewing the supporting documentation and other information that has been submitted, asking questions and in many cases requesting additional support. In addition, policy provisions regarding business interruption/lost profits may also dictate the period of loss. Smaller product recalls may only involve the cost of replacing product in the marketplace and have little or no other effect on the bottom line. Larger product recalls and/or those getting significant media attention, on the other hand, could result in long-term business interruption, lost profits and damage to a brand that might go well beyond policy limits. Typical policies tend to limit business interruption/lost profits coverage to the lesser of the time for the Insured to remove and replace product in the marketplace or one year, with the option of an extended period of indemnity.
B. Practical Advice

Several studies have been done regarding best practices in recall-related insurance recoveries. Outside counsel, forensic accountants and other consultants consistently recommend the following actions in order to achieve complete and accurate indemnification from insurers:

1. Put a claim team in place prior to a loss event (adjuster, claim assistance, recovery resources, public relations, etc.).
2. Establish protocols for communication early in the claims process.
3. Make critical decisions as soon as possible based on best business practices, including safety and brand integrity, and NOT necessarily insurance.
4. Include the insurer in the decision making process.
5. Proactively manage the claims process (preliminary loss estimates, adequate documentation for all losses, and identification of issues that can affect the claim recovery).
6. Have a strong client “champion” leading the process, acting as single point of contact for insurers, and serving as a gatekeeper of information for all parties.

CONCLUSION

Any company in manufacturing, packaging or distribution of any product must consider the possibility that something could go wrong with the product, and that a recall might be necessary. Many companies choose to focus their risk management for product recalls on avoiding the necessity for such recalls in the first place, but the right insurance policy at the right price could be part of a prudent strategy for managing and minimizing a recall’s impact on the company’s bottom line. The insurance industry continues to develop its coverage products to address such risks.

At a minimum, companies may already have coverage available for certain specific types of losses under the company’s CGL and first-party property insurance. Those companies desiring greater assurances with regard to coverage may turn to contamination insurance or product recall coverage, or even bespoke, manuscript policies. However, as case law continues to develop to clarify the scope of CGL, first-party property, and specialized insurance policies, companies must be prepared to navigate the terms and conditions of their coverage in the event a recall must be conducted, and ensure that the specifics of the policies purchased are appropriately tailored to the recall risks they face.